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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

The authority with jurisdiction over medicines and biologicals is the State Agency of Medicines (SAM). The authority responsible for applying and enforcing the regulatory framework in relation to medical devices is the Health Board.

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

The primary national legislation for the authorization and pricing of medicines and biologicals is the Medicinal Products Act (MPA) and its regulations. Authorization of medical devices is primarily regulated by the Medical Devices Act (MDA) and its regulations. Pricing of medical devices is not regulated. Reimbursement of medicines, biologicals and medical devices is mainly regulated by the Health Insurance Act (HIA) and its regulations.

3. What are the steps to obtaining authorization to develop, test, and market a product?

A) MEDICINES:

For manufacture of medicinal products, an activity license for the manufacture of medicinal products must be obtained.

For every specific medicinal product, marketing authorization valid in Estonia is required. Marketing authorization is not required for:

- medicinal products prepared as magistral and officinal formulae and medicinal products divided up into retail packaging by pharmacies;
- medicinal products imported based on a single import authorization and a single distribution permit granted by the State Agency of Medicines;
- whole blood and blood components;
- herbal substances;
- medicinal products prescribed for use on aquarium fish, cage birds, terrarium animals, small rodents as well as ferrets and rabbits kept as pets provided that the use of such medicinal products on any other animal species is precluded;
- advanced therapy medicinal products that have been, by way of exception, made on the basis of a doctor's prescription and subject to doctor's professional liability for the purpose of use by a specific patient upon provision of in-patient health services in Estonia.

Please see chapter 3 question 22 for details on different procedures for obtaining a marketing authorization in Estonia.

B) MEDICAL DEVICES:

Specific authorization for manufacture of medical devices is not required; however, manufacture of medical devices may, depending on the circumstances, include activities for which authorization is required (for example handling of chemicals, usage of radiation, etc.).

Basic requirements for placing the medical device on the market and putting it into service are the following:

- the device meets the requirements of applicable legislation;
- clinical evaluation has been provided for the device, and where necessary, a clinical investigation of the device has been conducted;
- conformity assessment of the device has been carried out;
- the device is accompanied by conforming information necessary for identification of the manufacturer and for the safe use of the device for its intended purpose.

To market a medical device, marketing authorization is not required, but at least 10 days before the medical device is placed on the market, the Health Board must be notified thereof.

4. What are the approximate fees for each authorization?

A) MEDICINES:

State fee for the review of application for issue of an activity licenses for manufacture of medicinal products is EUR 1,000.

Fees for the review of application for issue of a marketing authorization of a medicinal product are the following:

- state fee is EUR 32;
- fee for professional assessment of the application is up to EUR 1,275;
- additional fee is EUR 14,000 (initial decentralized marketing authorization procedure or marketing authorization procedure of mutual recognition where the reference country is Estonia).

State fee for the review of an application for clinical trial of a medicinal product is EUR 385.

B) MEDICAL DEVICES:

As specific authorization for manufacture of medical devices and marketing authorization of a medical device is not required, specific state fees are not applicable.

5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?

A marketing authorization of a medicinal product is initially granted for 5 years. After 5 years, a marketing authorization is renewed for an unspecified term (except in cases where the marketing authorization is based on the assessment report provided by a competent authority of another Member

State of the European Economic Area, in which case the authorization is renewed for the period of validity of the marketing authorization in the reference state).

Depending on the safety information of a medicinal product, including a small number of patients who have used the medicinal product, the State Agency of Medicines may decide that a second limited term of validity of 5 years is required.

For the renewal of the marketing authorization, a marketing authorization holder must submit an application together with supplementary documentation to the State Agency of Medicines at least 9 months before the expiry of the authorization.

Fees for the renewal are the following:

- state fee EUR 32;
- fee for professional assessment of the application is up to EUR 639;
- additional fee EUR 3,000 (decentralized marketing authorization procedure or marketing authorization procedure of mutual recognition where the reference country is Estonia).

6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

The main difference, in general terms, is that for brand-name products, the safety and efficacy must be demonstrated and for generic products, the interchangeability and bio-comparability must be demonstrated **(please see chapter 3 question 23 for details).**

There are no differences for local manufacturers versus foreign-owned manufacturers. However, only marketing authorizations holders whose place of residence or seat is located in a Member State of the European Economic Area can apply for the marketing authorization.

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated

A) Combination products drug + drug and drug + biologic fall under regulatory framework of medicinal products and Medicinal Products Act shall be applied to these combination products.

B) Combination products drug + device, biologic + device and drug + biologic + device:

- If a medical 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 shall be governed by the Medicinal Products Act and Medical Devices Act shall be applied only as far as safety and performance related to device features are concerned.
- Where a medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in the Medicinal Products Act and which is liable to act upon the

body with action ancillary to that of the device, only the requirements of Medical Devices Act shall be applied to the device.
• A device intended for the administration of medicinal product shall be deemed to be a medical device and the provisions of Medical Devices Act shall be applied to it.

The State Agency of Medicines has the right to classify the status of substances and products as medicinal products, and of products as homeopathic preparations. If a product complies with the characteristics specified in Medical Devices Act, the Health Board has the right to identify the product as a medical device.

8. How is compliance with regulation monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?

A) MEDICINES:

The State Agency of Medicines exercises state and administrative supervision over the performance of Medicinal Products Act and legislation established on the basis thereof. SAM is empowered to enter into premises and facilities, to examine premises and facilities, to take movables into storage, to take samples of products and substances, to question and summon persons, to require presentation of documents, etc., to monitor and evaluate compliance with applicable legislation.

In respect of pharmacovigilance, the pharmacovigilance system is used by the State Agency of Medicines and marketing authorization holders. The system is enacted by the Medicinal Products Act and is designed to monitor the safety of authorised medicinal products and detect changes to their risk-benefit balance.

B) MEDICAL DEVICES:

The Health Board exercises state and administrative supervision over the performance of Medical Devices Act and legislation established on the basis thereof. The Health Board is empowered to enter into premises and facilities, to examine premises and facilities, to take movables into storage, to take samples of products, to question and summon persons, to require presentation of documents, etc., to monitor and evaluate compliance with applicable legislation.

In respect of safety and adverse incidents, manufacturers, distributors and healthcare providers are required to share information with and report adverse events to Health Board. For example, the manufacturer of a medical device shall inform the Health Board of any important changes in the device, of any malfunction or deterioration in the characteristics or performance of a medical device and technical reasons thereof, as well as of any inadequacy in the labelling or instructions.

9. What is the potential range of penalties for noncompliance?

A) MEDICINES:

Upon exercising supervision, the State Agency of Medicines has, by its precept, the right to suspend the sale and dispensing of a medicinal product, terminate