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Practical cross-border insights into digital health law

Digital Health

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1 Digital Health

1.1 What is the general definition of "digital health" in your jurisdiction?

Under Belarus law, digital health is a set of information systems and resources, and information and communication technologies, functioning in the healthcare sector on the basis of common principles and rules, providing information interaction between organisations and citizens, as well as serving their information needs. This definition is included in the Concept for the Development of Digital Health in the Republic of Belarus for the period up to 2022 (**Concept**), approved by the order of the Ministry of Healthcare. The Concept sets key goals, objectives and principles of digital health development as well as expected results.

1.2 What are the key emerging digital health technologies in your jurisdiction?

One of the main directions of digital health in Belarus is the creation and use of the Centralised Healthcare Information System (**CHIS**), which is an integrated information system that provides centralised storage and processing of medical information, as well as users' access to it in accordance with the established procedure. The main roles of the CHIS include:

- e-health development;
- collection, accumulation and storage of information regarding the state of patients' health;
- protection of information;
- transfer of medical services to electronic form;
- creation of a unified electronic archive of medical information about patients based on the patient's electronic medical record; and
- provision of patient access to healthcare services using the patient's personal electronic account, etc.

The CHIS includes information:

- contained in the patient's electronic medical record and other electronic medical documents;
- regarding healthcare organisations;
- regarding people who receive medical care;
- regarding statistical observations in the field of healthcare; and
- regarding high-tech medical care organisations, etc.

Receiving, transferring, collecting, processing, accumulating, storing and providing medical information contained in the CHIS is performed by healthcare specialists without consent of patients or their representatives, unless they have refused to enter information constituting medical secrecy into the CHIS.

The system of electronic prescriptions is also worthy of note. Its principle is that doctors issue e-signed prescriptions in electronic form through a special system where healthcare organisations and pharmacies are registered. Patients can obtain prescribed pharmaceuticals upon presentation in pharmacies of special personal cards issued by healthcare institutions where their electronic prescriptions are reflected. To obtain the special personal card of medical care the patient should verify their passport data. The list of pharmacy chains where patients can purchase pharmaceuticals with electronic prescriptions is limited but becomes broader each year. It is worth mentioning that an electronic prescription is issued only if there is written consent from the patient with regard to processing personal data and information constituting medical secrecy. This written consent is drawn up in the form of a paper document signed by the patient.

Moreover, telemedicine technologies are currently the most developed part of the digital health sector in Belarus, enabling the provision of medical assistance to patients remotely, conducting medical monitoring and medical examinations, as well as consultations between medical specialists. Please see question 3.1 for details.

1.3 What are the core legal issues in digital health for your jurisdiction?

Although the development of digital health in Belarus was planned in the Concept to take place in 2022, at the time of writing (January 2023) the CHIS is still not functioning and the use of telemedicine technologies is working in a fragmented way. In this regard, the core legal issue and the main vector for Belarus is the further development and improvement of a legal base with specific standards and regulations for the performance of healthcare activities using information technologies.

1.4 What is the digital health market size for your jurisdiction?

There is no publicly available information on the digital health market size in Belarus.

1.5 What are the five largest (by revenue) digital health companies in your jurisdiction?

The CHIS is a state information system, the general coordination of which is carried out by the Ministry of Healthcare. The Republican Scientific and Practical Centre for Medical

Technologies, Informatisation, Management and Economics of Health is responsible for the informatisation in the healthcare sector. Consequently, the main players currently in digital health in Belarus are the state, state authorities and organisations, so it is not possible to highlight the five largest companies in the digital health sector.

2 Regulatory

2.1 What are the core healthcare regulatory schemes related to digital health in your jurisdiction?

Regulation of digital health in Belarus is covered by the Law of the Republic of Belarus "On Healthcare". It establishes the specifics of the regulation of health information support.

There are also acts of the government and sectoral authorities that regulate digital health: the Resolution of the Council of Ministers "On the Functioning and Use of the Centralised Healthcare Information System"; the Resolution of the Ministry of Healthcare "On Approval of the Regulation on the Specifics of Providing Medical Care Using Telemedicine Technologies"; the Order of the Ministry of Healthcare "On Certain Issues of Telemedicine Consulting in the Republic of Belarus"; etc.

2.2 What other core regulatory schemes (e.g., data privacy, anti-kickback, national security, etc.) apply to digital health in your jurisdiction?

The general rules for the regulation of information protection, including personal data, creation and use of information resources, information systems and information networks are contained in the Law of the Republic of Belarus "On Personal Data Protection" (**Law on PDP**) and the Law of the Republic of Belarus "On Information, Informatisation and Data Protection".

