New or changed procedures related to the new pharmacovigilance legislation in transitional period

overview

Version 2, 20.11 2012

A. Introduction

This document is addressed to marketing authorisation holders, qualified persons for pharmacovigilance (QPPV) and nominated persons for pharmacovigilance. Its objective is to give information on new procedures connected with new pharmacovigilance legislation and on submission of documents to SIDC. Details are presented on website of SIDC (in Slovak language) in sections:

- Registrácia humánnych liekov - Pokyny a oznamy
- Bezpečnosť liečiv - Pokyny

B. Summary of procedures

Procedure	Type of procedure	Submission addressee/format	Note
Electronic submission of information on medicines via the XEVMPD	Each MAH has to submit information on its authorised medicinal products. Information on QPPV and PSMF is submitted as well.		
Pharmacovigilance system master file (PSMF)	Should be prepared by all MAHs regardless of the type of drug. It is not part of the registration dossier. Not to be submitted to the SIDC. It shall be accessible for inspection and a copy shall be available upon request within 7 days.		
Description of the pharmacovigilance system (DDPS)	For authorised medicinal products and pending marketing authorisation applications shall remain in force until preparation of the pharmacovigilance system master file and submission of summary of the pharmacovigilance system. Not to be submitted for new applications after 2/21 July 2012		
Change of the Description of the pharmacovigilance system	Variations of IA_{IN} (Module 1.8.1)	SIDC, Section of Registration eCTD format or CD	To be submitted until submission of summary of pharmacovigilance system, at the latest by 2 / 21 July 2015.
Summary of the pharmacovigilance system	Newly authorised medicinal products - part of the documentation (Module 1.8.1) Medicinal products authorised before 2/21 July 2012: Variations IA_{IN} Variations grouping possible	SIDC, Section of Registration eCTD format or CD	Except for the traditional herbal medicines and homeopathics authorised by simplified procedure: • to be submitted with an application for authorisation of the product, • if the drug has already been authorised, at the following dates, whichever is earlier: o with renewal application, o in term of annual renewal of product conditionally authorised via centralised procedure, o by 2 / 21 July 2015 at the latest.
Change of Summary of the pharmacovigilance	Variations IA_{IN}	SIDC, Section of Registration	

Procedure	Type of procedure	Submission addressee/format	Note
system including change of the person responsible for pharmacovigilance (QPPV)	Variations grouping possible	eCTD format or CD	
An application for a renewal	Renewal	SIDC, Section of Registration eCTD format or CD	No later than 9 months before the expiry of the marketing authorisation, to the Section of registration of SIDC, the template has not yet been approved, it should contain a summary of the pharmacovigilance system (please follow the CMDh and EMA websites for further information)
Risk Management Plan (RMP)	Part of new marketing authorisation applications Module 1.8.2	SIDC Section of Registration eCTD format or CD	To be submitted with all new marketing authorisation applications after 2/21 July 2012, except of traditional herbal medicines and homeopathics authorised via simplified procedure. From 10 January 2013, the new format of RMP should be used.
Summary of RMP in Slovak language	After approval of the RMP, should be submitted together with Slovak version of the SmPC and PIL during national phase for approval and publication	SIDC, Section of Registration eCTD format or CD	SIDC is obliged to publish summaries of RMPs. It is necessary to submit translation of the approved Summary of RMP (for MRP/DCP) or Summary of RMP directly in Slovak language (for purely nationally authorised products). The summary of the RMP may be also provided to other applicants for the marketing authorisation of drug containing the same active substance.
RMP - changes	Variations Ib or II.	SIDC, Section of Registration eCTD format or CD	After the functionality of the PSUR repository has been established and announced, RMPs and all their changes should be submitted using the repository. Please see GVP Module V for further information.
Nominated Person / Local safety contact	Notification Change of notification	SIDC, Section of Drug Safety and Clinical Trials table (See below)	Every MAH is required to have a local safety contact person. MAH is strictly asked to inform SIDC about contact detail of this person and any changes.
PSUR for centrally authorised product or for medicinal product containing the active substance included in	Submission	SIDC, Section of Drug Safety and Clinical Trials	For generic drugs, the PSUR should be submitted, only if required by EURD list. For further information on EURD list and transitional period please follow

Procedure	Type of procedure	Submission addressee/format	Note
EURD list		1xCD or eCTD	EMA and HMA websites. PSURs should be submitted for hybrid medicinal products. From 10 January 2013, the new format should be used.
PSUR for medicinal product containing active substances not included in EURD list	Submission	SIDC, Section of Drug Safety and Clinical Trials 1xCD or eCTD	Submission should continue in terms under previous procedures (theoretically such medicinal products should not occur, unless they are registered in one MS only). MAH may ask any substance or combination of substances to be added to the EURD list. For further information follow the EMA website.
PSUR for well-established medicines, traditional herbal medicines or homeopathics authorised via simplified procedure	No need to prepare PSURs		
Notification of International PASS	Notification	SIDC, Section of Drug Safety and Clinical Trials by a letter	After approval by PRAC and registration in the ENCePP database
PASS application for approval	Application for approval	SIDC, Section of Drug Safety and Clinical Trials by letter (See special instructions)	Only studies performed exclusively in Slovakia, initiated, managed or financed by the MAH voluntarily or pursuant to obligations. From 10 January 2013, the new study protocol template should be used.
Direct communication with healthcare professionals (DHPC)	Application for approval	SIDC, Section of Drug Safety and Clinical Trials email to gibala@sukl.sk	Regardless of the reason for the preparation of DHPC (referral, an important change in terms of safe use of the product, an error in the quality of product, which is a potential threat to patients, etc.).
Serious adverse reactions occurring in Slovakia	Electronic submission to the SIDC, will be submitted directly to the EudraVigilance after announcement of its full functionality (~ 2015)		
Non-serious adverse reactions occurring in Slovakia	Not to be sent to the SIDC, will be submitted directly to the EudraVigilance after announcement of its full functionality (~ 2015)		
Cases from third countries	Serious adverse reactions to be sent directly to the Eudravigilance		
Conditions of registration, e.g.	Application for approval	SIDC, Section of Drug Safety and	Version in Slovak language has to be approved

