**1. SIGNAL NOTIFICATION/FOLLOW UP (FU) - General Guidance**

This form should be used to **notify signals and Follow-Up information on signals** according to *Guideline No.: SAHPGL-CEM-PV-04*.

*Please note that this form is not applicable for the submission of any documentation related to signals with a SAHPRA-assigned signal ID.*

**Once completed, please submit the form to SAHPRA’s Pharmacovigilance Unit at** **pvsubmissions@sahpra.org.za****.**

All applicable sections must be completed with the requested information, or a justification must be provided. **Sections should not be left blank.**

**2. DETAILS OF THE SIGNAL**

**Date of notification:**

**Initial notification** [ ]  **Follow-Up notification** [ ]

**If Follow-Up notification, please provide the following information:**

|  |  |
| --- | --- |
| **Date of initial notification** |  |
| **FU number** (e.g., 1, 2, etc.) |  |
| **Active substance** **\_** **Brand name (therapeutic class) \_ Adverse reaction (MedDRA term)** |  |

**3. DETAILS OF HOLDER OF CERTIFICATE OF REGISTRATION (HCR)/APPLICANT**

|  |  |
| --- | --- |
| **Company Name:** |  |
| **Address:** |  |
| **PV Officer** |  |
| **Email/Tel** |  |

**4. MEDICINE INFORMATION**

|  |  |
| --- | --- |
| **Trade name (s) of concerned products** | **Registration numbers** |
| 4.1  |  |
| 4.2  |  |
| 4.3  |  |
| **Active substance(s)** |  |
|  |  |
|  |  |

**5. SIGNAL DESCRIPTION**

# Please indicate the “Day 0:

# Definition of day 0:

Signals/procedures of foreign authorities (European Medicines Agency (EMA), United States-Food & Drug Authority (US-FDA), Medicines & Healthcare products Regulatory Agency (MHRA), Swissmedic, Canada, Therapeutic Goods Administration (TGA), Pharmaceutical & Medical Device Agency (PMDA), Health Sciences Authority (HAS), and Medsafe):

Day 0 = HCR informed of the procedure status of the foreign authority's signal evaluation/referral procedure (information provided by the evaluating authority to the HCR/applicant or, if this does not apply, publication of the information by the respective authority).

Risk minimisation measures ordered by foreign authorities in connection with PSUR/PBRER/PSUSA procedures:

Day 0 = day on which the HCR/applicant was informed about the necessary measures by the evaluating authority.

|  |
| --- |
| **5.1 MedDRA term** |
|  |

|  |  |
| --- | --- |
| **5.1.1 Emerging safety issue** | [ ]  Yes [ ]  No |

|  |  |
| --- | --- |
| **5.1.2 Signal or referral procedure of foreign authority***(If yes, please specify the authority)* | [ ]  Yes [ ]  No |
|  |

|  |  |
| --- | --- |
| **5.1.3 Risk minimisation measures imposed by foreign authorities following PSUR / PRBER evaluation (incl. PSUSA procedures)***(If yes, please specify the authority)* | [ ]  Yes [ ]  No |
|  |

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| --- |
| **5.2 Short description of the safety issue***(Concise summary of available evidence and information on the safety issue)* |
|  |

|  |
| --- |
| **5.3 Planned risk minimisation measures by evaluating authority** *(including timeline)* |
|   |
| * **If the evaluation is ongoing, please indicate the anticipated timeline for the next FU information submission to SAHPRA:**
 |

|  |
| --- |
| **5.4 Planned risk minimisation measures for South Africa** *(including timeline)* |
|  |

|  |  |  |
| --- | --- | --- |
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| * **If applicable:**

**Wording of the variation** *(Please provide the text proposal in English language)*  |
|  |

**Rationale** *(If discrepancies between planned risk minimisation measures in other countries and South Africa)* |

|  |
| --- |
| **5.5 Annexes***(e.g., source documents, assessment reports, study reports, list of literature references, links to open-source references)* |
|  |  |
|  |  |
|  |  |
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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **6.** **SIGNATURE**

|  |
| --- |
| **All the entries made in this form are certified to be complete and accurate.** |

***Authorised******signatory***

|  |  |
| --- | --- |
| **Date/Signature:** |  |
| **Name:** |  |
| **Position:** |  |
| **Telephone (contact person):** |  |
| **E-mail (contact person):** |  |

|  |  |
| --- | --- |
| **The signal notification form must be submitted via email to:** | **For enquiries contact** |
| pvsubmissions@sahpra.org.za  | E-mail: pvsubmissions@sahpra.org.za  |

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**Formal requirements**

The requirements can be found on SAHPRA’s website [www.sahpra.org.za](http://www.sahpra.org.za)