The particularities of the legal regulation of information relationships concerning state secrets and medical secrets, as well as specifics in terms of personal data protection, are regulated by the Law of the Republic of Belarus "On State Secrets" and the Law of the Republic of Belarus "On Healthcare".

Regulation of the anti-kickback issues is stipulated in the Law of the Republic of Belarus "On Measures to Prevent Legitimisation of Money Obtained by Criminal Actions, Financing of Terrorist Activities and Financing Weapons of Mass Destruction Proliferation".

2.3 What regulatory schemes apply to consumer healthcare devices or software in particular?

Belarus legislation does not contain legal regulation of consumer healthcare devices or software in particular.

In Belarus, medical devices means any instruments, apparatus, devices, equipment, materials and other items that are used for medical purposes separately or in combination with each other, as well as with accessories necessary for the intended use of medical devices (including special software), intended by the manufacturer to provide medical care, including monitoring of the human body, conducting medical research, recovery and other uses. This definition, as well as general questions of regulation of the circulation of medical products, is contained in the Law of the Republic of Belarus No. 2435-XII dated 18 June 1993 "On Healthcare".

Being essentially a software, consumer healthcare devices should not be subject to medical device regulations, unless they have suitable features. For example, if relevant consumer healthcare devices are accompanied with certain hardware, they may be subject to medical device regulations. As a general rule, medical devices are permitted for production, sale and medical use in Belarus after their state registration or registration within the Eurasian Economic Union.

The procedure for state registration of medical devices is set out in the Regulation on state registration (re-registration) of medical devices and medical equipment, approved by the Resolution of the Council of Ministers of the Republic of Belarus No. 1269 dated 2 September 2008.

The Law of the Republic of Belarus "On the Protection of Consumer Rights" deals with relations in the field of consumer rights protection, including rights of the consumers of medical devices.

2.4 What are the principal regulatory authorities charged with enforcing the regulatory schemes? What is the scope of their respective jurisdictions?

The regulatory authority for digital health is the Ministry of Healthcare of the Republic of Belarus. The Ministry of Healthcare has the role of organising the provision of healthcare to the population, providing pharmaceuticals and medical devices, conducting scientific research and training scientists, and providing information support in the field of healthcare. There are state organisations under the supervision of the Ministry of Healthcare which assist it in carrying out its functions and duties.

2.5 What are the key areas of enforcement when it comes to digital health?

The key areas of enforcement relating to digital health are confidentiality, data security, data protection obligations, legal qualification as a medical device, medical secrecy regime, liability in case of damage, safety and intellectual property specifics.

2.6 What regulations apply to software as a medical device and its approval for clinical use?

Please see our response to question 2.3. Under Belarus law, software should not be identified as a medical device, but may be an accessory necessary for the use of a medical device, unless they have suitable features (e.g. accompanying hardware).

2.7 What regulations apply to artificial intelligence/machine learning powered digital health devices or software solutions and their approval for clinical use?

Belarus legislation does not contain legal regulation of artificial intelligence/machine learning powered digital health devices or software solutions. Being essentially a software, they should not be subject to medical device regulations, unless they have suitable features (please see question 2.3). For example, if relevant software is accompanied with certain hardware, it may be subject to medical device regulations. As a general rule, medical devices are allowed for production, sale and medical use in Belarus after their state registration or registration within the Eurasian Economic Union.

3 Digital Health Technologies

3.1 What are the core issues that apply to the following digital health technologies?

- **Telemedicine/Virtual Care**
  Telemedicine technologies are one of the most innovative IT manifestations in healthcare in Belarus.
  Personal data protection in the framework of medical secrecy regime seems to be the core issue in telemedicine regulation. The introduction of an intelligent system for remote monitoring of health (telemedicine, robotics in high-tech operations) is provided for in the program of social and economic development of the Republic of Belarus for 2021–2025.
  Telemedicine technologies are defined as information technologies which provide for remote interaction of healthcare specialists between each other and with patients for the purposes of:
  - conducting medical consultations;
  - providing an additional medical opinion on the assessment of a patient's health status, clarifying the diagnosis, determining the prognosis and methods of medical care;
  - healthcare specialists remotely carrying out medical monitoring of a patient's health after an in-person appointment (examination, consultation); and
  - conducting medical examinations.

  Thus, taking into account the purposes of using telemedicine technologies, two main types of use of such technologies can be distinguished in Belarus: telemedicine counselling; and medical care with the use of telemedicine technologies.
  Telemedicine counselling does not provide for direct involvement with a patient – it is instead a tool for:
  - elimination of the negative consequences of staffing issues (when a healthcare organisation does not have the necessary kind of specialised physician); and
  - interactions between doctors of the same profile who have different skill levels, making it possible to make better decisions regarding the diagnosis and treatment of patients (a kind of "online consultation").

