Q&A – ROYAL DECREE OF 28TH MAY 2013 AND CIRCULAR N° 600

1. ***What procedure should be followed to notify someone as a local contact person for 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 28th May, which was published in the Monitor (Belgian official journal) on the 10th of June 2013. This function replaces the function of 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   The approval number (the « P number ») is no longer valid and should no longer be applied for.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° 600 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) the details of the local contact person and the pharmacovigilance system.

   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° 600, 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   The rules concerning P numbers are no longer valid.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° 600 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 new Royal Decree of 28th May 2013 stipulates that the local contact person must carry out his activities in pharmacovigilance in Belgium. That 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?***

It is the marketing authorisation holder or registration holder, who is responsible for verifying that 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 600?***

Sub-contracted activities that have to be notified within the framework of circular 600, annex II, only include the local responsibilities or activities in Belgium that are sub-contracted.

11. ***Which address should be given for the electronic database within the framework of circular 600?***

    Regarding the electronic database you have to indicate an address in the EEA at which there is full access to the database. This can be different from the place where the data is entered or processed or from the place where the data is stored. The location of the server is not asked in annex II of circular 600.

12. ***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 600?***

    Each marketing authorisation holder or registration holder in Belgium should submit annex I and annex II of circular 600 to the famhp, irrespective whether they use the same pharmacovigilance system or belong to the same parent company.

13. ***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.

14. ***Does a medically qualified person need 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 medically qualified person, 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.

15. 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.
But 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.

16. 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 who markets his medicines in Belgium, by whatever procedure, must have a local contact person for pharmacovigilance.

17. 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.

18. If the marketing authorisation holder or registration holder has more than one PSMF can another local contact person be designated for each PSMF?

GVP Module II gives more explanations about appointing several European QPPV's if the same marketing authorisation or registration holder has several Master Files.
Regarding the appointment of the local contact person in Belgium the rule is as follows: one local contact person per PSMF. If the same marketing authorisation or registration holder has several PSMF's another local contact person can be appointed for each PSMF. It is also possible for the same person to act as local contact person for different PSMF's as long as this person can carry out his tasks and fulfil his responsibilities in a correct manner.

19. ***If medicines, covered by the same master file (PSMF) of a marketing authorisation holder or registration holder, are sold by different distributors in Belgium, can one local contact person be appointed per distributor?***

No, if medicines sold by different distributors are related to the same master file (PSMF) only one local contact person can be appointed. The rule is that there is always one local contact person per PSMF.

20. ***If a marketing authorisation holder or registration holder has several PSMF's, must they be shown separately in the table in annex 2 of circular 600?***

If the holder of a MA or a registration has more than one PSMF and maybe also more than one QPPV and local contact person, it is asked to indicate all the persons and locations of the different PSMF's in one table. If there are several PSMF's at the same location please indicate the numbers and the references in brackets. You don't have to submit individual tables per Master File.