Position Paper

Inspection Risk-Based Questionnaires

Date: 2021-01-05

Version: 01

1. Executive summary

Medicine for Europe presents and proposes to national competent authorities to assess options for harmonisation within the EU for the risk-based inspection planning.

2. Abbreviations

Table 1 – Abbreviations.

ADR	Adverse Drug Reaction	JAZMP	Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (Slovenian Competent Authority)
AMG	Medicinal Products Act	MAH	Marketing Authorisation Holder
ANSM	Agence Nationale de Sécurité du Médicament et des produits de santé (French Competent Authority)	MEB	Medicines Evaluation Board (Dutch Competent Authority)
ATU	Temporary Authorisation for Use in France	MRP	Mutual Recognition Procedure
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte (German Competent Authority)	NP	National Procedure
CAP/CP	Centralised Procedure	PASS	Post-Authorization Safety Study
CAPA	Correction Actions and Preventive Actions	PBRER	Periodic Benefit-Risk Evaluation Report
DCP	Decentralised Procedure	PEI	Paul Erlich Institute
DE	Germany	PV	Pharmacovigilance
DHPC	Dear HealthCare Professional Communication	PRAC	Pharmacovigilance Risk Assessment Committee
DSUR	Development Safety Update Report	PSMF	Pharmacovigilance System Master File
EEA	European Economic Area	PSP	Patient Support Program
EMA	European Medicines Agency	PSUR	Periodic Safety Update Report
EU	European Union	PSUSA	PSUR single assessment
EU QPPV	Qualified Person responsible for PV in Europe	RMM	Risk Minimisation Measure
EVPM	EudraVigilance Post-Marketing module	RMP	Risk Management Plan
GCP	Good Clinical Practices	RPV	Reference person for PV for France
GDP	Good Distribution Practices	SI	Republic of Slovenia
GMP	Good Manufacturing Practices	SmPC	Summary of Product Characteristics
GVP	Good Vigilance Practices	SUSAR	Suspected Unexpected Serious Adverse Reaction
INSEVI	ANSM's Inspections des Essais et des Vigilances (INSEVI) department		

3. Scope

This position paper applies to risk assessment questionnaires issued by National Competent Authorities in Europe for the establishment of their risk-based programmes for pharmacovigilance inspection of Marketing Authorisation Holders (MAHs).

4. Background information and problem statement

GVP III states that each European Union (EU) member states need to perform routine inspections of MAHs scheduled according to a risk-based approach.

Legislation requires each MAH to produce and maintain a Pharmacovigilance System Master File (PSMF) to describe the pharmacovigilance system and support/document its compliance with the requirements.

Per GVP II.B.1. Objectives, *"The requirements for submission of a summary of the marketing authorisation holder's pharmacovigilance system, provision of the content of PSMF and the history of changes to the relevant authority(ies) should enable the appropriate co-ordination of inspections by the Agency,* ***and the planning and effective conduct of inspections by national competent authorities, based on a risk assessment approach****."*

It is observed that National Competent Authorities are currently using different approaches to establish their risk-based inspection programmes. Namely, three main methods are used:

- Use of internally available data only.
- Combination of internally available data and PSMF request to MAHs.
- Combination of internally available data and customised national risk-assessment questionnaire sent to MAHs.

In Appendix 1, the questions from the 2018 Slovenian, 2020 German, 2020 Dutch and 2020 French questionnaires have been listed to identify the items which are covered either by current PSMF content requirements, through the shared inspection data among EU inspectorates, Article 57 database, other national databases or nationally required documents (such as the "Update of the Pharmaceutical site", submitted yearly to ANSM in France).

Among the 140 questions from 4 countries presented in Appendix I, it is estimated that 111 responses (79% of the questions) can currently already be found either in the PSMF or the data that is readily available to national competent authorities.

Table 2 - Estimated proportion of questions covered by other sources as assessed from Appendix 1.

Questionnaire country	France	Germany	Netherlands	Slovenia	**Total**
Total number of questions	42	26	24	48	**140**
Number of answers available in any of the sources (such as PSMF, national authority data etc.)	37 (88%)	21 (80%)	21 (87%)	32 (67%)	**111 (79%)**
Number of answers available in PSMF	17 (40%)	14 (54%)	17 (71%)	24 (50%)	**72 (51%)**

It can be concluded that the EU PSMF is not used to its full potential and intended purposes.

