

IRISH MEDICINES BOARD [IMB]

**GUIDANCE NOTE FOR
HEALTHCARE PROFESSIONALS**

This is a summary of the most frequently asked questions by healthcare professionals and should only be used to assist in the understanding of the medicinal products legislation in Ireland.

Full details of the medicinal products legislation are available on the Attorney General's website at www.irlgov.ie/ag.

A. Medicines Legislation:

Question 1: What is a medicine/medicinal product?

Response: In accordance with European medicines legislation as applicable in Ireland, a medicinal product is defined as:

'Any substance or combination of substances presented for treating or preventing disease in human beings.

Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product'.

Question 2: What is an authorised medicine/medicinal product?

Response: An authorised medicinal product is one that has been licensed for sale in Ireland following a review of the quality, safety and efficacy data for the product by the Irish Medicines Board. Authorised medicinal products can be recognised as they carry a PA or EU number, an expiry date and the name and address of the company on the product label. It should be noted that products that do not carry these identification numbers are considered to be unauthorised in Ireland.

Question 3: Where can I find information on authorised medicinal products?

Response: Authorised medicinal products generally contain a package leaflet, which details relevant information for the safe and appropriate use of the product for both the healthcare professional and the patient, and is updated to reflect any new information relevant to the quality, safety and efficacy of the product.

Information on many authorised medicinal products is also available in the Irish Pharmaceutical Healthcare Association [IPHA] Data Sheet and Summary of Product Characteristics Compendium, which is sent to doctors and pharmacists every two years. The first copy is free of charge with a small fee for additional copies. Details of the publication of the Compendium are also published in the medical and pharmacy press with an invitation to doctors and pharmacists to contact IPHA if they have not already received their copies.

The Compendium will also be made available on the Internet later in summer 2003. IPHA will be producing a CD-ROM version and which they intend to send to doctors and pharmacists instead of the book. It will still be possible to order the book version for a fee.

Question 4: [As a medical practitioner/dentist can I supply a medicinal product to my patients?](#)

Response: Yes. However, such supply may only be made to an individual patient in the course of an individual consultation as part of a professional practice [Medicinal Products (Prescription and Control of Supply) Regulations 1996-2002].

Question 5: [As a medical practitioner/dentist/pharmacist can I supply a medicinal product by mail order?](#)

Response: No. In accordance with the Medicinal Products (Prescription and Control of Supply) Regulations 1996-2002, it is an offence for any person, including a medical doctor, dentist or pharmacist, to supply medicinal products by mail order.

Question 6: [As a medical practitioner/dentist/pharmacist can I supply medicinal products using the Internet?](#)

Response: No. The supply of medicinal products through the Internet is considered to be mail order supply and as such is prohibited in Ireland [see Question 5].

Question 7: [As a medical practitioner/dentist can I supply vitamins, minerals and food supplements to my patients?](#)

Response: The supply of food supplements is outside the remit of the IMB and any queries in this regard should be directed to the Food Safety Authority of Ireland.

However, you should be aware that products containing vitamins and minerals above a certain level i.e. in excess of the recommended dietary allowance [RDA] may be considered to be medicinal products.

Question 8: [As a medical practitioner/dentist can I buy a medicinal product from a wholesaler?](#)

Response: Yes. However, it should be noted that a wholesaler supplying medicinal products is required to hold a Wholesaler's Licence from the Irish Medicines Board. You are advised that you should only purchase medicinal products from such a licensed wholesaler.

Question 9: [As a medical practitioner/dentist can I buy a medicinal product from a pharmacist?](#)

Response: Yes. Under these circumstances, the pharmacist is not required to hold a Wholesaler's Licence.

Question 10: [As a medical practitioner/dentist can I supply medicinal products to other healthcare professionals for supply to their patients?](#)

Response: No. In accordance with the Medicinal Products (Wholesale Licences) Regulations, 1993-1996, this activity is considered to be 'supply by way of wholesale dealing' and only persons holding a Manufacturer's or Wholesaler's License from the Irish Medicines Board can engage in such an activity.

Question 11: [How do medicines switch from prescription-only to over-the-counter or general sale status?](#)

Response: The company is responsible for initiating the process for deregulation of a medicinal product from prescription-only to over-the-counter or general sale status. Representation must be made to the Department of Health and Children and a variation application submitted to the IMB. Such an application should include appropriate safety data to support the deregulation of the medicinal product in question.

Question 12: [Why are medicinal products removed from the market?](#)

Response: Medicinal products may be withdrawn from the market by the company and in such cases the decision to withdraw may be for commercial reasons or may be due to problems with the quality, safety or efficacy of the product.

The IMB may suspend or withdraw a product from the market where problems with the quality, safety or efficacy of the product are identified either in Ireland or abroad. In addition, the IMB may initiate a product recall to immediately remove the product from the market. This is normally done in conjunction with the company. The company in consultation with the IMB normally communicates such actions to healthcare professionals.

