International Comparative Legal Guides

Drug & Medical Device Litigation 2020

A practical cross-border insight into drug & medical device litigation

First Edition

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Industry Chapter

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Belarus


Marina Golovnitskaya


Kirill Laptev


Maria Rodich

Sorainen

1 Regulatory Framework

1.1 Please list and describe the principal legislative and regulatory bodies that apply to and/or regulate pharmaceuticals, medical devices, supplements, over-the-counter products, and cosmetics.

Parliament is the key legislative body in Belarus. Also, state policy in the life sciences field is defined by the President, which is implemented by the Government.

The principal regulatory body in the life sciences sector is the Ministry of Healthcare. It is responsible for medical products registration, licensing pharmaceutical activities, pharmacovigilance system functioning, state registration and certification of particular cosmetics products.

There are several other state bodies performing particular functions. The Republican Unitary Enterprise "Center for Examinations and Tests in Healthcare" (**CETH**) conducts state registration of pharmaceuticals/medical devices and issues permits for pharmaceuticals/medical devices advertising. The Republican Unitary Enterprises "*Belpharmatsiya*" and "*Belmedtechnika*" organise pharmaceutical and medical devices' public procurement accordingly.

Belarus is a member of the Eurasian Economic Union (**EAEU**) along with Russia, Kazakhstan, Armenia and Kyrgyzstan. The single pharmaceuticals market within the EAEU is currently being launched, with the Eurasian Economic Commission being the key body issuing a broad range of decisions, while also covering the healthcare sector.

1.2 How do regulations/legislation impact liability for injuries suffered as a result of product use, or other liability arising out of the marketing and sale of the product? Does approval of a product by the regulators provide any protection from liability?

Belarus law does not contain special legislation for injuries suffered as a result of using healthcare products. Instead, general civil law and consumer protection laws would apply. For example, if an individual is injured, compensation shall be made for that individual's income lost and additional expenses (treatment costs, additional nutrition, pharmaceuticals purchased, nursing care, health resort treatment, etc.). Approval of a product *per se* does not protect from liability.

1.3 What other general impact does the regulation of life sciences products have on litigation involving such products?

Life sciences product regulation should be considered and applied on a case-by-case basis in case of litigation involving life sciences products.

1.4 Are there any self-regulatory bodies that govern drugs, medical devices, supplements, OTC products, or cosmetics in the jurisdiction? How do their codes of conduct or other guidelines affect litigation and liability?

Yes, there is the Belarus Association of International Pharmaceutical Manufacturers (**AIPM**), a non-profit organisation representing the professional and business interests of international pharmaceutical companies/manufacturers.

AIPM has its Code of Practice. It is not part of Belarus legislation, but represents obligations undertaken by its members. The Code specifies a range of principles and processes related to pharmaceuticals' promotion, interaction with healthcare professionals, advertising, studies, and charitable activities. The Code is based on Belarus legislation and often mirrors its provisions.

The Code establishes a dispute resolution procedure related to Code violations by AIPM members. According to this procedure, the members or other interested parties can file a complaint to the AIPM Front Office. The Front Office arranges letters exchanged between involved parties. If a dispute is not settled, it is considered by the AIPM Supervisory Council. Possible sanctions include online training regarding the Code of Practice or recommending that the AIPM General Meeting exclude the company from AIPM.

As for medical devices, supplements, over-the-counter (**OTC**) products, or cosmetics, there are no similar self-regulatory bodies.

1.5 Are life sciences companies required to provide warnings of the risks of their products directly to the consumer, or to the prescribing physician (i.e., learned intermediary), and how do such requirements affect litigation concerning the product?

Life sciences companies are required to warn of the risks of their products in several ways:

- indicating information on safe and effective medical use of pharmaceuticals in the instructions on the medical application and a package leaflet;
- warning in the advertisement of the need for consumers to familiarise themselves with instructions on the medical application/package leaflet, and/or consult with a physician; and
- in case of adverse reactions, manufacturers should report to CETH within 15 calendar days after they receive information on adverse reactions.

These requirements have no direct impact on litigation concerning the product.