  The provision of medical care using telemedicine technologies involves interaction between a doctor and a patient and, in fact, can replace a regular face-to-face visit to a healthcare organisation.
- **Robotics**
  There are no specific robotics regulations in Belarus healthcare.
  The introduction of an intelligent system for remote monitoring of health (telemedicine, robotics in high-tech operations) is provided for in the program of social and economic development of the Republic of Belarus for 2021–2025.
  Legal qualification as a medical device, personal data protection in the framework of medical secrecy regime and liability in case of damage seem to be the core issues in case special regulation is introduced with regard to robotics in healthcare.
- **Wearables**
  There are no specific wearables regulations in Belarus healthcare.
  Legal qualification as a medical device, considering wearables may have functions different to a medical nature, processing personal data considering medical secrecy regime and safety seem to be the core issues in case special regulation is introduced with regard to wearables in healthcare.
- **Virtual Assistants (e.g. Alexa)**
  There are no specific virtual assistants regulations in Belarus healthcare.
  To the best of our knowledge, virtual assistants (such as Alexa or Siri) do not have special medical functions. They potentially can be used for collecting medical information from patients. In this case, legal qualification as a medical device and processing personal data considering medical secrecy regime seem to be the core issues in case special regulation is introduced with regard to virtual assistants in healthcare.
- **Mobile Apps**
  There are no specific mobile app regulations in Belarus healthcare.
  To the best of our knowledge, the Eurasian Development Bank, an international financial institution whose members are Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russia and Tajikistan, launched the mobile app "Travelling without COVID-19" during the relevant pandemic. This app serves the purposes of collecting results of COVID-19 tests and demonstrating them when crossing borders.
  The implementation of mobile applications in healthcare is included in the priorities of the Commonwealth of Independent States, of which Belarus is a member.
  Legal qualification as a medical device and processing personal data considering medical secrecy regime seem to be the core issues in case special regulation is introduced with regard to mobile apps in healthcare.
- **Software as a Medical Device**
  There are no specific healthcare regulations in Belarus with regard to software considered as a medical device.
  Legal qualification as a medical device considering such software has other components and may have functions different to a medical nature and processing personal data considering medical secrecy regime seem to be the core issues in case special regulation is introduced with regard to software considered as a medical device.
  Please also see the comments regarding legal protection of such software from an intellectual property perspective in question 6.5.
- **Clinical Decision Support Software**
  There are no specific healthcare regulations in Belarus with regard to Clinical Decision Support Software.
  Legal qualification as a medical device, processing personal data considering medical secrecy regime and medical ethics seem to be the core issues in case special regulation is introduced with regard to Clinical Decision Support Software.
- **Artificial Intelligence/Machine Learning Powered Digital Health Solutions**
  There are no specific artificial intelligence/machine learning regulations in Belarus healthcare.
  Processing personal data considering medical secrecy regime, liability in case of damage and interaction with healthcare specialists seem to be the core issues in case special regulation is introduced with regard to artificial intelligence/machine learning in healthcare.
  Please also see the more detailed comments in questions 8.1–8.4.
- **IoT (Internet of Things) and Connected Devices**
  There are no specific IoT regulations in Belarus healthcare. IoT-connected devices can be used to provide remote health monitoring and emergency alert systems.

Legal qualification as a medical device and processing personal data considering medical secrecy regime seem to be the core issues in case special regulation is introduced with regard to IoT and connected devices in healthcare.

- **3D Printing/Bioprinting**
  There are no specific bioprinting regulations in Belarus healthcare.
  The development of new methods of treatment based on bioprinting is provided for in the program of social and economic development of the Republic of Belarus for 2021–2025.
  Licensing such type of activity, legal qualification from civil law and intellectual property perspective, medical ethics and liability seem to be the core issues in case special regulation is introduced with regard to bioprinting.
- **Digital Therapeutics**
  There are no specific healthcare regulations in Belarus with regard to digital therapeutics.
  Licensing such type of activity, legal qualification as a medical device, processing personal data considering medical secrecy regime, liability in case of damage and interaction with healthcare specialists seem to be the core issues in case special regulation is introduced with regard to digital therapeutics.
- **Natural Language Processing**
  There are no specific healthcare regulations in Belarus with regard to natural language processing.
  Legal qualification as a medical device and processing personal data considering medical secrecy regime seem to be the core issues in case special regulation is introduced with regard to natural language processing in healthcare.

3.2 What are the key issues for digital platform providers?

Digital platform/solution providers face issues derived either from lack of specific regulation in relevant regulation or continuous development of the legal framework in the sphere.

Providers of those digital platforms that are being developed and operated as a part of state digital healthcare mostly focus their efforts on the creation and implementation of platforms in line with scope, time and budgets agreed for their development.

