Medical Devices

LITHUANIA
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1. **Definition of medical devices**
What is the definition of a medical device in your jurisdiction?

The definition of medical device originated from Directive 93/42/EEC as amended, which was implemented in Lithuanian act, called Recommendation of usage of the MDD93/42/EEC in the country and further repeated, for example, in Article 9.1 of the Lithuanian Medical Norms MN 4:2009 "Medical Devices Safety Technical Regulation" No. V-18 established by the Order No. V-18 of the Minister of Health (hereinafter – **MoH**) as of 19 January 2009 (hereinafter – **Norms MN 4:2009**).

Medical device means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

2. Combination products

i. Which legal regime (on medicinal product or on medical devices) applies to combination products incorporating both medicinal products (drugs/biologics) and medical devices?

If a medical device is placed on the market in such a way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, the relevant medical device is governed by 22 June 2006 Law on Pharmacy (hereinafter – **Law on Pharmacy**) and by those requirements of Lithuanian laws (i.e. Norms MN 4:2009) that concern safety and performance related features of the device.

ii. Are combination products (combining drugs and medical devices) subject to separate regulation in your jurisdiction?

No, separate regulations have not been adopted with respect to combination products. According to the regulations, where a medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medical product, as described under the Article 2 of Law on Pharmacy, and which may have an separate impact for the human's body, additional to the impact made by the medical device, the quality, safety and efficacy shall be examined under the methods, analogous to those, set forth under the Law on Pharmacy.

iii. If the answer to (i) is negative, what is the scope of application of the legal regimes: evaluating both the drug and device components of the combination product?

The medicinal device part shall undergo separate conformity assessment procedure in accordance with medical device regulations (e.g. Norms MN 4:2009); hence the State Medicines Control Agency (hereinafter – **SMCA**) only evaluates the drug part.

iv. What are the general conditions for review, approval and marketing the combination product?

Since combination products would be equated to medicinal devices, the registration and review process would be similar to that of medical devices, apart from the fact that the medicine should have a marketing authorization in Lithuania or an application for obtaining the marketing authorization shall be submitted in accordance to the Law on Pharmacy.

Only products with proper marketing authorizations in place can be marketed in Lithuania, thus marketing can be commenced only after grant of marketing authorization. In Lithuania it is prohibited to advertise prescription medicines and medicines which are included in the state reimbursement list. Pricing of medicines distributed in Lithuania (wholesale, retail markups, reimbursement) is regulated to certain extent. One of the base elements for regulation is the manufacturers' price,

which has to be notified of upon placement of the product in the market. The aforesaid would equally apply to the drug and device combination product.

3. Borderline products

Are there any official and binding criteria for determination whether the product is a medicinal product or medical device, or whether a product is a device requiring pre-review or a non-medical device?

i. Are there any legal and binding criteria for determination whether the product is a medical device or medicinal product?

The medical device regulations (e.g. Norms MN 4:2009) contain definition of medical devices (see above), whereas the Law on Pharmacy contains definition of medicines. If questions arise regarding the qualification of the product (medical device, foodstuff, cosmetics, biocide) under the definition of medicine, the SMCA is entitled to issue respective statement. However, apart from the definitions provided in the noted legal acts, there are no further binding criteria published by the SMCA.

ii. If the answer to (i) is positive, what are the main principles for differentiation?

Please see Answer 3 (i).

iii. Are there any significant court or administrative judgments demonstrating the rules of product differentiation?

To the best of our knowledge there are no such judgments.

iv. How is software that may have some related-medical applications regulated in your jurisdiction?

The definition of medical devices relates also to software, which is necessary in order that a person may utilize the medical device as intended by the manufacturer. Separate software, pursuant to qualification of medical devices, is regarded as active medical device. Whereas software which is used to control a medical device is automatically classified in the same group as the device it is controlling. The software, which is medical software or a part of medical device, must be validated in accordance with the industry latest developments, taking into account life cycle development, risk management, validation and approval principles (Para. 13.2. of Annex 1 of the Norm 4:2009). *In vitro* medical devices, including their software, must be developed to ensure consistency of operations of the device, safety and compliance with *in vitro* diagnostics appliance functions.

4. Cellular or tissue based products

Are there any official or binding criteria for determination whether a product is a animal or human based tissue or a medical device?

The terms and conditions of treating and implanting cells, tissues and organs of human origin are set forth under the Law of 19 November 1996 on Donation and Transplantation of Human Tissues, Cells and Organs.

The terms and conditions for the manufacturers, manufacturers' authorised representatives, importers, which supply the medical devices, manufactured by using animal tissues, to the market under the Medical Norms MN 104:2004 "Safety Technical Regulation for the Medical Devices, Manufactured by Using Animal Tissues", established by the Order No. V-280 of the MoH as of 27 April, 2004 (hereinafter – **Norms MN 104:2004**).