2 Manufacturing

2.1 What are the local licensing requirements for life sciences manufacturers?

Pharmaceuticals can be manufactured by legal entities and individual entrepreneurs holding a pharmaceutical licence issued by the Ministry of Healthcare. The licence is perpetual and allows manufacturing and wholesale trade of pharmaceuticals in accordance with Good Manufacturing Practice (**GMP**) and Good Wholesale Practice. There are particular licensing requirements; for example, having an employee with higher pharmaceutical education responsible for licensed activity, and having sufficient and appropriate premises, technical equipment, etc.

Manufacturing other life sciences products such as cosmetics or medical devices does not require a licence.

2.2 What agreements do local regulators have with foreign regulators (e.g., with the U.S. Food and Drug Administration or the European Medicines Agency) that relate to the inspection and approval of manufacturing facilities?

Local regulators do not have particular agreements with foreign regulators such as the FDA or EMA. There is cooperation between regulators within the EAEU framework; for example, under the EAEU GMP.

2.3 What is the impact of manufacturing requirements or violations thereof on liability and litigation?

Manufacturing requirements or violations thereof do not have a specific impact on liability against consumers and litigation.

There is liability for breaching licensing regulations. For example, manufacturing pharmaceuticals without a licence may lead to administrative liability such as fines and received income confiscation. Licences can be suspended or even cancelled in case of gross infringements; for example, selling pharmaceuticals prohibited for sale, violating storage conditions leading to the non-compliance of pharmaceuticals' quality, performing licensed activities in places not specified in the licence, etc.

3 Transactions

3.1 Please identify and describe any approvals required from local regulators for life sciences mergers/acquisitions.

Life sciences mergers/acquisitions may require merger clearance/approval issued by the Ministry of Antimonopoly Regulation and Trade. It may be needed if the merger/acquisition is considered an economic concentration and relevant thresholds are exceeded. Also, it might be necessary to amend marketing authorisation if its holder is changed. Please note that, currently, a new Law on Pharmaceuticals is being considered in the Parliament, which may introduce relevant procedures as well as change the regulatory framework applicable to drugs in general.

3.2 What, if any, restrictions does the jurisdiction place on foreign ownership of life sciences companies or manufacturing facilities? How do such restrictions affect liability for injuries caused by use of a life sciences product?

Belarus law does not contain specific restrictions related to foreign ownership of life sciences companies or manufacturing facilities. Rather, general legal and tax requirements should be observed.

4 Advertising, Promotion and Sales

4.1 Please identify and describe the principal legislation and regulations, and any regulatory bodies, that govern the advertising, promotion and sale of drugs and medical devices, and other life sciences products.

The principal legislation governing advertising, promotion and sale of drugs and medical devices is the Law on Advertising. This Law establishes general advertising regulations and describes specifics related to drugs and medical devices advertising. For example, such advertising, as a general rule, can occur with approval of Ministry of Healthcare and provided there is a marketing authorisation. The key regulatory bodies governing the advertising, promotion and sale of drugs and medical devices and other life sciences products are the Ministry of Antimonopoly Regulation and Trade and the Ministry of Healthcare.

4.2 What restrictions are there on the promotion of drugs and medical devices for indications or uses that have not been approved by the governing regulatory authority ("off label promotion")?

Belarus law does not allow "off label promotion".

4.3 What is the impact of the regulation of the advertising, promotion and sale of drugs and medical devices on litigation concerning life sciences products?

Regulation of advertising, promotion and sale of drugs and medical devices does not have a specific impact on litigation concerning life sciences products.

There is liability for breaching advertising regulations. For example, advertising without approval of the Ministry of Healthcare when such an approval is required may lead to administrative liability in the form of a fine.

5 Data Privacy

5.1 How do life sciences companies which distribute their products globally comply with GDPR standards?

Since Belarus is not an EU Member State, GDPR may apply to locally established life sciences companies according to the GDPR Art. 3 rules on exterritorial effect. To the best of our

knowledge, certain life sciences companies established in the EU and that transfer personal data to Belarus implement data processing agreements and special measures for personal data transfer to countries which are not considered adequate by the European Commission.

