Russian Journal of World Politics and Law of Nations. 2022. 1(4). P. 77–92
DOI 10.24833/RJWPLN-2022-4-77-92 Research Article

The Rise of International Health Law[1]

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Abstract. In recent decades, demographic processes, economic shocks, increased morbidity and other systemic problems have led to the gradual appearance at the international level of a whole spectrum of threats to health, characterized by severe socio-economic consequences for each country regardless of the welfare level. Today, the challenges of ensuring universal coverage of services, access to safe, high-quality medicines, affordable healthcare, effective response to health emergencies, and antibiotic resistance are not limited to WHO regulations, but are included in the agendas of the United Nations, the International Labour Organization (ILO), the Food and Agriculture Organization (FAO) and other intergovernmental organizations. The need to form a unified approach to regulate the activities of numerous participants in international healthcare regulation has served as an incentive for the gradual development of international legal regulation of the field of health protection, becoming the subject of study of leading legal scholars, as well as international organizations. The present article provides a comprehensive analysis of the main historical stages in the development of international cooperation in the field of health protection, which served as the basis for the formation of international health law in the field of health protection as a new branch of international law. Special attention is paid to the assessment of the role of globalization processes in changing the nature of threats to human and public health and their impact on the formation of the concept of global health governance. Based on the systemic problems that emerged during the COVID-19 pandemic, the author formulates the main areas for improvement in the international legal regulation of the health sector.

The research portion involved studying the following documents: acts of a universal and regional nature; resolutions of international organizations; and the legal positions of UN Specialized Agencies, as well as of professional scientific associations. The theoretical basis of the research is the scientific works of Russian and foreign experts in international law and international relations in the field of health protection. The article was prepared using the general scientific method of cognition, including the formal logical and situational method and private law methods, such as comparative, historical and formal legal methods.

The paper formulates a conclusion about the creation of "international health law" as a new branch of international law, uniting international legal norms and principles governing the relations of subjects of international law, as well as other participants in

1 English translation from the Russian Text: Malichenko V.S. 2021. Formirovanie mezhdunarodnogo prava zdravookhraneniia. *Moskovskii Zhurnal Mezhdunarodnogo Prava [Moscow Journal of International Law]*. No. 4. P. 6-20. https://doi.org/10.24833/0869-0049-2021-4-6-20.

international relations in the field of human health. In the work, the author presents the main sources of "international health law" and formulates the subject of regulation of this branch of law.
Describing the features of international cooperation in the field of health protection, expressed in an increase in the number of involved international organizations and other participants who are not subjects of international law, the author substantiates the formation of the concept of global health management and analyzes the main scientific publications in this area. Having studied the nature of health threats that have formed over the past decade under the influence of globalization processes, as well as the systematic problems of international cooperation demonstrated by the coronavirus pandemic, the authors emphasize the need to implement the repeatedly proposed initiative to develop a universal act that forms the basis of international legal regulation of health protection.

Keywords: right to health, international law, health law, global health governance, human security, public health emergency of international concern, soft law, WHO.

Historical stages in the development of international cooperation in healthcare

The first mention of cooperation between states to counter threats to health is associated with initiatives to combat infectious diseases, which spread rapidly across Europe as a result of trade developments (Malichenko 2021: 174–197). For example, in 1348, Venice passed the first law establishing quarantine measures to contain the spread of the bubonic plague. The first semblance of an international health organization emerged in 1838 with the establishment of the Superior Health Council in Constantinople, formed by Ottoman Empire officials and the heads of maritime states to oversee sanitary regulation of Turkish ports.

Yet the first formal interstate dialogue on human health issues at the international level was only held in 1851, during the First International Sanitary Conference in Paris, which was aimed at developing a unified strategy to control the spread of cholera, plague and yellow fever that had hit Europe. The International Sanitary Convention was adopted in 1882, following the most recent International Sanitary Conference. The document sets out measures to prevent the spread of cholera and, as such, it was the first international legal instrument regulating health matters.