All the issues referred to in answer to question 3.1 above are relevant for digital platform providers, as well as specific obligations related to platform operation that may be prescribed in the legal acts regulating particular digital solutions/platforms (e.g. those developed for the use of telemedicine in Belarus).

4 Data Use

4.1 What are the key issues to consider for use of personal data?

The key issue to consider for use of personal data is the correlation between general requirements for personal data protection and specific rules established in the healthcare sphere. Personal data operated in healthcare may also be subject to medical secrecy regime, which triggers protection of the same information both from personal data and medical secrecy perspectives. Under medical secrecy, the following information should be protected:

- information about a patient's request for medical assistance and his/her health status;
- data about diseases;
- diagnosis;
- possible methods of medical assistance;
- risks related to medical intervention as well as alternatives to it; and
- other data, including personal data, obtained when providing medical assistance, and results of postmortem examinations.

4.2 How do such considerations change depending on the nature of the entities involved?

A service provider shall take into account territorial scope of the Law on PDP, which does not specify whether it has an extraterritorial effect.

The definition of the operator (analogue to the controller under the GDPR) comprises "other organisations" without clarification whether foreign organisations processing personal data of Belarusians are concerned. However, the Belarusian Data Protection Authority (**DPA**) currently maintains the position that the scope of the Law on PDP is limited to the territory of Belarus and does not apply to foreign organisations having no local presence. Therefore, providing services and performing processing of personal data from abroad by a non-Belarusian legal entity without local presence should not fall in the direct scope of the Law on PDP application.

Application of the Law on PDP does not differ depending on the state/private type of company ownership. Laws may establish specific requirements/obligations for personal data processing, which can be used as a valid legal basis therefore.

4.3 Which key regulatory requirements apply?

The Law on PDP provides for a specific list of legal bases for the processing of personal data. Generally, the processing of personal data is carried out on the basis of the data subject's consent. Exceptions to that rule are stipulated by the Law on PDP and other legislative acts. The list of legal bases vary depending on the type of personal data: special (sensitive); or other types.

The laws in the sphere of healthcare also provide for certain deviations for the general requirements in certain aspects. For instance, healthcare regulations establish specific procedure for giving consent to process personal data and information that constitutes medical secrecy in the central informational healthcare system. Moreover, information constituting medical secrecy could be disclosed without the patient's (his/her legal representative's, guardian's, spouse's or close relative's) consent in certain cases as defined in legislation (e.g. upon written request of bodies of criminal prosecution and courts in relation to conducting an investigation or court proceedings).

With regard to clinical trials, participation of patients in clinical trials is voluntary and subject to written, informed consent. The investigator must fully inform a potential patient or their legal representative about all significant aspects of a trial, *inter alia*, providing information about the trial in writing.

Operators should also note other key requirements, such as rules for cross-border transfer, requirements for the contracts with authorised persons (analogue to the processor under the GDPR), respect for the rights of data subjects, developing data processing policies, etc.

4.4 Do the regulations define the scope of data use?

The Law on PDP covers the protection of personal data while processing of such data is accomplished with the use of:

- automated means (tools); or
- non-automated means (tools), if such means (tools) provide the possibility to search for personal data and (or) access personal data with the help of certain criteria (card-indexes, lists, databases, logs, etc.).

Processing means any type of actions taken in relation to personal data, including the collection, systematisation, storage, modification, use, depersonalisation, blocking, distribution, provision and erasure of personal data.

The Law on PDP will not apply to the processing of personal data that is:

- accomplished for personal use, not relating to professional and entrepreneurial activity; or
- related to state secrets.

As for the scope of data use, it may be established either by the operator itself (e.g. describing the purpose and scope of processing in a privacy policy, when the processing performed is based on consent) or established in the legislation (e.g. a particular number of data that should be reflected in the patient file).

4.5 What are the key contractual considerations?

An operator may authorise another person or entity for the processing of personal data based on the agreement. The agreement between the operator and the authorised person shall contain the following provisions:

- a list of actions in regard to personal data that could be performed by the authorised person;
- the purposes of the above actions;
- confidentiality obligations with respect to personal data; and
- measures to ensure the protection of personal data in accordance with the Law on PDP.

Mandatory measures to ensure the protection of personal data are:

- legal measures, such as publication of documents defining the policy of the operator (authorised person) regarding the processing of personal data;
- organisational measures, such as appointment of a structural unit or a person responsible for the control over the processing of personal data (**DPO**); familiarisation of employees and other persons directly engaged in the processing of personal data with the provisions of the legislation on personal data, including the requirements for the personal data documents of the operator (authorised person) as well as training of these employees and other persons; establishing the procedure for accessing personal data; and
- technical measures, such as implementation of technical and cryptographic protection of personal data.

