Health and Youth Care Inspectorate
Ministry of Health, Welfare and Sport

Template for Risk-Assessment Questionnaire Pharmacovigilance

Frequently Asked Questions

This template is to help marketing authorization holders during the collection of information from different departments or contractors, if necessary. The final questionnaire should be completed and submitted via *My IGJ* using the personalized URL link that you received by email or letter.

Section 1. Introduction

The questionnaire has 10 sections with questions related to the following topics:

1. Introduction
2. Contact details European Qualified Person for Pharmacovigilance (EU-QPPV)
3. Pharmacovigilance (PV) system and general information about the marketing authorization holders (MAHs)
4. Information about the marketing authorizations (MAs)
5. EU Qualified Person for Pharmacovigilance (EU-QPPV) turnover and changes to the pharmacovigilance (PV) system
6. Compliance with expedited reporting, submissions of periodic safety update reports (PSURs) and safety variations
7. Outsourcing pharmacovigilance activities
8. Quality management system
9. Previous pharmacovigilance inspections
10. Conclusion

Key notes to take into account:

1. Please complete one questionnaire per pharmacovigilance system, i.e. per MFL number. If more than one MAH falls under the pharmacovigilance system master file (PSMF), the information of all concerned MAHs should be completed in this questionnaire. The questions in this questionnaire apply to all Dutch MAs that are covered by the concerned pharmacovigilance system, unless stated otherwise. Dutch MAs are authorizations which enable you to place a medicinal product on the Dutch market.
2. The information of other MAHs (that are part of the same pharmacovigilance system) that should be provided only concerns the general information (name and contact details) and information about the MAs. The questionnaire should only be filled out once per pharmacovigilance system. It is the responsibility of the EU-QPPV to make sure that the information of all MAHs that are covered by the pharmacovigilance system is correct.
3. If your organization has more than one pharmacovigilance system (MFL code for PSMF), then this questionnaire should still be completed separately for all systems. You will receive login details for the other systems separately. If you have not received these yet, please contact farmacovigilantierisicomodel@igj.nl
4. If your organization has Dutch MAs, but does not have offices located in the Netherlands, then the questionnaire should still be completed.
5. If your organization is not currently marketing (selling) any of the medicinal products in the Netherlands, but still holds the MA, the questionnaire should still be completed.
6. If you do not complete the questionnaire, then the highest score will be allocated to your organization.
7. In case of questions please click the button **Frequently Asked Questions (FAQ)** in the right corner of each page on *My IGJ*. In case the answer to your question is not included, please send an email to farmacovigilantierisicomodel@igj.nl.

Section 2. Contact details EU-QPPV

Contact details European Qualified Person for Pharmacovigilance

Please check and complete all parts of this section. If some parts (such as address or postal code) are not correct or outdated, please provide the correct/updated information.

Questionnaires should be completed per pharmacovigilance (PV) system / per pharmacovigilance system master file (PSMF) EudraVigilance (EV) code. If the EU-QPPV is responsible for more than one PV system, then the EU-QPPV should complete a questionnaire per PV system and provide the PSMF EV code in this section.

EU-QPPV last name*

EU-QPPV first name*

EU-QPPV email address*

EU-QPPV postal address*

EU-QPPV telephone*

EU-QPPV fax

EU-QPPV mobile number*

PSMF EV Code (MFL number) *

PSMF location* Select an option...

Fields with are mandatory*

Section 3. PV System & General info MAHs

Pharmacovigilance (PV) System

If more than one PV system is used to cover the marketing authorizations (in the Netherlands), that are held by the same marketing authorization holder (MAH), please complete one questionnaire per PV system. This should be done by the EU-QPPV who is responsible for the concerning PV system.

General information about the marketing authorization holders

This section should be completed for each MAH (with marketing authorizations in the Netherlands) covered by the same pharmacovigilance (PV) system. The dropdown menu includes the MAHs which according to our information are covered by the same PV system.

*Please select the applicable MAHs and update/complete the auto populated information (if needed) for each applicable MAH. In case one or more MAHs (with marketing authorizations in the Netherlands) are not included in the drop-down menu, please add them by clicking the button "**+ add MAH**" at the bottom of this page.*

MAH 1

Select a MAH — Select an option...

Information regarding MAHs in the list can be added in the fields below

more information

MAH EV Code (ORG number as registered in Eudravigilance)*

Name*

Address*

Postal code*

Town/City*

Country*

Did you change one or more of the fields above? * Yes No

Email address for correspondence*

Dutch Chamber of Commerce number (KVK)

+ add MAH

Fields with are mandatory*

Section 4. Information MAs

Information about the marketing authorizations (MAs)

Are any of the following statements applicable to **all MAHs** in the pharmacovigilance system?

- ○ Yes
- ○ No

1. There are **no products** on the market (i.e. for sale, in supply) in the Netherlands, and/or
2. All the MAs are obtained through parallel import procedure, and/or
3. All the MAs are obtained through the simplified registration procedure under Article 14(1) of Directive 2001/83/EC for homeopathic medicinal products.

