PHV-6 version 3 SÚKL requirements for reporting changes in the PSMF, for appointing the qualified person for pharmacovigilance and for appointing the contact person for pharmacovigilance issues in the Czech Republic

This guideline replaces PHV-6 version 2 with the effect from 08-Apr-2022.

This Guideline further defines the terminology and lays down the conditions which govern the provision of information and documents to the State Institute for Drug Control (hereinafter referred to as SÚKL) in the domain of the Pharmacovigilance System Master File. The Guideline also sets requirements regarding appointment of the qualified person responsible for pharmacovigilance of the marketing authorisation holder for a medicinal product, as well as an obligation to appoint the contact person for pharmacovigilance issues in the Czech Republic.

The Guideline is being issued on the basis of and in accordance with the provision of Sections 91 and 91a of Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts, and Guideline on Good Pharmacovigilance Practices (GVP), Module I, II.

The Guideline is legally binding.

Amendments in this version:

- Obligation to appoint the contact person for pharmacovigilance issues is valid for all marketing authorization holders.
- Unification of the deadlines for reporting the changes required by this guideline and clarification of the method of notifying the changes.

Resources, including the legislative basis of the Guideline

Act No. 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (the Act on Pharmaceuticals), as amended, (hereinafter the "Act on Pharmaceuticals")
Guideline on good pharmacovigilance practices (GVP), Module I, II

Abbreviations

EU	European Union
GVP	Guideline on Good Pharmacovigilance Practices
PSMF	Pharmacovigilance System Master File
QPPV	Qualified Person for Pharmacovigilance
SÚKL	State Institute for Drug Control (Státní ústav pro kontrolu léčiv)

1. Definition of terms

- **Pharmacovigilance System Master File (PSMF)** – a detailed description of the pharmacovigilance system used by the marketing authorization holder with respect to one or more authorized medicinal products
- **Qualified person for pharmacovigilance** – a person nominated by the marketing authorization holder, responsible for the establishment and maintenance of the pharmacovigilance system of the marketing authorisation holder
- **Contact person for pharmacovigilance issues** – a person appointed by the marketing authorization holder, based in the European Union and reporting to the qualified person responsible for pharmacovigilance

2. Changes to the Pharmacovigilance System Master File which need to be reported to SÚKL

Pursuant to Sec. 91(2)(b) of the Act on Pharmaceuticals, marketing authorization holders are obliged to inform SÚKL about a change in the Pharmacovigilance System Master File, if this master file document is located in the territory of the Czech Republic.

Changes in PSMF, which need to be reported to SÚKL:

- Change of the QPPV
- Change of the contact details of the QPPV
- Change of the PSMF location
- Change of the Deputy QPPV
- Change of/ new pharmacovigilance database
- New contractual / licensing partner who carries out some of the pharmacovigilance activities
- New patient program or register, etc.
- Information on a completed pharmacovigilance system audit (internal or external) which resulted in critical or major findings

How to report requested PSMF changes to SÚKL

Marketing authorization holders shall inform the Pharmacovigilance Department of SÚKL via e-mail to farmakovigilance@sukl.cz. The subject of the e-mail shall include information on the type of change (PSMF change) and the name of the marketing authorization holder. For shared pharmacovigilance systems, only the first marketing authorization holder indicated on the front page of the PSMF shall be included in the subject of the e-mail, the other marketing authorization holders shall be listed in the body of the e-mail.

Deadline for reporting requested PSMF changes to SÚKL

Marketing authorization holders shall notify the Pharmacovigilance Department of SÚKL within 7 calendar days following the implementation of changes.

3. Requirements for the qualified person for pharmacovigilance and reporting of appointment/change of the QPPV to SÚKL

QPPV shall reside and operate in the EU, Norway, Iceland or Liechtenstein. GVP Module I Pharmacovigilance systems and their quality systems, defines the requirements to be fulfilled by QPPV. In order to carry out their activities, QPPVs must have

- both theoretical and practical knowledge for the performance of pharmacovigilance activities,
- expertise and access to expertise in the fields of medicine, pharmaceutical sciences, epidemiology, and biostatistics,
- where the QPPV does not have medical education, the marketing authorisation holder shall ensure that the QPPV is assisted by a medically trained person and this assistance shall be duly documented.

How to report QPPV appointment/change to SÚKL

Marketing authorization holders shall inform the Pharmacovigilance Department of SÚKL via e-mail to farmakovigilance@sukl.cz. The subject of the e-mail shall include information on the type of change (QPPV change or appointment) and the name of the marketing authorization holder. For shared pharmacovigilance systems, only the first marketing authorization holder indicated on the front page of the PSMF shall be included in the subject of the e-mail, the other marketing authorization holders shall be listed in the body of the e-mail.

Deadline for reporting QPPV appointment/change to SÚKL
Marketing authorization holders shall notify the Pharmacovigilance Department of SÚKL within 7 calendar days following the appointment/change of the QPPV or change of their contact details.

4. Appointment/change of the contact person for pharmacovigilance issues in the Czech Republic

Pursuant to Sec. 91a (3) of the Act on Pharmaceuticals, the State Institute for Drug Control hereby

requests

the marketing authorisation holders to appoint a contact person for pharmacovigilance issues in the Czech Republic and to notify about this the Pharmacovigilance Department via e-mail to farmakovigilance@sukl.cz.

Requirements for the contact person for pharmacovigilance issues
The contact person for pharmacovigilance issues shall fulfil the following:

- be able to communicate in Czech or Slovak language,
- be contactable on a phone number with the Czech country code,
- reside in the EU.

The QPPV and the contact person for pharmacovigilance issues may be the same person.
The contact person for pharmacovigilance issues is a part of the marketing authorization holder's pharmacovigilance system, whose responsibilities are set out and listed in the PSMF. The minimum responsibility of the contact person for pharmacovigilance issues is to provide the contact between SÚKL and the QPPV.

How to report contact person for pharmacovigilance issues appointment/change to SÚKL
Marketing authorization holders shall inform the Pharmacovigilance Department of SÚKL via e-mail to farmakovigilance@sukl.cz. The subject of the e-mail shall include information on the type of change (contact person for pharmacovigilance issues appointment or change) and the name of the represented marketing authorization holder. In case of change involving several marketing authorization holders, all represented holders shall be indicated in the body of the e-mail, only one of them shall be indicated in the subject of the e-mail.
The contact information in the body of the e-mail must include the e-mail address and telephone number of the contact person for pharmacovigilance issues and the name of the represented marketing authorization holder (all represented marketing authorization holders).
The marketing authorization holder may also inform SÚKL of the contact person's deputy if one is appointed. The procedure is the same as for the contact person for pharmacovigilance issues.

Deadline for reporting contact person for pharmacovigilance issues appointment/change to SÚKL
Marketing authorization holders shall notify the Pharmacovigilance Department of SÚKL within 7 calendar days following the appointment/change of the contact person for pharmacovigilance issues or change of their contact details.

Marketing authorization holders who do not have the contact person for pharmacovigilance issues appointed in the Czech Republic as of 08-Apr-2022 must appoint the contact person for pharmacovigilance issues by 30-Jun-2022 at the latest. SÚKL therefore asks marketing authorization holders not to wait at the last possible date.

Note: In connection with the request to appoint a contact person for pharmacovigilance issues, the PHV-4 guideline is being amended at the same time.