EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Summaries of Risk Management Plan

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Risk Management – EU legal basis

- First introduced in the legislation (Regulation (EC) No 726/2004) in 2005.
- New legislation:
  - Risk Management Plan (RMP) required for all new applications
  - Prospective, dynamic and risk proportionate
  - Key role of PRAC
  - PASS/PAES may be condition of marketing authorisation
  - Monitoring effectiveness of risk minimisation
  - Summary of the RMP to be made public

Summary of the RMP

- Article 26 of Regulation (EC) 1235/2010
- Article 106 of Directive 2010/84/EU

"EU Member States and the European Medicines Agency to make public RMP – summaries for all medicines authorised in the EU."

Summary of the RMP - Workshop

- Workshop on 8th May 2012 at EMA

- Aims of the workshop:

  - Confirm target audience
  - Identify key information (content)
  - Explore the most suitable format (tools/structure/template)
  - Propose key principles for a process (including roles and responsibilities)

Existing EU experience and stakeholder expectations

- EU existing experience:
  - UK – MHRA pilot (2008 – 2009)
  - French experience – RMP summaries published since 2007
- Industry expectations
- Contribution from patients, consumers (PCWP) and healthcare professionals (HCP WG)

Workshop conclusions

- Target audience
- Content
- Format – Tools to communicate information on the RMP
- Process

Target audience

- Summary to be written for the lay reader
  - Someone without scientific or regulatory knowledge but with an interest in the medicine
- Healthcare professionals, patients and consumers with a particular interest on the medicine
- Acknowledging a wider interest (industry, researchers, etc)

Content

- Clear, concise, summary
- Risk to be put in the context of the benefit
- Avoid being alarming
- Use of adequate language – “potential risk”, “missing information” – communication challenge
- Consistency and complementary with other public documents (EPAR, Product Information)
- Minimise overlapping and duplication (EPAR, Product Information)

Tools to communicate information on the RMP

1. Maintain tabular summary in EPAR

2. Develop a stand-alone RMP summary

3. Update EPAR summary template
   - Incorporate key information on main safety concerns and measures taken to mitigate the risk

Stand-alone RMP Summary

Proposed structure

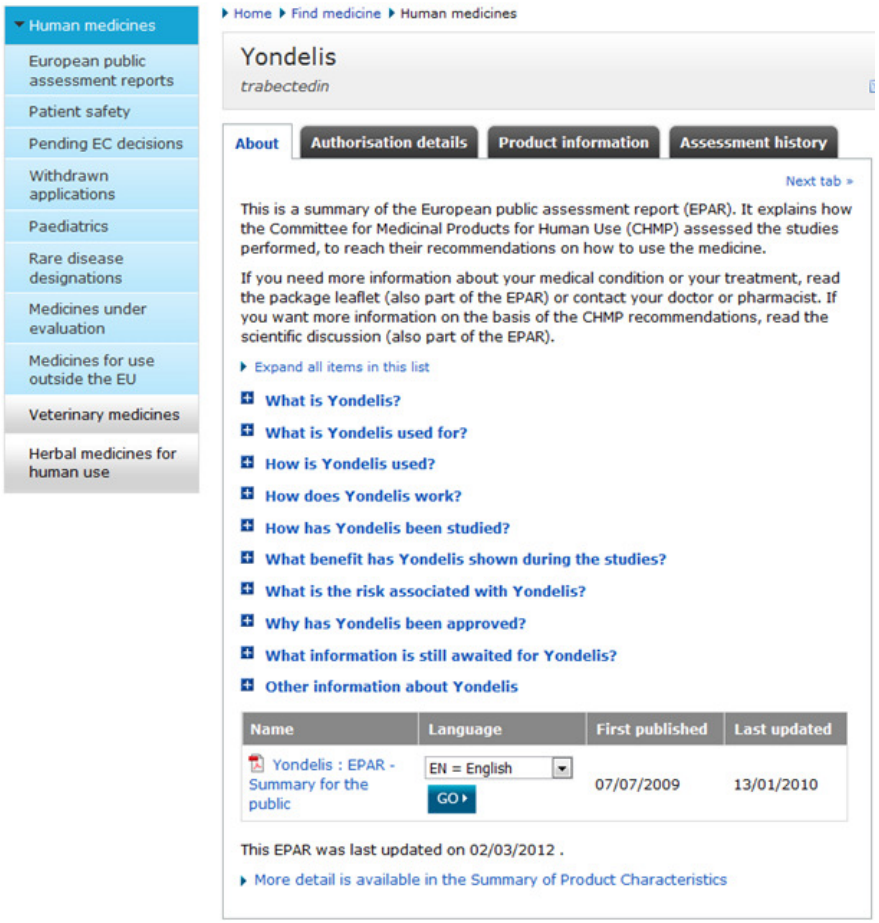
- Overview of disease epidemiology
- Summary of the benefit/efficacy
- Summary of main safety concerns (identified, potential and missing information)
- Summary of risk minimisation measures by safety concern (routine and additional)
- Planned post-authorisation (safety and efficacy) development plan
- Major changes over time

With links to Product Information

Update of EPAR summary template

Objectives

- To communicate on main safety concerns
- To communicate on main risk minimisation measures addressing identified concerns
- To direct interested readers to the stand-alone RMP summary



Update of EPAR Summary template

Proposed structure

In line with stakeholders expectations:

- Product name (+active substance)
- Indication/what is X used for?
- How is X used for?
- Which are the benefits of X?
- Which is the risk associated with X?
- Which additional measures are being taken to ensure safe use of X?

With link to Package Leaflet, glossary of terms and stand alone RMP-summary

Update of EPAR Summary template

For *routine* risk minimisation measures

Standard sentence for all medicines:

"Which is the risk associated with <X>?

The most common side effects with...(…)

Measures have been put in place to minimise and manage the risks with <X> and to ensure that the medicine is used as safely as possible. Details of these measures can be found here in the summary of the risk management plan."

Update of EPAR Summary template

For *additional* risk minimisation measures

Extra paragraph:

"**Which additional measures are being taken to ensure the safe use of <X>**?

In addition to routine measures for promoting the safe use of medicines, the company that makes <X> will set up a specific prevention programme in each Member State…The boxes containing <X> will include a warning stating that <X> is harmful under certain conditions."

Process - timing

- Stand-alone RMP summary to be submitted by applicant at the time of initial application
- Stand-alone RMP summary to be evaluated as part of the RMP and to be adopted by PRAC/CHMP at the time of Recommendation / Opinion
- EPAR summary to be produced as per current procedure in place
- Publication at the time of Commission decision

Process - timing

- Update of RMP
  - EPAR summary update – procedure in place
  - Stand-alone RMP summary – major changes to the RMP over time
  - Publication at time of Commission decision

Roles & Responsibilities

- Applicant to provide 1st draft of RMP – summary at the time of submitting application
- Preparation of RMP summary: EMA, Rapporteurs and assessors
- Wherever necessary, review by patients and healthcare professionals during preparation
- Industry to receive document prior to its publication

Translation

- EPAR summary: available in all EU official languages (translation process already in place)

- Stand alone RMP summary – available in English

Next steps

- Final decision on implementation
- final template for stand-alone RMP to be published
- Guidance to be provided
- Implementation is expected to:
  - Increased visibility of information on RMP on website
  - Increased awareness of the concept of risk management
  - Improve information on the benefit and risk of each medicine