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LEGAL REGULATION OF CERTAIN ISSUES RELATED TO VACCINATION

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14 bldg. 3 Kadashevskaya Naberezhnaya
Moscow, 119017, Russia

+7 495 640 65 65
info@iclrc.ru www.iclrc.ru

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ABBREVIATIONS

APAs	Advanced Purchase Agreements, European Union
CCRF	Civil Code of the Russian Federation
CDC	Centers for Disease Control and Prevention, the United States
CDSCO	Central Drugs Standard Control Organization, India
CHMP	Committee for Medicinal Products for Human Use of the European Medical Agency
CMA	Conditional Marketing Authorization
COVAX	COVID-19 Vaccines Global Access Facility
CTR	Medicines for Human Use (Clinical Trials) Regulations of 2004, the United Kingdom
Drug Administration Law	Revised Drug Administration Law of 2019, China
EAEU	Eurasian Economic Union
EMA	European Medical Agency
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
EUA	Emergency Use Authorization

FDA	Food and Drug Administration, the United States
Federal Law No. 61	Federal Law No. 61-FZ of April 12, 2010, "On Circulation of Medicines", the Russian Federation
FEMA	Federal Emergency Management Agency, the United States
FSBI SCEEMP	Federal State Budgetary Institution "Scientific Centre for Expert Evaluation of Medicinal Products" of the Ministry of Health of the Russian Federation
GATT	General Agreement on Tariffs and Trade of 1994
GPA	German Patent Act, Germany
GPTMO	German Patent and Trademark Office, Germany
HMR	Human Medicine Regulations of 2012, the United Kingdom
ICMR	Indian Council of Medical Research
ICTRP	International Clinical Trials Registry Platform, Germany
IHR	International Health Regulations of 2005
JPCM	Joint Prevention and Control Mechanism of the State Council, China
MAH	Marketing Authorization Holder, China
Measures	Measures for the Supervision and Administration of Drug Registration of 2020, China
MHRA	Medicines and Healthcare products Regulatory Agency, the United Kingdom
MPA	Medicinal Products Act of 2005, Germany

New Drugs and Clinical Trial Rules	New Drugs and Clinical Trial Rules of 2019, India
NHS	National Health Service, the United Kingdom
NMPA	National Medical Products Administration, China
Order No. 316	Order of the Ministry of Economic Development of the Russian Federation No. 316 of May 25, 2016
Patent Law	The Patent Law of the People's Republic of China of 1984
PEI	Paul-Ehrlich-Institut, Germany
PHE	Public Health England, the United Kingdom
RKI	Robert Koch Institute, Germany
Rospotrebnadzor	Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing, the Russian Federation
Roszdravnadzor	Federal Service for Surveillance in Healthcare, the Russian Federation
STIKO	Standing Committee of Vaccination, Germany
TRIPS	WTO Agreement on Trade-Related Aspects of Intellectual Property Rights
USPTO	Unites States Patent and Trademark Office
Vaccines Administration Law	Vaccines Administration Law of 2019, China
WHO	World Health Organization

INTRODUCTION

Vaccination is one of the most important tools for combating infectious diseases, including COVID-19. The legal regulation of certain issues related to the development and production of vaccines and the vaccination process exists at the universal, regional, and national levels. In the context of the COVID-19 pandemic, it is crucial to determine whether the existing regulation is effective and identify ways to improve it.

The purpose of the present research is to find effective mechanisms for legal regulation of certain issues related to the development and production of vaccines and the vaccination process at the universal, regional, and national levels. It examines international legal regulation at the universal and regional levels, including the law of the Eurasian Economic Union and the European Union, as well as the legislation of seven states: the Russian Federation, Germany, Sweden, the United Kingdom, the United States, China, and India.

The results of this research can be used to improve existing regulation, introduce the best approaches and practices for the more operative introduction of vaccines into civil circulation in a case of the spread of infectious diseases in the future. Information in the research is relevant as of May 2021.

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CONCLUSIONS

1. Vaccination is one of the most essential tools for combating infectious diseases, including COVID-19. This study examines international legal regulation at the universal and regional levels, including the law of the Eurasian Economic Union and the European Union, as well as the legislation of seven states: the Russian Federation, Germany, Sweden, the United Kingdom, the United States, China, and India.

International Law

2. To date, international legal regulation at the universal level **does not contain legally binding norms** regulating the issues of immunoprophylaxis of infectious diseases, research, and development of vaccines. In this regard, in the context of such a global public health emergency as the COVID-19 pandemic, **the principles of state cooperation, mutual assistance, and solidarity** come to the fore.

3. Such cooperation is carried out primarily within the framework of the WHO, which, among other things, issues instructions and recommendations that States can follow when developing vaccines. In addition, there are several mechanisms within the WHO aimed at strengthening global cooperation in the field of immunoprophylaxis in general and during the COVID-19 pandemic in particular.

4. In order to simplify the process of introducing new or unlicensed medicines, including vaccines, into civil circulation, the WHO has developed **a procedure involving the inclusion of certain medicines in the list for their use in emergency situations** (Emergency Use Listing). This procedure provides for the analysis of data on the safety, efficacy, and quality of a drug, as well as a risk management plan by the WHO. The inclusion of a drug in this list is a prerequisite for its delivery through the COVAX mechanism, which allows states to speed up the process of registration, import and use of this drug against COVID-19.

5. **The COVAX mechanism**, implemented by the WHO in cooperation with the UN, several international funds, States, and vaccine manufacturers, is aimed at accelerating the development and production of means to combat COVID-19, including vaccines, and ensuring fair and equal access of the population to them.

6. **To address the shortage of medicines, including vaccines, some WTO members temporarily restricted or banned their export during the COVID-19 pandemic**. Despite the fact that, as a general rule, quantitative restrictions are prohibited in international law, there are some exceptions that have been used to introduce them. For example, the EU restricted the export of the COVID-19 vaccine to

third countries, referring to the exceptions to the general GATT regime set out in Article XX — the introduction of restrictions to prevent or mitigate the consequences of a critical shortage of food or other goods that are essential or necessary to protect human life or health. At this stage, the WTO does not assess the legality of the restrictions imposed, but only calls on States to be open and transparent by notifying the WTO about the restrictions applied in the context of the COVID-19 pandemic. The issue of conformity of the restrictions imposed by States with the WTO rules may arise later if a complaint against a State is filed. In accordance with the law of the WTO, during the COVID-19 pandemic, India and South Africa put forward a proposal for the temporary suspension of certain TRIPS rules concerning the availability of vaccines, diagnostic tools, and therapeutic treatment, which was supported by a number of States and international organizations.

7. At the same time, given the shortage of medicines and limited access to vaccines, **the question about the compliance of the imposed restrictions on the export of vaccines with the UN Sustainable Development Goals arises**.

8. One of the Goals of sustainable development is to ensure healthy lives and promote well-being for all people of all ages. The pandemic as a public health emergency has demonstrated the urgent need for States to be prepared for such situations. Since the primary responsibility of a State is to ensure the protection of public health, this is the goal that most countries were guided by when taking measures provided for by the WTO law to temporarily restrict the export of certain types of goods, including vaccines.

9. At the same time, the lesson learned in the fight against the COVID-19 pandemic shows that ensuring the health protection of the population in all countries of the world requires the coordination of efforts and mutual support at the universal level. In this regard, **it seems important that the introduction of temporary restrictions by States or regional associations is resulted from the urgent need of the situation and is carried out in compliance with the proportionality principle**. Otherwise, the establishment of unjustified barriers to universal and equal access to vaccines, for example, may contradict both the UN principles and Sustainable Development Goals and the international legal obligations of States considered below.

10. **Human rights**, primarily the right to life, the right to health, and the prohibition of discrimination, are an important guideline for States in the legal regulation of research and development of vaccines and immunoprophylaxis of infectious diseases.

11. In particular, States have an obligation to take steps to the maximum of their available resources to ensure the realization of the right to health. At the same time, the fulfillment of the obligation to provide the population with financially affordable medicines directly depends on the resources of a State. The right to health is closely

linked to the human right to life. The failure of a State to take all reasonable measures to treat infected persons, as well as to ensure that all citizens can receive a vaccine, may lead to a violation of the State's obligation of due diligence and the exercise of the right to life.

12. Besides, national legislation of some States provides for **the possibility of mandatory routine vaccination** of certain groups of the population that are particularly vulnerable to infection. This raises the question of **a possible violation of the right to privacy**. For example, the Oviedo Convention of the Council of Europe provides that "intervention in the health [including vaccination] may only be carried out after the person concerned has given free and informed consent to it". At the same time, the Convention provides for the possibility of imposing restrictions on the exercise of rights and freedoms in cases that are prescribed by law and are necessary in a democratic society for the protection of public health. In one of its recent decisions, the European Court of Human Rights, having analyzed the provisions of international law, concluded that, in general, interference with the right to privacy by mandatory vaccination of certain categories of citizens **can be justified by the presence of a legitimate goal, such as protecting public health, with the compliance with the principle of proportionality by a State**.

13. At the international level, the possibility of issuing passports or certificates of vaccination against COVID-19, granting the right of free movement, is also being discussed. Issuing such documents exclusively to persons who have been vaccinated against COVID-19 may lead to discrimination against those who have not been vaccinated. The granting of different scope of rights to individuals, depending on the vaccination, should be based on a legitimate goal and a fair balance between protecting the interests of society as a whole and respecting the rights and freedoms of a particular person or group of persons. Compliance with these criteria will prevent violation of the principle of non-discrimination. In order to eliminate discrimination at the level of the European Union, for example, the European Digital COVID Certificate was adopted, which confirms not only that a person has been vaccinated against COVID-19, but also that she or he has received a negative test result or has already recovered from COVID-19. It is noted that for its effective implementation, all States of the European Union shall provide **universal, affordable, timely, and free testing of the population**.

Regional Integration Law

14. The regulation of the EAEU in terms of creating a single market for medicines is still at the formation stage. In this regard, currently, drug developers do not register new medicines in accordance with the requirements of the EAEU. In the context of the COVID-19 pandemic, the EAEU law did not have a significant impact on aspects related to the creation, registration, introduction into civil circulation, import, and export of vaccines against COVID-19.

15. At the level of the European Union, there is **a centralized procedure for approving vaccines**, allowing their subsequent use in all member States. In the context of the pandemic, the EU has come up with a unified strategy to reduce the time for creating and introducing new vaccines into circulation and granting public access to them. **Two main mechanisms** were used in this regard:

- **conditional approval of a new vaccine**, which existed in EU legislation even before the pandemic, allowed issuing permits for the introduction of drugs into civil circulation on the basis of submitting an incomplete registration dossier, i.e. before the completion of all clinical trials;

- during the COVID-19 pandemic, the above-mentioned mechanism was supplemented by **the rolling review procedure**, which, unlike the usual procedure, provides for the possibility of evaluating data from ongoing clinical trials as they are conducted and submitting it to the competent authority of the European Union.

National Regulation

16. In general, the regulation of the development, approval, and introduction of vaccines into civil circulation, the vaccination of the population, as well as the export and import of vaccines in the examined jurisdictions is largely similar. It imposes strict requirements for conducting clinical trials and is aimed at ensuring the safety and effectiveness of a vaccine before its introduction into civil circulation. The regulation of these issues in relation to vaccines does not differ from other medicines.

17. At the same time, there are several legal instruments aimed at **speeding up the process of introducing newly developed vaccines and vaccines used for the first time into civil circulation.**

18. One of such legal instruments is **the procedure of issuing a permit for the emergency use of unapproved medicines in an emergency situation**. In addition to EU law, such a mechanism exists, for example, in the legislation of the United States and China. At the same time, it was the COVID-19 pandemic that revealed the need for its legal embodiment in national legislation. For example, in the Russian Federation, it was first put into effect during the COVID-19 crisis (it is applied on a temporary basis until January 1, 2022). In India, a permit for the emergency use of the vaccine was issued even in the absence of legal grounds for it stipulated in the legislation.

19. **The patent protection of medicines** provided for by national laws **has been criticized during the COVID-19 pandemic**. This is primarily due to the fact that it is perceived as an obstacle to increasing rates of the production of vaccines and other

medicines necessary to combat the pandemic and ensuring access to them by States experiencing difficulties in purchasing them.

20. **Despite the possibility of removing such protection in an emergency situation existing in the legislation of a number of States, only the Russian Federation used it**. Besides, in 2021, the Russian Federation introduced amendments to civil legislation, expanding the competence of the Government to allow the use of an invention without the consent of the patent owner in case of extreme necessity related to the protection of life and health of citizens. At the same time, the removal of patent protection in an emergency situation is not only consistent with the provisions of international law, but also allows ensuring the safety of life and health of the population of other States by providing the opportunity to use technologies for the production of vaccines and other medicines without any obstacles. However, despite the support of this idea from a number of States, including China and the United States, representatives of the EU, Germany, and the United Kingdom still oppose this initiative.

21. The regulation of the vaccination process itself in the States considered in the study does not differ significantly. The possibility of mandatory vaccination of certain groups of population against COVID-19, provided by the legislation of a number of States, at the time of conducting the present research (May 2021) had not been used. At the same time, in some States, the legislation provides only for the responsibility of a vaccine developer **for the harm caused to a person during the vaccination process** (for example, in Sweden and India), in others — of a vaccine developer and the State itself (for example, in the Russian Federation, Germany, the United Kingdom, the United States, and China).

22. An important issue is the responsibility of vaccine manufacturers for the quality of a vaccine, as well as for possible harm caused to a person during the vaccination process. During the study, a trend that **States tend to limit the responsibility of COVID-19 vaccine manufacturers due to insufficient grounds for it was identified**.

23. In general, States responded to the COVID-19 pandemic promptly and were able to approve the possibility of using the first COVID-19 vaccines in a short time. At the same time, the legal regulation of vaccination during the COVID-19 pandemic represents a unique experience of applying existing legislation and legislation adopted during the pandemic in the context of a health emergency. The analysis of the relevant national legal regulation has demonstrated **the need for its harmonization by taking into account the experience of other States in the development and introduction of COVID-19 vaccines into civil circulation**. Such harmonization can make a great contribution to the progressive development of national legislation of States, ensure openness, transparency, and predictability of the entire vaccination process, including the rules for access of vaccines to foreign markets, as well as strengthen international cooperation in the event of public health emergencies in the future.

24. In particular, considering the fact that States and large pharmaceutical companies have been making efforts to harmonize the standards for conducting clinical research and developing medicines over the past years, the proposal to adopt **a model law** could be relevant. The model law, which is aimed, among other things, at developing a single standard for the procedure of introducing vaccines and other medicines into civil circulation, may be the result of the work of an international commission of experts with its subsequent implementation at a national level. This law could contain:

- basic requirements for conducting clinical trials in a public health emergency;
- mechanisms of cooperation in the field of conducting clinical trials of a new medical product and assessing its quality;
- requirements for conditional approval of a medical product for its introduction into civil circulation;
- conditions for the emergency use of medicines;
- rules of patent protection in relation to medicines in case of their shortage.

25. Besides, in the absence of the resources necessary for conducting clinical trials, **a large number of States are interested in gaining access to vaccines against new infectious diseases, including COVID-19**. In this regard, at the international level, **the procedure for mutual recognition of studies to register a vaccine could be simplified with the increase of its transparency**. Despite the existence of such a procedure within the framework of regional associations and several individual States, including the Russian Federation, its consolidation and implementation at the universal level would speed up the processes of spreading a vaccine among the population of all countries of the world.

26. Applying the results of the study to the legal reality of the Russian Federation, it should be noted that the legal regulation of the processes of vaccine development and production and the vaccination process itself, which existed before and was supplemented during the COVID-19 pandemic, generally corresponds to the international legal regulation and provides for the possibility of adaptation to initiatives and proposals made within international organizations.

SUMMARY

International Law

27. To date, international law does not contain legally binding norms regulating the issues of immunoprophylaxis of infectious diseases, research, and development of vaccines. At the same time, within the framework of the WHO, which coordinates the cooperation between States on these issues, recommendations are adopted, including those concerning the use of certain vaccines in emergency situations before their introduction into civil circulation (Emergency Use Listing) (**paras. 44–47 of the Analytical Report**).

28. In the context of the COVID-19 pandemic, special attention has been paid to the principles of cooperation between States, mutual assistance, and solidarity in order to ensure the availability of the COVID-19 vaccines in all countries of the world (**paras. 48–55 of the Analytical Report**). In this regard, the COVAX mechanism created in the context of the pandemic is aimed, *inter alia*, at ensuring fair and equal access of the population to vaccines (**para. 56 of the Analytical Report**).

29. The lack of vaccines against COVID-19 and other medicines has prompted some States to impose temporary restrictions or a ban on their export. Despite the general prohibition of quantitative restrictions on exports in international law, the law of the WTO provides for a number of exceptions that States referred to when introducing restrictive measures on the export of certain goods (**paras. 61–63 of the Analytical Report**).

30. Within the framework of the WTO law, several States have put forward an initiative to introduce temporary exemptions from intellectual property rights. In particular, the initiative concerned the suspension of patents on medicines, including the COVID-19 vaccines. Such a waiver would provide an opportunity for the free transfer and use of a license to produce vaccines to low-income countries (**paras. 64–66 of the Analytical Report**).

31. Activities related to the development of vaccines and clinical trials are closely related to the regime of international human rights law, in particular the right to life (**paras. 69–70 of the Analytical Report**), the right to health (**paras. 71–72 of the Analytical Report**), the prohibition of discrimination (**paras. 73–75 of the Analytical Report**), and the right to privacy in the context of the introduction of mandatory vaccination of the population (**paras. 76–78 of the Analytical Report**).

Regional Integration Law

32. The issues of legal regulation of certain issues related to vaccination in the European Union (**paras. 79–126 of the Analytical Report**) and the Eurasian Economic Union (**paras. 127–161 of the Analytical Report**) are examined in the Report.

33. The degree of legal regulation within the EU is comparable to national legislation. For example, in the EU, there is a centralized procedure for approving vaccines, allowing their subsequent use in all Member States (**para. 79 of the Analytical Report**).

34. During the COVID-19 pandemic, the EU authorities developed and applied a unified strategy for the accelerated introduction of new vaccines into civil circulation (**paras. 101–105 of the Analytical Report**). In this regard, two main mechanisms were used:

- the conditional approval of new medicines, which allows issuing permits for their introduction into civil circulation even if an incomplete registration dossier is submitted, i.e. before the completion of all clinical trials (**paras. 95, 101 of the Analytical Report**);

- the procedure of sequential examination of a registration dossier (rolling review), which, unlike the usual procedure, provides a possibility to evaluate the data of current clinical trials as they are conducted and submitted to the competent EU authority (**paras. 102–103 of the Analytical Report**).

35. Within the framework of the EAEU, the single market of medicines and legal regulation of their development are at the stage of formation. As a result, in the context of the COVID-19 pandemic, the EAEU legislation has not had a significant impact on aspects related to the development, registration, introduction into civil circulation, import, and export of vaccines against COVID-19 (**paras. 127–131, 155 of the Analytical Report**).

National Regulation

36. The Report examines the legal regulation of the development, approval, and introduction of vaccines into civil circulation, the vaccination of the population, as well as the export and import of vaccines in seven states: the Russian Federation (**paras. 162–249 of the Analytical Report**), Germany (**paras. 250–291 of the Analytical Report**), Sweden (**paras. 292–319 of the Analytical Report**), the United Kingdom (**paras. 320–350 of the Analytical Report**), the United States (**paras. 351–393 of the Analytical Report**), China (**paras. 394–450 of the Analytical Report**), and India (**paras. 451–507 of the Analytical Report**).

37. In the course of the research, both common features and differences in the legal regulation of those issues in the examined jurisdictions were identified.

38. The common features are:

- strict legal requirements for conducting clinical trials, including the need to obtain a permit for conducting a clinical trial and an ethical examination (**paras. 167–168, 252–255, 294–296, 325–326, 356–357, 398–399, 454–459 of the Analytical Report**);

- absence of statutory deadlines for conducting clinical trials (**paras. 166, 252, 294, 323, 355, 401, 460 of the Analytical Report**);

- existence of control mechanisms for the development of vaccines, which, among other things, include the possibility of suspending clinical trials due to non-compliance with certain requirements (**paras. 172–179, 253–258, 295–296, 325–327, 357–358, 402–410, 465–469 of the Analytical Report**);

- the need to submit an extensive list of documents for filing a registration dossier in order to obtain permission to use a vaccine (**paras. 181, 258, 297, 328, 351, 410, 470–471 of the Analytical Report**);

- availability of a single standard for obtaining a permit for the introduction of a vaccine into civil circulation, including an analysis of the pharmaceutical quality, effectiveness, and safety of a vaccine (**paras. 182, 258, 297, 328, 359, 411, 471 of the Analytical Report**);

- patent protection of the developed vaccine (**paras. 191, 264, 300, 331, 363, 418, 473 of the Analytical Report**);

- ensuring the rights of citizens to receive credible information about a vaccine (**paras. 218, 271, 307, 337, 375, 428, 486 of the Analytical Report**);

- requirements for the quality standard of imported vaccines and the need for their approval and introduction into circulation on the territory of the importing country (**paras. 245, 288, 317, 347, 389, 446, 502–503 of the Analytical Report**);

- absence of general restrictions on the export of vaccines (**paras. 244, 287, 317, 346, 388, 445, 499 of the Analytical Report**).

39. The most significant differences in the legal regulation are the following:

- in some jurisdictions, for example, in Germany (**para. 262 of the Analytical Report**), the United Kingdom (**para. 330 of the Analytical Report**), the United States (**para. 360 of the Analytical Report**), and China (**para. 416 of the Analytical Report**), even before the COVID-19 pandemic it was possible to issue a permit for the emergency use of a vaccine. The Russian Federation and India have put this mechanism into effect only during the pandemic on a temporary basis (**paras. 190, 480–481 of the Analytical Report**). At the same time, in India, a permit for the emergency use of the vaccines was issued in the absence of legal grounds stipulated in the legislation (**para. 472 of the Analytical Report**);

- in a number of States, for example, in the Russian Federation (**paras. 199–202 of the Analytical Report**) and Germany (**para. 265 of the Analytical Report**), it is possible to use a vaccine without the permission of the patent owner;

- in some States, the possibility of mandatory vaccination in some cases is provided. For example, in Germany, in order to be allowed to work in kindergartens, schools, medical institutions, as well as places of refugee accommodation, it is essential to be vaccinated against measles (**para. 272 of the Analytical Report**), and in the United States depending on a state (**para. 377 of the Analytical Report**) and in China (**paras. 429–430 of the Analytical Report**), the possibility of children to attend schools and kindergartens depends on a particular set of vaccinations received. Refusal to vaccinate in such cases may entail administrative and criminal liability (**paras. 273, 377, 430 of the Analytical Report**);

- in some jurisdictions, for example, in the Russian Federation (**para. 229 of the Analytical Report**), Germany (**para. 278 of the Analytical Report**), the United Kingdom (**para. 342 of the Analytical Report**), the United States (**para. 380 of the Analytical Report**) and China (**para. 434 of the Analytical Report**), the State's responsibility for the harm caused to a person in the process of vaccination and guarantees of compensation are provided.

40. The Analytical Report pays special attention to the peculiarities of applying the existing legal regulation in the examined States to the process of developing and introducing COVID-19 vaccines into civil circulation. The legal regulation of certain issues related to vaccination during the COVID-19 pandemic is a unique experience of applying existing legislation in the context of a public health emergency.

41. The pandemic has required the introduction of special regulatory legal acts, in particular on simplifying the procedure for introducing a vaccine into civil circulation (the Russian Federation, India) (**paras. 214, 480–481 of the Analytical Report**) or speeding up the consideration of applications for registration of a vaccine (the EU Member States, the US) (**paras. 104, 368 of the Analytical Report**). The adoption of such acts is based on the existing powers of state bodies and powers expanded during the pandemic to respond to emergency situations. There are both common features and differences in the approaches of States.

42. The following common features could be identified:

- the focus on maintaining the quality standard of approved vaccines against COVID-19 (**paras. 209, 268, 297, 335, 368, 424, 480, 484 of the Analytical Report**);

- the analysis of the ratio of the expected benefit and possible risk when using a vaccine as the main criterion for the introduction of the vaccine into civil circulation (**paras. 209, 268, 305, 335, 368, 425, 481 of the Analytical Report**);

- striving for the most flexible approach regarding the approval of new vaccines against COVID-19 (**paras. 208, 267, 304, 336, 367, 426, 481 of the Analytical Report**);

- reduction in the time taken for consideration of applications for approval of clinical trials and registration of a vaccine (**paras. 210, 268, 304, 336, 426, 482–483 of the Analytical Report**).

43. The following differences can be highlighted:

- approaches to accelerating the process of introducing new vaccines into civil circulation. For example, the EU Member States have resorted to the procedure of conditional approval of vaccines (**paras. 95, 101 of the Analytical Report**), the Russian Federation has introduced a simplified procedure for approving vaccines (**paras. 208–210 of the Analytical Report**), India has taken the path of issuing emergency approval for the use of developed vaccines against COVID-19 (**para. 481 of the Analytical Report**);

- attitude to the issue of removing patent protection from medicines. For example, against the background of the pandemic, Germany has made changes to the patent legislation, providing for the possibility of issuing a free license by the Government (**para. 265 of the Analytical Report**). The need to issue a free license in order to remove restrictions on the transfer of technologies for the production of a vaccine against COVID-19 is being discussed in the United States

(**para. 373 of the Analytical Report**). In 2021, the Russian Federation introduced amendments to civil legislation, expanding the competence of the Government to allow the use of an invention without the consent of the patent owner in case of extreme necessity related to the protection of life and health of citizens (**para. 198 of the Analytical Report**);

- approaches to prioritizing groups of the population for vaccination. The formation of priority groups for vaccination largely reflects the socio-demographic priorities of each individual State. At the same time, there is a tendency to prioritize vaccination of elderly people, people with chronic diseases, and medical workers (**paras. 227, 279, 313, 343, 382, 433, 495 of the Analytical Report**).

I. INTERNATIONAL LAW

1. Global Cooperation

a. International Regulatory Framework on Vaccine Development and Authorization

44. There are no legally binding international legal norms on vaccine development. However, the WHO as "co-ordinating authority on international health work"[1] and its various international groups of experts coordinate efforts on the development of vaccines.

45. The WHO's Immunization, Vaccines and Biologicals Department is responsible for guiding immunization research and establishing immunization policy.[2] The Department maintains the list of available vaccines, providing States with the WHO policy recommendations on their use and the list of "pipeline vaccines" which are currently being developed.[3] The WHO's Product Development for Vaccines Advisory Committee prepares a summary of vaccine research and development for each vaccine in production.[4] The Committee's task is to accelerate the development of vaccines that are urgently needed and "ensure they are appropriately targeted for use in low and middle income contexts".[5]

46. Authorization procedure shall guarantee the safety and quality of vaccines. The WHO collaborates with States on the development and maintenance of global standards for vaccine authorization and production.[6] The Global Advisory Committee on Vaccine

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[1] Constitution of the World Health Organization. Article 2 (a). URL: https://www.who.int/governance/eb/who_constitution_en.pdf (the date of access: May 2, 2021).

[2] WHO. Immunization, Vaccines and Biologicals. URL: https://www.who.int/teams/immunization-vaccines-and-biologicals/about (the date of access: May 2, 2021).

[3] WHO. Vaccines & Diseases. URL: https://www.who.int/teams/immunization-vaccines-and-biologicals/diseases (the date of access: May 2, 2021).

[4] Product Development for Vaccines Advisory Committee. URL: https://www.who.int/immunization/research/committees/pdvac/en/ (the date of access: May 2, 2021).

[5] Ibid.

[6] WHO. Vaccine and immunization quality and safety. URL: https://www.who.int/immunization/quality_safety/en/ (the date of access: May 2, 2021).

Safety was established as an independent advisory body that reviews the scientific evidence with regards to any type of issue relating to the safety of a vaccine product.[7]

47. Following the West Africa Ebola outbreak of 2014–2016, the WHO developed the Emergency Use Listing mechanism. It aims at ensuring availability of "unlicensed medical products needed in public health emergency situations, to assist interested UN procurement agencies and Member States in determining the acceptability of using specific products in the context of a public health emergency, based on an essential set of available quality, safety, and efficacy data."[8]

b. Scientific Cooperation and Exchange of Information

48. Access to scientific knowledge plays an important role in reducing inequalities in the vaccination process. The UN Office of the High Commissioner for Human Rights, the UN Educational, Scientific and Cultural Organization, and the WHO, with the participation of the European Organization for Nuclear Research, initiated a call for Open Science.[9] The main idea behind Open Science is to allow scientific information, data, and outputs to be more widely accessible (Open Access) and more reliably used (Open Data) with the active engagement of all participants (Open to Society).[10]

49. In a similar vein, the WHO launched the COVID-19 Technology Access Pool to voluntarily share knowledge, intellectual property, and data relevant to response to the pandemic.[11] There are calls from nations and international organizations to require pharmaceutical companies to share their patent knowledge to assist in the creation of vaccines in less developed counties.[12] The UN Secretary-General stated that "COVID-19

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[7] WHO. Global Advisory Committee on Vaccine Safety. URL: https://www.who.int/vaccine_safety/initiative/communication/network/_gacvs/en/ (the date of access: May 2, 2021).

[8] WHO. Emergency Use Listing Procedure. URL: https://cdn.who.int/media/docs/default-source/medicines/eulprocedure_a63b659c-1cdc-4cee-aa2d-ef5dd9d94f0b.pdf (the date of access: May 2, 2021).

[9] Joint Appeal for Open Science. URL: https://www.ohchr.org/Documents/Press/WebStories/JointAppeal_OpenSciences_EN.pdf (the date of access: May 2, 2021).

[10] Ibid.

[11] WHO. COVID-19 Technology Access Pool. URL: https://www.who.int/initiatives/covid-19-technology-access-pool (the date of access: May 2, 2021).

[12] Statement by UN Human Rights Experts Universal access to vaccines is essential for prevention and containment of COVID-19 around the world. November 9, 2020. URL: https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26484&LangID=E (the date of access: May 2, 2021); Oxfam. People over profits: Make COVID-19 medicines and vaccines free and fair for all. URL: https://www.oxfam.org/en/blogs/people-over-profits-make-covid-19-medicines-and-vaccines-free-and-fair-all (the date of access: May 2, 2021).

vaccines must be seen as a global public good."[13] However, major pharmaceutical companies have refused to voluntarily share their COVID-19 technologies with other nations.[14] States are reluctant to take over the intellectual property rights of the vaccine or otherwise influence prices and dissemination.[15]

50. Exchange of information on the COVID-19 vaccines and combined affords to monitor their safety is important to facilitate the vaccination process, especially for the sake of less developed countries.[16] In that vein, the Strategic Advisory Group of Experts on Immunization within the WHO has developed a number of specific policies on the use of vaccines and issued recommendations on prioritization of COVID-19 vaccination.[17] Those policies and recommendations do not have any legally binding nature, but they serve as guidelines for States to adopt their own vaccination policies.

51. Further, the WHO upon recommendation of the Global Advisory Committee on Vaccine Safety adopted the COVID-19 Vaccines: Safety Surveillance Manual.[18] The manual provides guidance to countries on the safety monitoring and adverse events data sharing for the new COVID-19 vaccines.[19] WHO continues to review the safety data from all COVID-19 vaccines and provide advice, when necessary.[20]

c. Global Solidarity and Cooperation

52. The notion of "global solidarity" has become one of the keywords in the fight against COVID-19. Some soft law instruments, such as, for example, the ILC Draft

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[13] Statement of the UN Secretary-General. March 11, 2021. SG/SM/20620. URL: https://www.un.org/press/en/2021/sgsm20620.doc.htm (the date of access: May 2, 2021).

[14] *Gebrekidan S., Apuzzo M.* Rich Countries Signed Away a Chance to Vaccinate the World. NY Times. 2021. URL: https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html (the date of access: May 2, 2021).

[15] Ibid.

[16] See WHO. Statement on the seventh meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic. URL: https://www.who.int/news/item/19-04-2021-statement-on-the-seventh-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic (the date of access: May 2, 2021).

[17] WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination. URL: https://www.who.int/publications/i/item/who-sage-values-framework-for-the-allocation-and-prioritization-of-covid-19-vaccination (the date of access: May 2, 2021).

[18] WHO. Covid-19 vaccines: safety surveillance manual. URL: https://www.who.int/publications/i/item/10665338400 (the date of access: May 2, 2021).

[19] Statement of the WHO Global Advisory Committee on Vaccine Safety (GACVS) COVID-19 subcommittee on safety signals related to the AstraZeneca COVID-19 vaccine. URL: https://www.who.int/news/item/19-03-2021-statement-of-the-who-global-advisory-committee-on-vaccine-safety-(gacvs)-covid-19-subcommittee-on-safety-signals-related-to-the-astrazeneca-covid-19-vaccine (the date of access: May 2, 2021).

[20] Ibid.

Articles on Protection of Persons in the Event of Disasters, impose upon States a duty to cooperate in emergency situations.[21]

53. Since the COVID-19 outbreak, the UN bodies have been calling for active cooperation and emphasized the need for creative and coordinated response to the challenge.[22] The UN General Assembly underlined that the pandemic "requires a global response based on unity, solidarity and renewed multilateral cooperation".[23] The UN Security Council stressed that "combating this pandemic requires greater national, regional and international cooperation and solidarity".[24] Later on it underlined that so far "the progress in vaccine access has been uneven".[25] The UN Human Rights Experts strengthened the need for pharmaceutical companies to "join the collective and global efforts to effectively contain COVID-19."[26] The efforts of pharmaceuticals companies are of particular importance in view of their pricing policies and reliance on international and national patent protection mechanisms.[27]

d. Fair Distribution of Vaccines

54. The issue of equitable access to COVID-19 vaccines is frequently raised at the international level. The UN Security Council underlines the need for strong global cooperation to ensure fair access to vaccines for all countries.[28] "Isolationist health policies and procurement" are being criticized by UN human rights experts as contrary to international human rights standards.[29]

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[21] See, e.g., ILC. Report of the International Law Commission on the Work of its 68th session. UN Doc. A/71/10. Chapter IV. Article 7.

[22] United Nations. Shared responsibility, global solidarity: responding to the socio-economic impacts of COVID-19. URL: https://www.un.org/sites/un2.un.org/files/sg_report_socio-economic_impact_of_covid19.pdf (the date of access: May 2, 2021).

[23] UN General Assembly Resolution No. 74/270. April 3, 2020. URL: https://undocs.org/pdf?symbol=en/A/RES/74/270 (the date of access: May 2, 2021).

[24] UN Security Council Resolution No. 2532. July 1, 2020. URL: https://undocs.org/en/S/RES/2532(2020) (the date of access: May 2, 2021).

[25] UN Security Council Resolution No. 2565. February 26, 2021. URL: https://undocs.org/en/S/RES/2565(2021) (the date of access: May 2, 2021).

[26] Statement by UN Human Rights Experts. Universal access to vaccines is essential for prevention and containment of COVID-19 around the world. November 9, 2020. URL: https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26484&LangID=E (the date of access: May 2, 2021).

[27] See, e.g., Oxfam. Pharmaceutical giants shell out billions to shareholders as world confronts vaccine apartheid. URL: https://www.oxfam.org/en/press-releases/pharmaceutical-giants-shell-out-billions-shareholders-world-confronts-vaccine (the date of access: May 2, 2021).

[28] See UN Security Council Resolution 2565. February 26, 2021.

[29] Statement by UN Human Rights Experts. Universal access to vaccines is essential for prevention and containment of COVID-19 around the world. November 9, 2020.

55. On April 24, 2020, the WHO launched the Access to COVID-19 Tools Accelerator partnership. This initiative was welcomed by the UN Secretary-General.[30] The initiative focuses on the acceleration of the development, production, and equitable access to COVID-19 vaccine. Within the Accelerator, the WHO, the UN, governments, vaccine manufacturers, and other actors are working on the COVAX.

56. The COVAX is a global procurement mechanism aimed at guaranteeing fair access to vaccines for all countries. Participating countries act together in supporting the research, development, and manufacturing of a wide range of COVID-19 vaccine candidates and have rapid access to doses of vaccines as soon as they receive regulatory approval. It is intended that all participating countries, regardless of income levels, "will have equal access to these vaccines."[31] So far, more than 38 million doses of vaccines were delivered under the COVAX program to over 100 countries.[32] The COVAX aims to supply vaccines in the first half of 2021.[33] To reach this end, the EU Commission and the EU States, for example, have pledged over EUR 2.2 billion to the COVAX.[34]

e. Transportation of COVID-19 Vaccines

57. Another area for global cooperation is the regulation of vaccine transportation. COVID-19 vaccines need to be delivered safely and swiftly. Moreover, the storage and transportation of vaccines is a highly specialized matter.[35] Almost all vaccines shall be transported under ultra-low temperature. Supply chain readiness is a key element for the success of the vaccination campaign.[36] The WHO has issued the supply and logistics guidance for COVID-19 vaccines.[37] The Emergency Committee regarding the coronavirus

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[30] Secretary-General's remarks at the launch of the Statement of Commitment and Call for Support for the Global Collaboration to Accelerate the Development, Production and Equitable Access to New COVID-19 Tools. URL: https://www.un.org/sg/en/content/sg/statement/2020-04-24/secretary-generals-remarks-the-launch-of-the-statement-of-commitment-and-call-for-support-for-the-global-collaboration-accelerate-the-development-production-and (the date of access: May 2, 2021).

[31] COVAX explained. URL: https://www.gavi.org/vaccineswork/covax-explained (the date of access: May 2, 2021).

[32] WHO. COVAX reaches over 100 economies, 42 days after first international delivery. URL: https://www.who.int/news/item/08-04-2021-covax-reaches-over-100-economies-42-days-after-first-international-delivery (the date of access: May 2, 2021).

[33] Ibid.

[34] Safe COVID-19 vaccines for Europeans. URL: https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans_en (the date of access: May 2, 2021).

[35] DHL. Vaccine Logistics: Cold chain, hot topic. URL: https://www.dhl.com/global-en/home/about-us/delivered-magazine/articles/2021/issue-1-2021/cold-chain-hot-topic.html (the date of access: May 2, 2021).

[36] WHO. COVID-19 vaccination: supply and logistics guidance. February 15, 2021. URL: https://www.who.int/publications/i/item/who-2019-ncov-vaccine-deployment-logistics-2021-1 (the date of access: May 2, 2021).

[37] Ibid.

disease advised the WHO Secretariat to continue cooperation with relevant actors in the fields of international travel and transport for the regular review, update, and dissemination of practice-based guidance on travel-related risk reduction measures.[38]

58. Further, to facilitate preparedness for COVID-19 vaccine transportation, the International Air Transport Association, in collaboration with several leading authorities and organizations and global humanitarian agencies, released Guidance for Vaccine and Pharmaceutical Logistics and Distribution.[39] Other stakeholders in freight transport and logistics issue recommendations and practical insights for effective COVID-19 vaccine air transportation and handling.[40]

59. To strengthen the capacity to prompt smooth delivery of vaccine, some States adopted such measures as priority clearance channels, lessening, and simplifying documentary requirements and electronic processing, and improving border agency cooperation.[41]

f. Common Standards for COVID-19 Vaccination Certificates

60. Further, there is a recognized need to achieve consensus on common standards for COVID-19 vaccination certificates[42] to ensure that certificates issued in one country will be recognized elsewhere. According to paragraph 2 of Annex 6 of the IHR, persons undergoing vaccination shall be provided with an international certificate of

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[38] Statement on the seventh meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic: Advice to the WHO Secretariat.

