SORAINEN

EUROPEAN LAW FIRM OF THE YEAR
Awarded by The Lawyer

SORAINEN PHARMACEUTICALS CARD

Main pharmaceuticals and clinical trials regulation in the Baltics and Belarus

ESTONIA

MANUFACTURING OF PHARMACEUTICAL PRODUCTS

- Pharmaceutical products may be manufactured only by the holder of a manufacturing licence (**licence**) issued by the Estonian State Medicines Agency (**SMA**). A licence may be applied for by authorities of executive power (ie governmental authorities and stated authorities administered by governmental authorities), local authorities, self-employed persons and other legal persons in public and private law, except non-profit associations.
- An activity licence for manufacture of medicinal products authorises total or partial manufacture of medicinal products, including making active substances for medicinal products and investigatory medicinal products, as well as partial manufacturing operations such as labelling and packaging.
- Pharmaceutical products must be manufactured in compliance with good manufacturing practice standards, including standards drawn up on the basis of Article 47 of Directive 2001/83/EC of the European Parliament and of the Council.
- A licence grants the right to distribute pharmaceutical products manufactured by the licence holder and to import these from third countries.
- **Requirements for obtaining a licence**
  An applicant for a licence must:
  - specify the pharmaceutical forms, the location where they will be manufactured and (or) controlled as well as a description and scheme of manufacturing processes;
  - have at its disposal sufficient and appropriate premises, technical equipment and control facilities complying with requirements established by law;
  - enter into a contract with a person to fulfil the duties of a qualified person responsible for manufacture and (or) import and
  - comply with other requirements established by law.
- **Issue of licence**
  The SMA decides to issue (or to decline to issue) a licence within 60 days from receiving an application. A Licence is issued indefinitely, unless the applicant has specifically requested that the Licence be issued for a fixed term.

ENTERING THE MARKET

- Medicinal products manufactured industrially or involving an industrial process may be supplied to the Estonian market only if registered in the Register of Activity Licences for Handling Pharmaceuticals. Marketing authorisation for pharmaceuticals is issued by the SMA. The European Commission (EC) grants marketing authorisations covering all European Union Member States.
- **Requirements for marketing authorisation**
  An applicant for marketing authorisation must:
  - apply together with the documents and information required by law; and
  - provide results of pharmaceutical (physico-chemical, biological or microbiological), pre-clinical (toxicological and pharmacological) and clinical trials; or
  - prove that the medicinal product is a generic medicinal product of a reference medicinal product which is or has been authorised for not less than eight years in a European Economic Area (**EEA**) state or in the European Community.
- **Issuing marketing authorisation**
  The SMA decides to issue (or to decline to issue) marketing authorisation within 210 days from receiving the application. Marketing authorisation is granted for five years and may be renewed for an indefinite period.
- **Wholesale licence**
  A wholesale licence is needed to:
  - distribute wholesale medicinal products, active substances and excipients included in the EC list that are used in manufacturing medicinal products;
  - obtain a permit for parallel import of a medicinal product;
  - bring into Estonia from another EEA state medicinal products not granted marketing authorisation or to import from a third country bearer prescription medicinal products.

A wholesale licence is issued according to the procedure set by law. Conditions for issuing a wholesale licence are similar to the conditions for issuing a manufacturing licence as described above.

CLINICAL TRIALS

- All clinical trials of pharmaceuticals must be planned, performed, recorded and reported in accordance with good clinical practices. Clinical trials may only be conducted if specific biomedical research has scientific and practical merit, if protection of the interests of the subject and confidentiality of information about the subject have been ensured, and if the free consent of the subject has been obtained.

