**APPLICATION[[1]](#footnote-2)**

**National procedures**

*\* select*









**Type of the medicinal product**

*\* select*





**Type of the application**

*\***fill in, by specifying the number (from the 1st column) and the name (from the 2nd column) of the application type according to the Annex N 1 to the decision of the Government of the Republic of Armenia N166-N of February 28, 2019*

|  |  |
| --- | --- |
| Number |  Name |
|  |  |





*\*\*Document confirming the payment of the assessment fee is not attached if the number of application type is 8. In this case, fill in point mentioned below.*



**Name of the medicinal product**

*\*fill in*

|  |
| --- |
|  |

**Strength**

*\*fill in only if the medicinal product contains one active substance*

|  |
| --- |
|  |

**Pharmaceutical form**

*\*fill in*

|  |
| --- |
|  |

**Common name of the active substance or Common names and strengths of the active substances**

*\*fill in, if the medicinal product contains one active substance*

|  |
| --- |
|  |

*\*\*fill in, if the medicinal product contains more than one active substance*

|  |  |
| --- | --- |
|  Common names |  Strengths |
|  |  |
|  |  |

*\*\*\*fill in, if the medicinal product is kit*

|  |  |  |
| --- | --- | --- |
| N/description | Common names | Strengths |
|  |  |  |
|  |  |  |

**Excipients**

*\*fill in*

|  |  |  |
| --- | --- | --- |
|  Common names |  Strengths |  Functions |
|  |  |  |
|  |  |  |

**Packaging, presentation**

*\*fill in by specifying type and size of the inner and outer packagings, administration devices, medical devices, common names, strengths and packagings of the solvents*

|  |
| --- |
|  |

**Shelf life**

*\*fill in*

|  |
| --- |
|  |

**Storage conditions**

*\*fill in*

|  |
| --- |
|  |

**ATC code**

*\*fill in, if assigned by WHO*

*For medicinal products for human use* <https://www.whocc.no/atc_ddd_index/>

*For veterinary medicinal products* <https://www.whocc.no/atcvet/atcvet_index/>

|  |
| --- |
|  |

*\*\*fill in, by specifying pharmacotherapeutic group, if ATC code is not assigned by WHO*

*For medicinal products for human use* <https://www.whocc.no/filearchive/publications/2019_guidelines_web.pdf>

*For veterinary medicinal products* <https://www.whocc.no/atcvet/atcvet_index_and_guidelines/guidelines_for_atcvet_classifica/>

|  |
| --- |
|  |

**Therapeutic indications**

*\*fill in*

|  |
| --- |
|  |
|  |
|  |
|  |
|  |

**Route of Administration**

*\*fill in (e.g. oral, parenteral and etc.)*

|  |
| --- |
|  |

**Legal status for supply**

*\*select*







**Manufacturer(s)**

fill in, if all stages of production are carried out by the same manufacturer

**Manufacturer of the medicinal product including batch releaser (name, location)**

*\*fill in*

|  |  |
| --- | --- |
|  Company name |   |
|  Address |   |
|  City/Locality/Town/Vilage |   |
|  State |   |
| County |   |
| Postcode |   |
| Country |  |
| Telephone |   |
| E-mail |   |

fill in, if stages of production are carried out by different manufacturers

**Dosage form manufacturer (name, location)**

*\*fill in*

|  |  |
| --- | --- |
|  Company name |   |
|  Address |   |
|  City/Locality/Town/Vilage |   |
|  State |   |
| County |   |
| Postcode |   |
| Country |  |
| Telephone |   |
| E-mail |   |

**Immediate packager (name, location)**

*\*fill in*

|  |  |
| --- | --- |
|  Company name |   |
|  Address |   |
|  City/Locality/Town/Vilage |   |
|  State |   |
| County |   |
| Postcode |   |
| Country |  |
| Telephone |   |
| E-mail |   |

**Outer packager (name, location)**

*\*fill in*

|  |  |
| --- | --- |
|  Company name |   |
|  Address |   |
|  City/Locality/Town/Vilage |   |
|  State |   |
| County |   |
| Postcode |   |
| Country |  |
| Telephone |   |
| E-mail |   |

**Quality control (name, location)**

*\*fill in*

|  |  |
| --- | --- |
|  Company name |   |
|  Address |   |
|  City/Locality/Town/Vilage |   |
|  State |   |
| County |   |
| Postcode |   |
| Country |  |
| Telephone |   |
| E-mail |   |

**Batch releaser of the medicinal product (name, location)**

*\*fill in*

|  |  |
| --- | --- |
|  Company name |   |
|  Address |   |
|  City/Locality/Town/Vilage |   |
|  State |   |
| County |   |
| Postcode |   |
| Country |  |
| Telephone |   |
| E-mail |   |

**In case of Blood products and Vaccines, mention the details of the National Regulatory Authority designated for the purpose of official batch release**

*\*fill in*

|  |  |
| --- | --- |
| Name |   |
| Address |   |
| City/Locality/Town/Vilage |   |
| State |   |
| County |   |
| Postcode |   |
| Country |  |
| Telephone |   |
| E-mail |   |

**Qualified person on Pharmacovigilance for the RA**

*\*fill in*

|  |  |
| --- | --- |
| Company name (if applicable) |   |
| First Name, Surname |  |
| Address |   |
| City/Locality/Town/Vilage |   |
| State |   |
| County |   |
| Postcode |   |
| Country |  |
| 24H Telephone |   |
| E-mail |   |

**Contact person with overall responsibility for product defects and recall for the RA**

*\*fill in*

|  |  |
| --- | --- |
| Company name (if applicable) |   |
| First Name, Surname |  |
| Address |   |
| City/Locality/Town/Vilage |   |
| State |   |
| County |   |
| Postcode |   |
| Country |  |
| 24H Telephone |   |
| E-mail |   |

**Registration certificate holder (name, location)**

*\*fill in*

|  |  |
| --- | --- |
| Company name |   |
| Address |   |
| City/Locality/Town/Vilage |   |
| State |   |
| County |   |
| Postcode |   |
| Country |  |
| Telephone |   |
| E-mail |   |

**Authorized representative of the registration certificate holder in the RA[[2]](#footnote-3)**

*\*լրացնել / fill in*

|  |  |
| --- | --- |
|  Company name |   |
|  First Name, Surname |  |
|  Address |   |
|  City/Locality/Town/Vilage |   |
| State |   |
| County |   |
| Postcode |   |
| Country |  |
| Telephone |   |
| E-mail |   |



*(*[*Requirements for the Power of Attorney*](http://www.pharm.am/attachments/article/4810/PoA-requirements%20web_eng.pdf)*)*

*\*select, if submitted previously*



**On behalf of applicant[[3]](#footnote-4)**

|  |  |
| --- | --- |
| First Name, Surname |  |
| Job function |  |
| Signature |   |



[*(Acts on handling-acceptance of documents, samples and standards*](http://www.pharm.am/index.php/en/registration-application/4759-registration-application)*)*

1. *This application concerns to national procedures of human use and veterinary (except for veterinary vaccines, serums and diagnostics) medicinal products.*

*It is necessary to submit separate application for each name, composition, strength, pharmaceutical form, presentation, new indication, manufacturer (including each manufacturing activity performer), registration certificate holder of the medicinal product.* [↑](#footnote-ref-2)
2. Person designated as Registration certificate holder contact person/company with the Scientific Centre [↑](#footnote-ref-3)
3. Person authorized by the Registration certificate holder to sign application [↑](#footnote-ref-4)