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REVIEW ARTICLE

EMA EXPECTATION WITH THE REVISED GUIDELINE OF RISK MANAGEMENT PLAN [GVP MODULE V]

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Abstract

The European Medicines Agency (EMA) has revised the guideline of Risk Management Systems (Revision 02). This article provides the expectation of EMA with recently published revised guideline of Risk Management Systems (Revision 02).

Keywords: European Medicines Agency, Risk Management Plan

Introduction

The European Medicines Agency has revised the Good Pharmacovigilance Practices (GVP) Module V on Risk Management Systems. The revised module (Revision 02) is effective from March 31, 2017. These revisions to the GVP Module V are intended to provide a more concise and clear description of risk management and how safety risks evolve through a product's lifecycle based on the evidence from a variety of sources. The guidance is updated in parallel to an amended Risk Management Plan (RMP) template for initial marketing authorization application.

Major changes in revision 02 of RMP guideline

- Clarification of what RMPs should focus on in relation to an important identified or important potential risk and missing information
- Removal of duplication of information within GVP Module V

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- Guidance on the expected changes in the RMP during the life cycle of the product
- Updated requirements for different types of initial marketing authorisation applications, with the aim to create risk-proportionate, fit for purpose RMPs
- An amended RMP template for initial marketing authorisation application

The comparison between the initial guideline (version 01) and revised guideline of risk management systems (revision 02) [1-3]

Section of the RMP	Revised Guideline of RMP (Version 02)
Part II Module SVII	The significant change in the revised guideline is the presentation of Module SVII which differs significantly from the initial guideline, in keeping with the ongoing theme of focussing on the RMP as dynamic document and a risk-proportionate RMP. The significant changes are • Both important and unimportant risks are to be discussed with a justification as to why risks have been classified as not important • For each important identified risk and potential risk, an evaluation of the impact on the risk-benefit of the product • Missing information data are now also to be presented in this module
Part III Pharmacovigilance Plan	The revised guideline conveys that routine PV activities which go beyond adverse reaction reporting and signal detection should be described.
Part IV Post authorisation efficacy studies	The scope of this module is more restricted than the initial guideline. It conveys that this should only include a list of post-authorisation efficacy studies (PAES) imposed as conditions to the marketing authorisation or when included as specific obligations in the context of a conditional marketing authorisation or a marketing authorisation under exceptional circumstances. If no such studies are required, RMP Part IV may be left empty.
Part V Risk minimisation measures	The revised guideline conveys that over time consideration should be given as to whether additional risk minimisation measures could be removed.
Annexes	The initial guideline of RMP contains twelve annexes, while the revised RMP contains only eight annexes.

Transitional arrangements for RMP version 02

According to EMA, RMPs submitted for initial marketing authorization applications and D121 responses applying GVP Module V Rev 1 will be accepted for a further 6 months, and all other RMP submissions (including D91 responses for an initial application under accelerated assessment) will be accepted for one further year until 31 March 2018. Thus, all RMPs submitted after 31 March 2018 will be required to be submitted in accordance with revised guideline of RMP and comply with the Revision 02 format.

Conclusion

The revised guideline of the RMP and the RMP template provide substantive changes for RMPs and provide a welcome risk proportionate approach. The documents have provided clarification on previous grey areas and allow clearly for a change to the risk profile over time with the opportunity to remove or modify risks as appropriate. As a result it is likely that a more scientifically valuable RMP will be created which is better adapted to considering the use of the product in the real world setting over time.

References

[1] Guideline on good pharmacovigilance practices (GVP) Module V – Risk management systems (Rev 1) Dated 15 April 2014 Available at https://www.scribd.com/document/336440833/Guideline-on-good-pharmacovigilance-practices-GVP-Module-V-Risk-management-systems-Rev-1-pdf

[2] Guideline on good pharmacovigilance practices (GVP) Module V – Risk management systems (Rev 2) Dated 28 March 2017 Available at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500129134.pdf

[3] NEW! EMA Guidance on RMPs in the EU Dated 03 April 2017 Available at http://www.ubc.com/blog/new-ema-guidance-rmps-eu.