



**e-form**

## "Sunset Clause" - Request for an Exemption from the invalidation of a Marketing Authorisation



The Marketing Authorisation(s) for the below-mentioned product(s) will become invalid in Malta in accordance with Articles 24(4) and 24(5) of Directive 2001/83 as amended. The product(s) has/have not been marketed in any presentation since the Marketing Authorisation(s) was/were granted.

Name of medicinal product(s):

Marketing Authorisation  
number(s):

Marketing Authorisation Holder  
name and address:

Date of issue of the Marketing  
Authorisation(s):

Please consider allowing the Marketing Authorisation(s) to remain valid for an additional \_\_\_\_\_ years.

An exemption may be requested for a minimum of one and a maximum of three years.

Justification for the request for  
exemption(s):

Further documentation may be attached to this form in support of the request.

I declare that the above information is correct and that any changes will be communicated to the Medicines Authority with immediate effect.

**Name:**

**Address:**

**Position within the  
company:**

**If the signatory is not the Marketing Authorisation Holder, please attach a letter of authorisation on his behalf**

**Signature:** Kindly fill in the Declaration form at the following link  
<http://www.medicinesauthority.gov.mt/onlineapplications>  
A Declaration form should be submitted for each signatory.

**Date:**