HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide for
Suppliers of First Aid Kits Containing Medicinal Products Supplying Solely to the End-User

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

1 SCOPE

The purpose of this document is to provide guidance to suppliers of first aid kits containing medicinal product(s), where the kit is then sold to an entity or organisation, which may be regarded as the end-user.

2 INTRODUCTION

The Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 539 of 2007)*, are the current primary legislative basis for wholesaling of medicinal products for human use in Ireland. The Regulations define sale by wholesale as the 'sale or supply for the purposes of sale in the course of a business or for administration to patients in the course of a professional practice and cognate words shall be construed accordingly. Such term shall also include all activities consisting of the procuring, holding or exporting of medicinal products other than activities involving the sale or supply of such products to the public.' The provisions of the Regulations require that any such wholesale business may only be lawfully conducted under a wholesale authorisation issued by the Health Products Regulatory Authority.

Directive 2001/83/EC of the Community code relating to medicinal products for human use*, defines wholesale distribution of medicinal products as 'all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public'.

Consequently, the activities of suppliers of first aid kits containing medicinal products can be categorised into three areas. These are as follows:

1 First aid kit suppliers that assemble a kit containing a medicinal product, where the kit is then sold to a purchasing entity that sells or supplies the kit onwards.
2 First aid kit suppliers that assemble a kit containing a medicinal product, where the kit is then sold to an entity or organisation, which may be regarded as the end-user.
3 First aid kit suppliers that conduct both activities set out under points 1 and 2 above.

In the case of activities conducted as set out under point 1 above, the first aid kit supplier, in selling for the purpose of resale or onward supply, is conducting a wholesaling activity and, in accordance with the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 539 of 2007)*, is required to have a wholesaler's authorisation to enable the conduct of this business. For further guidance on this aspect, please refer to the HPRA's 'Guide to Wholesaling and Brokering of Medicinal Products for Human Use in Ireland' which is available on www.hpra.ie.

**as amended*

Similarly, a first aid kit supplier whose business activities may be categorised under point 3 above, is also conducting wholesaling activities, and as such is required, in accordance with the Regulations, to also have a wholesaler's authorisation.
The guidance set out below concerns those suppliers of first aid kits carrying out only the activities outlined under point 2 above, where the kit contains one, or more, medicinal products and is being sold/supplied to what may be regarded as the end-user. Any further reference to the term 'first aid kit supplier' included in this guide is assumed to relate to those supplying the kit, or a medicinal product component of the kit, to the end-user.

Note: first aid kits, and other kit systems which do not contain any medicinal products, are outside the scope of this guide.

Further information on systems and procedures packs may be obtained through reference to the 'Guide for manufacturers of systems and procedures packs regarding legislative requirements' which is available on www.hpra.ie.

3 INTERPRETATION ON 'SUPPLIED TO THE PUBLIC'

The HPRA considers that where a first aid kit supplier supplies a kit containing a medicinal product, or a medicinal product component of a kit or a medicinal product separate to a first aid kit, to an end-user customer, such as a club or society, the transaction in this circumstance is, in effect, analogous to a retail transaction where the medicinal product is supplied to the public. Similarly, a company supplied with a first aid kit for the purposes of providing first aid supplies for use at a place of work is considered to be the end-user. In the context of the definition of wholesaling, the HPRA considers that this type of activity is outside the defined scope of wholesaling and may be considered as a retail activity.

4 CRITERIA TO BE MET

There are certain criteria that must be fulfilled by the first aid kit supplier for its business to be categorised as a retail activity involving supply to the public. These are outlined below.

4.1 Supply to the end-user

The first aid kit, or a medicinal product component for a first aid kit, must be supplied to an organisation, which is the end-user. As such, the kits, or their individual components, should not be re-sold or supplied outside of that organisation or to any other person. If either of these activities are carried out the organisation has performed a retail transaction, and the first aid kit supplier has acted as a wholesaler, an activity requiring a wholesaler's authorisation as described under the 'Introduction' section.

Particular care is required where the activities of the customer include retail or supply elements, for example, a club which has a retail outlet. In such circumstances, the first aid kit supplier must be satisfied that any medicinal product supplied to the club is used for its own purposes and is not retailed by the club or supplied outside of its organisation.

First aid kit suppliers should, therefore, take appropriate measures to ensure that their customers are, in fact, the end-users of the kit or the medicinal product component.

4.2 Medicinal products included in first aid kits

It is essential that any medicinal product included in a kit should be supplied intact in its original pack. Any activity involving the splitting or breaking down of individual packs in which a medicinal product is contained must, in accordance with the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No 539 of 2007)*, be carried out by a holder of a manufacturer's authorisation which entitles the holder to carry out this activity.