- **Requirements for clinical trials**
  Clinical trial authorisation is received in parallel by obtaining a permit from the SMA and approval (positive opinion) from the Clinical Trial Ethics Committee (**CTEC**).
  Authorisation of a clinical trial requires the following information:
  - trial protocol indicating the objective, design, methodology, statistical criteria and organisation of the trial;
  - other documents and information required by law, including an investigator's brochure, an informed consent form, evidence of the investigator's civil liability insurance policy and others.
- **Issue of permit**
  CTEC approval and SMA permit are issued within 60 days in the case of phase I trials, within 30 days in the case of phase II-IV trials, and in the case of a clinical trial involving pharmaceuticals for gene therapy or somatic cell therapy, immunological pharmaceuticals or pharmaceuticals containing genetically modified organisms, within 90 days after receiving the application and required documents. CTEC may prolong the term by 90 days.

PROMOTION OF PHARMACEUTICAL PRODUCTS

- **Advertising**
  Advertising pharmaceuticals that require a medical prescription to the general public is illegal. When advertising non-prescription pharmaceuticals to the general public, it must be clear that this is an advertisement and that the product advertised is a pharmaceutical. Advertisements to the general public must be up-to-date, understandable and unambiguous. An advertisement must ensure the distinguishability of the medicinal product from other medicinal products and contain sufficient information for the correct and safe use of the medicinal product.
  Pharmaceutical advertisements must include the following text: *"Attention! This is a medicinal product. Before using the product, carefully read the information leaflet contained in the packaging. Consult a doctor or pharmacist if complaints persist or adverse reactions occur"*.
  All advertisements for medical products must also comply with the general requirements for advertisements established under the Estonian Advertising Act or any other applicable acts.
- Advertising to doctors and pharmacists is subject to different rules. Nevertheless, the information presented in these advertisements must also be accurate, up-to-date and sufficiently complete to enable persons qualified to prescribe medicinal products, and for pharmacists and assistant pharmacists to form their own opinion of the benefit and risks of the medicinal product.
- **Presents**
  It is prohibited to supply samples of medicinal products to persons not qualified to prescribe medicinal products, and, for promotional purposes, to sell or give away items connected to medicinal products or to organise raffles or lotteries related to medicinal products for those persons, and to offer them other medicinal products, goods or services free of charge or at a discount rate in connection with the purchase of a medicinal product. As to doctors qualified to prescribe pharmaceuticals, dispensing chemists and pharmacists, a holder of marketing authorisation must not give them presents and services worth more than EUR 6.40.
- **Professional medical training**
  A holder of marketing authorisation may support participation of doctors and pharmacists in professional events organised by research institutes or trade associations, where they may cover participation fees and other expenses up to a reasonable amount. A holder of marketing authorisation may organise scientific events for doctors and pharmacists if the entertainment programme is not excessive.
  By 1 February each year, a holder of marketing authorisation in respect of a medical product must submit to the SMA a report indicating support provided to pharmacists, assistant pharmacists, persons qualified to prescribe medicinal products and their associations for the purpose of participation in or organisation of medical or pharmaceutical events, at meetings and patient information events organised, also indicating any samples distributed and discounts made for such persons. A report on advertising of medicinal products submitted by a marketing authorisation holder is public information and will be published by the SMA webpage by 1 June each year.

LATVIA

MANUFACTURING OF PHARMACEUTICAL PRODUCTS

- Pharmaceutical products may be manufactured only by a merchant (individual merchant, partnership or company) or by a performer of economic activities that holds a manufacturing licence (**licence**) issued by the Latvian State Medicines Agency (**SMA**). A licence authorises entire or partial production of pharmaceuticals and a variety of processes related to packaging, labelling, and the like. Pharmaceutical products must be manufactured in compliance with good manufacturing practice standards. A license grants the right to distribute pharmaceutical products manufactured by the licence holder to wholesalers and to import pharmaceutical products from third countries. It is not necessary to obtain a special permit (licence) from the SMA for a trader who has a special permit (licence) issued in a European Union (EU) Member State or in a state of the European Economic Area (**EEA**), which entitles the holder to wholesale or manufacture medicinal products.
- **Requirements for obtaining a licence**
  An applicant for a licence must:
  - specify the pharmaceutical forms, describe the manufacturing plant, as well as describe particular acts to be performed with medicinal products;
  - have at its disposal sufficient and appropriate premises, technical equipment and control facilities complying with the requirements established by law;
  - enter into a contract with a person for fulfilling the duties of a qualified person responsible for manufacture and (or) import and
  - comply with other requirements set by law.
- **Issue of licence**
  The SMA decides to issue (or justifies not issuing) a licence within one month from receiving the application with all the required information and documents. A licence is issued for an indefinite period.

