HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Registration Requirements for Brokers of Medicinal Products in Ireland

1 INTRODUCTION

Directive 2011/62/EU, known as the Falsified Medicines Directive (FMD), was published in the Official Journal on 1 July 2011. It amends Directive 2001/83/EC by including measures aimed at preventing the entry of falsified medicines into the legal supply chain.

The FMD defines the brokering of medicinal products as:

'All activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person.'

2 BROKERING AND WHOLESALING

Based on the above definition, the key factors which distinguish the activity of brokering of medicinal products for human use from wholesale distribution include the following:

- Brokering is a financial activity focused on the sale or purchase of medicinal products and consists of negotiating independently and on behalf of another legal or natural person.
- Brokering does not involve taking title or ownership for the medicinal products.
- Brokering is limited to negotiation of the relevant financial transactions. It is an intermediary role where the broker acts on behalf of another operator within that supply chain.
- Brokering does not involve the operator physically handling the medicinal products. Wholesaling may or may not involve physical handling.

Along with other control measures, the Directive introduced a requirement for brokers of finished medicinal products to be registered with the competent authority in the Member State in which they are based.

Brokers are required to:

- maintain a quality system,
- adhere to specific good distribution practice requirements; and
- maintain a sufficient level of documentation relating to transactions carried out, in order to assist with ensuring full traceability for medicinal products across the supply chain.

Wholesalers are required to ensure that brokers used by them are registered and also fulfil the requirements set out within the Directive.

Wholesaling of medicinal products, which involves taking title (ownership) and/or direct handling of the product is not within in the scope of this document. Further information on this subject can be obtained from the 'Guide to Wholesaling and Brokering of Medicinal Products for Human Use in Ireland'; please see www.hpra.ie.

3 REGISTERING AS A BROKER

Brokers operating within the Irish State are required to register with the Health Products Regulatory Authority (HPRA) prior to commencing brokering activity within the supply chain.

An application form 'Application for registration of broker of finished medicinal products for human use' must be submitted in order for a broker to be included on the HPRA brokers' register. The application form is available from the 'Make a submission – medicines for human use' section of www.hpra.ie.

3.1 Assessment of the application for a registration

In order for an application to be deemed valid, all sections must be completed in full. The HPRA reserves the right to independently verify all submitted details and also to conduct an inspection at the site of the applicant in order to ensure that the proposed broker meets the provisions set out in the Directive. The requirement for inspection will be based on assessment of the risk presented by the operation.

When an application is acceptable, the details of the broker will be entered into the brokers' register maintained by the HPRA. This register is publicly accessible on the HPRA website. The broker will be notified of their successful application by letter.

3.2 Maintenance of a registration document

Brokers are required to notify the HPRA of any changes to their registered details without delay, using the form 'Application for registration of broker of finished medicinal products for human use'. The form is available at the 'Make a submission – medicines for human use' section of www.hpra.ie.

4 SPECIFIC PROVISIONS

4.1 Specific provisions for wholesalers

The Directive sets out specific provisions for wholesalers using the services of a broker. These include a requirement for wholesalers to ensure that any broker they use is registered and complies with the relevant good distribution practice (GDP) requirements.

The Directive does not include a provision for competent authorities to certify broker operations for compliance with these GDP requirements. As such, wholesalers are required to verify the GDP compliance of any broker they use, through inspection of their quality system. Third party service providers can be engaged for the purpose of conducting these inspections. However, wholesalers using third party support must ensure appropriate control and oversight of the service provider.

4.2 Specific provisions for brokers

The Directive sets out specific provisions with which brokers must comply. These include the following requirements set out under Article 85b.

1 Maintain an emergency plan which ensures effective implementation of any recall from the market either ordered by the HPRA or carried out in cooperation with the manufacturer or marketing authorisation holder for the medicinal product concerned.

2 Keep records either in the form of purchase/sales invoices or on computer, or in any other form. For any medicinal products brokered the records must list at least the following information:
   - Date
   - Name of the medicinal product
   - Quantity brokered
   - Name and address of the supplier and consignee
   - Batch number of the medicinal products, at least for products bearing the safety features referred to in point (o) of Article 54 of the Directive

3 Ensure that medicinal products brokered have a marketing authorisation in the European Economic Area (EEA).

4 Keep the records referred to under point 2 available to the HPRA, for inspection purposes, for a period of five years.

5 Comply with the principles and guidelines of good distribution practice for medicinal products as laid down in Articles 84 and 85b of the Directive.

6 Maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities.

7 Immediately inform the HPRA and, where applicable, the marketing authorisation holder, of medicinal products identified as falsified or suspected to be falsified.

8 Shall have a permanent address and contact details in the Union.

5 CONTACT DETAILS

For more information, please contact:

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3 November 2025