Notwithstanding the terms of the agreement, the operator remains the party responsible for the proper processing of personal data (but not the authorised person).

4.6 What are the key legal issues in your jurisdiction with securing comprehensive rights to data that is used or collected?

Generally, operators and their authorised persons are not required to notify the DPA of the processing of personal data. Nevertheless, the DPA is entitled to request and receive any information concerning the operators' and their authorised persons' compliance with data protection rules.

Right to be informed: The operator involved in the processing of personal data shall give clarifications to the data subject regarding their rights related to the processing of their personal data prior to consent collection. Prior to obtaining consent, the operator is obliged to provide the data subject with information concerning the processing of personal data, which includes, *inter alia*:

- the operator's name;
- the purposes of processing;
- a list of personal data;
- the period of consent; and
- a list of actions in regard to personal data.

Furthermore, the operator is obliged to clarify to the data subject, in plain and simple language, his/her rights and the consequences of giving consent or refusing to give it.

Right to access: The operator shall also provide certain information following the data subject's request. Data subjects are entitled to receive information on the processing of their personal data, as well as information on the transfer of the data to third parties, including:

- the name of the operator;
- confirmation of the fact of data processing;
- a description of the personal data and the sources of data;
- legal grounds and the purposes for the data processing;
- the period of the data subject's consent; and
- information on the authorised person.

Information on the transfer of personal data to third parties can be obtained from the operator by the data subject free of charge once a year.

Right to rectification: Under the Law on PDP, an operator involved in the processing of personal data shall fulfil the request of data subjects to amend (update) their personal data, if such data are incomplete, obsolete or inaccurate.

Right to erasure: A data subject has the right to erasure of such data at any time without giving reasons in case of absence of lawful grounds (including the data subject's consent) for the processing of personal data.

Right to object/opt-out: Under the Law on PDP, a data subject may:

- withdraw his/her consent for the processing of personal data; and
- require the termination of the processing of personal data at any time without giving reasons, if there are no legal grounds for the processing.

In that case, the operator is obliged to erase or, if erasure is not possible, to block the personal data as well as to ensure that the data is no longer processed by the authorised person.

Other rights: The Law on PDP provides for the right of the data subject to claim compensation for damage, including moral damage, caused by the violation of his/her rights, stipulated thereby. Compensation for moral damage is not dependent on real damage and losses faced (or not) by the data subject.

The data subject can also appeal against the actions (including omissions) and decisions of the operator or the authorised party to the DPA.

4.7 How are issues with data inaccuracy, bias and/or discrimination addressed by the regulatory authorities in your jurisdiction?

The Law on PDP introduces a number of principles, including accuracy of the personal data processed by the operator and, if

necessary, their rectification. Current legislation does not establish the right not to be subject to automated decision-making in terms of personal data processing.

There is no specific regulation of data bias and/or discrimination in the healthcare sphere in Belarus.

5 Data Sharing

5.1 What are the key issues to consider when sharing personal data?

When sharing personal data, one should generally consider (i) the availability of proper legal basis for sharing data, e.g. consent of the data subject, and (ii) whether the sharing party complies with cross-border data transfer requirements (if applicable).

Personal data may also be subject to medical secrecy regime, which triggers protection of the same information as medical secrets. This, among others, affects the scope of the parties who may claim for sharing information that constitutes a patient's medical secrets.

In particular, the patient has the right to decide to whom information about his/her health condition can be disclosed, or to forbid disclosure to certain persons. Medical secrecy concerning a patient who is a minor is provided to the patient's legal representatives: parents; adoptive parents; guardians; custodians; etc. If the patient is not able to make a conscious decision due to health reasons, information constituting medical secrecy may be shared with the patient's spouse or one of their close relatives (parents, adult children, siblings, grandchildren, grandparents). The persons mentioned above have the right to receive extracts from medical documents, medical certificates on the state of health and other documents containing information on the patient's health, in accordance with the procedure established by Belarus legislation. Legislation also stipulates cases in which medical secrecy may be provided to certain public authorities and organisations without the consent of the patient or persons mentioned above.

5.2 How do such considerations change depending on the nature of the entities involved?

Regarding the personal data requirements, please see the answer to question 4.2.

5.3 Which key regulatory requirements apply when it comes to sharing data?

Please see the answers to questions 4.3 and 4.5 regarding (i) proper legal basis, and (ii) necessary contractual arrangements between an operator and an authorised party.

According to the general rule provided by the Law on PDP, the cross-border transfer of personal data to countries not ensuring sufficient measures of personal data protection is prohibited. The list of "adequate" jurisdictions refers to states that are (i) parties to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, adopted in Strasbourg on 28 January 1981, or (ii) members of the Eurasian Economic Union.