[39] Guidance for Vaccine and Pharmaceutical Logistics and Distribution. URL: https://www.iata.org/contentassets/028b3d4ec3924cb393155c84784161ac/guidance-for-vaccine-and-pharmaceutical-logistics-and-distribution---global-collaboration_onepager_general.pdf (the date of access: May 2, 2021).

[40] See, e.g., Transportation of COVID-19 Vaccines (Sunrays Project to help air cargo industry get ready). URL: https://tiaca.org/sunrays/ (the date of access: May 2, 2021); Vaccine Logistics: Cold chain, hot topic. URL: https://www.dhl.com/global-en/home/about-us/delivered-magazine/articles/2021/issue-1-2021/cold-chain-hot-topic.html (the date of access: May 2, 2021). ICAO/WCO Joint Statement on the global transportation and distribution of COVID-19 vaccines and associated medical supplies. URL: https://www.icao.int/Security/COVID-19/PublishingImages/Pages/Statements/%28English%29.pdf (the date of access: May 2, 2021); White Paper: Delivering Pandemic Resilience. URL: https://www.dhl.com/global-en/home/insights-and-innovation/thought-leadership/white-papers/delivering-pandemic-resilience.html (the date of access: May 2, 2021).

[41] WTO. How WTO Members Have Used Trade Measures to Expedite Access to COVID-19 Critical Medical Goods and Services. Information note. September 18, 2020. P. 5–7. URL: https://www.wto.org/english/tratop_e/covid19_e/services_report_16092020_e.pd (the date of access: May 2, 2021).

[42] WTO. Smart Vaccination Certificate Working Group. URL: https://www.who.int/groups/smart-vaccination-certificate-working-group (the date of access: May 2, 2021).

vaccination.[43] The WHO is cooperating with Member States on the elaboration of requirements for proof of COVID-19 vaccination for international travelers, in accordance with relevant IHR provisions.[44] The focus currently lies in the development of standards for creation of a common digital form of certificates proving the COVID-19 vaccination. Digital technologies could be safer in view of possible fraud and falsification.[45]

2. Rules and Regulations of the WTO Relevant to the COVID-19 Vaccines

a. Export and Import Regulations

61. To address the shortage of the COVID-19 vaccines, some WTO members have temporarily restricted or banned export of vaccines or, more generally, all pharmaceutical products for human use from their territories.[46] Export prohibitions or limits on the quantity of a good which may be exported or imported qualify as quantitative restrictions under Article XI of the GATT.[47] Article XI of the GATT directly prohibits such measures. However, such prohibition is subject to justifications. Article XI(2)(a) allows Member States to impose temporary export restrictions to "relieve critical shortages of foodstuffs and other products essential to the exporting country". The WTO Appellate Body explained in the *China – Raw Materials* case that critical shortage shall be understood as: "deficiencies in quantity that are crucial, that amount to a situation of decisive importance, or that reach a vitally important or decisive stage, or a turning point".[48]

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[43] International Health Regulations. Annex 6. URL: https://www.who.int/publications/i/item/9789241580496 (the date of access: May 2, 2021).

[44] Interim guidance for developing a Smart Vaccination Certificate. P. 2. URL: https://cdn.who.int/media/docs/default-source/documents/interim-guidance-svc_20210319_final.pdf (the date of access: May 2, 2021).

[45] Ibid.

[46] See, e.g., Commission Implementing Regulation (EU) 2021/442 of March 11, 2021, making the exportation of certain products subject to the production of an export authorization. Article 1 (1) (7). URL: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021R0442&from=EN (the date of access: May 2, 2021). See also WTO. COVID-19: Measures affecting trade in goods. URL: https://www.wto.org/english/tratop_e/covid19_e/trade_related_goods_measure_e.htm (the date of access: May 2, 2021).

[47] WTO. General Agreement on Tariffs and Trade of 1994. URL: https://www.wto.org/english/docs_e/legal_e/06-gatt_e.htm (the date of access: May 2, 2021).

[48] WTO. *China-Measures Related to the Exportation of Various Raw Materials*. WT/DS394/AB/R. Report of the Appellate Body. January 30, 2012. Para. 324.

62. Another ground for justification of export restrictions is stipulated by the general exceptions contained in Article XX of the GATT. Article XX(b) allows Members to take measures "necessary to protect human, animal or plant life or health" that otherwise violate their GATT obligations. The adoption of those measures is being justified by the need to protect human health and lives in face of the COVID-19 pandemic.[49] Thus, they fall within the category of measures embraced by Article XX(b) of the GATT.[50]

63. Further, examination of "necessity" requires to balance the importance of the interests at stake, the extent of the contribution to the measure's objective, and the trade restrictiveness.[51] The balancing test includes consideration of the existence of an alternate measure that would be more in conformity with the WTO rules.[52] In addition, the degree of trade restrictiveness shall correspond to the proclaimed objective and there should be no better alternatives which would be more in conformity with WTO rules. Thus, the GATT grants a policy space to Member States to react to the COVID-19 pandemic, which may include export restrictions and limitations.

b. Trade-Related Aspects of Intellectual Property Rights

64. The TRIPS Agreement provides for an international standard for patent protection of medicine, including vaccines.[53] As stated in the Doha Declaration on the TRIPS Agreement and Public Health, "intellectual property protection is important for the development of new medicines".[54] However, in the context of effective and fair distribution of intellectual property rights are viewed as potentially hindering availability of affordable vaccine to less developed countries.[55]

65. The TRIPS foresees various relevant exemptions from the existing regime. For instance, under Article 27 States may exclude from patentability inventions that are necessary to protect health and therapeutic methods for the treatment of humans.[56] Article 31 of the TRIPS allows compulsory licensing and government use of a patent

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[49] See WTO. COVID-19: Trade and trade-related measures. URL: https://www.wto.org/english/tratop_e/covid19_e/covid19_e.htm (the date of access: May 2, 2021).

[50] See, e.g., WTO. *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*. WT/DS135/AB/R. Report of the Appellate Body of March 12, 2001. Paras. 157–163.

[51] WTO. THAILAND-RESTRICTIONS ON IMPORTATION OF AND INTERNAL TAXES ON CIGARETTES. DS10/R-37S/200. REPORT OF THE PANEL. NOVEMBER 7, 1990. PARA. 75.

[52] WTO. *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*. Para. 172.

[53] WTO. Agreement on Trade-Related Aspects of Intellectual Property Rights. URL: https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm (the date of access: May 2, 2021).

[54] WTO. Declaration on the TRIPS Agreement and Public Health. WT/MIN(01)/DEC/W/2. Ministerial Conference. November 14, 2001. Para. 3.

[55] See Statement by UN Human Rights Experts Universal access to vaccines is essential for prevention and containment of COVID-19 around the world.

[56] Agreement on Trade-Related Aspects of Intellectual Property Rights. Article 27.

without the authorization of its owner under certain conditions aimed at protecting the legitimate interests of the patent holder.[57] Thus, as such, it would be in conformity with the current TRIPS regime if States grant compulsory licensing and government-use orders for vaccines. Some States have recently amended their national law to enable national competent authorities to order the use of patent-protected inventions to ensure the supply of various health technologies, including vaccines.[58] There have also been examples of States granting a compulsory license to produce a certain medicine.[59] Thus, there are available legal mechanisms allowing governments to overcome intellectual property rights barriers if they were to arise.

66. In view of the COVID-19 pandemic, the governments of India and South Africa initiated a waiver from the implementation, application, and enforcement of Sections 1 (copyright), 4 (industrial design), 5 (patent), and 7 (protection of undisclosed information) of Part II (standards concerning the availability, scope and use of intellectual property rights) of the TRIPS Agreement.[60] The UN Human Rights Experts explicitly welcomed this idea,[61] a number of developing States have also supported the initiative.[62]

c. WTO Call for Transparency

67. As mentioned above, the current WTO regime allows States to address the shortage and the need for manufacturing, development, and distribution of the COVID-

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[57] Ibid. Article 31.

[58] For instance, Bill C-13 amends Canada's Patent Act to empower the Commissioner of Patents, on the application of the Minister of Health, to authorize the Government of Canada or another specified person to supply a patented invention to the extent necessary to respond to a public health emergency that is a matter of national concern. The Bill ensures that a patent holder receives adequate remuneration. In Germany, the Federal Ministry for Health was given a competence to order the competent authority to allow the use of patent-protected inventions to ensure the supply of various health technologies, including medicines, diagnostics and personal protection equipment. See also WTO. Measures regarding trade-related intellectual property rights. URL: https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm (the date of access: May 2, 2021).

[59] For instance, the Hungarian Intellectual Property Office issued three compulsory licenses for domestic use of Remdesivir. The Russian Federation issued an Order granting a compulsory license with regards to a number of patents related to Remdesivir until the end of 2021 with the aim of supplying the population of the Russian Federation. For more information see WTO. COVID-19: Measures regarding trade-related intellectual property rights.

[60] Communication from India and South Africa. Waiver from certain provisions of the TRIPS Agreements for the Prevention, Containment and Treatment of COVID-19. IP/C/W/669. October 2, 2020. URL: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True (the date of access: May 2, 2021).

[61] Statement by UN Human Rights Experts Universal access to vaccines is essential for prevention and containment of COVID-19 around the world.

[62] See Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19. Communication from India and South Africa. Addendums. URL: https://cutt.ly/CbY9ilL (the date of access: May 2, 2021).

19 vaccines by exceptional measures. However, Article X of the GATT, Article III of the General Agreement on Trade in Services, and Article 63 of the TRIPS Agreement impose an obligation of transparency upon Member States of the WTO. This obligation requires States to notify the WTO Secretariat of any measures related to international trade policy.

68. The WTO emphasizes the importance of transparency with respect to trade and trade-related measures taken in the context of the COVID-19 crisis.[63] The WTO Secretariat collects and publishes notifications of the Member States of the measures adopted in response to the COVID-19 pandemic.[64] Those publications are made without prejudice to the legality of the notified measures.

3. Vaccination in the Context of Human Rights

a. Right to Life

69. The right to life finds its prominent recognition in most international human rights treaties[65] and declarations.[66] This right belongs to non-derogative rights even in exceptional circumstances[67] and corresponds to the State's duty to protect life.[68] The UN stressed out that the protection of the human right to life shall remain in focus in the current pandemic.[69] Vaccination is an effective tool to save lives.[70] The duty to take reasonable steps to protect life in the context of the COVID-19 pandemic results in a duty to ensure access to the COVID-19 vaccine.[71]

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[63] WTO. COVID-19: Support measures. URL: https://www.wto.org/english/tratop_e/covid19_e/covid19_e.htm (the date of access: May 2, 2021).

[64] See WTO. COVID-19: Trade and trade-related measures.

[65] See, e.g., International Covenant on Civil and Political Rights. Article 6; Arab Charter on Human Rights. Articles 5–6; African Charter on Human and Peoples' Rights. Article 4; European Convention for the Protection of Human Rights and Fundamental Freedoms. Article 2; American Convention on Human Rights. Article 4.

[66] Universal Declaration of Human Rights. Article 3. URL: https://www.un.org/en/about-us/universal-declaration-of-human-rights (the date of access: May 2, 2021).

[67] International Covenant on Civil and Political Rights. Article 4(2).

[68] OHCHR. International Standards. URL: https://www.ohchr.org/EN/Issues/Executions/Pages/InternationalStandards.aspx (the date of access: May 2, 2021).

[69] UN. COVID-19 and Human Rights. April 2020. P. 4. URL: https://www.un.org/victimsofterrorism/sites/www.un.org.victimsofterrorism/files/un_-_human_rights_and_covid_april_2020.pdf (the date of access: May 2, 2021).

[70] UN Security Council Resolution No. 2565. February 26, 2021.

[71] Statement by UN Human Rights Experts Universal access to vaccines is essential for prevention and containment of COVID-19 around the world. November 9, 2020.

70. In a similar vein, the administration of the vaccination process shall be organized with a view to the need to protect the right to life. For instance, prioritizing the order in which people receive their vaccine shall depend on the level of risk they face from becoming seriously ill and/or by the likelihood that they will be exposed to the virus. Otherwise, it may result in failure to protect life.[72]

b. Right to Health

71. The right to health equally belongs to fundamental human rights recognized in numerous international instruments.[73] It imposes on States the obligation to ensure available and financially accessible medicine to their population.[74] It also requires States to organize the vaccination process on a non-discriminatory basis, with particular attention to vulnerable or marginalized groups.[75] However, many States are currently facing difficulties in ensuring the availability of COVID-19 vaccines.[76]

72. Also, in assuring the right to health States are under the obligation to "provide protection against every possible cause of human ill health".[77] Since vaccination may have negative health repercussions, by authorizing the use of a vaccine States shall ensure that its potential benefits outweigh possible risks. This obligation also requires

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[72] Human Rights Committee. General comment No. 36. CCPR/C/GC/36. September 3, 2019. URL: https://tbinternet.ohchr.org/_layouts/15/treatybodyexternal/Download.aspx?symbolno=CCPR/C/GC/36&Lang=en (the date of access: May 2, 2021).

[73] See Universal Declaration of Human Rights. Article 25(1); International Covenant on Economic, Social and Cultural Rights. Article 12(1); European Social Charter. Article 11; African Charter on Human and Peoples' Right. Article 16; Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights. Article 10.

[74] UN Committee on Economic, Social and Cultural Rights. General Comment No. 14 (2000): The right to the highest attainable standard of health. August 11, 2000. Para. 12. URL: https://www.ohchr.org/EN/Issues/Education/Training/Compilation/Pages/e)GeneralCommentNo14Therighttothehighestattainablestandardofhealth(article12)(2000).aspx (the date of access: May 2, 2021).

[75] UN Committee on Economic, Social and Cultural Rights. General Comment No. 14 (2000): The right to the highest attainable standard of health. August 11, 2000. Para. 12.

[76] UN. Unequal Vaccine Distribution Self-Defeating, World Health Organization Chief Tells Economic and Social Council's Special Ministerial Meeting. URL: https://www.un.org/press/en/2021/ecosoc7039.doc.htm (the date of access: May 2, 2021); Oxfam. Small group of rich nations have bought up more than half the future supply of leading COVID-19 vaccine contenders. URL: https://www.oxfam.org/en/press-releases/small-group-rich-nations-have-bought-more-half-future-supply-leading-covid-19 (the date of access: May 2, 2021).

[77] Ibid. Para. 9.

States to carefully track reported adverse events related to vaccines and appropriately react to serious instances.[78]

c. Freedom of Movement in View of the Principle of Non-Discrimination

73. The process of vaccination against COVID-19 is associated with the hope of facilitating the safe movement of people in the context of the current pandemic. A number of international law instruments prescribe the right to liberty of movement for everyone.[79] In this regard, States are currently considering the idea of vaccine passports or certificates as a prerequisite for the safe movement of persons.[80]

74. As a general rule stipulated in Article 31 of the IHR, vaccination shall not be required as a condition for entry to a State.[81] However, a State Party may require a person to undergo vaccination, or other preventive measures, for example, when it is necessary to determine whether a public health risk exists. If a traveler fails to consent to any such measure, the State Party concerned may deny entry to that traveler.[82]

75. In case States would opt for requiring proof of vaccination as a condition for entry, the principle of non-discrimination prohibits any unjustified differentiations in that regard.[83] Allowing people who received the vaccine to move freely is a differential treatment compared with those who for various reasons did not get a vaccine or refused to vaccinate. Such treatment requires an objective and reasonable justification.[84] The IHR Emergency Committee for COVID-19 advised the WHO Secretariat to "strongly

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[78] For instance, currently States consider limiting AstraZeneca vaccine due to the evidence linking it to rare blood clots. See, e.g., Covid: Under-30s offered alternative to Oxford-AstraZeneca jab. URL: https://www.bbc.com/news/health-56665517 (the date of access: May 2, 2021); Covid: Germany limits use of AstraZeneca Covid jab for under-60s. URL: https://www.bbc.com/news/world-europe-56580728 (the date of access: May 2, 2021).

[79] See Universal Declaration of Human Rights. Article 13; International Covenant on on Civil and Political Rights. Article 12; Protocol No. 4 to the Convention for the Protection of Human Rights and Fundamental Freedoms, securing certain rights and freedoms other than those already included in the Convention and in the first Protocol thereto. Article 2; African Charter on Human and Peoples' Rights. Article 12; American Convention on Human Rights. Article 22. At the same time, the same articles of the listed international treaties provide for the possibility of imposing restrictions on the exercise of the right to liberty of movement in certain circumstances.

[80] See, e.g., European Commission. Coronavirus: Commission proposes a Digital Green Certificate. URL: https://ec.europa.eu/commission/presscorner/detail/en/IP_21_1181 (the date of access: May 2, 2021).

[81] International Health Regulations. Article 31 (1).

[82] Ibid. Article 31 (2).

[83] See, e.g., International Covenant on Civil and Political Rights. Article 2(1).

[84] See, e.g., Guide on Article 14 of the European Convention on Human Rights and on Article 1 of Protocol No. 12 to the Convention. Prohibition of discrimination. Updated on December 31, 2020. URL: https://www.echr.coe.int/Documents/Guide_Art_14_Art_1_Protocol_12_ENG.pdf (the date of access: May 2, 2021).

encourage" States to acknowledge that requiring proof of vaccination as a condition of entry on their territories may potentially "deepen inequities and promote differential freedom of movement" and, thus, "not to require proof of vaccination as a condition of entry".[85] To prevent discrimination against individuals who are not vaccinated, the EU Commission suggested creating COVID-19 test certificates and certificates for persons who have recovered from COVID-19 in addition to an interoperable vaccination certificate.[86]

d. Permissibility of Compulsory Vaccination and the Right to Private Life

76. The national law of some States provides an option of mandating vaccination in certain situations (**paras. 272–273, 308, 376–377, 429–430, 487–489 of the Analytical Report**). At the same time, it is crucial to note that, for example, the Oviedo Convention provides that "an intervention in the health field [vaccination is included] may only be carried out after the person concerned has given free and informed consent to it", which can be withdrawn at any time.[87] Besides, the person "shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks".[88] In case the person "has suffered undue damage resulting from the intervention, she/he is entitled to fair compensation according to the conditions and procedures prescribed by law".[89] While "no restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention", the exception is made for those "prescribed by law and necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others".[90]

77. The European Court of Human Rights has recognized that a requirement to undergo medical treatment or a vaccination may amount to interference with the human

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[85] Statement on the seventh meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic: the WHO Secretariat.

[86] See Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate). URL: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0130 (the date of access: May 2, 2021).

[87] The Council of Europe. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. ETS No. 164. April 4, 1997. Article 5. URL: https://www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168007cf98 (the date of access: May 2, 2021) (hereinafter, "**Oviedo Convention**").

[88] Ibid.

[89] Ibid. Article 24.

[90] Ibid. Article 26.

right to private life recognized under international or regional human instruments.[91] However, such interference may be justified by the existence of legitimate aim, such as the protection of public health,[92] and it has to satisfy the principle of proportionality.[93]

78. In case States opt for mandatory vaccination against COVID-19 or other viruses in the future, human rights standards would require them to carefully assess the necessity and safety of a vaccine for individuals.[94] Thus, upon fulfillment of the mentioned criteria, compulsory vaccination against COVID-19 could be compatible with the human rights regime.

[91] European Court of Human Rights. *Vavřička and others v. the Czech Republic*. Application no. 47621/13. Judgement of April 8, 2021. Para. 263; European Court of Human Rights. *Solomakhin v. Ukraine*. Application no. 24429/03. Judgement of September 24, 2012. Para. 33; European Court of Human Rights. *Matter v. Slovakia*. Application no. 31534/96. Judgment of July 5, 1999. Para. 64.

[92] See European Commission on Human Rights. *Jeffrey Dudgeon v. the United Kingdom*. Application no. 7525/75. Report of the Commission of March 13, 1980. Paras. 51–53; European Court of Human Rights. *X, Y and Z v the United Kingdom*. Application no. 75/1995/581/667. Judgment of April 22, 1997. Para. 44.

[93] Guide on Article 14 of the European Convention on Human Rights and on Article 1 of Protocol No. 12 to the Convention. Prohibition of discrimination. Updated on December 31, 2020. P. 19–20.

[94] European Commission on Human Rights. *Jeffrey Dudgeon v. the United Kingdom*. Application no. 7525/75. Report of the Commission of March 13, 1980. Paras. 51–53.

II. REGIONAL INTEGRATION LAW

1. European Union

1.1. Vaccine Development

a. General Legal Framework

General information

79. All vaccines must be authorized before they can be marketed and made available to patients in the EU. There are two main procedures for authorizing medicine: a centralized procedure[95] and a national one.[96] Under the EU legislation, the centralized authorization procedure is compulsory for the listed diseases (such as cancer, diabetes, HIV, etc.) as well as for medical products derived from biotechnology and orphan medicinal products.[97] For other medicine, the use of the centralized procedure is optional, if such medical product contains a new active substance or constitutes a significant therapeutic, scientific, or technical innovation.[98] According to the mentioned requirements, new vaccines are thus eligible for being authorized under the centralized procedure.

80. The main legal framework governing medicinal products for human use includes Directive 2001/83/EC on the Community code relating to medicinal products for human use[99] and Regulation (EC) No. 726/2004, laying down Community procedures for

[95] Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. URL: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0001:0033:en:PDF (the date of access: April 30, 2021) (hereinafter, "**Regulation (EC) No. 726/2004**").

[96] Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use. URL: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf (the date of access: April 30, 2021) (hereinafter, "**Directive 2001/83/EC**").

[97] Regulation (EC) No. 726/2004. Article 3 (1).

[98] Ibid. Article 3 (2).

[99] This directive applies to industrially produced medicinal products for human use intended to be placed on the market in Member States (national authorization procedure).

authorization and supervision of medicinal products for human and veterinary use.[100] Regulation (EC) No. 776/2004 established the EMA. Regulation No. 536/2014 provides for a legal framework for the conduct of clinical trials in the EU Member States.[101]

Stages and time frameworks for conducting clinical trials

81. Under normal conditions, vaccine development is a long process which might take up to 10 years from initial concept to authorization.[102] Clinical trials are normally preceded by extensive testing by the vaccine developer to try the vaccine effects and its safety in the laboratories. Clinical trials may only be undertaken if the vaccine developer is able to demonstrate a positive balance in weighting the foreseeable risks and inconveniences against the anticipated benefit for the trial subjects.[103] The conduct of clinical trials is also subject to authorization by the competent authority of the Member State in which the clinical trials are planned to be conducted.[104]

82. The clinical trials are meant to investigate the safety, efficacy, and immunogenicity of vaccine candidates in three phases with large numbers of people involved in each phase.[105] The trial subjects shall give their informed consent to take part in the trials of vaccines.[106]

83. The EU legislation does not mandate timelines or set deadlines either for the development of a vaccine in general or the conduct of clinical trials in particular. The legislation only defines timelines for authorization and approval of submitted applications and requests. For instance, consideration of the valid request for authorization by the competent authority of the Member State in which the clinical trials are planned to be conducted shall be carried out as rapidly as possible and may not exceed 45 days.[107] The applicable legal provisions, as follow from the examples above, only set the time limits and do not preclude the possibility of reducing the time frame.

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[100] This Regulation laying down Community procedures for the authorization, supervision and pharmacovigilance of medicinal products for human and veterinary use (centralized authorization procedure).
[101] Regulation No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use. URL: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf (the date of access: April 30, 2021) (hereinafter, "**Regulation No. 536/2014**").
[102] Approval of vaccines in the European Union. URL: https://vaccination-info.eu/en/vaccine-facts/approval-vaccines-european-union (the date of access: April 30, 2021).
[103] Regulation No. 536/2014. Articles 3, 28 (1) (e).
[104] Ibid. Articles 4, 8.
[105] Ibid. Article 2 (2).
[106] Ibid. Article 29.
[107] Ibid. Articles 6 (4), 7 (2).

Legal control mechanisms

84. Prior to the starting of the clinical trials, vaccine manufacturers must submit a request for authorization to the competent authority of the EU Member State in which the conduct of the clinical trials is being planned.[108]

85. If a Member State has objective grounds for considering that the conditions for authorization are no longer met or has information raising doubts about the safety or scientific validity of the clinical trial, it may suspend or prohibit the clinical trial.[109]

Vaccine authorization

86. Upon completion of clinical trials, the vaccine developer submits the application for the marketing authorization to the EMA.[110] The EMA's CHMP is responsible for the examination of the submitted application.[111]

87. The comprehensive application dossier includes the following components:[112]

- scientific justifications for the vaccine effect and its safety (results of all conducted trials, description of the manufacturing process, description of control mechanisms employed by the manufacturer, confirmation of compliance with good-manufactory practice);

- product information (the list of all the constituents of vaccine, description of the manufacturing process);

- educational material to health care professionals, labeling (a proposed labeling text for packaging as well as for the package leaflet), etc.

88. The list of the required documents and information is stated in Appendix I of Directive 2001/83/EC. By virtue of Article 6 of the Regulation (EC) No. 726/2004, the same list of documents applies for centralized procedures.

89. The EMA's CHMP is authorized to carry out inspections and investigations to verify the information submitted by the vaccine developer.[113] It also has the competence

[108] Ibid. Articles 4, 8.
[109] Ibid. Article 38.
[110] Regulation (EC) No. 726/2004. Article 4 (1).
[111] Ibid. Article 5.
[112] See Ibid.
[113] Ibid. Articles 7 (a), 8 (2).

to request a Member State of the applicant to provide required proof and information[114] or request any supplementary information from the applicant.[115] The core criterion for the granting of marketing authorization is a proper and sufficient demonstration of a vaccine's quality, safety, and efficacy.[116] The vaccine candidate can only be approved if a scientific evaluation of the clinical test results demonstrates that the vaccine's benefits are greater than its risks.[117]

90. The duration of the analysis of the scientific data in the file concerning the application for marketing authorization must be at least 80 days.[118] The EMA shall ensure that the final decision of the CHMP on the application is taken within 210 days after the receipt of the valid application.

91. When an application is submitted for marketing authorization in respect of medicinal products for human use which are of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may request an accelerated assessment procedure.[119]

92. The European Commission is the authorizing body for all centrally authorized products, which takes a legally binding decision based on EMA's recommendation.[120] Before taking its decision, the Commission invites the Member States to forward their written observations on the draft decision of the Commission.[121]

93. At the point when the European Commission authorizes a vaccine as safe and effective for the EU market, it may be licensed and manufactured throughout the European Community.[122] Under normal conditions, an initial marketing authorization is valid for five years.[123] Once renewed, the marketing authorization is valid for an unlimited period of time.[124]

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[114] Ibid. Article 8 (1).
[115] Ibid. Article 7 (c).
[116] Ibid. Article 12 (1).
[117] Ibid. Article 16 (2).
[118] Ibid. Article 6 (3). This Article provides for an exception for a situation where the rapporteur and co-rapporteur declare that they have completed their assessment before that time.
[119] Ibid. Article 14 (9). See also EMA's Guideline on the scientific application and the practical arrangements necessary to implement the procedure for accelerated assessment pursuant to Article 14 (9) of Regulation (EC) No. 726/2004. 2015. URL: https://www.ema.europa.eu/en/guideline-scientific-application-practical-arrangements-necessary-implement-procedure-accelerated (the date of access: April 30, 2021).
[120] Regulation (EC) No. 726/2004. Article 10.
[121] Ibid. Article 10 (3) (b).
[122] Ibid. Article 13.
[123] Ibid. Article 14 (1).
[124] Ibid. Article 14 (3).

94. Further, all pharmaceutical manufacturers need a manufacturing license from the national competent authority where they operate.[125] National competent authorities carry out good manufacturing practice inspections to check that manufacturers comply with EU standards, the conditions of their license and the marketing authorization.[126]

95. The EU legislation provides for a possibility of marketing authorization under exceptional circumstances.[127] The so-called CMA may be granted only when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use, for objective, verifiable reasons.[128] This type of authorization is reviewed annually to reassess the risk-benefit balance.[129] CMA may be granted subject to specific obligations, such as to complete the identified studies, conduct additional studies, and provide the required data.[130]

Emergency use authorization

96. EUA allows for the temporary use of medicine (including unauthorized vaccine) under specific conditions as long as emergency circumstances apply and unless the product gets a proper marketing authorization.[131] Issuing an EUA lies in the competence of Member States. In case a Member State has issued such an authorization, it is restricted to the authorizing Member State only and remains to be its responsibility. In this vein, Member States decide on the requirements imposed for the use and supervision of vaccines circulated under EUA.

Vaccine patent protection

97. The EU Member States shall protect vaccines under national patent law and international agreements. Generally, a patent can be granted for any invention having a

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[125] Directive 2001/83/EC. Article 40.
[126] See Regulation (EC) No. 726/2004. Article 19. See also Directive 2001/83/EC. Titles IV, XI.
[127] Regulation (EC) No. 726/2004. Article 14 (8). Directive 2001/83/EC. Article 22.
[128] Directive 2001/83/EC. Article 22. Valid reasons for not being able to provide with the full data might be as follows: the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, or in the present state of scientific knowledge, comprehensive information cannot be provided, or it would be contrary to generally accepted principles of medical ethics to collect such information. See Directive 2001/83/EC. Annex I. Part II. See also EMA's Guideline on procedures for the granting of a marketing authorization under exceptional circumstances, pursuant to Article 14 (8) of Regulation (EC) No. 726/2004. 2005. URL: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-procedures-granting-marketing-authorisation-under-exceptional-circumstances-pursuant/2004_en.pdf (the date of access: April 30, 2021).
[129] Directive 2001/83/EC. Article 22.
[130] See EMA's Guideline on procedures for the granting of a marketing authorization under exceptional circumstances, pursuant to Article 14 (8) of Regulation (EC) No. 726/2004.
[131] Directive 2001/83/EC. Article 5 (2).

technical character provided that it involves innovation and is susceptible to industrial application.[132] A patent on a new vaccine may cover its entire composition, technological process, individual component, manufacturing process, delivery systems, and distribution networks.[133]

98. Patents have territorial application. In the EU protection is possible either by national patents or by European patents granted centrally by the European Patent Office. A national patent is granted by the competent national IP authorities in the EU Member States and is regulated by the national law of each EU State. Generally, vaccines are patentable if they fulfill the general requirements for patentability, i.e. novelty, inventiveness, and industrial applicability.

99. A compulsory license for the invention protected by the patent exists in the EU legislation.[134] Same mechanism is also provided for in national legislation of some EU Member States.

b. Legal Framework for the COVID-19 Vaccine Development

100. On June 17, 2020, the European Commission presented the EU Vaccination Strategy. The Strategy aims at ensuring the quality, safety, and efficiency of vaccines, securing timely access to vaccines for Member States, ensuring equitable access for the EU Member States to an affordable vaccine.[135]

101. All currently authorized COVID-19 vaccines went through the centralized procedure. The situation of pandemic justifies reliance upon provision for CMA. The CMA contains the same rights and liability for its holder as per that of a standard marketing authorization. In addition, the holder of a CMA has specific obligations such as to complete or conduct new studies within a defined time period in order to confirm that the benefit/risk balance remains positive.

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[132] See Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe. URL: https://ec.europa.eu/health/sites/health/files/human-use/docs/pharmaceuticals_incentives_study_en.pdf (the date of access: April 30, 2021).

[133] Ibid.

[134] Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998, on the legal protection of biotechnological inventions. URL: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:31998L0044&from=EN (the date of access: April 30, 2021).

[135] Communication from the Commission to the European Parliament, the European Council, the Council and the European Investment Bank: EU Strategy for COVID-19 vaccines. URL: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0245&from=EN (the date of access: April 30, 2021).

102. For further acceleration of the process, the EMA has put in place rapid review procedures, so-called "rolling review".[136] This procedure allows in public health emergencies to assess data for promising medicines or vaccines as they become available instead of waiting until all trials have concluded to start their work. Through these rolling reviews, EMA's CHMP can start evaluating data while the development is still ongoing, and before the vaccine developer has submitted a request for marketing authorization.

103. By the time when a marketing authorization is officially requested, the formal assessment can proceed much more quickly, as the data have already been scrutinized during the rolling review. This allows saving time provided for taking decisions on submitted applications.

104. The European Commission is also ensuring that the process leading to the marketing authorization can take place as quickly as possible by shortening administrative steps, such as the period for consulting Member States (in a normal case up to 22 days to only three days following a positive recommendation from the EMA) and by allowing for the translation of the product information in all official languages to take place in the first instance in electronic form to save time.

105. The Commission entered into APAs with individual vaccine producers on behalf of the EU Member States.[137] Such power of the Commission derives from the European Council Regulation on the provision of emergency support within the EU.[138] APAs provide for that in return for the right to buy a specified number of vaccine doses in a given timeframe and at a given price. The Commission financed a part of the upfront costs faced by vaccine producers.[139]

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[136] Legal basis for accelerated assessment procedure is provided by the Regulation (EC) No. 726/2004. Articles 14 (9), 33. Practical arrangements therefore were made in the Guideline on the scientific application and the practical arrangements necessary to implement the procedure for accelerated assessment pursuant to Article 14(9) of Regulation (EC) No. 726/2004.

[137] European Commission Decision of June 18, 2020, approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures. URL: https://ec.europa.eu/info/sites/info/files/decision_approving_the_agreement_with_member_states_on_procuring_covid-19_vaccines_on_behalf_of_the_member_states_and_related_procedures.pdf (the date of access: April 30, 2021).

[138] Council Regulation (EU) 2016/369 of March 15, 2016, on the provision of emergency support within the Union, as amended by Council Regulation (EU) 2020/521 of April 14, 2020, activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak. URL: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0369&from=EN (the date of access: April 30, 2021).

[139] Emergency Support Instrument. URL: https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/emergency-support-instrument_en (the date of access: April 30, 2021).

106. The APAs concluded between the European Commission and the vaccine producers limit liability of vaccine manufacturers for lack of safety or efficiency of the vaccine, subject to compliance with applicable EU regulatory requirements.[140]

107. The APAs concluded between the European Commission and the vaccine producers entail provision, which empowers the Commission or any third party designated by the Commission, to obtain a license or sublicense from vaccines manufacturers for the intellectual property right on vaccines if it would be required to support the development efforts for the Vaccine for the EU market. The prerequisite, therefore, is that a particular vaccine manufacturer abandons the development efforts itself.[141]

108. In such a case the Commission or any third party designated by the Commission shall be solely liable for any royalties, costs, and expenses incurred by the vaccine manufacturer and payable to the third party in consideration for such license or sublicense, including payment obligations to any upstream licensor for the vaccine.[142]

109. All currently authorized vaccines against COVID-19 in the EU were authorized under exceptional circumstances and were granted CMA.[143]

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[140] See, e.g., Advanced Purchase Agreement for the production, purchase and supply for a COVID-19 vaccine in the European Union. Ref. Ares (2020) 4440071. Article 15. URL: https://ec.europa.eu/info/sites/info/files/apa_astrazeneca.pdf (the date of access: April 30, 2021); Advance Purchase Agreement for the development, production, and advance purchase and supply for a COVID-19 vaccine for the EU Member States. SANTE/2020/C3/049. Article 1.14.3. URL: https://ec.europa.eu/info/sites/info/files/curevac_-_redacted_advance_purchase_agreement_0.pdf (the date of access: April 30, 2021); Advanced Purchase Agreement for the development, production, priority-purchasing options and supply of a successful COVID-19 vaccine for EU Member States. SANTE/2020/C3/043–SI2.838335. Article II.6.4. URL: https://ec.europa.eu/info/sites/info/files/redacted_advance_purchase_agreement_biontech-pfizer_0.pdf (the date of access: April 30, 2021).

[141] Advanced Purchase Agreement for the production, purchase and supply for a COVID-19 vaccine in the European Union. Ref. Ares (2020) 4440071. Article 11.

[142] Ibid.

[143] See EU Vaccines Strategy. URL: https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en#eu-vaccines-strategy (the date of access: April 30, 2021).

1.2. Legal Regulation of Immunoprophylaxis

a. General Legal Framework

General information

110. The rights and obligations of people in the implementation of immunoprophylaxis activities are governed by the national legislation of the EU Member States.

111. The nature of vaccination and consequences of the vaccination refusal are regulated by the EU Member States.

112. The EU legislation does not define any priority groups for vaccination. The European Centre for Disease Prevention is working on a modeling exercise on prioritization to support Member States in the development of their national vaccination plans.[144]

113. The organization of the domestic vaccination process remains in the competence of the EU Member States. The EU regulations do not affect the powers of the Member States' authorities either as regards the setting of prices for vaccines or their inclusion in the scope of national health insurance schemes, on the basis of health, economic, and social conditions.[145]

Liability for the harm caused by a vaccine

114. The marketing authorization holders and manufacturers are responsible for the product quality and its safe use. In particular, the marketing authorization holders are liable if they fail to observe any obligations laid down in connection with the authorization or submit incorrect information.[146]

115. Further, the EU legislation provides for liability for defective vaccines. A vaccine is defective when it does not provide the safety which a person is entitled to expect. After the authorization has been granted its holder has an obligation to take account of technical and scientific progress and make any variations that may be required to enable

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[144] See, e.g., ECDC model for national pandemic preparedness. URL: https://www.ecdc.europa.eu/en/publications-data/ecdc-model-national-pandemic-preparedness (the date of access: April 30, 2021).
[145] Regulation (EC) No. 726/2004. Article 1; Directive 2001/83/EC. Article 4(3).
[146] Regulation (EC) No. 726/2004. Articles 15, 84.

the medical product to be manufactured and checked by means of generally accepted scientific methods.[147]

116. The EU legislation provides for specific rules on liability for vaccines granted emergency use authorization. EU legislation requires Member States to remove administrative and civil liability from the manufacturer and marketing authorization holder when the emergency use is recommended or required by the Member State.[148]

b. Special Case of COVID-19 Vaccination

117. The EU set the target of having 70% of adults in the European Union vaccinated. To achieve the aim, the EU Commission has asked national authorities to prepare as early as possible for organizing the fast and accessible deployment of vaccines, according to national vaccination plans.[149]

118. On March 17, 2021, the European Commission presented a proposal to create a Digital Green Certificate to facilitate the safe free movement of citizens within the EU during the COVID-19 pandemic.[150] The aim as proclaimed in the Proposal is to ensure increased coordination among Member States considering the adoption of measures restricting free movement on grounds of public health in the context of the pandemic.[151]

119. The Commission suggested: "to establish an EU-wide framework for the issuance, verification and acceptance of vaccination certificates within the EU as part of a 'Digital Green Certificate'. At the same time, this framework should also cover other certificates issued during the COVID-19 pandemic, namely documents certifying a negative test result for SARS-CoV-2 infection as well as documents certifying that the person concerned has recovered from a previous infection with SARS-CoV-2. This allows persons who are not vaccinated or who have not yet had the opportunity to be vaccinated to benefit from such an interoperable framework as well, facilitating their free movement. While children, for example, cannot benefit from COVID-19 vaccination for

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[147] Ibid. Article 16 (1).
[148] Directive 2001/83/EC. Article 5.
[149] European Commission. Statement by President von der Leyen on developments in the Vaccines Strategy. April 14, 2021. URL: https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT_21_1741 (the date of access: April 30, 2021).
[150] Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate). URL: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0130 (the date of access: April 30, 2021).
[151] Ibid. P. 1–2.

the time being, they should be able to receive a test or recovery certificate, which could also be received by their parents on their behalf."[152]

120. On May 20, 2021, the European Parliament and the Council reached agreement on the Regulation governing the EU Digital COVID Certificate.[153] On June 1, 2021, the EU Digital COVID Certificate has reached another important milestone with the go-live of the technical system at the EU level, which allows to verify certificates in a secure and privacy-friendly way.[154] While the Regulation will be applied from July 1, 2021, all EU Member States, which have passed the technical tests and are ready to issue and verify certificates, can now start using the system on a voluntary basis.[155]

1.3. Legal Regulation of Vaccine Export and Import

a. General Legal Framework

Conditions for export of vaccine to third countries

121. Conditions and requirements for the export of vaccines to third countries are imposed by the national law of the EU Member States. The EU does not generally prohibit the export of vaccines.

