<insert date DD Month 20YY>

< insert Doc ref ID> Corr[[1]](#footnote-1)

Pharmacovigilance Risk Assessment Committee (PRAC)

Signal assessment report on <adverse event/reaction> with <INN(s)>[[2]](#footnote-2)

EPITT no:<xxx>
Procedure no: <SDA xxx>[[3]](#footnote-3)

General guidance

Send this report to list-h-pharmacovigilance@eudra.org using as e-mail message subject the following format: Signal AR on <adverse event/reaction> with INN(s)2 - EPITT <number> - SDA <number>3. Copy the EMA signal management team (H-SD@ema.europa.eu).

All validated signals (confirmed or not) should continue to be entered into the European Pharmacovigilance Issues Tracking Tool (EPITT). This AR should only be used for confirmed signals. Signals concerning safety topics that are being addressed within another ongoing parallel procedure, e.g. PSURs or variation, should in principle not be confirmed; this should be investigated before a decision on confirmation is made. For non-confirmed signals, a justification should be provided in EPITT.

This template should be used throughout all stages from signal confirmation until adoption of PRAC recommendation(s). It will therefore be completed by different stakeholders, as specified below:

- Timetable and administrative information: whoever drafts the AR as relevant information becomes available.

- Background and initial evidence: whoever confirms the signal

- Additional evidence: PRAC Rapporteur appointed for the signal

- Adopted PRAC recommendation(s): EMA

If the PRAC recommends that the signal follow-up is to be handled within another procedure such as periodic safety update report (PSUR), referral, etc., the relevant template for these procedures should be used at that point.

In case data have been requested from a marketing authorisation holder (MAH), the assessment report will be shared with them after appropriate redaction by the EMA.

|  |  |
| --- | --- |
| Confirmation assessment report | DD Month YYYY |
| Adoption of <first> PRAC recommendation | DD Month YYYY |
| <Preliminary assessment report on additional data>[[4]](#footnote-4) | <DD Month YYYY> |
| <Deadline for comments>4 | <DD Month YYYY> |
| <Updated rapporteur assessment report>4 | <DD Month YYYY> |
| <Adoption of <second> PRAC recommendation>4 | <DD Month YYYY> |

### Administrative information

|  |  |
| --- | --- |
| **Active substance(s) (invented name)**2 | <Text> |
| **Strength(s)** | <Text> *[Only if relevant to the signal]* |
| **Pharmaceutical form(s)** | <Text> *[Only if relevant to the signal]* |
| **Route(s) of administration** | <Text> *[Only if relevant to the signal]* |
| **Indication(s)** | <Text> *[Only if relevant to the signal]* |
| **Marketing authorisation holder(s)** | <Name(s)> |
| **Authorisation procedure** *[Tick the appropriate box(es) below.]* |
| [ ]  | Centralised |
| [ ]  | Mutual recognition or decentralised |
| [ ]  | National |

|  |  |
| --- | --- |
| **Adverse event/reaction:[[5]](#footnote-5)** |  |

|  |  |
| --- | --- |
| **Signal validated by:** | <Member State>/<EMA> |
| **Date of circulation of signal validation report:** | DD Month YYYY |
| **Signal confirmed by:** | <Member State>/<EMA> |
| **Date of confirmation:** | DD Month YYYY |
| **PRAC Rapporteur appointed for the assessment of the signal:** | <PRAC member's name (Member State)><E-mail address> |
| **Assessor(s):** | <Name><E-mail address> |
| **Rapporteur’s contact person:** | <Name><E-mail address> |
| **EMA signal management team member:** | <Name><E-mail address> |

**Declarations**

[ ]  The assessor confirms that this assessment does not include any commercially confidential information (e.g. ASMF, reference to on-going assessments or development plans etc), non-public information shared by other competent authorities or organisations, irrespective from which entity was received\*, or reference to pharmacovigilance inspections.

*\*If the entity from which commercial confidential information and/or non-public information originates has consented to its further disclosure, the box should be ticked and there would be no need to add details below.*

Whenever the above box is un-ticked please indicate the section and page where the confidential information is located here:

*Confidential information:*

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1. Background

<Text here.>

[This section should be copied from EPITT by whoever confirms the signal.]

1. Initial evidence
	1. Signal validation

<Text here.>

[This section should be completed at the time of confirmation by whoever confirms the signal. The signal validation section from EPITT should be copied into this section. Case narratives may be included here in full, summarised (e.g. in a table) or provided in an Annex, as appropriate.]