First aid kit suppliers should ensure that the medicinal products supplied within the kit strictly adhere to all of the legal requirements governing the sale or supply of the products concerned, including the following:

- It should be ensured that the medicinal product supplied is classified as a general sale product in accordance with the Medicinal Products (Prescription and Control of Supply) Regulations 2003*.
- A medicinal product included as a component of a kit must be one which can be legally sold in non-pharmacy retail outlets, and should also comply with any other legal restrictions governing the sale of the product concerned.
- Medicinal products that are classified 'pharmacy confined' or 'prescription only' cannot be legally included within a kit or as a replacement component.
- The pack size for the medicinal products concerned should be one that can be legally sold in a non-pharmacy retail outlet.
- The product must be authorised for sale on the Irish market and as such must have a Product Authorisation (PA) number, displayed on the outer carton and, where appropriate, on the primary pack inside.

For reference purposes only, a listing of medicinal products that may be sold as 'general sale' are available on the HPRA website at www.hpra.ie. Any query relating to the method of sale or supply of a medicinal product can be referred to the HPRA.

Note: the HPRA does not endorse the inclusion of any medicinal products in first aid kits. In this context, the Health and Safety Authority (HSA) and relevant publications issued by the HSA should be consulted for further guidance on the use of first aid kits in an occupational setting. It is the understanding of the HPRA that the HSA's inspectors routinely monitor the contents of first-aid kits in the workplace for adherence with relevant legislation and guidelines.

It is also recommended that medicinal products that are administered orally, in particular those containing paracetamol, are not included within first aid kits. Paracetamol containing products are subject to regulatory restrictions as specified in the Medicinal Products (Prescription Control of Supply) Regulations 2003*. Only one pack of 12 tablets of 500mg strength may be sold by a non-pharmacy retail outlet in any one transaction. This requirement may prove difficult to adhere to in the context of the business activities conducted by kit suppliers.

4.3 Obtaining supplies of medicinal products

To ensure compliance of a medicinal product with the requirements of its marketing authorisation and the various legislative requirements governing distribution and supply, all stocks of medicinal products should be obtained by a first aid kit supplier from a wholesaler, authorised to supply medicinal products. It should also be ensured that the products are authorised to be placed on the Irish market (i.e. that they bear a PA number). This should be verified by the wholesaler supplying the medicinal product to the first aid kit supplier. If a first aid kit supplier is sourcing medicinal products from wholesalers located outside of Ireland, it is recommended that contact is made with the HPRA for further guidance.

Wholesalers of medicinal products are required under legislation to establish that their customers are legally entitled to receive medicinal products. This extends to the categories of medicinal products ordered by a customer. Before obtaining a medicinal product from an authorised wholesaler, a first aid kit supplier should provide the wholesaler with a declaration, in writing and signed by the person responsible for the operation, which clarifies the circumstances for which the medicinal product is required. The declaration should state that the medicinal product(s) concerned is/are intended for inclusion in first aid kits, which are to be sold only to the end-user.

A suggested format for the declaration is attached in Appendix 1.

The declaration need only be provided in the first instance in which the medicinal product concerned is obtained from a wholesaler, and is not necessary for subsequent orders of the product.

Any proposed change to the circumstances of sale or supply of the kits, should, as a matter of course, be immediately notified to the authorised wholesaler and to the Compliance department of the Health Products Regulatory Authority, as appropriate. Additionally, any legal implications arising from the proposed change should be addressed in advance of its implementation.

4.4 Traceability in the event of a medicinal product recall

It should also be noted that in the event of the need for the removal of the first aid kit, or a medicinal product contained within it, from the market, a system to ensure traceability of the medicinal products received and those supplied as first aid kit components should be in place.

As such, first aid kit suppliers should, for each purchase of a medicinal product and for each sale of a first aid kit containing a medicinal product, maintain records of the following:

- Date
- Product/quantity
- Name and address of the supplier/consignee

Recording of the batch number for the medicinal products involved would considerably assist the effectiveness of the traceability system.

5 CONTACT DETAILS

For further information contact:
Compliance Department
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
D02 XP77

Telephone: +353-1-6764971
Fax: +353-1-6764061
Email: compliance@hpra.ie

APPENDIX 1

Customer declaration form to be completed by first aid kit suppliers

I/We

Name: _____

Address: _____

have ordered from

Name: _____

Address: _____

the following medicinal products

_____

_____

_____

I/We confirm that the medicinal products concerned will be solely used for inclusion in/replenishment of first aid kits.

I/We further confirm that the first aid kits will be sold or supplied to an organisation solely for end-use by that organisation and that the kits or any medicinal product contained within these kits will, to my/our knowledge, not be sold or supplied onwards to any other organisation or person.

Name: _____ (in block capitals)

Signature: _____

Position: _____

Date: _____