**Concerned Member State Comments**

**on Day 120 Draft Assessment Report**

**to be sent at Day 145 at the latest**

### 1. This document is sent by:

|  |  |
| --- | --- |
| CMS |  |
| Contact point, project team leader (name) phone e-mail | 🕿 |
| Assessors, if applicable (name e-mail, phone) |  |
| Date/Day of procedure |  |

### 2. This document concerns:

|  |  |
| --- | --- |
| Procedure number |  |
| Name of the medicinal product in the RMS |  |
| Name of the active substance |  |
| Applicant |  |
| Deadline for comments |  |

### 3. Comments, general

3.1 Assessment of the RMS

We endorse the RMS assessment, but also have additional comments

We do not fully endorse the RMS assessment, and have other comments

3.2 Conclusions on the product

Our conclusion is that the product is:

Approvable, provided that satisfactory responses are given to the list of outstanding issues and/or the SmPC/PL/labelling is changed according to the comments

Non-approvable

3.3. List of Outstanding Issues/Proposed conditions for marketing authorisation

We have grounds of potential serious risks to public health on the following part of the assessment report not already raised by the RMS as major objections

Quality

Non-Clinical

Clinical

Risk Management Plan

SmPC

PL

Labelling

We have additional other concerns on the following part of the assessment report

Quality

Non-Clinical

Clinical

Risk Management Plan

SmPC

PL

Labelling

Module 1 – Application related comments (including product name)

### 4. Potential serious risk to public health

**Quality**

|  |
| --- |
| Potential serious risk to public health not already raised by the RMS as major objection |
| Rationale |

**Non-clinical**

|  |
| --- |
| Potential serious risk to public health not already raised by the RMS as major objection |
| Rationale |

**Clinical**

|  |
| --- |
| Potential serious risk to public health not already raised by the RMS as major objection |
| Rationale |

**Risk management plan**

|  |
| --- |
| Potential serious risk to public health not already raised by the RMS as major objection |
| Rationale |

**SmPC**

|  |
| --- |
| Potential serious risk to public health not already raised by the RMS as major objection |
| Rationale |

**PL**

|  |
| --- |
| Potential serious risk to public health not already raised by the RMS as major objection |
| Rationale |

**Labelling**

|  |
| --- |
| Potential serious risk to public health not already raised by the RMS as major objection |
| Rationale |

### 5. Additional other concerns

**Quality**

|  |
| --- |
| Other concerns not already raised by the RMS |
| Rationale |

**Non-clinical**

|  |
| --- |
| Other concerns not already raised by the RMS |
| Rationale |

**Clinical**

|  |
| --- |
| Other concerns not already raised by the RMS |
| Rationale |

**Risk management plan**

|  |
| --- |
| Other concerns not already raised by the RMS |
| Rationale |

**SmPC**

|  |
| --- |
| Other concerns not already raised by the RMS |
| Rationale |

**PL**

|  |
| --- |
| Other concerns not already raised by the RMS |
| Rationale |

**Labelling**

|  |
| --- |
| Other concerns not already raised by the RMS |
| Rationale |

**Module I – Application related comments (including product name)[[1]](#footnote-1)**

|  |
| --- |
| Other concerns not already raised by the RMS |
| Rationale |

**6. Additional information for the Applicant**

Additional information on the submission of response documents within the Member State should be included within this section. E.g. Institutional mailbox, etc.

1. Please note that for 10.1 applications with a centrally authorised product as reference product, the product name in RMS and all CMS must be the same. It is therefore important that comments on the product name are sent early in the procedure in order to reach agreement before day 210/90. [↑](#footnote-ref-1)