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SORAINEN PHARMACEUTICALS CARD 2013

Main pharmaceuticals and clinical trials regulation in the Baltics and Belarus

Effective 1 May 2013

ESTONIA

MANUFACTURING OF PHARMACEUTICAL PRODUCTS

- Pharmaceutical products may be manufactured only by a legal entity that holds a manufacturing licence (**Licence**) issued by the Estonian State Agency of Medicines (**SAM**). The Licence authorises the entire or partial production of pharmaceuticals and (or) a variety of processes related to packaging, labelling, etc. 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 to obtain 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 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 established by law.
- **Issue of licence**
  SAM decides to issue (or refuse to issue) a Licence within 60 days from receiving the application. The Licence is issued for up to 5 years.

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 of Pharmaceuticals. Marketing authorisation for pharmaceuticals is issued by SAM. The European Commission (**EC**) grants marketing authorisations covering all European Union Member States.
- **Requirements for marketing authorisation**
  A person seeking 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 8 years in a European Economic Area (**EEA**) state or in the Community.
- **Issuing marketing authorisation**
  SAM decides to issue (or refuse to issue) marketing authorisation within 210 days from receiving the application. Marketing authorisation is granted for 5 years and may be renewed for an indefinite period.
- **Wholesale licence**
  A wholesale licence is needed for entitlement to:
  - wholesale distribution of 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 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 free consent of the subject has been obtained.
- **Requirements for clinical trials**
  Clinical trial authorisation is received in parallel by obtaining a permit from SAM 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 a trial;
  - other documents and information required by law, including an investigator brochure, an informed consent form, evidence of the investigator's civil liability insurance policy and others.
- **Issue of permit**
  CTEC approval and SAM permit are issued within 60 days, 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 and presents**
  Advertising pharmaceuticals that require a medical prescription to the general public is illegal. When advertising pharmaceuticals to the general public, it must be clear that this is an advertisement and that the product advertised is a pharmaceutical. Advertising to doctors and pharmacists is subject to different rules.
  A holder of marketing authorisation must not give presents and services worth more than EUR 6.40 to doctors qualified to prescribe pharmaceuticals, dispensing chemists and pharmacists.
- **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, provided that the entertainment programme is not excessive.

LATVIA

MANUFACTURING OF PHARMACEUTICAL PRODUCTS

- Pharmaceutical products may be manufactured only by a legal entity that holds a manufacturing licence (**Licence**) issued by the Latvian State Agency of Medicines (**SAM**). The Licence authorises entire or partial production of pharmaceuticals and a variety of processes related to packaging, labelling, etc. Pharmaceutical products must be manufactured in compliance with Good Manufacturing Practice standards. The License grants the right to distribute pharmaceutical products manufactured by the Licence holder to wholesalers and import these from third countries. It is not necessary to obtain a special permit (licence) from SAM 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**
  A legal entity seeking to obtain a Licence must:
  - specify the pharmaceutical forms, the location where they will be manufactured and controlled, as well as the 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**
  SAM decides to issue (or justifies not issuing) a Licence within 90 days from receiving the application. The 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 SAM. The European Commission (**EC**) grants marketing authorisations covering all EU Member States.
- **Requirements for marketing authorisation**
  A person seeking marketing authorisation must:
  - apply together with the documents and information required by law (description of the manufacturing technique, therapeutic indications, contraindications, adverse reactions, doses and route of administration etc); 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 8 years in a EEA state or in the 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 10 years with a recognised efficacy and acceptable safety level.
- **Issuing marketing authorisation**
  SAM decides to issue (or to refuse to issue) marketing authorisation within 210 days from receiving the application (for generic medicinal products – within 90 days). Marketing authorisation is granted for 5 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, 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 it 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 SAM and approval (positive opinion) from the Ethics Committee.
  An opinion from the Ethics Committee and a permit from SAM for conducting 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 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 SAM 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 and presents**
  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, 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, is prohibited. Distribution of medicinal products to the general public for promotional purposes is prohibited.
  Advertising to medicinal specialists is subject to different rules. No material or other kind of benefit may be offered for the prescription or distribution of medicinal products, except where the benefit is to be used in the practice of medicine or pharmacy and its material value is insignificant. Latvian law does not specify what is considered a gift of insignificant material value.
- **Professional medical training and marketing events**
  If exhibitions of medicinal products, seminars, conferences, congresses, competitions and other events related to the advertising of medicinal products are organised, the event organiser must inform the Health Inspectorate not later than 7 days before the event by delivering the event programme and indicating the place and time of event activities, the organisers 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. Representation expenses for events with professional and scientific orientation must be subordinated to the main purpose of the event, and they must be applied only to specialists.

