## Guidance on format of the risk management plan (RMP) in the EU part VII: Annexes

<table>
<thead>
<tr>
<th>Active substance</th>
<th></th>
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</thead>
<tbody>
<tr>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Product(s) concerned (brand name(s)):</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MAH/Applicant name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

Data lock point for this module <Enter a date>

Version number of RMP when this module was last updated <Enter a version no>

This guidance should be used in conjunction with the information in Good Pharmacovigilance Practices: Risk Management Systems.
Table of contents

Annex 1 – EudraVigilance Interface ............................................................................... 3
Annex 2 - SmPC & Package Leaflet ............................................................................... 4
Annex 3 - Worldwide marketing authorisation by country (including EEA) ....................... 5
A3.1 Licensing status in the EEA .................................................................................. 5
A3.2 Licensing status in the rest of the world .................................................................. 5
Annex 4 - Synopsis of on-going and completed clinical trial programme ....................... 6
Annex 5 - Synopsis of on-going and completed pharmacoepidemiological study programme 7
Annex 6 - Protocols for proposed and on-going studies in categories 1-3 of the section
“Summary table of additional pharmacovigilance activities” in RMP Part III .................. 8
Annex 7 - Specific adverse event follow-up forms ....................................................... 9
Annex 8 - Protocols for proposed and on-going studies in RMP Part IV ......................... 10
Annex 9 - Newly available study reports for RMP Parts III & IV .................................. 11
Annex 10 - Details of proposed additional risk minimisation measures (if applicable) ..... 12
Annex 11 - Mock-up of proposed additional risk minimisation measures (if applicable) .. 13
Annex 12 - Other supporting data (including referenced material) ............................... 14
Annex 1 – EudraVigilance Interface

Available in electronic format only
Annex 2 - SmPC & Package Leaflet

Current (or proposed if product is not authorised) EU (centralised/mutual recognition/decentralised/national) summary of product characteristics (SmPC) and package leaflet(s) for each product in the RMP.

If multiple versions are included for a product, they should show in which Member State(s) they are applicable. In addition, if available, a core SmPC should be provided with an overview of the changes applicable to the SmPC in each Member State.
Annex 3 - Worldwide marketing authorisation by country (including EEA)

For each product in the RMP provide:

### A3.1 Licensing status in the EEA

<table>
<thead>
<tr>
<th>Country</th>
<th>Current licence status</th>
<th>Date of licence action ¹</th>
<th>Date first marketed in country</th>
<th>Brand name(s)</th>
<th>Comments</th>
</tr>
</thead>
</table>
|         | Choose one of the following:  
|         | • Approved  
|         | • Refused  
|         | • Under review  
|         | • Suspended  
|         | • Expired  
|         | • Withdrawn  
|         | <Enter a date>  
|         | <Enter a date>  
|         | If product has different routes of authorisation e.g. national + MRP in the EEA, note here which one applies |

¹ Enter the date of the most recent change to the licence status: eg date of approval or date of suspension

### A3.2 Licensing status in the rest of the world

<table>
<thead>
<tr>
<th>Country</th>
<th>Current licence status</th>
<th>Date of licence action ¹</th>
<th>Date first marketed in country</th>
<th>Brand name(s)</th>
<th>Comments</th>
</tr>
</thead>
</table>
|         | Choose one of the following:  
|         | • Approved  
|         | • Refused  
|         | • Under review  
|         | • Suspended  
|         | • Expired  
|         | • Withdrawn  
|         | <Enter a date>  
|         | <Enter a date>  

Guidance on format of the risk management plan (RMP) in the EU part VII: Annexes  
EMA/716217/2012
Annex 4 - Synopsis of on-going and completed clinical trial programme

<table>
<thead>
<tr>
<th>Study</th>
<th>Description (Phase, short description of study (1 – 2 sentences including comparator name(s)/placebo))</th>
<th>Countries</th>
<th>Study design</th>
<th>Planned/actual number of patients</th>
<th>Duration of follow up</th>
<th>Estimated/Actual completion date</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;E.g. Study ABC&gt;</td>
<td>&lt;E.g. Study versus ibuprofen in adults with mild postoperative pain Phase III&gt;</td>
<td>&lt;E.g. Germany, USA, Chile&gt;</td>
<td>&lt;E.g. Randomised double-blind&gt;</td>
<td>&lt;E.g. 4075&gt;</td>
<td>&lt;E.g. 14 days&gt;</td>
<td>&lt;E.g. Jan 2005&gt;</td>
</tr>
</tbody>
</table>

Further safety/efficacy studies

Studies in special populations (e.g. paediatric, elderly)
**Annex 5 - Synopsis of on-going and completed pharmacoepidemiological study programme**

<table>
<thead>
<tr>
<th>Study</th>
<th>Research question</th>
<th>Study design</th>
<th>Population &amp; study size</th>
<th>Duration of follow up</th>
<th>Milestones &amp; dates</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

Choose one of the following:
- Planned
- Protocol under development
- Protocol agreed
- Data collection started
- Data collection ended
- Study completed
### Annex 6 - Protocols for proposed and on-going studies in categories 1-3 of the section “Summary table of additional pharmacovigilance activities” in RMP part III

Overview of included protocols

<table>
<thead>
<tr>
<th>Study title</th>
<th>Protocol status ¹</th>
<th>Version of protocol</th>
<th>Date of protocol version</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Choose one of the following:</td>
<td></td>
<td>&lt;Enter a date&gt;</td>
</tr>
<tr>
<td></td>
<td>• Draft</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Approved</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Final</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹Draft = not approved or final
Approved = when agreed by PRAC or CHMP as appropriate
Final = final version when PRAC/CHMP agreement not required
Annex 7 - Specific adverse event follow-up forms

Provide forms
## Annex 8 - Protocols for proposed and on-going studies in RMP part IV

<table>
<thead>
<tr>
<th>Study title</th>
<th>Protocol status $^1$</th>
<th>Version of protocol</th>
<th>Date of protocol version</th>
</tr>
</thead>
</table>
|             | Choose one of the following:  
• Draft  
• Approved  
• Final |                       | <Enter a date> |

$^1$Draft = not approved or final  
Approved = when agreed by CHMP  
Final = final version when CHMP agreement not required
Annex 9 - Newly available study reports for RMP parts III & IV

Include the study abstract. For non-interventional studies use the abstract format detailed in Module: VIII Post Authorisation Safety Studies of Good Pharmacovigilance Safety Studies
Annex 10 - Details of proposed additional risk minimisation measures (if applicable)
Annex 11 - Mock-up of proposed additional risk minimisation measures (if applicable)

Mock up examples in English (or the National language if the product is only authorised in a single Member State) of the material provided to healthcare professionals and patients as a requirement of Annex II of the Commission Decision or as a requirement of national authorisations including those using the mutual recognition or decentralised procedure as applicable.
Annex 12 - Other supporting data (including referenced material)

Index of included material