122. At the same time, the EU legislation emphasizes that Member States shall take all appropriate steps to ensure that the manufacture of the vaccine in their territory that is intended for export shall be subject to the holding of the same authorization as required for the vaccine that is intended for internal use.[156]

Conditions for import of vaccine from third countries

123. Imported vaccines may not be placed on the market within the European Community unless a marketing authorization has been granted.[157] All imported vaccines

[152] Ibid.
[153] European Commission. EU Digital COVID Certificate: European Parliament and Council reach agreement on Commission proposal. May 20, 2021. URL: https://ec.europa.eu/commission/presscorner/detail/en/ip_21_2593 (the date of access: May 30, 2021).
[154] European Commission. EU Digital COVID Certificate: EU Gateway goes live with seven countries one month ahead of deadline. June 1, 2021. URL: https://ec.europa.eu/commission/presscorner/detail/en/ip_21_2721 (the date of access: June 1, 2021).
[155] Ibid.
[156] Directive 2001/83/EC. Article 40.
[157] Regulation (EC) No 726/2004. Article 3; Directive 2001/83/EC. Article 6.

must meet the standard requirements (**paras. 79–99 of the Analytical Report**), and the EU does not automatically recognize approvals of vaccines granted outside the EU.[158]

b. Special Case of COVID-19 Vaccines Export and Import

124. The APAs concluded between the EU Commission and pharmaceutical companies allow the EU Member States to re-sell, export, and distribute COVID-19 vaccine upon its own disposal. However, this right is subject to restrictions and limitations stipulated in the APAs.[159]

125. In January 2021, the EU Commission adopted Implementing Regulation making the export of COVID-19 vaccines subject to an export authorization.[160] The decision was motivated by the global shortage of supply of COVID-19 vaccines and delays in production. As to the current state, the restriction of export remains in effect until June 30, 2021.[161] The export of vaccines against COVID-19 requires approval from the competent authority of the exporting State where vaccines are manufactured.[162]

126. In accordance with Regulation (EU) 2021/442, export authorizations are to be refused by the Member States where the exports concerned pose a threat to the execution of the APAs between the EU and vaccine manufacturers in view of their volume or other relevant circumstances, at the time of the request.[163]

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[158] Ibid.

[159] See, e.g., Advance Purchase Agreement for the development, production, and advance purchase and supply for a COVID-19 vaccine for the EU Member States. SANTE/2020/C3/049. Article 1.10.

[160] Commission Implementing Regulation (EU) 2021/111 of January 29, 2021, making the exportation of certain products subject to the production of an export authorization. URL: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=OJ:L:2021:031I:FULL&from=EN (the date of access: April 30, 2021).

[161] Commission Implementing Regulation (EU) of March 24, 2021, making specific arrangements to the mechanism making the exportation of certain products subject to the production of an export authorization. URL: https://trade.ec.europa.eu/doclib/docs/2021/march/tradoc_159498.pdf (the date of access: April 30, 2021).

[162] Commission Implementing Regulation (EU) 2021/442 of March 11, 2021, making the exportation of certain products subject to the production of an export authorization. Article 1 (1) (4). URL: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021R0442&from=EN#ntr2-L_2021085EN.01019001-E0002 (the date of access: April 30, 2021).

[163] Ibid. Article 1 (1) (7).

2. Eurasian Economic Union

2.1. Vaccine Development

a. General Legal Framework

General information

127. In accordance with the Treaty on the Eurasian Economic Union, a single market for medicines is functioning on the territory of the Union, starting from January 1, 2016.[164]

128. International treaties and legal acts constituting the law of the Union and the laws of the Member States are applicable in the territory of the Union.

129. Legal norms of the EAEU take precedence over national norms, while at the same time, the supranational legislation of the EAEU does not regulate all issues related to the circulation of medicines (**para. 181 of the Analytical Report**).

130. Preclinical and clinical trials for authorization (registration) of medicinal products, as well as the authorization procedure itself from July 1, 2021 (for the Russian Federation — from January 1, 2021), must be conducted in accordance with the requirements of the EAEU. At the same time, due to imperfections in the EAEU legislation, developers are in no hurry to bring existing medicines into line and register new products, as indicated by the absence in the registry information about authorization of currently used Russian vaccines against COVID-19.[165] There is no longer any possibility of state registration under national legislation in the Russian Federation, the exception being COVID-19 medicines which are commonly registered in accordance with the emergency legislation (**paras. 208–216 of the Analytical Report**).

131. The EAEU legislation does not contain special requirements for the developers of vaccines. General issues and applicable requirements related to the production and

[164] Treaty on the Eurasian Economic Union (Astana, May 29, 2014). Article 100. URL: https://cutt.ly/2vUYbkQ (the date of access: April 19, 2021).

[165] Unified Register of Registered Medicines of the Eurasian Economic Union URL: https://portal.eaeunion.org/sites/commonprocesses/ru-ru/Pages/DrugRegistrationDetails.aspx (the date of access: April 26, 2021).

circulation of medicines are contained in the relevant Decisions of the Eurasian Economic Commission.[166]

Stages and time frameworks for conducting clinical trials

132. Preclinical studies and clinical trials of medicinal products, including vaccines, for further circulation of medicinal products on the territory of EAEU Member States are conducted in accordance with the rules and good practices of EAEU.[167]

133. There are no specific terms for conducting preclinical studies in the EAEU legislation. The aims and terms of preclinical studies of vaccines on animals should be determined in accordance with the guidelines for preclinical safety studies on a case-by-case basis.[168]

134. The scope (stages and terms) of preclinical studies or necessity to conduct them varies depending on the degree of scientific knowledge of the drug and whether it is an original or a generic drug (biosimilars in relation to vaccines) and depends on the composition of the particular vaccine, such as the presence of adjuvants (immunostimulants or immunomodulators) in it.[169]

135. For vaccines containing adjuvants, there are other requirements for determining the scope of preclinical studies, which are set out in Chapter 16 of Eurasian Economic Commission Council Decision No. 89. In particular, the need for separate toxicity and tolerability studies for a particular adjuvant substance, which consequently significantly affects the scope and final length of the preclinical study.

136. To initiate a clinical trial of a vaccine, the applicant submits to the authorized body of the EAEU Member State the results of preclinical or previously conducted

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[166] Eurasian Economic Commission. Acts in the sphere of circulation of medicinal products. URL: http://www.eurasiancommission.org/en/act/texnreg/deptexreg/LSMI/Pages/drug_products.aspx (the date of access: April 9, 2021).

[167] Agreement on Common Principles and Rules for Circulation of Medicinal Products within the Eurasian Economic Union (Moscow, December 23, 2014). Article 6. URL: https://cutt.ly/Xc1dheK (the date of access: April 09, 2021). Good pharmaceutical practices are rules that cover all stages of drug circulation: good laboratory practice, good clinical practice, good manufacturing practice, good distribution practice, good pharmacy practice, good pharmacovigilance practice and other practices. See Ibid. Article 1. Para. 1.

[168] Recommendation of the Collegium of the Eurasian Economic Commission No. 11 of July 17, 2018, "On Guidelines on General Issues of Clinical Trials". Section II. Subsection 1. Para. 4. URL: https://cutt.ly/Wc1xF3e (the date of access: April 09, 2021).

[169] Decision of the Eurasian Economic Commission Council No. 89 of November 3, 2016, "On the Adoption of the Rules for investigation of biological medicinal products of the Eurasian Economic Union". Chapter 16. Part 4.3. URL: https://cutt.ly/BcHdFqE (the date of access: April 7, 2021).

clinical trials confirming the safety of the planned clinical trial.[170] Procedural issues related to the process of approving a trial are not currently regulated by EAEU law. In this regard, the national laws of the Member States should be referred to.

137. The legislation of the EAEU does not stipulate specific terms for clinical trials to be conducted. The term of a clinical trial is determined by the design[171] and specifics of the study[172] and is specified by the developer in the protocol of the clinical trial.[173]

Legal control mechanisms

138. State control over the development, preclinical studies, clinical trials, and production of vaccines (medical products)[174] is carried out in accordance with the laws of the EAEU Member States.[175]

139. The EAEU also has a system of pharmaceutical inspections, in which inspectors of Member States check manufacturers for compliance with good manufacturing practices for licensing, registration, or investigations related to vaccine quality.[176]

Vaccine authorization

140. Circulation of vaccines in the EAEU is carried out after the procedures of expertise and state registration[177] by the authorized bodies of the Member States.[178]

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[170] Recommendation of the Collegium of the Eurasian Economic Commission No. 11 of July 17, 2018, "On Guidelines on General Issues of Clinical Trials". Section II. Subsection 1. Para. 4.
[171] Ibid. Section II. Subsection 2.
[172] Decision of the Eurasian Economic Commission Council No. 89 of November 3, 2016, "On the Adoption of the Rules for investigation of biological medicinal products of the Eurasian Economic Union". Section 1.
[173] Decision of the Eurasian Economic Commission Council No. 79 of November 3, 2016, "On approval of Rules of good clinical practices of the Eurasian Economic Union". Section 6. URL: https://cutt.ly/qc1QXWC (the date of access: April 9, 2021).
[174] Agreement on Common Principles and Rules for Circulation of Medicinal Products within the Eurasian Economic Union (Moscow, December 23, 2014). Article 1.
[175] Ibid. Article 13.
[176] Decision of the Eurasian Economic Commission Council No. 83 of November 3, 2016, "On Adoption of the Rules for Conducting Pharmaceutical Inspections". Paras. 1–2. URL: https://cutt.ly/nvqKuq7 (the date of access: April 12, 2021); Decision of the Eurasian Economic Commission Council No. 77 of November 3, 2016, "On approval of Rules of good manufacturing practices of the Eurasian Economic Union". Appendix 2. URL: https://cutt.ly/rvqKmlW (the date of access: April 12, 2021).
[177] Decision of the Eurasian Economic Commission Council No. 78 of November 3, 2016, "On the Rules of marketing authorization and assessment of medicinal products for medical use". Para. 163. URL: https://cutt.ly/WbE74LP (the date of access: April 12, 2021).
[178] Ibid. Articles 9–16.

141. For a marketing authorization of a vaccine (medicinal product), the applicant must submit a registration dossier in the format of a common technical document in accordance with the established requirements[179] to the authorized body of the Member State.

142. The procedure of expertise and review terms vary depending on the procedure chosen by the applicant: a decentralized procedure[180] or a mutual recognition procedure.[181]

143. The vaccine registration dossier for filing for authorization is prepared considering special requirements:[182]

- for well-studied vaccines produced in the territories of Member States before 2000, it is allowed to submit reviews for preclinical studies and clinical trials without conducting new studies;[183]

- for new vaccines that contain a new vaccine antigen, there are no exceptions to the composition of the registration dossier.[184] The expert body also examines the master files for each new antigen that is part of the new vaccine. If the expert body makes a positive decision on the results of the examination, it issues a conclusion on the master file, valid throughout the territory of EAEU, which is used by the authorized bodies when carrying out vaccine registration procedures (confirmation of authorization, dossier amendments[185]).

144. If the authorized body decides to register the vaccine, a marketing authorization is issued for five years, after confirmation of authorization — indefinitely.[186] An application for confirmation of authorization may be submitted not earlier than 210 calendar days before the expiration date of the marketing authorization, but no later than the date of its expiration.[187]

[179] Ibid. Appendix 1.
[180] Ibid. Chapter VI.
[181] Ibid. Chapter V.
[182] Ibid. Appendix 1. III.
[183] Ibid. Section 12.3.
[184] Ibid. Para. 12.2.2.
[185] Ibid.
[186] Ibid. Para. 18.
[187] Ibid. Para. 126.

145. The legislation provides mechanisms for conditional authorization:

- in the absence of a registered pandemic-ready vaccine,[188] it is permitted to change the strain composition of an existing seasonal or pre-pandemic vaccine[189] without providing certain preclinical and clinical data on its effectiveness, provided that such changes would preserve the quality, safety, and effectiveness of the vaccine and that such changes are scientifically feasible, and on condition that such data are subsequently provided in an appropriate order;[190]

- in the event of a pandemic declared by the WHO or in the case of an epidemic caused by a pandemic virus type declared by the relevant authorized bodies of Member States, registration of new pandemic vaccines shall be carried out as a matter of urgency.[191] Prior to a pandemic, an applicant may submit a registration dossier containing incomplete data, on the condition that after a pandemic has been declared by the WHO she/he can submit the missing clinical data to the relevant authorized body (expert body) of the reference state with the obligation to perform the necessary post-registration activities,[192] including conducting post-registration safety and efficacy studies.[193] However, currently, the legislation does not define the procedure for emergency registration in the event that the WHO never declares a pandemic.

Emergency use authorization

146. The possibility of issuing a permit for emergency use of the vaccine in the EAEU is not provided.

[188] Ibid. Appendix 24 (II). "Pandemic-ready vaccine" is a candidate vaccine (or vaccine preparation technology) for the prevention of influenza, designed to immunize the public in the event of influenza caused by pandemic strains of influenza virus."
[189] Ibid. Appendix 24. Section 4.2.
[190] Ibid. Appendix 19. Section 4.1 (4.1.3.).
[191] Ibid. Appendix 24. Section 4 (4.1.).
[192] Ibid.
[193] Ibid. Chapter VII (118).

Vaccine patent protection

147. In EAEU Member States, vaccines, if they are granted patent protection, are protected as inventions according to national legislations.[194]

148. On the territory of the EAEU, legal protection of vaccines can be applied for under the procedures under the Eurasian Patent Convention.[195]

149. Requirements of the Eurasian Patent Convention and national legislations in the field of intellectual property of EAEU Member States in regard to the patentability of inventions are identical.[196]

150. Traditionally, preclinical and clinical trial data are classified as data subject to protection against unfair competition.[197] However, this practice is not represented in the EAEU legislation, and therefore the legal regime of data exclusivity of these studies is defined in the national legislations, with regard to the obligations assumed by these states when joining the WTO.[198]

151. The EAEU rules of authorization of medicinal products establish the obligation of the applicant to indicate information on the protection of intellectual property rights to the medicinal product in the registration dossier of a medicinal product.[199] Such information must contain information on the number of the patent, the patentee, the date of issuance, the duration of the patent. In addition, the applicant must provide a written confirmation that the intellectual rights of third parties protected by a patent or transferred under a license are not violated in connection with the authorization of the medicinal product.[200]

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[194] Protocol for the Protection and Enforcement of Intellectual Property Rights (Appendix No. 26 to the Treaty on the Eurasian Economic Union) (Astana, May 29, 2014). Para. 24. URL: https://cutt.ly/6vq3lCh (the date of access: April 12, 2021).

[195] Eurasian Patent Convention (Moscow, September 9, 1994) URL: https://cutt.ly/JvUJkAK (the date of access: April 19, 2021).

[196] *Isabaeva Z.* Original drugs vs generics: the situation on the unified pharmaceutical market of the EAEU // Intellectual Property. Industrial Property. 2019. No. 8. URL: https://cutt.ly/bvq8byB (the date of access: April 12, 2021).

[197] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (WTO, Uruguay Round of Multilateral Trade Negotiations, April 15, 1994). Article 39 (3). URL: https://cutt.ly/VvyyoOR (the date of access: April 13, 2021).

[198] *Neverova O.* Protection Guarantee // Rossiyskaya Gazeta - Special Issue. 2020. No. 170 (8224) URL: https://cutt.ly/UvyyXBk (the date of access: April 13, 2021).

[199] Decision of the Eurasian Economic Commission Council No. 78 of November 3, 2016, "On the Rules of marketing authorization and assessment of medicinal products for medical use". Appendix 2. Paras. 3.4, 4.3.

[200] Ibid. Para. 4.4.

152. At the same time, the possibility of using the invention (vaccine) without the permission of the patent holder is referred to the competence of the Member States.[201]

153. Intellectual property rights are subject to legal protection in accordance with international treaties and acts constituting the law of the Union and the legislation of the Member States.[202]

154. As for the mechanism of exhaustion of intellectual property rights to a vaccine as an invention, it is governed by national laws of the EAEU Member States (for the relevant regulation of the Russian Federation see **para. 206 of the Analytical Report**).

b. Legal Framework for the COVID-19 Vaccine Development

155. During the COVID-19 pandemic, no special legislation regulating research and/or vaccine development processes was introduced in the EAEU.

2.2. Legal Regulation of Immunoprophylaxis

156. The EAEU legislation does not regulate issues related to the administration of immunoprophylaxis. The rights and obligations of citizens and other issues in the context of vaccination do not belong to the scope of the objectives of the Union.[203]

2.3. Legal Regulation of Vaccine Export and Import

a. General legal framework

Conditions for export of vaccine to third countries

157. Procedures for the export of vaccines are not regulated by EAEU legislation. As a rule, subjects exporting[204] medicines are obliged to comply with the established quality requirements.[205]

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[201] Protocol for the Protection and Enforcement of Intellectual Property Rights (Appendix No. 26 to the Treaty on the Eurasian Economic Union) (Astana, May 29, 2014). Para. 29.
[202] Ibid. Para. 2.
[203] Treaty on the Eurasian Economic Union (Astana, May 29, 2014). Article 4.
[204] Decision of the Eurasian Economic Commission Council No. 80 of November 3, 2016, "On approval of Rules of good distribution practice in the framework of the Eurasian Economic Union". Section II. Para. 4. URL: https://cutt.ly/4vpbidN (the date of access: April 14,.2021). ("Distribution" – activities related to the purchase (procurement, acquisition), storage, import, export, sale (except for sales to the consumer) without limitation in volume and transportation of medicines").
[205] Ibid. Section I. Para. 2

Conditions for import of vaccine from third countries

158. There are no special requirements applicable to the import of vaccines under the EAEU legislation.

159. Import of medicines authorized in the territory of EAEU Member States is carried out upon provision of information on the availability of such medicine in the relevant register of authorized medicines without the need to obtain permits unless such medicine is supplied for humanitarian aid and (or) assistance in emergencies (if provided for by the national legislation of a Member State).[206]

160. Import of non-authorized medicines for clinical trials and expertise of medicines for their subsequent state registration is carried out on the basis of a permit issued by an authorized public authority of a Member State in the manner prescribed by the national legislation[207] (**paras. 245–247 of the Analytical Report**).

b. Special Case of COVID-19 Vaccines Export and Import

161. No distinctive features regulating the import/export of vaccines during the COVID-19 pandemic have been indicated.

[206] Decision of the Eurasian Economic Commission Council No. 30 of April 21, 2015, "On Non-Tariff Regulatory Measures". Appendix 21. Paras. 3–4. URL: https://cutt.ly/lvpYmo6 (the date of access: April 15, 2021).
[207] Ibid. Paras. 10–11.

III. NATIONAL LEGAL REGULATION

1. The Russian Federation

1.1. Vaccine Development

a. General Legal Framework

General information

162. In the Russian Federation, the development, preclinical studies and clinical trials, expertise, state registration, standardization and quality control, production, manufacture, storage, transportation, import into the Russian Federation, export from the Russian Federation, advertising, release, sale, transfer, use, destruction of vaccines are regulated by Federal Law No. 61.[208]

163. At the same time, from January 1, 2021, in the Russian Federation, the provisions of supranational legislation of the EAEU within the framework of the single market of medicines in accordance with the Treaty on the Eurasian Economic Union of May 29, 2014, are fully applicable (**paras. 127–161 of the Analytical Report**).

164. Vaccines are immunobiological drugs.[209] The development and production of such drugs are carried out by the developer and the manufacturer, respectively.

165. The developer and/or manufacturer can only be a legal entity.[210] Other restrictions on the legal form or foreign participation in the development and manufacture of medicines are not stipulated by the current legislation. The logical conclusion of the drug development process is its state registration, without which it cannot be used (applied).[211]

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[208] Federal Law No. 61-FZ of April 12, 2010, "On Circulation of Medicines". Article 1. URL: https://cutt.ly/ucHsMaB (the date of access: April 7, 2021).
[209] Ibid. Article 4(7).
[210] Ibid. Article 4. Paras. 30, 32.
[211] Ibid. Article 13(1).

Stages and time frameworks for conducting clinical trials

166. The legislation does not contain imperative norms defining the duration of clinical trials.

167. A clinical trial of a medicinal product shall be conducted in accordance with the clinical trial protocol on the basis of permission issued by the Ministry of Health of the Russian Federation following an ethical review and expert review of the documents submitted to obtain permission to conduct a clinical trial.[212]

168. Information about the expected timeframe of a clinical trial is included in the application for obtaining approval for a clinical trial.[213]

169. Expert review of documents with an assessment of the possibility of conducting the trial (including the sufficiency of terms) is performed by the FSBI "SCEEMP".[214]

170. Ethical review for the purpose of issuing permission to conduct a clinical trial is carried out by the Ethics Committee of the Ministry of Health.[215]

171. In addition to the above-mentioned ethical review, an independent ethics committee is responsible for evaluating the possibility of conducting clinical trials in a particular site. The functions of the independent ethics committee also include control over the observance of ethical norms and the rights of trial participants.[216]

Legal control mechanisms

172. General provisions in the field of control over the circulation of medicines are listed in Chapter 4 of Federal Law No. 61. The federal state surveillance in the field of drug circulation on the territory of the Russian Federation is carried out by the Roszdravnadzor.[217]

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[212] Order of the Ministry of Health of Russia No. 200n of April 1, 2016, "On Approval of the Rules of Good Clinical Practice". Paras. 5–7. URL: https://cutt.ly/RcHfhWN№ (the date of access: April 7, 2021).
[213] Federal Law No. 61-FZ of April 12, 2010, "On Circulation of Medicines". Article 39(2).
[214] Ibid. Article 15.
[215] Ibid. Article 39.1.
[216] Order of the Ministry of Health of the Russian Federation No. 200n of April 1, 2016, "On Approval of the Rules of Good Clinical Practice". Part II. Paras. 10–15.
[217] Resolution of the Government of the Russian Federation No. 323 of June 30, 2004, "On Approval of the Provision on the Federal Service for Surveillance in Healthcare". Part II. Para. 5.1.4.1. URL: https://cutt.ly/ocHf19q (the date of access: April 7, 2021). Federal Service for Surveillance in Healthcare (Roszdravnadzor) is the federal executive body responsible for control and supervision of the healthcare system.

173. Among the mechanisms of control exercised by Roszdravnadzor that are relevant to the issue under consideration is the organization and conduct of inspections of subjects of drug circulation for compliance with the requirements for preclinical studies and clinical trials of medicines.[218]

174. The above activities are carried out by Roszdravnadzor through scheduled and unscheduled, documentary and field inspections in accordance with Articles 9–12 of the Federal Law No. 294-FZ of December 26, 2008, "On Protection of Rights of Legal Entities and Individual Entrepreneurs in the Implementation of State Control (Supervision) and Municipal Control".[219]

175. Roszdravnadzor also performs a routine monitoring function — pharmacovigilance which is defined as a type of activity to monitor the effectiveness and safety of drugs, aimed at identifying, assessing, and preventing adverse effects of drugs.[220] As part of pharmacovigilance (including during clinical trials), subjects of drug circulation submit to Roszdravnadzor periodic reports on the use of the drug, as well as on adverse reactions, serious adverse reactions, unforeseen adverse reactions when using the drug, including those affecting the ratio of the expected benefit to the possible risk of using the drug.

176. The Ministry of Health may suspend the use of a medicinal product on the basis of information received by Roszdravnadzor in the course of pharmacovigilance,[221] such a[222] reports of adverse reactions received during the use of the drug, non-compliance with the information on efficacy and safety declared in the instructions for use, other information indicating harm to life and health, information on the unreliability of the results of clinical trials, identified violations of good clinical practice rules during trials, etc.

177. A clinical trial may also be suspended by decision of the head of the medical organization or the organization that has obtained the permission to organize the trial where in the process of conducting the trial a danger to life or health of patients is found.

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[218] Federal Law No. 61-FZ of April 12, 2010, "On Circulation of Medicines". Article 5.

[219] Resolution of the Government of the Russian Federation No. 1043 of October 15, 2012, "On Approval of the Provisions on Federal State Supervision in the Sphere of Circulation of Medicines". Article 6. URL: https://cutt.ly/ocHf19q (the date of access: April 7, 2021).

[220] Order of the Federal Service for Surveillance in Healthcare No. 1071 of February 15, 2017, "On Approval of the Procedure for Pharmacovigilance". Article 2. URL: https://cutt.ly/VcHgLDl (the date of access: April 7, 2021).

[221] Order of the Ministry of Health of the Russian Federation No. 777n of November 14, 2018, "On Approval of the Procedure for Suspending the Use of a Medicinal Product for Medical Use". Para. 3. URL: https://cutt.ly/WcHg8mv (the date of access: April 7, 2021).

[222] Ibid. Para. 2.

Such danger shall be reported to the Ministry of Health which may decide to terminate the clinical trial.[223]

178. The legislation stipulates that the developer or organizer of a clinical trial must submit a clinical trial report to the Ministry of Health within three months of its completion (termination).[224]

179. The protocol of a clinical trial may also provide for the inclusion of consent to the publication of the results of the clinical trial.[225]

Vaccine authorization

180. Conditions for approval should be understood as state registration of a medicinal product (marketing authorization) and obtaining permission to launch into civil circulation. State registration is a prerequisite for introducing a drug into civil circulation.

181. The procedure for state authorization is defined in the Eurasian Economic Commission Council Decision No. 78 "Rules of authorization and assessment of medicinal products for human use" (**paras. 140–144 of the Analytical Report**). Despite this, national legislation continues to apply (for example, in the part not regulated by the EAEU legislation, or if the EAEU legislation has direct references to the national legislation of Member States), while appropriate amendments are made to harmonize it with the EAEU law.[226]

182. State registration of medicinal products is performed by the Ministry of Health based on the results of expert examination of 1) the quality of the medicinal product and 2) the ratio of the expected benefit to the possible risk of using the medicinal product.[227]

183. The expertise is performed by the subordinate institution — FSBI "SCEEMP" under the assignment of the Ministry of Health[228] on the basis of the submitted

[223] Federal Law No. 61-FZ of April 12, 2010, "On Circulation of Medicines". Article 40(6).
[224] Ibid. Article 40(11).
[225] Order of the Ministry of Health of Russia No. 200n of April 1, 2016, "On Approval of the Rules of Good Clinical Practice". Para. 7(24).
[226] Treaty on the Eurasian Economic Union (Astana, May 29, 2014). Article 30 (For a consistent discussion of the conditions of vaccine approval and its marketing authorization process, the text will refer to national legislation, if it does not contradict the EAEU regulations).
[227] Federal Law No. 61-FZ of April 12, 2010, "On Circulation of Medicines". Articles 13–14.
[228] Ibid. Article 15.

application for state registration together with the required documents, of which the registration dossier for the medicinal product for medical use is formed.[229]

184. If the submitted information is sufficient and the quality and benefit-risk examinations are successfully passed, the Ministry of Health takes a decision on the state registration of the medicinal product, after which the information about the registered product is entered into the state register of medicinal products and the applicant receives marketing authorization for the medicinal product.[230]

185. The regular legislation does not provide for the possibility of fast-track registration, but there is an express examination procedure for medicines,[231] although it does not apply to reference (first-time registered in Russia) medicines and biosimilars (biological medicines with parameters similar in quality, effectiveness, and safety to those of the reference biological medicine), unlike some reproductions of medicines of chemical origin.[232]

186. A possibility of conditional vaccine registration is reflected in the **para. 145 of the Analytical Report.**

187. At the same time, during the COVID-19 pandemic, a simplified and fast-track procedure for state registration was introduced (**paras. 208–216 of the Analytical Report**).

188. Regarding the launch into civil circulation, in comparison with classical medicines, higher requirements are set for vaccines.[233]

Emergency use authorization

189. The possibility of issuing approval for emergency administration of a vaccine (before the completion of clinical trials and/or state registration) was not contained in national legislation until amendments were made to Federal Law No. 61, allowing the

[229] Ibid. Articles 18–19.
[230] Federal Law No. 61-FZ of April 12, 2010, "On Circulation of Medicines". Article 27(3).
[231] Ibid. Article 26.
[232] Ibid. Article 26(2).
[233] Ibid. Article 52.1(7). Vaccines are launched into civil circulation on the basis of a permit issued by the Roszdravnadzor for each series or batch of such a drug, based on conclusions on the compliance of the series or batch of the immunobiological medicinal product with the requirements set forth in its state registration.

Russian Government to determine the circulation procedure for medicines intended to prevent and treat diseases that pose a threat to the life and health of the public.[234]

190. As a part of the implementation of these amendments, the Resolution of the Government of the Russian Federation No. 441 of April 3, 2020, was introduced, defining such an order of circulation until January 1, 2022[235] (**paras. 209–214 of the Analytical Report**).

Vaccine patent protection

191. The conditions and procedure for granting a patent for a vaccine are regulated by the provisions of Chapter 4 of the CCRF.[236] The national legislation contains no special norms regulating the patent protection of medicines.

192. For the purposes of patent protection as an invention, the vaccine must meet the criteria of novelty, have an inventive step, and be industrially applicable.[237]

193. The main requirements for the content of information in a patent application, including for substances of biological origin, the method of filing the application, and the terms for its consideration are given in Order No. 316.

194. According to Article 1350 of the CCRF, patent protection may be granted to the substance (molecule) itself, the method of its production, and the method of its application, which is confirmed by patent practice. For example, Rospatent has issued several patents for the vaccine Sputnik V: the substance, the composition of the first and second components of the vaccine, the method of application,[238] etc.

195. The legal protection regime for clinical trials in terms of intellectual property law is not defined in the Russian Federation. It can be concluded that it is impossible to classify the results of clinical trials as belonging to any of the objects of intellectual rights that are subject to legal protection. A different mechanism of legal protection, not related to the instruments of legal protection of intellectual property rights, data

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[234] Federal Law No. 98-FZ of April 1, 2020, "On Amendments to Certain Legislative Acts of the Russian Federation on the Prevention and Elimination of Emergency Situations". Article 7. URL: https://cutt.ly/EcHLaDi (the date of access: April 7, 2021).

[235] Resolution of the Government of the Russian Federation No. 441 of April 3, 2020. Article 5. URL: https://cutt.ly/7cHXJZ9 (the date of access: April 7, 2021).

[236] Civil Code of the Russian Federation (Part IV). Articles 1350–1351, 1353–1354. URL: https://cutt.ly/RcHhsVNo (the date of access: April 7, 2021).

[237] Ibid. Article 1350.

[238] Federal Service for Intellectual Property. Description of the Invention of Patent No. 2720614. URL: https://cutt.ly/nbEOa6O (the date of access: April 7, 2021).

exclusivity, is applied to clinical trial data. The data exclusivity regime is one of the ways to protect against unfair competition. The initial provisions on the data exclusivity regime were introduced by Federal Law No. 271-FZ of October 11, 2010, and came into force on the date of Russia's accession to the WTO on August 22, 2012.[239]

196. The provisions of Russian law on data exclusivity protection are based on the standards contained in Article 39.3 of the TRIPS Agreement. In the Russian Federation, it is not allowed to use for commercial purposes information on the results of pre-clinical studies of medicinal products and clinical trials of medicinal products for medical use submitted by the applicant for state registration of a medicinal product without his or her consent within six years from the date of state registration of the reference drug[240] in the Russian Federation.[241]

197. On the territory of the Russian Federation, two main patenting procedures may be distinguished: the national patent and the Eurasian patent. When registering under the second procedure, a patent for an invention will be subject to protection in eight EAEU Member States at once.[242]

198. At the same time, the CCRF provides for the ways of using a patent without the patentee's permission. Such the use is possible:

- under extraordinary circumstances (natural disasters, catastrophes, accidents) with notification of such use to the patentee as soon as possible and with subsequent payment of commensurate compensation;[243]

- upon permission of the Government of the Russian Federation in cases of extreme necessity connected with ensuring defense and security of the state, protection of life and health of citizens with notification of such use to the patentee in the shortest possible time and with payment of a commensurate compensation.[244]

199. Thus, the use of an invention under extraordinary circumstances is not considered a violation of the law if the conditions for notification and payment of

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[239] Federal Law No. 271-FZ of October 11, 2010, "On Amendments to the Federal Law 'On Circulation of Medicines'". Article 2. URL: https://cutt.ly/GcHbo4X (the date of access: April 7, 2021).
[240] Ibid. Article 4(11). A reference drug is an original drug first registered in the Russian Federation with which a generic or biosimilar drug is compared for the purposes of state registration.
[241] Federal Law No. 61-FZ of April 12, 2010, "On Circulation of Medicines". Article 18(18).
[242] Eurasian Patent Convention (Moscow, September 9, 1994).
[243] Civil Law of the Russian Federation (Part IV). Article 1359(3).
[244] Ibid. Article 1360.

compensation are met, while the CCRF does not contain references to the need for court involvement to consider the possibility of using the invention, as it is defined for another similar institution — compulsory licensing[245] (**para. 204 of the Analytical Report**).

200. There is no relevant court practice on the application of Article 1359 of the CCRF. This may be due to the fact that the article contains a closed list of emergency circumstances that are not the subject of regulation by the Federal Law No. 98-FZ of April 1, 2020, "On Amendments to Certain Legislative Acts of the Russian Federation on the prevention and liquidation of emergency situations", which does not allow to apply the specified article referring to the pandemic.

201. As for the permission by the Russian Government to use a patent (**para. 197 of the Analytical Report)**, the first case of application of Article 1360 of the CCRF in national practice should be highlighted, when by the Order of the Government of the Russian Federation No. 3718-r of December 31, 2020, Pharmasintez Joint Stock Company was allowed to use the inventions protected by Eurasian patents No. EA02065, EA025252, EA025311, EA029712, and EA032239 owned by American biopharmaceutical company Gilead Sciences, Inc. and Eurasian patent No. EA028742 owned by Gilead Pharmasset LLC for one year without the consent of the Gilead Sciences, Inc. and Gilead Pharmasset LLC respectively in order to provide the Russian Federation with medicines with the international nonproprietary name Remdesivir. Herewith, on April 1, 2021, Gilead Sciences, Inc. and Gilead Pharmasset LLC filed a lawsuit to the Judicial Board for Administrative Cases of the Supreme Court of the Russian Federation to challenge the mentioned decree of the Government of the Russian Federation.[246]

202. A compulsory license means granting a person (entitle) the right to use the result of intellectual activity, the exclusive right to which belongs to another person, on the basis of and on the conditions specified in the court decision. The decision on granting a compulsory license may be made by the court only in cases directly provided for by the CCRF: for insufficient use of the invention[247] and for a dependent invention.[248]

203. In order to obtain a compulsory license for a dependent invention, the applicant must prove that it represents an important technical achievement and has significant economic advantages over the invention of the first patent holder. In this case, the court decides to grant the applicant a compulsory simple (non-exclusive) license.

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[245] Ibid. Article 1239.
[246] Supreme Court of the Russian Federation. Record of Proceedings. Case No. ACPI21-303. URL: https://vsrf.ru/lk/practice/cases/11085980 (the date of access: April 27, 2021).
[247] Civil Code of the Russian Federation (Part IV). Article 1362(1).
[248] Ibid. Article 1362(2).

204. In the context of drug circulation, the first case of compulsory license issuance occurred in 2019 in *Sugen LLC v. Nativa LLC* case. The court found that the issue of determining economic advantage was related to the need for economic development, national security, and social importance.[249]

205. While a compulsory license can be terminated at any time by court action at the request of the patentee (if the circumstances which conditioned the granting of such a license cease to exist and are unlikely to reappear), the granting of permission under Article 1360 of the CCRF does not directly provide any method of appeal against such decision for the patentee.[250]

206. Apart from the lack of a possibility to terminate such use without the patentee's permission in the CCRF, the legislator has not yet approved the method of determining compensation with reference to the fact that the methodology for determining its amount and the procedure for the payment is approved by the Russian Government,[251] but the relevant decree has not yet been adopted (the draft has gone through several iterations but has not yet been approved).

207. Regarding the use of intellectual property rights for an imported vaccine, it is advisable to note the institution of exhaustion of rights in studies. For example, the use of a vaccine for clinical trials for the purposes of state registration of a biosimilar medicinal product by another patent holder (comparison with a patented vaccine) would not be considered an infringement of intellectual rights.[252]

b. Legal Framework for the COVID-19 Vaccine Development

208. During the COVID-19 pandemic, the Russian government was empowered[253] to establish a procedure for state registration of medicines for use in emergency situations, prevention of emergencies, prevention and treatment of diseases posing a risk to the public.[254]

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[249] Resolution of the Court of Intellectual Rights No. C01-906/2019 of October 29, 2019, in case No. A40-166505/2017 "On satisfaction of the claim for a compulsory simple (non-exclusive) license: left unchanged, as the courts recognized, according to the evidence presented in the case file, that the plaintiff's invention has significant economic advantages over the defendant's invention." URL: http://base.garant.ru/72938784/ (the date of access: April 7, 2021).

[250] Civil Code of the Russian Federation (Part IV). Article 1360.

[251] Ibid. Article 1360 (2).

[252] Ibid. Article 1359(2).

[253] Federal Law No. 98-FZ of April 1, 2020, "On Amendments to Certain Legislative Acts of the Russian Federation on the Prevention and Elimination of Emergency Situations". Article 17. Part 1(2).

[254] Federal Law No. 61-FZ of April 12, 2010, "On Circulation of Medicines". Article 13(8).

209. Resolution of the Government of the Russian Federation No. 441 of April 3, 2020, defines the specifics and procedure for the authorization of such medicines, from the application of a simplified registration procedure for a medicinal product to the completion of clinical trials. Based on the results of such trials, a brief report on the results of studying the efficacy and safety of the medicinal product to the date shall be provided to the authorized bodies. Herein information must be provided that in the course of preclinical studies a positive effect of the medicinal product was confirmed when tested on several animal species, which is associated with the expected positive effect of the active substance and allows selecting an effective dose for humans.[255]

210. Thus, the opportunity to reduce the volume of clinical data when submitting documents for state registration allows reducing the volume of studies required for registration. The above Resolution also provides for a fast-track procedure according to which the state registration of a medicinal product is carried out within no more than 20 working days from the date of receipt of the application and documents.[256]

211. In addition, state registration is allowed without conducting an examination of the quality of the medicine and an examination of the expected benefit to possible risk ratio, which makes it much easier to bring foreign medicinal products intended for use in emergency situations onto the Russian market. This applies to medicinal products duly registered in Member States of the European Union, the United States of America, Canada, or another state from the list established by the Ministry of Health.[257]

212. Additional requirements (varying at the discretion of the Ministry of Health) are established for medicinal products registered under the procedure stipulated by Resolution of the Government of the Russian Federation No. 441 of April 3, 2020, namely:

- introduction of restrictions on use;
- mandatory post-registration clinical trials, based on the results of which the ratio of expected benefit to possible risk of the use of the medicinal product is assessed;

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[255] Resolution of the Government of the Russian Federation No. 441 of April 3, 2020, "On peculiarities of circulation of medicines for medical use, which are intended for use in conditions of threat, emergence and liquidation of an emergency situation and for organization of medical assistance to persons affected by emergency situations, prevention of emergencies, prevention and treatment of diseases endangering the environment, diseases and lesions caused by adverse chemical, biological, radiation factors" (hereinafter, "**Resolution of the Government of the Russian Federation No. 441 of April 3, 2020**"). Paras. 4–5.

