



**GENERAL GUIDELINES ON THE REPACKAGING OF MEDICINAL  
PRODUCTS FOR HUMAN-USE**

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## 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.

This document is intended to provide general guidance on the repackaging of medicinal products authorised nationally. 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/>

Labels and leaflets submitted to the Medicines Authority as part of the application for the granting of a marketing authorisation or the granting of a parallel import licence will be assessed on a case-by-case basis in accordance with the requirements of these guidelines and those of the legislation.

### WHAT IS REPACKAGING?

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. Therefore, any parallel imported product undergoing repackaging must bear this information. Moreover, where the parallel importer has added to the packaging an extra article from a source other than the trade mark owner, he must ensure that the origin of the extra article is clearly

indicated in such a way as to dispel any impression that the trade mark owner is responsible for it.

For products with a marketing authorisation, the addition of information on the packaging to come in line with the Marketing Authorisation in Malta (e.g. addition of MA number and MA holder) does not require an indication on the outer packaging of who carried out the repackaging as this is carried out on behalf of the Marketing Authorisation Holder

#### **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 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 have to 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.

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.

#### **GENERAL CONSIDERATIONS FOR INFORMATION ON LABELLING**

Information to be included in the labelling should be in line with current QRD requirements and must contain all elements required by article 54 of Directive 2001/83/EC – the below are considered as critical for the safe use of medicinal products (and are required to be in line with the reference MA product):

Name of the medicine (as approved in the SmPC)  
Expression of strength (where applicable)  
Route of administration  
Posology (for non-prescription medicines)  
Warnings as required by current guidelines

The above information should appear in the same field of view, where practical.

**Name of product:**

The name of the product in general should include the strength and the pharmaceutical form. The name should appear on at least two non-opposing faces of the pack to aid accurate identification of the medicine.

**Posology:**

Where products are intended for self-medication, the posology should be included in the labelling.

**Warnings:**

The warnings considered critical and included in the approved labelling following authorisation are to be included on the labelling/packaging. These warnings are usually necessary immediately prior to administering the product.

**Excipients of known effect**

Excipients known to have a pharmacological effect are to be included on the label. These are included in [EU guidance](#).

**CONSIDERATIONS FOR SMALL CONTAINERS**

Where the labelling requirements of article 54 of Directive 2001/83/EC cannot be legibly applied to a container, the requirements of article 55(3) should be applied. These criteria are in general considered to apply to containers with a nominal value of 10 mL or less.

**BLISTER PACKS**

When a blister pack is enclosed in a container which meets the requirements of article 54 of Directive 2001/83/EC the requirements of article 55(2) apply to the blister packs. The minimum information to be included is:

The name of the medicinal product

The name of the marketing authorisation holder

The expiry date

The batch number

The name and strength of the product should appear over each blister or be oriented centrally across the pack. The particulars should remain available to the user up to the point at which the last dose is removed from the blister pack. Sufficiently large font should be used for ease of use by the patient.

**FIXING OF PACKAGING INFORMATION AND PATIENT INFORMATION LEAFLET (PL) IN THE OFFICIAL LANGUAGES OF MALTA**

Where:

- The medicinal product is not in any one of the official languages of Malta (Maltese and English) or,
- In the case of packs which would not be compliant with the dossier submitted to the Medicines Authority or with the current regulatory framework,

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 or inserted in the pack). Best practice would be to insert the package leaflet in Maltese and/or English directly 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 clearly evident that tampering of the product has occurred if the affixed label is removed.

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.

**REMOVAL OF THE IMMEDIATE PACKAGING FROM THE ORIGINAL EXTERNAL PACKAGING AND THEIR INSERTION INTO NEW EXTERNAL PACKAGING**

It is acceptable to remove blister packs, flasks, phials, 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 (MEDICNES 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.

Where the above operation is being carried out for a parallel importation activity, an indication must be clearly shown on the outer packaging of who repackaged the product. 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. The parallel importation number of the product and the parallel importer name and address must also be included.

## **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. However this '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 etc. This activity does not require a manufacturer's licence.

## **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.

## **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.

## **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 fulfill two purposes; firstly to provide a sample for analytical testing (if required) and secondly 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 / patient information 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 no or little risk of product mix up. Where the packs are opened, for example, to replace the carton or patient information 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.

## **CONSIDERATIONS FOR PARALLEL IMPORTED PRODUCTS**

Re-labelling and re-packaging requirements described above are all relevant for parallel imported products.



Moreover, the proprietor of the trade mark must be given advance notice of the repackaged/relabelled product being put on sale of at least a month, submitting a sample of the re-packaged/relabelled product. Further guidance is given by Communication from the Commission COM (2003) 839 final and in the [Guide to parallel importation](#).

#### Labelling of outer packaging

Parallel imported medicinal products are issued a parallel import licence number by the Medicines Authority. This licence number must be printed (or introduced by fixing a self-stick label) on the outer packaging of the medicinal product, together with the name and full address of the product licence holder and the name of the re-packaging site.

#### Labelling of immediate packaging

The information on the immediate labelling should be understood by local patients and essential information (e.g. warnings, important safety information) should be translated where necessary and included also on the immediate packaging (e.g. on a bottle, blister). If labels are added to the immediate packaging for any reason, the name and address of the manufacturer carrying out the re-labelling should be included on the label being affixed.

#### Package leaflet

When a package leaflet is produced specifically for the local market, the name and address of both PI holder and re-packager should be included at the end of the text of the package leaflet.

## **GUIDE ON PREMISES**

All packaging/repackaging operations should satisfy the requirements of EU GMP guidelines and are subject to the holding of valid manufacturers' licence and GMP certificate.