ENTERING THE MARKET

- Medicinal products manufactured industrially or involving an industrial process (including parallel imports of medicinal products) may be supplied to the Latvian market only if registered in the Latvian Medicinal Products Register or in the Community Register of medicinal products. Marketing authorisation for pharmaceuticals is issued by the SMA. The European Commission (EC) grants marketing authorisations covering all EU Member States.
- **Requirements for marketing authorisation**
  An applicant for marketing authorisation must:
  - apply together with the documents and information required by law (description of the manufacturing technique, therapeutic indications, contraindications, adverse reactions, doses, route of administration and the like); and
  - provide results of pharmaceutical (physico-chemical, biological or microbiological), non-clinical (toxicological and pharmacological) and clinical trials; or
  - prove that the medicinal product is a generic medicinal product of a reference medicinal product which is or has been authorised for not less than eight years in a EEA state or in the European Community, or that the active substance(s) within the formulation of medicinal products in a EEA Member State is (are) widely used in medicine in the formulation of already registered medicinal products for at least ten years with recognised efficacy and acceptable safety level.
- **Issuing marketing authorisation**
  The SMA decides to issue (or to decline to issue) marketing authorisation within 210 days from receiving the application (for generic medicinal products – within 90 days). Marketing authorisation is granted for five years and may be renewed indefinitely.
- **Wholesale licence**
  A wholesale licence is needed for entitlement to:
  - wholesale distribution of medicinal products, active substances and excipients included in the EC list and used in manufacturing medicinal products;
  - obtain a permit for parallel import of a medicinal product;
  - bring into Latvia from another EEA state medicinal products not granted marketing authorisation.

  A wholesale licence is issued according to the procedure established by law. Conditions for issue of a wholesale licence are similar to the conditions for issuing a manufacturing licence as described above.

CLINICAL TRIALS

- All clinical trials, including bioavailability and bioequivalence studies, must be scientifically sound, guided by ethical principles in all aspects and planned, conducted

and reported in accordance with good clinical practice regulations. Clinical trials may be conducted only if the anticipated therapeutic benefit for the trial subject and other present or future patients, as well as for society at large, has been assessed and justifies the anticipated risk. A clinical trial may be continued if conformity with this requirement is permanently monitored.

- **Requirements for clinical trial authorisations**
  Clinical trial authorisation is received in parallel by obtaining a permit from the SMA and approval (positive opinion) from the Ethics Committee.
  An opinion from the Ethics Committee and a permit from the SMA to conduct a clinical trial requires the following information:
  - trial protocol indicating the objective, design, methodology, statistical criteria and organisation of the trial;
  - other documents and information required by law, including investigator's brochure, informed consent form, as well as documents regarding civil liability insurance policy, consent of the clinical site to conduct the clinical trial, and others.
- **Issue of permit**
  The opinion from the Ethics Committee should be issued within 30 days but the permit from the SMA within 60 days from receiving the application and required documents. Both authorities may request further information and thus prolong the period for issue of a decision pending receipt of supplementary information.