[256] Ibid. Para. 8.

[257] Ibid. Para. 10.

- random sampling quality control of this medicinal product in circulation;
- requirements for its labeling;
- notification of Roszdravnadzor of each fact of using the drug;
- submission to the agency of information on side effects, adverse reactions in connection with the use of the drug, on the specifics of its interaction with other drugs, individual intolerance, and other circumstances that affect the change in the expected benefit to the possible risk of use ratio, identified at any stage of circulation.[258]

213. For drugs registered under Resolution of the Government of the Russian Federation No. 441 of April 3, 2020, a stricter registration confirmation procedure has been established until December 1, 2021.[259] In addition, if the Ministry of Health decides to confirm state registration, the marketing authorization is issued not indefinitely, as the standard rules stipulate, but for five years, and until no later than December 31, 2025.[260]

214. The Russian Ministry of Health has been given the possibility to issue a permit for the temporary (until January 1, 2022) circulation of an unregistered medicinal product in the Russian Federation in case of an emergency if there are no registered analogs (in substance and dosage form) in the Russian Federation or the projected consumption volumes of similar medicinal products exceed the projected volumes of their import or production in the Russian Federation.[261]

215. Permission for temporary circulation shall be issued for a series (batch) of a medicinal product on the basis of the conclusion of the special interdepartmental commission.[262]

216. A distinctive feature of the mechanism for issuing temporary circulation permits compared to the described registration procedures (**paras. 210–213 of the Analytical Report)** is that the legislator has limited the list of conditions for taking such a decision to a single one — an emergency situation.[263] The decision on the possibility (or impossibility) of issuing a temporary circulation permit is taken by the interdepartmental

[258] Ibid. Para. 7
[259] Ibid. Para. 17.2.
[260] Ibid. Para. 17.12.
[261] Ibid. Paras. 18–19.
[262] Ibid. Para. 19.
[263] Ibid. Para. 18.

commission on the basis of the applications received from legal entities.[264] Information on the decisions taken is posted by the Ministry of Health on its official website.[265]

1.2. Legal Regulation of Immunoprophylaxis

a. General Legal Framework

General information

217. Basic rights and obligations in the implementation of immunoprophylaxis[266] are established in Federal Law No. 157-FZ of September 17, 1998, "On Immunoprophylaxis of Infectious Diseases", Federal Law No. 52-FZ of March 30, 1999, "On Sanitary and Epidemiological Welfare of the Population" and Federal Law No. 323-FZ of November 21, 2011, "On the Fundamentals of Health Protection of Citizens in the Russian Federation" as well as the by-laws to them.

218. Citizens have the following rights under immunoprophylaxis:

- to receive full and objective information from health care professionals about the need for preventive vaccinations, the consequences of not vaccinating, and possible post-vaccination complications;

- to choose a medical organization or individual entrepreneur who carries out the medical activity;

- for free preventive vaccinations included in the national calendar of preventive vaccinations and the calendar of preventive vaccinations based on epidemiological indications, in medical establishments of the State and municipal health care system;

- for medical examinations and, if necessary, medical screening before vaccination, and medical care in health care centers in the event of post-

[264] Order of the Ministry of Health of the Russian Federation No. 211n of March 16, 2021. Para. 3 URL: https://cutt.ly/0cKZcug (the date of access: April 7, 2021).
[265] Resolution of the Government of the Russian Federation No. 441 of April 3, 2020. Para. 25.
[266] Immunoprophylaxis is understood as a system of measures carried out in order to prevent, limit the spread, and eliminate infectious diseases by means of preventive vaccinations. See Federal Law No. 157-FZ of September 17, 1998, "On Immunoprophylaxis of Infectious Diseases". Article 1. URL: https://cutt.ly/scKCilY (the date of access: April 7, 2021).

vaccination complications, as part of the program of State guarantees of free medical care for citizens;

- for social support if they experience post-vaccination complications;
- to refuse preventive vaccinations.[267]

219. Citizens have the following obligations under immunoprophylaxis:

- to follow the instructions of health care professionals;
- to confirm in writing their refusal of preventive vaccination.[268]

220. The State provides vaccination free of charge at medical institutions of the State and municipal health care system in accordance with the national calendar of prophylactic vaccinations and the calendar of prophylactic vaccinations for epidemic indications and offers social support in the event of post-vaccination complications, expressed in the form of State guarantees.[269]

Nature of vaccination

221. Vaccination can only be administered upon informed, voluntary consent to medical intervention of a citizen or his or her legal representative.[270] A citizen has the right to refuse vaccination, but a written refusal is a prerequisite.[271]

222. The law does not provide penalties for not vaccinating, but failure to vaccinate may have the following consequences:[272]

- prohibiting citizens from traveling to countries where, in accordance with IHR or international treaties of the Russian Federation, specific prophylactic vaccinations are required;

[267] Ibid. Article 5(1).
[268] Ibid. Article 5(3).
[269] Ibid. Article 4(2).
[270] Federal Law No. 323-FZ of November 21, 2011, "On the Fundamentals of Health Protection of Citizens in the Russian Federation". Article 20. URL: https://cutt.ly/CcKM9R5 (the date of access: April 7, 2021).
[271] Federal Law No. 157-FZ of September 17, 1998, "On Immunoprophylaxis of Infectious Diseases". Article 5.
[272] Ibid. Article 5(2).

- temporary refusal of admission to educational and recreational establishments in the event of mass infectious diseases or the threat of epidemics;

- refusing to hire citizens or suspending them from work involving a high risk of infectious disease.

Domestic vaccination process

223. Vaccinations are carried out by appropriately trained health care workers[273] in health care centers licensed to carry out medical activities.[274]

224. The legislation does not limit the legal form of the organization carrying out immunoprophylaxis. Prophylactic vaccinations are administered to citizens in State, municipal or private health care organizations or by citizens engaged in private medical practice under a medical license.[275]

225. Vaccination at home by vaccination teams during mass preventive vaccinations is allowed for epidemic indications and also for social indications (for people with disabilities, children in asocial families, etc.) by agreement with the territorial authorities of Rospotrebnadzor[276] and health care authorities.[277]

226. Vaccination is allowed only with authorized vaccines on the basis of the signed voluntary informed consent of the citizen or his or her legal representative and after prior examination by a doctor ("paramedic") (uniformly for both preventive vaccination

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[273] Resolution of the Chief State Sanitary Doctor of the Russian Federation No. 34 of June 4, 2008, "On Approval of Sanitary and Epidemiological Rules SP 3.3.2367-08". Para. 7.1. URL: https://cutt.ly/ycK4dxw (the date of access: April 7, 2021).

[274] Federal Law No. 157-FZ of September 17, 1998, "On Immunoprophylaxis of Infectious Diseases". Article 11(1).

[275] Resolution of the Chief State Sanitary Doctor of the Russian Federation No. 34 of June 4, 2008, "On Approval of Sanitary and Epidemiological Rules SP 3.3.2367-08". Para. 2.5. "Citizens" refer to individual entrepreneurs, since the legislation contains a closed list of subjects eligible for a license. See the Resolution of the Government of the Russian Federation No. 291 of April 16, 2012, "On Licensing Medical Activities (with the exception of the above activities carried out by medical organizations and other organizations belonging to the private health care system, on the territory of the Skolkovo Innovation Center)". Para. 2. URL: https://cutt.ly/1cKMJhU (the date of access: April 7, 2021).

[276] The Russian Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (Rospotrebnadzor) is the federal agency that works to provide oversight and control of wellbeing and consumer rights and protection of the citizens of the Russian Federation. Rospotrebnadzor reports directly to the Government of the Russian Federation. For more information see the official website. URL: https://www.rospotrebnadzor.ru/en/ (the date of access: April 7, 2021).

[277] Resolution of the Chief State Sanitary Doctor of the Russian Federation No. 34 of June 4, 2008, "On Approval of Sanitary and Epidemiological Rules SP 3.3.2367-08". Para. 2.8.

procedures approved by the Order of the Ministry of Health of Russia No. 125n of March 21, 2014).[278]

227. Priority categories of citizens, types, and terms of preventive vaccinations are established in the national calendars and approved by the Ministry of Health[279] in consideration of the socio-economic significance of infections and national and international experience in preventing infectious diseases.[280]

228. Categories of citizens subject to compulsory vaccination and terms of preventive vaccination for epidemic indications are established in the National Calendar of Preventive Immunization and the Calendar of Preventive Immunization for Epidemic Indications respectively, approved by the Order of the Ministry of Health of Russia No. 125n of March 21, 2014.

Liability for the harm caused by a vaccine

229. In the Russian Federation, a monetary compensation mechanism distinct from the civil law mechanism of redress is provided for by law.[281]

230. In the event of post-vaccination complications, citizens are entitled to state lump sum benefits, monthly monetary compensation, and temporary incapacity allowances.[282] The list of complications subject to compensation was approved by Resolution of the Government of the Russian Federation No. 885 of August 2, 1999, and is exhaustive.

231. Receipt of state lump-sum benefits, monthly monetary compensation, or temporary disability allowances does not replace the possibility for the injured person to claim compensation from the medical organization in connection with post-vaccination complications if the medical organization is at fault.[283]

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[278] Order of the Ministry of Health of the Russian Federation No. 125n of March 21, 2014, "On Approval of the National Preventive Immunization Calendar and the Calendar of Preventive Immunization on Epidemic Indications". Paras. 3–5. URL: http://base.garant.ru/70647158/ (the date of access: April 7, 2021).
[279] Ibid. Paras. 9–10.
[280] Guidelines MU 3.3.1889-04 "Procedure for prophylactic vaccinations" (approved by the Chief State Sanitary Inspector of the Russian Federation on March 4, 2004). Section 2. URL: https://cutt.ly/OcK8saM (the date of access: April 7, 2021).
[281] Federal Law No. 157-FZ of September 17, 1998, "On Immunoprophylaxis of Infectious Diseases". Chapter V.
[282] Ibid. Article 18(1).
[283] Civil Code of the Russian Federation. Article 1064. Paras. 1–2.

232. The manufacturer is obliged to compensate for damage to citizens' health if it is proved that:

- the medicinal product was used as prescribed in accordance with the instructions for medical use and harm was caused by the launch into civil circulation of a substandard medicinal product;

- the damage to health is caused by false information in the instructions for medical use issued by the manufacturer of the medicinal product.[284]

233. It is difficult to prove a causal link in order to claim civil liability from the manufacturer. This is due to the fact that very strict quality control rules apply to medicinal products, especially immunobiological medicinal products (**para. 210–211 of the Analytical Report**). As a rule, liability will be incurred by parties who have failed to comply with these rules and the product has become unusable as a result.[285]

234. Damage caused to the life and/or health of citizens during the provision of medical care shall be compensated by medical organizations to the extent and in accordance with the procedure established by the legislation of the Russian Federation.[286] Thus, even if there is fault on the part of the health care worker who administers the vaccination, civil liability for damages to health will be held by the organization.

235. Compensation for harm caused to the life and/or health of citizens does not exempt medical and pharmaceutical personnel from liability in accordance with Russian law[287] (moral damages, disciplinary responsibility, administrative responsibility, criminal responsibility).

236. Regarding the liability of organizations, it should be considered that in law enforcement practice[288] there is a presumption of poor quality of the product and the potential for harm to human health. This conclusion follows from Article 69(2) of Federal Law No. 61: non-compliance with storage rules does not guarantee the preservation of physical and chemical properties and quality of medicinal products and, consequently, their effectiveness and safety when used. In line with the courts' positions, the mere fact

[284] Federal Law No. 61-FZ of April 12, 2010, "On Circulation of Medicines". Article 69.
[285] Ibid. Article 69(2).
[286] Federal Law No. 323-FZ of November 21, 2011, "On the Fundamentals of Health Protection of Citizens in the Russian Federation". Article 98.
[287] Ibid. Article 98(4).
[288] Resolution of the Arbitration Court of the West Siberian District of May 24, 2017, in case No. A45-19165/2016. URL: https://cutt.ly/mcLwLVj (the date of access: April 7, 2021).

that products, for example, were transported in breach of storage rules presumes that there is no need for further proof of a threat to the life and health of citizens.[289]

237. A health care organization may also be liable if the harm to health is caused by a breach by the health care organization of its responsibilities in the implementation of immunoprophylaxis and not the quality of the product, e.g.:

- in the event of not providing complete and objective information on the necessity of preventive vaccinations, the consequences of not doing so, and possible post-vaccination complications;

- in case of not carrying out a medical examination and if a medical examination is necessary before preventive vaccinations;

- in case of violations of sanitary regulations and other requirements for prophylactic vaccination.[290]

238. The procedure for compensation by organizations and the manner in which such compensation is determined are set out in Articles 1084–1094 of the CCRF.

b. Special Case of COVID-19 Vaccination

239. The initiative to introduce vaccination and "COVID passports" is of a controversial nature and is not currently regulated in any way in the federal legislation.[291]

240. A distinction must be made between the concept of a "COVID passport" and a certificate of vaccination. The vaccination certificate is a routine practice in immunoprophylaxis.

241. Since vaccination against SARS-CoV-2 (COVID-19) has been added to the Calendar of prophylactic vaccinations for epidemic indications, approved by the Order of the Ministry of Health of Russia No. 125n of March 21, 2014, information on the preventive vaccination must be recorded and entered in the medical record forms.[292]

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[289] Resolution of the Eighth Arbitration Court of Appeal of October 31, 2017, in case No. A75-3283/2017. URL: https://cutt.ly/WcLeuTI (the date of access: April 7, 2021).
[290] Federal Law No. 52-FZ of March 30, 1999, "On Sanitary and Epidemiological Welfare of the Population". Article 44. Para. 1(4). URL: https://cutt.ly/6cLiVNk (the date of access: April 7, 2021).
[291] *Klyuchevskaya N.* "COVID passports" in Russia: pros and cons. URL: https://www.garant.ru/article/1442254/ (the date of access: April 7, 2021).
[292] Guidelines MU 3.3.1889-04 "Procedure for prophylactic vaccinations" (approved by the Chief State Sanitary Inspector of the Russian Federation on March 4, 2004). Para. 10.4.

The vaccination certificate is a document where all vaccinations are recorded. It records information on preventive vaccinations, post-vaccination complications, and vaccination failures.[293] Prophylactic vaccination certificate form is approved by the Order of the Ministry of Health of Russia No. 220 of September 17, 1993.

242. Currently, obtaining a separate certificate of vaccination against COVID-19 in a simplified form (in the form of a certificate) may be required for citizens to leave the Russian Federation and to cross state borders of foreign countries.[294] In this regard, the Ministry of Digital Development, Communications and Mass Media has made it possible to obtain an electronic COVID-19 vaccination certificate, including in English, on the Public Services Portal.

243. In addition to vaccination certificates, records of COVID-19 vaccination at stages I and II, including information on the vaccinated person, personal data, the name of the vaccine used and some information from its packaging, are recorded in the register of the Unified State Health Information System, which operates according to the established procedure.[295]

1.3. Legal Regulation of Export and Import of Vaccines

a. General Legal Framework

Conditions for export of vaccine to third countries

244. There are no restrictions on the export of a vaccine to third countries under national law.[296] In addition, medicinal products intended for export are not subject to state registration.[297] For such medicinal products, Resolution of Ministry of Industry and Trade of the Russian Federation No. 4369 of December 31, 2015, defines the procedure for obtaining documents confirming that the medicinal product for medical use has been manufactured in accordance with the Good Manufacturing Practice rules to provide (upon request) such documents to the authorized bodies of the country to which the medicinal product is exported.

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[293] Federal Law No. 157-FZ of September 17, 1998, "On Immunoprophylaxis of Infectious Diseases". Article 17(2).
[294] See Interfax. COVID-certificates on "Public Services" can be linked to an international passport. URL: https://www.interfax.ru/russia/759894 (the date of access: April 7, 2021).
[295] Resolution of the Government of the Russian Federation No. 555 of May 5, 2018, "On a unified state information system in the field of health care". URL: https://cutt.ly/mcLoYOY (the date of access: April 7, 2021).
[296] Federal Law No. 61-FZ of April 12, 2010, "On Circulation of Medicines". Article 47. Part 8.
[297] Ibid. Article 43. Part 5 (7).

Conditions for import of vaccine from third countries

245. Under the general rules, it is prohibited to import medicinal products not registered in the Russian Federation,[298] except for those intended for clinical trials of medicinal products and expert examination of medicinal products for state registration of medicinal products on the basis of authorization issued by the authorized federal executive body.[299]

246. Applicants for import authorization may be: pharmaceutical manufacturers, pharmaceutical distributors, foreign pharmaceutical developers, and foreign pharmaceutical manufacturers or other legal entities on behalf of the medicinal product developer.[300]

247. The procedure for import and issuance of an import authorization, including the grounds for refusal to issue an import authorization, are set out in the Eurasian Economic Commission Council Decision No. 30 of April 21, 2015, "On Non-Tariff Regulatory Measures" and Resolution of the Government of the Russian Federation No. 771 of September 29, 2010, "On Procedure for Importing Medicinal Products for Medical Use into the Russian Federation".

248. There are no specific requirements applicable to the import of vaccines under national legislation.

b. Special Case of COVID-19 Vaccines Export and Import

249. There are no distinguishing features governing import/export of vaccines during the COVID-19 pandemic. The exception is the possibility of obtaining an import authorization for unregistered products for their subsequent use (**paras. 213–215 of the Analytical Report**).

[298] Ibid. Article 47(2).
[299] Ibid. Article 47(3).
[300] Ibid. Article 48.

2. Germany

2.1. Legal Regulation of Vaccine Development

a. General Legal Framework

General information

250. In Germany, the MPA governs the production and quality control of drugs, including vaccines.[301] The MPA does not impose any requirements on a vaccine developer. In practice, the development of vaccines often occurs in cooperation between pharmaceutical entities, universities, and research institutions.[302] However, according to § 21 (3) of the MPA, the marketing authorization is being granted to pharmaceutical companies only.[303]

251. The German Government financially supports the development of the COVID-19 vaccines and offers grants. Yet, only commercial companies are eligible to apply therefor.[304] In addition, applicants are required to have a permanent establishment or a subsidiary in the territory of Germany.[305]

Stages and time frameworks for conducting clinical trials

252. The MPA[306] and the Ordinance on the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for use in humans of August 9, 2004,[307] provide for the legal framework of conducting clinical trials in Germany. Timelines and stages for conducting clinical trials and creating a vaccine are not mandated by law but depend on the progress of relevant clinical trials. There are also

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[301] Gesetz über den Verkehr mit Arzneimitteln. § 4 (4). URL: https://www.gesetze-im-internet.de/amg_1976/ (the date of access: April 30, 2021).

[302] See Strategy to Introduce and Evaluate a Vaccine against Sars-CoV-2 in Germany. P. 4. URL: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/C/Coronavirus/Impfstoff/German_National_COVID-19_Vaccination_Strategy_long_eng_061120.pdf (the date of access: April 30, 2021).

[303] Gesetz über den Verkehr mit Arzneimitteln. § 21 (3).

[304] Richtlinie für ein Sonderprogramm zur Beschleunigung von Forschung und Entwicklung dringend benötigter Impfstoffe gegen SARS-CoV-2. URL: https://www.bmbf.de/foerderungen/bekanntmachung-3035.html (the date of access: April 30, 2021).

[305] Ibid.

[306] Gesetz über den Verkehr mit Arzneimitteln. §§ 40–42b.

[307] Verordnung über die Anwendung der Guten Klinischen Praxis bei der Durchführung von klinischen Prüfungen mit Arzneimitteln zur Anwendung am Menschen. URL: https://www.gesetze-im-internet.de/gcp-v/ (the date of access: April 30, 2021).

no specific provisions on the possibility of reducing the time frameworks or stages for clinical trials.[308]

Legal control mechanisms

253. The clinical trials are subjects to legally imposed requirements.[309] For example, there is a requirement to conduct clinical trials in conformity with ethical standards on the clinical trials.[310] Further, any possible harm to the participants of clinical trials shall be covered by insurance.[311] Since 2004, clinical trials are subject to approval by the competent federal authority (*zuständige Bundesoberbehörde*).[312]

254. In Germany, the PEI, a Federal Institute for Vaccines and Biomedicines, approves clinical trials of vaccines (all phases).[313] Detailed information on submission of a request for approval of a clinical trial is provided in the joint publication of the Federal Institute for Drugs and Medical Devices and the PEI.[314] The decision to approve the conduct of clinical trials is taken based on a careful assessment of the potential benefit-risk profile of the vaccine candidate.[315] Clinical trials could be terminated or suspended at any time if any violation of the ethical requirements or suspected adverse event take place.[316]

255. In addition, the conduct of clinical trials requires a favorable opinion from the competent Ethics Committee.[317] Ordinance on the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for use in humans aims to guarantee compliance with Good Clinical Practice in the design, conduct, and documentation of clinical trials in humans and reporting on such trials.[318]

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[308] Gesetz über den Verkehr mit Arzneimitteln. §§ 40–42b.
[309] Verordnung über die Anwendung der Guten Klinischen Praxis bei der Durchführung von klinischen Prüfungen mit Arzneimitteln zur Anwendung am Menschen.
[310] Gesetz über den Verkehr mit Arzneimitteln. § 40 (1).
[311] Ibid. § 40 (1) (8).
[312] Ibid. § 40.
[313] Ibid. § 77 (2).
[314] Notification on the clinical trial of medicinal products for human use. A joint publication of the Federal Institute for Drugs and Medical Devices and the Paul Ehrlich Institute. URL: https://www.bfarm.de/SharedDocs/Bekanntmachungen/EN/drugs/clinTrials/bm-KlinPr-20060810-klinPr-pdf-en.pdf;jsessionid=B78D2B5047D9AD75B146616E3AF1F562.1_cid354?__blob=publicationFile&v=3 (the date of access: April 30, 2021).
[315] Gesetz über den Verkehr mit Arzneimitteln. § 41.
[316] Ibid. § 42a.
[317] Ibid. § 40 (1).
[318] Verordnung über die Anwendung der Guten Klinischen Praxis bei der Durchführung von klinischen Prüfungen mit Arzneimitteln zur Anwendung am Menschen. § 1 (1).

256. Further the results of the clinical studies shall be published.[319] Germany is collaborating with the WHO on the initiative to register clinical trials on the ICTRP.[320] The German Clinical Trials Register is an approved member of the ICTRP network.[321] It allows a comprehensive analysis of the clinical research situation in Germany. The main idea behind the creation of the worldwide clinical trial register is a contribution to the standardization of data quality.[322]

257. The vaccine developers are subject to reporting obligations on any complications during the clinical trials.[323] The PEI may choose to halt clinical trials if significant safety concerns are discovered during clinical trials.[324]

258. Upon completion of clinical trials, vaccine manufacturers submit a request for marketing approval with sufficient safety and efficacy data for approval by the PEI.[325] The market authorization procedure is an important control mechanism. Once a vaccine is approved for use, the continuous monitoring of the side effect is put in place.[326] Patients, health care professionals, and pharmaceutical companies may report any suspected side effects to the PEI.[327] If experts agree that there is a safety concern with a vaccine, the PEI may either require any changes in the use of the vaccine (for instance, stop its use on people who are more likely to suffer the side effect) or in exceptional cases it can also stop the entire use of the vaccine.[328]

Vaccine authorization

259. There are different types of procedures available for the approval of medicinal products for the use in the German market: national procedure,[329] procedure of mutual

[319] Gesetz über den Verkehr mit Arzneimitteln. § 42b.
[320] German Clinical Trials Register. URL: https://www.drks.de/drks_web/navigate.do?navigationId=about&messageDE=Wir%20%C3%BCber%20uns&messageEN=About%20us (the date of access: April 30, 2021).
[321] Ibid.
[322] Ibid.
[323] Gesetz über den Verkehr mit Arzneimitteln. § 67 (1).
[324] Ibid. § 42a (2).
[325] Ibid. § 22 (2).
[326] Ibid. § 63c (1).
[327] Gesetz zur Verhütung und Bekämpfung von Infektionskrankheitenbeim Menschen. § 6 (1) (3). URL: https://www.gesetze-im-internet.de/ifsg/IfSG.pdf (the date of access: April 30, 2021).
[328] Gesetz über den Verkehr mit Arzneimitteln. § 30 (1).
[329] Gesetz über den Verkehr mit Arzneimitteln. § 22. The requirements for the marketing authorization documentation are laid down in §§ 22 to 24 of the MPA.

recognition,[330] decentralized procedure,[331] and centralized procedure for the EU.[332] The type of authorization procedure depends on the drug itself and on where the pharmaceutical company wants to market it.

260. The focus in all the approval procedures lies in sufficient proof of the vaccine's pharmaceutical quality, efficiency, and safety.[333] For Germany, the PEI assesses the quality, efficacy, and safety of the medicinal products, for which a marketing authorization application has been submitted.

261. European authorization is coordinated by the EMA. Even in case of centralized procure the PEI remains responsible for the necessary examinations and it works in close cooperation with the European authority.[334]

Emergency use authorization

262. Emergency use authorization (authorization to apply a particular drug without it being authorized by any of the described above procedures) is possible under the German legislation. The Act on the Prevention and Control of Infectious Diseases entails a legal basis therefor.[335]

263. An assessment from the competent federal authority — the PEI — is a prerequisite for this decision. For this purpose, the PEI establishes that the quality of the medicinal product is ensured and that a favorable risk/benefit ratio with regard to the prevention or treatment of the respective disease can be expected from its use based on the state of medical knowledge.[336]

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[330] This procedure applies for drugs that have already been approved by other EU Member States. See Gesetz über den Verkehr mit Arzneimitteln. § 37 (1).

[331] The pharmaceutical company applies for a marketing authorization in all the EU Member States simultaneously, where it intends to apply for such authorization. See Gesetz über den Verkehr mit Arzneimitteln. § 25b.

[332] Zulassungsverfahren. URL: https://www.pei.de/DE/regulation/zulassung-human/zulassungsverfahren/zv-node.html;jsessionid=D0D7E7C1AAAA12A17272A340A992B0D1.intranet241 (the date of access: April 30, 2021). See also New Drugs: Evidence Relating to Their Therapeutic Value After Introduction to the Market. URL: https://www.aerzteblatt.de/int/archive/article/122468 (the date of access: April 14, 2021).

[333] Licensing Procedures. URL: https://www.bfarm.de/EN/Drugs/licensing/zulassungsverfahren/_node.html (the date of access: April 14, 2021).

[334] Zentralisiertes Verfahren. URL: https://www.pei.de/DE/regulation/zulassung-human/zulassungsverfahren/zv-node.html;jsessionid=5AF2779A65E8660213A5297356753CFD.intranet231 (the date of access: April 30, 2021).

[335] Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen. § 5 (2) (4).

[336] Verordnung zur Sicherstellung der Versorgung der Bevölkerung mit Produkten des medizinischen Bedarfs bei der durch das Coronavirus SARS-CoV-2 verursachten Epidemie. § 4 (3). URL: http://www.gesetze-im-internet.de/medbvsv/BJNR614700020.html (the date of access: April 30, 2021).

Vaccine patent protection

264. The Patent Act (*Patentgesetz*) provides for a legal basis for national patent protection in Germany.[337] Patent protection in Germany can also be obtained under the EPC.[338] Pursuant to the Patent Cooperation Treaty, German applicants can file a single application and receive patent protection in over 151 nations.[339] The procedure largely depends on the chosen option. Applications for a national German patent must be filed with GPTO. The GPTO is responsible for registering patents, utility models, trademarks, and designs. Applications for an EPC patent can be filed with the EPO. The application shall contain proof of innovation and that the product is capable of industrial application.[340] These are the main conditions for granting a patent for the created vaccine.

265. In Germany, § 13 of the GPA allows the restriction of patent rights by means of an administrative order issued by state authorities. The recent amendment to the Act on the Prevention and Control of Infectious Diseases complements existing provisions of German patent law and directly enables the federal Ministry of Health for grounds of public interest or national security to allow the use of patented inventions for public interest purposes in accordance with § 13 of the GPA.[341] Patent owners will be entitled to reasonable compensation from the federal government, and not third parties, where their patents are made available to others in this way.

b. Legal Framework for the COVID-19 Vaccine Development

266. In view of the pandemic, Germany adopted the EU Guidance on the management of clinical trials during the COVID-19 pandemic.[342] In addition, the Federal Institute for Drugs and Medical Devises together with the PEI issued supplementary

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[337] Patentgesetz. URL: https://www.gesetze-im-internet.de/patg/PatG.pdf (the date of access: April 30, 2021).
[338] The European Patent Convention is an international treaty, which applicants to obtain patent protection in the 38 EPC Member States by filing a single patent application. See The European Patent Convention. URL: https://www.epo.org/law-practice/legal-texts/epc.html (the date of access: April 30, 2021).
[339] Patent Cooperation Treaty. June 19, 1970. URL: https://www.wipo.int/treaties/en/registration/pct/ (the date of access: April 30, 2021). See also WIPO-Administered Treaties. URL: https://wipolex.wipo.int/en/treaties/ShowResults?search_what=C&treaty_id=6 (the date of access: April 30, 2021).
[340] Patentgesetz. §§ 3, 5. URL: https://www.gesetze-im-internet.de/patg/PatG.pdf (the date of access: April 30, 2021).
[341] Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen. § 5 (2) (5).
[342] Supplementary recommendations of BfArM and PEI to the European Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic. URL: https://www.bfarm.de/SharedDocs/Downloads/EN/Drugs/licensing/clinicalTrials/Supplementary%20Recommendations%20to%20EU%20Guidance%20on%20the%20Management%20of%20Clinical%20Trials%20during%20the%20COVID-19.pdf?__blob=publicationFile&v=6 (the date of access: April 30, 2021).

recommendations to the EU Guidelines, addressing the issues of monitoring and the potential shipment of investigational medicinal products during COVID-19.[343]

267. All applications and requests for advice in direct connection with clinical trials and drug development related to COVID-19 are treated with utmost priority and flexibility.[344] The Federal Institute for Drugs and Medical Devises created a special e-mail address for inquiries on medical trials related to COVID-19.[345]

268. All so far authorized COVID-19 vaccines were approved by the European Commission following a centralized assessment procedure coordinated by the EMA. The PEI remains responsible for authorization and control of clinical trials in the territory of Germany.[346] The specificity of the centralized assessment procedure in view of the COVID-19 vaccines was described above (**paras. 100–103 of the Analytical Report**).

269. In cause of the pandemic situation, Germany has intensified its emergency law and strengthened legal options for a more flexible response to the current need of the situation. As mentioned above, the amended legislation grants the Federal Ministry for Health power to allow the use of a patent-protected vaccine to ensure the supply.[347]

2.2. Legal Regulation of Immunoprophylaxis

a. General Legal Framework

General information

270. In Germany, all legal residents must have either state or private health insurance. German health insurance system includes immunoprophylaxis.[348] Persons who hold health insurance in Germany are entitled to free vaccinations within the meaning of § 2 (9) of the Infection Protection Act.[349] The Standing Committee on Vaccination at the Robert Koch Institute develops the national immunization schedule, which forms the basis for the federal states' vaccination guidance.

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[343] Ibid.

[344] Clinical Trials during the COVID-19 Pandemic. URL: https://www.bfarm.de/EN/Drugs/licensing/clinicalTrials/news/CT_COVID19.html;jsessionid=6414FF140CC4FADF2B6E0CAAB6F22EFB.2_cid354 (the date of access: April 30, 2021).

[345] Ibid.

[346] Gesetz über den Verkehr mit Arzneimitteln. § 40 (1) (2).

[347] Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen. § 5 (2) (5).

[348] Sozialgesetzbuch (SGB V) Fünftes Buch Gesetzliche Krankenversicherung. URL: https://www.sozialgesetzbuch-sgb.de/sgbv/20i.html (the date of access: April 30, 2021).

[349] Ibid. § 20 (i).

271. People in Germany enjoy the freedom to accept or refuse medical treatment, which follows from the individual's right to the physical integrity of the person.[350] However, in context of immunoprophylaxis of infectious diseases, the Federal Ministry of Health bears a right to mandate vaccination.[351]

Nature of vaccination

272. Generally, vaccination in Germany is voluntary. However, some vaccines may be ordered by law. For instance, the Act on the Prevention and Control of Infectious Diseases as amended by the Measles Protection Act orders vaccination against measles.[352] The Measles Protection Act, which aims to provide better protection against measles, particularly for children, entered into force on March 1, 2020. Under this Act, children of at least 1 year old, adults born before 1970 who wish to work at child daycare facilities, schools, medical facilities, as well as persons living in refugee and asylum-seeker accommodation and those employed there must be able to prove that they had received two measles vaccinations or adequate immunity to measles.[353] However, individuals are allowed exemptions for documented medical reasons.[354]

273. The German Protection against Infection Act as amended by the Measles Protection Act states that unvaccinated children can be barred from attending child daycare facilities.[355] Unvaccinated personnel may not be employed in community or health care facilities.[356] The responsible authorities may also introduce fines up to EUR 2,500 for parents who fail to vaccinate their children attending community facilities.[357] The fine can also be imposed on the management of daycare facilities that admit unvaccinated children.[358] The same applies to unvaccinated personnel in community and health care facilities, as well as refugee accommodation facilities and residents of the latter.[359]

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[350] Grundgesetz für die Bundesrepublik Deutschland. Article 2 (2). URL: https://www.gesetze-im-internet.de/gg/BJNR000010949.html (the date of access: April 30, 2021).
[351] Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen. § 20 (6).
[352] See Gesetz für den Schutz vor Masern und zur Stärkung der Impfprävention. URL: https://www.bvktp.de/media/masernschutzgesetz_bundesrat.pdf (the date of access: April 30, 2021).
[353] Ibid. Art. 1 (8), (e).
[354] Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen. § 20 (8) (3).
[355] Ibid. § 20 (12).
[356] Ibid. § 20 (12).
[357] Ibid. § 73 (1) (2).
[358] Ibid. § 73 (1) (2).
[359] Ibid. § 73 (1) (2).

Domestic vaccination process

274. § 20 (4) of the German Act on the Prevention and Control of Infectious Diseases authorizes every doctor regardless of his or her specialization to carry out protective vaccinations.[360] The Federal Ministry of Health is authorized to adopt special rules for regulation of the domestic vaccination process.[361] People who are vaccinated in Germany receive documentary proof that they received the vaccine.[362]

275. National legislation of Germany does not generally create groups for standard vaccinations. In the event of flu or other types of pandemic, priority groups for vaccination may be determined due to the limited availability of vaccines (e.g. in case of COVID-19).[363] In each situation, the priority groups will be determined case-by-case basis, following recommendations of the STIKO at the Robert Koch Institute.

Liability for the harm caused by a vaccine

276. Liability caused by medical products, including vaccines, is regulated by the Medical Protection Act.[364] The provisions of the Act limit liability for harms resulting from vaccines. Pharmaceutical companies might only be deemed liable for harm attributable to vaccine development and manufacturing process. Moreover, the scope of liability is limited to harmful effects which exceed the limits considered tolerable in the light of current medical knowledge. The Act does not contain any specific regulation on the liability of health workers.

277. Liability of vaccine manufactures, pharmaceutical companies, and health workers may also be regulated under contractual terms applicable between the parties.

278. In any case, the federal government guarantees appropriate compensation and care in accordance with the Federal Supply Act to people who are harmed by publicly recommended protective vaccination.[365]

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[360] Ibid. § 20 (4).

[361] Ibid. § 5 (2). See also Bundesministerium für Gesundheit. Bundesministerium für Gesundheit Verordnung zum Anspruch auf Schutzimpfung gegen das Coronavirus SARS-CoV-2. Februar 8, 2021. URL: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/C/Coronavirus/Verordnungen/CoronaImpfV_BAnz_AT_08.02.2021_V1.pdf (the date of access: April 30, 2021).

[362] Ibid.

[363] Announcement from the German Standing Committee on Vaccination (STIKO) at the Robert Koch Institute. Decision of the STIKO for the recommendation of the COVID-19 vaccination and the corresponding scientific rationale. URL: https://www.rki.de/EN/Content/infections/Vaccination/recommandations/COVID-19-2nd-update.pdf?__blob=publicationFile (the date of access: April 30, 2021).

[364] Gesetz über den Verkehr mit Arzneimitteln. § 84–94a.

[365] Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen. § 60.

b. Special Case of COVID-19 Vaccination

279. In the event of initial limited availability of vaccine doses, dissemination of vaccines is based on the legally binding Coronavirus Vaccination Regulation (Coronavirus-Impfverordnung) which was issued by the Federal Ministry of Health followed the vaccination recommendations of the STIKO at the RKI. The Regulation introduces the following three groups for the priority vaccination:

- *Highest priority vaccination* — people over the age of 80 and those who care of them, as well as medical staff with an extremely high risk of exposure to the coronavirus, especially those working in intensive care units, accident, emergency, and ambulance services. Nursing staff whose patients have a high risk of suffering a severe or fatal outcome, e.g. those working in transplant medicine, also belong to this group;[366]

- *High priority vaccination* — people aged 70 or more along with people who run a high risk of suffering a severe outcome, such as transplant patients. They will be joined by the police forces' public order units who are exposed to risks in the course of their duties to uphold public safety, close contacts of people in need of long-term care, pregnant women, and people living in shelters for the homeless or asylum seeker accommodation;[367]

- *Increased priority vaccination* — people aged 60 or more and those with a higher-than-average risk of suffering a severe outcome, for instance, people with chronic kidney or liver disease, cancer, or an autoimmune condition, general practitioners, and employees of laboratories. The staff working for the police forces, the fire brigade, the judiciary, and in the education sector can then also be vaccinated, as can individuals working in the retail trade and people with precarious working conditions, including seasonal workers, those working in distributions centers and in the meat processing industry.[368]

280. The vaccination process against the COVID-19 has been organized in specially established vaccination centers.[369] Federal states are responsible for setting up the vaccination centers and for ensuring that the vaccines are properly distributed in accordance with the priority vaccination groups.[370] In addition, mobile vaccination teams

[366] Bundesministerium für Gesundheit. Verordnung zum Anspruch auf Schutzimpfung gegen das Coronavirus SARS-CoV-2. § 2.
[367] Ibid. § 3.
[368] Ibid. § 4.
[369] Ibid. § 6.
[370] Ibid.

conducted vaccination in long-term care facilities for older adults and people with disabilities.[371] Starting from mid-April 2021 primary care doctors in Germany began vaccinating patients against COVID-19.[372]

281. Under Article 28c of the Infection Protection Act, the Federal Government can issue regulations by ordinance for people who have been vaccinated or people who have been tested.[373] The ordinance must be approved by the two chambers of the Parliament.

