EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Summaries of Risk Management Plan

A transparency or a communication tool?

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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
  - Summary of the RMP to be made public
    - 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 by means of EU webportal RMP summaries for all medicines authorised in the EU."

What is Risk Management plan (RMP)?

- In the European Union (EU), companies must **submit an RMP** at the time of application for market approval.

- RMPs include information on:
  - a medicine's safety profile;
  - risk factors for developing side effects;
  - how its risks will be prevented or minimised in patients;
  - plans for studies and other activities to gain more knowledge about the safety and efficacy of the medicine;
  - measuring the effectiveness of risk-minimisation measures.

Summary of the RMP

- Several discussions with Member States
- Involvement of stakeholders:
  - patients, healthcare professionals and industry
  - Workshop in 2012
- RMP template adapted: part VI.2 of RMP
  - Elements of the summary
- Process for review, preparation and publication in place

Part VI of RMP – elements for RMP Summary

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

Information on RMP is available through:

1. Tabulated information included in the assessment report

2. Summary of the medicine –adapted to include key information

3. (Stand alone) Summary of RMP has been developed (pilot phase)

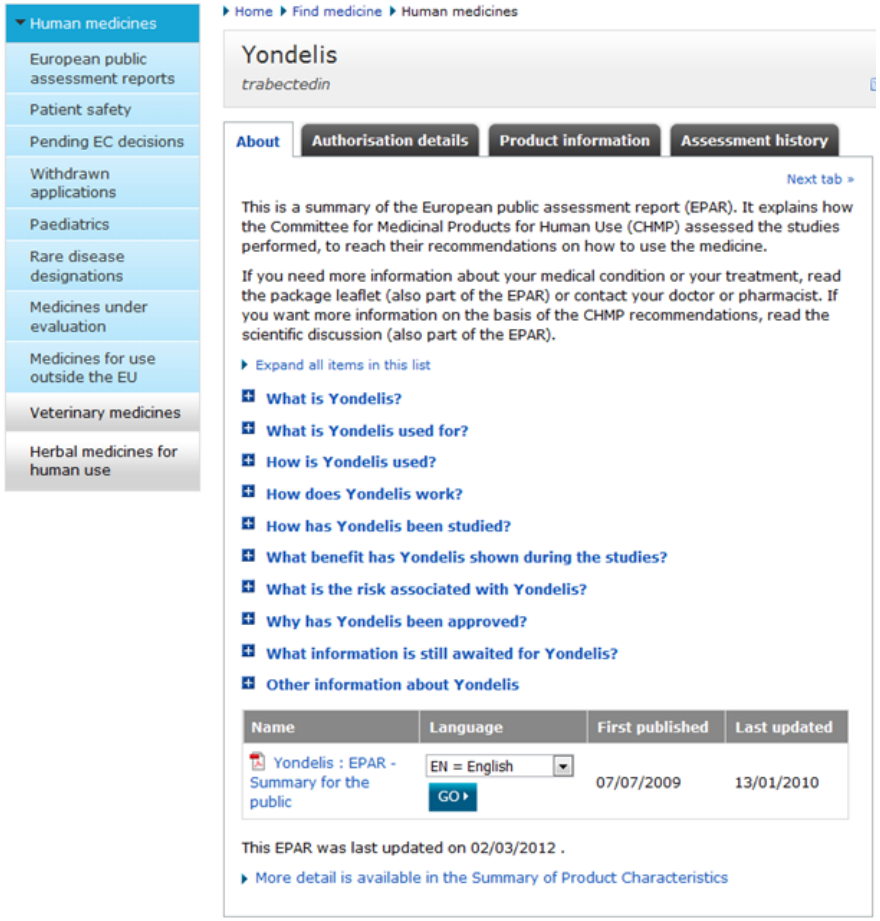
Content

- Clear, concise, summary
- Always put risk in the context of the benefit
- Avoid from being unduly alarming
- Consistency and complementary with other public documents (summary of the medicine, Product Information)
- Minimise overlapping and duplication (EPAR, Product Information)

Update of summary of the medicine (EPAR summary)

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 summary of the medicine (EPAR summary)

New structure

In line with stakeholders expectations:

- Product name (+active substance)
- Indication/what is X used for?
- How is X used for?
- What benefits of X have been shown in studies?
- What are the risks associated with X?
- What measures are being taken to ensure the safe and effective use of X?

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

Update of summary of the medicine (EPAR summary)

For *routine* risk minimisation measures

Standard sentence for all medicines:

"What measures are being taken to ensure the safe and effective use of <X>?

A risk management plan has been developed to ensure that <X> is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for <X>, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found here in the summary of the risk management plan.

Update of summary of the medicine (EPAR summary)

For *additional* risk minimisation measures

Extra paragraph:

"**What measures are being taken to ensure the safe and effective 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."

Implementation – key principles

- First published in March 2014 - 1 year pilot phase
- Increased transparency and access to relevant (safety) information
- Complements and links to the EPAR summary and Product Information

- Target audience:
  - *Primarily – stakeholders with professional interest in medicines*
  - *Secondary – useful resource for any member of the public who wants to know more about his/her medicine*

Example: Sirturo

The 1-year pilot phase

- Scope:
  - *New medicines recommended for approval during 2014*
  - *Does not cover so far:*
    - *Medicines already authorised*
    - *Updates to the RMP*
- Acquire and analyse experience during this year
- Discuss such experience with stakeholders (patients, healthcare professionals, EU regulators and industry)
- Decide then the way forward

Main questions to be addressed during the pilot phase

- Is it useful, worth the investment? Or can the summaries be substituted by existing information?
  - Information in the summary of the medicine (EPAR summary) and the assessment report
- What should be the target audience?
- Is the format and content adequate to the target audience?
- Does the interest justify that the summaries are translated into all EU languages?
- Should patients and healthcare professionals revise the draft summaries while they are being prepared?

Thank you