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 Medicinal Control Agency (**SMCA**). The Licence authorises entire or partial production of pharmaceuticals and (or) a variety of processes related to packaging, labelling, etc. 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
  - 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.

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 marketing authorisation**
  A person seeking 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 8 years in a European Economic Area (**EEA**) state or in the Community.
- **Issuing marketing authorisation**
  The SMCA decides to issue (or not to issue) marketing authorisation within 210 days from receiving the application. Marketing authorisation is granted for 5 years and may be renewed for an indefinite period.
- **Wholesale licence**
  A wholesale licence is needed for entitlement to:
  - wholesale distribution of 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 marketing authorisation 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 brochure, informed consent form, list of investigators, civil liability insurance policy and others.

  Thereafter a tripartite agreement must be concluded between the trial site, the principal investigator and the sponsor. In practice, this may contain only the general conditions, leaving it to the parties to agree on detailed terms and conditions in a separate agreement. The sponsor and the principal investigator of a clinical trial must be covered by third-party insurance against damage which could be incurred by the subject of the trial.
- **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 6-7 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. As a general rule any provision of inducements to doctors and pharmacists to prescribe, supply or sell/dispense medicinal products by giving remuneration whether in money or in kind is prohibited. Additionally, these same specialists are prohibited from requesting or accepting remuneration. Lithuanian law does not specify what might be considered as minimal value gifts.
- **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.

BELARUS

MANUFACTURING OF PHARMACEUTICAL PRODUCTS

- Pharmaceutical products (**pharmaceuticals**) can be manufactured only by a legal entity that holds a pharmaceutical licence covering manufacturing (**manufacturing licence**) issued by the Ministry of Healthcare of the Republic of Belarus (**Ministry**). This licence allows industrial manufacturing of and wholesale trade in pharmaceuticals, which must be performed in compliance with Good Manufacturing Practice and Good Wholesale Practice approved by the Ministry.
- **Requirements for obtaining a licence**
  A legal entity seeking a manufacturing licence must:
  - specify the nomenclature 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;
  - enter into an employment contract with a qualified person responsible for the quality of the manufactured pharmaceuticals.

  Additional requirements may be established depending on the type of product being manufactured.
- **Issue of licence**
  The Ministry decides to issue the manufacturing license (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 for 10 years and can be renewed.

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 unless intended for the purposes of 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:
  - 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-clinica and clinical trials, information on experience of application of the pharmaceutical).
- **Issuing marketing authorisation**
  On the basis of the application and upon examination of a pharmaceutical, CETH prepares a draft decision to issue (or to refuse 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 for 5 years, then re-registration is required.
- **Trade license**
  Retail or wholesale trading (without manufacturing) requires a pharmaceutical licence covering trade services (**trade license**). 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 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 a 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 10 days. Then the CETH conducts a specialised examination of the material of the clinical trials within 30 days. This term can be extended if the CETH requests additional information.

PROMOTION OF PHARMACEUTICAL PRODUCTS

- **Advertising and presents**
  Advertising pharmaceuticals requires approval of the Ministry. Advertising pharmaceuticals that require medical prescription to the general public is prohibited. Advertising may not contain images or statements of 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 under a Letter from the Ministry which binds PHI. 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 44 is allowed.
- **Professional medical training and marketing events**
  Sponsoring medical training or marketing events is qualified as gratuitous aid which is subject to specific regulation. Sponsoring by a foreign entity is considered as foreign gratuitous aid which must be registered by the recipient of the aid according to the procedure established by law and must fit the purpose "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 "support of activity in the sphere of protection of the population's health, promotion of a healthy lifestyle".

SORAINEN

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As a leader in innovation, SORAINEN recognises the great importance of research and development, providing comprehensive legal services related to pharmaceuticals, health care 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.

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