|  |  |  |
| --- | --- | --- |
| 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 a Repeat Mutual Recognition Procedure (rMRP): Zero days rMRP**

We, *[Applicant name]*, intend to submit a zero days repeat-use procedure for *[Name of the Product]* with Cyprus as a/ the only (choose as appropriate) CMS. *[Name of the Product]* is authorized via MRP/DCP *[choose as appropriate*] with *[Name of the Country]* as RMS.

|  |  |
| --- | --- |
| Name of the medicinal product |  |
| Proposed name of the medicinal product in in Cyprus |  |
| Dosage Form |  |
| Strength |  |
| Active Ingredient |  |
| MRP / DC procedure number |  |
| Other CMS in the zero Days procedure (if applicable) |  |
| Proposed Legal Status in Cyprus |  |

**Statements regarding the application:**

Approved common SmPC attached.

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 Zero Days rMRP procedure for the above mentioned product.

Signature of the applicant

*(Form Ph. S. 164)*