5. Opportunities to regulators

Same approach to risk-based inspection planning across all Member States would ensure risk is managed in harmonised way across all Member States and inspection plans are built in comparable manner.

Streamline resources used for risk assessment and inspection planning.

6. Challenges to stakeholders

As the questionnaire content is not known in advance, the data may not be readily retrievable in the format specific to a particular questionnaire.

Compiling data may be resource-consuming and technically challenging. Outputs from computerised systems may not be set up to enable quick retrieval of data to allow easy calculation needed for a specific questionnaire. Source systems may not contain all of the data required, data may need to be pulled from multiple systems.

Despite the efforts made by national competent authorities and industry to formulate questions in a clear way, and provide explanations, different interpretations are still inevitable, depending on the company organisation. As a result, resources are spent from both regulator and MAH side to clarify ambiguities and may lead to the responses between companies still not being fully comparable.

The questions from different competent authorities are similar, but not the same, meaning that the data used for one questionnaire in most cases may not be used for others. Moreover, because there is no synchronisation regarding the data lock point dates for these assessments, even if the questions were the same, administering at different moments in time, would result in the need to regenerate the responses, but also in different periods of analysis that make the comparison and extrapolation more difficult.

7. Proposed solutions

1. At the time of risk assessment, national competent authorities should request PSMFs of all MAHs and use the data available for risk analysis.

In future updates of GVP module, the requirements for PSMF format and content may be re-assessed to better fit inspection planning needs, for example, to include a harmonised questionnaire for inspection planning purposes.

2. Develop a harmonised questionnaire for all countries within EU, which may still include local data, to be always requested in the same way.

3. Use the data already available at the competent authority or Article 57 database.

4. Request only those data which are not already available to the competent authority.

8. Annex 1 - Mapping of questions included in questionnaires from national competent authorities

The questions included in the four national risk-assessment questionnaires from Slovenia, Netherlands, Germany and France are listed below to identify the items which are covered either by current PSMF content requirements, through the shared inspection data among EU inspectorates or various other sources such as Article 57 database.

Table 3 - Mapping of questions included in questionnaires from national competent authorities.

Question	Where answer can be found in the current documentation
Slovenia	
Number of medicinal products for HUMAN use, for which you are responsible, authorized through CP	PSMF annex: list of products Article 57 database
Number of medicinal products for HUMAN use, for which you are responsible, authorized through MRP/DCP	PSMF annex: list of products Article 57 database
Number of medicinal products for HUMAN use, for which you are responsible, authorized through NP	PSMF annex: list of products Article 57 database
Number of medicinal products for VETERINARY use, for which you are responsible, authorized through CP	
Number of medicinal products for VETERINARY use, for which you are responsible, authorized through MRP/DCP	
Number of medicinal products for VETERINARY use, for which you are responsible, authorized through NP	
Number of medicinal products, for which you are responsible, with authorization in accordance with the third paragraph of Article 20 of the ZZdr-2	Data of the local competent authority
Number of medicinal products, for which you are responsible, with a parallel import licence	Data of the local competent authority
Number of medicinal products, for which you are responsible, with a parallel distribution certificate	Data of the local competent authority
Number of medicinal products, for which you are responsible, with authorization for compassionate use	
Number of critical and/or major findings identified in inspections (please consider all PhV, GCP, GMP and/or GDP inspections from 2015 until the date of completion of the questionnaire)	Sharing of inspection data among EU inspectorates
Number of medicinal products, for which you are responsible, with marketing authorizations conditions related to safety (e.g. request for PASS, request for additional monitoring of safety)	PSMF annex: list of products and additional risk minimisation measures