Please note that a Draft Law on personal data protection passed its first reading by the lower chamber of Parliament in June 2019, and may be adopted during the next Parliament session. The draft provides for a one-year period to take effect, so we do not expect it to enter into force earlier than 2021. The draft provides for certain standards for personal data protection similar to those established in the GDPR (e.g. cross-border transfer and requirements for consent).

5.2 What rules govern the confidentiality of documents produced in litigation? What, if any, restrictions are there on a company's ability to maintain the confidentiality of documents and information produced in litigation?

Procedural code rules govern the confidentiality of documents produced in litigation. As a general rule, parties not involved in the case have no access to familiarisation with case materials.

Litigation is usually held in an open court, but upon certain conditions could be held in closed sessions (e.g. if it relates to secrets protected by law or information disclosure on intimate aspects of a person's life). In closed sessions, parties involved sign a non-disclosure notice and could be held liable for disclosure.

5.3 What are the key regulatory considerations and developments in Digital Health and their impact, if any, on litigation?

The key regulatory document providing the main areas of the e-health system development is the Concept of e-Health Development until 2022, as approved by the Order of the Ministry of Healthcare. It provides for key goals, objectives and principles of e-Health development as well as expected results.

The concept of telemedicine is developing in Belarus. Relevant amendments to the Law on Healthcare providing regulation of telemedicine were introduced to Parliament at the end of 2019 and are expected to be approved during 2020.

Another technical development in the healthcare sector – the electronic prescriptions system – is used by doctors for issuance of e-signed prescriptions in electronic form. Healthcare institutions and pharmacies are registered in the system. Patients can present a special personal card, issued by the healthcare institution, in pharmacies with their electronic prescriptions and get prescribed drugs.

6 Clinical Trials and Compassionate Use Programmes

6.1 Please identify and describe the regulatory standards, guidelines, or rules that govern how clinical testing is conducted in the jurisdiction, and their impact on litigation involving injuries associated with the use of the product.

The key regulation governing clinical trials is Good Clinical Practice (**GCP**). It reflects international standards of conducting clinical trials.

GCP establishes that clinical trials are conducted in state healthcare organisations defined by the Ministry of Healthcare and per the latter's authorisation. Trials can be commenced only if pre-trial research shows that the pharmaceutical is safe and effective and if the risk of side effects is reasonable in the light of the expected positive effects. GCP sets a range of subjects' rights and establishes the legal framework for clinical trials (for example, no direct agreements are allowed between the sponsor and doctors).

There is no specific impact of clinical trial regulations on litigation involving injuries associated with product use.

6.2 Does the jurisdiction recognise liability for failure to test in certain patient populations (e.g., can a company be found negligent for failure to test in a particular patient population)?

No, Belarus law does not establish specific liability for the failure to test in certain patient populations.

6.3 Does the jurisdiction permit the compassionate use of unapproved drugs or medical devices, and what requirements or regulations govern compassionate use programmes?

Belarus law permits compassionate use of unapproved drugs. Legal entities and individuals, including individual entrepreneurs, are allowed to import drugs without marketing authorisation intended for treatment of a limited number of patients with a rare pathology. Importers should have a licence for medical activity and the Ministry of Healthcare's permit, subject to a procedure set by law.

6.4 Are waivers of liability typically utilised with physicians and/or patients and enforced?

No, waivers of liability are not typically utilised with physicians and/or patients and enforced when conducting clinical trials or compassionate use programmes.

6.5 Is there any regulatory or other guidance companies can follow to insulate or protect themselves from liability when proceeding with such programmes?

No, there is no specific regulatory or other guidance to be followed to insulate or protect from liability when proceeding with such programmes.

7 Product Recalls

7.1 Please identify and describe the regulatory framework for product recalls, the standards for recall, and the involvement of any regulatory body.

The key provisions governing drug recalls are established by the Regulations of the Government and Ministry of Healthcare. Low-quality and falsified drugs, drugs with expired expiration dates, as well as drugs with suspended or cancelled marketing authorisations are subject to recall by suppliers or holders of marketing authorisation upon decision of the Ministry of Healthcare. The decision of the Ministry of Healthcare is circulated to a range of market players and state authorities, including suppliers, the Republican Unitary Enterprises "*Belpharmatsiya*", "*Minskaya Pharmatsiya*", "*Pharmatsiya*", the State Customs Committee, and the Ministry of Internal Affairs. Information on the decision is posted on the websites of CETH and the Ministry of Healthcare.

