DH Circular 270/06 29th September 2006

Attention all Medical Officers
Dentists
Pharmacists
Wholesale dealers
Importers
Manufacturers

Guidelines for the supply of medicinal products for human use through processes which are not covered by the Medicines Act, 2003 and its subsidiary legislation (unlicensed medicinal products)

The Medicines Act, 2003 defines a **medicinal product** as any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

1. Definition of unlicensed medicinal product

For the purpose of these guidelines, an **unlicensed medicinal product** is a medicinal product which is not placed on the market in Malta by the provisions specified in the Medicines Act, 2003 and its subsidiary legislation or through the European Union.

1.1 Supply of medicines through legislative means

Wherever possible the means available through the legislation should be used to get the supply of medicines for a patient. These are:

a. marketing authorisation as per Article 20 of the Medicines Act, 2003 and L.N. 387 of 2004 and its amendments
b. marketing authorisation through the Central Procedure (Regulation 726/2004)
c. parallel import license (L.N. 437/2004)
d. authorization in line with article 4(2) of LN387 of 2004 (Medicines Marketing Authorisation Regulations) in accordance with article 126a of Directive 2001/83/EC of the European Parliament and of the Council of 6th November 2001 on the Community Code relating to medicinal products for human use, as amended by

Directive 2004/27/EC of the European Parliament and of the Council of 31st March 2004

e. approval by the Licensing Authority for a product to be allowed in exceptional cases, subject to such conditions as the Licensing Authority may attach to it (Article 20 (1) of the Medicines Act, 2003)

1.2 Use of unlicensed medicinal products

The supply of medicinal products through processes which are not covered by the legislation should be restricted to circumstances where the product cannot be obtained through the above means or the patient is not in a position to obtain the product for **personal use** (Annex 1).

Unlicensed medicinal products include:

1. medicinal products which are not placed on the market through means of the legislation specified in 1.1 above
2. medicinal products which have a marketing authorisation in other European Union states or 'reputable' third countries but not in Malta
3. products which do not have a marketing authorisation in the country where they are manufactured. Such products known as "specials" are manufactured by a manufacturer holding a "specials" licence. These unlicensed medicinal products may be needed to treat patients with special clinical needs that cannot be met by other medicinal products.

1.3 'Unlicensed products' do not include:

a. products undergoing clinical trials
b. products which can be approved for compassionate use (Regulation 726/04) – for which a different procedure is to be followed
c. products prepared in a pharmacy in response to a prescription
d. products prepared by division of authorized packs into smaller units in a pharmacy for dispensing to patients within the same pharmacy
e. reconstituted intravenous preparations and products prepared in centralised intravenous additive services
f. products used outside the clinical indications of their marketing authorisation
g. medicinal products obtained by patients directly and personally for personal use (Annex 1)

2 Request and approval of unlicensed medicinal products

A request for the use of an unlicensed medicinal product must be filled. There are three different forms depending on the intention for use of the unlicensed medicinal product as follows:

Form I: Request for the use of an unlicensed medicinal product on a named patient basis, for a specific patient (applies to the Government Health Services)
Form II: Request for the use of an unlicensed medicinal product by a Hospital Department within the Government Health Services
Form III: Request for the use of an unlicensed medicinal product by a Hospital/Clinic outside the Government Health Services

2.1 A request for the use of an unlicensed medicinal product must:

- be submitted by a doctor or a dentist registered in Malta
- clearly explain the reasons for requesting the use of an unlicensed product and outline why a licensed product is not suitable as an alternative
- include a declaration by the prescriber that he/she is fully aware that the product requested is unlicensed and that he/she takes direct personal responsibility for the use of the product
- include the name of the wholesale dealer supplying the medicine and the signature of the person in charge and responsible for the supply, when the request is on a named patient basis
- indicate the hospital/clinic or community pharmacy from which it will be supplied and the pharmacist responsible for the supply, preparation (if required) and dispensing to the patient
- when the request is on a named patient basis, include the patient's signature confirming that he/she is aware that the medicinal product is unlicensed. Lack of a signature has to be justified
- be submitted through to the Superintendent of Public Health (SPH)

2.2 The approval for the use of an unlicensed medicinal product:

- is issued by the SPH in favour of the doctor to meet the special need of an individual patient, for a definite period of time (not more than one year), when there is no authorised alternative
- is only issued for a specific quantity
- authorizes the doctor to prescribe and the wholesale dealer and pharmacist to supply the requested unlicensed product as approved

3 Liabilities and Responsibilities

Whilst medicinal products with a marketing authorisation are subject to stringent control by the legislation to assure their quality, safety and efficacy, neither prescriber nor pharmacist can offer guarantee of the same assurances for unlicensed medicinal products.

