**Notification of the EU Qualified Person for Pharmacovigilance (EU QPPV) and the contact person for pharmacovigilance at national level (or local person for pharmacovigilance/LPPV)**

Please complete the form and return it by e-mail to: **pharmacovigilance@ms.etat.lu**

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| **New notification / notification of change** |
| [ ] [ ]  | Notification of the EU QPPV Change of EU QPPV |
| [ ] [ ]  | Notification of the LPPV Change of LPPV  |
| [ ]  | Change related to the PSMF |

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| --- | --- | --- | --- |
|  | **MAH**  | **LPPV\*** | **EU QPPV** |
| Name |  |  |  |
| Effective start date  |  |  |  |
| Address (Street, n°, postal code and city) |  |  |  |
| Phone number (24h availability) |  |  |  |
| E-mail  |  |  |  |
| PSMF Number  |  |
| PSMF Location |  |
| Additional comments  |  |

***(MAH Company name and address)*** declares the above-mentioned local contact person for pharmacovigilance according to national legislation, Grand-Ducal Regulation of 10 September 2012 amending the Grand-Ducal Regulation of 15 December 1992 relating to the marketing of medicinal products, Article 45.-3.

**\*The local contact person should meet the following requirements:**

* He/she reports to the European qualified person responsible for pharmacovigilance (EU-QPPV).
* He/she should reside and carry out his/her activities in the European Union.
* He/she should be reachable 24 hours a day, 7 days a week.
* He/she should have documented experience in all aspects of pharmacovigilance in order to fulfil the responsibilities and tasks of the position.
* He/she should have the appropriate knowledge of languages to communicate at national level with different stakeholders: English and/or one of the official national languages (French, German, Luxembourgish) is strongly recommended.

Place Click or tap here to enter text. date Click or tap to enter a date.