**Application Form for Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report (PBRER) and any Safety updates**

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| **Application Form for** Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report (PBRER) and any Safety updates. application form* Within 70 calendar days of the data lock point (day 0)\*\* for PSURs covering intervals up to 12 months (including intervals of exactly 12 months); and

within 90 calendar days of the data lock point (day 0) for PSURs covering intervals in excess of 12 months |
| **1** | **Application field** |  |
|  | Submission date |  |
|  | Agent Name |  |
| **2** | **General information** Only for the registered products  |
|  | Manufacture  |  |
|  | Trade/Brand Name. |  |
|  | Generic Name |  |
|  | Dosage form |  |
| **3** | **Local Safety responsible Person (LSRP)**  |
|  | Name |  |
|  | Contact no. |  |
|  | Email |  |
| **4** | **PSUR and PBRER Details** |
|  | PSUR and PBRER title page |  |
|  | PSUR and PBRER executive summary |  |
|  | Action taken | Checkbox:[ ] Update SPC[ ] Update PIL[ ] Update core datasheet[ ] Recall[ ] Other, specify ……………….. |
|  | Identified risk | [ ] Potential[ ] Not potential |
| **5** | **Department comment** | **[ ] Approved****[ ] Not approved****[ ] Others ……………..** |