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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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.

Lithuania's supreme legislative body is the *Seimas* (Lithuanian Parliament). It adopts laws (primary legislation). The executive power in Lithuania is vested in the Government, which executes laws and *Seimas*' resolutions implementing the laws.

Lithuania is a Member State of the European Union; therefore, all legislation introduced at an EU level also applies to the Lithuanian market. EU Directives are transposed into Lithuanian laws. Regulations issued by the European Union are directly applicable in Lithuania and no transposition is required. Apart from EU regulations related to pharmaceuticals, medical devices, supplements, and over-the-counter products, the principal legislation for pharmaceuticals, medical devices, supplements, and over-the-counter products consists of the following laws: the Lithuanian Law on Pharmacy; Lithuanian Law on the Health System; and Lithuanian Law on Food. As regards cosmetics, there is no principal national law in respect of such products; the principal legislation is EU Cosmetics Regulation (EC) No 1223/2009. Secondary legislation consists of the resolutions of the Government and various regulations approved by the regulatory authorities.

The authorities responsible for applying and enforcing the regulatory framework and performing control functions in relation to pharmaceuticals, medical devices, supplements, over-the-counter products, and cosmetics are as follows:

(i) the State Medicines Control Agency under the Ministry of Healthcare (pharmaceuticals including over-the-counter drugs);
(ii) the State Health Care Accreditation Agency under the Ministry of Healthcare (medical devices);
(iii) the State Food and Veterinary Service (supplements);
(iv) the National Public Health Centre under the Ministry of Healthcare (cosmetics); and
(v) the State Consumer Rights Protection Authority (cosmetics).

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?

Pursuant to the Lithuanian Law on Pharmacy, being granted a medicinal product marketing authorisation will not exempt the manufacturer of the medicinal product and holder of the medicinal product manufacturing authorisation from liability established in legal acts.

Lithuanian regulations implementing Medical Devices Directive 93/42/EEC stipulate that all medical devices (except several exclusions) must bear the CE marking. By placing the CE marking on a product, a manufacturer is declaring, on his sole responsibility, conformity with all of the legal requirements to achieve such marking. In order to place a medical device on the Lithuanian market, an applicant has to register the medical device with the State Health Care Accreditation Agency under the Ministry of Healthcare, which only checks whether an application form is completed correctly and all necessary documents have been submitted, i.e. it does not check the safety of the product. Thus, registration of the medical product does not provide any protection from liability.

The supply of food supplements to Lithuania may be conducted only following notification to the State Food and Veterinary Service, which only checks whether an application form is completed correctly and all necessary documents have been submitted, i.e. it does not check the safety of the product. Thus, notification of the food supplements does not provide any protection from liability.

As regards cosmetics, pursuant to Cosmetics Regulation (EC) No 1223/2009, notification is required for all cosmetics intended for sale in the EU prior to their market launch. Notification does not provide any protection from liability.

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

Litigation involving life sciences products is very limited in Lithuania; therefore, the impact of the regulation of life sciences products on litigation involving such products cannot be properly assessed.

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?

There are two self-regulatory bodies involved in the governing of drugs: the Innovative Pharmaceutical Industry Association (IFPA); and the Lithuanian Association of Generic Pharmaceuticals Manufacturers (VGA). Their Code of Ethics for Pharmaceutical Marketing regulates pharmaceutical marketing and relations with healthcare professionals, as well as relations between the pharmaceutical industry and patient organisations and disclosure of information about transfers of value to healthcare professionals and healthcare organisations, applicable to companies engaged in pharmaceutical marketing in Lithuania. The Code provides for an independent enforcement mechanism: a special committee examines violations of the rules established by the Code; procedures before or measures taken by the committee and procedures before or measures taken by courts/regulatory authorities are unrelated.

The self-regulatory system for medical devices is controlled by the Association of Manufacturers of Medical Equipment (MIGA). The Code of Ethics of the Lithuanian Association of Manufacturers of Medical Equipment regulates the industry's relationship with healthcare professionals and healthcare organisations, such as company-organised events, arrangements with consultants, research and financial support for medical education, amongst others. The Code provides for an independent enforcement mechanism: a special committee examines violations of the rules established by the Code; procedures before or measures taken by the committee and procedures before or measures taken by courts/regulatory authorities are unrelated.

