# Legal framework for pharmacovigilance inspection

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## Introduction

The safety of drugs is of paramount importance for patients and healthcare professionals.

Well established pharmacovigilance system is pivotal for monitoring the safety, efficacy and effectiveness of drug use throughout its life cycle and identification of any potential risk in post marketing period.

As part of the pharmacovigilance system, the MAH shall have permanently and continuously at its disposal an appropriately qualified person responsible for pharmacovigilance in the EU (QPPV). The PSMF, shall describe the pharmacovigilance system for one or more medicinal products of the MAH.

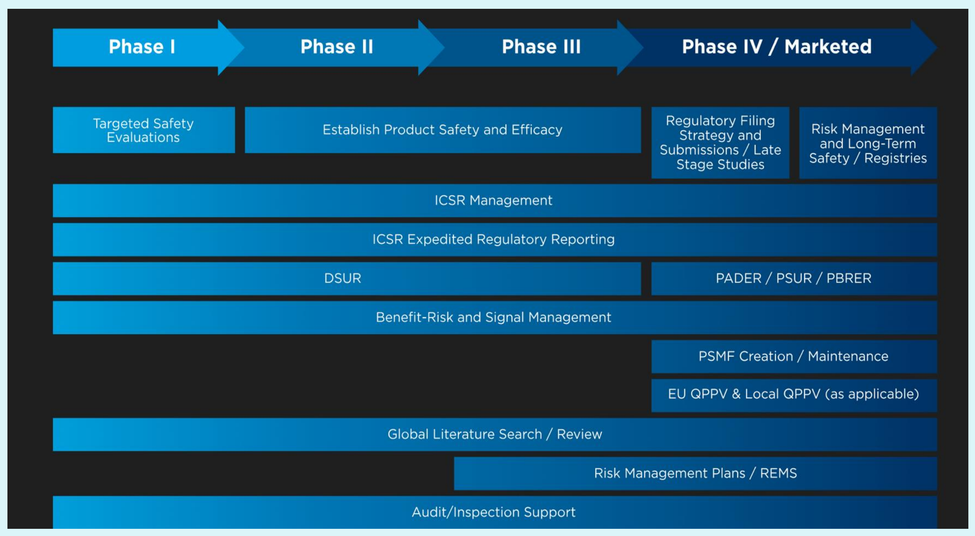


**Figure 1. Pharmacovigilance Global Life Cycle Management**

## Materials and methods

Relevant European, US and Macedonian legislations have been reviewed, in particular, Directive 2010/84/EU, Regulative (EU) 1235/2010, rulebooks, as well as PubMed, Medline and other relevant web sites for articles with empirical analysis, are evaluating the impact of European and non-European regulatory activities.

## Results and discussion

Every marketing authorization holder (MAH) is obligated to maintain pharmacovigilance system for all marketed drugs. This system ensures fulfillment of legal tasks and responsibilities of MAH for pharmacovigilance and surveillance of authorized medicinal products safety and detection of any alteration to their risk-benefit balance. As part of the pharmacovigilance system, the MAH shall have permanently and continuously at its disposal an appropriately qualified person responsible for pharmacovigilance in the EU (QPPV). The Pharmacovigilance System Master File PSMF, shall describe the pharmacovigilance system for one or more medicinal products of the MAH.

In order to determine that MAH, comply with pharmacovigilance obligations established within the EU, and to facilitate compliance, competent authorities of the Member States concerned shall conduct, in cooperation with the Agency, pharmacovigilance inspections of marketing authorization holders or any firms employed to fulfil marketing authorizations holder's pharmacovigilance obligations. Such inspections shall be carried out by inspectors appointed by the national competent authorities. Such inspections are conduct with risk-based methodology.

| 2019 | QPPV/PSMF (MAH) site | Global PhV site | Subcontractor/ Licensing partner/affiliate site | Total |
|---|---|---|---|---|
| CHMP requested | 3 | 1 | 0 | 4* |
| National inspection programmes | 23 | 2 | 0 | 25 |
| **Total** | **26** | **3** | **0** | **29**** |

* Two inspections were requested by the CHMP in 2019 but were conducted in 2020.

| 2020 | QPPV/PSMF (MAH) site | Global PhV site | Subcontractor/ Licensing partner/affiliate site | Total |
|---|---|---|---|---|
| CHMP requested | 6 | 3 | 3 | 12* |
| National inspection programmes | 24 | 1 | 5 | 30 |
| **Total** | **30** | **4** | **8** | **42***** |

* Three inspections were requested by the CHMP in 2020 but were conducted in 2021.