Lithuanian legislation recognizes that medicines or medical devices may contain animal or human origin tissues and there would be further requirements set forth for such products as compared to medical devices.

Nevertheless, there are no criteria for determination if the product is animal or human based tissue versus a medical device.

i. How are products composed of cells or animal/human tissue regulated in your jurisdiction?

   Human origin medicinal products (tissue, blood, plasma) are generally excluded from the scope of regulation applicable to medical devices. Such products are generally regulated under the applicable regulation towards medicines. However, animal origin medical devices would be covered by the general regulations applicable to medical devices.

ii. Are there any legal and binding criteria for determination whether the product is a medical device or cellular/tissue based product?

   No, there are no specific criteria for determination if the product shall be classified as cellular/tissue based product. As a general rule, the manufacturer shall issue a statement whether the product is a medical device. However, the State Health Care Accreditation Agency under MoH is the competent authority to issue statements regarding the classification of the medical device.

iii. If the answer to (ii) is positive, what are the main principles for differentiation?

   N/A.

iv. Are there any significant court or administrative judgments demonstrating the rules of product differentiation?

   We are not aware of any such court or administrative judgments.

5. Admission to trade of medical devices

What are the requirements for admission (import) of medical devices into trade?

In order to place a medical device on the Lithuanian market, the device must undergo conformity assessment in one of the notified EU assessment institutions. Generally medical devices shall bear the CE marking. Some further registration requirements apply to devices which are not CE certified (i.e. purpose made devices, intended for clinical trials, do not correspond to material requirements).

i. Is clinical assessment required for admitting (importing) medical devices into trade?

Clinical data must be submitted to the notified institution (i.e. institution which any of the Member States has notified as the competent to perform conformity assessment) in order to obtain the EC conformity declaration. Clinical data would have to be described, for example, within the review of the quality assurance system. Thus, since conformity declaration is required to put the product into trade, clinical assessment would be required.

ii. If the answer to (i) is positive, are clinical trials required or is there an alternative basis for clinical assessment?

Results of clinical trials can serve as one of the methods to prove that the product meets the essential requirements (incorporated in Medical Devices Regulations from Annex I of Directive concerning medical devices). Trials would have to be conducted in accordance with Cabinet of Ministers Regulations 891, 21.09.2010, "Procedures for conduct of clinical trials for human use medical devices". Trial results are also needed in order to register medical device which does not bear CE marking. Finally, clinical trials are also foreseen as an element under the quality assurance system that the manufacturer must have in place in order to obtain EC conformity declaration from the notified institution (Para. 46. of the Norm 4:2009).

iii. Is certification by an external certifying body required for compliance assessment of medical devices, or is a manufacturer's declaration of conformity sufficient?

Manufacturer's declaration of conformity is sufficient when the product is marketed, but the manufacturer must also have the EC conformity declaration form one of the notified institutions (Para 33. of the Norm 4:2009). Thus, before manufacturer can declare compliance with essential requirements, an external body (notified institution) shall verify that the product complies with all the applicable EC requirements.

iv. Is administrative pre-clearance or pre-approval of medical devices required for admission of medical devices into trade, or is post-launch notification sufficient?

Only products that have either undergone the conformity assessment and bear the CE marking can be launched in the market. The notified authority shall be notified about the start of the usage of medical devices (Class II a, II b and III) in the territory of the Republic of Lithuania (Para 44. Of the Norm 4:2009).

6. Processing of personal data (privacy)

What are the rules of processing of personal data in a number of activities performed by manufacturer/s distributors/ healthcare units with the use of medical devices.

i. Are there any specific rules protecting the privacy of personal data of consumers purchasing medical devices, by manufacturer/distributors?

There are no specific rules in respect to applicable personal data processing practices when it comes to medical devices. Thus, the general rules of personal data processing and

the specific rules of personal data processing in the healthcare sector should be observed. For example, the Law of 3 October 1996 on Rights of Patients and Compensation for Damage to their Health provides the applicable rules with respect to processing of patient health information – i.e. generally limits the scope of persons to whom such information should be available and the purpose, e.g. information about the facts of the patient's life may be collected only with the patient's consent and only if necessary for diagnosing, treating the disease or nursing the patient.

Within conduct of clinical trials the names of the patients shall be disclosed, hence the manufacturer may get access to clinical information, but should not be able to identify the particular patient. Finally, the Law on Legal Protection of Personal Data provides the general rules for legitimate personal data processing. The applicable requirements vary depending on the purpose of data processing. The Law on Legal Protection of Personal Data provides that sensitive (i.e. health data) data can be processed by automatic means (i.e. by using the medical devices), also for scientific medical research purposes the data may be processed only having notified the State Data Protection Inspectorate. In this case the State Data Protection Inspectorate must carry out prior checking.

ii. Are there any specific rules of processing of personal data sourced by means of medical devices containing software, by healthcare units?