Question	Where answer can be found in the current documentation
How many medicinal products, for which you are responsible, have no parallels (alternatives) on the market of Republic of Slovenia?	Data of the local competent authority
Number of contractual partners who are performing certain pharmacovigilance activities on your behalf	PSMF annex: list of contractual agreements covering delegated activities
Number of subscribers for whom you perform certain pharmacovigilance activities as a contractual partner	
The number of medicinal products, for which you are responsible, and have the volume of sales in the SI 100,000 packs or more per year (a large number of exposed patients)	
We are a MA holder, which has acquired first MA in the year 2017 or later. (yes/no)	PSMF annex: list of products
We are representative/contractor of a MA holder, which has acquired first MA in the year 2017 or later. (yes/no)	PSMF annex: list of products
In the period from 2015 until the date of completion of the questionnaire, we increased the number of pharmacovigilance personnel. (yes/no)	
For at least one PhV system, for which we are responsible, the current EU QPPV is living in SI. (yes/no)	PSMF body: section on QPPV Article 57 database
For at least one PhV system, for which we are responsible, we provide a contact person for pharmacovigilance in SI, which is listed in the PSMF or communicated to the competent authority. (yes/no)	PSMF body/annexes: sources of safety data
In the years 2018-2020, there may be changes in the PhV system, changes in pharmacovigilance databases, changes in the ownership of a business entity, or the transfers of MA. (yes/no)	PSMF body/annexes
We have never had an inspection of the pharmacovigilance system by the pharmaceutical inspectors of JAZMP. (yes/no)	Data of the local inspectorate
Some pharmacovigilance activities are performed by our contractors. (yes/no)	PSMF annex: list of contractual agreements covering delegated activities
In the period from 2015 until the date of completion of the questionnaire, contractual arrangements with our contractors/subscribers of pharmacovigilance activities have been significantly changed at least once. (yes/no)	
In the period from 2015 until the date of completion of the questionnaire, the relevant pharmacovigilance databases were subject to change (in the database itself or related databases, in the status of validation, data transfer/migration). (yes/no)	
Safety variation cannot be implemented in less than 6 months. (yes/no)	PSMF annex: performance indicators regarding safety variations

Question	Where answer can be found in the current documentation
Only our employees who perform pharmacovigilance activities are trained in our company in the field of pharmacovigilance. (yes/no)	PSMF body: section on the quality system including training
We are MA holder who authorised another business entity for managing PSMF, which is not connected with us or with the manufacturer of the medicinal product. (yes/no)	PSMF annex: list of contractual agreements covering delegated activities Article 57 database – QPPV information
We do not have quality documents (working instructions) for the implementation of pharmacovigilance activities. (yes/no)	PSMF annex: list of processes
We are a contractual partner who provides the EU QPPV. (yes/no)	PSMF body: section on the organisational structure of the MAH Article 57 database – QPPV information
We are a contractual partner who is responsible for managing the PSMF. (yes/no)	PSMF body
We have contracts with wholesalers that do not include pharmacovigilance articles (no pharmacovigilance information exchange is required). (yes/no)	
Information about various PhV systems for which you are responsible: MAH, name and address of QPPV, contact person in SI, PSMF location	PSMF body/annex Article 57 database
How many reports from the spontaneous reporting system about suspected ADRs have you received/processed in the period from 2015 until the date of completion of the questionnaire?	EudraVigilance database National Competent authority ICSR database
How many reports about adverse events and suspected ADRs from clinical trials have you processed in the period from 2015 until the date of completion of the questionnaire?	EudraVigilance database National Competent authority ICSR database
How many PSUR/DSUR have you submitted in the period from 2015 until the date of completion of the questionnaire?	EMA PSUR repository Data of the local competent authority for DSURs
For how many medicinal products you have RMP?	Data of the local competent authority
For how many medicinal products you perform additional risk minimisation measures required by the regulatory authorities?	PSMF annex: list of products and risk minimisation measures Data of the local competent authority (they are approving these before implementation)
For how many medicinal products you perform additional risk minimisation measures on your own initiative?	PSMF annex: list of products and risk minimisation measures
For how many medicinal products you have prepared educational materials?	PSMF annex: list of products and risk minimisation measures Data of the local competent authority (they are approving these before implementation)
How many DHPC letters have you prepared in the period from 2015 until the date of completion of the questionnaire?	PSMF annex: list of products and risk minimisation measures Data of the local competent authority (they are approving these before dissemination)

