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| Republic of Cyprus Colour Big |  |  |
| **REPUBLIC OF CYPRUS** |  | **PHARMACEUTICAL SERVICES** |
| **MINISTRY OF HEALTH** |  | 1475 ΛΕΥΚΩΣΙΑ |

Drugs Council Date:

Pharmaceutical Services

1475 Nicosia

Cyprus

**Letter of Intent for Administrative zero Days MRP (initial wave)**

We, *[Applicant name]*, intend to submit an Administrative zero days MRP procedure (initial wave) for *[Name of the Product]* with Cyprus as a/the only (choose as appropriate) CMS. *[Name of the Product]* is authorized via national procedure in *[Name of the Country]* which will act as RMS.

|  |  |
| --- | --- |
| Name of the medicinal product in RMS |  |
| Proposed name of the medicinal product in in Cyprus |  |
| Dosage Form |  |
| Strength |  |
| Active Ingredient |  |
| Other member states where the product is authorised |  |
| Intended submission date |  |
| Other CMS in the zero Days procedure (if applicable) |  |
| Proposed Legal Status in Cyprus |  |
| Name and address of the applicant  Tel:  Fax:  Email: |  |
| Contact person for communication on behalf of the applicant  Name:  Tel.:  Fax:  Email: |  |

**Statements regarding the application:**

Approved SmPC, PL and Labelling attached.

Greek and/or English translation of the SPC, PL and Labelling attached *(where the approved in the RMS is in a different language*).

Is the product authorized in CY via exceptional MA (art.126a of the Directive 2001/83/EC)?

Yes  No

If yes, please indicate the special MA Number……………….

It is confirmed that the product will be marketed in CY following approval of the MA.

It is confirmed that there will be no pending variations at the time of submission.

It is confirmed that the product is not affected by the market exclusivity of any orphan medicinal product at the time of submission.

We kindly ask the Drugs Council to confirm the receipt of this documentation and its agreement in following the Administrative zero Days MRP procedure (initial wave) for the above-mentioned product.

Signature of the applicant

Date:

*(Form PhS. 167)*