Answer = Yes - *You have reached the end of the questionnaire.*

Answer = No - *This section should be completed for each marketing authorization holder (MAH) that is covered by the current pharmacovigilance (PV) system (i.e. each MAH included in the previous question should answer the questions below).*

MAH 1

To which MAH do the following answers refer to? * Select an option...

How many MAs do you have in the Netherlands? *

More information

A Dutch MA is an authorization that enables a marketing authorization holder to place the medicinal product on the Dutch market (this should not be limited to products that are authorized via the national procedure only but should also include centralized MAs and MAs that are authorized through mutual recognition or decentralized procedure). The number of MAs should be counted based on the registration numbers (e.g. RVG).

How many of the MAs are for homeopathic or traditional herbal products which are not obtained via the simplified registration procedure (Article 14(1) of Directive 2001/83/ EC)? *

How many of the MAs were obtained through a centrally authorized procedure (CAP)? *

How many of the MAs are for biological, biosimilar or vaccine products? *

How many of the MAs are subject to additional monitoring (inverted black triangle)? *

How many of the MAs have additional (non-routine) pharmacovigilance activities? *

How many of the MAs have additional risk minimisation measures? *

To answer these questions for the remaining MAHs click the ***+add MAH*** *button.*

+ add MAH

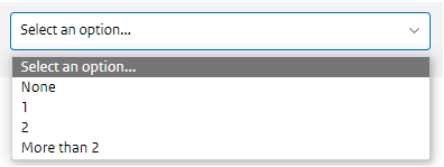
Fields with * *are mandatory*

Section 5. EU-QPPV turnover & Changes to PV system

EU Qualified Person for Pharmacovigilance (EU-QPPV) turnover

This section refers to the EU-QPPV turnover within a three-year period from 1 January 2020 to 31 December 2022. If there was one QPPV before the start of this period, and this person has changed once since this time, enter 2.

How many different QPPVs have you had between 1 January 2020 and 31 December 2022? *

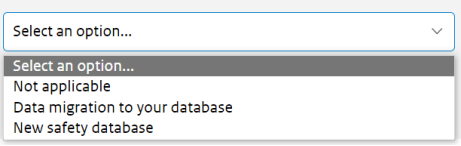


Changes to the pharmacovigilance (PV) system

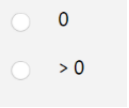
These questions relate to the changes in the PV system with regards to:

- *Changes in the location where pharmacovigilance activities are performed.*
- *Changes in the safety database. The question about the safety database applies to the safety database that is used to collect or enter data for case processing, such as Argus, ARISg etc.*
- *The increase of numbers of marketing authorizations (MAs) as a result of change of ownership. Please provide the number of MAs that you have acquired in the given period. This applies to all Dutch MAs that are covered by this pharmacovigilance system (this can be centrally authorized products, nationally authorized products or products authorized through the mutual recognition procedure or decentralized procedure).*
- *Changes in the service providers conducting PV (related) activities.*

Which of the following changes apply to the global safety database, for the period 1 January 2020- 31 December 2022 (irrespective of acquisition)? *



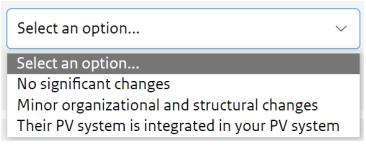
How many MAs have you acquired by change of ownership between 1 January 2020 and 31 December 2022? *



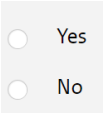
If answer is >0: the following questions are populated

Please specify the number of acquired MAs: *

What were the changes to the pharmacovigilance system as a result of this acquisition? *



Did you change or add Service providers for at least one of the following activities? *



- *Case Processing*
- *Expedited Reporting*
- *Signal Management*
- *PSUR writing*
- *Risk Management System*
- *European Qualified Person for Pharmacovigilance*

Fields with are mandatory*

Section 6. Compliance

Compliance with expedited reporting, submission of periodic safety update reports (PSURs) and safety variations

This section applies to all Dutch marketing authorizations that are covered by this pharmacovigilance system.

Expedited reporting

To EudraVigilance post-authorization module (EVPM)

Compliance figures for spontaneous and solicited post-marketing reporting should refer to both initial and follow-up reports including literature reports and non-interventional study cases (i.e. everything that is not from an interventional clinical study). If no Individual Case Safety Reports (ICSRs) (initial and follow up) were reported to EudraVigilance enter 0 (zero) for number of reports.

How many ICSRs originating in the Netherlands were reported to EVPM between 1 January 2020 and 31 December 2022 (excluding interventional clinical trial cases)? *

How many of these reports were submitted to EVPM on time? *

How many ICSRs originating outside the EU were reported to EVPM between 1 January 2020 and 31 December 2022 (excluding interventional clinical trial cases)? *

How many of these reports were submitted to EVPM on time?*

To EudraVigilance clinical trial module (EVCTM)

Clinical trial reporting should refer to both initial and follow-up reports arising from post-authorization interventional studies. If no ICSRs (initial and follow-up) were reported to EudraVigilance enter 0 (zero) for number of reports.