The history of international cooperation in healthcare, from the First International Sanitary Conference to the present day, can be divided into four stages, each having a significant impact on the development of international legal regulation in this field. The first phase, from the first Sanitary Conference to the establishment of the Health Organisation of the League of Nations, involved the establishment of standards and regulations to ensure the control and prevention of the spread of infectious diseases. In the second phase, between the First and Second World Wars, the main focus of international cooperation was on the creation of an effective mechanism to regulate

certain health issues within the framework of the League of Nations. The third phase of international cooperation, in the post-war period, saw the establishment of WHO to forge a unified approach to the regulation of health issues on the international agenda, taking into account the problems faced by states in the League of Nations era.

The modern stage of international cooperation in healthcare began in 1970, influenced by the explosive growth of health regulators and the increasing complexity involved in coordinating their activities, which prompted a rethinking of the role played by international law.

Shaping the concept of international health law

Historically, much of the focus of international cooperation in healthcare was on infectious diseases, and international law was shaped by advances in the science of public health. Under the influence of renowned scientists such as Rudolf Virchow, Louis Pasteur, Edwin Chadwick, Lemuel Shattuck and Robert Koch, four fundamental principles of public health science were formed in the 19th century: development of rules of conduct based on scientific data and static research; priority of public health over individual interests; equity and social justice; priority of preventive measures. According to one of the most comprehensive definitions, "public health is the science and the art of preventing disease, prolonging life, and promoting physical health and efficiency through organized community efforts for the sanitation of the environment, the control of community infections, the education of the individual in principles of personal hygiene, the organization of medical and nursing service for the early diagnosis and preventive treatment of disease" (Winslow 1920: 23–33).

Despite the fact that international legal norms in the sphere of regulating human health issues have been developing for more than a century, the concept of "international health law" or "international law in the field of healthcare" was first mentioned in scientific literature in the 1950s, in the context of protecting the social rights of those who suffered during military conflicts. The recognition of the new emerging mechanisms for health regulation at the international level made it possible, at the initiative of the Belgian government, to propose a study of "international medical law" in 1953, through WHO Resolution WHA6.40.[2]

The round table "The Future of International Health Law," which was held in 1988 to mark the 40th anniversary of the WHO, was instrumental in shaping the concept of international health law and its recognition as a branch of international law. The keynote speakers at the event were Prof. Valentin Mikhailov and Prof. Michel Bélanger (Bélanger 1989: 1–8). In particular, Valentin Mikhailov argued that "international health law constitutes a branch of public international law, and is rapidly evolving and

[2] Preparatory Study on International Medical Law. *World Health Organization*. URL: https://apps.who.int/iris/bitstream/handle/10665/85647/Official_record48_eng.pdf?sequence=1&isAllowed=y (accessed August 19, 2021).

encompassing a vast range of subjects" (Mihajlov 1989: 9–28). This branch of law has been formed by international legal mechanisms governing inter-governmental relations on health issues, both in peacetime and during armed conflicts. Furthermore, as part of his position, Mikhailov clarifies the usage of the term "international medical law," rightly noting that "international health law" is a more appropriate designation as it "more accurately reflects the content of the legal principles of this branch." In turn, Michel Bélanger pointed out in his report that the general objective of international health law is "to support, guide and coordinate national health law."

At the turn of the century, comprehensive studies examining international health law as an independent branch of international law have increasingly appeared in the academic literature. In particular, the preconditions and main components of its formation are analysed in detail in an article by Brigit Toebes (Toebes 2015: 299–328). For his part, Allyn Taylor elaborated that international health law included "aspects of biomedical science, human reproduction and cloning, disability, infectious and non-communicable disease, and safety control for health services, foods and pharmaceuticals" (Taylor et al. 2004: 359–386). Interest on the part of scientific community in studying the influence of international legal norms on the regulation of various issues in the sphere of healthcare made it possible to not only build the necessary foundation for theoretical research in order to foster a new focus of academic research, but also to identify promising areas for its development in the years to come.

