EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU Risk Management Plans
Update of the GVP Module V

7th industry stakeholder platform – operation of EU PV legislation

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Improving patient safety through more proactive risk management

News

29/02/2016

Improving patient safety through more proactive risk management

Revised good pharmacovigilance practices module on risk management systems released for public consultation

The European Medicines Agency (EMA) has published today a revision of module V of the good pharmacovigilance practices (GVP) on risk management systems for public consultation until 31 May 2016.

Risk management is a major component of the safety monitoring of medicines. Risk management entails putting in place measures to minimise potential risks and to fill knowledge gaps for medicines (e.g. through post-authorisation data). The goal is to ensure that throughout its lifespan the benefits of a particular medicine exceed the risks by the greatest achievable margin. Marketing authorisation holders are required to present the proposed activities in a risk management plan (RMP) that needs to be approved by the regulators before a medicine can be authorised.

GVP module V, released in 2012, advises developers of medicines, marketing authorisation holders and regulators on the design of effective risk management systems and plans. This first major revision is based on the experience gained since the Agency's Pharmacovigilance Risk Assessment Committee (PRAC) started its operations, which

Related content

- Pharmacovigilance
- Pharmacovigilance legislation
- Good pharmacovigilance practices
- Risk management plans

Related documents

- Guidelines on good pharmacovigilance practices (GVP) - Introductory cover note, last updated with draft revision 2 of module V on risk management system for public consultation. (29/02/2016)
- Guideline on good pharmacovigilance practices (GVP) 3 - Module V – Risk management systems (Rev 2) (29/02/2016)
- Submission of comments - GVP Module Risk Management Systems Rev. 2 (29/02/2016)
- Draft guidance on format of the

Guideline on good pharmacovigilance practices (GVP) 3 - Module V – Risk management systems (Rev 2)

Document details

Download document	Guideline on good pharmacovigilance practices (GVP) 3 - Module V – Risk management systems (Rev 2)
Reference number	EMA/838713/2011 Rev. 2
Status	draft: consultation open
First published	29/02/2016
Last updated	29/02/2016
Consultation start date	29/02/2016
Consultation end date	31/05/2016
Email address for submissions	gvp@ema.europa.eu

Draft guidance on format of the risk management plan (RMP) in the EU – in integrated format

Document details

Download document	Draft guidance on format of the risk management plan (RMP) in the EU – in integrated format
Reference number	EMA/PRAC/613102/2015 Rev.2 accompanying GVP Module
Status	draft: consultation open
First published	29/02/2016
Last updated	29/02/2016
Consultation start date	29/02/2016
Consultation end date	31/05/2016
Email address for submissions	rmptemplate@ema.europa.eu

Summary

The European Medicines Agency is consulting stakeholders on an amended risk management plan (RMP) template, to be used by medicine developers. The revision of the template is based on the principles described in the updated good pharmacovigilance practices (GVP) module V in the view of getting a focussed risk management system and simplifying the way information is submitted to the regulators.

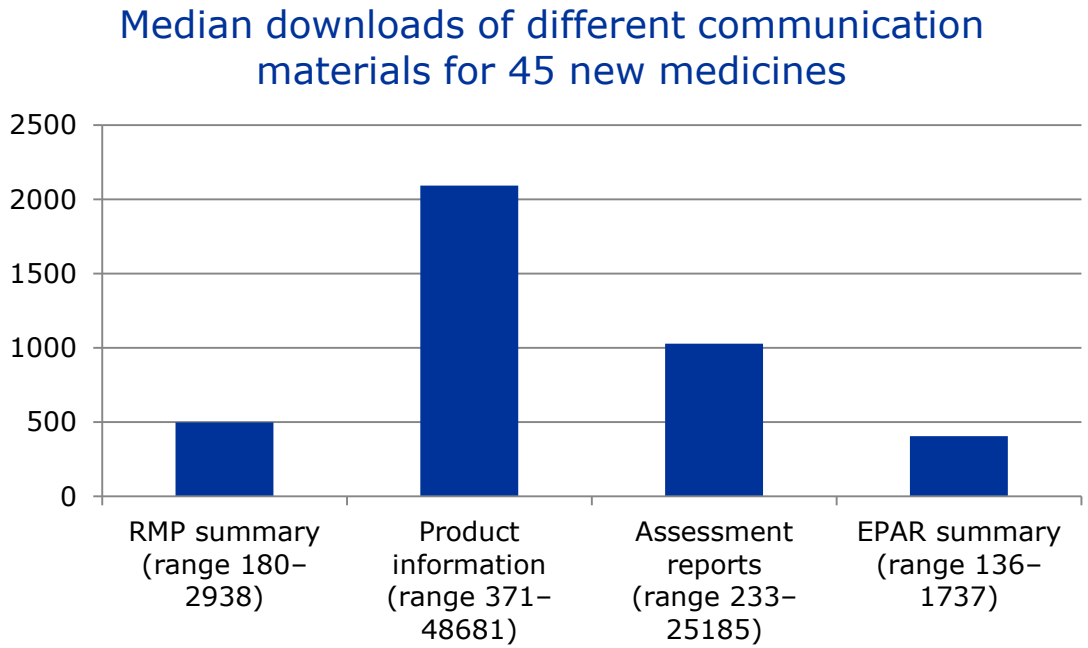
RMP summary – pilot phased implementation

- New information resource:
  - increased **public access** to relevant information on medicines,
  - in line with EU **legislation**

- 1 year pilot phase – new medicines recommended for authorisation by 2015

- Updated RMP summary template:
  - Improved, based on experience, to better meet the needs and expectations of different audiences
  - ongoing public consultation

Suggested interest



On average, RMP summaries were downloaded 37% as often as product information but there was wide variation across the 45 medicines (range: 4–123%)

RMP summary

Way forward – template simplification

- Wide interest from different audience groups - each with different needs and expectations of the document.
- Improvements needed to current format and content - template simplification
- For patients, *Package Leaflet* and *EPAR summary* remain primary source of information. RMP summary valuable to those requiring additional background to the package leaflet's safety information.
- Plain-language approach to be used. However, this does not mean that technical terms should be avoided.
- The content of the updated RMP summary will cover the RMP submission requirements for generic medicines.

RMP summary

Way forward – process simplification

- Simplify process, as much as possible to minimise resource investment, relying largely on the ability to easily transpose information from the full RMP into the summary
- Fully integrated in the preparation and publication of EPARs
- Consistency on the way information on RMPs is published at EU level
- Living document

Next steps

- End of pilot phase – discontinuation of publication of RMP summaries in current format
- Draft RMP summary template update –*ongoing public consultation*
- Gradual implementation as of 2016, once new template is finalised
- In the meantime, information on RMPs will continue to be made publicly available in CHMP assessment reports, part of the EPAR

Further information

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