The Pharma Legal Handbook

Poland

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms

PHARMA BOARDROOM

Poland

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Poland.
It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with DLA Piper, an international law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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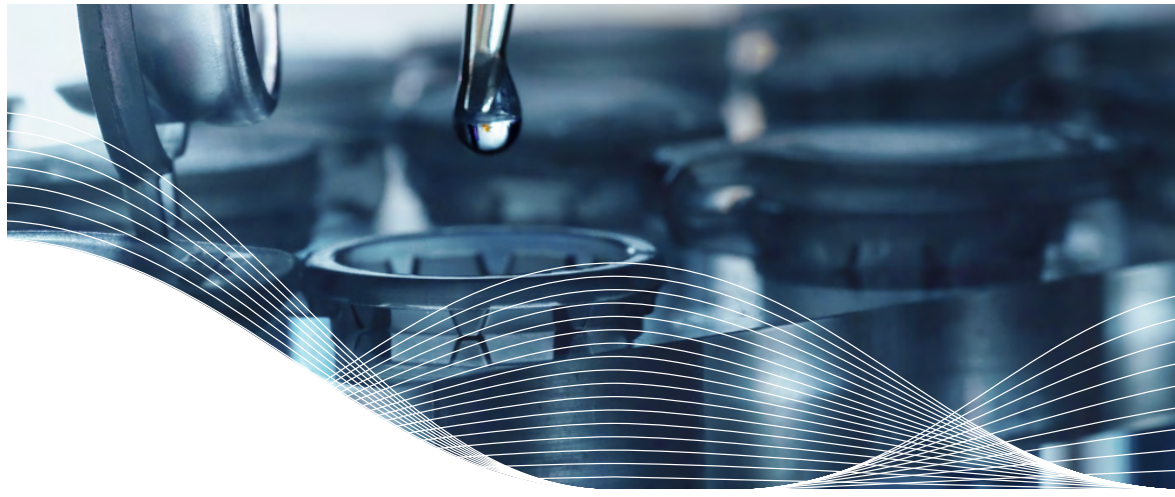

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- corporate, tax and M&A support in the sector

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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 President of the Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products (Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych oraz Produktów Biobójczych – "URPL", http://www.urpl.gov.pl/pl) is the Polish authority competent in matters regarding the placing of medicinal products (including biologicals) and medical devices on the market. It is also responsible for matters regarding registration/notification procedures, clinical trials, pharmacovigilance and the safety of medical devices.

The Chief Pharmaceutical Inspector (Główny Inspektor Farmaceutyczny – "GIF", https://www.gov.pl/web/gif) has jurisdiction over certain issues related to medicinal products for human use and veterinary medicinal products (e.g. manufacturing, import, distribution, advertising and promotion thereof).

The Chief Veterinary Inspector (Główny Inspektor Weterynarii – "GIW", https://www.wetgiw.gov.pl/) has jurisdiction over certain issues related to medicinal veterinary products, including the distribution thereof.

The Minister of Health (Minister Zdrowia, https://www.gov.pl/web/zdrowie) is generally responsible for public health-related matters and has certain powers in relation to medicinal products and medical devices (e.g. with regard to reimbursement).

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

A) AUTHORIZATION

Pharmaceutical Law of 6 September 2001 ("**Pharmaceutical Law**"), as well as a number of supplementary laws thereto, regulate the domestic market authorizations of medicinal products, including biologicals. At the EU level, Directive 2001/83/EC, implemented by the Polish Pharmaceutical Law, and Regulation (EC) 726/2004 set forth the main regulatory framework for the authorization of medicinal products.

Act of 20 May 2010 on *Medical Devices* ("**Act on Medical Devices**"), as well as a number of supplementary laws thereto, establish the main regulatory framework for the authorization of medical devices in Poland and implement Directive 93/42/ EEC, Directive 90/385/EEC and Directive 98/79/EC. This EU legislative framework for medical devices will soon be replaced by the new Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices, which is going to be mirrored in the new Polish Act on Medical Devices (bill is already in the legislative process).