The food supplements industry is not self-regulated in Lithuania.

The cosmetics industry is not self-regulated on a national level, but is self-regulated on an EU level only (Cosmetics Europe Charter on responsible advertising and marketing communication, and the Guiding Principles on Responsible Advertising and Marketing Communication).

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?

Medicinal products must be accompanied by a Package Information Leaflet (PIL) containing information on potential side effects of the drug. Instructions for the use of medical devices should also contain information on side effects. Therefore, in general, the learned intermediary doctrine is not applicable in Lithuania as consumers should carefully read the PIL/instructions. As regards food supplements and cosmetics, there is no mandatory requirement to inform customers/physicians about possible side effects.

2 Manufacturing

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

Pharmaceutical products may be manufactured only by a legal entity that holds a manufacturing licence issued by the State Medicines Control Agency.

A manufacturer of a medical device does not require any specific manufacturing licence in Lithuania. Instead, the manufacturer must ensure that its medical device is manufactured in accordance with the essential requirements set out in the relevant EU Medical Devices Directive.

The manufacture of food supplements is considered as processing of food and requires a certificate of food business operator approval, issued by the State Food and Veterinary Service.

As regards manufacturers of cosmetics, they are obliged to have hygiene-permit passports issued by the National Public Health Centre under the Ministry of Healthcare.

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?

Based on the mutual recognition agreement signed between the European Union and the United States to recognise inspections of manufacturing sites for human medicines conducted in their respective territories, the State Medicines Control Agency is recognised by the US Food and Drug Administration (FDA) as capable of carrying out good manufacturing practice (GMP) inspections at a level equivalent to the US.

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

In Lithuania, medicines, medical devices, food supplements, and cosmetics are subject to the general product liability rules. A strict liability regime (without fault) is applicable in respect of manufacturers of such products. Thus, in principle, manufacturing requirements and violations of such requirements do not impact liability and litigation.

3 Transactions

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

No approvals from local regulators for life sciences mergers/acquisitions are required except for the approval of the Competition Council of the Republic of Lithuania for transactions falling within the concept of "concentration".

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?

This is not applicable in Lithuania.

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.

Advertising, promotion and sale of drugs are governed by the Lithuanian Law on Pharmacy and the Rules on Advertising of Medicines approved by the Minister of Healthcare of the

Republic of Lithuania. Further, a self-regulation document – the Code of Ethics for Pharmaceutical Marketing adopted by IFPA and VGA – also regulates pharmaceutical marketing by establishing specific restrictions in relation to marketing of medicinal products, e.g. limitations related to: donations and grants to institutions; frequency, timing, and duration of visits with the aim of meeting healthcare professionals or visiting healthcare facilities; and samples of medicinal products, etc. In the case of violations of the requirements for the advertising of medicines established by the Lithuanian Law on Pharmacy and the Rules on Advertising of Medicines, supervision is carried out by the State Medicines Control Agency, whereas in case of violations of the rules established by the Code of Ethics for Pharmaceutical Marketing, supervision is carried out by the Supervisory Committee for the Code of Pharmaceutical Ethics.

Advertising of medical devices and other life sciences products is regulated by the Lithuanian Law on Advertising. Supervision is carried out by the State Consumer Rights Protection Authority.

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")?

Promotion of medicines and medical devices off-label is prohibited in Lithuania.

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?

Litigation involving life sciences products is very limited in Lithuania; therefore, the impact of the regulation of the advertising, promotion and sale of drugs and medical devices on litigation concerning life sciences products cannot be properly assessed.

5 Data Privacy

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

In general, global life sciences companies adhere to GDPR standards and put in a great deal of effort in order to comply with personal data processing requirements. However, no post-GDPR guidelines or recommendations have been introduced by the State Data Protection Inspectorate which would be welcomed, especially by the pharmacy sector dealing with the controller/processor relationship in relation to principal investigators and sites in clinical trials.

