Q&A – ROYAL DECREE OF 28 MAY 2013 AND CIRCULAR LETTER N° 601

1. ***What procedure should be followed to notify someone as a local contact person at the famhp and what requirements does the contact person need to meet?***

   The function of the local contact person was introduced in the Royal Decree of 28 May 2013, which was published in the Monitor (Belgian official journal) on the 10th of June 2013. This function replaces the function of the local QPPV.
   The approval number (the « P number ») is no longer valid and should no longer be applied for. Nor do you need to submit a file for approbation or have a doctor's / pharmacist's / vet's diploma.
   The local contact person must however meet the following requirements:

   - He/she must be contactable 24 hours a day, 7 days a week ;
   - He/she must carry out activities in pharmacovigilance in Belgium ;
   - He/she must have adequate qualifications to carry out his/her activities in pharmacovigilance, particularly the necessary language skills to talk to partners in the national language of their choice and to communicate with the qualified person responsible for pharmacovigilance.

   In circular n° 601 it is asked to designate a local contact person by means of the declaration form (Annex I) and also to indicate in a table (Annex II), amongst other information, the details of the local contact person.

   To be compliant with the new legislation, every marketing authorisation holder or registration holder must appoint a local contact person meeting the above-mentioned conditions; by means of sending the declaration form and the completed table, annex I and II respectively of circular n° 601, to the famhp.

2. ***What happens to my request for a P number if it is outstanding?***

   The rules concerning P numbers are no longer valid. Outstanding dossiers for the application of a P number will no longer be handled.

3. ***Does the European QPPV have to be notified in Belgium and registered on the minister's list (have a P number)?***

   The European QPPV only has to be notified. An approval number is no longer required.

   In circular n° 601 you are also asked to indicate in a table (Annex II), amongst other things, the details of the European QPPV.

4. ***Does the local contact person has to be available, 24 hours a day, 7 days a week? What does this mean in practice?***

   Availability 24 hours a day means that the local contact person can be reached 24 hours a day by the authorities, health care professionals and the public.
   In practice, people sometimes use call transfers, a call centre or an answering machine. These practices can be acceptable if the local contact person (or the person that replaces him at that moment) can be contacted straight away via the call transfer, the call centre or the answering machine. The answering machine must be checked regularly outside office hours and this should be described in procedures.

5. ***Does the local contact person has to work and live in Belgium?***

   The Royal Decree of 28th May 2013 stipulates that the local contact person must carry out his pharmacovigilance activities in Belgium. This means that the person must have a professional address in Belgium and a related telephone number. He/she does not have to live in Belgium.

6. ***Is it still necessary to appoint a local contact person if the European QPPV carries out his activities in Belgium?***

   Yes, a local contact person has to be appointed and communicated to the famhp at any time. If the European QPPV also meets the requirements of the local contact person, the same person can have both responsibilities.

7. Who can replace the local contact person?

Anyone designated by the marketing authorisation holder or registration holder who is sufficiently qualified for this can replace the local contact person. The back-up system must be described in the procedures.
This person does not necessarily has to work in Belgium, but during an inspection the back-up system will be tested to see if it is satisfactory and if the availability for the authorities and the public is maintained and if the assigned responsibilities are covered.

8. What is meant by "the necessary language skills to talk to partners in the national language of their choice and to communicate with the qualified person responsible for pharmacovigilance."?

The local contact person should master at least one national language to communicate with the authorities. At all times he must also be able to receive, handle, answer and follow up reports from Belgian citizens and health care professionals at least in the three national languages (French, Dutch and German). If the local contact person himself cannot fulfil this requirement then there must be a defined system to be able to receive, handle, answer and follow up reports in the three national languages.
The local contact person must be able to communicate with the QPPV.

9. What is meant by "must have the adequate qualifications to carry out his/her activities in pharmacovigilance" as written in the Royal Decree?

The marketing authorisation holder or registration holder is responsible for verifying if the local contact person is sufficiently competent to carry out his work and tasks. There is no particular requirement in terms of diplomas etc.

10. Which sub-contracted activities have to be notified within the framework of circular 601?

Sub-contracted activities that have to be notified within the framework of circular 601, annex II, only include the local responsibilities or activities in Belgium that are sub-contracted.

11. ***Should the different marketing authorisation holders or registration holders, belonging to the same parent company and making use of the same pharmacovigilance system both submit annexe I and annexe II of circular 601?***

    Each marketing authorisation holder or registration holder in Belgium should submit annex I and annex II of circular 601 to the famhp, irrespective whether they use the same pharmacovigilance system or belong to the same parent company.

12. ***Is the local contact person legally responsible for the compliancy of the pharmacovigilance system in Belgium?***

    The local contact person is responsible for the pharmacovigilance tasks assigned by the marketing authorisation holder or registration holder. From a legal point of view, it is the responsibility of the marketing authorisation holder or registration holder to have a pharmacovigilance system in Belgium that meets the Belgian and European regulations. He has to take the necessary measures for this. The local contact person is thus not legally responsible for meeting the regulations of the pharmacovigilance system.

13. ***Does a veterinary surgeonneed to be available 24 hours a day?***

    The local contact person who is 24 hours a day available is not obliged to have medical qualifications. But that person needs to have access to a veterinary surgeon, also outside office hours, if he/she has no such qualifications himself. That can be done at a local or European level. The marketing authorisation holder is responsible for setting up such a system.

14. ***Should the back-up for the local contact person be notified to the famhp?***

    The back-up for the local contact person does not need to be notified to the famhp.
    However, the marketing authorisation holder is required to have a back-up system for the function, tasks and responsibilities of the local contact person and ensure his availability 24 hours a day. The marketing authorisation holder or registration holder is free to decide how he meets these obligations and ensure availability. This should be described in procedures and be controlled at regular intervals.

15. Is it necessary to appoint a local contact person if the MAH has authorised medicines in Belgium solely by the central procedure (= CAP)?

Every marketing authorisation holder or registration holder marketing veterinary medicinal products in Belgium, by whatever procedure, must have a local contact person for pharmacovigilance.

16. Does a marketing authorisation holder or registration holder, with only one or more MA or registrations in Belgium, without marketing the medicines, also have to meet the pharmacovigilance regulations?

The requirements for pharmacovigilance matters are valid for every marketing authorisation holder or registration holder in Belgium, whether the medicines are marketed in Belgium or not. Every marketing authorisation holder or registration holder in Belgium must have a local contact person for pharmacovigilance and notify that person to the famhp and have a pharmacovigilance system that meets the relevant Belgian and European regulations.