MALTA
MEDICINES AUTHORITY

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

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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.

For parallel imported products, please also refer to the following guideline: "GUIDELINES FOR PARALLEL IMPORTATION OF MEDICINAL PRODUCTS FOR WHICH MARKETING AUTHORISATIONS HAVE ALREADY BEEN GRANTED"

2. Scope

This document is intended to provide to the industry general guidance on the labelling and packaging of nationally authorised medicinal products to be placed on the Maltese Market. Information regarding Centrally Authorised Products can be found on the European Medicines Agency (EMA) website.

3. Abbreviations

AA number - Authorisation number of products authorised in accordance with article 126a
CMDh – Co-ordination Group for Mutual Recognition & Decentralised Procedure - Human
DCP – Decentralised Procedure
GMP – Good Manufacturing Practice
MA – Marketing Authorisation
MAH – Marketing Authorisation Holder
MRP – Mutual Recognition Procedure
MS – Member State
MT - Malta
SmPC – Summary of Product Characteristics
PI – Parallel importation
PL – Package Leaflet
QP – Qualified Person
QRD – Quality Review of Documents

QR code- Quick Response Code

4. Specific guidelines and recommendations

4.1 General recommendations

Malta has two official languages: Maltese and English. The possibility of choosing **one** of these languages allows for more flexibility for supply and access and facilitates the use of joint packs.

Discussions on the labelling and packaging of a medicinal product can take place at any stage during the lifecycle of a medicinal product. 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. This includes the national details in Malta on the outer packaging, Authorisation number and Authorisation Holder name and address. This is applicable for all licensed products, irrespective of route of registration (MA, AA, PI).

For products authorised in accordance with article 126(a) of Directive 2001/83/EC, the following details should **also** be present on the outer packaging:

- The authorisation (126a) licence holder name and address
- The name of the local distributor
- The name and address of the re-packager of the medicinal product – as applicable (also refer to section 4.1.4)

Irrespective of route of registration, the above details can be included through over-labelling when an MT specific pack is not yet available, provided that such a process is done under GMP (refer to section 4.1.3).

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, where this is required (refer to sections 4.1.1, 4.1.2, 4.1.3).

4.1.1 Joint Packs

Joint packs can be defined as a shared packaging arrangement used across two or more countries within the EEA, whereby the same outer packaging, labelling and package leaflet are used in multiple Member States.

Such joint packs are acceptable in Malta and may be placed on the Maltese market, provided that the labelling and package leaflet as approved are being implemented.

Malta accepts joint packs with English-speaking countries, as well as with non-English-speaking countries, provided that the packaging includes information in at least one of Malta's official languages.
No regulatory submissions (e.g. Article 61(3) notifications) are required for the implementation of joint packs in Malta.

4.1.2 Multi-lingual packs

Malta also encourages the use of multi-lingual packs, to ensure availability. The information as highlighted in 4.1.1 is also applicable, taking also note of the principles and considerations mentioned in the CMDh Best Practice Guide on Multilingual Packaging.

Discussions are to be started as early as possible during a procedure, including discussions with other competent authorities if there is the intention of using multi-language packs in other territories. In line with the CMDh Best Practice Guide on Multilingual Packaging, this possibility can be used for products authorised through the MRP, DCP and national 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 or temporarily not available, 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: https://medicinesauthority.gov.mt/licensed-pharmaceutical-activities for manufacturers

licensed to perform such activities locally.

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.

It is in the Marketing Authorisations Holders' interest that the consumer should not be led to believe that the owner is responsible for repackaging. Thus, it should clearly be noted and shown on the external packaging, who repackaged the product, unless this is carried out with the consent of the Marketing Authorisation Holder.

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 the legislation (MEDICNES ACT, 2003 and Medicinal Products (Labelling and Packaging) Regulations,) with respect to labelling and packaging.

The inclusion of the information being affixed to the pack should be carried out 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, Braille 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. Samples may be requested at the discretion of the Malta Medicines Authority.

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), if no other changes are required:

• 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.

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, inhalers or other container closures 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 legislation (MEDICINES ACT, 2003, Medicinal Products (Labelling and Packaging) Regulations).

In case of repackaging, compliance with requirements of Title V of Directive 2001/83/EC as amended has to be ensured by the releasing QP.

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 National Health System 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 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. Such information needs to be reviewed by the Malta Medicines Authority prior to implementation of the QR code.

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, no regulatory submissions are needed (e.g. 61(3) notifications). It may also be included as part of a type IB or type II variation affecting the product information. 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.

If a pack already bearing the safety features is lawfully opened (e.g. by parallel traders/manufacturers replacing the leaflet), it can be resealed (e.g. by applying a new ATD on top of the original, broken ATD) provided the requirements in Article 47a (1) of Directive 2001/83/EC are fulfilled.

This implies that:
a. the authenticity of the unique identifier and the integrity of the ATD on the original pack were verified as authentic before breaking the original ATD/pack.

b. the replacement of the ATD is conducted in accordance with applicable Good Manufacturing Practice principles and is subject to supervision by the competent authority.

c. the replacement ATD must make it possible to verify, with the same effectiveness as an original ATD, that the outer packaging of a medicinal product has not been unlawfully opened - tampered with - between the time at which that medicinal product is repackaged and that at which it is supplied to the public. This assumes that it is evident for everybody that a new ATD has been placed and by whom. The latter implies that the name and address of the site where the re-packaging has taken place is clearly stated on the outer packaging.

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

Please refer to the requirements of the current version of Eudralex Volume 4 Annex 19, published on European Commission website.

For any queries regarding sample retention, please contact Inspectorate and Enforcement Directorate of Malta Medicines Authority via the following e-mail: inspectorate.adm@gov.mt

Signatures on file