* 1. Signal confirmation

<Text here.>

[This section should be completed by whoever confirms the signal. It should provide a critical discussion of the strengths and limitations of the available evidence supporting the signal validation. Any additional information available at the time of confirmation and not considered during validation may be presented.]

* 1. Proposed recommendation

<Text here.>

[This section should be completed by whoever confirms the signal. It should include details of the proposed actions, e.g. request for supplementary information, changes to the summary of product characteristics (SmPC) and/or package leaflet (PL), additional communication (e.g. direct healthcare professional communication -DHPC), etc. A brief rationale should be included. Timelines for e.g. submission and assessment of additional data, submission of variation, etc., should be specified. If changes to the SmPC and/or PL are proposed, please provide the exact wording (new text underlined, text to be removed ~~struck-through~~).]

* 1. Adopted PRAC recommendation

<Text here.>

*[This section should be completed by the EMA signal management team member. The exact text of the adopted PRAC recommendation should be included.]*

1. Additional evidence

[This section only applies when the PRAC recommends gathering additional evidence after initial discussion on the signal for assessment within the signal procedure. The following sub sections may be repeated if there is more than one round of assessment. If the PRAC recommends that the signal follow-up is to be handled within another procedure such as periodic safety update report (PSUR), referral, etc., the relevant template for these procedures should be used at that point.]

* 1. Assessment of additional data

<Text here.>

[This section should be completed by the PRAC Rapporteur appointed for the assessment of the signal. It should provide an appraisal of all the evidence gathered e.g. MAH responses, results of non-urgent information (NUI), additional analyses carried out by regulators or other stakeholders (e.g. studies in The Health Improvement Network - THIN, Clinical Practice Research Datalink – CPRD - or EudraVigilance).]

* 1. Rapporteur’s proposed recommendation

<Text here.>

[This section should be completed by the PRAC Rapporteur appointed for the assessment of the signal. It should specify whether further actions are warranted and the rationale behind them. Details of any proposed actions, e.g. (follow-on) request for supplementary information, changes to the SmPC and/or PL, additional communication (e.g. DHPC), etc., should be presented. Timelines for e.g. submission and assessment of additional data, submission of variation, etc., should be specified. If changes to the SmPC and/or PL are proposed, please provide the exact wording (new text underlined, text to be removed ~~struck-through~~).]

* 1. Comments from other PRAC members and MAH(s)

<Text here (if applicable).>

*[This section should discuss comments received. If no comment was received, please write “No comment received”.]*

* 1. Updated rapporteur's proposed recommendation

<Text here (if applicable).>

*[This section should provide an updated proposed recommendation, following comments received from PRAC members and MAH(s), when applicable, including rationale, details of proposed actions and timelines.]*

* 1. Adopted PRAC recommendation

<Text here.>

*[This section should be completed by the EMA signal management team member. The exact text of the adopted PRAC recommendation should be included.]*

1. References

<Text here.>

[A consistent style for references and citations should be used throughout the report. When referencing electronic publications, the date on which the publication was accessed should be shown after the web address. The Agency's standard style for citing (in the body of the report) and referencing (the full source in a list) is illustrated below:

*The effect of magnesium in myocardial infarctions has been reviewed (Woods, 1991 [1]). Ten years later, a number of recommendations were made to prevent the injection of vinca alkaloids by the intrathecal route (Woods, 2001 [2]).*

*1. Woods, K.L., 'Possible pharmacological actions of magnesium in acute myocardial infarction', Br J Clin Pharmac, 32, 1991, pp. 3–10.*

*2. Woods, K, 'The prevention of intrathecal medication errors: a report to the Chief Medical Officer', London, Department of Health, 2001 [cited 11 May 2009]. Available from:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\_4065044 [Accessed 11 May 2009].*

Specific referencing software may be used, if available.]

### <Annex>

1. Paragraph 2 of the general guidance provided on page 1 was amended on 20 October 2022. [↑](#footnote-ref-1)
2. In case there are several products authorised for the same active substance and the signal applies only to a specific product, please add the product name in brackets. For product classes, please only state the class and list the relevant active substances in the administrative information table. [↑](#footnote-ref-2)
3. An SDA number will only be available for CAPs, after the PRAC has requested the submission of additional data from an MAH. It needs to be updated in case of further requests for additional data. [↑](#footnote-ref-3)
4. Please delete or repeat as applicable [↑](#footnote-ref-4)
5. Please use MedDRA terminology whenever possible [↑](#footnote-ref-5)