ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ
REPUBLIC OF CYPRUS

ΦΑΡΜΑΚΕΥΤΙΚΕΣ ΥΠΗΡΕΣΙΕΣ
ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ

PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH

APPLICATION FORM FOR ISSUE OF AN 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]

ΑΙΤΗΣΗ ΓΙΑ ΕΚΔΟΣΗ ΕΙΔΙΚΗΣ ΑΔΕΙΑΣ ΚΥΚΛΟΦΟΡΙΑΣ ΦΑΡΜΑΚΕΥΤΙΚΟΥ ΠΡΟΪΟΝΤΟΣ ΓΙΑ ΑΝΘΡΩΠΙΝΗ ΧΡΗΣΗ ΣΥΜΦΩΝΑ ΜΕ ΤΟ ΑΡΘΡΟ 13Α.

[Περί Φαρμάκων Ανθρώπινης Χρήσης (Έλεγχος Ποιότητας, Προμήθειας και Τιμών) Νόμοι]

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This application concerns the

☐ **Issue of an exceptional marketing authorisation under article 13A.**

For Official Use	
File No	
Date	
Fee Paid	
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 use submitted 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.

_____
Signature(s)

_____
NAME

_____
Function

_____
Place and date (dd-mm-yyyy)

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

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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 current list 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 A. 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:
Company name:
Address:
Country:
Telephone:
Telefax:
E-Mail:

☐ If different to 1.3.1 above,
Attach letter of authorisation (Annex 2.2)

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.