Health issues on the agendas of international organizations

The vector of international cooperation in healthcare has changed since the International Conference on Primary Health Care held in 1978 in Almaty (then called Alma-Ata) and the official announcement by WHO in 1980 that smallpox had been eradicated from the planet. A shift has taken place from the efforts to control specific infectious diseases and address the short-term challenges associated with the introduction of necessary containment measures and the provision of drugs and medical devices towards longer-term strategies aimed at fundamentally changing approaches to healthcare delivery to ensure universal healthcare coverage. Under the influence of globalization processes, the need for a broader approach has gradually evolved, assuming an impact on the main determinants of health: nutrition, ecology, leading a healthy lifestyle, etc. The WHO's commitment to soft-law instruments, as well as its inadequate funding and complex operating model have gradually placed a number of health issues on the agenda of the UN General Assembly (UNGA) and other international and regional organizations.

The leading role of the United Nations in coordinating global initiatives and creating effective mechanisms for their regulation is largely responsible for reducing mortality from HIV/AIDS, tuberculosis and malaria. A vivid example of these changes is the establishment of the Joint United Nations Programme on HIV/AIDS (UNAIDS) in

1994, as well as the adoption of the Millennium Development Goals (MDGs)[3] and the subsequent elaboration of the Sustainable Development Goals,[4] with a particular focus on health-related targets. The issue of universal health coverage has been further elaborated in a number of UNGA resolutions. In particular, access to health technologies has been addressed in resolutions on the global health and foreign policy nexus, which have been adopted regularly since 2009.[5] The 2019 Political Declaration of the High-level Meeting on Universal Health Coverage pays particular attention to the problem of access to health technologies.[6] Specifically, the UNGA sets out a commitment to universal access to health services by 2030.

The 1992 Convention on Biological Diversity, under the United Nations Environment Programme,[7] and the 2010 Nagoya Protocol on Access and Benefit-Sharing[8] are two more important universal instruments for promoting scientific capacity and fostering the development of health technologies. These conventions establish the right of access to genetic resources, which forms the basis for research, health technology development and the development of the food industry.

Access to safe food is an important health issue and an area of cooperation between WHO and the Food and Agriculture Organization of the United Nations (FAO). In particular, the Codex Alimentarius Commission, set up jointly by WHO and FAO to develop international standards for food quality assurance, has been in operation for more than half a century. It is equally important to ensure that antibiotic therapy is used in agriculture to prevent the development of antimicrobial resistance.

The concept of universal health coverage implies that everyone should have access to essential health technologies. Among the main barriers to accessibility are rules establishing certain requirements to protect the exclusive rights of technology developers, which allow them to set prices for products that often exceed the economic power of states. International organizations are instrumental in finding a consensus between the interests of governments and manufacturers within the framework of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and regional trade agreements that set out additional requirements for the protection

[3] United Nations Millennium Declaration. *United Nations.* 2000. URL: https://www.un.org/ru/documents/decl_conv/declarations/summitdecl.shtml (accessed August 19, 2021).

[4] Transforming our World: The 2030 Agenda for Sustainable Development. *United Nations.* URL: https://undocs.org/ru/A/RES/70/1 (accessed August 19, 2021).

[5] Resolution adopted by the General Assembly on 12 December 2012 "Global Health and Foreign Policy". *United Nations.* URL: https://undocs.org/A/RES/67/81 (accessed August 19, 2021); Resolution adopted by the General Assembly on 11 December 2014 "Global Health and Foreign Policy". United Nations. URL: https://undocs.org/en/A/RES/69/132 (accessed August 19, 2021).

[6] Resolution adopted by the General Assembly on 10 October 2019 "Political Declaration of the High-Level Meeting on Universal Health Coverage". *United Nations.* URL: https://undocs.org/en/A/RES/74/2 (accessed August 19, 2021).

[7] Convention on Biological Diversity. 1992. URL: https://www.cbd.int/doc/legal/cbd-en.pdf/ (accessed August 19, 2021).

