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| **APPLICATION FORM FOR RENEWAL OF ΑN EXCEPTIONAL MARKETING AUTHORISATION OF A MEDICINAL PRODUCT FOR HUMAN UNDER ARTICLE 13A.** |
| **[The Medicinal Products for Human Use (Control of Quality, Supply and Prices) Laws]** |
| **ΑΙΤΗΣΗ ΓΙΑ ΑΝΑΝΕΩΣΗ ΕΙΔΙΚΗΣ ΑΔΕΙΑΣ ΚΥΚΛΟΦΟΡΙΑΣ ΦΑΡΜΑΚΕΥΤΙΚΟΥ ΠΡΟΪΟΝΤΟΣ ΓΙΑ ΑΝΘΡΩΠΙΝΗ ΧΡΗΣΗ ΣΥΜΦΩΝΑ ΜΕ ΤΟ ΑΡΘΡΟ 13A.** |
| **[Περί Φαρμάκων Ανθρώπινης Χρήσης (Έλεγχος Ποιότητας, Προμήθειας και Τιμών) Νόμοι]** |

**Registrar of the Drugs Council**

# Pharmaceutical Services

**Ministry of Health**

**Nicosia 1475, CYPRUS**

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**Please indicate,**

**File No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Exceptional Marketing Authorisation No.:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| --- | --- |
| For Official Use | |
| *File No* |  |
| *Applic. Date* |  |
| *Fee Paid* |  |
| *F288 No* |  |
| *Receipt Date* |  |

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| --- | --- |
| Pharmaceutical product  Name:  Strength:  Pharmaceutical form:  Active substance(s):  Exceptional MA number: | Exceptional MA holder  Name:  Address:  Telephone number:  Fax number:  E-mail:  Local QPPV/RPPV  Name:  Address:  Telephone number:  Fax number:  E-mail:  Contact Person  Name:  Address:  Telephone number:  Fax number:  E-mail: |

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| Attachments, other information | |
| I confirm that the product still has a valid MA and is placed on the market in the country of origin.  Evidence for placing the product on the private sector or through public procurement.  I confirm that there has been no change to the Patient Information Leaflet and packaging of the product, and therefore the ones approved are already enclosed in the product´s file with the initial application,  or  A variation approval from the national authority of the country of origin is enclosed, regarding a change in the Package Information Leaflet (PIL) and/or the packaging. I enclose the variation approval and the new PIL and packaging texts. | |
| Fees paid: Amount in Euro: | |
| Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Status (Job title)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Print name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date |
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