



**General Guidelines & Recommendations on the
Labelling & Packaging of Medicinal Products placed
on the Maltese Market**

1. Introduction

The labelling and packaging of medicinal products is very important for the safe use of these products by the patients and consumers. The main purpose of medicines labelling, and packaging is the clear and unambiguous identification of the medicines and the conditions for their safe use. The information on the labelling together with its format and style are essential for minimizing medication errors, enabling patients, carers and health professionals to select the correct medicine and use it safely.

2. Scope

This document is intended to provide to the industry general guidance on the labelling and packaging of Medicinal Products to be placed on the Maltese Market. Information regarding Centrally Authorised Products can be found on the European Medicines Agency (EMA) website which may be accessed through the following link <http://www.ema.europa.eu/ema/>

3. Abbreviations

CMDh – Co-ordination Group for Mutual Recognition & Decentralised Procedure - Human

DCP – Decentralised Procedure

MAH – Marketing Authorisation Holder

MRP – Mutual Recognition Procedure

MS – Member State

SmPC – Summary of Product Characteristics

PL – Package Leaflet

QP – Qualified Person

QRD – Quality Review of Documents

4. Specific guidelines and recommendations

4.1 General recommendations

Malta has two official languages: Maltese and English. The possibility of choosing one of the languages, avoids the need to provide Maltese translations throughout the lifecycle of a medicinal product and may also encourage the use of joint packs with other English-speaking countries.

Discussions on the labelling and packaging of a medicinal product can be discussed at any stage during the lifecycle of a medicinal product. However, information to be included in the

labelling and package leaflet should be in line with current QRD requirements and must contain all elements required by articles 54, 55 and 56 of Directive 2001/83/EC.

Malta has no additional and country-specific requirements for the labelling and package leaflets such as “blue-box” requirements, thus facilitating the use of joint packs, multilingual packs and over-labelling of packs.

Any form of repackaging must not have an adverse effect on the original condition of the product. The concept of adverse effects on the original condition of the product refers to the condition of the product inside the packaging. It is accepted that the condition of the product is not adversely affected when repackaging affects only the external layer, leaving the inner packaging intact.

On the other hand, the original condition of the product inside the packaging might be indirectly affected where, for example:

- The external or inner packaging of the repackaged product, or a new set of user instructions or information, omits certain important information or gives inaccurate information concerning the nature, composition, effect, use or storage of the product, or
- An extra article inserted into the packaging by the importer and designed for the ingestion and dosage of the product does not comply with the method of use and the doses envisaged by the manufacturer.

Since it is in the trade mark owner's interest that the consumer should not be led to believe that the owner is responsible for the repackaging, an indication must be clearly shown on the external packaging of who repackaged the product, unless this is carried out with the consent of the Marketing Authorisation Holder. That indication must be printed in such a way as to be understood by a person with normal eyesight, exercising a normal degree of attentiveness.

4.1.1 Joint Packs

Joint packs may be used to market products in Malta provided that the labelling and package leaflet as approved are being implemented.

4.1.2 Multi-lingual packs

For multi-lingual packs it is emphasised that discussions with other competent authorities is initiated if the multi-language pack will also be marketed in their territory. In line with the [CMDh Best Practice Guide on Multilingual Packaging](#), multilingual packaging is possible for products authorised through the MRP, DCP and national-only procedures if the medicinal product in the involved MS has:

- The same invented name and strength
- Harmonised SmPC, package leaflet and product labelling text
- The same legal status

In view of these key principles, it is recommended that the national details for Malta including but limited to name of medicinal product, MAH name and address and pack sizes are harmonised amongst the member states involved in the multi-lingual pack to facilitate its use.

4.1.3 Over-labelling packs

When joint-packs and multilingual packs are not feasible, fixing of official language packaging information to a pack that is not in any one of the official languages of Malta is also possible. Please refer to the following link <http://www.medicinesauthority.gov.mt/licensed-pharmaceutical-activities> for manufacturers capable of performing such activities locally.

4.1.3.1 Fixing of packaging information and package leaflet (PL) in the official languages of Malta

A complete translation of the packaging and PL information in any one of the official languages of Malta may be fixed to the outer packaging of the product (if no changes to the immediate labelling are required) or inserted in the pack.

The re-labelling or repackaging must contain all the information as required by local legislation (MEDICNES ACT, 2003 and Medicinal Products (Labelling and Packaging) Regulations,) with respect to labelling and packaging.

The information being affixed to the pack should be done in a tamper proof way whereby it is clear that tampering of the product has occurred if the affixed label is removed. The requirements of the Falsified Medicines Directive apply. Please refer to Section 4.1.4.

The fixing of packaging information and PL should not cover any existing information on the packaging, especially if the information being covered is not being replaced by the information being affixed e.g. expiry date, batch number, etc. All information present on these labels must be printed using indelible ink.

The labels may be used on the outer packaging as well as on the immediate packaging.

Labels must be of the permanent type i.e. any attempt to remove the label will create permanent damage to the packaging. They must be large enough to contain the required

information in a large enough font for adequate legibility and occupy a prominent place on the box.

The font is of great significance to legibility. Simple fonts are suitable. Narrow (condensed) or wide fonts should be avoided. Clear areas around the text improve legibility. The various text items should not therefore be located too close together. Fonts less than 7 points should be avoided. Justification should be provided if smaller fonts are used.

If coloured text or background is used the greatest possible contrast must be aimed for.