No specific rules apply with respect to data sourced by means of medical devices containing software. The general rules of data processing must be observed. Such data might be classified as automated data under the Law of 11 June 1996 on Legal Protection of Personal Data. However, the exact applicable rules would vary depending on the type of data collected and purposes for which the data are collected. Also, further requirements might apply depending whether data are to be exchanged with any third parties, including third parties outside EU/EEA.

iii. Are there any specific rules of processing of personal data by manufacturers/distributors in case of collecting reports on medical incidents from customers?

The general rules of data processing must be observed. Since each manufacturer shall have pharmacovigilance system in place, data processing based on the received reports from customers would be justified on statutory grounds. Still, if manufacturer/distributor would thereby collect information regarding customer's health, data processing with State Data Protection Inspectorate would need to be registered.

iv. What is the standard for reporting adverse events, and is reporting of events in foreign countries required, and using what standards?

Reporting of adverse events is part of the vigilance system that a manufacture must have in place. Such system provides that any adverse events (certain exceptions apply) are reported to the competent authority (State Health Care Accreditation Agency under MoH (hereinafter – **Agency**). The system shall allow the manufacturer to trace the whole batch of certain products. The purpose of the notification system is that the manufacturer informs the competent authority where the adverse event has occurred, whereas if the affected batch of products is also placed on other markets and corrective

action is required, the competent authorities and European Commission would be informed by the authority in the Member State where the information was received. Pursuant to Medical Device Regulations, the SMCA shall publish non-binding guidelines as to how manufacturers should set-up their vigilance systems, nevertheless currently SMCA website provides only an electronic link to the EC guidelines on medical devices vigilance system (August 2011). It must be concluded that SMCA is advocating adherence to the EC guidelines.

If the medical device is being used by the institution, its director shall report the Agency and the manufacturers or the authorized representatives of the medical device as detailed in the Para 13. of the Medical Devices Installation, Usage and Maintance Instructions issued by the Order No. V-383 of the MoH as of 3 May 2010 (hereinafter – **Instructions**). The patient who has an implanted medical device shall also be informed about the actions, which shall be taken and that such person shall visit a doctor (Para 46. of the Instructions).

7. Reimbursement

What is the optimal model of reimbursement of medical devices?

Reimbursement of medical devices (medical help device) in Lithuania is organized under common system with medicines. According to the Order No. V-741 of the MoH as of 1 August 2011, the MoH has approved a list of conditions for which medical treatment would be compensated from state budget.

Base and the highest retail prices of reimbursable medical devices are approved only of those devices which has been entered in the List of Diseases and Reimbursable Medical Devices for their Treatment (so called C-List) approved by the Ministry of Health, and in respect whereof an application has been received for entering them in the Price-List of Reimbursable Medicinal Products.

Government reimburses only base price of the medicinal product and only certain compensation level of such base price (either 100%, 90%, 80% or 50%). Base price is calculated under the certain formula and in principle is a certain part of the lowest retail price of the medicinal product within certain group of medicines. Accordingly, patients buying reimbursable medicinal products have to pay additionally (so called co-payment) for reimbursable medicinal product.

In general, the selling price of medical devices in the whole distribution chain is not statutory fixed in Lithuania. Wholesale and retail prices are set by wholesalers (distributors) of the medical devices and retailers (pharmacies) respectively. However, certain highest price thresholds which can not be exceeded while selling medical devices in distribution chain (wholesaler, retailer or final customer / patient) are statutorily set: the MoH approves the base, the highest retail prices and highest wholesale and retail mark-ups of reimbursable medical devices, and the highest wholesale and retail mark-ups of non-reimbursable medical devices.

In Lithuania wholesalers and retailers are remunerated via maximum mark-ups of reimbursable medical devices, regulated by Order No. V-267 of the Ministry of Health of the Republic of Lithuania, 6 April 2010. Wholesale mark-ups for reimbursable medical devices

range from 3,5% to 14% and are capped at 10,50 LTL per unit depending on ex-factory price. Retail mark-ups rangefrom 5% to 20% and are capped at 15,00 LTL per unit depending on pharmacy purchace price. This involes a combination of linear and regressive schemes.

i. What are the rules of granting reimbursement of medical devices in your jurisdiction?