Question	Where answer can be found in the current documentation
How many safety variations have you implemented in the period from 2015 until the date of completion of the questionnaire?	
How many PSP (Patient Support Programs) did you have in the period from 2015 until the date of completion of the questionnaire?	PSMF annex: sources of safety data
Germany	
1. Company name and address Please list the names of all MAHs in the EU/EEA integrated in the PV system.	PSMF body/annex
2.a. Are you the holder of MAs for medicinal products and/or registrations of medicinal products, finished medicinal products within the meaning of the Medicinal Products Act (AMG), homoeopathic medicinal products, anthroposophic medicinal products, herbal medicinal products and/or traditional medicinal products in the EU/EEA (in accordance with Section 77(1) AMG)?	Data of the local competent authority
2.b. Are you the holder of MAs 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)?	Data of the local competent authority
3. Has the “Stufenplanbeauftragte” (commissioner for the graduated plan) been notified to BfArM? Has the “Stufenplanbeauftragte” been notified to PEI? When?	Data of the local competent authority
4.a. Are the EU-PSMF / PSM files registered in Art 57 database?	Article 57 database
4.b. Is / Are the PSMF / the PSM files localised in DE?	PSMF body Article 57 database
4.c. Are more than 2 PSM files maintained in the EU/EEA?	
5. 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).	PSMF annex: list of products Article 57 database
6. How many of your medicinal products approved in the EU/EEA are subject to "additional monitoring"?	Publicly available list of additional monitoring products
7. 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)?	PSMF annex: list of products *(per GVP II.B.4.8. “The list should be organised per active substance and, where applicable, should indicate what type of product specific safety monitoring requirements exist”)*
8. Please indicate the number of your marketing Authorisations for medicinal products in DE with active substances with supply relevance incl. “Orphan Drugs”.	

Question	Where answer can be found in the current documentation
9.a. Do you have PV-related contractual partners (s. Annex B PSMF)? Number of license partners including distributors	PSMF annex: list of contractual agreements covering delegated activities
9.b. Do you have PV-related contractual partners (s. Annex B PSMF)? Number of PV service providers	PSMF annex: list of contractual agreements covering delegated activities
10. 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?	PSMF annex: list of products
11. 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?	PSMF body/annex Article 57 database
12. Please provide details of worldwide contracted pharmacovigilance service providers for the EU PV system (database providers are not to be indicated).	PSMF annex: list of contractual agreements covering delegated activities
13. 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	PSMF annex: sources of safety data
14. 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?	PSMF body: section on organisational structure or quality system
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?	PSMF annex: performance indicators

Question	Where answer can be found in the current documentation
Please count each adverse drug reaction report for medicinal products authorised in the EU; follow-ups How many serious cases did you report to the EMA in the last calendar year? How many of them were reported in time? How many non-serious cases did you report to the EMA in the last calendar year? How many of them were reported in time?	
16. How many PSURs, PSUSAs and/or PBRERs did you submit in the last calendar year? How many PSURs, PSUSAs and/or PBRERs did you submit in the last calendar year? How many of them were submitted in time?	PSMF annex: performance indicators
17. 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. 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?	
19. How many for the EU-PV-System relevant audits of global partners have been carried out in the last three calendar years?	PSMF annex: list of all completed audits, for a period of five years, and a list of audit schedules
20. Has the PV-System or parts of it been PV-inspected by a European authority within the last four calendar years?	Sharing of inspection data among EU inspectorates
The Netherlands	
1. Contact details European Qualified Person for Pharmacovigilance (EU-QPPV)	PSMF body: section on QPPV Article 57 database
2. MAHs covered by the PV system	PSMF body/annex
3. How many marketing authorisations do you have in the Netherlands?	PSMF annex: list of products Article 57 database
4.2 How many of the marketing authorisations (as specified in 4.1) are subject to additional monitoring (inverted black triangle)?	PSMF annex: list of products Publicly available list of products under additional monitoring
4.3 How many of the MAs (as specified in 4.1) are for biological, biosimilar or vaccine products?	PSMF annex: list of products
4.4 How many of the MAs (as specified in 4.1) are for homeopathic or traditional herbal products?	PSMF annex: list of products
4.5 How many of these MAs (as specified in 4.1) have been marketed on the Dutch market?	PSMF annex: list of products and risk minimisation measures
4.6 How many of these MAs (as specified in 4.1) have RMPs that contain a requirement for additional non-routine	PSMF annex: list of products and risk minimisation measures