[8] The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity. 2010. URL: https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf (accessed September 1, 2022).

of the exclusive rights of pharmaceutical and medical industry manufacturers. In particular, the role of international law in ensuring access to health technologies is the subject of a joint study by WHO, WTO and WIPO.[9]

This list of issues included on the agendas of international organizations is not exhaustive, but it demonstrates the increasing role of health in the development of international cooperation and the need for effective coordination of all actors involved and for better standard-setting processes.

Global health governance

The rapid expansion of health issues on the international agenda, as well as their significant impact on sustainable development goals and the socio-economic well-being of countries, underpins the concept of "global health," which has gradually replaced "international health" in international documents and scientific publications. Between 2005 and 2010, a significant number of studies were published that highlighted the complex relationship between globalization processes and population health indicators, which has implications for strengthening public health regulation (Huynen, Martens, Hilderink H. 2005: 1–12; Martens et al. 2010: 1–14).

The concept of "global health" implies the provision of public health by regulating the interrelations and interdependencies of international actors under the influence of globalization processes. The word "global" in the context of health regulation has been used since the middle of the last century. Examples here include the Global Malaria Programme launched by the WHO in the mid-1950s, the 1958 pamphlet of the WHO Public Relations Committee "The World Health Organization: Its Global Battle Against Disease" (Deutsch 1958), the 1971 US House of Representatives report "The Politics of Global Health,"[10] and many studies on global population problems. As early as 1989, for example, George Gellert pointed out that "the traditional and historic bases for differentiating domestic and international health in Western nations have […] lost meaning" (Gellert 1989: 421– 424). The profound impact of globalization on public health was addressed in a special issue of the 2001 WHO Bulletin[11] and a number of other publications from the early 2000s (Walt 1998: 434–437; Taylor, Bettcher 2001: 920–929; Bettcher, Yach 2000: 521–534; Yach, Bettcher 1998: 738–741; McMichael, Beaglehole 2000: 577–582).

[9] Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade. *World Trade Organization.* 2013. URL: https://www.wto.org/english/res_e/booksp_e/who-wipo-wto_2020_e.pdf (accessed August 31, 2022).

[10] See: *The Politics of Global Health,* Prepared for the Subcommittee on National Security Policy and Scientific Developments of the Committee on Foreign Affairs, US House of Representatives. Washington, DC: US Government Printing Office. 1971.

[11] See: Theme Issue on Globalization. *Bulletin of the World Health Organization.* 2001. 79(9): 802–905. URL: https://www.ncbi.nlm.nih.gov/pmc/issues/173061/ (accessed August 19, 2021).

Threats and challenges to health associated with the globalization processes transcend national borders and require coordinated cross-sectoral collaboration. In such circumstances, international organizations that were set up to deal with specific issues in sectors such as the environment, labour relations, intellectual property, and health, are no longer able to "single-handedly" address the issues at hand.

The trend towards an increase in the number of organizations that are not subjects of international law and traditional actors in international relations, but which are involved in international health issues, has been clearly visible since the beginning of the 21st century, when it became clear that the ambitious objectives of the MDGs require a significant financial investment and institutional support. A recent publication on the subject has shown that some 203 different intergovernmental and non-governmental organizations are involved in health regulation (Hoffman, Cole 2018: 1–19). The need for effective coordination of all actors involved in the management of health processes has triggered the concept of global health governance, aimed at ensuring the more efficient allocation of resources to achieve global health goals.

Today, the following groups of actors in global health governance can be distinguished: states; international organizations within the United Nations system and other international organizations dealing with social issues as part of their respective agendas; and non-governmental organizations uniting many different structures that are not related to traditional subjects of international law (philanthropic organizations, public-private partnerships, non-profit organizations, scientific associations, and transnational corporations).