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?

Confidentiality of documents produced in litigation is governed by the Lithuanian Code of Civil Procedure. Upon passing a judgment or final ruling in court proceedings in a public court session, the court shall have the right, at the request of participants in the proceedings or on its own initiative, to determine by a reasoned ruling that the case file or a part thereof is not public, when it is necessary to protect private family life or property, keep information about a person's health confidential, and also when there are grounds to deem that a state, official, professional, commercial or other secret protected by law may be disclosed. A separate appeal may be filed against the court ruling denying the request.

Furthermore, where there are reasonable grounds for believing that commercial secrets may be disclosed, upon a duly substantiated request of the parties or of its own motion, the court may designate persons who are entitled to access the case files, attend closed court hearings and obtain a copy of the court decision or order disclosing the information constituting a commercial secret.

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

On 26 June 2014, the Lithuanian Parliament (*Seimas*) approved the National Health Strategy 2015–2025. Among the main goals of the strategy is the goal of completing the development of the Lithuanian eHealth system. The programme of the eHealth system aims to ensure that all healthcare institutions participate in the development of the eHealth system to guarantee that all such institutions in Lithuania are able to provide patients' health records through electronic means via a designated portal.

Litigation involving Digital Health is very limited in Lithuania. Therefore, the impact of the key regulatory considerations and developments in Digital Health concerning litigation cannot be properly assessed.

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 legislation that governs clinical trials of medicinal products in Lithuania is the Law on Pharmacy and the Law on Ethics of Biomedical Research.

Clinical trials of medicinal products may be commenced only after the State Medicines Control Agency (the main authority supervising clinical trials) has issued its approval and the Lithuanian Bioethics Committee (which coordinates the ethical review of biomedical research projects in Lithuania) has expressed its positive opinion. The approvals by the two authorities are issued within 60 calendar days but the term may be extended up to 90 additional days in case consultations with experts are necessary.

In addition, Good Clinical Practice standards must be adhered to when designing, conducting and reporting clinical trials, and an insurance policy must also be obtained by the sponsor and principal investigator where interventional research methods posing a risk to the subject's health are used. An insurance policy must provide for a coverage of at least EUR 29,000 for pecuniary and non-pecuniary damage per subject.

The key legislation that governs biomedical research of medical devices in Lithuania is the Law on Ethics of Biomedical Research.

Biomedical research on medical devices can only be performed with the permission of the Lithuanian Bioethics Committee after obtaining a conclusion of the State Health Care Accreditation Agency regarding the compliance of medical devices with the requirements for biomedical research.

Litigation involving injuries associated with the use of the product is very limited in Lithuania. Therefore, the impact of the legal regulation on the litigation cannot be properly assessed.

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)?

There is no specific liability for failure to test in certain patient populations; therefore, general liability rules for the clinical trial sponsor and the principal investigator apply.

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

Presently, there is no clear and/or special regulation on the use of unapproved drugs or medical devices in Lithuania. Nevertheless, Article 20 of the Law on the Health System envisages such possibility, stating that a healthcare professional may use new, scientifically based, but not yet approved healthcare technology if:

(i) it is used for the treatment of the patient, trying to save the patient or prolong the patient's life;
(ii) the patient's consent is obtained; and
(iii) the consent of the ethics commission of the relevant healthcare institution is obtained.

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

In case a healthcare professional uses new, scientifically based, but not yet approved healthcare technology, responsibility lies with the healthcare professional and s/he cannot waive liability because of the prohibition under the Lithuanian Civil Code to exclude or limit civil liability for health impairment or deprivation of life.

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

As mentioned in the answer to question 6.3, there is no clear or special regulation for the use of unapproved drugs or medical devices in Lithuania. To date, no healthcare institutions and physicians have been challenged because of illegal or improper use of unapproved drugs or medical devices.

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 Lithuanian Law on Product Safety is a law of a general nature establishing general rules for product recalls. Additional rules in respect of certain products are established by the laws applicable to the respective products.

