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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 productName:      Strength:      Pharmaceutical form:      Active substance(s):      Exceptional MA number:       | Exceptional MA holderName:      Address:      Telephone number:      Fax number:      E-mail:      Local QPPV/RPPVName:      Address:      Telephone number:      Fax number:      E-mail:      Contact PersonName:      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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