When studying the phenomenon of global health governance, one has to refer to the works that define the concept of "global governance." To date, the scientific literature has developed a variety of approaches to defining this notion (Weiss, Ramesh 2010: 448; Bjola, Kornprobst 2011: 320; Finkelstein 1995: 367–372).[12] In particular, Fyodor Martens uses the term "international governance," defined as a set of tasks and legal relations that transcend state borders (Martens 2014: 3–7). Thus, guided by current trends in international relations and the evolution of international legal mechanisms to regulate them, global governance should be understood as a set of formal and informal institutions, mechanisms, relations and processes between states, markets, citizens and organizations (both inter-governmental and non-governmental) with collective interests and clearly articulated rights and responsibilities.

The term "global health governance" first emerged in the academic literature in the late 1990s, describing a variety of governance arrangements that go beyond intergovernmental cooperation in health (Dodgson, Lee, Drager 2002: 1–28). A review study by Kelley Lee and Adam Kamradt-Scott analyses various publications on global health governance, demonstrating the significant differences in the definition of this concept, as well as the situations in which it applies (Lee, Kamradt-Scott 2014: 1–10).

[12] See also: Riazati S. A Closer Look. Professor Seeks Stronger UN. *Daily Bruin.* October 17, 2006. URL: http://dailybruin.com/2006/10/17/a-closer-look-professor-seeks/ (accessed August 21, 2021).

At the same time, referring to the research of the most renowned theorists in this field, one can identify the main characteristic features of the global health governance phenomenon. For example, David Fidler defined global health governance as the processes undertaken by states, international organizations and other international actors to respond to global health threats and challenges. Lawrence Gostin, a prominent researcher of global health governance, argued that the concepts of law and governance are interlinked as the law is the main aspect of governance and governance mechanisms can take the form of legal norms (Gostin 2014: 560). Based on the analysis of scientific publications, "global health governance" should be understood as processes aimed at ensuring the effective coordination of activities of all participants of international relations in healthcare, achieving the agreed global objectives, and preventing and counteracting health emergencies.

Definitions of the terms "international health law" and "global health law"

It is only logical that, under the influence of globalization and the concept of global health governance discussed above, the term "international health law" (or "international law in the field of health") has evolved in the academic literature into "global health law." The question arises whether the term "global law" should be used instead of "international law" in the field of health. The more traditional term "international" in defining health law is consistent with definitions used in relation to other branches of international law (Toebes 2015: 299–328). On the one hand, the term "global health law" potentially reflects the implications of globalization for health, including the growing role and influence of multiple actors in global health governance, bringing together binding and soft-law instruments adopted by international and regional intergovernmental organizations, as well as associations of other kinds. As Professor Jennifer Prah Ruger rightly points out, while international health law has a more traditional, rules-based approach to relations between states, global health law takes a more general approach, regulating the relations of the global community as a whole (Ruger 2008: 423). The professor has articulated the key differences between the concepts of "international health law" and "global health law." In her view, the former is a more traditional notion that relates to the interaction between subjects of international law, while the latter regulates relations between all possible subjects that have a direct or indirect impact on the regulation of health issues at the international level.

To date, there have been many fundamental studies on global health law, forming the background to the emergence of this branch of law and setting out the principles and characteristics of its application in the context of contemporary threats and challenges to human health (Gostin 2014: 560; Freeman, Hawkes, Bennett 2014: 635; Burci 2016). Lawrence Gostin and Allyn Taylor defined "global health law" as "a field that encompasses the legal norms, processes, and institutions needed to create the condi-

tions for people throughout the world to attain the highest possible level of physical and mental health." The norms of global health law are designed to ensure that all actors in international cooperation, including international bodies, the media, multinational corporations, charities and NGOs, have the right approach to regulating issues in this area. It should be noted that this approach goes beyond the traditional boundaries of formal sources and subjects of international law (Gostin, Taylor 2008: 53–63).

