PHV-6 version 1 - SÚKL requirements for reporting changes in PSMF and for appointing local contact person for pharmacovigilance in the Czech Republic

Effective as of: 1.7.2013

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 (SÚKL) in the domain of the Pharmacovigilance System Master File, as well as concerning the qualified person responsible for pharmacovigilance of the marketing authorisation holder for a medicinal product, or lays down the conditions under which a contact person for pharmacovigilance in the Czech Republic will have to be appointed.

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

PSMF	Pharmacovigilance System Master File
QPPV	Qualified Person for Pharmacovigilance
SÚKL	State Institute for Drug Control
CR	Czech Republic
GVP	Guideline on Good Pharmacovigilance Practises
PASS	Post-Authorization Safety Study

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
PSMF Summary – set of information to be submitted to SÚKL as part of the registration dossier (Part 1.8.1) instead of the whole PSMF document
Qualified person for pharmacovigilance – 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– person appointed by the marketing authorization holder, based in the Czech Republic 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 immediately about a change in the Pharmacovigilance System Master File, if this master file document is located in the Czech Republic. This concerns information not contained in the summary of PSMF (change of information contained in the summary of PSMF needs to be submitted as a variation to the marketing authorisation).

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

- Change of the 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 found serious (critical or significant) deficiencies

Way of reporting requested PSMF changes to SÚKL

Marketing authorization holders shall inform the Pharmacovigilance Department electronically via email to farmakovigilance@sukl.cz.

Deadline for reporting requested PSMF changes to SÚKL

Marketing authorization holders shall notify the Pharmacovigilance Department without delay (with a maximum tolerance of 15 days from the implementation of changes).

3. Requirements for the qualified person for pharmacovigilance

QPPV shall be an EU resident and shall carry out their tasks in the field of pharmacovigilance in the EU. GVP, Module I Pharmacovigilance systems and their quality systems, defines the requirements to be fulfilled by QPPV. In order to carry out their activities, they 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.

Should any change of the QPPV or their contact details occur, the marketing authorization holder shall immediately inform SÚKL about this effect.

SÚKL can ask marketing authorization holders to appoint a contact person for pharmacovigilance issues in the Czech Republic (see Act on Pharmaceuticals, 91a(3)), who will report to the qualified person for pharmacovigilance.

When is the appointment of the contact person for pharmacovigilance issues in the Czech Republic required?

Pursuant to Sec. 91a (3) of the Act on Pharmaceuticals, the Institute hereby requests the marketing authorisation holders

- represented by a QPPV not mastering Czech or Slovak language

and therewithal

- on whom the decision on marketing authorisation of a medicinal product imposed an obligation to collect pharmacovigilance data, or
- on whom the decision on marketing authorisation of a medicinal product imposed an obligation to perform PASS in - CZ or to participate in funding of patient support programs in CZ etc.,

to appoint a contact person for pharmacovigilance in the Czech Republic and to notify about this the Pharmacovigilance Department electronically via email to farmakovigilance@sukl.cz immediately.

Requirements for the contact person for pharmacovigilance in the Czech Republic

Ability to communicate in Czech or Slovak language

Method of informing SÚKL about the appointment of a contact person for pharmacovigilance in the Czech Republic

If the marketing authorization holder complies with the requirements set out above for the appointment of a contact person for pharmacovigilance in the Czech Republic, it shall inform the Pharmacovigilance Department electronically via email to farmakovigilance@sukl.cz.

Should any change of the contact person for pharmacovigilance or their contact details occur, the marketing authorization holder shall immediately inform SÚKL about this effect.