The Pharma Legal Handbook

Ireland

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labelling 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 LLP, a leading law firm in Ireland, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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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 with responsibility for drugs, biologicals and medical devices in Ireland is 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, as well as cosmetics.

The National Standards Authority of Ireland (NSAI) is an Irish notified body designated by the HPRA to carry out conformity assessment procedures to ensure compliance with relevant legislation relating to medical devices. A notified body (NB) is an organisation designated by a European Union (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 (EC).

The Health Services Executive (HSE) also plays a significant role in respect of drugs, biologicals 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. The HSE's Corporate Pharmaceuticals Unit acts as the interface between the HSE and the pharmaceuticals industry with regards to medicinal pricing and reimbursement, and the operation of national pricing framework agreements.

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

Medicinal Products:

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 Procedure (CP) applicants can make a single MA application to the European Medicines Agency (EMA); this method ensures that once granted, the MA is valid in all EU Member States (MS). The legal framework governing the CP is contained in Regulation (EC) 726/2004. Medicinal products listed in the Annex to the Regulation (EC) 726/2004 must

use this procedure for authorisation. The majority of new medicines in the EU obtain authorisation via the CP.

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 (S.I. 540/2007). 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 more than one EU Member State (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, an applicant can hold an MA in the RMS and various other CMS. If a medicinal product is required to be authorised under the CP 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 CP or the product is not eligible for the CP.

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.

Medical Devices:

'CE' (Conformité Européene) 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. Not all products sold

in the EU require CE marking, however it is mandatory for medical devices and in-vitro diagnostic devices (IVDs). CE markings cannot be affixed to products until all necessary certifications have been obtained from a NB (or self-certification in some cases depending on the risk classification of the device). The HPRA has designated NSAI as a NB in Ireland to carry out conformity assessment procedures to ensure compliance with applicable medical devices legislation however manufacturers are free to choose any NB in the EU that has been legally designated to carry out the necessary conformity assessment procedure in respect of their device(s).

Directive 93/42/EEC contained the basic legal framework for the regulation of medical devices in the EU, however this has now been replaced by the Medical Devices Regulation 2017/745 (MDR). The MDR came into effect on 26 May 2021, having been postponed for a period of one year under Regulation 2020/561 due to the COVID-19 pandemic. In Ireland, the Medical Devices Regulations 2021 (S.I. 261/2021) (the 2021 Regulations) were enacted on 26 May 2021 to confer on the HPRA various regulatory functions provided for under the MDR such as classification, market surveillance, clinical investigations and enforcement. The European Union (National Research Ethics Committee for Clinical Investigations of Medical Devices) Regulations 2021 (S.I. 260/2021) have also been enacted to provide for the establishment of a National Research Ethics Committee for Medical Devices (NREC-MD), and the rules procedures applicable to its functions. An opinion from NREC-MD is required as part of the application process for clinical investigations on medical devices in Ireland.

In-Vitro Diagnostic Devices:

Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices (IVDD) provides for regulation of the safety and marketing of IVDs placed on the EU market and is transposed in Ireland using the European Communities (In-Vitro Diagnostic Medical Devices) Regulations 2001 (S.I. 304/2001). Regulation 2017/746 on In-Vitro Diagnostic Devices (IVDR) entered into force on 25 May 2017 and will take full effect on 26 May 2022. This will bring about a number of significant changes such as new classes of IVDs, there will now be four categories ranging from Class A (lowest risk), to Class D (highest risk). Further, the IVDR also expanded the definition of an IVD to include software, introduced a unique device identifier (UDI) for each device to enhance traceability, as well as making it obligatory for IVDs and testing services offered online to comply with the IVDR the moment they are offered for use in the EU. Owing to concerns over market disruptions expected to be caused by a lack of appropriately designated notified bodies, the European Commission has recently proposed an extension of the 2-year transition phase currently provided for under the IVDR. Under this proposal, the highest risk devices (Class D) would have until May 2025 to undergo conformity assessment by a notified body. Moderate-risk devices (Class C) would have until May 2026 and lower risk Class B and Class A sterile devices would have until May 2027.