

Guidelines for the placing of medicinal products on the market in Malta through an application for an Authorisation in line with regulation 4(2) of the Medicines (Marketing Authorisation) Regulations, in accordance with article 126(a) of Directive 2001/83/EC of the European Parliament and of the Council of 6 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 31 March 2004.



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\* For the purpose of these guidance notes “An Authorisation” or “said Authorisation” shall be taken to refer to an Authorisation granted in line with regulation 4(2) of the Medicines (Marketing Authorisation) Regulations.

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## PURPOSE

These guidelines outline the procedure involved for placing on the local market a medicinal product for human use that does **not** have a marketing authorisation in Malta. If a medicinal product has a marketing authorisation in Malta this procedure cannot be used (in such cases a parallel import licence can be applied for).

## LEGAL REFERENCE

This Authorisation is issued in accordance with regulation 4(2) of the Medicines (Marketing Authorisation) Regulations and is based on article 126(a) of Directive 2001/83/EC (*Official Journal L 311, 28/11/2001 P. 0067 – 0128*) of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, as amended by Directive 2004/27/EC (*Official Journal L 136, 30/04/2004 P. 0034 – 005*) of the European Parliament and of the Council of 31 March 2004.

## IDENTIFICATION OF PRODUCTS ELIGIBLE TO APPLY FOR AN AUTHORISATION

In the absence of a marketing authorisation or of a pending application for a marketing authorisation for a medicinal product in Malta, the Licensing Authority, may, for justified public health reasons, authorise the placing of that medicinal product on the market in Malta, provided that the said medicinal product is authorised in another Member State<sup>1</sup>.

The Authorisation should be used for medicinal products for which it is not possible to apply for a Marketing Authorisation by the established procedures.

The medicinal product must have a valid marketing authorisation in another Member State via the national procedure or the mutual recognition procedure (MRP) or the decentralised procedure (DCP) and Malta had not been included as concerned member state in the procedure, for a reason. **The actual pack placed on the market in Malta should be the same pack as that placed on the market in the country of source.** Packs intended for third country (i.e. outside the EU/EEA) markets, also known as international or export packs are **not** acceptable. The authorisation number granted by the country of source and printed on the pack should be visible. The language of the pack of the

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<sup>1</sup> *Member State* means the member state in which the medicinal product concerned is authorised. Only the product with a valid marketing authorisation in the said Member State shall be eligible to be authorised with such an Authorisation.

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medicinal product (package leaflet and labelling) to be placed on the market in Malta must be English or Maltese. If the language of the package leaflet and labelling is not English or Maltese, re-packaging and/or re-labelling is possible. This should be done in accordance with GMP requirements. Notarised translated versions (in English/Maltese) of the summary of product characteristics (SmPC), package leaflet (PL) and labelling of those authorised in the country of source should be submitted with the application form and the declaration in Annex 4 of the application form should be duly signed by the applicant.

The medicinal product to be placed on the market in Malta through the said Authorisation granted in line with regulation 4(2) of the Medicines (Marketing Authorisation) Regulations, has to conform and comply with all the legal requirements applicable to medicinal products for which a marketing authorisation has been issued, in particular: Medicinal Products (Advertising) Regulations; Medicinal Products (Labelling and Packaging) Regulations; Pharmacovigilance Regulations; any provisions with respect to the classification of medicinal products, as laid down in the Medicines Act, 2003, or in any regulations made there under; and, articles 99 to 104 of the Medicines Act, 2003, or in any regulations made under this act.

## APPLICATION FORM AND OTHER REQUIREMENTS

The proposed *Authorisation Holder* intending to place the particular medicinal product on the market in Malta, through the *Authorisation*, must be established in an EU/EEA country. The applicant will have to submit to the Medicines Authority the application form:

Authorisation in line with regulation 4(2) of the Medicines (Marketing Authorisation) Regulations in accordance with article 126(a) of Directive 2001/83/EC of the European Parliament and of the Council of 6 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 31 March 2004 which is to be submitted together with the required annexes specified in the same application form.

The application form must be completed in Maltese or English. Separate application forms need to be completed for each product (for each strength and pharmaceutical form) and for each country of source.

The relevant fee<sup>2</sup> must be paid according to the bank details outlined below. Appropriate proof of payment of the fee should always be attached with the application form.

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<sup>2</sup>When executing payment the amount should be remitted in full, net of all bank charges

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<b>Bank Details</b>	HSBC Malta plc. Gzira Branch Malta
<b>Account No.</b>	039-011176-002
<b>Swift Code</b>	MMEBMTMT
<b>IBAN</b>	MT78MMEB44392000000039011176002

## FILLING IN THE APPLICATION FORM

### **Section 1**

#### **PRODUCT DETAILS**

The information requested in the application form can be obtained from the Summary of Product Characteristics (SmPC) approved in the country of source. A list of EU/EEA countries can be found in Annex 1 of this guideline and Annex 1 of the application form.

### **Section 2**

#### **AUTHORISATION HOLDER/CONTACT PERSONS/ MANUFACTURERS**

The requested information needs to be filled in for all this section. The applicant may designate a person/company responsible for communication (section 2.3 and Annex 2 of the application form) if he/she so wishes, such that any communication is carried out with the person/s indicated on behalf of the applicant.