B) PRICING AND REIMBURSEMENT

The pricing of medicinal products and medical devices is not subject to regulation, unless a product is reimbursed (partially or fully) from the state budget. The legal framework for the reimbursement of both medicinal products and medical devices from the state budget is set forth in the Act of 12 May 2011 *on the Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Use, and Medical Devices* ("**Reimbursement Act**").

A medicinal product is reimbursed on the basis of a decision of the Ministry of Health issued in proceedings initiated by a pharmaceutical company submitting a reimbursement application form. The price of a product is negotiated by the applicant with a special unit of the Ministry of Health. The negotiated price of the product and other terms of reimbursement are set forth in the decision of the Ministry of Health. The price is fixed at a specific amount, with the exception of sales to the hospitals, where a maximum price is fixed. Additionally, risk-sharing schemes may be applied to reimbursed products (e.g. special terms of sale to hospitals), but in contrast to fixed prices, they are not made public.

There are four levels of reimbursement for medicinal products: free-of-charge, lump sum, and co-payment levels of 50% and 30% of the financing limit. A fixed wholesale margin (5%) is applied to reimbursed products and the margin for pharmacies is strictly regulated in the Reimbursement Act.

Medical devices are reimbursed in one of two ways: within the framework for medicinal products as described above (tablets, dressings, gels, etc.) or within the completely different reimbursement model for so-called medical devices provided on prescription (wheelchairs, diapers, CPAP devices, etc.). The Regulation of the Ministry of Health of 29 May 2017 *on the list of medical devices provided on prescription* sets forth the types of medical devices that are reimbursed in this model, their characteristics, and the limits of their financing from the state budget. Only the type of device and the characteristics are specified, not the manufacturer or trade name. No application or individual decision of any public authority is required to have a product from the list reimbursed. The devices are reimbursed if they satisfy the criteria set forth in the above-mentioned regulation and are prescribed for and bought at a special medical store by a patient who has received confirmation of the prescription from the National Health Fund. Their prices are not fixed, but state financing is limited to a certain amount.

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

A new medicinal product may be placed on the market once it has obtained a marketing authorization from either the URPL or the European Commission. In order to obtain a marketing authorization, the pharmaceutical company in question has to gather quality, safety and efficacy data, which will be included in a dossier of the product. Depending on the character of the medicine (innovative vs generic), the above-mentioned data may be collected in pre-clinical and clinical trials, or a reference may be made to the dossier of another, already registered, medicine. Clinical trials are regulated in the Pharmaceutical Law

and the Regulation of Ministry of Health of 2 May 2012 on *Good Clinical Practice*. Pre-clinical trials are not regulated.Medical devices do not require any authorization for them to be placed on the market. However, the URPL must be notified in (among others) the following situations:

- at least 14 days before the first device is placed on the market by the manufacturer or its authorized representative residing or established in Poland;
- within 7 days of the date on which the first product is placed on the market in Poland by the distributor or importer residing or established in Poland, which has placed the product on the market in Poland intending it to be used in Poland (not applicable to custom-made devices).

Medical devices of all classes must have a CE mark in order to be placed on the market. In order for a medical device to have a CE mark, a conformity assessment procedure must be performed.

4. What are the approximate fees for each authorization?

It depends on the type of a medicinal product that is subject to the procedure. Basically, the fees for the market authorization of medicinal products vary between approx. EUR 5.000 - EUR 20.000. These fees may be higher or lower depending on (among other things) the type of registration procedure, number of motions that differ only in strength or form of the product etc.

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

A) MEDICINAL PRODUCTS

A marketing authorization is valid for five years. When this period ends, the marketing authorization holder ("**MAH**") may apply for an extension. If no application is submitted, the marketing authorization expires.

The MAH must submit the application for the extension of the marketing authorization at least nine months before its expiry date (six months for a veterinary medicinal product). If the application is approved, the authorization is extended for an indefinite period. In justified cases, the URPL will issue a decision to extend the validity of the authorization for another five years instead of for an indefinite period.

Additionally, if the medicinal product is not placed on the market within three years of the date of obtaining the authorization, or if it is not marketed for a period of three consecutive years, the authorization expires (so-called "sunset clause"). This may be prevented by submitting a relevant application to the URPL.

B) MEDICAL DEVICES

Only notification is required - and it is valid for an indefinite period of time.