How many interventional clinical trial ICSRs originating in the Netherlands were reported to EVCTM between 1 January 2020 and 31 December 2022? *

How many of these reports were submitted to EVCTM on time? *

Fields with are mandatory*

PSUR submission

If no PSURs were submitted to the PSUR repository, please enter 0 (zero) reports as number submitted and 0 (zero) for submitted on time. Timeliness for PSUR submission should be calculated from data lock point (DLP) to submission date.

How many PSURs (concerning Dutch marketing authorizations) were submitted between 1 January 2020 and 31 December 2022? *

How many (number) of these PSURs were submitted on time? *

Submission of safety variations to the Medicines Evaluation Board (MEB) or European Medicines Agency (EMA)

This question relates to safety variations ***that amend Dutch labeling*** *e.g. summary of product characteristics (SmPC) and patient information leaflets (PILs) and were submitted to the MEB or EMA. If no safety variations for products authorized in the Netherlands via centralized procedure (CAP), national procedure (NAP), mutual recognition or decentralized procedure (MRP/DCP) were submitted to the MEB or EMA, please enter 0 (zero) reports as number submitted and 0 (zero) for submitted on time.*

Timelines for submission of safety variations should be calculated from the submission due date (either internal or competent authority). This does not include pending safety variations during the given period (which were submitted prior to the given period).

How many safety variations were submitted to the MEB or EMA between 1 January 2020 and 31 December 2022? *

How many (number) of these safety variations were submitted on time? *

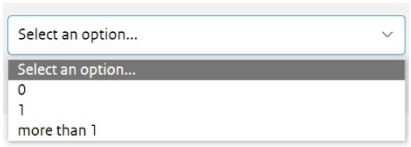
Fields with * *are mandatory*

Section 7. Outsourcing PV

Outsourcing pharmacovigilance activities

These questions cover the outsourcing of pharmacovigilance activities, both on a global level as well as on a local (e.g. Dutch) level. An activity is considered outsourced if all or any components of the activity are performed by a third party. This does not include activities delegated to other affiliates or the headquarters where the same pharmacovigilance system is used.

Please indicate to how many different service providers pharmacovigilance activities are outsourced. *



If ≥ 1

Please indicate if the following activities have been outsourced or not. *

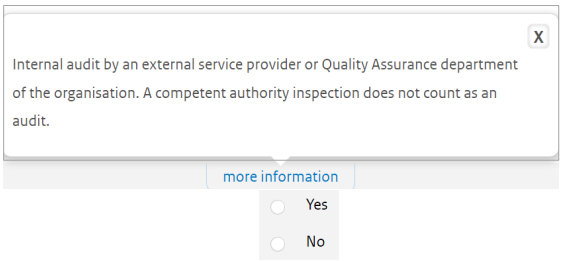
*European Qualified Person for Pharmacovigilance**	Yes / No
*National contact person in the Netherlands**	Yes / No
*Providing medical information**	Yes / No
*Quality complaints processing**	Yes / No
*Global literature searching**	Yes / No
*Local literature searching in the Netherlands**	Yes / No
*Case processing**	Yes / No
Electronic reporting	Yes / No
*PSUR production**	Yes / No
*Signal management**	Yes / No
*Variation submission**	Yes / No
*Database maintenance and support**	Yes / No
Risk Management System (production and maintenance of RMPs and implementation of aRMMs) *	Yes / No
Audits (internal, external) *	Yes / No
*PSMF preparation and maintenance**	Yes / No

Fields with are mandatory*

Section 8. Quality Management System

Quality Management System

Has the pharmacovigilance system been audited in the past 3 years? *



Have you conducted external audits (distributors, partners) in the past 5 years? *

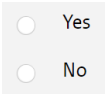
Fields with are mandatory*

Section 9. Previous inspections

Previous pharmacovigilance inspections

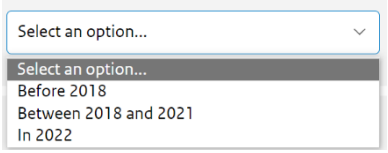
The following questions only refer to pharmacovigilance inspections conducted by competent authorities (no audits).

Has your pharmacovigilance system been inspected before by one of the member states within the EEA? *

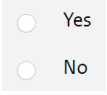


Answer = No – *You have reached the end of the questionnaire.*
Answer = Yes *– Following questions are populated:*

When was the last pharmacovigilance inspection? *

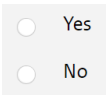


Has the inspection been closed? (CAPA approved, but not necessarily implemented)*



Answer = No – *You have reached the end of the questionnaire.*
Answer = Yes *– Following question is populated:*

Has the CAPA been successfully implemented? *



Fields with are mandatory*

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Section 10. Conclusion

You have reached the end of the questionnaire.

Before sending the completed questionnaire, you are requested to certify that the information provided in this questionnaire is true, complete and correct.

I hereby declare that the information provided in this questionnaire is true, complete and correct to the best of my knowledge. *

Location*

Date*

Name of the person completing this questionnaire*

Job title*

Email address*

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Fields with are mandatory*