7.2 What, if any, differences are there between drugs and medical devices or other life sciences products in the regulatory scheme for product recalls?

The main difference is that the procedure is specified in detail for drugs, while for other products regulations are much less specific. For example, cosmetics manufacturers should be guided by general consumer protection laws.

7.3 How do product recalls affect litigation and government action concerning the product?

Product recalls do not specifically affect litigation and government action concerning the product.

7.4 To what extent do recalls in the United States or Europe have an impact on recall decisions and/or litigation in the jurisdiction?

Belarus law is silent regarding the impact of recalls in the United States or Europe on recall decisions and/or litigation in Belarus. Still, such information can be taken into account by local controlling authorities.

7.5 What protections does the jurisdiction have for internal investigations or risk assessments?

Belarus law does not set specific protections for internal investigations or risk assessments.

7.6 Are there steps companies should take when conducting a product recall to protect themselves from litigation and liability?

The key steps are following the applicable laws and minimising possible negative consequences, depending on the case peculiarities.

8 Litigation and Dispute Resolution

8.1 Please describe any forms of aggregate litigation that are permitted (i.e., mass tort, class actions) and the standards for such aggregate litigation.

Such forms could be exercised by a procedural co-participation, which involves the consolidation of separate claims and consumer protection bodies' claims in favour of an unlimited number of consumers.

Procedural co-participation is possible where the dispute has a common subject, actual and legal grounds, and homogeneous rights and duties of the persons participating in the case. Co-participants may entrust their co-participants to conduct the case in their name.

With respect to consumers at large, consumer protection bodies are entitled to bring a case before the court to declare the manufacturer's actions unlawful or file a consumer protection lawsuit.

8.2 Are personal injury/product liability claims brought as individual plaintiff lawsuits, as class actions or otherwise?

Generally, these claims are brought as individual plaintiff lawsuits but could be also brought by the consumer protection bodies in favour of an unlimited number of consumers.

8.3 What are the standards for claims seeking to recover for injuries as a result of use of a life sciences product? (a) Does the jurisdiction permit product liability claims? (b) Are strict liability claims recognised?

Each party shall prove the facts to which it refers as the basis of its claims or objections. Moral harm caused to a consumer shall be compensated by the wrongdoer based on the fault which is presumed:

(a) Harm caused due to defects in the goods, or failure to provide comprehensive or reliable information about goods shall be compensated by either the seller or manufacturer at the victim's discretion. The seller or manufacturer/contractor shall not be held liable provided they prove damage occurred as a result of *force majeure* or the consumer's violation of rules for the use of the goods.

(b) Strict liability is realised in relation to legal entities and citizens whose activity is connected with an increased danger for bystanders (e.g. use of mechanisms or explosive substances). They shall compensate for any harm caused by the source of increased danger unless they prove that the harm occurred due to *force majeure* or the victim's intent.

8.4 Are there any restrictions on lawyer solicitation of plaintiffs for litigation?

A lawyer (only Bar-admitted attorneys can litigate) must not impose assistance on individuals and engage them as clients via personal connections with law enforcement and judicial officials, offering to assist the client instead of the chosen attorney, promising the client a successful outcome of a case because of the attorney's participation and other unworthy means. Advertising in the conventional sense, using the common means of advertising goods and services, seems to be unacceptable for an attorney.

8.5 What forms of litigation funding are permitted/utilised? What, if any, regulation of litigation funding exists?

Forms of litigation funding in Belarus include exemption from state fee payment for certain categories of cases (e.g. product liability claims) and the possibility of state fee payment by a third party, which are regulated by the Tax Code. In the instances specified by law, legal assistance shall be rendered at the expense of state funding. Commercial funding of litigation is not used in Belarus; no specific regulation exists.

