

Questionnaire for risk-based PV inspections

Pharmacovigilance System Master File Location EV Code

The MFL number mentioned in the e-mail belongs to the PSMF used by the holder of the authorisations/approvals/registrations.

If the MFL number mentioned in the e-mail does not belong to a PSMF used in your company, but you know the user of the PSMF with the MFL number mentioned, we ask you to answer "No" and to send a message to pv-questionnaire@bfarm.de. In this e-mail please mention the MFL number and the contact data of the user.

1. Company name and address

Please list the names of all holders of authorisations/approvals/registrations in the EU/EEA integrated in the PV system.

Answers can be transferred by copy & paste from other files (e.g. Office programs, pdf files).

Please enter as address only the PSMF-Location.

Name(s) marketing authorisations holder(s) in the EU/EEA

Street and house number

Postcode

City / Country

Telephone number

E-mail address

e.g. the functional contact e-mail address given in Art.57 database

A valid format (xxx@xxx.xxx) is required.

2. Are you the holder...

a. of marketing authorisations for medicinal products and/or registrations of medicinal products, finished medicinal products within the meaning of the Medicinal Products Act (AMG), homeopathic medicinal products, anthroposophic medicinal products, herbal medicinal products and/or traditional medicinal products in the EU/EEA (in accordance with Section 77(1) AMG)?

b. of marketing authorisations for sera, vaccines, blood preparations, tissue preparations, tissue, allergens, advanced therapy medicinal products, xenogenic medicinal products and blood components manufactured using genetic engineering and/or an authorisation pursuant to Section 4b AMG in the EU/EEA (in accordance with Section 77(2) AMG)?

3. Stufenplanbeauftragter (commissioner for the graduated plan)

Has the "Stufenplanbeauftragte" (commissioner for the graduated plan) been notified to BfArM?

Has the "Stufenplanbeauftragte" (commissioner for the graduated plan) been notified to PEI?

When?

We kindly ask you to also electronically register the commissioner for the graduated plan if he has only been notified in writing:

- BfArM: please notify the commissioner for the graduated plan with contact details and 24-hour availability (for medicinal products in accordance with Section 77(1) AMG in DE) (see https://www.bfarm.de/DE/Service/Formulare/functions/Pharmakovigilanz/_node.html).
- PEI: please notify the commissioner for the graduated plan with contact details and 24-hour availability (for medicinal products according to § 77(2) AMG in DE) to Pharmakovigilanz1@pei.de

4. Pharmacovigilance System Master File (PSMF)

Please provide information on the maintenance of the Pharmacovigilance System Master File (PSMF) for medicinal products authorised in the EU/EEA.

If the PSMF has not yet been notified to the Art. 57 database, please register (see

<https://www.ema.europa.eu/en/human-regulatory/post-authorisation/data-medicines-iso-idmp-standards/reporting-requirements-marketing-authorisation-holders>)

a. Is / Are the EU-PSMF / PSM files registered in Art 57 database?

b. Is / Are the PSMF / the PSM files localised in DE?

c. Are more than 2 PSM files maintained in the EU/EEA?

5. Marketing authorisations / registrations

Please provide information on the number of marketing authorisations/registrations in the EU/EEA (according to current Annex H EU-PSMF) (products authorised via DCP/MRP, national authorised products and CAPs).

Different pack sizes of the same medicinal product count as one medicinal product

a. Total number of marketing authorisations in the EU/EEA, of which marketed	authorised /registered medicinal products according to § 77(1) AMG	marketed medicinal products according to § 77(1) AMG	authorised medicinal products according to § 77(2) AMG	marketed medicinal products according to § 77(2) AMG
b. Total number of purely national authorisations in the EU/EEA	authorised /registered medicinal products according to § 77(1) AMG	marketed medicinal products according to § 77(1) AMG	authorised medicinal products according to § 77(2) AMG	marketed medicinal products according to § 77(2) AMG
c. Total number of authorisations from MRP/DCP in the EU/EEA	authorised /registered medicinal products according to § 77(1) AMG	marketed medicinal products according to § 77(1) AMG	authorised medicinal products according to § 77(2) AMG	marketed medicinal products according to § 77(2) AMG
d. Total number of centrally authorised products in the EU/EEA	authorised /registered medicinal products according to § 77(1) AMG	marketed medicinal products according to § 77(1) AMG	authorised medicinal products according to § 77(2) AMG	marketed medicinal products according to § 77(2) AMG

e. In how many countries at most have centrally authorised products been marketed in the last calendar year?