4.1.3.2 Self-stick labels

Labels may be used for the addition of the following information (as required by legislation):

- The Marketing Authorisation Number of the product in Malta, granted by the Medicines Authority
- The name and address of the Marketing Authorisation Holder of the product in Malta, responsible for placing it on the market.

The labels may be used on the outer packaging as well as on the immediate packaging.

Labels must be of the permanent type i.e. any attempt to remove the label will create permanent damage to the packaging. They must be large enough to contain the required information in a large enough font for adequate legibility and occupy a prominent place on the box.

If coloured text or background is used the greatest possible contrast must be aimed for.

Labels should not cover any existing information on the packaging, especially if the information being covered is not being replaced by the information being affixed e.g. expiry date, batch number etc., and it is in English.

All information present on these labels must be printed, using indelible ink.

4.1.3.3 Removal of the immediate packaging from the original external packaging and their insertion into new external packaging

It is acceptable to remove blister packs, vials, ampoules or inhalers from their original external packaging and to replace the external packaging without affecting the original condition of the product inside the packaging.

The new outer packaging must be fully compliant with the local legislation (MEDICINES ACT, 2003, Medicinal Products (Labelling and Packaging) Regulations).

In case of repackaging, compliance with requirements of article 47a of Directive 2001/83/EC as amended has to be ensured. The releasing QP must ensure that the safety features referred to in point (o) of Article 54 of the Directive have been affixed on the packaging.

The new pack must also include the original batch number and expiry date.

The indication must be printed in such a way as to be understood by a person with normal eyesight, exercising a normal degree of attentiveness. An assembly batch number must also be printed on the outer packaging.

4.1.2 Ink stamping

The stamping of medicinal products with ink is not allowed except for the addition of the 'D.H.' mark or any other required markings on medicinal products procured by the Department of Health only. The 'D.H.' mark or other markings must be placed on an area having no information and must not cover any information such as expiry date, batch number, QR codes, 2D barcodes, etc. This activity does not require a manufacturer's licence.

4.1.3 Addition of Quick Response (QR) codes

The QR code (Quick Response Code) is a two-dimensional bar code that is used to provide easy access by patients and/or Health Care Professionals to information through a smart phone.

QR codes should not be confused with 2D barcodes which are added to labelling at the time of packaging to enable batch number, expiry date and other product specific details to be recorded on the labelling.

QR codes may be included on the packaging as long as they are not replacing any statutory information as approved (e.g. it cannot replace the inclusion of a package leaflet). Such codes should link to information which has been approved and is therefore in line with article 62 of Directive 2001/83/EC i.e. it is as agreed in the approved SmPC, is giving useful information to the patient and is not promotional in nature. The information may include, for example, educational material as approved through a Risk Management Plan.

The QR code could be included in the outer carton and/or the package leaflet if the legibility is not negatively affected by its inclusion.

For information on the addition of the QR code for products authorised by the Mutual Recognition or Decentralised procedure please refer to CMDh Position Paper on the CMDh website.

If the QR code only links to the approved product information, it may be added to the product via an article 61(3) notification. It may also be included as part of a type IB or type II variation affecting the product information or could be introduced during a renewal. If the information included in the QR code is beyond that approved, a variation must be submitted.

4.1.4 Safety features to be included on the packaging of medicinal products

The Falsified Medicines Directive requires the placing of safety features, a unique identifier carried out by a 2-D barcode and an anti-tampering device, on the packaging of prescription only medicines and certain non-prescription medicines for the purposes of authentication and identification.

Please refer to the [Commission Questions and Answers Document](#) and the information published by the CMDh for more information on the Falsified Medicines Directive and its implementation.

4.1.5 Reference and retention samples for repackaged medicinal products

Samples/specimens may be requested at any time by the Medicines Authority. These may be retained to fulfil two purposes:

- to provide a sample for analytical testing (if required) and
- to provide a specimen of the fully finished product.

Samples may therefore fall into two categories:

Reference sample: a sample of a batch of starting material, packaging material or finished product which is stored for the purpose of being analysed should the need arise during the shelf life of the batch concerned. Where stability permits, reference samples from important intermediate stages of manufacture should also be kept. Examples include tablet cores and different stages of coating processes.

Retention sample: a sample of a fully packaged unit from a batch of finished product. It is stored for identification purposes. For example, presentation, packaging, labelling, summary of product characteristics / package leaflet, batch number, expiry date) should the need arise during the shelf life of the batch concerned.

The reference and/or retention samples serve as a record of the batch of finished product or starting material and can be assessed in the event of, for example, a dosage form quality complaint, a query relating to compliance with the marketing authorisation/licence, a labelling packaging query, a Pharmacovigilance report or a stability query.

Reference and retention samples from each batch of finished product should be retained for at least one year after the expiry date.

The reference sample should be of sufficient size to permit the carrying out, on two occasions, of the full analytical controls on the batch in accordance with the Marketing Authorisation File which has been assessed and approved.

The Qualified Person who releases a batch for sale should ensure that all relevant reference and retention samples are accessible at all reasonable times.

Where the packs are not opened, only the packaging material used needs to be retained, as there is negligible risk of product mix up. Where the packs are opened, for example, to replace the carton or package leaflet, then one retention sample, per packaging operation, containing the product should be taken, as there is a risk of product mix-up during the assembly process. It is important to be able to identify quickly who is responsible in the event of a mix-up (original manufacturer or parallel import assembler) as it would affect the extent of any resulting recall.

Signatures on file