Recall of medicinal products is specifically regulated by the Lithuanian Law on Pharmacy. A recall may be initiated by a manufacturer or the State Medicines Control Agency. The State Medicines Control Agency recalls a medicinal product when it determines at least one of the following circumstances: (i) the medicinal product is harmful under normal conditions of use; (ii) the medicinal product lacks therapeutic efficacy; (iii) the qualitative and quantitative composition of the medicinal product is not as declared; (iv) the risk-benefit balance is not favourable; or (v) the controls on the product or the ingredients have not been carried out or some other obligation relating to the granting of the market authorisation is not fulfilled.

Recall of medical devices is specifically regulated by the Lithuanian Law on the Health System. A manufacturer/importer/distributor of medical devices is obligated to recall such devices when it finds out that they are not in compliance with technical regulations applicable to medical devices. Recall may be voluntary or imposed by the State Health Care Accreditation Agency under the Ministry of Healthcare (the institution may recall medical devices by itself when a manufacturer/importer/distributor of medical devices fails to fulfil the obligation to recall the medical devices).

If a manufacturer/importer/distributor of food supplements/cosmetics finds out that products are unsafe, it is obligated to immediately inform consumers and relevant authorities to withdraw those products from the market and to recall them when necessary. The State Food and Veterinary Service obligates the recall of unsafe food supplements. The National Public Health Centre under the Ministry of Healthcare obligates the recall of unsafe cosmetics.

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?

As mentioned in the answer to question 7.1, the Lithuanian Law on Product Safety is a law of a general nature establishing general rules for product recalls. Additional rules in respect of certain products are established by the laws applicable to the respective products.

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

A manufacturer/importer/distributor of products is obligated to inform the relevant public authorities about recalls. Product recall announcements are released on the respective public authority's website. In case a recall is initiated by public authorities and the manufacturer/importer/distributor of the products fails to recall the products, the recall is conducted by the authorities. The expenses incurred have to be recovered from the manufacturer/importer/distributor of the recalled products. Failure to comply with the public authority's requirement to recall a product is subject to a fine from EUR 2,500 to EUR 6,500. Placement of dangerous products on the market which caused damage to the health of a consumer is subject to a fine from EUR 2,500 to EUR 15,000. Placement of dangerous products on the market which caused the death of a consumer is subject to a fine from EUR 6,500 to EUR 25,000.

As regards litigation, a recall does not automatically make a manufacturer liable. A plaintiff must still prove that the defect of the recalled product caused his or her injuries.

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?

Lithuania, as an EU Member State, uses EU rapid alert systems for respective products, evaluating information received from other EU Member States in respect of recalls of products, i.e. whether the recalled products concern Lithuania and, if so, taking appropriate measures:

(i) for medical products – Rapid Alert System;
(ii) for medical devices – vigilance reporting system (MEDDEV);
(iii) for food supplements – Rapid Alert System for Food and Feed (RASFF); and
(iv) for cosmetics – Rapid Exchange of Information System (RAPEX).

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

In Lithuania, internal investigations carried out as part of the ordinary course of business (for instance, by in-house counsel) do not enjoy legal privilege. Only advocates, who are members of the Lithuanian Bar, are protected by legal privilege, whereas other legal professionals, including in-house counsel, are not covered by the laws of legal privilege in Lithuania. Thus, internal investigations carried out by advocates are subject to legal privilege.

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

As mentioned, a strict liability regime (without fault) is applicable in respect of manufacturers of such products; therefore, it is impossible to avoid liability. However, in order to minimise possibilities of litigation and limit liability, it is advisable to coordinate all communication in relation to recalls with legal advisers and, in case of necessity, to recall defective products as soon as possible, and to collect properly all the evidence in relation to the recall and returned products.

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.

In Lithuania, two types of aggregate litigation are possible under the Lithuanian Code of Civil Procedure:

(i) A class action, which must meet the following requirements:
- there are at least 20 natural or legal persons (a group) whose rights have been infringed and who are willing to file a lawsuit together;
- legal or factual claims of the suit are common for the entire group;
- a class action will be more efficient than numerous individual cases;
- the group has notified the defendant of the intention to file a class action;
- the group must have a representative who may be elected from the members of the group and act in the name of the group; and
- the group must also be represented by an advocate.