The designated qualified person for pharmacovigilance needs to be stated in this section. He/she has to be established in any country listed in Annex 1 (Annex 1 to these guidelines and Annex 1 to the application form). Curriculum vitae must also be submitted with the application (Annex 6.3 of the application form).

For blood products and vaccines, the details of the OMCL (Official Medicines Control Laboratory) or laboratory designated for the purpose of official batch release (in accordance with Articles 111(1), 113, 114(1)-(2) and 115 of Directive 2001/83/EC as amended), are required.

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### Section 3

#### DETAILS OF THE PRODUCT AS AUTHORISED IN THE EU/EEA MEMBER STATE WHERE THE PRODUCT HAS THE MARKETING AUTHORISATION.

The details regarding how the product was authorised (by which type of authorisation procedure) and the details of the Reference Member State in case of a MRP or DCP procedure should be included, if known.

#### PROCESSING OF THE APPLICATION

Upon receipt of the application form by the Medicines Authority, a complete validation takes place. Incomplete applications will not be positively validated and processed until the missing documentation is submitted. Once the missing information/documentation is submitted, the application forms and annexed documents will be reviewed and any queries will be forwarded to the applicant or person responsible for communication on behalf of the applicant (if this is requested by the applicant).

The Medicines Authority will then, as per the requirements in article 126(a):

1. notify the marketing authorisation holder in the EU/EEA Member State, of its intention to grant said *Authorisation* in respect of the product concerned, and
2. will request the competent authority in the EU/EEA Member State to furnish a copy of the assessment report (if available in English) and a copy of the valid marketing authorisation of the medicinal product (unless these have not already been submitted by the applicant).

An *Authorisation* is granted and will be submitted to the *Authorisation Holder* (or his representative, if applicable). An Authorisation number will be assigned to each product for administration purposes **only**.

The Medicines Authority will subsequently notify the European Commission in order to include the product in the publicly accessible register, which is set up by the Commission for this purpose. The Medicines Authority will also notify the Commission in case of any products for which such *Authorisation* ceases to be valid.

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## NOTIFICATION AND LETTER OF ACCESS

**The wholesale dealer, not being the *Authorisation Holder*, in respect of each product he is distributing,** must be in a position to furnish to the Authority a copy of the *Authorisation* and the declaration of access issued and signed by the *Authorisation Holder* granting the wholesale dealer the right of use of such *Authorisation* [in accordance with Regulation 8(2) of the Wholesale Distribution of Medicinal Products Regulations, under the Medicines Act, 2003].

Wholesale dealers have the same obligations for products with *said Authorisation* as for those products with a marketing authorisation, as outlined in the Wholesale Distribution of Medicinal Products Regulations.

## RENEWALS

The *Authorisation* will be valid for **five (5) years**. The Medicines Authority would need to be notified of the intention for renewal (if applicable) at least 3 months prior to the end of validity of the *Authorisation*. The licence will not be renewed unless a Renewal Application Form is submitted. If during the 5-year period the product has been granted a marketing authorisation, the *Authorisation* in line with regulation 4(2) of the Medicines (Marketing Authorisation) Regulations, will not be renewed.

## VARIATIONS

During the validity of the *Authorisation*, the Medicines Authority must be notified by the *Authorisation Holder* of any variations approved in the country of source that will affect the product information (that is the SmPC, package leaflet and/or immediate and/or outer labelling and packaging) of the authorised product as approved in the Member State.

The Variations Notifications Form for an *Authorisation* in line with regulation 4(2) of the Medicines (Marketing Authorisation) Regulations needs to be submitted before the product can be placed on the Maltese market. The Medicines Authority will issue an acknowledgement letter. No approval of the said notification of variation/s, is issued. However, for variations that will result in a change in any of the details on the authorisation document, a new authorisation document is issued updated with the new details.

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As outlined earlier in this guidance document, if the language of the package leaflet and labelling is not in English or Maltese, re-packaging and/or re-labelling is possible, and notarised translated versions of the SmPC, PL and labelling of those authorised in the country of source should be submitted with the application form and the declaration in Annex 4 of the application form should be duly signed by the applicant. Likewise, for notification of variations for such products, the variations notification form should be accompanied by both the approved text (variation approved text for the product information, namely SmPC, PL and labelling) in the language of the country of source **and** the corresponding notarised English/Maltese translated text (for the product information, namely SmPC, PL and labelling) for the pack to be placed on the market in Malta.

#### OTHER OBLIGATIONS

The obligations of the Marketing Authorisation Holder in the Member State and the Authorisation Holder are detailed in the Medicines Act, 2003 and all the Legal Notices under the act.

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## **Annex 1**

### **EU/EEA Countries**

#### **EU Country**

Austria  
Belgium  
Bulgaria  
Cyprus  
Czech Republic  
Denmark  
Estonia  
Finland  
France  
Germany  
Greece  
Hungary  
Ireland  
Italy  
Latvia  
Lithuania  
Luxembourg  
Malta  
Poland  
Portugal  
Romania  
Slovakia  
Slovenia  
Spain  
Sweden  
The Netherlands  
United Kingdom

#### **EEA Country**

Iceland  
Liechtenstein  
Norway