

Manual

Importation and exportation of medicinal products and unauthorised or counterfeit medical preparations

Instructions relating to the control, detention, seizure, investigation and prosecution of offences relating to the importation/exportation of medicinal products and unauthorised or counterfeit medical preparations, i.e. goods which come within the control and the remit of the Irish Medicines Board (IMB).

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1. Introduction

In recent years there has been a marked increase in the trafficking of medical preparations and medicinal products, which are subject to import/export controls into Ireland and the EU. Furthermore, some of these products have been found to be counterfeit. In Ireland last year the number of such detections made by Revenue's Customs Service and the Irish Medicines Board increased by 300%. The dangers to society and our citizens from the use and abuse of such products are of serious concern from a public health and economic perspective.

2. Control regime

The licensing and control of such products are a matter for the Department of Health and Children and the Irish Medicines Board (IMB). All legitimate importations and exportations are subject to normal Customs controls such as report and entry and production of valid authorisations, where required. However, travellers clearing Customs are permitted to import on their person or in their baggage a reasonable amount of such medicines for personal use without an authorisation.

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[...]

This "personal use" exemption does not apply to products imported by other means, i.e. in the post, by express couriers or in merchandise. All unauthorised imports of medicines, except by travellers for personal use as specified above, should be dealt with in accordance with the procedures outlined in paragraph 3 below.

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[...]

A schedule of products which are controlled by the IMB is to be found in [SI No 540 of 2003](#)

3. Enforcement

The IMB has responsibility for the control of medical products in the State. Revenue's Customs Service, which is strategically placed at our sea, air and land borders and at Postal Depots, has responsibility for the implementation of import/export controls and is committed to support the IMB in its work. A Memorandum of Understanding has

now been signed between Revenue and the IMB to ensure effective enforcement co-ordination and co-operation in deterring the international trafficking in such products.

The powers available to Revenue's Customs Officers and the arrangements for dealing with detections are detailed at paragraphs (A) to (E) below.

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[...]

(A) Revenue and IMB powers available to officers

Revenue's Enforcement Officers are empowered to deal with the detention, sampling and seizure of prohibited or restricted **medical preparations and medicinal products** imported from **third countries** under the Customs acts and to refer serious cases for prosecution under current standing instructions. All such products, subject to prohibition or restriction on importation are deemed to be prohibited to be imported under the Customs Acts, specifically Sec 42 of the CCA 1876, as amended.

Additionally, an Officer of Customs & Excise is deemed to be an authorised officer under the Section 32B of [Irish Medicines Board Act, 1995](#), as amended by Sec 17 of the [Irish Medicines Board \(Miscellaneous Provisions\) Act, 2006](#). An authorised officer is entitled to examine and detain any product for the purposes of enforcement of the IMB controls whether such product has been imported from a third country or has been consigned to the State from another Member State (OMS).

(B) Small consignments

Most medicinal products encountered by Revenue are of the nature of small quantities consigned to private individuals for their own personal use.

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[...]

(E) Exports

All exports of medicinal products to third countries are prohibited unless authorised by the IMB Sec 5 [SI 538 of 2007](#)- Medicinal Products (Control of Wholesale Distribution) Regulations 2007. Officers are empowered to act under the Customs Acts, specifically the Customs Act 1956 in respect of exports to third countries and also as authorised officers under the IMB Act. The general procedures outlined in paragraphs (A), (B) and (C) above should be followed.

4. Revenue/IMB Liaison Network

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[...]

5. Samples/Product Identification/Custody

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[...]

6. Information/ Intelligence Sharing

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7. Investigations

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[...]

8. Joint Operations

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[...]

9. Role of an Garda Siochana

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[...]

10. Publicity

All publicity regarding the Revenue role in this matter and in enforcement operations will be cleared through the Revenue Press Office.

11 Related Documents and Instructions:

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[...]

12 Enquiries concerning this manual

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