3.1 The prescriber

The clinical use of all unlicensed medicinal products is the responsibility of **the prescriber.**

All persons involved in the supply chain of unlicensed medicinal products, including the patient, must be made aware of the unlicensed status of the product. Wherever clinically possible the prescriber should inform the patient that the medicinal product is not licensed and the implications of this. The prescriber may request that the patient fills a patient consent form.

Adverse drug reactions from unlicensed medicinal products should be reported in the same manner as for licensed medicinal products.

3.2 The wholesale dealer

The **wholesale dealer** and responsible person supplying an unlicensed medicinal product must ensure that

- the medicinal product conforms with the national legislation as far as possible
- medicinal products which have a marketing authorisation outside Malta have a valid marketing authorisation
- the manufacturer of products classified as ‘specials’ holds the appropriate licenses for manufacturing

- formal checks are carried out on all batches upon receipt of the product from any supplier. Checks should include
    i. appearance of the product and packaging
    ii. information appearing on the label
    iii. a check of the requested certificate of analysis / certificate of conformity against the current specification upon receipt of goods
    iv. independent analysis for products which are supplied under a 'specials' manufacturing license.

3.3 The pharmacist

The **dispensing pharmacist** must ensure that:

- the prescriber is fully aware of the unlicensed status of the product
- the frequency of use of the unlicensed product is carefully monitored
- whenever the unlicensed product is dispensed, it is to be issued against the order of the authorised prescriber

3.4 Record keeping and other responsibilities

Any person supplying, storing, dispensing, or administering unlicensed products (including manufacturers, importers/wholesale dealers, dispensing pharmacists, and doctors/dentists where appropriate) must:

i) Keep the following records for 5 years:

a. Specification (name, strength, dosage form and other necessary information)
b. Source of supply of the product
c. Batch number of the product
d. Any records related to adverse effects
e. Any records related to the quality of the product
f. The person to whom and the date on which the product was supplied, dispensed or administered
g. The quantities of each transaction
h. The prescriber requesting the unlicensed medicinal product
i. Relevant copies of approved Form I, II or III, as applicable

ii) Make these records available to the SPH or authorized inspectors for inspection if the need arises

iii) Store unlicensed products segregated from other medicinal products and well labeled, indicating that they are unlicensed

iv) Ensure that the unlicensed product is supplied by the wholesale dealers directly to pharmacies and cannot be supplied or sold to third parties

v) Inform the Medicines Authority of adverse safety or quality issues of which they have been notified.

No advertisement relating to the unlicensed medicinal product can be carried out. Requests for information on specific products by health care professions can be answered.

4 Government Health Services

The use of unlicensed medicinal products within the Government Health Services is also subject to an internal policy.

Dr R Busuttil
Director General (Health)

Annex 1

The use of medicinal products by individuals for personal use

Any individual may get medicinal products for personal use from abroad provided that:

- the products are to be used by himself and not sold or supplied to any other person.
- the quantity obtained is adequate for the use by the patient in the specific time period
- the products do not contain blood products, are not cold chain products and the products are not covered by the Third Schedule part A and B in Chapter 31 of the Medical and Kindred Professions Ordinance, or the Dangerous Drugs Ordinance.
- a prescription by a registered Maltese doctor/dentist is presented at customs

Liability for the use of medicinal product imported for personal use:

The prescriber is responsible for the clinical use of the medicinal product. The patient importing the medicinal product must be aware of possible risks associated with the product. Both the prescriber and the patient must be aware that such products are imported without guarantee regards their quality, safety and efficacy.

Requirements:

- The prescription should include all patient details including relevant identification.
- The prescription should not exceed 3 month's supply each time and the prescribed quantity should not exceed the recommended maximum dosage for treatment.
- Each time the product is obtained, a new prescription is required and repeat importation cannot be done more frequently than every 2 months.
- Customs will supply the relevant stock directly to the patient for whom the prescription was made or someone authorized by the patient, acting on his/her behalf, who delivers directly to the patient.
- Customs officer will retain all prescriptions for six months.
- Prescriptions will be vetted vis a vis imported medicinal products by a Medical Officer as is current procedure.