Figure 2. - Pharmacovigilance inspections requested in 2019 and 2020 in the context of the programme for pharmacovigilance inspection of companies with CAPs

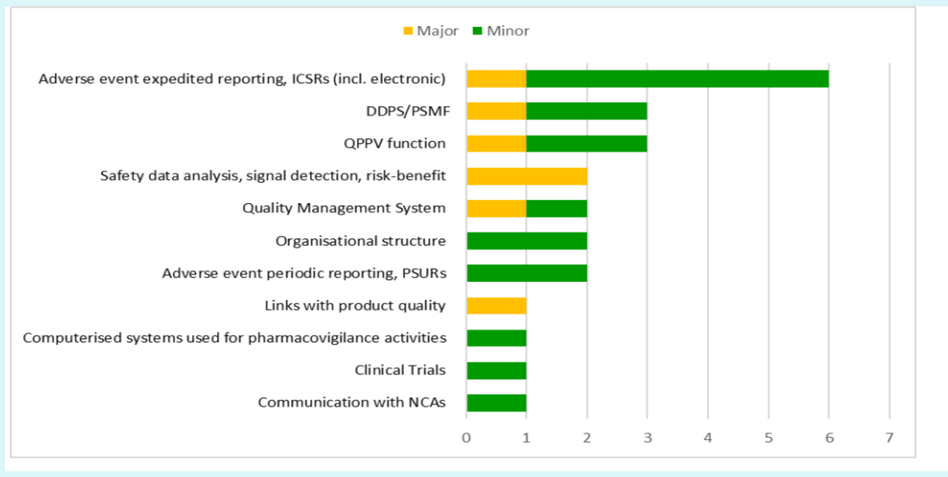


Figure 3 - Number of findings with regard to the main categories graded by critical, major and minor for CHMP inspections conducted in 2019

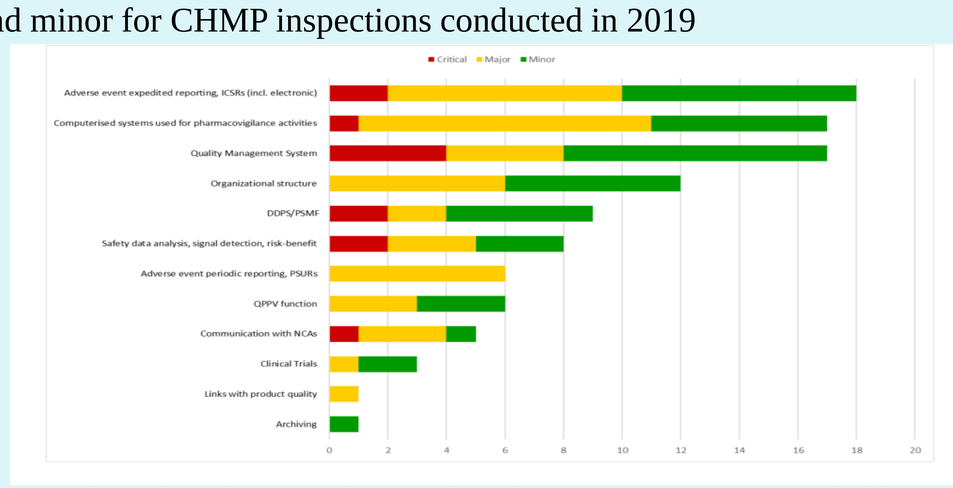


Figure 4 - Number of findings with regard to the main categories graded by critical, major and minor for CHMP inspections conducted in 2020

## Conclusion

Pharmacovigilance Iispections will apply a revised risk-based methodology in the future, selecting pharmacovigilance systems, products and non-interventional studies considered to be the highest risk to inspect under the relevant inspection arms. Unprecedented change and challenges, pharmacovigilance inspections will respond accordingly to enable continued supervision of pharmacovigilance systems and ensure ongoing regulatory compliance. This will ensure safe and effective medicines.

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