Inspectie voor de Gezondheidszorg
Ministerie van Volksgezondheid, Welzijn en Sport

Questions & Answers Risk-Based Pharmacovigilance Questionnaire

1. Who is a PSMF owner?

In our questionnaire, the PSMF owner is defined as follows: “A PSMF owner is the marketing authorisation holder (MAH) who is responsible for the pharmacovigilance activities for the products covered by the pharmacovigilance system. This can be the MAH where the QPPV works, the headquarters or an affiliate in the Netherlands. This should be a MAH who is able to complete all sections of the questionnaire. In most cases this is the MAH conducting the majority of the PV tasks for Dutch marketing authorizations.”

2. Should I fill in the complete questionnaire or only a section of it?

The questions or sections of this questionnaire are allocated to your organisation depending on whether you are the ‘PSMF owner’ or not. If one of the following situations apply for your organisation, please complete the questionnaire as follows:

A. **The PSMF is located in the Netherlands and there are no other MAHs sharing the same PV system.**
   All sections of the questionnaire should be completed by the PSMF owner.

B. The PSMF is located in the Netherlands and there are multiple MAHs sharing the same PV system. My organisation is conducting the majority of the PV tasks for Dutch marketing authorisations (this also includes CAPs or MRPs). I am able to complete all sections of the questionnaire.
   All sections of the questionnaire should be completed by the PSMF owner.
   Names of all MAHs that fall under this pharmacovigilance system should be provided including the username of the questionnaire. The username is the FV code which is provided by IGZ to all MAHs.

C. **The PSMF is located in the Netherlands and there are multiple MAHs sharing the same PV system. My organisation is only involved in data collection and is NOT conducting the majority of the PV tasks for Dutch marketing authorisations. I am not able to complete all sections of the questionnaire.**
   You are requested to complete the questionnaire, but not all sections/questions will be applicable for you. Further instructions will be provided in the questionnaire. Please note that it is important to provide the name of the MAH (PSMF owner), PSMF number (MFL) and username (FV code) of the PSMF owner, the MAH who completes all sections of the questionnaire . This way we will be able to link your organisation to the answers that will be provided by the PSMF owner.

D. **The PSMF is not located in the Netherlands, but my organisation is conducting the majority of the PV tasks for Dutch marketing authorisations. I am able to complete all sections of the questionnaire (in collaboration with HQ).**
   All sections of the questionnaire should be completed by the PSMF owner.
   Names of all MAHs that fall under this pharmacovigilance system should be provided including the username of the questionnaire. The username is the FV code which is provided by IGZ to all MAHs. .

E. **The PSMF is not located in the Netherlands and my organisation is not conducting the majority of the PV tasks for Dutch marketing authorisations. I am not able to complete all sections of the questionnaire.**
The questionnaire with all sections should be completed on your behalf by the PSMF owner, the MAH who is able to complete the questionnaire. If this is not possible, then you should collect the necessary information from the PSMF owner and fill it in yourself.

F. **I am a service provider conducting PV tasks for several MAHs. The PV system for all these MAHs is the same but they have different PSMF (MFL) numbers. Can I complete only one questionnaire (with all sections) for all MAHs?**
No, the questionnaire should be completed per pharmacovigilance system/ PSMF number. The questionnaire should be completed for each MAH separately.

G. **My product portfolio is covered by two (or more) pharmacovigilance systems (PSMF numbers). How should I complete the questionnaire?**
The questionnaire should be completed for each pharmacovigilance system separately. You cannot use the same login codes to complete the questionnaire for the other systems as the login codes are linked to the name of the MAH. Please contact us via meldpunt@igj.nl and we will send you the login codes for the other PV systems.

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3. As a marketing authorization holder (MAH) for products authorized for the Dutch market, we have more than one pharmacovigilance system. How many questionnaires should we fill in?

You should fill in a separate questionnaire for each pharmacovigilance system. You can fill in one questionnaire per login code. Have you not received separate login codes for each system? Please contact us via meldpunt@igj.nl.

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4. Several MAHs use the same pharmacovigilance system. Should I fill in a questionnaire for each MAH?

You should fill in one questionnaire (which includes all 14 sections) for each pharmacovigilance system. When multiple MAHs are using the same pharmacovigilance system, then the questionnaire should still be completed by each MAH separately, but a shorter version of the questionnaire will be available. It is up to the MAHs (falling under the same system) to decide which MAH will complete all 14 sections of the questionnaire (indicated as the 'PSMF owner') and which MAHs will only complete the shorter version of the questionnaire. You are able to indicate this in the questionnaire, once you are logged in, by using the login details that were provided to you. Please ensure that at least one questionnaire with all 14 sections is completed per pharmacovigilance system.