PROMOTION OF PHARMACEUTICAL PRODUCTS

- **Advertising**
  Only advertising of non-prescription medicinal products is allowed. Advertising of medicinal products intended for the general public must include at least the name of the medicinal product, information necessary for correct use of the medicinal product, an invitation to read the package leaflet carefully and to consult with a physician or pharmacist regarding use of the medicinal product, name of the advertiser, plus a warning text on harm through unreasonable use of medical health products. Advertising where medicinal products are offered as a gift or compensation for the purchase of goods or receipt of a service, or where a gift is offered for the purchase of medicinal products, or where a particular medicinal product is offered with a discount or as a gift, or by organising competitions, games or similar events where the participants may receive prizes for participation or winning, as well as advertising that promotes medicinal products as safe, non-toxic or non-additive without proper examination, is prohibited. Distribution of medicinal products to the general public for promotional purposes is prohibited.
- Advertising to medicinal specialists is subject to different rules. Advertising intended for specialists is allowed only in professional literature or in advertising materials or on websites intended only for professionals. The advertiser must ensure that prior to accessing such advertising on the website there is a warning that the webpage content is designated only for specialists.
- **Presents**
  No material or other kind of benefit may be offered for the prescription or distribution of medicinal products. A medicinal specialist may only accept informative and educational materials or medicinal objects for education and healthcare purposes if these objects do not substitute those that a medicinal specialist must possess by law. The value of such objects must not exceed EUR 10 (excl. VAT).
- **Professional medical training and marketing events**
  Medical training and marketing events may only have a professional and scientific theme, and the event must not be related to sports, tourism, leisure or entertainment. Only the entrance fee, educational materials, travel and accommodation expenses may be compensated to a medicinal specialist; and material support must not facilitate prescription or use of a particular medicinal product. By 31 March every year (starting from 31 March 2016 for year 2015) the registration owner or its authorised representative, or an advertiser, must submit a report to the Health Inspectorate about support provided in the previous year. If seminars, conferences, congresses, competitions, exhibitions and other events where advertising of medicinal products is organised, the event organiser or the advertiser must inform the Health Inspectorate in writing not later than seven days before the event by delivering the event programme and indicating the place and time of event activities, the organisers, advertisers and sponsors of the event, participants, intended type of advertising and other information related to medicinal products, as well as the persons responsible for advertising medicinal products. Book-keeping documents, including source documents, regarding the event, its financing and support, as well as advertising materials, must be kept for at least two years.

LITHUANIA

MANUFACTURING OF PHARMACEUTICAL PRODUCTS

- Pharmaceutical products may be manufactured only by a legal entity that holds a manufacturing licence (**licence**) issued by the State Medicines Control Agency (**SMCA**). The Licence authorises entire or partial production of pharmaceuticals and (or) a variety of processes related to packaging, labelling, and the like. Pharmaceutical products must be manufactured in compliance with good manufacturing practice standards. The licence grants the right to distribute pharmaceutical products manufactured by the licence holder and imports of these from third countries.
- **Requirements for obtaining a licence**
  A legal entity seeking a licence must:
  - specify the medicinal products and pharmaceutical forms as well as the location where they will be manufactured and (or) controlled;
  - have at its disposal sufficient and appropriate premises, technical equipment and control facilities complying with the requirements established by law;
  - enter into an employment contract with a person for fulfilling the duties of a qualified person responsible for manufacture and (or) import and
  - be ready to operate in compliance with good manufacturing practice;
  - comply with other requirements established by law.
- **Issue of licence**
  The SMCA decides to issue the licence (or justifies refusal) within 90 days from receiving the application. The licence is issued indefinitely, until it is cancelled.

ENTERING THE MARKET

- Medicinal products manufactured industrially or involving an industrial process may be supplied to the Lithuanian market only if registered in the Register of Medicinal Products, in the Community Register of medicinal products or entered into the List of Parallel Imported Medicinal Products. Marketing authorisation for pharmaceuticals is issued by the SMCA. The European Commission (EC) grants marketing authorisations covering all European Union Member States.
- **Requirements for registration of the pharmaceuticals**
  A person seeking to register a pharmaceutical must:
  - apply together with the documents and information required by law; and
  - provide results of pharmaceutical (physico-chemical, biological or microbiological), pre-clinical (toxicological and pharmacological) and clinical trials; or
  - prove that the medicinal product is a generic medicinal product of a reference medicinal product which is or has been authorised for not less than eight years in a European Economic Area (**EEA**) state or in the European Community.
- **Issuing pharmaceuticals registration**
  The SMCA decides to issue (or not to issue) pharmaceuticals registration within 210 days from receiving the application. Pharmaceuticals registration is granted for five years and may be renewed for an indefinite period.
- **Wholesale licence**
  A wholesale licence is needed for entitlement to:
  - distribute wholesale medicinal products, active substances and excipients included in the EC list used in manufacturing medicinal products;
  - obtain a permit for parallel import of a medicinal product;
  - bring into Lithuania from another EEA state medicinal products not granted registration or import from a third country bearer prescription medicinal products.