Question	Where answer can be found in the current documentation
pharmacovigilance activities and/or additional risk minimisation measures?	
5. How many different QPPVs have you had between 1 January 2018 and 31 December 2019?	PSMF body Article 57 database
6.1. How many marketing authorisations have you acquired by change of ownership between 1 January 2018 and 31 December 2019?	Article 57 database
6.2 What were the changes to the pharmacovigilance system as a result of this acquisition?	
6.3 Which of the following changes apply to the global safety database, for the period 1 January 2018 – 31 December 2019 (irrespective of acquisition)?	
7.1.1 How many PSURs were submitted between 1 January 2018 and 31 December 2019?	PSMF annex: performance indicators EMA PSUR repository
7.1.2 How many (number) of these PSURs were submitted on time?	PSMF annex: performance indicators
7.2.1. How many safety variations were submitted to the MEB or EMA between 1 January 2018 and 31 December 2019?	PSMF annex: performance indicators
7.2.2 How many (number) of these safety variations were submitted on time?	PSMF annex: performance indicators
8. Please indicate to how many service providers the activities (related to pharmacovigilance) are outsourced.	PSMF annex: list of contractual agreements covering delegated activities
9.1 Has the pharmacovigilance system been audited in the past 3 years? (internal audit by an external service provider or Quality Assurance department of the organisation. A competent authority inspection does not count as an audit)	PSMF annex: list of all completed audits, for a period of five years, and a list of audit schedules
9.2 Do you have agreements with distributors or partners who are subject to audits?	PSMF annex: list of contractual agreements covering delegated activities
9.3 Have you conducted external audits (distributors, partners) in the past 5 years?	PSMF annex: list of all completed audits, for a period of five years, and a list of audit schedules
10.1 Has your pharmacovigilance system been inspected before?	Sharing of inspection data among EU inspectorates
10.2 When was the last pharmacovigilance inspection?	Sharing of inspection data among EU inspectorates
10.3 Has the inspection been closed? (CAPA approved, but not necessarily implemented)	Sharing of inspection data among EU inspectorates
10.4 Has the CAPA been successfully implemented?	
France	
2-1: Number of active substances (or fixed combinations)* for which a MA is marketed in France as of 31/12/2019	PSMF annex: list of products Data of the local competent authority (Répertoire des spécialités pharmaceutiques)
2-2: Increase in the number of active substances for which a MA is marketed in France between 01/01/2017 and 31/12/2019	Data of the local competent authority (Répertoire des spécialités pharmaceutiques)

Question	Where answer can be found in the current documentation
Number of cohort Temporary Autorisation for Use (ATU) in progress as of 31/12/2019 (if applicable)	Data of the local competent authority
3-1: Number of initial serious cases which occurred in France and reported (by the MA holder or the competent authorities) in the EudraVigilance Post-Marketing module (EVPM) over the period (01/01/2017 - 31/12/2019).	Eudravigilance
3-2: Number of Periodic Safety Update Reports (PSURs) submitted to the EMA/ANSM for products with a MA in France over the period (01/01/2017 - 31/12/2019).	EMA PSUR repository and local competent authority data
3-3: Number of organised collection systems - deployed in France, active over the period (01/01/2017 - 31/12/2019) - which may be the source of solicited cases* (patient recruitment or data analysis in progress). *Cf GVP Module VI point VI.B.1.2 solicited reports	PSMF annex: sources of safety data
3-4: Number of " PASS " * studies deployed in France and active over the period (01/01/2017 - 31/12/2019) (patient recruitment or data analysis in progress). *See Public Health Code, Article R. 5121-152 paragraph 7.	PSMF annex: sources of safety data
4-1: Number of signals validated by the structure and/or the MA holder or by the competent authorities (PRAC, ANSM) over the period for products marketed in France	
4-2: Number of products marketed in France whose product information (SmPC/package leaflet) has been changed over the period, following a validated signal.	Data of the local competent authority (Répertoire des spécialités pharmaceutiques)
4-3: Withdrawal outside France, for safety reasons, of one or more products still marketed in France	
4-4: Report of an urgent safety measure for one or more products marketed in France over the period	
4-5: Number of products marketed in France under reinforced surveillance (black triangle) over the period	PSMF annex: list of products Publicly available list of products under additional monitoring
4-6: Number of products marketed in France with 6 monthly PSURs	
4-7: Number of products marketed in France with risk minimization measures (excluding routine measures) or additional PV measures over the period (whether or not there is a RMP)	PSMF annex: list of products and risk minimisation measures
4-8: Number of products marketed in France (01/01/2017 to 31/12/2019) that are or have been the subject of a national PV monitoring or PV survey in the last 6 years	Data of the local competent authority and Regional Pharmacovigilance centers (CRPVs)
5.1: Change in the responsibility of the person(s) responsible for the EU PV (EU QPPV) between 01/01/2017 and 31/12/2019	Article 57 database
5.2: Change in the responsibility of the reference person for PV for France (RPV) between 01/01/2017 and 31/12/2019	Data of the local competent authority