282. There are intensive discussions on the rights of those who got vaccinated against COVID-19 or were recovered from the infection.[374] It is reported that based on the report from the RKI, the Health Minister proposed to treat persons presumed to be immune to COVID-19 as if they had tested negative. Thereby they would be exempted from COVID-19 test and quarantine regulations. However, such individuals would still have to abide by mask and social distancing rules.[375]

283. Given the discriminatory impact of the above-discussed initiatives, the consideration of those initiatives requires consideration in the context of the principle of non-discrimination. The official position of the government is evolving as vaccine supply increases and the scientific data regarding the potential infectiousness of fully vaccinated individuals grows.

284. Further, the European Commission presented a proposal to create a Digital Green Certificate to facilitate the safe free movement of citizens within the EU during the COVID-19 pandemic.[376] The certificate is intended to serve as proof that the person has either been vaccinated against COVID-19, received a negative test results, or recovered from COVID-19.[377] After the proposal will be approved by the European Parliament, national authorities will be in charge of issuing those certificates.[378]

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[371] Ibid.

[372] Bundesministerium für Gesundheit Fragen und Antworten zum Impfen in Arztpraxen. URL: https://www.bundesgesundheitsministerium.de/coronavirus/faq-covid-19-impfung/impfen-in-arztpraxen.html (the date of access: April 30, 2021).

[373] Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen. § 28c.

[374] See Keine Kontaktbeschränkung für Geimpfte? URL: https://www.tagesschau.de/inland/geimpfte-genesene-entwurf-lambrecht-101.html (the date of access: April 30, 2021).

[375] COVID and ethics: Germany debates "freedoms" for the vaccinated. URL: https://www.dw.com/en/covid-and-ethics-germany-debates-freedoms-for-the-vaccinated/a-57299890 (the date of access: April 30, 2021).

[376] Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate). URL: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0130 (the date of access: April 30, 2021).

[377] Ibid.

[378] Ibid.

285. The developments in this pandemic are currently very dynamic which can lead to rapid changes in any of the described above issues.

286. The SARS-CoV-2 Medicinal Products Supply Ordinance by the Federal Ministry of Health as *lex specialis* explicitly excludes the liability of vaccine manufactures, pharmaceutical companies, and health workers.[379]

2.3. Legal Regulation of Vaccine Export and Import

a. General Legal Framework

Conditions for export of vaccine to third countries

287. The German government does not generally prohibit the export of vaccines. Also, the vaccines that under the Medical Production Act have failed to be approved for application in Germany may be exported to third countries if the competent authority of the country of destination has authorized the import thereof.[380] Such authorization shall implicitly indicate that the competent authority of the third country is informed that the exported vaccine fails to meet the quality standard for the German market.

Conditions for import of vaccine from third countries

288. For the import of a vaccine from third countries outside the EU to Germany, the Medical Products Act requires an import permit issued by the PEI.[381] Such permit shall confirm that the vaccine meets the quality standards.[382]

b. Special Case of COVID-19 Vaccines Export and Import

289. In view of the global shortage of supply of COVID-19 vaccines and delays in production, export of COVID-19 vaccines outside of the EU is restricted. In January 2021, the EU Commission adopted Implementing Regulation making the export of COVID-19 vaccines subject to an export authorization.[383] As to the current state, the restriction of

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[379] Verordnung zur Sicherstellung der Versorgung der Bevölkerung mit Produkten des medizinischen Bedarfs bei der durch das Coronavirus SARS-CoV-2 verursachten Epidemie. § 3 (4). URL: http://www.gesetze-im-internet.de/medbvsv/BJNR614700020.html (the date of access: April 30, 2021).

[380] Gesetz über den Verkehr mit Arzneimitteln. § 73 (a).

[381] Ibid. § 72 (1).

[382] Ibid. § 72.

[383] Commission Implementing Regulation (EU) 2021/111 of January 29, 2021, making the exportation of certain products subject to the production of an export authorization. URL: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=OJ:L:2021:031I:FULL&from=EN (the date of access: April 30, 2021).

export remains in effect until June 30, 2021.[384] The export of a vaccine against COVID-19 requires approval from the competent authority of the exporting State, where vaccines are manufactured.[385] Such restrictions apply in Germany as a Member State of the EU.

290. In accordance with Regulation (EU) 2021/442, export authorizations are to be refused by the Member States where the exports concerned pose a threat to the execution of the APAs between the Union and vaccine manufacturers in view of their volume or other relevant circumstances, such as the volume of vaccines delivered to the Union at the time of the request.[386]

291. Germany did not enact any special legislation on the matter of importing the vaccines against COVID-19.

[384] Commission Implementing Regulation (EU) 2021/2081 of March 24, 2021, making specific arrangements to the mechanism making the exportation of certain products subject to the production of an export authorization. URL: https://trade.ec.europa.eu/doclib/docs/2021/march/tradoc_159498.pdf (the date of access: April 30, 2021).

[385] Commission Implementing Regulation (EU) 2021/442 of March 11, 2021, making the exportation of certain products subject to the production of an export authorization. Article 1 (1) (4). URL: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021R0442&from=EN#ntr2-L_2021085EN.01019001-E0002 (the date of access: April 30, 2021).

[386] Ibid. Article 1 (1) (7).

3. Sweden

3.1. Legal Regulation of Vaccine Development

a. General Legal Framework

General information

292. In Sweden, the Medicinal Products Act (SFS 2015:315) and the Medicinal Products Ordinance (SFS 2015:458) are the main legislations governing the production and quality control of drugs, including vaccines.[387] The Swedish regulatory framework for medicinal products is largely based on EU directives.[388] Further, the EU Regulations are directly applicable in Sweden.[389]

293. The Medical Products Agency (*Läkemedelsverket*) is the Swedish national authority responsible for the regulation and surveillance of the development, manufacturing, and marketing of pharmaceuticals and other medicinal products.[390]

Stages and time frameworks for conducting clinical trials

294. Timelines and stages for conducting clinical trials and creating a vaccine are not mandated by law.[391] Clinical trials that are planned to be conducted in Sweden are

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[387] The basic legal acts on the matter are Läkemedelslag. 2015:315. URL: https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lakemedelslag-2015315_sfs-2015-315 (the date of access: April 30, 2021) and Läkemedelsförordning. 2015:458. URL: https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lakemedelsforordning-2015458_sfs-2015-458 (the date of access: April 30, 2021). Full texts of all the legal acts on the matter are available at Läkemedelsverket. Svensk lagstiftning. URL: https://www.lakemedelsverket.se/sv/lagar-och-regler/svensk-lagstiftning (the date of access: April 30, 2021).

[388] See Directive 2001/83/EC of the European Parliament and the Council of November 6, 2001, on the Community code relating to medicinal products for human use. URL: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf (the date of access: April 30, 2021); Directive 2001/20/EC of the European Parliament and of the Council of April 4, 2001, on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. URL: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32001L0020&qid=1618378861041 (the date of access: April 30, 2021).

[389] The full list of the relevant documents is available at Läkemedelsverket. EU-direktiv. URL: https://www.lakemedelsverket.se/sv/lagar-och-regler/eu-direktiv-och-eu-forordningar/eu-direktiv (the date of access: April 30, 2021) and *Läkemedelsverket*. EU-förordningar. URL: https://www.lakemedelsverket.se/sv/lagar-och-regler/eu-direktiv-och-eu-forordningar/eu-forordningar (the date of access: April 30, 2021).

[390] Läkemedelsverket. URL: https://www.lakemedelsverket.se/en (the date of access: April 30, 2021).

[391] Läkemedelslag. 2015:315. Chapter 7.

subjected to authorization by the Swedish Medical Products Agency, which keeps a record of all registered vaccines.[392] This agency evaluates the benefits and risks of a vaccine based on data from extensive clinical trials and authorizes it.[393] However, the approval for the use of vaccines is given by the European Commission,[394] including COVID-19 ones.[395]

Legal control mechanisms

295. The clinical trials are subjects to legally imposed requirements.[396] For instance, all the participants shall give their informed consent and have a right to refuse their participation in clinical trials.[397] Further, vaccine testing may be carried out on people only by a licensed physician.[398]

296. The EU law on clinical trials on medicinal products, including vaccines, for human use is applicable in Sweden (**paras. 81–83 of the Analytical Report**).

Vaccine authorization

297. In Sweden, all vaccines must be approved (licensed) as "safe and effective" by the Medical Products Agency before they can be manufactured and used on humans.[399] An applicant (a vaccine developer) shall submit the required documents and data for consideration.[400]

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[392] Läkemedelsverket. Godkända eller registrerade läkemedel. URL: https://www.lakemedelsverket.se/sv/sok-lakemedelsfakta?atcCode=J07&status=1&activeTab=1&medProdFormExpanded=true (the date of access: April 30, 2021).
[393] Ibid.
[394] European Parliament and Council. Regulation (EC) No. 726/2004 of March 31, 2004, laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. URL: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R0726&from=EN (the date of access: April 30, 2021).
[395] European Commission. Questions and answers on COVID-19 vaccination in the EU. Authorization process of COVID-19 vaccines. URL: https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/questions-and-answers-covid-19-vaccination-eu#authorisation (the date of access: April 30, 2021).
[396] Läkemedelslag. 2015:315. Chapter 7.
[397] Ibid. Chapter 7. Para. 3.
[398] Ibid. Chapter 7. Para. 1.
[399] Ibid. Chapter 4.
[400] Ibid.

298. On receipt of a complete application and payment of the application fee, the Medical Products Agency has 90 days to render its decision.[401]

Emergency use authorization

299. The EU legislation provides for a possibility of an EUA of a vaccine. The competence of issuing the EUA fall within the jurisdiction of the EU Member States, including Sweden. In case Sweden decides to issue such an authorization, it will be restricted to its territory (**para. 96 of the Analytical Report**).

Vaccine patent protection

300. Swedish legislation provides for the possibility of granting patents for created vaccines[402] under conditions and procedures similar to those provided for in the relevant EU legislation.[403] While Sweden is not developing its own COVID-19 vaccine, the conditions and procedure for granting a patent are identical to the general patent granting procedure stipulated by the EU law on the matter[404] and Swedish law applied in accordance with it.[405]

301. Besides, the Swedish Patent Act (1967:837) allows individuals to apply to the Swedish Patent and Market courts for the granting of compulsory license to make use of patented inventions without the consent of the patent owner due to public interest of exceptional importance.[406] However, no compulsory license has ever been granted in Sweden.[407]

302. While Swedish law does not establish specific provisions regarding intellectual property rights for the development of medicines and vaccines, clinical research data acquired during their development is not the exclusive right of the copyright holder, whose consent is required for their use and distribution if they are used to create generic

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[401] Ibid.

[402] Patentlag 1967:837. December 1, 1967. URL: https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/patentlag-1967837_sfs-1967-837 (the date of access: April 30, 2021).

[403] European Parliament and Council. Regulation (EC) No. 469/2009 of May 6, 2009, concerning the supplementary protection certificate for medicinal products. URL: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R0469&from=EN (the date of access: April 30, 2021).

[404] Ibid.

[405] Patentlag 1967:837.

[406] Ibid. Section 47.

[407] Sweden: Q&A on the use of patented products and processes without authorization of patent holder National compulsory licence laws. P. 4. URL: https://www.twobirds.com/~/media/pdfs/in-focus/coronavirus/lsh-tracker/bird--bird-compulsory-licensing-sweden.pdf (the date of access: April 30, 2021).

drugs.[408] The use of the vaccine without the permission of the copyright holder can be appealed in the Patent and Market Court (*Patent-och marknadsdomstolen*).[409]

303. Sweden is a member of the WTO, which means that exported vaccines are subject to the provisions of the TRIPS.[410] The WTO is currently discussing the idea of waiving a part of the TRIPS provisions regarding patenting and protection of intellectual rights in relation to vaccines against COVID-19.[411] The Swedish Parliament also discussed this issue[412] and noted that Sweden is committed to the EU position and that the TRIPS patent system can exist without conflicting with the goal of making vaccines available to low-income countries.[413]

b. Legal Framework for the COVID-19 Vaccine Development

304. The vaccines that have been approved by the European Commission and can be used in Sweden are: Comirnaty (Pfizer/BioNTech) authorized on December 21, 2020, Moderna authorized on January 6, 2021, AstraZeneca authorized on January 29, 2021, Vaccine Janssen authorized on March 11, 2021.[414]

305. Despite the reported cases of blood clots after the vaccination by the AstraZeneca's COVID-19 vaccine, based on the opinion of the EMA the Public Health

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[408] Patentlag 1967:837. 1 kap. 3 §; Kommittén om patentskydd för biotekniska uppfinningar. Patentskydd för biotekniska uppfinningar. SOU 2008:20. P. 362. URL: https://www.regeringen.se/49bb8e/contentassets/2f307b79b3dd48cc9f11c9674ac746e2/patentskydd-for-biotekniska-uppfinningar-hela-dokumentet-sou-200820 (the date of access: April 30, 2021).

[409] Patentlag 1967:837. 1 kap. 4 §.

[410] World Trade Organization. Amendment of the TRIPS Agreement. Members and dates of acceptance. URL: https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (the date of access: April 30, 2021).

[411] World Trade Organization. Members discuss TRIPS waiver, LDC transition period and green tech role for small business. URL: https://www.wto.org/english/news_e/news21_e/trip_11mar21_e.htm (the date of access: April 30, 2021); Council for Trade-Related Aspects of Intellectual Property Rights. Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19. URL: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True (the date of access: April 30, 2021).

[412] Sveriges riksdag. Patent och immaterialrättsskydd på vaccin mot covid-19. URL: https://www.riksdagen.se/sv/dokument-lagar/dokument/interpellation/patent-och-immaterialrattsskydd-pa-vaccin-mot_H810305 (the date of access: April 30, 2021); Sveriges riksdag. Riksdagens snabbprotokoll. 2020/21:73. P. 20–23. URL: https://data.riksdagen.se/fil/A8EBB6BC-4D32-4317-958B-A8E2DD85BA22 (the date of access: April 30, 2021).

[413] Sveriges riksdag. Riksdagens snabbprotokoll. 2020/21:73. Anf. 39. P. 20–21. URL: https://data.riksdagen.se/fil/A8EBB6BC-4D32-4317-958B-A8E2DD85BA22 (the date of access: April 30, 2021).

[414] Läkemedelsverket. COVID-19 vaccine. URL: https://www.lakemedelsverket.se/en/coronavirus/covid-19-vaccine (the date of access: April 30, 2021).

Agency of Sweden recommended that the vaccine should continue to be used in Sweden to protect people aged 65 and over.[415]

306. In addition, Sweden is a party to five EU agreements with manufacturers Moderna,[416] CureVac,[417] Pfizer/BioNTech,[418] Janssen Pharmaceutica NV,[419] and AstraZeneca[420] to supply the COVID-19 vaccines to EU countries.

3.2. Legal Regulation of Immunoprophylaxis

a. General Legal Framework

General information

307. Since 2013, national vaccination programs have been regulated by the Communicable Diseases Act (2004:168).[421] National vaccination programs are divided into general vaccination programs (for the entire population) and special vaccination programs (for certain risk groups). Regions and municipalities are required to offer the population vaccination, which is part of the national vaccination programs. For instance, all children are offered vaccinations that protect them against 12 diseases.[422]

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[415] Folkhälsomyndigheten. Information on the continued use of the Astra Zeneca vaccine in the vaccination of people 65 and older. March 26, 2021. URL: https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-disease-control/covid-19/vaccination-against-covid-19/information-on-the-continued-use-of-the-astra-zeneca/ (the date of access: April 30, 2021).

[416] Regeringskansliet. Sverige ingår EU-gemensamt avtal om covid-19-vaccin med Moderna. URL: https://www.regeringen.se/pressmeddelanden/2020/12/sverige-ingar-i-eu-gemensamt-avtal-om-covid-19-vaccin-med-moderna/ (the date of access: April 30, 2021).

[417] Regeringskansliet. Sverige ingår EU-gemensamt avtal om covid-19-vaccin med CureVac. URL: https://www.regeringen.se/pressmeddelanden/2020/11/sverige-ingar-eu-gemensamt-avtal-om-covid-19-vaccin-med-curevac/ (the date of access: April 30, 2021).

[418] Regeringskansliet. Sverige ingår EU-gemensamt avtal om covid-19-vaccin med Pfizer/BioNTech. URL: https://www.regeringen.se/pressmeddelanden/2020/11/sverige-ingar-eu-gemensamt-avtal-om-covid-19-vaccin-med-pfizerbiontech/ (the date of access: April 30, 2021).

[419] Regeringskansliet. Sverige ingår EU-gemensamt avtal om covid-19-vaccin med Janssen Pharmaceutica NV. URL: https://www.regeringen.se/pressmeddelanden/2020/10/sverige-deltar-i-eu-gemensamt-vaccinavtal-med-janssen-pharmaceutica-nv/ (the date of access: April 30, 2021).

[420] Regeringskansliet. Sverige ingår EU-gemensamt avtal om covid-19-vaccin. URL: https://www.regeringen.se/pressmeddelanden/2020/08/sverige-ingar-eu-gemensamt-avtal-om-covid-19-vaccin/ (the date of access: April 30, 2021).

[421] Socialdepartementet. Smittskyddslag (2004:168). April 7, 2004. URL: https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/smittskyddslag-2004168_sfs-2004-168 (the date of access: April 30, 2021).

[422] Folkhälsomyndigheten. Vaccination programmes. URL: https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-disease-control/vaccinations/vaccination-programmes/ (the date of access: April 30, 2021).

Vaccinations carried out within the framework of national programs are free of charge for the individual and must be registered in the national register of vaccinations.[423]

Nature of vaccination

308. In general, the vaccination process in Sweden is entirely voluntary, forcing someone to vaccinate would contradict the right to integrity of the person,[424] protected at the constitutional level.[425] At the same time, according to the Act on Preventative Vaccination During War or Threat of War (1952:270), the government may mandate vaccination during times of war and/or in other extraordinary circumstances.[426]

Domestic vaccination process

309. The process of vaccination is carried out in a polyclinic or a vaccination clinic by booking the time and date of the vaccination.[427] The Swedish National Health Agency (*Folkhälsomyndigheten*) has developed a number of recommendations for vaccination against specific diseases in situation of shortage of appropriate vaccines, which include measures ranging from using reduced doses[428] to separating those in need of vaccine

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[423] Folkhälsomyndigheten. Nationella vaccinationsregistret. URL: https://www.folkhalsomyndigheten.se/smittskydd-beredskap/vaccinationer/nationella-vaccinationsregistret/ (the date of access: April 30, 2021). See also Lag om register över nationella vaccinationsprogram m.m. 2012:453. URL: https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lag-2012453-om-register-over-nationella_sfs-2012-453 (the date of access: April 30, 2021).

[424] See Arbetsgivar Alliansen. Kan du tvinga dina medarbetare att ta vaccin? URL: https://www.arbetsgivaralliansen.se/nyheter2/kan-du-tvinga-dina-medarbetare-att-ta-vaccin/ (the date of access: April 30, 2021).

[425] Kungörelse om beslutad ny regeringsform. 1974:152. 2 kap. 6 §. URL: https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/kungorelse-1974152-om-beslutad-ny-regeringsform_sfs-1974-152 (the date of access: April 30, 2021).

[426] Lag (1952:270) om skyddsympning vid krig eller krigsfara m.m. Ändring införd: t.o.m. SFS 1991:271. URL: http://rkrattsbaser.gov.se/sfst?bet=1952:270 (the date of access: April 30, 2021).

[427] 1177 Vårdguiden. När och hur kan jag boka tid för vaccination? URL: https://www.1177.se/Stockholm/sjukdomar--besvar/lungor-och-luftvagar/inflammation-och-infektion-ilungor-och-luftror/om-covid-19--coronavirus/om-vaccin-mot-covid-19/nar-och-hur-kan-jag-vaccinera-mig-mot-covid-19/ (the date of access: April 30, 2021).

[428] See, e.g., Folkhälsomyndigheten. Möjliga strategier vid vaccinbrist av fulldosvaccin motdifteri-stelkramp-kikhosta-polio (DTaP-IPV) i Sverige. URL: https://www.folkhalsomyndigheten.se/globalassets/smittskydd-sjukdomar/vaccinationer/vaccinbrist/strategier--vaccinbrist--fulldosvaccin-dtp-ipv.pdf (the date of access: April 30, 2021).

into priority groups.[429] The final decision on the need for such measures is taken by the health authorities in the regions based on the current situation.[430]

310. The Swedish law does not generally create priority groups for standard vaccines.[431] However, priority groups may be created in the event of flu or other types of pandemic. Persons over 65 years old, pregnant women, and persons with certain underlying diseases are recommended annual influenza vaccination.[432]

Liability for the harm caused by a vaccine

311. In general, the liability of vaccine manufacturers for the harm caused by a vaccine is governed by the Law on Damages (1972:207).[433] It regulates the liability for the harm caused by an individual, its employer, and a state.[434] All vaccines approved and used in Sweden are covered by the Swedish Pharmaceutical Insurance.[435]

b. Special Case of COVID-19 Vaccination

312. While combatting the COVID-19 spread, the state assumes all financial costs for the purchase of vaccines and the vaccination process, while the local authorities commit themselves to the implementation of this process.[436] All this takes place within the framework of the agreement on the organization of vaccination with Swedish Association

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[429] See, e.g., Folkhälsomyndigheten. Rekommendationer om influensavaccination tillriskgrupper. September 2020. URL: https://www.folkhalsomyndigheten.se/contentassets/af9f68e3cb324aaf818f8e7d53132090/rekommendationer-influensavaccination-riskgrupper-20118.pdf (the date of access: April 30, 2021).

[430] For example, in Västernorrland region in 2018 in the situation of vaccine shortage the people were separated into three groups of risk in the following priority: most susceptible persons (pregnant women, children, and persons with certain diseases), persons over 65 years (not included in the first group), and medical staff. See Region Västernorrland. Rekommendationer vid brist på influensavaccin. November 28, 2018. URL: https://www.rvn.se/sv/v1/Arkiv/Nyhetsarkiv/rekommendationer-vid-brist-pa-influensavaccin/ (the date of access: April 30, 2021).

[431] Vaccination programmes. URL: https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-disease-control/vaccinations/vaccination-programmes/ (the date of access: April 30, 2021).

[432] Ibid.

[433] Skadeståndslag (1972:207). June 2, 1972. URL: https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/skadestandslag-1972207_sfs-1972-207 (the date of access: April 30, 2021).

[434] Ibid. Parts 2–4.

[435] European Commission. Employment, Social Affairs and Inclusion. Sweden – Healthcare. URL: https://ec.europa.eu/social/main.jsp?catId=1130&intPageId=4809&langId=en (the date of access: April 30, 2021).

[436] Regeringen. Överenskommelse om genomförande av vaccinering mot covid-19, 2021. Överenskommelse mellan staten och Sveriges Kommuner och Regioner. S2020/09215. 2.2 §. URL: https://www.regeringen.se/4aeccb/contentassets/49f4f9e4cfbc45a792b3b3720fcc2897/overenskommelse-om-genomforande-av-vaccinering-mot-covid-19-2021.pdf (the date of access: April 30, 2021).

of Local Authorities and Regions (*Sveriges Kommuner och Regioner*), whose activities are related to ensuring cooperation on various issues between local governments in Sweden.[437]

313. In the situation of the spread of COVID-19, the Swedish State Health Agency established four phases of vaccination, indicating the population groups that will be included in each of them (in order of priority):[438]

- ***First phase***: persons living in or patronized by nursing homes, staff and persons who care of them and live with them;

- ***Second phase***: persons aged over 65 years (the older the person, the higher the priority); persons who have undergone a bone marrow or other organ transplantation and those living with them; people who have undergone dialysis treatment and people living with them; persons over 18 years receiving disability payments; nursing staff;

- ***Third phase***: persons aged 60 to 64 years who have one of the diseases listed above[439]; persons aged 60 to 64; persons aged 18 to 59 years who have one of the diseases listed above; people with medical conditions that make it difficult for them to adhere to infection control recommendations;

- ***Fourth phase***: persons aged over 18 years who do not have any of the above-mentioned priorities.[440]

314. As with the other medicines, the harm caused by a vaccine is reimbursed through the compulsory health insurance.[441] Noteworthy, the Swedish Government is currently developing the law on compensation for the harm caused by the COVID-19

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[437] Sveriges Kommuner och Regioner. Om SKR. URL: https://skr.se/tjanster/omskr.409.html (the date of access: April 30, 2021).

[438] Folkhälsomyndigheten. Nationell plan för vaccination mot covid-19. Rekommendation för prioritering av vaccination mot covid-19. February 4, 2021. P. 8–10. URL: https://www.folkhalsomyndigheten.se/contentassets/43a1e203f7344a399367b816e2c7144c/nationell-plan-vaccination-covid-19-delrapport-3.pdf (the date of access: April 30, 2021).

[439] Ibid. P. 9.

[440] Noteworthy, pregnant women and persons aged under 18 are not recommended for vaccination and, thus, they do not fall within any of the above-mentioned phases. The decision on vaccination may be confirmed only after the consultations with a physician. See Folkhälsomyndigheten. Nationell plan för vaccination mot covid-19. Rekommendation för prioritering av vaccination mot covid-19. February 4, 2021. P. 11. URL: https://www.folkhalsomyndigheten.se/contentassets/43a1e203f7344a399367b816e2c7144c/nationell-plan-vaccination-covid-19-delrapport-3.pdf (the date of access: April 30, 2021).

[441] See Patientskadelag 1996:799. URL: https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/patientskadelag-1996799_sfs-1996-799 (the date of access: April 30, 2021).

vaccines,[442] which provides that if the pharmaceutical insurance does not cover all the harm caused to a vaccinated person, the government will pay compensation that supplements the pharmaceutical one but no more than SEK 10 million per person.[443]

315. At the same time, the aforementioned compulsory health insurance includes the insurance against the harm caused by the use of the COVID-19 vaccines,[444] which also covers the vaccines whose manufacturers do not participate[445] in the program of pharmaceutical insurance.[446]

316. Since the beginning of 2021, the data on vaccination against COVID-19 have been included into the national register of vaccinations.[447] The Swedish Government is actively working on the issue of introducing the so-called "electronic certificates of vaccination", which they want to implement by the summer of 2021 in case the internationally accepted standard for similar certificates will be developed.[448] The reason for the interest in this idea is to provide an opportunity for citizens to prove the fact of vaccinations, especially abroad.[449]

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[442] Regeringskansliet. Ersättning för personskada orsakad av covid-19-vaccin. URL: https://www.regeringen.se/pressmeddelanden/2021/03/ersattning-for-personskada-orsakad-av-covid-19-vaccin/ (the date of access: April 30, 2021).

[443] Ibid.

[444] Regeringskansliet. Staten tecknar överenskommelse om skador till följd av vaccinering mot covid-19. URL: https://www.regeringen.se/pressmeddelanden/2021/01/staten-tecknar-overenskommelse-om-skador-till-foljd-av-vaccinering-mot-covid-19/ (the date of access: April 30, 2021).

[445] For example, by January 2021 the Moderna vaccine was not included into the insurance programme. Yet, one could receive a compensation from the harm caused by it through the mentioned insurance. See Kammarkollegiet. Överenskommelse tecknat för eventuella skador till följd av vaccinering mot covid-19. URL: https://www.kammarkollegiet.se/aktuellt/pressmeddelanden/2021-01-14-overenskommelse-tecknat-for-eventuella-skador-till-foljd-av-vaccinering-mot-covid-19 (the date of access: April 30, 2021).

[446] Kammarkollegiet. Överenskommelse tecknat för eventuella skador till följd av vaccinering mot covid-19. URL: https://www.kammarkollegiet.se/aktuellt/pressmeddelanden/2021-01-14-overenskommelse-tecknat-for-eventuella-skador-till-foljd-av-vaccinering-mot-covid-19 (the date of access: April 30, 2021).

[447] Lag om register över nationella vaccinationsprogram m.m. 2012:453. 1, 6–8 §§ URL: https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lag-2012453-om-register-over-nationella_sfs-2012-453 (the date of access: April 30, 2021); Folkhälsomyndigheten. Nationella vaccinationsregistret.

[448] Regeringen. Vaccinationsintyg blir digitala. URL: https://www.regeringen.se/pressmeddelanden/2021/02/vaccinationsintyg-blir-digitala/ (the date of access: April 30, 2021).

[449] Ibid.

3.3. Legal Regulation of Vaccine Export and Import

a. General Legal Framework

317. In Sweden, the import of innovative medicines, including vaccines,[450] is connected to the authorization procedure from the EMA.[451] In particular, the EMA's Committee for Medicinal Products for Human Use carries out a scientific assessment of the application and gives a recommendation on whether the medicine should be marketed or not. Based on that recommendation, the European Commission takes a legally binding decision concerning the authorization.[452] At the same time, most generic medicines and medicines available without a prescription are assessed and authorized at a national level, by the Medical Products Agency in Sweden.[453] The export of medicines has no general restrictions, except for the transportation of certain types of medicines by individuals outside the EU.[454]

b. Special Case of COVID-19 Vaccines Export and Import

318. As of the COVID-19 vaccines, Sweden has banned their export outside the EU[455] in accordance with the recent EU regulation,[456] that requires prior approval from the competent authorities of the exporting country to export such vaccines.[457] In Sweden, the National Council for Trade (*Kommerskollegium*) plays the role of such an authority.[458]

319. Sweden did not enact any special legislation on the matter of importing the vaccines against COVID-19.

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[450] See Läkemedelslag. 2015:315. URL: https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lakemedelslag-2015315_sfs-2015-315 (the date of access: April 30, 2021).
[451] See European Medical Agency. Authorization of medicines. URL: https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines#national-authorisation-procedures-section (the date of access: April 30, 2021).
[452] Ibid.
[453] Ibid.
[454] See Läkemedelsverket. Schengenintyg. URL: https://www.lakemedelsverket.se/sv/handel-med-lakemedel/apotek/apotekskunder/schengenintyg (the date of access: April 30, 2021).
[455] Tullverket. Exportrestriktioner för vaccin. February 1, 2021. URL: https://www.tullverket.se/nyheter/nyheter/exportrestriktionerforvaccin.5.422c8052175b1d827691980.html (the date of access: April 30, 2021).
[456] European Parliament and Council. Commission implementing Regulation (EC) No. 2021/111 of January 29, 2021, making the exportation of certain products subject to the production of an export authorization. URL: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0111&from=EN (the date of access: April 30, 2021).
[457] Ibid. Article 1(1).
[458] Kommerskollegium. Att ansöka om exporttillstånd för covid-19-vaccin och aktiva substanser för vaccinet. URL: https://www.kommerskollegium.se/om-handel/corona-import-export/exporttillstand-covid-19-vaccin/ (the date of access: April 30, 2021).

4. The United Kingdom

4.1. Legal Regulation of Vaccine Research and Development

a. General Legal Framework

General information

320. In the UK, the production and trade of medicine, including vaccines, is regulated by the HMR.[459] Since December 31, 2020, when the transitional period under the Withdrawal Agreement took to an end,[460] the EU Law remains applicable as being incorporated in the form of so-called "retained EU-legislation"[461] with the exception of those laws, which were not binding upon the United Kingdom before January 31, 2020.[462]

321. The UK national legislation on the matter is broadly based on the EU directives and regulations[463] on the same issues and provides for a similar legal framework on the stages, control mechanisms, development, and creation of a vaccine, as well as the duration of clinical studies which were adopted based on the rules established by the EMA[464] (**paras. 79–99 of the Analytical Report**).

322. Since the UK no longer remains part of the European Single Market, the effective changes with regards to the applicability of the EU laws on the medicinal products concern the market authorization procedures relating to the EMA and the cooperation

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[459] The Human Medicines Regulations of 2012. Part 1. URL: https://www.legislation.gov.uk/uksi/2012/1916/contents/made (the date of access: April 29, 2021).

[460] Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy. 2019/C 384 I/01. Article 126. URL: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12019W/TXT(02)&from=EN (the date of access: April 29, 2021).

[461] European Union (Withdrawal) Act of 2018. Retention of existing EU law. Sections 2–4. URL: https://www.legislation.gov.uk/ukpga/2018/16/contents (the date of access: April 29, 2021).

[462] Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy. 2019/C 384 I/01. URL: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12019W/TXT(02)&from=EN (the date of access: April 29, 2021). See also European Commission. Questions and Answers on the United Kingdom's withdrawal from the European Union on January 31, 2020. URL: https://ec.europa.eu/commission/presscorner/detail/en/QANDA_20_104 (the date of access: April 29, 2021).

[463] Ibid. Annex 2. Para. 20.

[464] See European Medicines Agency. Brexit: the United Kingdom's withdrawal from the European Union. URL: https://www.ema.europa.eu/en/about-us/brexit-united-kingdoms-withdrawal-european-union (the date of access: April 29, 2021).

of the Agency at large.[465] There are no specific requirements imposed on vaccine producers regarding their institutional-legal form or the possibility of attracting foreign investment.

Stages and time frameworks for conducting clinical trials

323. The UK statutory legislation does not set any mandatory timelines for the vaccine development, neither does it in relation to the description of what stages shall the research and development of a vaccine undergo.[466] According to the guidelines[467] issued by the UK Vaccine Network, a governmental body that makes targeted investments in vaccine technologies,[468] the whole process can be summarized to the following four stages: target product profiling, pre-clinical approval, pre-clinical development, and clinical development (the last three stages are accompanied by the regulatory affairs and ethical approvals).[469]

324. The clinical trials as one of the core components of the vaccine development process are regulated by the CTR.[470]

Legal control mechanisms

325. The CTR imposes several requirements on how to conduct the clinical trials, including the application and review of the ethics committee, authorization procedures, and good clinical practice standards.[471] Since the regulations are based on the EU

[465] Ibid. See also European Commission. Notice to Stakeholders. Withdrawal of the United Kingdom and EU Rules for Medicinal Products for Human Use and Veterinary Medicinal Products. URL: https://ec.europa.eu/info/sites/default/files/notice_to_stakeholders_medicinal_products.pdf (the date of access: April 29, 2021); Explanatory Memorandum to the Human Medicines (Amendment etc.) (EU Exit) Regulations of 2020. URL: https://www.legislation.gov.uk/uksi/2020/1488/pdfs/uksiem_20201488_en.pdf (the date of access: April 29, 2021).

[466] See The Medicines for Human Use (Clinical Trials) Regulations of 2004. Parts 3–4. URL: https://www.legislation.gov.uk/uksi/2004/1031/contents/made (the date of access: April 29, 2021).

[467] See Vaccine Development Process Map. URL: https://www.vaccinedevelopment.org.uk/ (the date of access: April 29, 2021); Cabinet Office Briefing Rooms. Vaccine Development Timelines. P. 1. URL: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/934360/Data_Briefing_Slides_11112020.pdf (the date of access: April 29, 2021).

[468] UK Vaccine Network. URL: https://www.gov.uk/government/groups/uk-vaccines-network (the date of access: April 29, 2021).

[469] Each of the mentioned stages involves numerous other required steps. For more information on what each of the mentioned stages involves see Vaccine Development Process Map. URL: https://www.vaccinedevelopment.org.uk/ (the date of access: April 29, 2021).

[470] The Medicines for Human Use (Clinical Trials) Regulations of 2004.

[471] Ibid. Parts 3–4, 6.

Clinical Trial Directive, the control mechanism established is mostly identical to the one provided in the directive.[472]

326. For instance, the CTR imposes various obligations to ensure the safety of the clinical trial subjects, since "the rights, safety, and well-being of the trial subjects are the most important considerations and shall prevail over interests of science and society".[473] Further, the persons who take responsibility for the initiation, management, and financing of a clinical trial shall report annually about the subjects' safety to the MHRA.[474]

327. If the MHRA receives information that raises doubts about the safety of the trial or a particular trial site, it may require the trial to be suspended or terminated.[475]

Vaccine authorization

328. The vaccine manufacturers submit their applications to the MHRA to receive authorization for their vaccines' manufacture and export.[476] The application should contain various information relating to information about the medical product and the results of the above-mentioned testing procedures.[477] The applicants must also be able to report pharmacovigilance and adverse event reports during clinical development and post-marketing[478] and have staff qualified as "qualified person(s)" for manufacturing and batch release.[479] The applicants shall also publish the summary of the clinical trials conducted.[480]

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[472] Parliamentary Office of Science and Technology. Regulating Clinical Trials. 2017. P. 1. URL: https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwi_pfnJ5ojwAhUEjosKHdAhDrwQFjALegQIGxAD&url=https%3A%2F%2Fresearchbriefings.files.parliament.uk%2Fdocuments%2FPOST-PN-0561%2FPOST-PN-0561.pdf&usg=AOvVaw2KwvgmOzC1DAlmm3uTuwFO (the date of access: April 29, 2021).

[473] The Medicines for Human Use (Clinical Trials) Regulations of 2004. Part 2. Regulation 3.

[474] Ibid. Part 5. Regulation 35(1)(b).

[475] Ibid. Part 4. Regulation 31(1)(b).

[476] Ibid. Part 6. Regulation 36. See also Clinical trials for medicines: apply for authorization in the UK. Guidance. URL: https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk#registration-of-your-clinical-trial (the date of access: April 29, 2021).

[477] Ibid. Part 6. Regulation 38(3); Schedule 6.

[478] Ibid. Part 5.

[479] Ibid. Part 6. Regulation 40.

[480] See Registration of clinical trials for investigational medicinal products and publication of summary results. Guidance. URL: https://www.gov.uk/guidance/registration-of-clinical-trials-for-investigational-medicinal-products-and-publication-of-summary-results#publishing-trial-results (the date of access: April 29, 2021); National Institute for Health Research. NIHR policy on clinical trial registration and disclosure of results. URL: https://www.nihr.ac.uk/documents/nihr-policy-on-clinical-trial-registration-and-disclosure-of-results/12252 (the date of access: April 29, 2021).

329. The marketing authorization process for the vaccines involves the submission of the relevant application to the MHRA. The authorization lasts for 10 years and may be renewed within the following three months after its expiration.[481]

Emergency use authorization

330. The HMR provides for an opportunity for emergency use of vaccines and other medicines without undergoing the regular authorization procedure on a basis of a temporary authorization by the MHRA in situations of the suspected or confirmed spread of pathogenic agents, toxins, chemical agents, or nuclear radiation which may cause harm to human beings.[482]

Vaccine patent protection

331. The patent grant procedure for the developed vaccines is conducted in accordance with the Patents Act 1977 that provides a general framework on this type of procedure.[483] While the Act specifies certain regulations pertaining the derogation from patent protection in respect of biotechnological inventions,[484] the procedure for a vaccine to obtain a patent connotes with the general one.[485]

332. The patenting process involves the following steps: an assessment of the vaccine's novelty, making of the application, conduction of the search procedures and the substantive examination on the inventiveness of the vaccine, and, finally, the grant or refusal of the application by the Intellectual Property Office.[486]

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[481] The Medicines for Human Use (Marketing Authorizations Etc.) Regulations of 1994. Regulation 4. URL: https://www.legislation.gov.uk/uksi/1994/3144/contents/made (the date of access: April 29, 2021). See also Apply for a licence to market a medicine in the UK. Guidance. URL: https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk (the date of access: April 29, 2021).

[482] The Human Medicines Regulations of 2012. Regulation 174. URL: https://www.legislation.gov.uk/uksi/2012/1916/contents/made (the date of access: April 29, 2021).