In support of the thesis that a new scientific field is emerging, it is worth noting that over the past decade, several expert groups have been formed to examine the distinctive features of global health law as a branch of international law. For example, in 2014, the International Law Association established the Global Health Law Committee to support the development of this distinctive area of international law and to identify common priorities for the development of international legal regulation in such areas as human rights protection, intellectual property protection, and trade and investment regulation. Public health regulation touches on many areas of law at subnational, national, regional and international levels. One of the Committee's main tasks, therefore, is to systematize the sources of the new branch of law by analysing and codifying the decisions of international organizations, international and national judicial bodies, and universal and regional instruments that directly or indirectly affect healthcare. At the Association's second conference in Sydney in 2018, the Committee recognized that global health law had established itself as a new branch of international law, despite the absence of clearly articulated regulatory principles.[13] The conference report stresses that global health law is not comparable to other branches of international law, where a substantial number of instruments of a universal nature have emerged with an agreed object and purpose.

As part of the evolution of global health law as an independent branch of international law, a joint Lancet–O'Neill Institute/Georgetown University Commission on Global Health and Law was set up in 2019 to prepare a report on the role of national and international law in confronting global health challenges (Gostin et al. 2019: 1857–1910).

Though scientific research generally tends to substantiate the concept of "global health law" based on the universally acknowledged theoretical principles of international law, we should conclude that international health law is emerging as a new branch of international law that unites international legal norms and principles regulating relations between the subjects of international law, as well as other participants of international relations in the field of human healthcare.

[13] Sydney Conference "Global Health Law". *International Law Association*. 2018. URL: https://frederickabbott.com/sites/default/files/draft%20ILA%20Global%20Health%20Law%20Committee%20Australia%20Biennial%20Report%2018%20June.pdf (accessed August 19, 2021).

Sources of international health law

In identifying the sources of international health law as a branch of international law, it is necessary to find key differences with the previously mentioned concept of global health law. According to Brigit Toebes, international health law is shaped by a limited set of binding and non-binding instruments adopted by the WHO and regional organizations to deal with the spread of specific diseases or the organization of healthcare delivery (Toebes 2015: 299–328).

Global health law covers a wide range of issues with varying degrees of impact on public health and is also guided by instruments developed by actors in global health governance that are not subjects of international law. According to a publication by Lawrence Gostin and Benjamin Meier, the distinctive feature of global health law is that it seeks to deal with "new health threats" to regulate "new health actors" in international relations and, in so doing, to be guided by "new health norms" (Gostin, Meier 2019: 788–793). In particular, apart from the soft-law instruments adopted by intergovernmental organizations, one of the characteristics of global health law is the dissemination and influence of international standards and guidelines developed by various non-state organizations. The best known examples are standards for regulating the circulation of medicines and medical devices developed by the International Organization for Standardization (ISO), the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, and the International Medical Device Regulators Forum.

International health law, more than any other branch of international law, is characterized by an extensive discussion of the importance of hard law and soft law in regulating the field. It should be noted that in the 70-plus years of the WHO's history, despite its substantial statutory standard-setting powers, only two binding instruments have been adopted: the International Health Regulations (IHR) and the WHO Framework Convention on Tobacco Control (FCTC). The IHR, adopted in 1951 and substantially revised in 2005, established a list of mandatory measures to control the spread of communicable diseases. The FCTC was the first binding act to ensure control of tobacco smoking as a major contributor to noncommunicable diseases.

Under Article 23 of the WHO Constitution, the WHO can make recommendations relating to soft-law instruments that can be adopted in the form of a resolution by a simple majority of WHO members. However, the fact that WHO recommendations are not universally binding does not mean that such documents lack executive power. Examples of the most effective WHO recommendations include the Pandemic Influenza Preparedness Framework, as well as the 1981 International Code of Marketing Breast-Milk Substitutes and the 2010 Global Code of Practice on the International Recruitment of Health Personnel.

A study by Sharifah Sekalala on the role of soft law in global health highlights its important role in filling regulatory gaps and, using malaria and tuberculosis control mechanisms as examples, stresses the potential effectiveness of soft law over binding

instruments (Sekalala 2017: 317). The regulatory framework for global health processes is dominated by the soft law instruments of codes, declarations and policies. Given that many international treaties have been awaiting entry into force for many years, soft law rules facilitate a timely response to emerging threats and challenges in various areas.

