AKBPM MA Form No. 2

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| **NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES**  AGJENCIA KOMBËTARE E BARNAVE DHE PAJISJEVE MJEKËSORE  Rruga e Dibrës, No. 359/1,  Tiranë, Shqipëri | **Date Received:** | **Protocol No:** |
| **Application start date :** | |
|  | |
| Application for renewal of marketing authorisation for a medicinal product |

(AKBPM to fill out)

# Declaration and signature

Product (invented) name:

Strength(s):

Pharmaceutical form:

Active substance(s):

MAH:

Person authorised for

communication on

behalf of the applicant\*:

It is hereby confirmed that all existing data which are relevant to the quality, safety and efficacy of the

medicinal product have been supplied in the dossier as appropriate and samples of the finished product, \*\*.

# \* Attach letter of authorisation for communication/signing on behalf of the applicant and agency

# agreement

# \*\* Attach samples (in final immediate packaging with final labelling) in sufficient quantity

# to permit a full assay and the verification of the control methods used by the manufacturer.

# \*\*\* The fee should be paid by the applicant no longer than 60 days after he received the application form for the renewal of marketing authorisation and the invoice from the Agency.

# 1. Type of Product and Type of Application

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| --- |
| 1.1 Type of medicinal product 3 |
| (i) Chemical active substance(s)   (iii) Herbal  (v) OTC    (ii) Biological active substance(s)  (iv) Other (Specify)  (Mark relevant box(es) with X) |

**2. Application particulars**

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| **2.1 Trade (invented) name of the medicinal product** |
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| **2.2 Name of the active substance** |
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| **2.3 Proposed therapeutic indications** |
| **ATC Code:**  (for main indication) |

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| **2.4 Pharmaceutical form and strength** |
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| **2.5 Route(s) of administration** |
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| **2.6 Packaging and package size(s)** attach list of Mock-ups or Samples | | |
| **(i) Immediate packaging:** | **(ii) Outer packaging:** | **(iii) Package size(s):** |
| **(iv) Shelf life:** | **(v) Shelf life** (after first opening of the blister)**: ---** | **(vi) Shelf life** (after reconstitution or dilution)**:**  ---- |

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| **2.7 Summary of Product Characteristics (SPC)** |
| **English  Other languages (optional)** (Specify): |

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| **2.8 Package Leaflet proposal** |
| **Albanian**  and **English**   or **Other**  (Specify): |

|  |
| --- |
| **2.9 Marketing authorization holder / contact persons / company** |
| **(i) Applicant (future marketing authorization holder):**  Company name:  Country: |

|  |
| --- |
| **2.10 Manufacturer(s)** |
| Company name:  Country :  Attach original / notarized copy of valid manufacturing authorization |

**3. Annexed documents**

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| --- | --- | --- | --- |
|  |  | Yes | N/A |
| **3.1** | Authorisation by the company for the responsible person (in English or Albanian) who must have a university degree in medicine, pharmacy, dentistry. |  |  |
| **3.2** | A written statement of the marketing authorization holder that is not seated in the Republic of Albania of the appointment of a local representative that is seated in the Republic of Albania and the appropriate contact information |  |  |
| **3.3** | Certificate of Pharmaceutical Product (CPP) specify: |  |  |
| **3.4** | Samples of the finished medicinal product + certificate of analyses |  |  |
| **3.5** | Summary product Charachteristics |  |  |
| **3.6** | Package leaflet, package insert proposal (in Albanian and English and/or other languages) |  |  |
| **3.7** | GMP of the finished product manufacturer(s) |  |  |
| **3.8** | Marketing Authorization certificate/decision |  |  |
| **3.9** | Summary of the dossier |  |  |
| **3.10** | List of all variations that have been approved in Albania during the 5 years of the marketing authorization. A copy of the approval of these variations |  |  |
| **3.11** | Mock-up of the primary and secondary packaging |  |  |
| **3.12** | Expert report on quality documentation |  |  |
| **3.13** | Expert report on the preclinical documentation |  |  |
| **3.14** | Expert report on the clinical documentation |  |  |
| **3.15** | Description and composition of the medicinal product |  |  |
| **3.16** | Manufacturing process |  |  |
| **3.17** | Quality control of the medicinal product |  |  |
| **3.18** | Stability of the Finished Product |  |  |

Number of CD:

**Documentation for: accepted  not accepted **

**Signature of AKBPM Specialist of Marketing Authorization Department:**

**Signature of AKBPM Chief of Marketing Authorization Department:**

**Date:**

**Date of last Marketing Authorization:**

(AKBPM to fill out)

## 

Payment 350 € for each dosage form submitted for renewal of marketing authorization:

According to the provision of the Law No. 105, date 31.07.2014 “On Medicines and Pharmaceutical Service”.

**The Bank Commission fee should be paid by you.**

National Agency for Medicines and Medical Devices

Raiffeisen BANK- Tirana, ALBANIA

Accounting No. 0104030780

Confirmation for prepayment ....................Date. / / 2018

**DIRECTOR**

**Name SURNAME**