  A wholesale licence is issued according to the procedure established by law. Conditions for issuing a wholesale licence are similar to the conditions for issuing a manufacturing licence as described above.

CLINICAL TRIALS

- All clinical trials of pharmaceuticals must be planned, performed, recorded and reported in accordance with good clinical practice regulations. Clinical trials should only be conducted if specific biomedical research has scientific and practical merit, protection of interests of the subject and confidentiality of information about the subject has been ensured and free consent of the subject has been obtained.
- **Requirements for clinical trial authorisations**
  Clinical trial authorisation is received in parallel by obtaining a permit from the SMCA and the approval (positive opinion) of the Lithuanian Bioethics Committee (or territorial bioethics committee) (**LBC**).
  Authorisation of a clinical trial requires the following information:
  - trial protocol, which indicates the objective, design, methodology, statistical criteria and organisation of the trial;
  - other documents and information required by law, including investigator's brochure, informed consent form, list of investigators, civil liability insurance policy and others.

- **Issue of permit**
  A permit from the SMCA and the approval of the LBC should be issued within 60 days from receiving the application and required documents. Both authorities may request further information, so that in practice approvals may frequently be obtained within a six to seven week timeframe.

PROMOTION OF PHARMACEUTICAL PRODUCTS

- **Advertising and presents**
  When advertising pharmaceuticals to the general public, it must be clear that this is an advertisement and that the product is identified as a pharmaceutical. Advertising intended for the general public must be only of non-prescription pharmaceuticals. Advertising pharmaceuticals that require a medical prescription to the general public is prohibited. Advertising to doctors and pharmacists is subject to different rules. Any provision of inducements to doctors and pharmacists to prescribe, supply or sell/dispense medicinal products by remuneration whether in money or in kind is prohibited and the above specialists are prohibited from asking for or accepting remuneration. When disseminating advertisement to specialists, providing any gifts, souvenirs and other items related or not related to their professional activities is also prohibited.
- **Professional medical training and marketing events**
  Only payment for travel, accommodation, catering and/or registration expenses of doctors and pharmacists is allowed in the case of professional/scientific events. It should be noted that for sales promotion events (intended for marketing and sale of medicinal products) payment for travel, accommodation and other expenses is prohibited. Hospitality at such events must be reasonable and must be secondary to the main purpose of the event, and it cannot be extended to persons other than participating doctors and pharmacists. Hospitality at promotional events should not influence prescription of pharmaceutical products, their sale prices or discounts. Reports indicating transfers of value and personal details of specialists will be electronically submitted to the State Medicines Control Agency once every calendar year, before 1 February.

BELARUS

MANUFACTURING OF PHARMACEUTICAL PRODUCTS

- Pharmaceutical products (**pharmaceuticals**) can be manufactured only by legal entities and individual entrepreneurs that hold a pharmaceutical licence covering manufacturing (**manufacturing licence**) issued by the Ministry of Healthcare of the Republic of Belarus (**Ministry**). The licence allows industrial manufacturing of and wholesale trade in pharmaceuticals, which must be performed in compliance with good manufacturing practice (**GMP**) and good wholesale practice approved by the Ministry.
- **Requirements for obtaining a licence**
  A legal entity/individual entrepreneur seeking a manufacturing licence must:
  - specify the names of the pharmaceuticals preliminarily adjusted by the Department of the Pharmaceutical Industry of the Ministry;
  - have at its disposal sufficient and appropriate premises as well as technical equipment complying with the requirements established by law;
  - have a plan-scheme and characteristics of premises for storing raw materials;
  - enter into an employment contract with a qualified person responsible for the quality of the manufactured pharmaceuticals that meets certain requirements (eg has higher pharmaceutical education).