The PDP Law provides for the exceptions where transfers are allowed to the jurisdictions that are not in the list defined by the DPA. For example, such cases include the consent of the data subject with due notification on the relevant risks or a permit for cross-border transfer issued by the DPA.

6 Intellectual Property

6.1 What is the scope of patent protection?

The main Belarus legal act describing patent protection is the Law of the Republic of Belarus "On Patents for Inventions, Utility Models, Industrial Designs".

The exclusive right to an invention is protected and is certified by a patent which is issued upon application. The scope of patent protection related to an invention is determined by the invention claims.

Legal protection is granted to an invention in any field of technology (e.g. medical devices and equipment), if it relates to a product or a method, appears as novel, involves an inventive step and is industrially applicable. Product implies an object of human labour. Method denotes a process, technique or method of performing interrelated actions on a material object with the help of material means.

Computer programs and mathematical methods are not patentable *per se*. However, if the invention (1) meets the above criteria, and (2) is created with the help of computer programs or artificial intelligence, it may be patentable.

According to Belarus law, only an individual can be the invention creator; the status of artificial intelligence activities is debatable.

The exclusive right to use an invention includes the right to use the invention at one's own discretion, assuming this does not violate the rights of others, and the right to prohibit others from using the invention.

The patent term related to an invention is 20 years from the application filing date (in some cases this term may be extended, but by no more than five years).

6.2 What is the scope of copyright protection?

The main Belarus legal act describing copyright protection is the Law of the Republic of Belarus "On Copyright and Related Rights".

Copyright protection arises by virtue of the fact of its creation. Acquisition and exercise of copyright do not require any formalities (e.g. receiving protection documents).

Copyright protection extends to works of science, literature and art that are the result of creative activity, regardless of the purpose and dignity of the works, as well as the way they are expressed.

Copyright is protected with regard to both published and unpublished works which exist in some objective form, for example: in sound or video recordings (mechanical, magnetic, digital, optical, etc.); or in electronic form, including in digital form.

Computer programs (including software, source code, designs) are eligible for copyright protection.

Copyright does not extend to ideas, methods, processes, systems, concepts, principles, discoveries or facts, even if they are expressed, displayed, explained or embodied in a work.

As mentioned in question 6.1 above, according to Belarus law, only an individual can be the author of a particular work and the status of artificial intelligence activities is debatable.

There are two types of rights under copyright: economic rights, which allow the owner of the rights to derive financial reward from the use of the works by others; and moral rights, which allow the author to take certain actions to preserve the personal link between himself/herself and the work. Economic rights are valid, as a general rule, during the life of the author and 50 years after his/her death. Moral rights are protected indefinitely.

6.3 What is the scope of trade secret protection?

The main Belarus legal acts describing trade secret protection are the Civil Code of the Republic of Belarus and the Law of the Republic of Belarus "On Commercial Secrecy".

Information constituting a trade secret is protected under the regime of commercial secrecy, if all of the following criteria are met:

- it is not generally known or available to third parties that usually deal with this kind of information;
- it has commercial value for its owner due to being unknown to third parties;
- it is not an object of exclusive rights to the results of intellectual activity; and
- it is not a state secret.

The commercial secrecy regime is considered to be established after (1) determining the list of information subject to protection, and (2) taking a set of measures necessary to ensure confidentiality by the information owner.

The legislation also defines the list of information which cannot fall under the commercial secrecy regime, for example: medical; attorney; banking; tax; or other secrets protected by law or information about the state of the environment.

The trade secret owner has the right to protect the trade secret from being used by others without permission. Trade secrets are protected without any procedural formalities (registration, acquisition of a certificate, etc.). They are not formally limited by any term and are valid while the above-mentioned criteria are met.

Unpatented digital technologies or medical devices, etc. can be protected as a trade secret, i.e.:

- trade secret protection can appear as an alternative to patenting; and
- if the rightsholder can obtain patent protection with regard to a significant solution; the information needed for its realisation may be protected as a trade secret.

6.4 What are the rules or laws that apply to academic technology transfers in your jurisdiction?

Academic technology transfers are not regulated in detail in Belarus. Overall, in such cases general rules related to works and inventions for hire should apply.

A work for hire is a work created in the course of performing an official assignment or official duties by an employee. The moral rights belong to its author; the economic rights belong to the author's employer.

An invention for hire is the invention which relates to the field of the employer's activity, and the activity which led to its creation relates to the official duties of the employee. Alternatively, the invention for hire may be created in the course of completing a specific task received from the employer, or the employee used the employer's experience or funds. The moral rights belong to the creator of the invention for hire; the right to obtain a patent and the economic rights belong to the creator's employer, unless otherwise provided by the agreement between them. By acquiring the economic rights, the employer also acquires the obligation to pay appropriate remuneration to the employee, of which the minimum amount is established by law.