8.6 What is the preclusive effect on subsequent cases of a finding of liability in one case? If a company is found liable in one case, is that finding considered *res judicata* in subsequent cases?

The "*res judicata*" rule has a limited effect expressed: in general, it is not the liability itself that has a preclusive effect, but rather the existence of certain facts established by a court's decision. Finding a company liable in one case does not necessarily entail its liability in the subsequent case, as the court may just rely on information regarding whether or not certain facts have ever occurred.

The preclusive effect only covers subsequent cases between entities that have legal interest in the previous case and their legal successors. Namely, those who were not involved in the

previous proceedings are not subject to the preclusive effect and may challenge relevant facts.

8.7 What are the evidentiary requirements for admissibility of steps a company takes to improve their product or correct product deficiency (subsequent remedial measures)? How is evidence of such measures utilised in litigation?

Any factual data obtained in accordance with the procedure provided by law can be treated as evidence. The general rule is that harm caused is subject to full compensation. Compensation of moral harm may depend, *inter alia*, on a company's behaviour.

8.8 What are the evidentiary requirements for admissibility of adverse events allegedly experienced by product users other than the plaintiff? Are such events discoverable in civil litigation?

Courts accept and examine only the evidence that can confirm or refute the facts to be proved in the case. Means of evidence include, *inter alia*, witness statements (including those obtained using video-conference systems), written and physical evidence, expert opinions and other information means. Information obtained in violation of the procedures established (e.g. unlawful collection of information constituting personal privacy without that person's consent) cannot be regarded as evidence.

8.9 Depositions: What are the rules for conducting depositions of company witnesses located in the jurisdiction for use in litigation pending outside the jurisdiction? For example, are there "blocking" statutes that would prevent the deposition from being conducted in or out of the jurisdiction? Can the company produce witnesses for deposition voluntarily, and what are the strategic considerations for asking an employee to appear for deposition? Are parties required to go through the Hague Convention to obtain testimony?

Mutual Legal Assistance Treaties allow for cross-border mechanisms of courts' co-operation, including conducting depositions. Such requests are accepted if the requested actions fall within the court's jurisdiction and do not contradict sovereignty or threaten state security. In case of absence of such treaties, the request may be satisfied on the reciprocity principle.

The company can produce witnesses for deposition voluntarily. The party to the dispute can name particular witnesses for deposition (stating the name and position within the company), grounding which circumstances can be testified by the indicated witness.

Where the Hague Convention is applicable, the parties are required to go through such Convention to obtain testimony. Belarus is also a party to a number of regional (e.g. within CIS Member States) and bilateral treaties, setting the legal framework for mutual assistance on deposition.

8.10 How does the jurisdiction recognise and apply the attorney-client privilege in the context of litigation, and with respect to in-house counsel?

Information constituting the attorney-client privilege cannot be obtained from an attorney and used as evidence in criminal, civil, economic and administrative processes. An attorney cannot be questioned as a witness about circumstances that constitute the attorney-client privilege, and government agencies and other organisations cannot request, seize, or otherwise obtain information from an attorney that constitutes the attorney-client privilege. Attorney-client privilege is applicable only towards Bar-admitted attorneys and thus cannot be exercised by in-house counsel.

8.11 Are there steps companies can take to best protect the confidentiality of communications with counsel in the jurisdiction and communications with counsel outside the jurisdiction for purposes of litigation?

As general steps, the company should take legal, organisational, technical and other measures to establish the regulation of commercial secrets in the company. In relations with counsel in the jurisdiction, the company shall additionally ensure:

- the signing of a confidentiality agreement with the counsel providing legal services. With regard to attorneys, there is no need to sign such separate agreement (attorney-client privilege); and
- the stamping of documents/email correspondence with the mark "Commercial secret" when transferring documents/information to the counsel who is the local state authority officer. Verbal communication with such officer should be protected as a respective secret (e.g., tax secret, procedural confidential information, etc.).

In relations with counsel outside the jurisdiction, we believe the best way to ensure confidentiality is to sign a confidentiality agreement with the counsel. With regard to the counsel who is the foreign state authority officer, there are no local regulations explicitly regulating confidentiality protection within such cross-border information transmission.