  Additional requirements may be established depending on the type of product being manufactured.
- **Issue of licence**
  The Ministry decides to issue a manufacturing licence (or justifies refusal to issue) within 15 days from receiving the application; the term may be prolonged for 10 days if additional examination is required. The licence is valid indefinitely.
  Manufacturing is inspected for compliance with GMP and certified as GMP-compliant by the Ministry. Manufacturing of pharmaceuticals is prohibited when manufacturing is noncompliant with GMP.

ENTERING THE MARKET

- Pharmaceuticals manufactured and/or sold within Belarus, including pharmaceutical substances used in the manufacturing process, must be registered by the Ministry in the State Register of Pharmaceutical Products, except in certain cases (for example, if pharmaceuticals are intended for clinical trials or made in a pharmacy). Marketing authorisation for pharmaceuticals is granted by the Ministry.
- **Requirements for marketing authorisation**
  A person seeking marketing authorisation must:
  - pass a set of preliminary technical work, which may include inspection for GMP-compliance, clinical trials, and the like;
  - conclude an agreement on provision of services with the Centre for Expertise and Testing in Healthcare (**CETH**); and
  - submit to the CETH the documents and information required by law (eg reports on pre-clinical and clinical trials, information on experience of applying the pharmaceutical).
- **Issuing marketing authorisation**
  On the basis of the application and upon examination of a pharmaceutical, the CETH prepares a draft decision to issue (or to decline to issue) marketing authorisation which is then adopted by the Ministry. Refusal must be justified. The whole procedure should take no more than 6 months from the day of receiving the application. Marketing authorisation is granted initially for five years, and then pharmaceuticals may pass the confirmation procedure and receive an indefinite marketing authorisation.
- **Trade license**
  Retail or wholesale trading (without manufacturing) requires a pharmaceutical licence covering trade services (**trade licence**). This licence may cover one or several of the following activities: preparation of pharmaceuticals in pharmacies, the pharmaceuticals retail trade, and the pharmaceuticals wholesale trade. Within Belarus retail trade can be performed exclusively through pharmacies. Requirements for obtaining this licence are similar to those for a manufacturing licence; particular requirements vary depending on the type of the activity planned.

CLINICAL TRIALS

- All clinical trials of pharmaceuticals must comply with good clinical practice adopted by the Ministry. Clinical trials can be commenced only if pre-trial research has shown that the pharmaceutical is safe and effective and if the risk of side effects is reasonable in the light of the expected positive effects. The rights of individuals participating in the trial must be protected according to law. Clinical trials of pharmaceuticals are performed by state healthcare organisations defined by the Ministry.
- **Requirements for clinical trial authorisations**
  Authorisation of clinical trials requires the following information to be submitted to the CETH:

- trial protocol indicating the objective, design, methodology, statistical criteria, and organisation of the trial;
- other documents and information required by law (eg investigator's brochure, information on investigator's qualification, informed consent form).

- **Clinical trial agreement**
  Performance of clinical trials as a subject matter can only be set in contracts between a sponsor (or a contract research organisation) and a healthcare organisation, not with an investigator. A clinical trials agreement requires approval by the Ministry. A template form of clinical trials agreement is set by legislation. The flexibility of institutions in accepting amendments to the template form differs.
- **Issue of permit**
  Preliminary investigation of the application is performed by the CETH within ten days. Then the CETH conducts a specialised examination of the material of the clinical trials within thirty days. This term can be extended if the CETH requests additional information.