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5. We lost the login codes for the questionnaire. What should we do?

Please contact us via meldpunt@igj.nl.

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6. We received a letter to fill in the questionnaire, but we are not a MAH anymore. What should we do?

You received a letter, because you are a MAH according to the Article 57 database. When this is not correct, please send us a letter, which states that you are no longer a MAH and change this in

the Article 57 database. Please contact us via meldpunt@igj.nl.

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7. We are a local affiliate in the Netherlands with headquarter outside the Netherlands, in Europe. Which address information should we fill in?

You should fill in the address of the Dutch affiliate. If other affiliates in Europe have products on the Dutch market and the same pharmacovigilance system, you should indicate this in the questionnaire. If they have a separate pharmacovigilance system, they should fill in a separate questionnaire.

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8. How should I determine the number of products?

Each registration number (RVG) and EU number counts as one product.

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9. We received a letter to fill in the questionnaire, but the link in the letter does not connect to a working web page. What should we do?

Please contact us via meldpunt@igj.nl.

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10. What is the deadline to complete in the questionnaire?

The deadline is indicated in the letter that you have received.

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11. I have a question. Can I contact you via phone?

Since we have to look up the information of the MAH in our system, we are not always able to help you efficiently during a call. It is better to contact us per email at meldpunt@igj.nl. You could provide us your phone number in the email, and then we will call you when necessary.

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12. I cannot go to the next page of the questionnaire. What should I do?

Please contact us via meldpunt@igj.nl.

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13. We cannot open the questionnaire. What should we do?

You could try to open the questionnaire in another web browser or to remove cookies and the browser history. If this does not work, please contact us via meldpunt@igj.nl.

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14. I cannot enter the questionnaire again. What should I do?

One of the possible reason that you are not able to enter the questionnaire again is because you have closed the 'questionnaire window' without logging out. Please make sure to log out if you close the questionnaire.

Contact us via .

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15. We are a parallel import company. Should we complete the questionnaire?

If you only market products in the Netherlands that are authorised via the parallel registration procedure, you can fill this out in the questionnaire. You are still requested to login and indicate this in de questionnaire, but you are not required to complete the whole questionnaire.

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16. As a MAH, we have products authorized for the Dutch market, but we did not receive a letter. Should we complete the questionnaire?

Every MAH with products authorized for the Dutch market should fill in the questionnaire. We have used information from the Article 57 database. If your organisation has not received a letter with login codes, please correct the information in the Article 57 database. Please contact us via meldpunt@igj.nl to ask for the login codes.

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17. We received a reminder letter to complete the questionnaire. However, we already completed this. What should we do?

It is possible that the letter was sent before we received the notification that you have completed the questionnaire. Please contact us via meldpunt@igj.nl.

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18. We have received two or more letters with login codes. Can we complete only one questionnaire?

If your organisation has products which are covered by multiple pharmacovigilance systems, then you should complete one questionnaire per pharmacovigilance system.

If your organisation has products which are covered by one pharmacovigilane system, then only one questionnaire should be completed. Please contact us via .

It is also possible that you have received two or more letters at the same address. Letters are sent out to every marketing authorisation holder with products for the Dutch market. If your organisation is located at the same address as other organisations, then each marketing authorisation holder should complete the questionnaire.

We have used the information (name organisation and address) from the Article 57 database to make the list with addresses and login codes. If the information is not correct, please correct this in the Article 57 database and contact us via meldpunt@igj.nl .

19. We have participated in the first or second pilot and completed the questionnaire. Should we still complete the questionnaire?

If you have participated in the pilot then you do not have to complete the questionnaire. Please contact us via .

However, if only one of the organisations within the pharmacovigilance system has completed the questionnaire during the pilot, the other MAHs within the same pharmacovigilance system are still required to complete the questionnaire.

20. Questions 7.3.1 and 7.3.2 about post authorisation safety studies is not clear to us. Should we provide the number of non interventional post-authorisation studies or the number of post authorisation safety studies (PASS)?

We understand that this question may be confusing. This will be corrected in the next version of the questionnaire. We ask you to provide the number of post authorisation safety studies (PASS) for question 7.3.1 and 7.3.2 (excl. PAES and other PAS).

21. Question 14.2 about the last pharmacovigilance inspection is not clear to us. We were recently inspected, but the inspection report has not been finalised yet. Should we provide date of the last inspection that was conducted or the last inspection that was conducted and finalised?

In question 14.3 and 14.4 we ask about the findings and CAPAs. Therefore, it is important that the inspection reports has been finalised (findings confirmed and CAPA proposed). Please provide the information of the last inspection that was conducted which has been finalised.

Is your question not mentioned above? Please contact us via meldpunt@igj.nl