8.12 What limitations does the jurisdiction recognise on suits against foreign defendants?

Belarus courts have jurisdiction over claims against foreign legal entities if the governing body or branch of such a legal entity is located in Belarus. Economic courts also consider disputes related to harm caused in Belarus territory, or in other cases if there is a close connection with Belarus.

8.13 What is the impact of U.S. litigation on "follow-on" litigation in your jurisdiction?

If a Belarus court exercises exclusive jurisdiction over the case, the court shall continue case consideration and render a decision even when a foreign court is considering or has already considered the identical case.

Earlier initiation of the case in a foreign court not falling within the exclusive jurisdiction of Belarus courts may entail identical case termination in Belarus.

8.14 What is the likelihood of litigation evolving in your jurisdiction as a result of U.S. litigation?

A foreign court decision (1) between the same parties, (2) on the same subject, and (3) on the same grounds, which has already come into force, shall entail case dismissal by a Belarus court on the condition that the case does not fall within the exclusive jurisdiction of Belarus courts and there are no grounds for refusal to recognise and enforce the said decision. If one of conditions (1)–(3) is not met, the case is not deemed identical and we see no objections for its consideration. Please also note that, in the absence of a treaty between Belarus and the US, recognition and US decision enforcement in Belarus is questionable.

Marina Golovnitskaya is a regional head of Sorainen Life Sciences and Healthcare Sector Group. She manages Sorainen's regional team and leads the life sciences-related projects in Belarus. For years she has worked with companies in the pharmaceuticals sector, learning the industry from within. Marina serves as a day-to-day advisor for both Big Pharma and boutique healthcare companies in a range of matters; for example, clinical trials, marketing of pharmaceuticals, patients' data protection, regulatory issues, compliance, anti-corruption and anti-bribery regulations, and white-collar crimes. She is also regularly engaged in drafting, negotiating and localising contracts under Belarusian and non-Belarusian law, as well as advising on antimonopoly compliance, and assisting clients with regulatory matters involving certification and licensing.
Marina is recommended by *The Legal 500* for Intellectual Property.

Sorainen
ul Internatsionalnaya 36-1
220030
Minsk
Belarus

Tel: +375 17 306 2102
Email: marina.golovnitskaya@sorainen.com
URL: www.sorainen.com

Kirill Laptev 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 possesses wide experience in high-profile international commercial and investment arbitration, including in the sphere of IT/IP uniquely for the local market. He has represented clients in arbitration cases at the world's top arbitration institutions: ICC (Paris); SCC (Stockholm); VIAC (Vienna); LCIA (London); and regularly pleads in the IAC at the BelCCI (Belarus). Wide practice in recognition and enforcement of foreign arbitral awards is also one of his key strengths.
He has been recognised as a Next Generation Lawyer for commercial, corporate and M&A by *The Legal 500*, alongside receiving nominations for arbitration and trade & customs by *Who's Who Legal*.

Sorainen
ul Internatsionalnaya 36-1
220030
Minsk
Belarus

Tel: +375 17 306 2102
Email: kirill.laptev@sorainen.com
URL: www.sorainen.com

Maria Rodich is a trial counsel skilled in handling contentious matters at both national and international levels, as well as regulatory and corporate crime investigations. She also heads the Compliance practice at Sorainen Belarus. With over 12 years' experience resolving complex, high-profile disputes, she always aims to produce creative, pragmatic solutions and manage clients' risks in an increasingly challenging legal environment. Being equipped with advanced legal, commercial and policy knowledge, as well as sectoral expertise, Maria is particularly skilled in disputes under the Vienna Convention on Contracts for the International Sale of Goods, competition and regulatory disputes. She is also experienced in tailored advice in bankruptcy proceedings, including acting on the creditors' committee board, protecting creditors' claims and effectively defending the interests of minority creditors. Maria is praised by her clients for focusing on detail and thinking tactically to achieve the best result, always being available to advise on a very urgent basis.

Sorainen
ul Internatsionalnaya 36-1
220030
Minsk
Belarus

Tel: +375 17 306 2102
Email: maria.rodich@sorainen.com
URL: www.sorainen.com

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