Please identify the centralised marketing authorisation that is marketed in most EU/EEA countries. For this authorisation, please state the number of EU/EEA countries where it is marketed. For example, some of your centrally authorised products are only marketed in 3 EU/EEA countries, one product is marketed in 8 EU/EEA countries, then enter 8.

f. Total number of medicinal products with narrow therapeutic range in the EU/EEA (see https://www.g-ba.de/informationen/richtlinien/anlage/11/ the critical active substances and their pharmaceutical forms are listed in Part B of Annex VII).		authorised medicinal products	marketed medicinal products
g. Total number of biotechnologically/genetically engineered biologics in the EU/EEA (see Regulation (EC) No 726/2004)(does not include ATMPs)		authorised medicinal products	marketed medicinal products
h. Total number of biosimilars in the EU/EEA (according to § 24b para. 5 AMG)		authorised medicinal products	marketed medicinal products
i. Number of new approvals within the last 2 calendar years in the EU/EEA (according to Art. 8 Directive 2001/83/EC or according to Art. 10b Directive 2001/83/EC)		authorised medicinal products	marketed medicinal products

j. Total number of medicinal products within the parallel import system in the EU/EEA (see PEI/BfArM Notice on the obligation to give consent for the notification of an imported medicinal product from a new importing country in parallel import in accordance to §29 of the AMG of 13 July 2018)	authorised medicinal products	marketed medicinal products
k. Total number of standardised marketing authorisations "Standardzulassungen" in the EU/EEA (§ 67 para. 5 AMG)	authorised medicinal products according to § 77(1) AMG	marketed medicinal products according to § 77(1) AMG
l. Total number of generics in the EU/EEA (according to § 24b AMG) (excluding those generics that have already been counted under f - k)	authorised medicinal products according to § 77(1) AMG	marketed medicinal products according to § 77(1) AMG
m. Total number of homoeopathic remedies in the EU/EEA (according to §§ 38 and 39 AMG)	registered medicinal products	marketed medicinal products
thereof number of sterilized medicinal products	registered medicinal products	marketed medicinal products
n. Total number of traditional herbal medicinal products in the EU/EEA (gem. §§ 39a ff. AMG)	registered medicinal products	marketed medicinal products
o. Total number of authorisations pursuant to Section 4b AMG in the EU/EEA	authorised advanced therapy medicinal products	marketed advanced therapy medicinal products

6. Additional Monitoring

(See <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/medicines-under-additional-monitoring>)

How many of your medicinal products approved in the EU/EEA are subject to "additional monitoring"?

7. Additional risk minimisation measures

How many of your medicinal products authorised in the EU/EEA have additional risk minimisation measures addressed in the RMP (e.g. Educational material, imposed studies, excluding studies measuring RMM effectiveness)?

8. Supply-relevant active substances

Please indicate the number of your marketing authorisations for medicinal products in DE with active substances with supply relevance. (see <https://www.bfarm.de/DE/Arzneimittel/Arzneimittelzulassung/Arzneimittelinformationen/Lieferengpaesse/versorgungsrisiko.html>) incl. „Orphan Drugs“.

Please note: Due to the special nature of the products within the jurisdiction of the PEI (medicinal products according to § 77(2) AMG) and the national differences, this answer is only required for products within the jurisdiction of the BfArM (medicinal products according to § 77(1) AMG) and only for Germany, including CAPs marketed in Germany.

How many of your medicinal products authorised in Germany contain supply-relevant active ingredients?

Total number of medicinal products according to § 77(1) AMG

9. Contractual partners

Do you have PV-related contractual partners (s. Annex B PSMF)?

If yes,

- a. Number of license partners including distributors
- b. Number of PV service providers

10. Acquired marketing authorisations

Have marketing authorisations been acquired in the EU/EEA in the last two calendar years (s. PSMF Annex H)?

Acquired authorisations in the EU/ EEA?

11. Change of the QPPV or the Stufenplanbeauftragter (commissioner for the graduated plan)

Has there been a change in the EU-QPPV in the last two calendar years?