[483] Patents Act of 1977. URL: https://www.legislation.gov.uk/ukpga/1977/37/contents (the date of access: April 29, 2021).

[484] Ibid. Schedules A1, A2.

[485] See Thomson Reuters Practical Law. Pharmaceutical IP and competition law in the UK (England and Wales): overview. URL: https://uk.practicallaw.thomsonreuters.com/1-567-9985 (the date of access: April 29, 2021).

[486] Patents Act of 1977. Part I. Sections 2, 14–16, 17–18. URL: https://www.legislation.gov.uk/ukpga/1977/37/contents (the date of access: April 29, 2021). See also Patenting your inventions. URL: https://www.gov.uk/patent-your-invention/decide-to-apply (the date of access: April 29, 2021).

333. The intellectual property law applicable to the imported medicines has the same features, as the law applicable to domestic ones.[487] Current legislation on the matter shares most of the features of the EU legislation.[488]

334. The Patents Act of 1977 provides a government exemption from the Act as regards the removal of patent protection in the public interest "for the services of the Crown".[489] Under this exemption, the Government may use the invention without the consent of the proprietor of the patent without infringing the patent.[490] In its turn, the Government compensates the losses of profits from the use of the patented invention to the proprietor of the patent.[491] By this day, the "crown services" exception had very little use in practice.[492]

b. Legal Framework for the COVID-19 Vaccine Development

335. With regards to the COVID-19 pandemic, the UK had resorted to the emergency use of the Pfizer/BioNTech vaccines while also imposing certain obligations on the vaccine producers in order for them to enjoy the possibility to be manufactured without conducting the required authorization procedures.[493] The Government had also resorted to the rolling review procedure, i.e. a review procedure when the applicant submits its common technical documents for the MHRA pre-assessment,[494] during the review of the Pfizer and AstraZeneca COVID-19 vaccines to accelerate their approval.[495]

336. To allow for emergency authorization during the COVID-19 pandemic the MHRA has developed flexibilities in the form of guidances for reducing authorization time

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[487] Apply for action to protect your intellectual property rights. Guidance. URL: https://www.gov.uk/guidance/apply-for-action-to-protect-your-intellectual-property-rights (the date of access: April 29, 2021).

[488] See JD Supra. IP in the UK After Brexit: What Does It Mean for UK Business and Trading with the EU? URL: https://www.jdsupra.com/legalnews/ip-in-the-uk-after-brexit-what-does-it-19558/ (the date of access: April 29, 2021).

[489] Patents Act of 1977. Part I. Sections 55–59. URL: https://www.legislation.gov.uk/ukpga/1977/37/contents (the date of access: April 29, 2021).

[490] Ibid. Part I. Section 55(1).

[491] Ibid. Part I. Section 57A.

[492] See Schlich. How broad is the Crown Use Defence? URL: https://www.schlich.co.uk/latest-howbroad-isthe-crown-use-defence.php (the date of access: April 29, 2021).

[493] Conditions of Authorization for Pfizer/BioNTech COVID-19 Vaccine. URL: https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/conditions-of-authorisation-for-pfizerbiontech-covid-19-vaccine (the date of access: April 29, 2021).

[494] Rolling review for marketing authorization applications. Guidance. URL: https://www.gov.uk/guidance/rolling-review-for-marketing-authorisation-applications (the date of access: April 29, 2021).

[495] Bloomberg. U.K. Accelerates Reviews of Pfizer and Astra-Oxford Vaccines. URL: https://www.bloomberg.com/news/articles/2020-10-30/pfizer-astra-vaccines-said-to-be-in-accelerated-u-k-reviews (the date of access: April 29, 2021).

frames.[496] These include expedited assessment of variations and initial applications, priority and expedited assessment of national variations (including batch-specific variations), and marketing authorizations that impact the medicines supply chain.[497] In addition, there are ongoing debates in the UK concerning an option to remove the patent protection from the COVID-19 vaccines in accordance with the "crown services" exemption under the Patents Act 1977.[498]

4.2. Legal Regulation of Immunoprophylaxis

a. General Legal Framework

General information

337. The UK legislation does not specifically provide for the right to health care, although the Human Rights Act of 1998 obliges[499] all public authorities to respect the human rights stipulated in the European Convention on Human Rights.[500] The legislation also provides for the right to informed consent, i.e. a right to accept or refuse medical treatment.[501]

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[496] MHRA regulatory flexibilities resulting from coronavirus (COVID-19). Guidance. URL: www.gov.uk/guidance/mhra-regulatory-flexibilities-resulting-from-coronavirus-covid-19 (the date of access: April 29, 2021). See also Managing clinical trials during Coronavirus (COVID-19). Guidance. URL: https://www.gov.uk/guidance/managing-clinical-trials-during-coronavirus-covid-19 (the date of access: April 29, 2021); Clinical trials applications for Coronavirus (COVID-19). Guidance. URL: https://www.gov.uk/guidance/clinical-trials-applications-for-coronavirus-covid-19 (the date of access: April 29, 2021); COVID-19 vaccine development timeline. URL: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/940421/2020-12-02_slides_for_Data_briefing.pdf (the date of access: April 29, 2021).

[497] Ibid.

[498] See Pinsent Masons. Coronavirus: manufacturing change in the fight against Covid-19. URL: https://www.pinsentmasons.com/out-law/analysis/coronavirus-manufacturing-change-covid-19 (the date of access: April 29, 2021).

[499] Human Rights Act of 1998. Introduction. URL: https://www.legislation.gov.uk/ukpga/1998/42/contents (the date of access: April 29, 2021).

[500] It is recognized throughout the ECtHR jurisprudence that Article 8 of the ECHR covers some of the aspects of this right, European Court of Human Rights. Health-related issues in the case-law of the European Court of Human Rights. Thematic Report. 2015. P. 5. URL: https://www.echr.coe.int/Documents/Research_report_health.pdf (the date of access: April 29, 2021). See also Each Other. There is a Human Right to Health, And This is How It Works. URL: https://eachother.org.uk/is-there-a-right-to-health/ (the date of access: April 29, 2021).

[501] See Department of Health. Reference guide to consent for examination or treatment. Second Edition. 2009. URL: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653__1_.pdf (the date of access: April 29, 2021). While this notion primarily refers to the treatment of the terminal diseases, it also applies to the vaccinations. See Blog of Journal of Medical Ethics. Altered vaccination schedules and informed consent. URL: https://blogs.bmj.com/medical-ethics/2021/01/26/altered-vaccination-schedules-and-informed-consent/ (the date of access: April 29, 2021).

Nature of vaccination

338. While previously the UK had a history of mandatory vaccination against smallpox,[502] currently the vaccination process in UK is voluntary, forcing someone to vaccinate would contradict the right to the integrity of the person, protected at the constitutional level.[503] At the same time, the PHE, an executive agency of the Department of Health and Social Care, publishes immunization information for health professionals and immunization practitioners in the form of the so-called "immunisation schedules" that indicate at what age which vaccine should be taken.[504]

Domestic vaccination process

339. Depending on the vaccine surplus, the PHE may introduce the plan for handling the vaccination process in a situation of a vaccine shortage.[505] Such plans may *inter alia* prioritize certain groups of the population for a vaccine.[506] The Joint Committee of Vaccination and Immunisation, an independent group of experts who advise the Government health departments on immunizations and the prevention of infectious disease,[507] brings up the recommendations on how to compose those groups.[508]

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[502] The Vaccination Act of 1853 made vaccination compulsory in the first three months of a child's life, the legislation had subsequently changed until in 1898 the so-called "conscientious objection" to vaccination had been introduced. See BBC. The anti-vaccination movement that gripped Victorian England. URL: https://www.bbc.com/news/uk-england-leicestershire-50713991 (the date of access: April 29, 2021).

[503] See UK Human Rights Blog. Compulsory vaccination – the next step for Covid-19? URL: https://ukhumanrightsblog.com/2020/11/05/compulsory-vaccination-the-next-step-for-covid-19/ (the date of access: April 29, 2021); House of Commons Library. UK Vaccination Policy. URL: https://commonslibrary.parliament.uk/research-briefings/cbp-9076/ (the date of access: April 29, 2021).

[504] See Public Health England. The routine immunisation schedule from June 2020. URL: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/899423/PHE_Complete_Immunisation_Schedule_Jun2020_05.pdf (the date of access: April 29, 2021).

[505] One of such plans had been introduced in 2018 during the hepatitis B vaccination that year. See Public Health England. Plan for phased re-introduction of hepatitis B vaccine for lower priority groups in 2018. URL: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/776971/Plan_for_phased_re-introduction_of_hepatitis_B_vaccine_for_lower_priority_groups_2018_.pdf (the date of access: April 29, 2021).

[506] See Public Health England. Plan for phased re-introduction of hepatitis B vaccine for lower priority groups in 2018. P. 9. URL: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/776971/Plan_for_phased_re-introduction_of_hepatitis_B_vaccine_for_lower_priority_groups_2018_.pdf (the date of access: April 29, 2021).

[507] Joint Committee on Vaccination and Immunisation. URL: https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation (the date of access: April 29, 2021).

[508] See Public Health England. Plan for phased re-introduction of hepatitis B vaccine for lower priority groups in 2018. P. 8.

340. The state assumes all financial costs for the purchase of vaccines and the vaccination process through the NHS that administers the whole process.[509] Vaccination can be conducted by the "healthcare professionals".[510] This definition includes both the doctors and the nurses with a proper qualification acting in accordance with the professional standards.[511] The whole immunization procedure is governed by the guidelines issued by the Department of Health and its subsidiary bodies in the form of so-called "green books" which apply equally throughout the whole territory of the UK.[512]

341. National legislation of the UK does not generally create groups for standard vaccinations. However, the Joint Committee on Vaccination and Immunisation may advise on propriety for vaccination to achieve higher vaccine uptake and to protect particularly vulnerable groups of the population.[513]

Liability for the harm caused by a vaccine

342. The UK implements the so-called Vaccine Damage Payment Scheme[514] that provides a single, tax-free payment to the people or their families who have suffered severe mental and/or physical disablement as a result of immunization against one or more of the diseases in the list.[515] The decision for the grant is delivered on behalf of the Secretary of State for Work and Pensions based on the assessment of the probability that the disability is the result of the immunization, and the percentage level of disablement attributed to immunization.[516]

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[509] See BBC. Budget 2021: Extra £1.6bn for UK's Covid vaccination rollout. URL: https://www.bbc.com/news/uk-56230704 (the date of access: April 29, 2021); The BMJ. Covid-19: NHS England pledges extra funding to local areas to reduce vaccine inequalities. URL: https://www.bmj.com/content/372/bmj.n580 (the date of access: April 29, 2021).

[510] Department of Health. Immunisation against infectious disease. 2006. Chapter 5. P. 35. URL: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/223734/Green-Book-updated-170713.pdf (the date of access: April 29, 2021).

[511] Ibid. Chapters 4–5.

[512] One of such "green books" was issued on the topic of vaccination and immunization. See Immunisation against infectious disease. Collection. URL: https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book (the date of access: April 29, 2021).

[513] Joint Committee on Vaccination and Immunisation: advice on priority groups for COVID-19 vaccination. December 30, 2020. URL: https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020/joint-committee-on-vaccination-and-immunisation-advice-on-priority-groups-for-covid-19-vaccination-30-december-2020 (the date of access: April 29, 2021).

[514] Ibid. Chapter 10.

[515] Ibid. Chapter 5. P. 75. Currently the Government takes steps to introduce COVID-19 into such list. See Government to add COVID-19 to Vaccine Damage Payments Scheme. Press release. URL: https://www.gov.uk/government/news/government-to-add-covid-19-to-vaccine-damage-payments-scheme (the date of access: April 29, 2021).

[516] Ibid.

b. Special Case of COVID-19 Vaccination

343. While there are ongoing discussions on whether the COVID-19 vaccination shall be obligatory, the official position on the matter remains similar to the ordinary vaccination.[517] In addition, the health care authorities will keep offering COVID-19 vaccination to those who initially refused it.[518] Since the UK cannot currently fulfill completely the demand for COVID-19 vaccine, PHE introduced its COVID-19 vaccination plan.[519] The plan includes the two following vaccination phases (with the groups of population written in the priority order):[520]

- ***First phase***: residents in a care home for older adults, staff working in care homes for older adults; all those 80 years of age and over and frontline health and social care workers; all those 75 years of age and over; all those 70 years of age and over and clinically extremely vulnerable individuals (older than 16 years); all those 65 years of age and over; adults aged 16 to 65 years in an at-risk group;[521] all those 60 years of age and over; all those 55 years of age and over; all those 50 years of age and over;

- ***Second phase***: all those aged 40–49 years; all those aged 30–39 years; all those aged 18–29 years.

344. Currently, the first phase of vaccination is ongoing, by virtue of that the groups of people that fall within the scope of the first phase of vaccination are currently the only ones eligible for the COVID-19 vaccination.[522] The people, both citizens and non-

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[517] Reuters. UK PM Johnson says COVID-19 vaccines should be voluntary. URL: https://www.reuters.com/article/health-coronavirus-britain-vaccine-johns-idINKBN28C1PC (the date of access: April 29, 2021).

[518] The BMJ. Covid-19: NHS England pledges extra funding to local areas to reduce vaccine inequalities. URL: https://www.bmj.com/content/372/bmj.n702 (the date of access: April 29, 2021).

[519] Green book. COVID-19 – SARS-CoV-2. 2021. Chapter 14a. URL: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/978508/Green_book_chapter_16April2021.pdf (the date of access: April 29, 2021).

[520] Ibid. P. 11.

[521] The list of diseases which indicate the clinical risk status is available at ibid. P. 12–13, 15.

[522] Despite the mentioned JVCI recommendation that sets the lowest age to be eligible for the first phase vaccination to 50 years of age, the NHS decided to lower it to 45 years of age. See NHS. Who can get the coronavirus (COVID-19) vaccine. URL: https://www.nhs.uk/conditions/coronavirus-covid-19/coronavirus-vaccination/who-can-get-the-vaccine/ (the date of access: April 29, 2021).

citizens,[523] can book their vaccination that may take place in a hospital, pharmacy, and vaccination centers.[524]

345. Besides, the Government currently considers the possibility of introducing the so-called "COVID passports" for the citizens to attend public venues.[525]

4.3. Legal Regulation of Vaccine Export and Import

a. General Legal Framework

Conditions for export of vaccine to third countries

346. In order to export the drugs and medicines from the UK to third countries, one should obtain the export certificate from the MHRA.[526] It can also impose a ban on the exports of certain medicines.[527]

Conditions for import of vaccine from third countries

347. The UK legislation allows medicines import, including vaccines, from other countries.[528] The procedure is dependent on what country one imports the medicines from, as well as whether they have the MHRA licenses, but in general, the importing medicines should undergo the same procedure for market entrance, as the domestic ones.[529] The MHRA reviews the whole procedure and decides upon the imports' authorization.[530] The procedure and requirements for such kinds of authorizations are identical with regards to both imported and domestic medicines **(paras. 328–329 of the Analytical Report**).

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[523] Reuters. All migrants living in UK eligible for COVID-19 vaccine. URL: https://www.reuters.com/world/uk/all-migrants-living-uk-eligible-covid-19-vaccine-2021-02-08/ (the date of access: April 29, 2021).
[524] NHS. Book or manage your coronavirus vaccination. URL: https://www.nhs.uk/conditions/coronavirus-covid-19/coronavirus-vaccination/book-coronavirus-vaccination/ (the date of access: April 29, 2021).
[525] See BBC. What are the UK plans for Covid passports? URL: https://www.bbc.com/news/explainers-55718553 (the date of access: April 29, 2021); BBC. Covid passports: Certification is "one option", vaccines minister says. URL: https://www.bbc.com/news/uk-56645208 (the date of access: April 29, 2021).
[526] This requirement does not apply to the EU countries. See Export drugs and medicines: special rules. Guidance. URL: https://www.gov.uk/guidance/export-drugs-and-medicines-special-rules (the date of access: April 29, 2021).
[527] Medicines that you cannot export from the UK or hoard. Guidance. URL: https://www.gov.uk/government/publications/medicines-that-cannot-be-parallel-exported-from-the-uk (the date of access: April 29, 2021).
[528] Import a human medicine. Guidance. URL: www.gov.uk/guidance/import-a-human-medicine (the date of access: April 29, 2021).
[529] Ibid.
[530] Ibid.

b. Special Case of COVID-19 Vaccines Export and Import

348. The UK did not enact any special legislation on the matter of importing the vaccines against COVID-19. As was mentioned earlier, the Government initiated the accelerated procedure for some of the COVID-19 vaccines' market authorization, including the imported ones, while also introducing some of the flexibilities in relation to their production authorization process (**paras. 330, 335–336 of the Analytical Report**).

349. With regards to the exports, there is no official information on any special regulations or any restrictions on it with regards to the COVID-19 vaccines either, although the EU accuses the UK of the ban imposition on any exports of such vaccines.[531]

350. The Government had not yet introduced any special regulation relating to the intellectual property rights of the COVID-19 vaccines, both imported and exported. However, the UK adheres to the group of countries within the WTO that opposes the proposals[532] to waive the parenting and protection of intellectual rights in relation to the vaccines against COVID-19.[533]

[531] Pharmaceutical Technology. UK denies EU accusations of Covid-19 vaccine export bans. URL: https://www.pharmaceutical-technology.com/news/uk-eu-vaccine-export-row/ (the date of access: April 29, 2021).

[532] World Trade Organization. Members discuss TRIPS waiver, LDC transition period and green tech role for small business. URL: https://www.wto.org/english/news_e/news21_e/trip_11mar21_e.htm (the date of access: April 29, 2021); Council for Trade-Related Aspects of Intellectual Property Rights. Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19. URL: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True (the date of access: April 29, 2021).

[533] Pharmaceutical Technology. Exploring the Covid-19 vaccine IP waiver proposal at the WTO. URL: https://www.pharmaceutical-technology.com/features/wto-ip-waiver-proposal-covid19-vaccine/ (the date of access: April 29, 2021).

5. The United States of America

5.1. Legal Regulation of Vaccine Development

a. General Legal Framework

General information

351. In the United States, all vaccines must be approved as "safe and effective" by the U.S. FDA before they can be used.[534] The FDA's Center for Biologics Evaluation and Research evaluates clinical, chemical, and biological properties of the vaccine and manufacturing processes to ensure safety, purity, and potency.

352. Under normal conditions, vaccines undergo extensive testing by a manufacturer to determine safety and effectiveness, including preclinical laboratory testing and three phases of human clinical trials.[535] Vaccine manufacturers must also support that any potential benefits of a vaccine in development outweigh the possible risks.[536]

353. Individual states do not play a direct role in vaccine research, development, or creation due to federal preemption of regulation over the safety, efficacy, and manufacture of vaccines. The federal government has sole authority to regulate vaccine development and manufacture. The individual state's role in the regulation of vaccines is largely limited to the logistics of distributing vaccines, considering limited supply and equitable distribution concerns. The U.S. CDC have issued nonbinding guidance to states on priorities for COVID-19 vaccine distribution specifically, but states ultimately determine how vaccines are distributed to the population.[537] States do have direct authority over medical practice licensing, which determines who may provide vaccinations.[538] States may also mandate vaccinations for specific populations, most

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[534] United States Food and Drug Administration. Ensuring the Safety of Vaccines in the United States. 2011. URL: https://www.fda.gov/files/vaccines, blood & biologics/published/Ensuring-the-Safety-of-Vaccines-in-the-United-States.pdf (the date of access: March 28, 2021).

[535] United States Food and Drug Administration. Ensuring the Safety of Vaccines in the United States.

[536] Ibid; United States Food and Drug Administration. Vaccines. URL: https://www.fda.gov/vaccines-blood-biologics/vaccines (the date of access: March 28, 2021).

[537] United States Centers for Disease Control and Prevention. How CDC is Making COVID-19 Vaccine Recommendations. 2021. URL: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html (the date of access: March 28, 2021); *Zettler, P.J. et al.* Chapter 23: Drug and Vaccine Development and Access // COVID-19 Policy Playbook II. 2021. P. 143. URL: https://static1.squarespace.com/static/5956e16e6b8f5b8c45f1c216/t/6058f30f79613532b7561f2e/1616442127170/Chp23-Zettler_COVIDPolicyPlaybook-March2021.pdf (the date of access: March 28, 2021).

[538] Ibid.

notably for school-aged children who in general must receive certain vaccinations to attend school.[539]

Stages and time frameworks for conducting clinical trials

354. Under normal conditions in the U.S., following an initial preclinical period, a vaccine manufacturer would begin a Phase 1 clinical trial with 20–100 healthy volunteers. At this stage, potential side effects and effectiveness may be assessed. Assuming Phase 1 determined there were no serious side effects, Phase 2 of a vaccine clinical trial would involve several hundred volunteers to refine understanding of side effects and dose sizes on the immune response. A Phase 3 trial would include hundreds or thousands of volunteers and would compare the effectiveness of one vaccine against another vaccine or placebo.[540]

355. The typical vaccine development process in the U.S. can take between five and ten years.[541] The preclinical and Phase 1 trials can take between one and ten years. The Phase 2 process usually lasts between two and three years and the Phase 3 trial can take between two and four years.[542]

356. At the point that the FDA approves a vaccine as safe and effective, it may be licensed and manufactured. FDA inspects manufacturing facilities to ensure they are produced following strict, established regulations. Vaccines are produced in batches, called lots, and may be distributed once released by the FDA.[543]

Legal control mechanisms

357. U.S. vaccine manufacturers must submit an Investigational New Drug application prior to starting human clinical trials. The FDA may choose to halt clinical trials if significant safety concerns are discovered during clinical trials.[544]

358. Upon completion of Phase 3 clinical trials, vaccine manufacturers must submit a Biologics License Application with sufficient safety and efficacy data for approval by

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[539] United States Centers for Disease Control and Prevention. State Vaccination Requirements. 2016. URL: https://www.cdc.gov/vaccines/imz-managers/laws/state-reqs.html (the date of access: March 28, 2021).
[540] Ibid.
[541] Johns Hopkins University & Medicine. Vaccine Research & Development: How Can COVID-19 Vaccine Development Be Done Quickly and Safely? URL: https://coronavirus.jhu.edu/vaccines/timeline (the date of access: March 28, 2021).
[542] Ibid.
[543] United States Food and Drug Administration. Ensuring the Safety of Vaccines in the United States.
[544] Johns Hopkins University & Medicine. Vaccine Research & Development: How Can COVID-19 Vaccine Development Be Done Quickly and Safely?

the FDA. Interim analysis of Phase 3 trials may be sufficient in the case of the accelerated approval EUA pathway, which has been used for COVID-19 vaccine approvals during the current pandemic (**paras. 360, 369 of the Analytical Report**).

Vaccine authorization

359. As stated previously, in the U.S., all vaccines must be approved as "safe and effective" by the FDA before they can be used.[545]

Emergency use authorization

360. Since 2004, the U.S. has had an EUA pathway, as authorized by Section 564 of the Federal Food, Drug, and Cosmetic Act, added by the Project BioShield Act of 2004.[546] The EUA pathway allows for combination of trials to accelerate approval specifically during public health emergencies, when no adequate, approved alternatives exist to meet medical needs for serious or life-threatening diseases.[547]

361. The FDA recognizes that specific effectiveness data and risk-benefit profiles of potential vaccines using this pathway will need to be assessed on a case-by-case basis. In general, the FDA will consider mechanisms of action, preclinical testing data, data on activity and effectiveness in animals, relevant human clinical trial activity and effectiveness, and proposed dosage for the intended use.[548]

362. In the specific case of COVID-19 vaccines, the FDA expects Phase 3 safety data on over 3,000 trial participants including the tracking of serious adverse events within this group for at least one month following the complete vaccine regimen. The FDA will consider multiple factors for vaccine approval through the EUA, sufficient to determine overall safety and effectiveness.[549]

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[545] United States Food and Drug Administration. Ensuring the Safety of Vaccines in the United States.

[546] 21 U.S.C. § 360bbb-3. December 12, 2017; United States Food and Drug Administration. Emergency Use Authorization for Vaccines Explained.

[547] Johns Hopkins University & Medicine. Vaccine Research & Development: How Can COVID-19 Vaccine Development Be Done Quickly and Safely?; United States Food and Drug Administration. Emergency Use Authorization for Vaccines Explained. URL: https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained (the date of access: March 28, 2021).

[548] United States Department of Health and Human Services, United States Food and Drug Administration. Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders. URL: https://www.fda.gov/media/97321/download (the date of access: March 28, 2021).

[549] United States Food and Drug Administration. Emergency Use Authorization for Vaccines Explained.

Vaccine patent protection

363. U.S. vaccine manufacturers are subject to the same patent approval process as other medical technologies manufacturers. Vaccine manufacturers must disclose the details of the proposed vaccine in the USPTO patent application process that would allow another vaccine manufacturer enough information to produce the vaccine.[550] The grant of a patent provides a baseline of 20 years for the "right to exclude others from making, using, or selling the invention throughout the United States."[551] This timeframe may be extended beyond 20 years based on USPTO criteria, for additional five-year terms for certain medical products including vaccines. A vaccine may rely on other patented technologies, requiring licensing arrangements between patent holders, in order to establish intellectual property rights for manufacture.[552]

364. Currently, U.S. patent applications take on average 22.9 months to receive approval.[553] To address urgent timeframes of patent protection with rapid COVID-19 vaccine development, the USPTO developed a Prioritized Pilot Program, which allows for accelerated patent review for applicants qualifying as "small or micro entities".[554] The pilot envisions patent review within six months to facilitate innovation.[555]

365. As part of Operation Warp Speed, an interagency collaboration between the U.S. Department of Health and Human Services and the Department of Defense, funding was provided to six private vaccine manufacturers by the U.S. government, organized by the Biomedical Advanced Research and Development Authority to develop COVID-19 vaccines.[556] The 1980 Bayh-Dole Act allows private companies to patent medicines that

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[550] *Mitchell, V.S., et al*. (eds). Institute of Medicine Committee on the Children's Vaccine Initiative: Planning Alternate Strategies. 1993.URL: https://www.ncbi.nlm.nih.gov/books/NBK236435/ (the date of access: March 28, 2021).

[551] 35 U.S.C. § 154 (2013).

[552] *Mitchell, V.S., et al*. (eds). Institute of Medicine Committee on the Children's Vaccine Initiative: Planning Alternate Strategies. 1993; Congressional Research Service. Drug Pricing and Pharmaceutical Patenting Practices. 2020. URL: https://fas.org/sgp/crs/misc/R46221.pdf (the date of access: March 28, 2021).

[553] United States Patent and Trademark Office. Patents Data, at a Glance February 2021 URL: https://www.uspto.gov/dashboard/patents/ (the date of access: March 28, 2021).

[554] United States Patent and Trademark Office. Press Release: USPTO Announces COVID-19 Prioritized Examination Pilot Program for Small and Micro Entities. URL: https://www.uspto.gov/about-us/news-updates/uspto-announces-covid-19-prioritized-examination-pilot-program-small-and (the date of access: March 28, 2021).

[555] Ibid.

[556] Congressional Research Service. Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials. 2021. URL: https://crsreports.congress.gov/product/pdf/IN/IN11560 (the date of access: March 28, 2021).

were developed with government funding and profit from related manufacture and sale.[557]

366. Generally, any intellectual property rights such as a patent on vaccine technology granted in the U.S. do not apply to other nations.[558] The USPTO provides guidance to companies on how they can protect their patents in several other nations.[559] However, pursuant to the Patent Cooperation Treaty, U.S. applicants can file a single application and receive patent protection in over 140 nations.[560]

b. Legal Framework for the COVID-19 Vaccine Development

367. In the case of the coronavirus pandemic, an accelerated process is available through an FDA-authorized EUA. In this process, typical clinical trial phases may be combined. High prevalence of COVID-19 among the population allowed for faster testing in the population, as trial participants were readily available.

368. The FDA has utilized this emergency pathway for COVID-19 vaccine development in the U.S. Under this process, tens of thousands of study participants are included to build required non-clinical, clinical, and manufacturing data for evaluation by the FDA. The FDA worked with vaccine manufacturers to determine what Phase 3 trial data needed to demonstrate COVID-19 vaccine effectiveness, and an independent data safety monitoring board evaluated the trial data so that the vaccine manufacturers could determine whether to submit formal EUA requests to the FDA. This determination included input from the FDA on the trial data. Specifically, for COVID-19 trials with an EUA, the FDA expects a Phase 3 clinical trial safety database for over 3,000 vaccine recipients. Those recipients must be tracked for one month following completion of the vaccine regimen to determine if there are any serious adverse events.[561]

369. Upon formal EUA submission, career scientists and physicians within the FDA began a formal review of the vaccine candidate. During the review, the FDA scheduled public meetings of its Vaccines and Related Biological Products Advisory Committee, which is made up of experts screened for conflict of interest, who reviewed the data and

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[557] Bayh-Dole Act. Pub. L. 96-517 (December 12, 1980).
[558] United States Patent and Trademark Office. Protecting intellectual property rights (IPR) overseas. URL: https://www.uspto.gov/ip-policy/ipr-toolkits (the date of access: March 28, 2021).
[559] Ibid.
[560] Ibid.
[561] United States Food and Drug Administration. Emergency Use Authorization for Vaccines Explained.

made recommendations to FDA staff. The FDA career professional staff will then make a determination of EUA for the proposed COVID-19 vaccine.[562]

370. The first COVID-19 vaccine to be distributed in the U.S. was Pfizer-BioNTech, approved by the FDA on December 11, 2020, under the EUA pathway.[563] Moderna's COVID-19 vaccine was approved for distribution in the U.S. on December 18, 2020, and the COVID-19 vaccine developed by Janssen Biotech Inc, a Janssen Pharmaceutical Company of Johnson & Johnson, was approved on February 27, 2021.[564]

371. Due to concerns over the politicization of the vaccine development process, several states, most notably New York, established independent state review bodies to review FDA-approved COVID-19 vaccines in late 2020. However, these bodies have not attempted to prohibit any federally authorized vaccines and such state action would likely be preempted due to federal authority over vaccine approval.[565]

372. Funding for COVID-19 vaccine development in the U.S. was largely spearheaded through Operation Warp Speed. This included initial direct government funding of approximately USD 10 billion for three core areas to accelerate vaccine production including (1) development, (2) manufacturing, and (3) distribution, as announced by the Trump Administration on May 15, 2020.[566] This direct domestic investment reduced the need for U.S. vaccine manufacturers to seek foreign investments in capacity building.

373. Though private vaccine manufacturers in the U.S. may make non-binding pledges to not enforce COVID-19 related patents during the pandemic, those patents are technically enforceable internationally if manufacturers have registered their patents properly through the Patent Cooperation Treaty. It allows U.S. applicants to file a single

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[562] Ibid.

[563] United States Department of Health and Human Services, United States Food and Drug Administration. Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders.

[564] United States Food and Drug Administration. Moderna COVID-19 Vaccine. 2021. URL: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine (the date of access: March 28, 2021); United States Food and Drug Administration. Press Release: FDA Issues Emergency Use Authorization for the Third COVID-19 Vaccine. URL: https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine (the date of access: March 28, 2021).

[565] *Zettler, P.J. et al.* Chapter 23: Drug and Vaccine Development and Access // COVID-19 Policy Playbook II. 2021. P. 143.

[566] United States Department of Health and Human Services. Press Release: Trump Administration Announces Framework and Leadership for 'Operation Warp Speed'. URL: https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html (the date of access: March 28, 2021).

application and receive patent protection in over 140 nations.[567] In 2020, the Trump Administration opposed a proposed waiver of international intellectual property rights around COVID-19 vaccines for WTO members.[568] However, on May 5, 2021, U.S. Trade Representative Katherine Tai released a statement announcing the Biden-Harris Administration's support for waiving intellectual property protections for COVID-19 vaccines.[569]

5.2. Legal Regulation of Immunoprophylaxis

a. General Legal Framework

General information

374. In the U.S., individuals do not have a recognized right to health care, and the government has no legal obligation to provide health care (including immunoprophylaxis) to its populace.[570] The U.S. has no nationwide system of health care or health insurance, and instead relies on a patchwork of mostly private and some public programs to provide health care to its populace.[571] In order to obtain and pay for health care services, most people purchase health insurance through their employer or a federally regulated marketplace — sometimes with the assistance of government subsidies — while certain individuals are eligible for federal entitlement programs like Medicare and Medicaid.[572]

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[567] United States Patent and Trademark Office. Protecting intellectual property rights (IPR) overseas.

[568] See In These Times. Biden Must Reject Trump's "Vaccine Apartheid" Policy at the WTO. January 12, 2021. URL: https://inthesetimes.com/article/world-trade-organization-trump-biden-vaccine-apartheid-covid-intellectual-property-patent (the date of access: March 28, 2021).

[569] Office of the United States Trade Representative. Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver. May, 5, 2021. URL: https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver (the date of access: May 6, 2021).

[570] *Record, K. L.* Litigating the ACA: Securing the Right to Health Within a Framework of Negative Rights // American Journal of Law and Medicine. 2012. Vol. 38. P. 540–541. See also United States Supreme Court. *Maher v. Roe*. Decision of June 20, 1977 (stating that the U.S. Constitution imposes no obligation to pay for the health care of people living in poverty).

[571] *De Lew, N., et al.* A layman's guide to the U.S. health care system // Health Care Finance Review. 1992. Vol. 14(1). P. 151–169. URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4193322/ (the date of access: March 28, 2021).

[572] Pan American Health Organization. United States of America. URL: https://www.paho.org/salud-en-las-americas-2017/?p=2432 (the date of access: March 25, 2021). As of 2019, over 10% of the non-elderly population had no health insurance coverage. *Tolbert, J., et al.* Key Facts about the Uninsured Population. 2020. URL: https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/ (the date of access: March 28, 2021).

375. Generally, individuals in the U.S. do have a right to informed consent — a right to accept or refuse medical treatment.[573] However, in the early 20th century, the U.S. Supreme Court held that state and local governments have a right to mandate vaccination — a right that supersedes an individual's right to liberty.[574]

Nature of vaccination

376. At the national level, the federal government does not mandate vaccination; however, the CDC make recommendations about vaccinations for children and adults.[575]

377. Currently, all 50 states and the District of Columbia (D.C.) have mandatory vaccination laws requiring children to be vaccinated against certain diseases in order to attend schools and daycare centers.[576] Aside from being unable to attend schools, the consequences of refusing vaccination vary by state; in some cases, parents have been found guilty of child neglect as a result of refusing vaccination.[577] However, all 50 states and D.C. have created medical exemptions to vaccine laws, allowing children to receive exemptions for documented medical reasons.[578] Additionally, as of January 2021, 45 states have religious exemptions (allowing parents to opt out of vaccinating their children when vaccines violate their sincerely-held religious beliefs) and 15 states have personal or philosophical exemptions (broader exemptions allowing parents to opt out

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[573] United States Supreme Court. *Cruzan v. Director, Mo. Dep't of Health*. Decision of June 25, 1990. P. 278.

[574] United States Supreme Court. *Jacobson v. Massachusetts*. Decision of February 20, 1905 (upholding law requiring adults to be vaccinated against smallpox and rejecting argument that the law unconstitutionally infringed on individual liberty); United States Supreme Court. *Zucht v. King*. Decision of November 13, 1922. P. 176–177 (noting that the constitutionality of mandatory vaccination laws was well-settled); *Chemerinsky, E. & Goodwin, M.* Compulsory Vaccination Laws are Constitutional // Northwestern University Law Review. 2016. Vol. 110. P. 604–608 (describing several lower court decisions upholding mandatory vaccination laws).

[575] CDC. ACIP Vaccine Recommendations and Guidelines. URL: https://www.cdc.gov/vaccines/hcp/acip-recs/index.html (the date of access: March 28, 2021).

[576] CDC: Office for State, Tribal, Local and Territorial Support. State School Immunization Requirements and Vaccine Exemption Laws. 2017. URL: https://www.cdc.gov/phlp/docs/school-vaccinations.pdf (the date of access: March 28, 2021); Specific requirements for certain diseases vary by state. Immunization Action Coalition. State Laws and Mandates by Vaccine (listing state vaccination laws by disease). URL: https://www.immunize.org/laws/ (the date of access: March 28, 2021).

[577] *Parasidis, E. & Opel, D.J.* Parental Refusal of Childhood Vaccines and Medical Neglect Laws // American Journal of Public Health. 2017. Vol. 107(1). P. 68–71. URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5308147/ (the date of access: March 28, 2021); *Sheridan, K.* Is It a Crime to Avoid Vaccines? People Who Refuse Are Being Punished with Jail and Job Loss. Newsweek. 2017. URL: https://www.newsweek.com/sending-parents-jail-refusing-vaccinate-doesnt-work-say-experts-730439 (the date of access: March 28, 2021).

[578] National Conference of State Legislatures. States with Religious and Philosophical Exemptions from School Immunization Requirements. 2021. URL: https://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx (the date of access: March 28, 2021).

of vaccinating their children based on objections to vaccines that need not be based on a religious belief).[579]

Domestic vaccination process

378. The federal government partners with state and local governments to help finance and administer vaccines.[580] Most people receive vaccines from their primary care doctor, through their school or employer, or (in the case of flu vaccines) at a local pharmacy. Some federal and state programs provide free or low-cost vaccines to uninsured and under-insured people.[581]

379. The United States does not generally create priority groups for standard vaccines. However, the CDC have created detailed guidance about the creation of tiered priority groups for vaccination in the event of flu or other types of pandemic.[582] Although the CDC encourages state governments to follow the guidance to ensure uniformity in a pandemic response across the nation, state governments have the authority to determine how to distribute vaccines and need not follow the guidance.[583] The guidance identifies priority groups based on age, certain medical conditions, and occupation, but notes that the priority groups will change based on the type and severity of the pandemic.[584]

Liability for the harm caused by a vaccine

380. In 1986, the U.S. enacted the National Childhood Vaccine Injury Act, which greatly limited vaccine manufacturer and health worker liability for harms resulting from vaccines.[585] Specifically, the Act prohibits lawsuits against vaccine manufacturers for unavoidable adverse side effects of vaccines.[586] Instead, the Act created the National Vaccine Injury Compensation Program, allowing people who are harmed by certain vaccines to file a petition in the U.S. Court of Claims to receive compensation (by the

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[579] Ibid.

[580] National Conference of State Legislatures. State Immunization Policy Overview. 2021. URL: https://www.ncsl.org/research/health/immunizations-policy-issues-overview.aspx#school (the date of access: March 28, 2021).

[581] Ibid.

[582] CDC. Allocating and Targeting Pandemic Influenza Vaccine During an Influenza Pandemic. 2018. URL: https://www.cdc.gov/flu/pandemic-resources/pdf/2018-Influenza-Guidance.pdf (the date of access: March 28, 2021).

[583] Ibid. P. 5.

[584] Ibid.

[585] Public Law Number 99-660, tit. III, § 311(a), 100 Stat. 3756 (1986).

