Questions & Answers:

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)

LPPV: Local Person responsible for PharmacoVigilance

EU QPPV: EU Qualified Person responisible for PharmacoVigilance

1. How to notify the qualified person responsible for pharmacovigilance activities (EU QPPV) and the contact person (LPPV) in Luxembourg?

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 marketing authorisation holder shall notify to the Directorate of Health and the Agency the name and contact details of the qualified person, as well as the reference person for pharmacovigilance at national level attached to the qualified person responsible for pharmacovigilance activities.

The notification form is available on the following Webpage: https://santesecu.public.lu/fr/espace-professionnel/domaines/pharmacies-et-medicaments/pharmacovigilance/info-amm-detenteurs.html

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

2. What are the requirements for the contact person (LPPV) in Luxembourg?

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.

3. When shall LPPV nomination be submitted to the authorities?

The nomination of a pharmacovigilance contact person at national level (LPPV) is mandatory at the moment of authorisation (MA granting), including products registered via the CP procedure where Luxembourg is automatically included.

4. Shall the MA holder declare a contact person (LPPV) if the medicinal product(s) is (are) not marketed in Luxembourg?

The pharmacovigilance requirements apply to each valid marketing authorisation, for marketed or not marketed medicinal product in Luxembourg. Each MA holder in Luxembourg shall have a local pharmacovigilance contact person and notify this person in accordance with the procedure described in question 1.

5. Is the LPPV still required when the products are withdrawn from the Luxembourg market or can the LPPV be withdrawn at that point?

The LPPV is mandatory as long as the marketing authorisation is valid.

6. Shall the local contact person (LPPV) be available 24h/7d? What does this condition mean in practice?

The local contact person should be reachable 24 hours a day, 7 days a week to the authorities, health professionals and the public.

In practice, this often involves the use of call forwarding, a call center or an answering machine. These systems are acceptable provided that the local contact person (or back-up) can be reached directly by these means. The automatic answering machine shall therefore be checked regularly outside office hours, and this shall be documented.

7. Is it necessary to appoint a deputy LPPV?

The appointment of a deputy LPPV is not mandatory. However, the MA holder shall have a suitably qualified person responsible for pharmacovigilance permanently and continuously at his disposal.

If the MA holder so wishes, he may appoint a deputy LPPV in addition to the LPPV, using the notification form available on the sante.lu website: https://santesecu.public.lu/fr/espace-professionnel/domaines/pharmacies-et-medicaments/pharmacovigilance/info-amm-detenteurs.html

8. Is it necessary to notify the withdrawal of the LPPV?

Any change or withdrawal of the contact person (LPPV) shall be notified as soon as possible.

This can also be done using the form and following the procedure described in question 1.

9. Is it possible to submit a single LPPV notification form where different MA holders belong to the same parent company and use the same pharmacovigilance system?

Each marketing authorisation holder shall submit a LPPV notification form, regardless of whether they use the same pharmacovigilance system or belong to the same parent company.

10. As part of a procedure to change the QPPV, shall the notification form be updated and returned? Is it sufficient to update the database in accordance with Article 57(2) of Regulation 726/2004/EU?

Updating the notification form is not mandatory when it only concerns the EU-QPPV but is strongly recommended. We would also ask you to inform us of any changes to the Article 57 database as soon as possible by e-mail (pharmacovigilance@ms.etat.lu).

11. If the MA holder has more than one PSMF, can another local contact person (LPPV) be designated for each PSMF?

If there are several PSMFs for the same MA holder, a different local contact person may be designated for each PSMF. It is also possible for the same person to act as contact person (LPPV) for different PSMFs, provided that this person is able to carry out his tasks/exercise his responsibilities correctly.

12. Is it possible to have a different contact person (LPPV) for each distributor acting for the same MA holder?

No, if the medicines at the various distributors are covered by the same PSMF, a single local contact person must be designated. There is always one local contact person for each PSMF.