Furthermore, Belarus law establishes obligatory commercialisation of the results of scientific activities at the expense of public funds. Intellectual property and documented scientific and technical information created in the course of scientific activity at the expense of public funds, in accordance with agreements for performing research, development and technological work, are considered as the results of scientific activity. Please see question 6.7 for more details.

6.5 What is the scope of intellectual property protection for software as a medical device?

Belarus law does not specifically describe protection for software as a medical device.

Software being interpreted as a computer program is not patentable in Belarus. As mentioned in question 6.2, software is eligible for copyright protection.

If software is a component of a medical device consisting of some other components (e.g. hardware), such medical device may still be patentable.

6.6 Can an artificial intelligence device be named as an inventor of a patent in your jurisdiction?

No, an artificial intelligence device cannot be named as an inventor of a patent in Belarus. According to Belarus law, only an individual can be the invention creator. Therefore, we believe that the results of artificial intelligence activities (e.g. devices) cannot be granted legal protection as inventions.

6.7 What are the core rules or laws related to government funded inventions in your jurisdiction?

The main Belarus legal act describing the rules applicable to government-funded inventions is the Edict of the President of the Republic of Belarus "On Commercialisation of the Results of Scientific and Scientific-Technical Activities Created at the Expense of Public Funds".

According to this Edict, Belarus law establishes obligatory commercialisation of the results of scientific activities at the expense of public funds. Intellectual property and documented scientific and technical information created in the course of scientific activity at the expense of public funds, in accordance with agreements for performing research, development and technological work, are considered as the results of scientific activity. Commercialisation implies the following options (the list is not exhaustive):

- sale of goods created with the use of the results of scientific activity, or use of these results for other needs;
- fee-based or gratuitous license of the right to use the results of scientific activity;
- fee-based or gratuitous assignment of property rights to the results of scientific activity;
- fee-based or gratuitous transfer of information constituting trade secrets; and
- fee-based or gratuitous transfer of documented scientific and technical information.

7 Commercial Agreements

7.1 What considerations apply to collaborative improvements?

In addition to determining: collaboration purposes; participants' rights and obligations; applicable regulations and liability allocation; and collaboration termination, it is also important to determine a specific intellectual property regime which should be applicable to the specific collaboration improvements.

7.2 What considerations apply in agreements between healthcare and non-healthcare companies?

Firstly, such agreements must comply with the general principles and rules of Belarus civil law on agreements, as well as competition legislation. In addition, prices and tariffs in the healthcare sector are regulated by the state, therefore pricing requirements must also be complied with. Finally, with regard to agreements between Belarus residents and non-residents, it is important to comply with local foreign trade rules.

8 Artificial Intelligence and Machine Learning

8.1 What is the role of machine learning in digital health?

Machine learning in digital health and, overall, in healthcare is not regulated in Belarus. Implementing machine learning in digital health will contribute to improving the quality of medical care and active early detection of diseases in the human body. Machine learning possibilities may also be effective in the development of pharmaceuticals, storage of medical records and other methods of assistance to healthcare professionals with research and practice.

8.2 How is training data licensed?

There are no regulations covering training data licences in Belarus. Instead, general regulations should apply: (1) if training data relates to using personal data and information constituting medical secrecy, rules of sharing such data should apply – please see question 5.3; and (2) if training data relates to using intellectual property, rules of copyright licensing should apply.

8.3 Who owns the intellectual property rights to algorithms that are improved by machine learning without active human involvement in the software development?

This matter is not regulated in Belarus.

According to Belarus law, only an individual can be the author of a particular work (e.g. a computer program) – please see question 6.2. Moreover, algorithms should not be protected as copyright because copyright does not extend to methods, processes or systems, even if they are expressed, displayed, explained or embodied in a work (e.g. a computer program).

8.4 What commercial considerations apply to licensing data for use in machine learning?

Confidentiality of personal data, permissions to use relevant data, the scope of rights to be licensed and regulatory restrictions may be key commercial considerations that apply to licensing data for use in machine learning.

9 Liability

9.1 What theories of liability apply to adverse outcomes in digital health solutions?

Belarus legislation does not contain specific rules and theories on liability for violations in the field of digital health; therefore, general principles on civil, administrative and criminal liability apply.

In particular, liability for breach of medical secrecy may include:

- disciplinary liability (reprimand, admonition, dismissal, in accordance with labour legislation);
- administrative fine, if disclosure does not contain elements of crime;
- civil liability (e.g. compensation of damages and (or) moral harm); or
- criminal liability.