According to the concept of international law, the binding sources in the field of healthcare also include instruments of a universal and regional nature aimed at regulating specific determinants of health, which are adopted by the United Nations, the ILO, FAO, WTO, the Council of Europe and other organizations.

In accordance with its Constitution, the ILO plays an important role, along with the WHO, in regulating health protection and counteracting the social and economic costs of lost productivity or incapacity to work. The ILO Constitution provides for the use of Recommendations and Conventions as the main tools in the work of the organization. A Recommendation is a non-binding document and, according to the Constitution, shall be used in a situation where the matter or aspect in question is not considered appropriate or relevant at the time of adopting a Convention. Recommendations are often more technical than Conventions and are used to supplement agreements or to provide more detailed information on the content of the standard. A Convention is a binding instrument and requires a consensus among participating countries on the instrument to be adopted, as well as subsequent ratification. One of the requirements for monitoring the implementation of Conventions is the submission of regular reports to the International Labour Office, which shall then be reviewed by legal experts. To date, some 190 Conventions and 206 Recommendations have been adopted by the ILO.

At the regional level, substantial progress has been made with regard to the adoption of binding acts to regulate certain health issues. As for the Council of Europe, mention should be made of the 1964 Convention on the Elaboration of a European Pharmacopoeia; the 2011 Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health (the MEDICRIME Convention); the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (the Convention on Human Rights and Biomedicine).

Subject of international health law

Today, international health law covers a broad range of issues (the field of biomedical science, human cloning, organ transplants, the fight against communicable and non-communicable diseases, international trade in health services, food and medical devices, access to health technology, and control over the circulation of powerful drugs), emphasizing the importance of this branch of law for peace and security, but at the same time resulting in the institutional fragmentation already mentioned and limiting the opportunity to focus on the development of universal instruments with

respect to issues of the highest priority. Based on the reports of international organizations, as well as academic publications on this topic, several major health issues regulated by international health law can be identified.

The first point to emphasize is the importance of international law in ensuring health security, which is an integral component of the concept of human security. Health security is not limited to counteracting the spread of communicable diseases, nor to protecting public health during an armed conflict (Harman 2012: 200). Uncontrolled releases into the environment, as well as the use of various infectious and biological agents, pose a significant threat to everyone's safety (Fidler, Gostin 2008: 320). In particular, the IHR draws attention to the origin of the threats, stressing that the provisions of the document apply to their "natural, accidental or deliberate release." In particular, Article 7 stipulates that "irrespective of origin or source, which may constitute a public health emergency of international concern", a State Party "shall provide to WHO all relevant public health information." Therefore, pandemic situations due to the deliberate spread of a virus fall into the realm of the IHR (Malichenko 2021: 174–197).

The second important focus of international health law regulation is the creation of the necessary conditions for the realization of the right to the highest attainable standard of health. As has been noted repeatedly in the General Comments of the Committee on Economic, Social and Cultural Rights (CESCR),[14] as well as the reports of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health,[15] and other international organizations, access to health technologies is an essential element of the right to the highest attainable standard of health, enabling the containment of life-threatening diseases, increasing life expectancy and reducing disabilities. The COVID-19 pandemic revealed the urgent need to establish international legal mechanisms to ensure the development of and sustainable access to health technologies. One example is the Pandemic Influenza Preparedness Framework, which recognizes the principle of sovereign rights of states over their biological resources and the importance of collective action to reduce risks to public health, while focusing on sharing influenza viruses with pandemic potential and exchanging data and developments.

