Regulatory Enforcement Power of Ireland's Health Products Regulatory Authority

The Health Products Regulatory Authority (HPRA) is the competent authority in Ireland for human and veterinary medicines; human blood, tissues and cells; cosmetic products and has a regulatory role in relation to medical devices, active pharmaceutical ingredients, controlled drugs and substances. HPRA regularly carries out announced and unannounced inspections (Dawn Raids) and audits to establish and monitor industry's compliance with relevant legislation and guidelines. It is important for industry to be aware of the key inspection and enforcement powers available to HPRA.

Powers of Authorised Officers

The Irish Medicines Board Act, 1995 (as amended) (Act) provides for the appointment of authorised officers and confers a wide range of powers which they may exercise when undertaking an investigation , inspection or other functions under the Act (or under Regulations made under the Act) on behalf of HPRA.

An authorised officer receives a warrant of appointment from the Chief Executive of HRPA and is obliged to produce the warrant for inspection on request when performing a function under the Act. The powers of an authorised officer include:

- The power to enter any premises where they reasonably believe any trade, business or activity connected with the manufacture, processing, disposal, export, import, distribution, sale, supply, storage, packaging or labelling of any medicinal product, cosmetic product, medical device is or has been carried out or where books, records or other documents relating to such activity are kept.
- In the case of a dwelling an authorised officer requires either the consent of the occupier or a warrant issued by a Judge of the District Court before he is entitled to enter the premises and exercise his powers under the Act. An authorised officer may be accompanied by members of an Garda Siochana, other authorised officers and persons with relevant expertise.
- The power to inspect any premises includes the power to search. Premises is defined widely to include any place, ship or other vessel , aircraft , railway wagon or other vehicle, and includes a container used to transport any medicinal product, cosmetic product, medical device, and any article or substance used in the manufacture, processing or storage of same.
- The power to require any person at the premises or the owner or the person in charge of the premises and any person employed there to give the authorised officer assistance and information and produce such books records or other documents that he may reasonably require for the purpose of his functions under the Act. Documents or records stored in illegible form must be produced in a legible format. The obligation to produce relates to documents or records as are in that person's power or procurement.
- The power to take copies (or extracts) of books, records or other documents including documents stored in non-legible form and to seize original books, records and documents and detain them for such period as he considers reasonably necessary for the purposes of his functions under the Act.
- The power to inspect and copy or extract information from any data within the meaning of the Data Protection Acts 1988 and 2003.
- The power to carry out tests, examinations, analyses , inspections and checks of the premises , equipment , machinery or plant and any medicinal product, cosmetic product, medical device and any article or substance used in the manufacture, processing or storage of same.
- The power to take samples (without payment) of any relevant thing found on the premises for the purpose of any test, examination or analysis;
- The power to take possession of and remove and detain any relevant thing for such period as he considers reasonably necessary for the purposes of his functions under the Act .This also includes the power to take samples from anything removed and detained.
- The power to direct that any medicinal product, cosmetic product, medical device and any article or substance used in the manufacture, processing or storage of same which the authorised officer reasonably believes to be in contravention of the Act not be sold, distributed or moved from the premises without his consent.
- The power to seal the premises (or part of the premises) in which any medicinal product, cosmetic product, medical device and any article or substance used in the manufacture, processing or storage of same or any books, records or documents are found or kept for such period as may reasonably necessary for the purposes of his functions under the Act.
- The power to require a person who provides facilities (post office boxes , tele- communications, electronic mail address or like facilities) to give the authorised officer such assistance or information as he may reasonably require for the purpose of his functions under the Act where he believes that any relevant thing is being supplied by mail.
- The power to require a person having authority to do so to break open any container or package or open any vending machine or to permit the authorised officer to do so.

Offences and Penalties

Section 32 of the Act gives the Minister for Health extensive powers to make regulations for the purposes of the Act. The regulations made under S 32 of the Act include:

- Medicinal Products (Control of Manufacture) Regulations 2007 (as amended).
- Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (as amended).
- Medicinal Products (Control of Advertising) Regulations 2007 (as amended).
- Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended).
- Medicinal Products (Control of Placing on the Market) Regulations 2007 (as amended).
- Medicinal Products (Control of Advertising) Regulations 2007 (as amended).

Section 32(4) of the Act makes it an offence to contravene a regulation made under S32 of the Act.

In addition it is an offence to:

- obstruct , interfere or impede an authorised officer in the course of performing his functions under the Act or a warrant under S 32B(6).
- fail or refuse to comply with a request or refuse to answer a question asked by the authorised officer.
- give information to an authorised officer that a person knows to be false or misleading in a material respect, in purported compliance with a request or requirement or in answer to a question.

Summary proceedings for an offence under the Act may be brought and prosecuted by the HPRA. The time limit for instituting summary proceedings for an offence is 2 years from the date of the offence. On summary conviction of an offence under S 32B in respect of a person's behaviour towards an authorised officer the penalties are: a Class C Fine not exceeding € 2,500 or imprisonment for a term not exceeding 3 months or both.

On summary conviction for an offence in contravention of regulations made under S 32 the penalties are: a Class C Fine not exceeding € 2,500 or imprisonment for a term not exceeding 1 year or both. In addition on summary conviction the District Court has a discretion to award costs to HPRA.

In the case of more serious offences in which summary proceedings in the District Court are not appropriate and trial will be on indictment by direction of the DPP in the Circuit Criminal Court the penalties for conviction on indictment are:

- First offence: a fine not exceeding € 120,000 or imprisonment for a term not exceeding 10 years or both.
- Subsequent offence/s: a fine not exceeding € 300,000 or imprisonment for a term not exceeding 10 years of both.

HPRAs Approach to Enforcement

The policy of HPRA is to prosecute where it is necessary to protect human health and where compliance based approached is not considered appropriate. In 2015 HPRA in its regulatory role undertook 344 inspections and audits to establish compliance with legislation, guidance and standards. It is unclear how many inspections or audits were unannounced or for cause. In the vast majority of cases compliance is achieved through the agreement of corrective and / or protective measures in response to identified non- compliance and follow up monitoring by HPRA to confirm implementation. HPRA has rarely exercised its power under regulations to revoke an authorisation. In 2015 the HPRA opened 3677 enforcement cases. The main focus of enforcement cases is the detection and seizure of falsified medicinal products and to prevent the sale of falsified and illegal medicines via illegal websites. Only 1 District Court prosecution was initiated by HPRA in 2015 and the average number of prosecutions over the past 5 years is 8 per annum.

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