B. Use of Unauthorised Medicines:

Question 13: Can a registered medical doctor/dentist use an unauthorised medicinal product?

Response: Yes. A medical practitioner or registered dentist may import or supply an unauthorised medicinal product for the treatment of a patient under his care [Medicinal Products (Licensing and Sale) Regulations 1998 [S.I. No. 142 of 1998]]. It should be noted that the use of unauthorised medicinal products falls within the professional responsibility of the prescriber.

In addition, a pharmacist [or ‘a person keeping open shop for a pharmacist’] may supply an unauthorised medicinal product, provided such a sale is carried out and the product is extemporaneously compounded by or under the supervision of a pharmacist; or may supply a prescription only medicinal product in response to a request in the form of a prescription written by a registered medical practitioner/dentist for the treatment of a patient under his care.

Question 14: Should a registered medical doctor/dentist inform the IMB when they supply an unauthorised medicine?

Response: No. The IMB does not have any responsibility for overseeing the use of unauthorised medicinal products by any person covered by the exemptions outlined above. It should be noted that the IMB does not hold any information on the quality, safety or efficacy of unauthorised medicines.

Question 15: What is ‘off-label’ use?

Response: ‘Off-label’ use is the use of an authorised medicine outside the terms of its product authorisation, e.g. use for an indication not specified in the authorised product information; use at a dose not specified in the authorised product information; use in a specific patient population or a specific age-group not specified in the authorised product information.

Question 16: Can a registered medical doctor/dentist use a medicine off-label?

Response: Yes. However, such use cannot be considered to be within the terms of the product authorisation as issued by the IMB and as such is outside the remit of the IMB. It should be noted that such use falls within the professional responsibility of the prescriber.

Question 17: Should a registered medical doctor/dentist inform the IMB when an authorised medicinal product is used off-label?

Response: No. The IMB does not have any responsibility for overseeing the off-label use of medicinal products by healthcare professionals.

C. Safety of Medicinal Products:

Question 20: What is an adverse drug reaction [ADR]?

Response: The internationally agreed definition of an ADR is ‘a reaction which is harmful and unintended and which occurs at doses normally used in humans for the prophylaxis, diagnosis or treatment of disease, or the modification of physiological function’. (This definition excludes accidental or deliberate excessive dosage or maladministration).

Question 21: What is a serious ADR?

Response: This is an ADR which is:

- Fatal
- Life-threatening
- Results in persistent or significant disability/incapacity
- Results in or prolongs hospitalisation
- Congenital anomalies/birth defects
- Reactions which result in serious adverse clinical consequences

Question 22: What ADRs should I report?

Response: The IMB encourages reporting of all suspected adverse drug reactions (ADRs), but in particular the following:

- All suspected reactions to new products (i.e. those available for < 2 years)
- Serious suspected reactions to older products (i.e. those available for > 2 years)
- Any suspected increase in the frequency of minor reactions
- All suspected reactions to vaccines
- All suspected teratogenic effects

Question 23: Who should submit suspected ADR reports?

Response: Doctors, dentists, pharmacists and nurses are all requested to report suspected ADRs.

Question 24: How do I report an ADR?

Response: The IMB will accept information on ADRs in any form. Healthcare professionals may use the free, post-paid report cards available from the IMB (Tel. 01 676 4971, Fax. 01 676 2517) or use the downloadable version of the form which may be accessed from the IMB’s website at <http://www.imb.ie>. Downloaded forms may be sent by freepost to the IMB – marking the envelope ‘Freepost’, IMB, The Earlsfort Centre, Earlsfort Terrace, Dublin 2. Report forms are also available in the IPHA Compendium [see Question 3].

Question 25: [Is ADR reporting mandatory?](#)

Response: ADR reporting is a voluntary activity with healthcare professionals actively encouraged to report suspected ADRs to facilitate the on going monitoring of the safety of medicinal products.

There are, however, legal requirements for companies to submit suspected ADRs and other safety information to the IMB.

Question 26: [Should I report ADRs with unauthorised products?](#)

Response: Yes. The IMB will accept reports of ADRs observed with use of unauthorised products. However, it should be noted that the IMB may have very limited information relating to the use of such products.

Question 27: [Where can I get further information on the safety of medicinal products?](#)

Response: Safety information is available in the package leaflet of individual products and in the IPHA Compendium [see Question 3 for further details].

In addition, information on ADR reporting together with an index of topics covered in the IMB's Drug Safety Newsletter, as well as copies of such items are available from the IMB website.

Question 28: [Does the IMB accept reports from consumers or members of the public?](#)

Response: On receipt of consumer reports, the IMB will request written permission from the member of the public to follow up with the patient's doctor for further information and in order to medically validate the report.