<Date>

<Company Reference>

To: <The address of the preferred Lead-RMS/Foreseen decision maker>

**Subject: Letter of intent (LoI) for the submission of a VNRA supergrouping**

**Supergrouping Applicant details:**

|  |  |  |
| --- | --- | --- |
| **Name** |  |  |
|  |  |  |
| **Address** |  |  |
|  |  |  |
| **Contact person details** (i.e. name, address, email address, phone number). |  |  |

**Application details**

This letter of intent (LoI) for the submission of a VNRA supergrouping concerns the following medicinal products:

1. ***List of marketing authorisations concerned:***

***MR/DC authorised products:***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product (trade name)** | **Active substance** | **Member State** | **MA holder name** | **MRP/DCP no.[[1]](#footnote-1) & MA number** |
|  |  |  |  |  |
|  |  |  |  |  |

***Nationally authorised products :***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product (trade name)** | **Active substance** | **Member State** | **MA holder name** | **MA number** |
|  |  |  |  |  |
|  |  |  |  |  |

1. ***Description of the changes***

The following variation(s) are intended to be part of the supergrouping:

|  |  |
| --- | --- |
| **Number as in the Implementing Regulation (EU) 2021/17** | **Title of variation as in the Implementing Regulation (EU) 2021/17** |
|  |  |
|  |  |

<See attachment>\*

(\* If the lists are very long they can be submitted as separate attachments to the Letter of intent)

1. ***Preferred Reference Authority***
2. ***Intended submission date***

<Signature>

1. Please provide both the MRP/DCP number and the national authorisation to aid identification [↑](#footnote-ref-1)