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[14] General Comment No. 14. *UN Committee on Economic, Social and Cultural Rights.* URL: http://hrlibrary.umn.edu/russian/gencomm/Rescgencom14.html (accessed August 21, 2021); General Comment No. 6. *UN Committee on Economic, Social and Cultural Rights.* URL: https://tbinternet.ohchr.org/_layouts/15/treatybodyexternal/Download.aspx?symbolno=INT%2fCESCR%2fGEC%2f6429&Lang=ru (accessed August 21, 2021)

[15] See: Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover, on Access to Medicines Dated May 1, 2013. *United Nations.* URL: https://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session23/A-HRC-23-42_en.pdf (accessed August 18, 2021); Visit to Ecuador – Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health Dated June 5, 2020. *United Nations.* URL: https://ap.ohchr.org/documents/dpage_e.aspx?si=A/HRC/44/48/Add.1 (accessed August 18, 2021); Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health – Expert Consultation on Access to Medicines as a Fundamental Component of the Right to Health Dated March 16, 2011. *United Nations.* URL: https://ap.ohchr.org/documents/dpage_e.aspx?si=A/HRC/17/43 (accessed August 18, 2021).

A third broad area of international law is the relationship between international trade processes and human health. The WTO agreements have an impact on a range of strategically important issues on the international health agenda. In particular, the provisions of the Agreement on Sanitary and Phytosanitary Measures are applied to counter the spread of antibiotic resistance; the TRIPS Agreement plays an essential role in balancing the interests of governments and health technology manufacturers;[16] the General Agreement on Trade in Services (GATS) Agreement applies to relations stemming from the provision of cross-border health services (medical tourism) and the use of e-health systems.[17] Balancing trade interests and health priorities is a critical element in increasing access to essential health technologies and, by extension, achieving universal health coverage goals.

Current problems of international legal regulation in the field of healthcare

The impact of the rapid spread of coronavirus infection, the biggest humanitarian disaster of the century, has exposed the systemic problems of international health law as a branch of international law. Current challenges facing international health law have been articulated in a number of reports by international organizations, as well as scientific publications analysing the impact of the coronavirus infection on global health. For instance, David Fidler, a recognized expert in the field, has pointed out that the established system of international legal regulation proved to be incapable of counteracting COVID-19, rightly calling for its consistent reform to ensure human security (Gostin, Habibi, Meier 2020: 376–381).

According to most experts, one of the prime concerns is the predominance of soft law in health regulation, largely due to the WHO's reluctance to exercise the extensive standard-setting powers assigned to it by its Constitution. The COVID-19 pandemic and the increasing burden of non-communicable diseases have demonstrated the need for a universal instrument that would set out basic principles for how international law actors and other international actors should work together to address global health challenges. Proposals for universal instruments have featured in many analytical reports and academic publications in recent years. Chief among these are conventions that focus on the development of health research, global health governance and combating infectious pandemics.

[16] The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). URL: https://www.wto.org/english/docs_e/legal_e/27-trips.pdf (accessed August 19, 2021).

[17] General Agreement on Trade in Services (GATS). URL: https://www.wto.org/english/docs_e/legal_e/26-gats.pdf (accessed August 19, 2021).

Given the rapid growth in the number of international health initiatives by various organizations that are not subjects of international law but have a significant impact on the international agenda, the question remains as to whether they can be considered a party to international disputes and be held accountable under international law.

Conclusions

Over the past decades, a great deal of scientific research has been devoted to the specifics of the international legal regulation of healthcare. This has led to the establishment of several schools of thought in different parts of the world, setting the stage for the development of "international health law" as a new branch of international law. Despite the multiplicity of different international legal sources influencing health regulation, international relations in this area need a universal instrument to lay down the basic principles of international health law and systematize the interaction of multiple actors in global health governance. The COVID-19 pandemic has only served to highlight this need, which to a large extent determines the priorities of both legal scholars and international organizations in the coming years.

Despite ongoing political tensions in the international arena, the Russian Federation continues to engage actively on global health issues, setting the agenda for a number of priority concerns. The recognition of healthcare as an important element of national security, and the need for Russia's further involvement in shaping the international agenda in this area, mean that consistent study of the specific features of international legal regulation of healthcare in the scientific work of leading Russian law schools is required.

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Conflict of interests:
The author declares the absence of any conflict of interests.

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