Template for post-authorisation commitments in MRP/DCP/SRP/VRA

The template letter regarding the agreed commitments is applicable for new applications as well as for variation applications requiring assessment and was prepared with the aim:

of clearly identifying commitments

to make the applicant/MAH aware of the harmonised form/mandatory points that should be included in the official letter

to avoid repeated explanations from national competent authorities (NCAs) to the applicant/MAH on what the commitment letter should include and/or to avoid the need for the applicant/MAH to repeat questions to NCAs

An official signed letter in a written format should be prepared and provided by the applicant/MAH to the RMS according to agreed commitments by the last day of the procedure and should include the following information:

product name/procedure number/the applicant details/NCA details

the applicant’s/MAH’s confirmation to fulfil requested commitments via the submission of the relevant data

the list of agreed commitments

the list of CMSs requesting each commitment

the deadlines/time limits for commitments fulfilment

|  |
| --- |
| **Commitment letter**  **MRP/DCP/SRP/VRA** |

<name of the applicant/MAH>

<address>

<contact person>

<telephone>

<email>

To whom it may concern

<Product name>

<Procedure number>

<RMS>

<CMS(s)>

The <marketing authorisation>/ variation requiring assessment > relating to the above product is subject to the following commitments.

The <applicant>/<marketing authorisation holder> <name> agrees to the following commitments resulting from the above procedure and confirms that the commitments will be fulfilled by taking the required action as identified in the table below within the specified deadline.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **The list of agreed commitments** | | | | |
| **No.** | **Commitment identification** | **Action required to fulfil the commitment \*** | **Deadline** | **Requested by**  **Member State** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*\*(e.g.variation submission, study submission, supplementary data submission)*

The <applicant>/<marketing authorisation holder> confirms that if they are unable to fulfil the commitment or to provide the necessary data within the specifed deadline, they will consult with the RMS.

<signature>

<name (print)>

<job title>

<date and place>