[586] 42 U.S.C. § 300aa-22(b)(1); United States Supreme Court. *Bruesewitz v. Wyeth LLC*. Decision of February 22, 2011.

federal government) for their claims.[587] Thus, in most cases, the federal government bears the responsibility for harms caused by vaccines.

b. Special Case of COVID-19 Vaccination

381. As with vaccinations generally, the federal government has not issued a COVID-19 vaccination mandate. Additionally, no state has issued a COVID-19 vaccination mandate.[588] Scholars argue that such a mandate would be unethical and possibly illegal because all of the currently available COVID-19 vaccines in the U.S. were authorized under the FDA's emergency approval mechanism.[589] Specifically, because the vaccines were authorized for emergency use, federal law requires people receiving the vaccine to be informed of their right to refuse the vaccine.[590] There is little guidance from either federal courts or federal agencies as to whether private employers can require their employees to take the vaccine despite an individual's right to refuse the vaccine; however, the Equal Employment Opportunity Commission (a federal agency) has issued non-binding guidance to employers suggesting that employers may be able to mandate vaccination in certain circumstances (such as where an unvaccinated employee might constitute a "direct threat" to the health and safety to other employees in the workplace).[591]

382. In December 2020, the CDC issued guidance on priority access to the COVID-19 vaccine.[592] The guidance creates the following phased priority groups:

- ***Phase 1a***: health care personnel and residents of long-term care facilities;
- ***Phase 1b***: people aged 75 years older and frontline essential workers;

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[587] Health Resources and Services Administration. National Vaccine Injury Compensation Program. URL: https://www.hrsa.gov/vaccine-compensation/index.html (the date of access: March 28, 2021); *Hamblin, J.* Why the Government Pays Billions to People Who Claim Injury by Vaccines. The Atlantic. 2019. URL: https://www.theatlantic.com/health/archive/2019/05/vaccine-safety-program/589354/ (the date of access: March 28, 2021).

[588] *Zettler, P.J. et al.* Chapter 23: Drug and Vaccine Development and Access // COVID-19 Policy Playbook II. 2021. P. 143.

[589] Ibid. P. 145.

[590] *Schwartzotta, J.M. & Rusnaka, T.E.* Can Private Sector Employers Require Employees to be Vaccinated for COVID-19? // New York State Bar Journal. 2021. Vol. 93. P. 38.

[591] Ibid. P. 37–38.

[592] CDC's COVID-19 Vaccine Rollout Recommendations. URL: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations.html (the date of access: March 28, 2021); The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID-19 Vaccine. 2020. URL: https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e2.htm (the date of access: March 28, 2021).

- *Phase 1c*: people aged 65–74 years, people with high-risk medical conditions, and essential workers not recommended for vaccination in Phase 1b.[593]

383. Most states have adopted a modified version of the priority guidance, with variations regarding who qualifies as an essential worker and which medical conditions are considered high-risk.[594] Some states are beginning to open up eligibility for the vaccine to all adults.[595]

384. Although state and local governments are primarily responsible for vaccine rollout, the federal government has supported the rollout by purchasing the vaccine and distributing doses throughout the nation, and additionally through supportive funding and programs.[596] For instance, FEMA has launched 100 vaccination sites in hard-hit communities and provided National Guard troops to assist with distribution at those sites.[597] The federal government also has partnered with pharmacies throughout the nation to increase access to the vaccine.[598] Additionally, the CDC has provided guidance to help state and local governments set up mobile vaccination sites.[599]

385. The federal government has not created or proposed a "COVID passport" initiative. Instead, President Biden's administration has stated that any such initiatives

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[593] Ibid.

[594] *Zettler, P.J. et al.* Chapter 23: Drug and Vaccine Development and Access // COVID-19 Policy Playbook II. 2021. P. 143; Kaiser Family Foundation. State COVID-19 Vaccine Priority Populations. 2021. URL: https://www.kff.org/other/state-indicator/state-covid-19-vaccine-priority-populations/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (the date of access: March 28, 2021).

[595] As of March 25, 2021, five states have opened up eligibility to all adults, and other states have announced that eligibility will be opened up in the coming weeks. *Marlene Lenthang M., Mitropoulos A.* Map shows which states offer COVID-19 vaccines to everyone. ABC News. 2021. URL: https://abcnews.go.com/Health/map-shows-states-offer-covid-19-vaccines/story?id=76487043 (the date of access: March 28, 2021). Some states allow the general population to pre-register for the vaccine. *Breen K.* When can I get my COVID-19 vaccine? See a state-by-state guide. Today.com. 2021. URL: https://www.today.com/health/how-register-covid-19-vaccine-state-state-guide-t205275 (the date of access: March 28, 2021).

[596] The White House. National Strategy for the COVID-19 Response and Pandemic Preparedness. 2021. P. 8–11, 36–58. URL: https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf (the date of access: March 28, 2021).

[597] FEMA. Federally Supported Community Vaccination Centers. URL: https://www.fema.gov/disasters/coronavirus/vaccine-support/vaccine-center (the date of access: March 28, 2021).

[598] CDC. Understanding the Federal Retail Pharmacy Program for COVID-19 Vaccination. URL: https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html (the date of access: March 28, 2021).

[599] CDC. Mobile Vaccination Resources. URL: https://www.cdc.gov/vaccines/covid-19/planning/mobile.html (the date of access: March 28, 2021).

will be left to the private sector.[600] Currently, people who are vaccinated in the U.S. receive documentary proof that they received the vaccine, but there are no federal laws requiring proof of vaccination to travel or access certain services.[601] However, the U.S. continues to advise against international travel and requires anyone entering the nation to provide proof of a recent negative COVID-19 test.[602]

386. On March 26, 2021, New York became the first state to announce that it was launching a COVID-19 vaccine passport program.[603] The state partnered with a private corporation to create a mobile application called the Excelsior Pass, which can be used to prove vaccination status to gain entry to certain venues.[604]

387. The federal government has invoked the Public Readiness and Emergency Preparedness Act to shield companies making and distributing the COVID-19 vaccine from civil lawsuits.[605] Anyone injured as a result of the COVID vaccine cannot utilize the National Vaccine Injury Compensation Program (as with most other vaccines); instead, people who have been seriously injured by the vaccine can file a claim through the Countermeasures Injury Compensation Program and may receive limited compensation from the government.[606] The federal government has also provided liability protections to health workers in the administration of the COVID-19 vaccines.[607]

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[600] *Weise E., Weintraub K.* Vaccine passports should be free, private and secure, White House says. But who will be issuing them? USA Today. 2021. URL: https://www.usatoday.com/story/news/health/2021/03/15/covid-19-vaccine-passports-free-private-secure-white-house-coronavirus/4703360001/ (the date of access: March 28, 2021).

[601] Ibid.

[602] U.S. Department of State. Covid-19 Testing Required for U.S. Entry. URL: https://travel.state.gov/content/travel/en/traveladvisories/ea/covid-testing-required-us-entry.html (the date of access: March 28, 2021).

[603] *Lonas L.* New York launches nation's first 'vaccine passport.' The Hill. 2021. URL: https://thehill.com/homenews/state-watch/545121-new-york-launches-first-in-nation-vaccine-passport (the date of access: March 28, 2021).

[604] Ibid. See also *Weintraub K., Weise E.* New York launches nation's first "vaccine passports." Others are working on similar ideas, but many details must be worked out. USA Today. 2021. URL: https://www.usatoday.com/story/news/health/2021/03/26/covid-vaccine-passports-new-york-first-vaccination-proof-system/6976009002/ (the date of access: March 28, 2021).

[605] *Sigalos M.* You can't sue Pfizer or Moderna if you have severe Covid vaccine side effects. The government likely won't compensate you for damages either. CNBC. 2020. URL: https://www.cnbc.com/2020/12/16/covid-vaccine-side-effects-compensation-lawsuit.html (the date of access: March 28, 2021).

[606] Ibid. See also Health Resources and Services Administration. Frequently Asked Questions: Will the National Vaccine Injury Compensation Program provide compensation to individuals injured by COVID-19 vaccine? URL: https://www.hrsa.gov/vaccine-compensation/faq (the date of access: March 28, 2021).

[607] Department of Health and Human Services. Expanding the COVID-19 Vaccination Workforce. 2021. URL: https://www.phe.gov/emergency/events/COVID19/Documents/covid19-vaccination-wrkfrc-factsheet-508.pdf (the date of access: March 28, 2021).

5.3. Legal Regulation of Vaccine Export and Import

a. General Legal Framework

Conditions for export of vaccine to third countries

388. The U.S. government does not generally prohibit the export of vaccines. A manufacturing company can request documentation from the FDA that shows that the vaccine or another drug has complied with U.S. regulations.[608]

Conditions for import of vaccine from third countries

389. The FDA, in conjunction with U.S. Customs and Border Protection, regulates the import of vaccines.[609] All imports must meet the standard FDA requirements (**paras. 351–353 of the Analytical Report**), and the FDA does not recognize other nations' approvals of vaccines.[610]

b. Special Case of COVID-19 Vaccines Export and Import

390. The federal government has not formally prohibited vaccine manufacturers from exporting COVID-19 vaccines. However, the U.S. has contracted with Pfizer and Moderna to purchase all of their U.S.-produced vaccines, so those companies have not exported their vaccines to other nations.[611] The U.S. recently agreed to send 4 million doses of the AstraZeneca vaccine — which is not yet authorized by the FDA for use in the U.S. — to Mexico and Canada.[612]

391. The same rules that apply to imports of vaccines generally apply to the import of COVID-19 vaccines. The U.S. has not imported COVID-19 vaccines on a large scale —

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[608] U.S. Food and Drug Administration. Human Drug Export Certificates. URL: https://www.fda.gov/media/140332/download (the date of access: March 28, 2021).

[609] U.S. Food and Drug Administration. Importing CBER-Regulated Products into the United States. URL: https://www.fda.gov/vaccines-blood-biologics/exporting-cber-regulated-products/importing-cber-regulated-products-united-states (the date of access: March 28, 2021).

[610] Ibid.

[611] *Wingrove, J.* Biden Uses Trump's 'America First' Vaccine Plan to Corner Market. Bloomberg News. 2021. URL: https://www.bloomberg.com/news/articles/2021-03-24/biden-uses-trump-s-america-first-vaccine-plan-to-corner-market (the date of access: March 28, 2021).

[612] The Guardian. US to send 4m AstraZeneca vaccine doses to Mexico and Canada. 2021. URL: https://www.theguardian.com/world/2021/mar/18/us-astrazeneca-vaccine-doses-mexico-canada (the date of access: March 28, 2021).

instead, the government remains focused on administering the vaccines manufactured within the nation.[613]

392. The U.S. has not modified its intellectual property rules in response to the COVID-19 pandemic. Despite calls from other nations around the world to require pharmaceutical companies to share their patented knowledge to assist in the creation of vaccines in other nations, the U.S. blocked a WTO proposal to suspend intellectual property rights related to COVID-19 vaccines.[614] Major pharmaceutical companies have refused to voluntarily share their COVID-19 vaccine technologies with other nations.[615] Although the U.S. provided funding to pharmaceutical companies to assist with the development of the vaccines, the publicly available information about those contracts shows that the U.S. declined to use its power to take over the intellectual property rights of the vaccines or otherwise influence vaccine prices and dissemination.[616]

393. However, the Biden administration recently invoked the Defense Production Act to forge a partnership between Merck and Johnson & Johnson — two competing pharmaceutical companies — to utilize Merck facilities to expand production of the Johnson & Johnson vaccine within the U.S.[617] Additionally, it was recently reported that the Biden administration is now considering temporarily suspending intellectual property protections related to COVID-19 technologies.[618]

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[613] *Wingrove, J.* Biden Uses Trump's 'America First' Vaccine Plan to Corner Market. Bloomberg News.

[614] *Cheng M., Hinnant L.* Countries urge drug companies to share vaccine know-how. AP News. 2021. URL: https://apnews.com/article/drug-companies-called-share-vaccine-info-22d92afbc3ea9ed519be007f8887bcf6 (the date of access: March 28, 2021).

[615] *Gebrekidan S., Apuzzo M.* Rich Countries Signed Away a Chance to Vaccinate the World. NY Times. 2021. URL: https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html (the date of access: March 28, 2021).

[616] Ibid.

[617] U.S. Department of Health and Human Services. Press Release: Biden Administration Announces Historic Manufacturing Collaboration Between Merck and Johnson & Johnson to Expand Production of COVID-19 Vaccines. 2021. URL: https://www.hhs.gov/about/news/2021/03/02/biden-administration-announces-historic-manufacturing-collaboration-between-merck-johnson-johnson-expand-production-covid-19-vaccines.html (the date of access: March 28, 2021).

[618] *Tausche K., Pramuk J.* White House weighs temporarily lifting intellectual property shield on Covid-19 vaccines. CNBC. 2021. URL: https://www.cnbc.com/amp/2021/03/26/covid-vaccine-updates-white-house-mulls-lifting-intellectual-property-shield.html (the date of access: March 28, 2021).

6. China

6.1. Legal Regulation of Vaccine Development

a. General Legal Framework

General information

394. In China, the major set of norms in regard to vaccines comes from two basic laws: the Vaccines Administration Law[619] and the newly revised Drug Administration Law.[620]

395. According to the Measures,[621] the NMPA is the national regulatory authority, responsible, not only for drug registration management, but also for the management of clinical trial applications.[622]

396. There are two NMPA departments in charge of drug registration: the Drug Administration Department, which formulates and monitors the implementation of quality management standards on pharmaceutical production for drugs, Chinese medicines and biological products, and in addition, it designs and carries out the drug adverse reaction monitoring and alert system; and the Drug Registration Management Department, which is responsible for formulating, controlling, and implementing drug standards, technical guidelines, and registration.

397. As for the MAH, under the legal regime, it can be a manufacturing company or a research institution. It is not required to be a Chinese company. Whenever the MAH is a foreign entity, the latter must designate a Chinese company to perform within the Chinese territory all legal obligations falling on the MAH.[623]

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[619] Vaccines Administration Law of the People's Republic of China. Adopted at the 11th Meeting of the Standing Committee of the Thirteenth National People's Congress on June 29, 2019 (entered into force on December 1, 2019). URL: www.npc.gov.cn/englishnpc/c23934/202012/0b1fd779c29e49bd99eb0e65b66aa783.shtml (the date of access: March 28, 2021).

[620] Drug Administration Law of the People's Republic of China. Adopted at the 12th Meeting of the Standing Committee of the Thirteenth National People's Congress on August 26, 2019 (entered into force on December 1, 2019). URL: www.npc.gov.cn/englishnpc/c23934/202012/3c19c24f9ca04d1ba0678c6f8f8a4a8a.shtml (the date of access: March 28, 2021).

[621] Measures for the Supervision and Administration of Drug Registration. Approved by the first executive meeting of the State Administration for Market Regulation on January 15, 2020 (entered into force on July 1, 2020). URL: http://gkml.samr.gov.cn/nsjg/fgs/202003/t20200330_313670.html (the date of access: March 28, 2021). The measures were not a direct response to COVID-19 as they were passed on January 15, 2020.

[622] Ibid. Article 5.

[623] Drug Administration Law. Article 38.

Stages and time frameworks for conducting clinical trials

398. Clinical trials of vaccines shall be implemented or organized by tertiary medical institutions or disease prevention and control institutions at or above the provincial level that meet the conditions prescribed by the State Drug Administration and the National Health Commission.[624]

399. After completing the pharmacology and toxicology studies that support the clinical trial, the applicant submits a drug clinical trial application, together with relevant research materials in accordance with the requirements of the application.[625] After formal review, if the application materials meet the requirements, the application will be accepted. The drug review center shall organize panels composed by pharmaceutical, medical, and other technical staff to review the accepted drug clinical trial applications.[626]

400. For a drug clinical trial application, the issue should be decided within 60 days from the date of acceptance, and the applicant should be notified of the approval result through the Drug Evaluation Center website; if it is not notified within the time limit, it will be deemed as authorized, and the applicant can develop the clinical trial according to the submitted plan.

401. The duration of clinical trials may be reduced.[627] This possibility is available to pharmaceutical products and vaccines that are: (1) aimed at treating serious life-threatening diseases that do not have effective treatments, as long as the drug's clinical trials have confirmed its efficacy and can predict its clinical value; (2) urgently needed in public health, and clinical trials of which have shown efficacy and allow to predict their clinical value; (3) urgently needed in response to major public health emergencies or other vaccines recognized by the National Health Commission as urgently needed, and benefits of which outweigh the risks after evaluation. Further, Article 66 of the Measures clarifies that for conditionally approved drugs the MAH shall take the corresponding risk management measures after the drug is on the market, complete drug clinical trials and other related research as required within the prescribed time limit and apply for the supplementary application.[628]

[624] Measures for the Supervision and Administration of Drug Registration. Article 22.
[625] Vaccines Administration Law. Article 19.
[626] See Measures for the Supervision and Administration of Drug Registration. Article 23.
[627] Ibid. Article 63.
[628] Ibid. Article 66.

Legal control mechanisms

402. The system of safety management shall be established and improved during the entire process of vaccine development, manufacture, and testing.[629]

403. The sponsor[630] of the clinical trial is in charge of designing the clinical trial protocol, laying down a system to evaluate and monitor the safety of the clinical trial, select the participants (having in consideration different age groups) and take effective measures to protect the safety of those participants.[631]

404. Vaccines clinical trials have to be previously approved by the Drug Registration Management Department of the NMPA in accordance with the law.[632]

405. All participants must provide their written informed consent. Information about the clinical trial objectives and risks shall be truthfully stated and explained to participants, who must then voluntarily sign an informed consent form.[633] Whenever the individual is deprived of legal capacity to consent, his or her guardian shall be the one to provide consent and sign the form. Regarding individuals with limited capacity to consent, the guardian shall also intervene and both of them must sign the consent form.[634]

406. The conduct of drug clinical trials shall comply with ethical principles and with a clinical trial protocol reviewed and approved by the ethics committee. The ethics committee shall establish an ethics review system to ensure that the ethics review process is independent, objective, and fair, supervise the standard conduct of drug clinical trials, protect the legitimate rights and interests of trial subjects, and safeguard the public interest.[635]

407. Further, vaccine research and development shall comply with the Good Laboratory Practice for Pharmaceuticals and the Good Clinical Practice for Pharmaceuticals, and the entire drug research and development process shall continuously comply with statutory requirements.[636] It is up to the producer to develop

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[629] Ibid. Article 11.
[630] The sponsor of a clinical trial is the person or legal entity (a company, institution, or organization) that oversees and pays for the clinical trial in order to collect and analyze the resulting data.
[631] Vaccines Administration Law. Article 17.
[632] Ibid. Article 16.
[633] Drug Administration Law. Article 21.
[634] Vaccines Administration Law. Article 18.
[635] Drug Administration Law. Article 20.
[636] Ibid. Article 17.

and monitor the vaccine life cycle and to promote its safety, effectiveness, and quality.[637] The conduct of drug research and development, manufacturing, distribution, and use shall comply with the applicable laws, regulations, standards, and norms, to ensure the authenticity, accuracy, integrity, and traceability of information throughout the process.[638]

408. Where safety issues or other risks are discovered during a clinical trial, the clinical trial sponsor shall promptly adjust the protocol, suspend or terminate the clinical trial, and report to the drug regulatory department under the State Council. If necessary, the drug regulatory department under the State Council may order the sponsor to adjust the clinical trial protocol or suspend or end the clinical trial.[639]

409. To make sure that the process of vaccine development, manufacture, distribution, and immunization complies with the existing regulations the drug regulatory departments and health departments shall exercise constant monitoring.[640] This monitoring might include on-site inspections and inspections to the entities or individuals that provide products or services for the vaccine development, manufacture, and distribution. The involved entities and individuals shall cooperate and are not allowed to reject the inspection or conceal any information.[641] Entities and individuals that have made significant contributions to drug development, manufacturing, distribution, use, supervision, and administration shall be commended and rewarded by the people's government and its relevant departments.[642]

Vaccine authorization

410. To manufacture a vaccine in China, it is necessary to obtain approval from the drug regulatory departments and get the drug registration certificate.[643] For this, a complete and accurate file with all relevant information and samples must be provided.[644]

411. During the approval process of the vaccine registration, the drug regulatory department under the State Council examines the production process, quality control standards, package inserts, and labels of vaccines. In case the submitted data allow to

[637] Vaccines Administration Law. Article 5. See also Drug Administration Law. Article 6.
[638] Drug Administration Law. Article 7.
[639] Ibid. Article 22.
[640] Vaccines Administration Law. Article 70.
[641] Ibid.
[642] Drug Administration Law. Article 15.
[643] Vaccines Administration Law. Article 19.
[644] Ibid.

come to a positive conclusion, the drug regulatory department under the State Council grants the respective approval.[645]

412. Chinse law provides for a special mechanism applicable for innovative vaccines necessary to prevent and control diseases.[646] Article 68 of the Measures specifies the type of drugs that can apply for such special procedure.[647] The drug regulatory department under the State Council shall give that product priority in evaluation, review, and approval.[648]

413. The use of drugs included in the special approval procedure may be limited to a certain period and scope according to the specific needs of disease prevention and control.[649]

414. The drug regulatory department under the State Council Conditional may also grant conditional approval for vaccines that are used to respond to major public health emergencies if benefits of those vaccines outweigh risks.[650]

415. The Vaccines Administration Law introduces the definition of MAH for the specific case of vaccines, as being the one responsible for the safety, effectiveness, and quality management of vaccines.[651] When a holder of the marketing authorization does not have capacity to satisfy the demand, the law allows to delegate manufacturing of vaccine to a different producer (commissioned production) subject to approval from the drug regulatory department.[652]

Emergency use authorization

416. Article 20 of the Vaccine Administration Law allows urgent use of vaccines based on the need for disease prevention and control in the situation of "particularly major public health emergencies or other emergencies which seriously threaten public health."[653]

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[645] Ibid. Article 21.
[646] Ibid. Article 19.
[647] Measures for the Supervision and Administration of Drug Registration. Article 68.
[648] Ibid. Article 70.
[649] Ibid. Article 74.
[650] Ibid. Article 20.
[651] Ibid. Article 5.
[652] Ibid. Article 22. The possibility of commissioned production was not allowed under the previous legal framework.
[653] Vaccines Administration Law. Article 20.

417. An urgent use of vaccines shall be proposed by the recommendation of the competent health department under the State Council. The drug regulatory department under the State Council shall evaluate the proposal and permit the urgent use "within certain scope and period of time."[654]

Vaccine patent protection

418. There are no special application conditions and procedures for vaccine patent applications in China. The Patent Law will apply to all intellectual property right issues in the process of vaccine development and production.[655] The research and development of vaccines may lead to various types of intellectual property rights. For example, patents can be granted to the isolation, purification, and identification of specific virus strains. The production methods of vaccines are also patentable.[656]

419. The Patent Law allows the compulsory license for vaccines in case of a public health crisis, when the patent is of great significance to the national/public interest. Compulsory license for vaccines is to be decided by the relevant competent departments of the State Council and the people's government of provinces, autonomous regions, and municipalities directly under the Central Government after reporting to the State Council for approval.[657] In such case, the implementing unit shall pay royalties to the patentee in accordance with national regulations.[658]

420. The compulsory license allows the manufacture and exportation of drugs to countries or regions that comply with the relevant international treaties to which the People's Republic of China has participated.[659]

421. Under Article 50 of the Patent Law, the Patent Administration Department of the State Council may make an announcement and implement the open licensing followed by the voluntary declaration of a patentee. Any entity or individual who wishes to apply for an open-licensed patent shall notify the patent holder in writing and pay the license

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[654] Ibid.

[655] Patent Law of the People's Republic of China. Adopted at the 4th Meeting of the Standing Committee of the Six National People's Congress on March 12, 1984. The Amendment to Patent Law was adopted at the 22nd Meeting of the Standing Committee of the Thirteen National People's Congress on October 17, 2020, and will enter into force on June 1, 2021. URL: https://www.cnipa.gov.cn/art/2020/11/23/art_97_155167.html (the date of access: March 28, 2021).

[656] Ibid. Articles 22, 25.

[657] Ibid. Article 49.

[658] Ibid.

[659] Ibid. Article 55. So far, China has never implemented compulsory license of a drug patent.

fee to obtain a patent license. During the implementation period of the open license, the annual patent fee paid by the patentee shall be reduced or exempted accordingly.[660]

422. There are no specific regulations for issues related to the intellectual property rights applicable to vaccines in importing countries. China acceded to the TRIPS and joined the Declaration on the TRIPS Agreement and Public Health. The latter "recognizes an unresolved problem relating to TRIPS and Public Health – the use of compulsory licensing in countries with little or no manufacturing capacity or insufficient market demand – and commits the governing body of the TRIPS, the TRIPS Council, to reach a solution in 2002."[661]

423. The Patent Law also establishes the consequences for a use of a vaccine without the authorization of the patent holder. It states that there will be compensation, the amount of which shall be assessed on the basis of the losses suffered by the patentee or the profits which the infringer has earned through the infringement. The ones infringing a patent shall be subject to disciplinary sanctions.[662]

b. Legal Framework for the COVID-19 Vaccine Development

424. No special regulation has been established for the research and development of COVID-19 vaccines in China. The JPCM stated that the existing legal framework that governs the research and development of vaccines should be applied to the supervision of the research and development of COVID-19 vaccines.[663] At the same time, the JPCM affirmed that, under the premise of safety, the government shall complete the technical review of a vaccine in the quickest way and let the safe, effective, and quality ensured vaccines to be launched as soon as possible.[664]

425. On August 14, 2020, the Center for Drug Review of the National Medical Products Administration formulated five guiding principles: the Guiding Principles for Trial and Development of New Coronavirus Preventive vaccines (Trial Implementation); New Coronavirus Guidelines for the Prevention of mRNA Vaccines for Pharmaceutical

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[660] Ibid. Article 51.

[661] *Correa C. M.* Implications of the Doha Declaration on the TRIPS Agreement and Public Health World Health Organization. June 2002. Para. 9. URL: https://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf (the date of access: March 28, 2021).

[662] Patent Law. Article 65.

[663] National Health Commission of the People's Republic of China. Press Conference of the Joint Prevention and Control Mechanism of the State Council on October 20, 2020, introducing the COVID-19 Vaccine-related information. 2020. URL: http://www.nhc.gov.cn/xwzb/webcontroller.do?titleSeq=11346&gecstype=1 (the date of access: March 28, 2021).

[664] Ibid.

Research Technology (Trial Implementation); Key Points for Research and Evaluation of Non-Clinical Efficacy of New Coronavirus Preventive Vaccine (Trial Implementation); Guiding Principles of Clinical Research Techniques for Trial Vaccines for Preventive Vaccines (Trial Implementation), and Guiding Principles for Clinical Evaluation of New Coronavirus Preventive Vaccines (Trial Implementation).[665] Those principles provide a reference technical standard for clinical research and development of COVID-19 vaccines.

426. Approval of the Chinese coronavirus vaccines occurred under the special mechanism applicable for innovative vaccines necessary to prevent and control diseases (**paras. 411–413 of the Analytical Report**). In accordance with Article 20 of the Vaccines Administration Law, in June 2020, the State Council approved the Novel Coronavirus Vaccine Emergency Use (Trial) Program, which aimed to authorize vaccines for high-risk groups, i.e., medical personnel and public transport support staff.[666] The CoronaVac vaccine, for example, was granted for the emergency use in June of 2020, while the conditional approval for this vaccine was granted later in February of 2021.[667] In this regard, the urgent use was approved prior to the conditional approval.

6.2. Legal Regulation of Immunoprophylaxis

a. General Legal Framework

General information

427. In China, State has a right to prepare immunization planning and implement vaccination programs. The national immunization plan shall be formulated by the health department of the State Council in conjunction with the financial department of the State Council.[668] It is up to the State Council's drug regulatory authority to make recommendations when there is a risk of a shortage of vaccine supply. The State

[665] The Center for Drug Review of the National Medical Products Administration. Notification of the Five Principles, including the Guidelines for the New Coronavirus Research and Development of Preventive Vaccines (Tentative). August 14, 2020. URL: https://www.nmpa.gov.cn/zhuanti/yqyjzxd/yqyjxd/20200814230916157.html (the date of access: March 28, 2021).

[666] Press conference of the Joint Prevention and Control Mechanism of the State Council. December 31, 2020. URL: http://www.gov.cn/xinwen/gwylflkjz143/wzsl.htm (the date of access: March 28, 2021).

[667] Xinhua News Agency. The vaccine of the Beijing Kexing Zhongwei Biotechnology Co Ltd. "Kierlaifu" was approved for the emergency use. February 7, 2021. URL: http://www.gov.cn/xinwen/2021-02/07/content_5585509.htm (the date of access: March 28, 2021).

[668] Vaccines Administration Law. Article 41.

Council's industry and information technology authority and the State Council's financial department shall take effective measures to ensure vaccine production and supply.[669]

428. Residents have the right (and eventually the obligation, in case of Vaccines under the Program) to vaccinate in accordance with the immunization program, which shall be free to a resident.[670]

Nature of vaccination

429. Under Chinese law, there are two main types of vaccines: vaccines under immunization programs and vaccines not covered by immunization programs.[671] The former, "Vaccines Under Program", are "vaccines to be inoculated in citizens as per the government provisions",[672] while the latter, the "Vaccines Beyond Program", are all the other that people can take according with their own wishes.[673] The different level of relevance of these two types of vaccines dictates different solutions in several domains, including their costs for citizens: for vaccines under program no fee can be charged, but for the remaining ones there can be a vaccine fee and a vaccination service fee.[674]

430. Vaccines under the program are mandatory. The types of vaccines under this mandatory program shall be formulated by the competent health department of the State Council in conjunction with the finance department of the State Council.[675] When a child enters school (at any stage), the institution must check the vaccination certificate, and if it is found that the vaccine record is not in accordance with the regulations, the child guardians must assure inoculation and obtain the respective inoculation certificate.[676] For guardians who fail to comply with that obligation, the law establishes "criticism and education", though the nature of this sanction is not clear.[677]

Domestic vaccination process

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[669] Ibid. Article 65.

[670] The Basic Medical Hygiene and Health Promotion Law of the People's Republic of China. December 28, 2019. Article 21. URL: https://npcobserver.com/legislation/basic-healthcare-and-health-promotion-law/ (the date of access: March 28, 2021). Vaccines Administration Law. Article 6.

[671] Vaccines Administration Law. Article 97.

[672] This category basically coincides with the previous classification of Class 1 vaccines that could be found in the Administrative Regulations on the Circulation of Vaccines and Vaccination of the PRC. In this regard see *Xiang Y., Li N*. Disclosure of Vaccine Risk and Emergency Legislation in China // Biotechnology Law Report. 2019. Vol. 38. No. 3. P. 166.

[673] It corresponds to Class 2 vaccines in the Administrative Regulations on the Circulation of Vaccines and Vaccination of the PRC. See Ibid.

[674] Vaccines Administration Law. Article 49.

[675] Ibid. Article 41.

[676] Ibid. Article 48.

[677] Ibid. Article 92.

431. Article 44 of the Vaccines Administration Law sets the requirements for the immunization entities: the institutions must obtain a practice license; the medical professionals (physicians, nurses, or village doctors) must have received proper professional training on immunization, under the supervision of the competent health departments of people's governments at the county level and passed the respective examinations; proper equipment must be available, such as cold storage facilities, equipment and cold storage systems in conformity with the prescribed guidance for vaccine storage and transportation.

432. Vaccines under the program can be taken at a qualified medical institution designated by a local health department at or above the county level, while vaccines beyond the program are taken at qualified medical institutions and subject to the report and record of the competent health department.[678]

433. There are no legal provisions concerning the priority groups of vaccination. However, government documents and administrative regulations emphasize vaccination of minors, as in Article 48 of the Vaccines Administration Law and in Article 90 of the Law of the People's Republic of China on the Protection of Minors, adopted on September 4, 1991, and currently the second revised version on October 17, 2020. Moreover, according to the Press Conference of the Joint Prevention and Control Mechanism of the State Council on March 21, 2021, after enough safety and effectiveness data are obtained in clinical trials, the government will carry out mass vaccination for the elderly over 60 years old.[679]

Liability for the harm caused by a vaccine

434. Whenever an adverse reaction to immunization is detected, the Center for Disease Prevention and Control shall promptly report it, investigate the incident and inform the vaccine recipient or his or her guardians.[680] According to the severity of the situation, drug regulatory authorities might order the vaccine MAH to conduct a post-marketing evaluation, or the latter can be carried out by the drug regulatory authority itself.[681] Ultimately, in case of severe adverse vaccine reaction, the drug registration certificate of the vaccine might be canceled by the drug administration department of

[678] Vaccines Administration Law. Article 44 (3).
[679] Press Conference of the Joint Prevention and Control Mechanism of the State Council on March 21, 2021, introducing the Safety and Effectiveness of COVID-19 Vaccines. 2021. URL: http://www.gov.cn/xinwen/gwylflkjz152/index.htm (the date of access: March 28, 2021).
[680] Vaccines Administration Law. Article 55.
[681] Ibid. Article 61.

the State Council.[682] Other consequences for the vaccine MAH include suspension of vaccine production, sales, and distribution.[683]

435. Drug regulatory departments shall establish a credit record system for vaccine MAHs and their related personnel, incorporate it into the national credit information sharing platform,[684] publicize their lack of compliance (the norm uses the expression "lack of honesty"), and implement joint punishments.[685] Negative consequences might also result for the authorities that failed to supervise the vaccine, as the person in charge can be demoted, dismissed, or even expelled.[686]

436. In case of manufacturing and sale of fake vaccines or sub-standard drugs, manufacturers face severe administrative penalties (stricter than the ones provided for other drugs in the Drug Administration Law): confiscation of unlawful income, suspension of activity, revocation of drug registration and certificate and/or drug manufacturing license and heavy fines. In addition, there are also personal administrative penalties: confiscation of unlawful income; prohibition of engaging in the manufacturing and sales of drugs for life, heavy fines, and administrative detention.[687]

437. Besides the referred administrative sanctions, criminal penalties can also be imposed on anyone who, besides violating these legal provisions, commits a crime, as proclaimed in Article 79 of the Vaccines Administration Law.

438. The person who suffered an injury connected to a vaccine is entitled to compensation paid by the vaccine MAH.[688] For vaccines under the program, compensations are paid by a vaccination fund, subsidized by finance departments of governments of provinces, autonomous regions, and municipalities directly under the Central Government.[689] For vaccinations beyond the program, compensation will be borne by the MAH, and the State encourages the contractualization of commercial

[682] Ibid. See also Measures for the Supervision and Administration of Drug Registration. Article 110.
[683] Vaccines Administration Law. Article 72.
[684] This is a nationwide information-sharing mechanism for checking the credit status of various social entities online established in 2015. It includes various kinds of administrative licenses and administrative penalties, lists of broken promises, lists of abnormal business operations, and other information.
[685] Vaccines Administration Law. Article 72.
[686] Ibid. Articles 94–95.
[687] Ibid. Articles 80, 83.
[688] Ibid. Article 96.
[689] Ibid. Article 56.

insurances to face such situations.[690] In any case, "compensation for adverse reactions of immunization shall be prompt, convenient and rational."[691]

439. In addressing the issue of harm caused by health workers to individual vaccinations, the legal liability falls into several categories specifically. The first cause of legal liability is that health workers who violate the cold-chain storage and transportation requirements of the regulatory code for vaccine storage and transportation; or fail to comply with vaccination work norms, immunization procedures, guidelines for the use of vaccines and vaccination programs; or carry out group vaccination without authorization. In all these cases the health worker will be suspended from practicing for one year to less than 18 months. If serious consequences have been caused, the main health workers-in-charge shall be dismissed according to the law, and the original license-issuing department shall revoke their practice certificates.[692]

440. Another cause of legal liability involves health workers who do not maintain records of the receipt, purchase, storage, distribution, supply, inoculation, and disposal of vaccines; or fail to inform or inquire about the relevant situation of the vaccinated patients or their guardians; or because of improper transportation or preservation damage is caused to the vaccinated patients. In the second scenario, the health workers will be suspended from practicing activities for six months to less than one year. If serious consequences are caused, they may be dismissed, and their practice certificate shall be revoked by the original certificate-issuing department.[693]

441. Thirdly, there is the case of health workers who fail to report suspected abnormal reactions to vaccination or vaccine safety incident; or fail to organize investigation and diagnosis of suspected abnormal reactions to vaccination. In this scenario, the health workers shall be ordered to make corrections and given a warning by the health management department. The health workers who are directly responsible

[690] To better reach this aim, Article 68 of the Vaccines Administration Law states that laws about compulsory liability insurance must be formulated. On October 12, 2020, the Measures for the Administration of Compulsory Vaccine Liability Insurance (Draft for Public Opinions) developed by the National Medical Products Administration, National Health Commission, and the China Banking and Insurance Regulatory Commission were officially out for seeking public opinions. The draft has not been established as an administrative regulation. URL: https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/zhqyj/zhqyjyp/20201012192242150.html (the date of access: March 28, 2021).

[691] Vaccines Administration Law. Article 56.

[692] Ibid. Articles 85, 87.

[693] Ibid. Articles 86, 88.

for causing serious consequences shall be dismissed according to law and their practice certificates shall be revoked by the original license-issuing department.[694]

b. Special Case of COVID-19 Vaccination

442. The COVID-19 vaccines seem to belong to the category of "Vaccines Beyond Program". Even though the Chinese government encourages residents, including foreigners living in China, to inoculate the COVID-19 vaccines, they are not mandatory.[695] They are free, just as the vaccines included in the National Immunization Programs category.

443. China has no additional legal regulations for the new COVID-19 vaccine. However, there are some measures to be considered in relation to the so-called "immunity passports". On March 7, 2021, the State Counsellor and Foreign Affairs Minister, Wang Yi, announced the launch of the Chinese version of the "International Travel Health Certificate" (also named the "International Version of Epidemic Prevention Health Code") at the press conference of the Foreign Ministers of the two sessions, as a mechanism to promote the recovery of the world economy and facilitate cross-border personnel exchanges.[696] On March 8, 2021, the "International Travel Health Certificate" WeChat Mini Program was officially launched. It is a comprehensive certificate that displays the holder's nucleic acid test results, serum IgG antibody test result, and vaccination status.[697] Moreover, it comprises all entrances and exits in and from the country. The "International Travel Health Certificate" contains an encrypted QR code for the relevant departments of various countries to verify its authenticity and read the personal information therein included. In addition to the electronic display, it can also be printed to generate a paper version. The ones returning to China, at their entrance, must fill various entry information forms, declare their COVID-19 test results, and obtain a health code required for returning home.[698]

444. With regard to foreigners who want to visit China and the respective issuing of visas, visas are solely available to applicants who have been vaccinated with one of the COVID-19 vaccines produced in China and hold a vaccination certificate. In order to resume the regular flow of visitors to China in an orderly manner, starting from March

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[694] Ibid. Article 89.
[695] China News Net. Inoculation of Chinese COVD-19 Vaccines: Voluntary, Informed, and Free. March 30, 2021. URL: https://oversea.huanqiu.com/article/42Vxg35U0qs (the date of access: March 30, 2021).
[696] China Consular Service Network. Good News! China's Version of "International Travel Health Certificate" Officially Launched. March 8, 2021. URL: http://cs.mfa.gov.cn/gyls/lsgz/fwxx/t1859289.shtml (the date of access: March 28, 2021).
[697] Ibid.
[698] Ibid.

