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| **ΦΑΡΜΑΚΕΥΤΙΚΕΣ ΥΠΗΡΕΣΙΕΣ** |
| **ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ** |
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| **ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ** |  | **PHARMACEUTICAL SERVICES** |
| **REPUBLIC OF CYPRUS** |  | **MINISTRY OF HEALTH** |

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| **APPLICATION FORM FOR ISSUE OF AΝ EXCEPTIONAL MARKETING AUTHORISATION OF A MEDICINAL PRODUCT FOR HUMAN USE UNDER ARTICLE 13A.** |

**[The Medicinal Products for Human Use (Control of Quality, Supply and Prices) Laws]**

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| **ΑΙΤΗΣΗ ΓΙΑ ΕΚΔΟΣΗ 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**

**Tel.: +357 22 608 635**

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**Fax: +357 22 608 649**

**This application concerns the**

**Issue of an exceptional marketing authorisation under**

**article 13A.**

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| *For Official Use* | |
| *File No* |  |
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| *F288 No* |  |
| *Date* |  |

**APPLICATION FORM FOR AN EXCEPTIONAL MARKETING AUTHORISATION UNDER ARTICLE 13A**

**[The Medicinal Products for Human Use (Control of Quality, Supply and Prices) Laws]**

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The application form, is to be used for an application for an exceptional marketing authorisation of a medicinal product for human usesubmitted to Cyprus under Arrticle 126 of Directive 2001/83/EC and Article 13A of Law N.70 (I)/2001.

**Usually a separate application form for each strength and pharmaceutical form is required.**

**DECLARATION and SIGNATURE**

**Product (invented) name:**

**Strength(s):**

**Pharmaceutical form:**

**Active Substance(s):**

**Applicant:**

**Person authorised for**

**communication\*, on behalf**

**of the Applicant:**

It is hereby confirmed that all existing data which are relevant to the issuing of an Exceptional Marketing Authorisation under Article 126a of Directive 2001/83/EC and Article 13A of N. (70)/2001 have been supplied in the dossier as appropriate.

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Signature(s)

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NAME

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Function

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place and date (dd-mm-yyyy)

*\* Note: please attach letter of authorisation for acting on behalf of the applicant (in Annex 2.2).*

**Table of contents**

**1. Marketing authorisation application particulars**

1.1 Name(s) and ATC code

1.2 Strength, pharmaceutical form, route of administration, container and pack sizes

1.3 Exceptional Marketing authorisation holder, Contact Persons, Company

1.4 Manufacturers

1.5 Qualitative and quantitative composition

**2. appended documents**

1. MARKETING AUTHORISATION APPLICATION PARTICULARS

**1.1. Name(s) and ATC code**

**1.1.1 Proposed (invented) name** of the medicinal product in Cyprus

**1.1.2 Name of the active substance(s):**

*Note: only one name should be given for each substance in the following order of priority: INN\*, Ph.Eur., National Pharmacopoeia, common name, scientific name;*

*\* the active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant (for further details, consult the Guideline on the SPC)*

**1.2 Strength, pharmaceutical form, route of administration, container and pack sizes**

**1.2.1 Strength and Pharmaceutical form (use current list of standard terms - European Pharmacopoeia)**

**Pharmaceutical form:**

**Active substance(s): Strength(s):**

**1.2.2 Route(s) of administration (use current list of standard terms - European Pharmacopoeia):**

**1.2.3 Container, closure and any administration device(s),**  (Use currentlist of standard terms - European Pharmacopoeia.)

**For each type of pack give:**

1.2.3.1 Package size(s):

1.2.3.2 Proposed storage conditions:

1.2.3.3 Proposed storage conditions after first opening:

Attach sample of the Patient Information Leaflet (PIL) and labelling (outer and primary) as well as a sample of the product

**1.3. Exceptional Marketing authorisation holder / Contact persons / Company**

**1.3.1** **Proposed exceptional marketing authorisation holder:**

(Company)Name:

Address:

Country:

Telephone:

Telefax:

E-Mail:

Attach proof of establishment of the applicant in the EEA (Annex 2.1)

**1.3.1 Α. Marketing authorisation holder/person legally responsible for placing the product on the market in the Member State of origin :**

(Company)Name:

Address:

Country:

E-Mail:

1.3.2 Person/company authorised for communication between the exceptional marketing authorisation holder and the competent authorities during and after authorisation in Cyprus:

Name:  If different to 1.3.1 above,

Company name: Attach letter of authorisation (Annex 2.2)

Address:

Country:

Telephone:

Telefax:

E-Mail:

1.3.3 Qualified person in the EEA/Cyprus for Pharmacovigilance. In case the Qualified person is in the EEA, state a contact person in Cyprus:

Name:

Company name:

Address:

Country:

24 H Telephone number:

Telefax:

E-Mail:

Attach C.V. of qualified person (Annex 2.3)

**1.4 Qualitative and quantitative composition**

**1.4.1 Qualitative and Quantitative composition in terms of the active substance(s) and the excipient(s):**

A note should be given as to which quantity the composition refers (e.g. 1 capsule).

List the active substance(s) separately from the excipient(s):

Name of active substance(s)\* Quantity /Unit

1.

2.

3.

etc.

Name of excipient(s)\*

1.

2.

3.

etc.

*Note:*  *\* only one name for each substance should be given in the following order of priority:*

*INN\*\*, Ph.Eur., National Pharmacopoeia, common name, scientific name*

*\*\* the active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant (for further details, consult the Guideline on the SPC)*

2. APPENDED DOCUMENTS (where appropriate)

**2.1** Proof of establishment of the applicant in the EEA.

**2.2** Letter of authorisation for communication on behalf of the applicant/MAH.

**2.3** Curriculum Vitae of the Qualified Person for Pharmacovigilance.

**2.4** Proposed labelling in Greek / English (mock-up)

**2.5** Proposed Patient Information Leaflet (PIL) in Greek / English

**2.6** Valid Marketing Authorization or other documentation attesting to the validity of the M.A. from a Member State.

**2.7** Authorised Wholesaler License of the Applicant or an aggrement between the Applicant and a licensed

Wholesaler who will undertake the storage and distribution of the medicinal product in Cyprus.