P046

A Harmonised Scheme to Support Developing Risk Management Guidelines Beyond ICH Countries

by the ISoP Special Interest Group on Risk Minimisation Methods for Asian Countries[1]

Introduction

❑ The principles of *proactive pharnacovigilance and risk minimisation*[2-6] remain to be enforced in a number of non-ICH countries. In order to address this need, a *Special Interest Group* (SIG) of the *International Society of Pharmacovigilance* (ISoP) was created early 2015[1].

❑ Whilst the primary objective of this group is to elaborate innovative methods for risk minimisation applicable to non-ICH countries, setting a regulatory framework was identified as a necessary preliminary step.

❑ To address this need, an open-source customizable *Template* was created in order to facilitate the elaboration of risk management guidelines.

A Customisable template for creating risk management guidelines

❑ Intended for Health Authorities developing a guideline on risk management/minimisation, this *Template* proposes customisable contents including: roles, responsibilities and obligations applicable to a.) health authorities, b.) medical institutions, c.) health care professionals, d.) applicants/ product license holders (during the development phase, at submission, and post-approval), e.) contract partners and, f.) product users.

❑ The *Template* proposes several options for the provision of risk management documents by the *Applicant,* making a clear distinction between foreign documents to be provided *for information* (Table 1) and the country-specific risk management document describing the pharmacovigilance and risk minimisation activities intended for implementation in the country.

Table 1: *Customisable selection of Foreign documents*

List of foreign risk management documents to be submitted by NDA Applicants for information (to be customized depending upon Country HA expectation)			
Country	*Risk management document*	*Always*	*Upon request*
European Union	Approval/most recent version* of the European risk management plan (EU-RMP)	Yes/No	Yes/No
European Union	Part VI (Summary) of the Approval/most recent version* of the EU-RMP	Yes/No	Yes/No
USA	Risk evaluation and mitigation strategy (REMS) as agreed upon by the US-FDA	Yes/No	Yes/No
Japan	Translation into English of Japanese RMP	Yes/No	Yes/No
Australia	Approval/most recent version* of the Australian-Specific Annex (ASA)	Yes/No	Yes/No
Other	Approval/most recent version* of [other country to be specified]-Specific Annex	Yes/No	Yes/No
Other	Approval/most recent version* of RMP submitted/approved in [other country to be specified]	Yes/No	Yes/No
Other		Yes/No	Yes/No
(*) *If Approval by the Foreign Authority is not yet granted at the time of submission in [Country], the latest interim version should be provided and the Approval version should be provided within 1 month after approval is granted. Subsequent revisions should be provided in a tabulated format describing the change versus the prior content.*			

❑ The *Template* proposes several customisable options for elaborating concise country-specific risk management documents depending upon country expectations and resources available for document review (Table 2).

Table 2: *Customisable selection sections to be included into the risk management document for implementation in the Country*

Concise Risk Management Document for implementation in [Country]			
Sections:		*Select below option*	
A1	Description of the medical need in [Country]	Required	Optional
A2	Consideration on the medical environment in [Country]	Required	Optional
A3	Relevant epidemiological data if available in [Country]	Required	Optional
A4	Indication as intended in SmPC for [Country]	Required	Optional
B	Safety Specification	Required	Optional
C	Pharmacovigilance Plan	Required	
D	Risk Minimisation Plan	Required	
E	Post Approval Studies or Programs	Required	Optional

❑ Whilst the *Template* refers to a basic categorisation of additional pharmacovigilance and risk minimisation activities such as: a.) educational activities, b.) structured collection of information, c.) restricting product prescription or dispensing, it is not intended to provide methodological details, which will be released in subsequent deliverables.

Next steps

❑ Designing risk minimisation methods to address the needs and specificity of the health care systems of Asian countries is the essential objective of the *ISoP Special Interest Group on Risk Minimisation Methods for Asian Countries*.

❑ Those methods elaborated by the Group will be delivered stepwise during the subsequent ISoP events in the upcoming 18 months then published in order to make those methods available to a wider array of countries globally.

References

1.http://isoponline.org/special-interest-groups/risk-minimisation-methods-for-asian-countries/
2.ICH Harmonised Tripartite Guideline, Pharmacovigilance Planning, E2E, Step 4 version,18 November 2004. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.
3.EU GVP Module V Guideline on good pharmacovigilance practices (GVP) Module XVI– Risk management systems.22 June 2012. EMA/838713/2011.
4.Guidance on format of the risk management plan (RMP) in the EU – in integrated format. EMA/365932/2013, Rev.1, 25 July 2013.
5.EU GVP Module XVI Guideline on good pharmacovigilance practices (GVP) Module XVI– Risk minimisation measures: selection of tools and effectiveness indicators.15 April 2014. EMA/204715/2012 Rev 1.
6.Practical Approaches to Risk Minimisation for Medicinal Products. Report of CIOMS Working Group IX, Geneva 2014.

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