Has there been a change in the Stufenplanbeauftragter (commissioner of the graduated plan) in the last two calendar years?

12. Pharmacovigilance service provider

Please provide details of worldwide contracted pharmacovigilance service providers for the EU PV system (database providers are not to be indicated).

- a. Is a part of the pharmacovigilance activities carried out by a pharmacovigilance service provider?
- b. Have there been any GVP-relevant changes to contractual arrangements with pharmacovigilance service providers over the last two calendar years?
- c. Is the EU-QPPV or the Stufenplanbeauftragter (commissioner of the graduated plan) provided by an external service provider?
- d. Is case processing (incl. coding, assessment, data entry and reporting) carried out by an external service provider (select "yes" even if it is just partly or temporarily carried out externally)
- e. Is case processing performed by the same service provider (corporate group) to which the EU-QPPV belongs?
- f. Is the implementation of regulatory pharmacovigilance measures relevant in the EU/EEA carried out by an external service provider (e.g. modification of PIL and SmPC, creation of EduMat)?

13. Study types/ patient support programmes

Are the following study types/patient support programmes currently being conducted worldwide for drugs approved in the EU/EEA?

- a. PSP (Patient Support Programs)
- b. PASS (Post Authorisation Safety Studies)
- c. Clinical studies with medicines approved in the EU/EEA
- d. Observational studies

14. Number of full-time equivalents

Please indicate (estimate if necessary, decimal numbers are possible) the number of full-time equivalent employees in pharmacovigilance in reference to the EU PSMF (including resources at service providers/headquarter).

If the staff also carry out non-PV-relevant tasks (e.g. regulatory affairs), please calculate proportionately.

How many full-time equivalents are available in pharmacovigilance?

15. Case load and compliance

Please count each receipt of a potential adverse reaction to medicinal products authorised in the EU/EEA; follow-ups and initial reports are counted separately.

- a. How many case reports (excluding cases from interventional clinical trials) from the EU/EEA did you add to your database in the last calendar year?
- b. How many cases (excluding cases from interventional clinical trials) from non-EU countries did you add to your database in the last calendar year?
- c. How many case reports from interventional clinical trials did you add to your database in the last calendar year?
- d. How many SUSARs (Suspected Unexpected Serious Adverse Reactions) did you add to your database in the last calendar year?

Please count each adverse drug reaction report for medicinal products authorised in the EU; follow-ups and initial reports are counted separately.

Reports that had to be sent to the BfArM or PEI must also be recorded here.

- e. How many serious cases did you report to the EMA in the last calendar year?
- f. How many of them were reported in time?
- g. How many non-serious cases did you report to the EMA in the last calendar year?
- h. How many of them were reported in time?

16. PSURs, PSUSAs, PBRERs submission

- a. How many PSURs, PSUSAs and/or PBRERs did you submit in the last calendar year?
- b. How many of them were submitted in time?

17. Database change

Has a migration or consolidation of PV data (e.g. in the context of a database change or company takeover or otherwise agreed cooperation with third parties) been performed within the last two calendar years?

Database migration within the last two calendar years?

18. Risk minimisation measures

Please indicate for your medicinal products authorised in the EU: How many PV processes (e.g. risk procedures, signaling procedures) have led to safety variations or other risk-minimizing measures within the last two calendar years?

PSUSA procedures: the necessary modification of marketing authorisations based on the scientific PSUR assessment by the Pharmacovigilance Risk Assessment Committee (PRAC), (see https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/PSURs/psusa/_node.html)

- a. Signal procedures
- b. Referrals
- c. PSUSA procedures
- d. Emerging Safety Issues (or „urgent safety restrictions“)

19. PV audits

How many for the EU-PV-System relevant audits of global partners have been carried out in the last three calendar years?

- | | | |
|---|--------------|-----------------|
| a. Number of service providers/contractors, thereof audited in the last 3 calendar years | Total number | thereof audited |
| b. Number of affiliated companies/affiliates, thereof audited in the last 3 calendar years | Total number | thereof audited |
| c. Number of distribution partners and licence partners, thereof audited in the last 3 calendar years | Total number | thereof audited |
| d. Number of internal partners, thereof audited in the last 3 calendar years | Total number | thereof audited |

20. PV inspection by European authority

Has the PV-System or parts of it been PV-inspected by a European authority within the last four calendar years?