Question	Where answer can be found in the current documentation
6.1: External subcontracting of the responsibility of the responsible reference person(s) for EU PV (EU QPPV)* between 01/01/2017 and 31/12/2019. *Please indicate the name(s) of the subcontractor(s) in section 11.	PSMF annex: list of contractual agreements covering delegated activities
6.2: External subcontracting of the responsibility of the reference person for PV for France (RPV)* between 01/01/2017 and 31/12/2019. *Please indicate the name of the subcontractor in section 11.	PSMF annex: list of contractual agreements covering delegated activities *Etat des lieux de l'établissement* Pharmaceutique (Yearly update of Pharmaceutical site submitted to ANSM)
7-1: PV France data are recorded locally by the entity: 1 : in a PV database or subsidiary interface module 5: a part in a PV database or subsidiary interface module and a part in an Excel table 5: in an Excel table 15: other (paper register, Word file, individual CIOMS forms etc.)	PSMF body: section on pharmacovigilance processes and section on computerised systems and databases
7-2: Validation of the global PV database Yes/no answer	PSMF body: section on computerised systems and databases Etat des lieux de l'établissement Pharmaceutique (Yearly update of Pharmaceutical site submitted to ANSM)
7-3: Change of the PV database between 01/01/2017 and 31/12/2019 (= start of production of a new PV database) Yes/no answer	PSMF body: section on computerised systems and databases Etat des lieux de l'établissement Pharmaceutique (Yearly update of Pharmaceutical site submitted to ANSM)
7-4: Migration of PV data to the global PV database between 01/01/2017 and 31/12/2019 (whatever the cause: e.g. change of PV database, product acquisition). Yes/no answer	
8-1: Were internal audits of the PV system carried out over the period? Yes/no answer	PSMF annex: list of all completed audits, for a period of five years, and a list of audit schedules
8-2: Did you audit your PhV service providers or PhV-relevant service providers over the period (see explanatory guide)? Exact number is not requested: ranges are Yes >50%; Yes<50%; no	PSMF annex: list of all completed audits, for a period of five years, and a list of audit schedules
9-1: Number of active partners with a contract in force with the French structure that are referenced in the European PSMF and/or the local PSMF as of 31/12/2019 Exact number is not requested: ranges are <5; 5 to 10; 11 to 20; >20	PSMF annex: list of contractual agreements covering delegated activities
9-2: Have you audited your major PV partners over the period (see explanatory guide)? Exact number is not requested: ranges are Yes >50%; Yes<50%; no	PSMF annex: list of all completed audits, for a period of five years, and a list of audit schedules
10-1: Percentage of regulatory compliance to the expedited reporting timelines for serious cases occurring	PSMF annex: performance indicators

Question	Where answer can be found in the current documentation
in the EEA and reported in the EudraVigilance Post-Marketing Module (EVPM) over the period 01/01/2017 to 31/12/2019. (compliance ≤ 15 days)	
10-2: Percentage of regulatory compliance to the expedited reporting timelines of non-serious cases occurring in the EEA and reported in the EudraVigilance Post-Marketing Module (EVPM) over the period (compliance ≤ 90 days)	PSMF annex: performance indicators
10-3: Percentage of regulatory compliance to the expedited reporting timelines of serious non-EEA cases reported in the EudraVigilance Post-Marketing Module (EVPM) over the period (compliance ≤ 15 days)	PSMF annex: performance indicators
10-4: Percentage of regulatory compliance to reporting timelines to the EMA (ANSM) of Periodic Safety Update Reports (PSUR) for specialties with a MA in France over the period	PSMF annex: performance indicators
Section 11: outsourced activities as of 31/12/2019 11-1: Subcontracting / PhV responsibility 11-2: Subcontracting / 24-hour on-call system (outside working hours) 11-3: Subcontracting / Med Info inquiries (France) 11.4: Subcontracting / Management and reporting of spontaneous PV cases occurred in France 11.5: Subcontracting / Management and reporting of solicited PV cases occurred in France 11.6: Subcontracting / Monitoring management of global and/or local medical literature France 11-7: Subcontracting / RMP writing 11-7bis: Subcontracting / PSUR writing 11-8: Subcontracting / Signal management 11.9: Subcontracting / PV database management	PSMF annex: list of contractual agreements covering delegated activities Etat des lieux de l'établissement Pharmaceutique (Yearly update of Pharmaceutical site submitted to ANSM)
12.1: Last inspection of the pharmacovigilance system carried out by ANSM's Inspections des Essais et des Vigilances (INSEVI) department.	Data of the local competent authority