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) will not be marketed in any presentation since the Marketing Authorisation(s) has/have been granted or when 3 years will elapse from the date of cessation of the product on the market.

1. Name of medicinal product(s):

2. Marketing Authorisation number(s):

3. Marketing Authorisation Holder name and address:

4. Choose as applicable:

☐ **The product(s) will not be marketed in any presentation since the Marketing Authorisation(s) has/have been granted [a]**

☐ **Three years will elapse from the date of cessation of the product on the market [b]**

If [b] is chosen, provide documentation/evidence regarding the last marketing status of the product.

Justification for the request for exemption(s)

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

The applicant is requested to inform the Malta Medicines Authority on miau.medicinesauthority@gov.mt and licensing.medicinesauthority@gov.mt when the product is marketed.

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

Name, email, address and position within the company

Name:	
Address:	
Position within the company:	
Email address:	

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

Date:	
Signature:	

The completed form should be sent by email to licensing.medicinesauthority@gov.mt or through CESP