There are several aspects which are considered when application is received from a manufacturer for inclusion of the product in the state reimbursement list as detailed in the Order No. 159 of the MoH as of 5 April 2002. First, the product must be intended for treatment of the listed conditions. The effectiveness of the product would also be assessed in comparison to the already included products, both in terms of clinical effectiveness and economical. New products are included only if they are superior to the already listed products in any way (cheaper, more efficient). These are the general rules for granting reimbursement; however there are also further rules depending on particular circumstances.

For example, prices for parallel imported products must be 4% to 10% lower (depending on the mark-up value) than the regularly imported product; the assessment criteria for including medical device in the C-list f. e. include whether the medical device compensates the functionality that patient has lost functionality, or helps patient to improve working capacities, or decreases the need for hospital care.

8. Distribution

Is distribution and promotion of medical devices subject to legal regulation?

Besides the fact that the medical device must undergo EC conformity assessment, have CE marking or be registered with SMCA (as described above), no further requirements apply towards distribution of medical devices. Promotion of medical devices is not specifically regulated.

CE marking is not needed for medical devices manufactured for (i) clinical-trial purposes and (ii) custom-made device.

i. Are there any specific regulations determining mode of business activity of medical devices distributors?

No, there are no specific regulations with respect to business model of medical device distributors; however any commercial activity in the territory of Lithuania must be registered in register (i.e. establishment of a company or opening a branch).

ii. Is administrative permit for medical devices distribution required?

No, distribution of medical devices does not require any permit or license. License is required for distribution of medicines, which might apply in case of combined products.

iii. Are there any specific limitations in distributing medical devices in your jurisdiction?

We are not aware of any specific limitations in our jurisdiction. Generally the medical devices regulations (i.e. Medical Norms) derive from the relevant EU directives;

hence it must be fairly similar throughout EU. Pursuant to the principle of free movement of goods, any product which can be legitimately placed on the market in another EU Member State can also be placed on the Latvian market, although some formalities might apply (notification, registration of the product, conformity assessment, etc).

iv. Are obligations of distributors of medical devices specifically legally regulated?

No, obligations of medical devices distributors are not specifically regulated.

v. What specific rules exist for advertising and promoting medical devices?

No specific rules exist with respect to advertising and promotion of medical devices.

9. Manufacturing

How are manufacturing practices regulated?

Manufacturing practices are regulated to the extent that the end product shall correspond to the essential requirements. The requirements are regulated by the Norms MN 104:2004 and Medical Norms MN 102:2001 "Safety Technical Regulation for the *in vitro* Diagnostics Medical Devices" established by the Order No. 679 MoH as of 29 December 2001 (hereinafter – **Norms MN 102:2001**).

i. Are there any specific standards or regulations determining the quality of manufacturing practices?

The detailed manufacturing practices regulation applies to medical devices mentioned in the list A and B of the Annex 2 of the Norms MN 102:2001 and to devices that are used to evaluate operation specific requirements established in the Norms MN 104:2004.

Therefore, the manufacturer who wants to supply medical devices to the market must comply with Annex 3 of the Norms MN 102:2001 and before supplying the market with the devices must prepare Declaration of the Conformity to EC.

ii. If the answer to (i) is positive, how are these good manufacturing practices or quality system regulations reviewed and enforced?

The manufacturing quality system is reviewed by the Notified Institution. The review of quality system and documents to be submitted are described in Annexes of the Norms 102:2001 and Norms 104:2004.

iii. Are establishments manufacturing medical devices, or components of medical devices, required to be registered with a government regulator?

The establishments manufacturing medical devices, or components of medical devices which are registered in Lithuania also must inform the Agency and provide with the following information:

(i) The address where the establishment manufacturing medical devices, or components of medical devices is registered at.

(ii) Information regarding the regents, the products which are manufactured from the regents, the materials of calibration and control, any amendments, including supply to the market and information about the devices.

The Agency must register the establishment manufacturing medical devices, or components of medical devices immediately in the European databank. The registration procedure before the Agency is specified in the part VII of Norms MN 102:2001.

iv. Are these establishments inspected regularly by government regulators or authorized bodies, and what is the mode of such inspections?

Products that undergo conformity assessment procedures in notified institutions are subject to inspections by the notified institutions.

10. Regulatory Guidance

How are the requirements communicated to medical device manufacturers?

i. In what form do the laws and regulations appear that are applicable to medical device manufacturers?

The applicable laws and regulations are passed by the Parliament or Government (normally – by the MoH). Since these documents are public, there is no specific communication of these requirements to medical device manufacturers.

ii. Are informal guidance or the opinions of regulators available to device makers, and in what form?

The Agency has published a series of recommendations and guidelines regarding medical devices. The information is available publicly in their website (link: http://www.vaspvt.gov.lt/node/81). Also, a Q&A section exists where the opinions and (or) guidance may be informally obtained (link: http://www.vaspvt.gov.lt/faq_questions_answers).