In relation to the illegal processing of personal data, non-compliance with requirements on data protection measures may lead to administrative fines. Some violations in the sphere of the protection of personal data may cause criminal liability; in particular:

- the unlawful collection or distribution of information relating to the private life, personal or family secrecy of another person without his/her consent; or
- the failure to comply with measures to ensure the protection of personal data by a person who processes personal data, which has inadvertently resulted in their dissemination and caused serious consequences.

9.2 What cross-border considerations are there?

There are some legal provisions that are subject to extraterritoriality in certain cases (e.g. personal data or antitrust regulation). In practice, however, the question of enforcement in such cases is open.

10 General

10.1 What are the key issues in Cloud-based services for digital health?

Information security and data protection are the key issues in Cloud-based services for digital health. Please see our responses to sections 4 and 5.

Distrust of service providers and the lack of standards that regulate this area are also worthy of mention. In particular, the lack of unified industry standards that require international standards HL7 FH1R, CDA, IHE, STB ISO/IEC 27001-2011 and reference books LOINC, SNOMED ST, which define the requirements for organising the storage, processing and transmission of information, ensuring the protection of personal data, identification of the system participants' healthcare and information interaction between the participants of a single medical information space.

Local parties involved in data processing may be affected by certain localisation requirements. According to the Presidential Edict No. 60 dated 1 February 2010, an activity involving selling goods, performing works or rendering services in the territory of Belarus through information networks, systems and resources, having connection to the Internet, is carried out by legal entities, their branches and representative offices, incorporated under the Belarus law with the seat in Belarus, as well as individual entrepreneurs, registered in Belarus, by using information networks, systems and resources located in Belarus and duly registered. In our opinion, this provision should be interpreted narrowly, and consequently applies only to Belarusian residents (e.g. when using Cloud-based solutions, located outside Belarus, to render services in Belarus) and shall not affect foreign Cloud-based providers directly.

10.2 What are the key issues that non-healthcare companies should consider before entering today's digital healthcare market?

Comprehensive regulatory due diligence, including data protection and investment issues, should be considered. Moreover, due to significant state-involvement in healthcare, it is important to consider local licensing and regulatory peculiarities. For example, clinical trials are conducted in state healthcare organisations defined and authorised by the Ministry of Healthcare. An agreement on conducting clinical trials is concluded between the sponsor and healthcare organisation; direct agreement with the investigator is not allowed.

10.3 What are the key issues that venture capital and private equity firms should consider before investing in digital healthcare ventures?

From a legal perspective, regulatory due diligence is recommended. As well as analysing the state of the field of venture capital and (or) direct financing, investors should identify negative trends on the Belarus market that affect its development.

10.4 What are the key barrier(s) holding back widespread clinical adoption of digital health solutions in your jurisdiction?

Based on the Concept, one of the main problems is the lack of necessary standards for the exchange of medical information in the healthcare system in accordance with the requirements of the legislation. Additionally, there is a lack of formed databases and data banks, as well as a lack of technical equipment.

10.5 What are the key clinician certification bodies (e.g., American College of Radiology, etc.) in your jurisdiction that influence the clinical adoption of digital health solutions?

There are no clinician certification bodies in Belarus; and we are not aware of any other bodies that have a power to influence the clinical adoption of digital health solutions. The relevant decisions are made in cooperation, mainly, between the Belarus government and the Ministry of Healthcare.

10.6 Are patients who utilise digital health solutions reimbursed by the government or private insurers in your jurisdiction? If so, does a digital health solution provider need to comply with any formal certification, registration or other requirements in order to be reimbursed?

There are no special regulations related to utilising digital health solutions and corresponding reimbursement. Instead, general reimbursement principles related to causing harm to patients' health should apply.

10.7 Describe any other issues not considered above that may be worthy of note, together with any trends or likely future developments that may be of interest.

Currently, Belarus is testing the central software platform of the CHIS. In case of successful completion of the tests, the intent is to introduce the platform. Preparations are also underway to switch to the new International Statistical Classification of Diseases and Related Health Problems, Revision 11 (ICD-11).

The plan for this platform is to provide access for each patient to their personal account and access to their medical data. The patient will be able to make an appointment through a personal account, receive test results and conclusions issued after consultations by specialists.

Kirill Laptev is a partner with Sorainen Law Firm in Belarus. He heads the TMT Sector Group and leads the Data Protection practice at Sorainen Belarus. Kirill is one of the shortlisted specialists for data protection and privacy matters, both on a national level and from an EU perspective, with a deep understanding of GDPR specifics. His key areas of expertise also include commercial contracts and regulatory matters. Kirill has broad experience in high-profile international commercial and investment arbitration, including in the sphere of IT/IP uniquely for the local market.

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