(ii) A civil claim brought by several co-plaintiffs together or against several defendants if the subject of a claim is:
- rights or liabilities assumed by them together in accordance with laws (compulsory joinder); or
- claims or liabilities of the same nature, based on the same points of fact and law, when each separate claim can constitute a subject of an independent claim (optional joinder).

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

In Lithuania, personal injury/product liability claims may be brought both as individual lawsuits and class actions. In practice, such claims are started as individual lawsuits.

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?

In Lithuania, product liability is held to a standard of strict liability. To succeed on a claim, the plaintiff must prove the defect, the damage and the causal link between the defect and the damage.

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

Neither the Lithuanian Law on the Bar nor the Code of Ethics of Lithuanian Attorneys establishes any rules for lawyer solicitation.

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

Lithuanian laws do not establish any specific regulation on litigation funding.

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?

A court judgment in one case may serve as a precedent (become a guide) in subsequent cases if the court's interpretation of law contained in the decision is relevant for the consideration of the subsequent case, i.e. in analogous cases. Precedents are advisory rather than mandatory within the Lithuanian legal system.

Pursuant to the Lithuanian Code of Civil Procedure, circumstances established in effective judgments in other civil or administrative proceedings where the participants were the same persons, except when the judgment causes legal consequences for other persons not involved in the proceedings (prejudicial facts), may not be proven anew. Thus, a finding that a company is liable made in one case is considered *res judicata* in subsequent cases only if that finding can be considered as a prejudicial fact under the Lithuanian Code of Civil Procedure.

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?

Lithuanian law does not establish any specific evidentiary requirements for product liability cases. Evidence in civil proceedings means any actual data serving as a basis for a court to make a finding under the statutory procedure as to existence or non-existence of circumstances substantiating claims and defences of the parties, as well as other circumstances important for a fair determination on the case. Any documents obtained in a legal way and relevant to the proceedings are admissible as evidence in Lithuania. No evidence has a predetermined effect that would be binding upon the court.

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?

The same rules apply as indicated in the answer to question 8.7. If the plaintiff succeeds in proving that information regarding adverse events allegedly experienced by product users other than the plaintiff are important for the proper determination of the case, any evidence in relation to such information is admissible.

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?

There are no specific rules for conducting depositions; general rules for testimony of witnesses are applied.

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?

Under Lithuanian legislation, the attorney-client privilege is applied only in respect of communications among advocates, assistant advocates and clients. In-house counsel do not enjoy such privilege, and communications between in-house counsel and officers, directors or employees of the companies they serve are not protected against disclosure. Pursuant to the Lithuanian Code of Civil Procedure, it is prohibited to summon an advocate as a witness or to give explanations as to circumstances that came to their knowledge in the course of their professional activities.

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?

Pursuant to the Code of Ethics of Lithuanian Attorneys, an attorney must ensure that all information given by the client and obtained by the attorney during the fulfilment of the client's assignment will be kept as the attorney's professional secret. Thus, attorneys are generally governed by the rules of professional conduct that prohibit them from revealing confidential client information without consent, and no specific measures are required for the protection of communications between the attorney and his or her client (in practice, it is usually indicated in the subject-matter line of the communication as well as at the end of the communication (below the signature) that the communication contains confidential information).

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

Lithuanian law provides no specific limitations on suits against foreign defendants. In certain cases, defendants are allowed to challenge the jurisdiction of Lithuanian courts on the ground of the *lis pendens* rule.

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

Lithuanian laws provide no particular rules with regard to the effect of U.S. litigation on "follow-on" litigation in Lithuania's jurisdiction. U.S. litigation might serve only as an example (guide) for Lithuanian litigation.

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

As mentioned in the answer to question 8.13, U.S. litigation might serve only as an example (guide) for Lithuanian litigation. Based on our practice, litigation in Lithuania may not evolve based on U.S. litigation, but parallel proceedings (in the U.S. and Lithuania) can take place.

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