PROMOTION OF PHARMACEUTICAL PRODUCTS

- **Advertising and presents**
  As a general rule, advertising pharmaceuticals requires approval of the Ministry which is obtained via CETH. Approval is valid for one year. Advertising pharmaceuticals that require medical prescription is prohibited to the general public. Advertising may not contain images of or statements by medical professionals and non-commercial healthcare organisations. Advertising to doctors and pharmacists is subject to different specific rules. No material or other kind of benefit for prescribing pharmaceutical products may be accepted by doctors of Public Health Institutions (**PHI**), since acceptance may be qualified as "illegal remuneration" from the criminal law perspective. Giving presents to PHI doctors may also be considered as financial motivation for recommending certain pharmaceuticals, which is prohibited. Moreover, some PHI doctors (eg heads of PHI) may be considered state officials from the perspective of anti-corruption laws so that gifts may be qualified as bribery; giving them souvenirs at protocol and other formal events with a value not exceeding EUR 48 is allowed. Activities of medical representatives are also subject to regulation, eg they are not allowed to disturb doctors, they should have higher medical or pharmaceutical education, etc.
- **Professional medical training and marketing events**
  Sponsoring medical training or marketing events is likely to be qualified as gratuitous aid which is subject to specific regulation. Sponsoring by a foreign entity is considered as foreign gratuitous aid which under general rule must be registered by the recipient of the aid according to the procedure established by law and must fit the purpose set by legislation, eg "research, development, training or implementation of research programs". If a sponsor is a local entity, an agreement on gratuitous aid must be concluded with the recipient; the aid must fit the purpose set by legislation, eg "support of activity in the sphere of protection of the population's health, promotion of a healthy lifestyle".
- **Single market of pharmaceuticals in the Eurasian Economic Union**
  2016 is expected to see the launch of a single market for medicines in the framework of the Eurasian Economic Union (**EEU**). Currently over 30 draft acts have been adopted, establishing EEU rules and principles for movement of medicines and covering such issues as registration, clinical trials, inspections, pharmacovigilance, and information exchange. One of the key features of the single market is anticipated to be EEU registration procedure, envisaging validity of marketing authorization throughout the EEU.

SORAINEN

ESTONIA LATVIA LITHUANIA BELARUS

As a leader in innovation, Sorainen recognises the great importance of research and development, providing comprehensive legal services related to pharmaceuticals, healthcare and related regulatory issues.

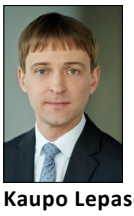
Sorainen Pharmaceuticals & Life Sciences Practice lawyers offer an understanding of the pharmaceuticals business, alongside comprehensive sector knowledge and experience. Understanding the Baltic and Belarusian pharmaceuticals market puts the firm in a unique position to assess risks and stay ahead of the innovation curve.

Sorainen offers expertise in all key pharmaceuticals areas in the Baltic States and Belarus, including:

- pharmaceuticals industry research;
- trade, marketing and distribution;
- licences, permits, certification, clinical trials and other regulatory issues;
- intellectual property protection;
- representation before local authorities and courts.

Local heads of the Sorainen Pharmaceuticals & Life Sciences Practice are:

ESTONIA



Kaupo Lepasepp
Partner

LATVIA

Agris Repšs
Partner

LITHUANIA

Renata Beržanskienė
Partner

BELARUS

Alexey Anischenko
Partner

Local heads of the Sorainen Pharmaceuticals & Life Sciences Sector Group are:

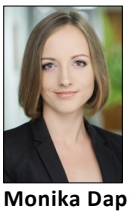
ESTONIA

Allar Jõks
Partner

LATVIA

Valts Nerets
Senior Associate

LITHUANIA



Monika Dapkute
Associate

BELARUS

Marina Golovnitskaya
Associate

Pärnu mnt 15
10141 Tallinn
phone +372 6 400 900
fax +372 6 400 901
estonia@sorainen.com

Kr. Valdemāra iela 21
LV-1010 Riga
phone +371 67 365 000
fax +371 67 365 001
latvia@sorainen.com

Jogailos 4
LT-01116 Vilnius
phone +370 52 685 040
fax +370 52 685 041
lithuania@sorainen.com

ul Internatsionalnaya 36-1
220030 Minsk
phone +375 17 306 2102
fax +375 17 306 2079
belarus@sorainen.com