Procedure	Type of procedure	Submission addressee/format	Note
educational materials for health professionals and patients approved by authorities		Clinical Trials email to gibala@sukl.sk	
Activities spanning from the RMP other than changes in SmPC and PIL or PASS	Application for approval	SIDC, Section of Drug Safety and Clinical Trials email to gibala@sukl.sk	Version in Slovak language has to be approved
SmPC or PIL – information on reporting of suspected adverse reactions – new wording or black symbol	Final version of information has not been approved so far - black symbol must be approved by the PRAC and EC. Standardised information on reporting of suspected adverse reactions will be included in the updated QRD template. Please follow the EMA website for the current version of QRD template in any EU language		
SmPC or PIL - new format	New QRD template has not yet been approved. The current format to be used in the meantime. Please follow the EMA website for the current version of QRD template in any EU language		

C. Nominated (contact) person for pharmacovigilance

Nominated (contact) person for pharmacovigilance is performing his/her tasks in Slovakia and is a part of MAH's pharmacovigilance system. His/her duties are clearly given and he/she is adequately trained in the field of pharmacovigilance. Besides guaranteeing contact between SIDC and QPPV, nominated person is involved in verifying data provided in adverse drug reaction reports (including follow-ups), translation and circulation DHPCs and educational materials as well as in fulfilment of additional registration requirements.

The table below should be filled in and sent as an attachment to an email with subject: "Oznámenie kontaktnej osoby pre farmakovigilanciu" or "Notification of nominated person for pharmacovigilance" to the email address: pharmacovigilance@sukl.sk
The table should be filled in separately for each MAH.

Oznámenie kontaktnej osoby pre farmakovigilanciu na Slovensku	
Držiteľ rozhodnutia o registrácii lieku	
Nominovaná osoba	
Poštová adresa	
Telefón	
Mobil	
email	
fax	
Dátum od ktorého sa vykonáva táto funkcia	
Dátum podania oznámenia	
Ďalšie funkcie vykonávané pre držiteľa (doplniť áno/nie)	
Osoba zodpovedná za farmakovigilanciu (QPPV)	
Osoba zodpovedná za registráciu v Slovenskej republike (§ 60 ods. 1 písmeno z) zákona č. 362/2011 Z.z.)	
Osoba zodpovedná za kvalitu	
Osoba zodpovedná za prepustenie šarže	

Marketing, farmaceutický reprezentant	
Klinické skúšanie liekov	
Kategorizácia liekov	
Iné (vypísať)	

D. Addresses for submitting documents for Section of Registration

1. Štátny ústav pre kontrolu liečiv
Sekcia registrácie
Kvetná 11
825 08 Bratislava 26
Slovak Republic

State Institute for Drug Control
Section of Registration
Kvetná 11
825 08 Bratislava 26
Slovak Republic

2. Filling room
Working hours: daily 10 - 12 h and 13 - 14 h

E. Addressees for submitting documents for Section of Drug Safety and Clinical Trials:

1. Štátny ústav pre kontrolu liečiv
Sekcia bezpečnosti liekov a klinického skúšania
Kvetná 11
825 08 Bratislava 26
Slovenská republika

State Institute for Drug Control
Section of Drug Safety and Clinical Trials
Kvetná 11
825 08 Bratislava 26
Slovak Republic

2. Filling room
Working hours: daily 10 - 12 h and 13 - 14 h
3. Only for reporting of adverse reactions to medicinal products:
Email: neziaduce.ucinky@sukl.sk or adverse.reactions@sukl.sk
Electronic submission after successful testing – ID SUKLSK
Directly to the EudraVigilance (reports from outside European Economic Area)
4. Other information and queries regarding pharmacovigilance:
Notification of nominated person for pharmacovigilance in Slovakia:
Email: pharmacovigilance@sukl.sk
5. Submission of DHPCs and educational materials in Slovak language:
Email: gibala@sukl.sk

F. Abbreviations:

CD – Compact Disc
CMDh – Coordination Group for Mutual Recognition & Decentralised Procedure - human
DDPS – Detailed Description of the Pharmacovigilance System
DHPC – Direct Healthcare Professional Communication
eCTD – Electronic Common Technical Document
EURD list – List of European Union Reference Dates and frequency of submission of Periodic Safety Update Reports
GVP – Good Pharmacovigilance Practices
MAH – Marketing Authorisation Holder
PASS – Post-authorisation Safety Studies
PIL – Package Information Leaflet
PRAC – Pharmacovigilance Risk Assessment Committee
PSMF – Pharmacovigilance System Master File
PSUR – Periodic Safety Update Report
QPPV – Qualified Person responsible for Pharmacovigilance
QRD – Quality review of documents
RMP – Risk Management Plan
RMS – Reference Member State
SmPC – Summary of Product Characteristics

G. Version list

Version	Date of publication on website
Version 1, 23.8.2012	24.8.2012
Version 2, 20.11.2002	