15, 2021, Chinese Embassies in foreign countries[699] restarted issuing visas to applicants who need to travel to China for specific reasons (family reunion, business, humanitarian motives, etc.). This measure is restricted to people inoculated with any of the inactivated vaccines produced in China and who have completed two injections at the specified interval or vaccinated with other types of single-dose vaccines produced in China and completed 14 days after the shot. In any case, vaccination certificates must be presented. It remains unchanged the requirements that passengers traveling to China must present double-negative certificates for COVID-19 nucleic acid testing and serum antibody testing. After entering the country, they still must abide by the relevant Chinese regulations on isolation and observation.[700]

6.3. Legal Regulation of Vaccine Export and Import

a. General Legal Framework

Conditions for export of vaccine to third countries

445. The production and export of vaccines is encouraged by the Chinese State,[701] in accordance with international procurement requirements, as well as the standards or contract requirements of the importing country or region.[702]

Conditions for import of vaccine from third countries

446. With regard to the import of vaccines, there are rules in place to guarantee the products' safety and quality. An inspection of imported vaccines is carried out by the drug regulatory department under the State Council and only if the vaccines are considered safe and efficient, lot of vaccines can be released.[703] When the assessment is negative the products shall be destroyed under the supervision of the medical products administration.[704] However, in case of vaccines urgently needed for the

[699] At least ten embassies have issued this notice, but no official document has been issued by the Chinese Ministry of Foreign Affairs about this new type of visa application condition. However, according to the transcript of the regular press conference held by the Ministry of Foreign Affairs on March 24, 2021, at present, Chinese embassies in many countries have issued new regulations on visas to China on March 15, 2021. URL:https://www.fmprc.gov.cn/web/fyrbt_673021/jzhsl_673025/t1863813.shtml (the date of access: March 28, 2021).

[700] See the Embassy of the People's Republic of China in the United States of America. The Notice on Providing Visa Facilitation for People Who Have Been Vaccinated with the New Coronary Pneumonia Vaccine Produced in China. March 15, 2021. URL: http://www.china-embassy.org/eng/visas/t1861379.htm (the date of access: March 28, 2021).

[701] Vaccines Administration Law. Article 98.

[702] Ibid. See also the Measures for the Supervision and Administration of Drug Products. Article 80.

[703] Vaccines Administration Law. Article 26.

[704] Ibid.

prevention and control of infectious diseases, or in emergency situations, the lot release procedure shall be exempted, with the approval of the medical products administration of the State Council.[705]

447. In accordance with this special regime, there are also special application procedures for the approval of entry/exit articles.[706] When the application meets the applicable requirements, the General Administration of Customs shall issue the so-called Form on the Approval of Health and Quarantine of Entry/Exit Special Articles.[707]

448. The person in charge of the entry or exit of the referred products must guarantee their safety and be accountable for eventual damages.[708] The customs offices, in turn, are accountable for articles entering or leaving their respective jurisdictions.[709]

449. Article 38 of the Regulation for the Implementation of Drug Administration Law of the People's Republic of China (2019 Amendment) also has special rules for specific products, but they do not coincide entirely with the products referred to in the previous provisions, since the latter refers to vaccines, blood products, diagnostic reagents in vitro for blood donor screening and other biological products regulated by the drug regulatory department under the State Council. The norm states that these products shall be subject to testing or review for approval, according to the provisions of the drug regulatory department before being marketed or imported. It adds that any product that fails in testing or that has not been approved shall not be marketed or imported.

b. Special Case of COVID-19 Vaccines Export and Import

450. The Chinese government has not made any additional legal provisions on the import and export of COVID-19 vaccines. China formally joined COVAX (a global enterprise aimed to guarantee fair and equitable access to COVID-19 vaccines) in October 2020.[710] China encourages national companies dealing with vaccine research and development to participate in COVAX and provide vaccines to developing countries with relevant sponsors. Chinese President Xi Jinping held a video conference with European leaders on February 9, 2021, where he said that China is willing to carry out

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[705] Ibid. Article 28.

[706] Order No. 243 of the General Customs Administration of the People's Republic of China. The Provisions on the Administration of the Health and Quarantine of Entry/Exit Special Articles. November 23, 2018. Articles 7–10. URL: http://www.gov.cn/gongbao/content/2019/content_5368593.htm (the date of access: March 28, 2021).

[707] Ibid. Article 12.

[708] Ibid. Article 5.

[709] Ibid. Article 6.

[710] Xinhua Net. China Officially Joins COVAX: Spokesperson. October 9, 2020. URL: http://www.xinhuanet.com/english/2020-10/09/c_139427883.htm (the date of access: March 28, 2021).

vaccine collaborations with Central and Eastern European countries.[711] There are special regulations on the transportation of COVID-19 vaccines. The Technical Guidelines for Road Transportation of COVID-19 Vaccines[712] state that all actors who are involved in the domestic transportation of export goods of new coronavirus vaccine "shall show the export transportation dispatch sheet of new coronavirus vaccine goods at the time of customs clearance. The customs department shall give priority to the inspection and customs clearance of those who hold the export transportation dispatch list of new coronavirus vaccine goods."

[711] Xinhua Daily Telegraph. Xi Jinping's Keynote Speech at the Summit of Leaders of China and Central and Eastern Europe. February 10, 2021. URL: http://mrdx.cn/PDF/20210210/02.pdf (the date of access: March 28, 2021).

[712] Technical Guidelines for Road Transportation of COVID-19 Vaccines. January 25, 2021. Para. 3.4. URL: http://www.gov.cn/zhengce/zhengceku/2021-01/28/content_5583157.htm (the date of access: March 28, 2021).

7. India

7.1. Legal Regulation of Vaccine Development

a. General Legal Framework

General information

451. India is one of the largest manufacturers and exporters of vaccines worldwide.[713] The Drugs and Cosmetics Act of 1940[714] and the Drugs and Cosmetics Rules of 1945[715] regulate the import, manufacture, and distribution of drugs in India. Those Acts do not impose any particular requirements on a vaccine developer. The New Drugs and Clinical Trials Rules[716] regulate the conduct of clinical trials on the territory of India and aim to promote clinical research in the country.

452. India has collaborated with the WHO on strengthening and building its regulatory capacity. In February 2017, a team of international experts convened by WHO assessed that India's CDSCO meets the WHO standards for vaccine regulation.[717]

453. The CDSCO established under the Directorate General of Health Services of the Ministry of Health and Family Welfare of the Government of India is the National Regulatory Authority of India.[718]

Stages and time frameworks for conducting clinical trials

454. According to the New Drugs and Clinical Trial Rules, any application to conduct a clinical trial of a new drug or investigational new drug by any person or institution will

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[713] See WHO. WHO finds India's vaccine regulatory authority compliant with international standards. URL: https://www.who.int/medicines/regulation/india-authority_reg_compliant-int-standards/en/ (the date of access: April 14, 2021).

[714] Government of India. Ministry of Health and Family Welfare. The Drugs and Cosmetics Act. April 10, 1940. Amended on December 31, 2016. P. 1–30. URL: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf (the date of access: April 14, 2021).

[715] Government of India. Ministry of Health and Family Welfare. The Drugs and Cosmetics Rules. December 21, 1945. Amended on December 31, 2016. P. 31–546. URL: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf (the date of access: April 14, 2021).

[716] Government of India. The New Drugs and Clinical Trial Rules. REGD. No. D. L.-33004/99. March 19, 2019. Rule 21. URL: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf (the date of access: April 14, 2021).

[717] Ibid.

[718] Central Drugs Standard Control Organization. URL: https://cdsco.gov.in/opencms/opencms/en/Home/ (the date of access: April 14, 2021).

be made to the Central Licensing Authority (*Drug Controller of India*). No fee for conducting a clinical trial may be paid by a person or institution or organization funded or owned, wholly or partially by the Central Government or a State Government.[719]

455. The Central Licensing Authority after conducting a thorough examination of the application may grant permission for conducting a clinical trial in India and such a decision shall be taken within a total of 90 working days from the date of the application.[720] Disposal of an application made for permission to conduct a clinical trial completes and fulfills the following conditions, namely:

- the drug is discovered in India; or
- research and development of the drug are being done in India and also the drug is proposed to be manufactured and marketed in India.

456. Such an application has to be disposed of by way of grant of permission or rejection or processed by way of communication to rectify any deficiency of the application within 30 working days from the date of receipt of the application. In the event no such communication has not been received from the Central Licensing Authority to the applicant within the said period of 30 working days, the permission to conduct trial shall be deemed to have been granted by the Central Licensing Authority and such permission shall be deemed to be legally valid for all purposes and the applicant shall be authorized to initiate a clinical trial in accordance with the New Drugs and Clinical Trial Rules.[721]

457. The application for permission to conduct a clinical trial for a new drug already approved outside India (in countries that have been identified in the Rules) must be disposed of by way of grant of permission or rejection or processed by way of communication to rectify any deficiency, by the Central Licensing Authority, within a period of 90 working days from the date of receipt of the application.[722] The Rules also provide that the permission to conduct a clinical trial in India is dependent on the satisfaction of various factors, including a six-monthly status report of the clinical trial,

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[719] The New Drugs and Clinical Trial Rules. Rule 21. These Rules are applicable to and regulate new drugs, investigational new drugs for human use, clinical trials, bioequivalence studies, bioavailability studies and Ethics Committee. The Rules further define that the Drugs Controller of India is the Central Licensing Authority. The Rules have also provided for a set up and registration of an Ethics Committee by anyone who intends to conduct clinical trials or bioavailability studies or bioequivalence studies. The Rules also discuss the compensation in the event of death or injury in clinical trial or bioavailability or bioequivalence studies of new drugs or investigational new drugs.

[720] Ibid. Rule 22.

[721] The New Drugs and Clinical Trial Rules. Rule 23.

[722] Ibid. Rule 24.

detailing if it is ongoing, completed, or terminated, that has to be submitted to the Central Licensing Authority electronically through a dedicated portal.[723] No permission for conducting an academic clinical trial is required from the Central Licensing Authority.[724]

458. The Rules also provide that an applicant may make an application for grant of permission to manufacture unapproved active pharmaceutical ingredient for the development of a pharmaceutical formulation for test or analysis or clinical trial or bioavailability and bioequivalence study, after furnishing the related documents, and the Central Licensing Authority may grant such permission after scrutiny of the information and documents furnished by the Applicant.[725]

459. The development methodology of a drug is described under two heads of non-clinical studies and clinical studies. The nature of non-clinical studies and their timing in respect of the conduct of a clinical trial are determined taking certain factors into consideration, including disease of conditions for which the new drug or investigation new drug is intended to be indicated.[726]

460. The following are the four phases of a clinical trial in India:

- ***Phase I*** aims at the estimation of safety and tolerability with the initial administration of an investigation of a new drug into humans. Trials in this phase are to be carried out by investigators trained in clinical psychology with access to the necessary facilities to closely observe and monitor the subjects. This is conducted in healthy humans or certain types of patients. Studies in this phase have non-therapeutic objectives;

- ***Phase II*** aims to evaluate the effectiveness of a drug for a particular indication or indications in patients with the condition under study and to determine the common short-term side effects and risks associated with the drug;

- ***Phase III*** aims at demonstrating or confirming therapeutic benefits. This phase confirms the preliminary evidence accumulated in Phase II that a drug is safe and effective for use in the intended indication and recipient population. For new drugs approved outside India, Phase III studies may need to be carried out if scientifically and ethically justified, primarily to generate evidence of efficacy

[723] Ibid. Rule 25 (viii).
[724] Ibid. Rule 28.
[725] Ibid. Rule 60
[726] Ibid. First Schedule, Rule 3.

and safety of the drug in Indian patients when used as recommended in the prescribing information;

- *Phase IV* aims at post-marketing trial of new drugs are performed after the approval of the drug and related to the approved indication. Such trials go beyond the prior demonstration of the drug's safety, efficacy, and dose definition.[727]

461. Separate rules are provided in the event the new drug substance is discovered or developed in India and when it has been developed/discovered outside India and the different stages of the clinical trial that may be applicable. If the drug is developed/discovered outside India the permission by the Central Licensing Authority may be granted to either repeat Phase I trials in India or directly proceed to Phase II onwards.[728] For a drug to be introduced for the first time in the country, Phase III trial may be required to be conducted in India before permission to market the drug is granted unless otherwise it has been exempted.[729]

462. The Rules also provide for "Accelerated Approval Process", which may be allowed to a new drug for a disease or condition, taking into account its severity, rarity, or prevalence and the availability or lack of alternative treatments, provided that there is a prima facie case of the product being of meaningful therapeutic benefit over the existing treatment.[730] Such approval shall be based on data generated in a clinical trial where surrogate endpoint shall be considered rather than using standard outcome measures such as survival or disease progression, which are reasonably likely to predict clinical benefit, or a clinical endpoint. The post-marketing trials shall be required to validate the anticipated clinical benefit. Further, if the remarkable efficacy is observed with a defined dose in the Phase II clinical trial of an investigational new drug for the unmet medical needs of serious and life-threatening diseases in the country, it may be considered for grant of marketing approval by the Central Licensing Authority based on Phase II clinical trial data. In such cases, additional post licensure studies may be required to be conducted after approval to generate the data on a larger population to further verify and describe the clinical benefits, as per the protocol approved by the Central Licensing Authority.[731] The Rules also discuss provisions where a quick or

[727] Ibid. First Schedule. Development Methodology.
[728] Ibid. Second Schedule, Rule 1. To be read with Rule 21 of the Rules, the Second Schedule provides further information on the application process for permission to import or manufacture new drug for sale or to undertake clinical Trial.
[729] Ibid. Second Schedule. Rule 1(1)(iv)(b).
[730] Ibid. Second Schedule. Rule 1(2)(A).
[731] Ibid. Rule 1 (2)(A)(d).

expeditious review process can be sought for approval of a new drug after clinical development, by the Central Licensing Authority.[732]

463. Rule 30 provides that the permission granted to any person or institution or organization for conducting clinical trials may be canceled if such person/institution/organization fails to comply with any provision of the Drugs and Cosmetics Act of 1940 or the New Drugs and Clinical Trial Rules.[733]

464. The Central Licensing Authority may give an opportunity to show cause, thereafter it can either issue a warning about the deficiency or defect observed during clinical trials; it may reject the results of a clinical trial, suspend the permission granted for conduct of clinical trials, or cancel such permission. The Central Licensing Authority may also debar the investigator or the sponsor (including his or her representative) from conducting any clinical trial in the future for a period considered appropriate by the Central Licensing Authority.[734]

Legal control mechanisms

465. The Drugs and Cosmetics Act of 1940 discusses and further regulates the manufacture of drugs by regulating and establishing the standards to be met for the manufacture of vaccines.[735] Such standards of quality have to be met and maintained while importing drugs in India, manufacturing, selling, and distributing drugs in India. The Act also describes the powers of various government actors like inspectors, government analysts as well as the procedure that has to be followed to ensure compliance with the Act.

466. The Drugs and Cosmetics Rules of 1945 provide for approvals and licenses that are required from the Licensing Authority before the manufacture of a new drug.[736] These Rules describe the functions of the Central Drugs Laboratory, various import and registration procedures involving licenses for examination, test, or analysis of drugs that are imported, conditions that an applicant has to satisfy to be eligible for licenses for import and/or manufacture. The Rules also describe the qualifications of various

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[732] Ibid. Rule 1 (2)(B).
[733] Ibid. Rule 30.
[734] Ibid.
[735] The Drugs and Cosmetics Act. April 10, 1940. The Second Schedule of the Act describes the standards to be complied with by imported drugs and by drugs manufactured for sale, sold, stocked, or exhibited for sale or distributed, specifically vaccines, must comply with the standards maintained at the International Laboratory for Biological Standards, Stantans Serum Institute, Copenhagen and at the Central Veterinary Laboratory, Way bride Surrey, U.K. and such other laboratories recognized by the WHO from time to time, and such further standards of strength, quality and purity, as may be prescribed.
[736] The Drugs and Cosmetics Rules. December 21, 1945.

government actors such as government analysts and inspectors under various provisions.

467. The New Drugs and Clinical Trial Rules provide that a clinical trial shall only be initiated after obtaining permission to conduct clinical trials by the Central Licensing Authority and approval from the respective Ethics Committee.[737] Such an Ethics Committee that is formed for a clinical trial applies for registration to the Central Licensing Authority.[738] Further, the results of the clinical trials shall be reported in compliance with the protocols and the Good Clinical Practice Guidelines.[739]

468. The ICMR also provides for ethical guidelines that have to be followed for conducting clinical trials of drugs and other inventions.[740]

469. These guidelines also discuss the importance of an Ethics Committee during humanitarian emergency situations. The Ethics Committee could be helpful in pre-emptive research preparation for future humanitarian emergencies, in informed consent requirements for potential research participants, privacy and confidentiality of the individuals and communities.[741]

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[737] The New Drugs and Clinical Trial Rules. Second Schedule, Rule 19. An "Ethics Committee" has been defined as a committee that has minimum seven members from medical, non-medical, scientific, and non-scientific areas with at least one lay person, one woman member, one legal expert and one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian. The constitution of such an Ethics Committee for Clinical Trial, Bioavailability and Bioequivalence study, has been explained in further detail under Rule 7 of the Rules.

[738] Ibid. Rule 6.

[739] Ibid. The Central Drugs Standard Control Organization has formulated the Good Clinical Practice Guidelines, which have been adopted by the Drugs Technical Advisory Board. See Government of India. Ministry of Health and Family Welfare. Central Drugs Standard Control Organization. Good Clinical Practices for Clinical Research in India. URL: http://www.sgpgi.ac.in/sop/GCP-%20Indian.pdf (the date of access: April 14, 2021).

[740] Indian Council of Medical Research. National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. October, 2017. URL: https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf (date of access: April 14, 2021). These guidelines provide for ensuring the risks and benefits even before the trial begins; clinical development of a new drug, its dose range, and different phases, steps involved in every phase, ethical considerations that have to be complied with.

[741] Ibid. Section 12.

Vaccine authorization

470. The CDSCO is the Indian national regulatory authority in charge of the marketing authorization of vaccines. The Drugs and Cosmetics Act of 1940 establishes the standard of quality to vaccines that are used in India.[742]

471. The CDSCO may only grant the license if it is satisfied that the applicant fulfills all the requirements and quality standards imposed by law.[743] The Act also establishes the procedure of application as well as provides for the list of required documents.[744]

Emergency use authorization

472. The Indian regulatory framework does not provide for a possibility of issuing an emergency use authorization for a vaccine. The terms "emergency use" or "restricted use" have not been defined under Indian laws.[745] Neither is there a provision for such "emergency use authorization". However, in the current pandemic, the CDSCO allowed applications "for approval of COVID-19 vaccines for restricted and emergency use."[746] The only provision that may be related to these approvals could be Section 2 of the Second Schedule of the New Drugs and Clinical Trial Rules, which discusses the accelerated approval process of a new drug.

Vaccine patent protection

473. The Indian Patent Act of 1970 is applicable for obtaining patents for vaccines.[747] It must be noted that the Indian Patent Act does not use the term "vaccine". An application for a patent may be made by any person who claims to be the true and first

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[742] The Drugs and Cosmetics Act. April 10, 1940. Rule 68.
[743] Ibid. Rules. 68–69.
[744] Ibid. Rule 69.
[745] The Indian Express. Explained: What is emergency use authorization firms are seeking for Covid-19 vaccines? December 10, 2020. URL: https://indianexpress.com/article/explained/covid-19-vaccine-emergency-use-authorisation-explained-7074852/ (the date of access: April 14, 2021).
[746] Government of India. Directorate General of Health Services. Central Drugs Standard Control Organization. Guidance for approval COVID-19 Vaccines in India for restricted use in emergency situation which are already approved for restricted use by US FDA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL). No. X-11026/07/2020-PRO. April 15, 2021. P. 2. URL: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/notice15april21.pdf (the date of access: April 30, 2021).
[747] Intellectual Property of India. The Patents Act of 1970. URL: https://ipindia.gov.in/writereaddata/Portal/IPOAct/1_31_1_patent-act-1970-11march2015.pdf (the date of access: April 11, 2021).

inventor of the invention.[748] An "invention" has been defined as a new product or process involving an inventive step and capable of industrial application.

474. The process of obtaining a patent involves an application by the true inventor and should be filed in the prescribed format at the Patent Office. The patent application must be accompanied by a provisional specification if a complete specification is not filed.[749] In such a case, a complete specification must be filed within 12 months from the date of filing of the application else the patent application is deemed to be abandoned.[750] Thereafter the Publication of Patent Application occurs in the Patent Journal issued by the Patents Office.[751] The patent application is not open to the public for 18 months from the date of filing of the application or date of priority of the application, whichever is earlier.

475. A request for examination of the patent application must be made by the applicant within 48 months from the date of priority of the application or the date of filing of the application, whichever is earlier.[752]

476. Thereafter, an examination of the patent application is made by the Patent Office.[753] After examination, a first examination report is issued by the Patent office. The Applicant must respond to the First Examination Report within six months. Once the patent applicant has responded to all the objections raised by the first examination Report, then the Controller of the Patents office, can either issue a hearing for further clarification or may grant a patent and publish it in the official journal of the Patent Office. A patent is granted for a period of 20 years.[754]

477. When the patent application has been published but the patent has not yet been granted, any person may oppose the grant of a patent to such a patent application.[755]

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[748] Ibid. Section 6.

[749] Ibid. The provisional specification and the complete specification are terms not defined under the Act. However, Section 10 of the Patents Act 1970 provides the contents of both the specifications. In practice, the provisional specification reveals the invention for which the patent is sought without the claims of a patent. This helps in getting a priority date for the patent. A complete specification describes the complete invention along with the patent claims.

[750] Ibid. Section 9.

[751] Ibid. Section 11A. It describes the publication of applications, read with Rule 24 of the Patents Rules of 2003. See Intellectual Property of India. The Patents Rules of 2003. URL- https://ipindia.gov.in/writereaddata/Portal/IPORule/1_70_1_The_Patents_Rules_2003_-_Updated_till_1st_Dec_2017-_with_all_Forms.pdf (the date of access: April 14, 2021).

[752] Ibid. Rule 24B.

[753] The Patents Act of 1970. Section 12.

[754] Ibid. Section 53.

[755] Ibid. Section 25 (1).

Further, after the grant of a patent and before the expiry of one year from the date of grant of a patent, any person may file a post-grant opposition of the patent.[756]

478. The Patents Act of India provides that under special provisions for compulsory licenses which may be issued if the Central Government is satisfied that a national emergency or an extreme urgency has arisen, then the Central Government may grant a compulsory license.[757]

479. In the current pandemic, a number of developing countries, including India, are supporting a temporary waiver of patent obligations under the TRIPS for the COVID-19 vaccines so that countries can ensure their citizens access to the COVID-19 vaccines in a timely manner by producing a generic version of the treatments and vaccines. However, the member nations of TRIPS have opposed such waiver as the TRIPS already has such protocols in the form of compulsory licensing.

b. Legal Framework for the COVID-19 Vaccine Development

480. The CDSCO granted emergency approvals for two vaccines during the COVID-19 pandemic.[758] CDSCO's approval was given on the basis of a recommendation by a Subject Expert Committee of Technical Experts for Covishield and Covaxin for Restricted Use in Emergency Situation subject to certain regulatory conditions. The third approval has been granted to Sputnik V. Earlier in June of 2020, such emergency approvals were granted to Remdesivir and Favipiravir.

481. Moreover, the CDSCO decided to follow the recommendation of the National Expert Group on Vaccine Administration for COVID-19 to grant Emergency Approval for COVID-19 vaccines in India, which have been "granted emergency approval for restricted use by the US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency

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[756] Ibid. Section 25 (2).

[757] Ibid. Section 12. Such licences may be granted under Section 92 of the Patents Act of 1970. The related sections, namely Section 92A and Section 100(6), discuss the availability of compulsory license for manufacture and export of patented pharmaceutical products to countries that do not have manufacturing capacity, and that the Central Government has the right to sell on a non-commercial basis or in cases of national emergency or in circumstances of extreme urgency. Section 102 provides that the Central Government may acquire a patent from the applicant or the patentee for a public purpose.

[758] Drugs Controller General of India. The official notice "Approval of Favipiravir Tablets to Glenmark Pharmaceuticals and Remdesivir Injection to Cipla Ltd, Hetero Drugsand Mylan Labs". July 2, 2020. URL: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjIxMw (the date of access: April 14, 2021). The CDSCO granted Emergency Use of Remdesivir and Favipiravir in the month of July 2020 to deal with severe COVID-19 infection.

Use Listing."[759] This decision is subject to the following conditions: first, the vaccine shall be used in accordance with the guidelines prescribed under the National COVID-19 Vaccination Programme, second, first 100 beneficiaries of such vaccines shall be assessed for seven days for safety outcomes before it is rolled out for further Vaccination program, third, the applicant shall initiate conduct of post-approval bridging clinical trials within 30 days of such approval. The Notice of the CDSCO also prescribes the procedure for applications.[760]

482. The Public Relation Office of the CDSCO issued a notice that in order to encourage research and development of vaccines for prevention or treatment of COVID-19, any application submitted to CDSCO will be processed on high priority.[761]

483. To facilitate the COVID-19 vaccines development, a guidance note was issued for the COVID-19 Vaccines Rapid Regulatory Pathways, where the preclinical, as well as clinical data generated outside India, was to be considered and examined based on scientific rationale and level of completeness of data in human trials.[762]

484. The Draft Guidelines for the Development of vaccines with special consideration for COVID-19 vaccines provide guidance to vaccine developers to ensure that adequate clinical data to establish safety and protective immunity are generated, consistency of production is essential and the demonstrated product does not differ from the bulk lot, development of appropriate laboratory methods to characterize a vaccine formulation

[759] Guidance for approval COVID-19 Vaccines in India for restricted use in emergency situation which are already approved for restricted use by US FDA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL). P. 1.
[760] Ibid. P. 2.
[761] Ministry of Health and Family Welfare of India. Central Drugs Standard Control Organization. Public notice. December 19, 2020. URL: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTc2OQ (the date of access: April 14, 2021).
[762] Ministry of Health and Family Welfare of India. Central Drugs Standard Control Organization. Office Memorandum. Rapid Response Regulatory Framework for COVID-19 Vaccine development. May 26, 2020. URL:https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTk1NA== (the date of access: April 14, 2021).

with respect to its components, as well as its safety and potency is a prerequisite to the clinical use of new or novel vaccines including a vaccine against COVID-19.[763]

485. The Rapid Response Regulatory Framework for COVID-19 provides for the applications that have been submitted in relation to the development of vaccines, diagnostics, prophylactics, and therapeutics, will be dealt with in a fast-track manner. The time taken for the regulatory approvals process to deal with applications for the development of vaccines, diagnostics, prophylactics, and therapeutics for COVID-19 was fast-tracked, and such approvals were to be given within 7–10 days of submission of applications.[764]

7.2. Legal Regulation of Immunoprophylaxis

a. General Legal Framework

General information

486. The Vaccination Act of 1880 "gives the power to prohibit inoculation and to make the vaccination of children compulsory in certain municipalities and cantonments."[765] The Immunization Program was introduced in 1978 as the Expanded Program of Immunization, under which the Government of India provides vaccination to prevent seven vaccine-preventable diseases in children.[766] There is no information provided if the universal vaccination is mandatory or not, and there is a lot of debate around this topic on whether it should be mandatory. In a vaccination drive for Measles and Rubella

[763] Ministry of Health and Family Welfare of India. Central Drugs Standard Control Organization. Notice on Draft regulatory guidelines for the development of vaccines with special consideration for COVID-19 vaccines. September 21, 2020. URL: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjQ5OQ (the date of access: April 14, 2021); The Draft Regulatory Guidelines for Development of Vaccines with special Consideration for COVID-19 vaccine. September 21, 2020. URL: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/Regulatory_guidelines_for__development_of_Vaccine_20.9.20.pdf (the date of access: April 14, 2021).

[764] Government of India. Ministry of Science and Technology. Department of Biotechnology. The public notice "Rapid Response Regulatory Framework for COVID-19 for development of vaccines". March 20, 2020. URL: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTc4Mw (the date of access: April 14, 2021).

[765] Central Government Act. The Vaccination Act No. 13. July 9, 1880. Preamble. URL: http://lexsunraj.com/wp-content/uploads/2019/03/The-Vaccination-Act-1880.pdf (the date of access: April 14, 2021).

[766] For more information about the immunization programme in India see Ministry of Health and Family Welfare of India. National Health Mission. Immunization. URL: http://www.nrhmhp.gov.in/content/immunisation (the date of access: April 14, 2021); National Health Portal of India. Universal Immunisation Programme. URL: https://www.nhp.gov.in/universal-immunisation-programme_pg (the date of access: April 14, 2021).

vaccine by the Delhi Government, the Delhi High Court in 2019 in a case said that vaccination cannot be forced on children, and parents' consent is required.

Nature of vaccination

487. Under the Epidemic Diseases Act of 1897, the State Government may take measures under the Act by means of various ordinances, notices that may be issued from time to time if the prevalent and ordinary provisions of law do not suffice to cover the situation of an epidemic or a dangerous disease.[767] The Act also discusses the penalty that may be applicable to any person who refuses or disobeys any law or ordinance that is passed in consonance with the Act, such an act of disobedience is considered a criminal offense under the Indian Penal Code.[768]

488. The Section 2A of the Epidemic Diseases Act of 1897, was substituted by the Epidemic Disease (Amendment) Ordinance of 2020, to mean that the Central Government's power to take measures where it is satisfied that India or any part thereof is threatened with an outbreak of any dangerous epidemic disease will include inspection of any bus or public transport or ship, vessel as may be necessary during an epidemic, to prevent the outbreak of such disease or its spread in India.[769]

489. The National Disaster Management Act of 2005 stipulates that compulsory vaccination may be covered under the head of "disaster management" where disaster includes a catastrophe or a situation that may arise due to natural or human-made causes leading to substantial loss of human life or human suffering.[770]

Domestic vaccination process

490. The National Vaccine Policy of 2011 mostly focuses on the vaccination of children.[771] Under the Universal Immunization Program, the timing and age for

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[767] The Epidemic Diseases Act No. 3. February 4, 1897. Section 2. URL: https://legislative.gov.in/sites/default/files/A1897-03.pdf (the date of access: April 14, 2021).

[768] Indian Penal Code. Act No. 45. October 6, 1860. Section 188. URL: https://www.indiacode.nic.in/bitstream/123456789/2263/1/AAAA1860___45.pdf (the date of access: April 14, 2021).

[769] Ministry of Law and Justice. The Epidemic Disease (Amendment) Ordinance No. 5. April 22, 2020. URL: http://egazette.nic.in/WriteReadData/2020/219108.pdf (the date of access: April 14, 2021). See also Ministry of Home Affairs. Order No. 40-3/2020-DM-I(A). March 23, 2021. URL: https://www.mha.gov.in/sites/default/files/MHAOrder_23032021.pdf (the date of access: April 19, 2021).

[770] National Disaster Management Act No. 53. December 23, 2005. Section 2(e). URL: https://legislative.gov.in/sites/default/files/A2005-53.pdf (the date of access: April 19, 2021).

[771] Government of India. Ministry of Health and Family Welfare. The National Vaccine Policy. April 2011. URL: https://main.mohfw.gov.in/sites/default/files/108481119000.pdf (the date of access: April 14, 2021).

vaccination given to children is specified. No specific rules are found for the organization of the vaccination process or vaccination sites.[772]

491. There is no consolidated law that can provide the information on this basis. Anyone willing to get vaccinated can go to a hospital and on the basis of their childhood vaccinations, will get vaccines. However, this is based on various articles published, and not on the basis of a consolidated law. The vaccination process varies from region to region.[773]

Liability for the harm caused by a vaccine

492. Under the Drugs and Cosmetics Act of 1940, every person who is responsible to the company for the conduct of the business of the company, as well as the company will be held liable for any offense committed under this Act.[774] The offenses under the Act are related to the import of a drug, i.e., if the quality is compromised or the standards require for import are not met or requisite licenses have not been acquired, and not with respect to harm caused to an individual.[775]

493. Under the New Drugs and Clinical Trial Rules, compensation may be provided in the event of injury, death, or permanent disability while conducting clinical trials, by the company or institution that initiated the clinical trial.[776]

b. Special Case of COVID-19 Vaccination

494. The COVID-19 Vaccines Operational Guidelines, issued by the Ministry of Health and Family Welfare, provide that the State and District Administrations will create a database of the health facilities under various heads of the state departments, for the creation of vaccinators and supervisor databases, for creation of session sites which will include the traditional routine immunization sites as well as additional outreach session sites.[777] Under these Guidelines, an individual may themselves register for getting vaccinated through the link provided on the Co-Win website. This website has been set

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[772] Government of India. Ministry of Health and Family Welfare. The Universal Immunization Program. URL: https://main.mohfw.gov.in/sites/default/files/5628564789562315.pdf (the date of access: April 14, 2021).
[773] Guidelines for vaccination in normal adults in India. April 26, 2016. URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4928530/ (the date of access: April 19, 2021).
[774] The Drugs and Cosmetics Act. April 10, 1940. Section 34.
[775] Ibid. Section 13.
[776] The New Drugs and Clinical Trial Rules. Rules 39–41.
[777] Government of India. Ministry of Health and Family Welfare. COVID-19 Vaccines Operational Guidelines. December 28, 2020.

up to tackle vaccine requirements as well as self-registration vaccine links.[778] Currently, the government has identified COVID-19 centers such as hospitals where vaccines are being administered.

495. The Guidelines also discuss that the first phase of vaccines will be provided to health care workers, frontline workers, people who are 50 and more years old (this category is divided into people who are between 50 and 60 years old and over 60), and people who are less than 50 years old with co-morbidities like diabetes, hypertension, cancer, lung disease, etc. The prioritization of groups will depend upon the disease incidence and prevailing pandemic situation.[779]

496. Vaccination certificates will be provided to all beneficiaries who have been successfully vaccinated.[780] Such vaccine certificates will help in establishing that an individual has been vaccinated. Such certificates are generated by the vaccination centers. These certificates are available online as well on the website set up by the Government.[781] These certificates are only provided after vaccination has been done. These certificates also show the date of vaccination and the number of doses that have been administered. Benefits like that of bypassing quarantine restrictions, domestic and international air travel may become easier for people who can show these vaccination certificates.[782]

497. The Government's purchase order to vaccine manufacturers clearly specifies that such companies will be liable for the vaccines. There is no official source of this information, other than newspaper reports.[783]

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[778] The Co-win website set up by the Government of India for Covid-19 vaccination. URL: https://www.cowin.gov.in/home (the date of access: April 14, 2021).

[779] Government of India. Ministry of Health and Family Welfare. COVID-19 Vaccines Operational Guidelines. December 28, 2020. Part 7.1.

[780] Government of India. Ministry of Health and Family Welfare. COVID-19 Vaccines Operational Guidelines. December 28, 2020. P. 34, 78. URL: https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf (the date of access: April 19, 2021).

[781] Frequently asked questions on Co-Win. URL: https://www.mohfw.gov.in/pdf/FAQCoWINforcitizens.pdf (the date of access: April 14, 2021).

[782] See, e.g., India.Com. Corona Passport: All You Need to Know About Vaccine Travel Pass, Benefits and Concerns. March 16, 2021. URL: https://www.india.com/travel/articles/corona-passport-all-you-need-to-know-about-vaccine-travel-pass-benefits-and-concerns-4494830/ (the date of access: April 19, 2021).

[783] The Economic Times. Bharat Biotech to pay compensation if Covaxin causes side effects. January 16, 2021. https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/bharat-biotech-to-pay-compensation-if-covaxin-causes-side-effects/articleshow/80301175.cms?from=mdr (the date of access: April 14, 2021).

7.3. Legal Regulation of Vaccine Export and Import

a. General legal framework

Conditions for export of vaccine to third countries

498. The Drugs and Cosmetics Rules of 1945 provide that labels on packages or containers of drugs for export shall be adapted to meet the specific requirements of the law of the country to which the drug is to be exported but certain particulars shall appear in a conspicuous position on the innermost container in which the drug is packed and every other covering in which that container is packed.[784]

499. Further, the Rules provide that export consignments shall be accompanied by requisite import license from the importing country and a no objection certificate from the Drugs Controller of India that is the Central Licensing Authority in India. No objection certificate shall also be obtained from the Narcotics Commission of India for the export of each consignment of a drug. The State Licensing Authority issues the manufacturing licenses for the formulation on each export order on the basis of no objection certificate received from the Drugs Controller of India.[785]

500. The CDSCO *inter alia* regulates the import and export of drugs in India through various notifications.[786]

Conditions for import of vaccine from third countries

501. The Drugs and Cosmetics Act of 1940 gives the Central Government power to prohibit the import of certain drugs in public interest.[787]

502. Under the Drugs and Cosmetics Rules of 1945, certain restrictions have been placed on the kind of drugs that may be imported, the standard quality of the drug that has to be maintained along with other requirements was established.[788]

503. Under the New Drugs and Clinical Trial Rules, any import of a new drug or any substance related to clinical trials may be imported only after obtaining a license from

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[784] Government of India. Ministry of Health and Family Welfare. The Drugs and Cosmetics Act No. 23 of 1940. As amended up to the December 31, 2016. Rule 94.
[785] Ibid. Rule 94.
[786] Government of India. Ministry of Health and Family Welfare. The Drugs and Cosmetics Act No. 23 of 1940. As amended up to the December 31, 2016. Parts IV, IX.
[787] Ibid. Sections 10A, Section 12(2)(f).
[788] The Drugs and Cosmetics Rules. December 21, 1945. Rule 94. See also Rules 30, 30AA, 30B.

the Central Licensing Authority.[789] An application for import of a new drug for sale or to undertake clinical trials under the New Drugs and Clinical Trial Rules must be made to the Central Licensing Authority.[790]

504. Under the Patents Act of 1970, the Central government can import any medicine, drug for the purpose merely of its own use or for distribution in any dispensary, hospital, or another medical institution maintained by or on behalf of the Government for public service.[791]

b. Special Case of COVID-19 Vaccines Export and Import

505. In the Public Notice by the Central Drug Standard Control Organization dated September 17, 2020, an importer of a COVID-19 vaccine is required to comply with the mandatory requirements of import license or the no objection Certificates under the Drugs and Cosmetics Act of 1940. Online clearance of applications was provided for ease of business during the pandemic for each importer to comply with the condition required for the import license or the no objection Certificates issued under the said Drugs and Cosmetics Act of 1940.[792]

506. Further, an amendment to the Courier Imports and Exports Regulations has been made on December 30, 2020, to facilitate the export of vaccines from India to other nations without any value limitation.[793]

507. A list of vaccines supplied to various countries and the number of vaccines supplied is being updated on the Ministry of External Affairs website.[794]

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[789] The New Drugs and Clinical Trial Rules. Sections 67–68, 70.
[790] Ibid. Footnote 72.
[791] The Patents Act of 1970. Section 102.
[792] Government of India. Directorate General of Health Services. Central Drugs Standard Control Organization (Import and Registration Division). Documents required for the import. September 17, 2020. URL: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjQ5Ng (the date of access: April 14, 2021).
[793] Government of India. Ministry of Finance. Department of Revenue (Central Board of Indirect Taxes and Customs). Notification No. 115/2020-Customs (N.T.). December 30, 2020. URL: https://www.indiantradeportal.in/uploads/General%20Documents/NU_SPS-TBT/31-12-2020/csnt115-2020.pdf (the date of access: April 14, 2021).
[794] Government of India. Ministry of External Affairs. Vaccine Supply. URL: https://www.mea.gov.in/vaccine-supply.htm (the date of access: April 14, 2021). The numbers in the table define the number of vaccines (quantity is given in lakhs) that has been either granted or commercially sold to nations. The formula to convert Lakh to Million is 1 Lakh = 0.1 Million.