The Pharma Legal Handbook

Ireland

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

Ireland

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

Prepared in association with MASON, HAYES & CURRAN, a leading law firm in Ireland, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

*** THIS REPORT WAS ORIGINALLY PUBLISHED IN JANUARY 2020 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**

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To find out how we can help, visit **MHC.ie** or contact:

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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 regulatory authority in Ireland for drugs, biological and medical devices in Ireland is known as the Health Products Regulatory Authority (HPRA). The HPRA is a state agency whose broad remit includes protecting and enhancing public and animal health by regulating medicines, medical devices, and other health products. In addition, it also monitors the safety of cosmetics.

The National Standards Authority of Ireland (NSAI) is the notified body in Ireland, and they are designated by the HPRA to carry out conformity assessment procedures to ensure compliance with all relevant legislation relating to medical devices. A notified body (NB) is an organisation designated by an EU country to assess the conformity of certain products before being placed on the market. NBs carry out tasks related to conformity assessment procedures set out in the applicable legislation, when a third party is required. A list of NBs is published by the European Commission.

The Health Services Executive (HSE) also plays a significant role in respect of drugs, biological and medical devices. It is charged with the provision of and running all the public health services in hospitals and communities in Ireland and is overseen by the Minister for Health.

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

1. Authorization

Medicines and Biologicals:

In the European Union (EU), all medicines must be authorised prior to their being marketed and being made available to patients. There are four different procedures that applicants can use in order to obtain a Marketing Authorisation (MA) depending on the type of medicine and the countries the product is going to be marketed in. The four procedures are:

- Centralised Application Process
- National Procedure
- Mutual Recognition Procedure
- Decentralised Procedure

Centralised Application Process:

Under the centralised authorisation procedure (CAP) applicants can make a single MA application to the European Medicines Agency (EMA); this method ensures that once granted by the European Commission (EC), the MA is valid in all EU Member States (MS). The legal framework is governed by Regulation (EC) No 726/2004. Medicinal products listed in the Annex to the Regulation must use this procedure for authorisation. The majority of new medicines in the EU obtain authorisation via CAP.

National Procedure:
Conversely, the majority of medicines already available in the EU were authorised at national level via national competent authorities (i.e. the HPRA in Ireland) after a full assessment. This procedure is not permitted where applicants already hold an MA in another MS. The HPRA grants MAs under the Medicinal Products (control of placing on the market) Regulations 2007. The HPRA in Ireland issues a MA along with a Product Authorisation (PA) number which is to be included on the box or container of the product. Details regarding applications are contained in EU Directive 2003/63/EEC and full applications must be submitted in accordance with a Common Technical Document (CTD) format.

If a company wishes to request an MA in several EU MS they can do so either using the Mutual – Recognition Procedure (MRP) (i.e. an MA granted in one MS can be recognised in others) or via the Decentralised Procedure (DCP) where a medicine or biological not yet authorised in the EU can be authorised simultaneously in several MS.

Mutual Recognition Procedure:
Under the MRP, a product is assessed by one MS known as a Reference Member State (RMS), and further on in the process, MAs can be sought from other MS who are known as Concerned Member States (CMS). CMS recognise the decision of the RMS rather than undertaking their own assessment process. Therefore the applicant will hold an MA in the RMS and all the CMS. If a medicinal product is required to be authorised under the CAP then this authorisation procedure cannot be used.

Decentralised Procedure:
The Decentralised Procedure (DCP) is used by applicants to apply for MAs in more than one MS where the product has not been authorised in any MS and where applicants do not want to use the CAP or the product is not eligible for the CAP.

The RMS does an initial evaluation of the product and issues a draft assessment report. The other CMS either agree with this initial evaluation or ask further questions or raise objections. If any potential issues are resolved, and each application is successful then each MS involved will issue an MA for that product in their country.

Devices:
Directive 93/42/EEC contains the basic legal framework for the regulation of medical devices in the EU, however this has been replaced by the new Medical Devices Regulation 2017/745 (MDR) which comes fully into effect in May 2020. Medical devices (products or equipment intended generally for medical use) are regulated by national competent authorities (HPRA in Ireland). The HPRA has designated NSAI as the NB in Ireland to carry out conformity assessment procedures to ensure compliance with applicable Medical Devices Legislation. Conformity assessments are a service to manufacturers in an area

of public interest. Manufacturers are free to choose any NB in the EU that has been legally designated to carry out the conformity assessment procedure.

'CE' (Conformité Européenne) markings appear on many products sold in the EU. CE Marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation. CE Markings cannot be affixed to products until all necessary certifications have been obtained from the NB (or depending on the medical device's class, through a self-certification). Not all products sold in the EU require CE marking, however it is mandatory for medical devices, in vitro medical devices and active implantable medical devices.

Certain persons who intend on placing medical devices on the market must register their contact details and details of their devices with the HPRA.

The three main EU Directives regulating the marketing and safety of medical devices placed on the market were:

(a) Directive 90/385/EEC concerning Active Implantable Medical Devices (AIMDD)

(b) Directive 93/42/EEC concerning General Medical Devices (MDD)

(c) Directive 98/79/EC concerning in-Vitro Diagnostic Medical Devices (IVDD)

These Directives and the related Irish Regulations require manufacturers, nominated Authorised Representatives or anyone seeking to place medical devices on the EU market to provide information to the HPRA (relevant competent authority).

Regulation 2017/745 on medical devices and Regulation 2017/746 on in vitro diagnostic devices entered into force on 25 May 2017 and will take effect in May 2020 and May 2022 respectively. These Regulations replace the above listed Directives to be transposed into national legislation.

2. Pricing & Reimbursement

In Ireland, in order to decide which medicines or medical devices will be reimbursed under the social security system, the HSE (like all other EU competent national authorities) has the independence to set the prices of medicinal products and medical devices (non – drug products).

The HSE has statutory responsibility for medicine and non – drug (medical device) pricing and reimbursement under the Health (Pricing and Supply of Medical Goods) Act 2013. Their website provides guidelines and lists for reimbursable items including medicines and aids (Reimbursement List). There is a standard application procedure (other than for cancer drugs) to have products included on this list via which suppliers can make reimbursement applications to the HSE. Ireland does not have a distinct approval procedure for reimbursements for rare disease medicines or hi – tech products.

The 2013 Act outlines the criteria for decisions regarding the reimbursement of medicines and non – drug products (medical devices). The decisions