



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Publication of Risk Management Plan (RMP) summaries:

Analysis of the experience of the 1-year pilot phase



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An agency of the European Union





Outline

- **Background on RMP summaries and pilot phase**
- Objectives of the analysis
- Results
- Conclusions and way forward

Why produce a Summary of the Risk Management Plan?

- New information resource:
 - increased **public access** to relevant information on medicines,
 - in line with EU **legislation**
- A **living** document
- **Complementary** to other information on medicines:
 - Product information (SmPC and Package Leaflet)
 - Summary of the medicine (EPAR summary)
 - Assessment report

RMP summary – pilot phased implementation

- 1 year pilot phase – started March 2014
- For all medicines authorised since March 2014
- Medicines already authorised & RMP updates: not included

Information published at the time of authorisation

EPAR Summary

- Plain-language summary of benefits and risks of the medicine and how was assessed

Lay audiences

Product Information

- Conditions of use of the medicine:
 - SmPC - *for health professionals*
 - Package Leaflet - *for patients*

Lay audiences

Summary of risk management plan

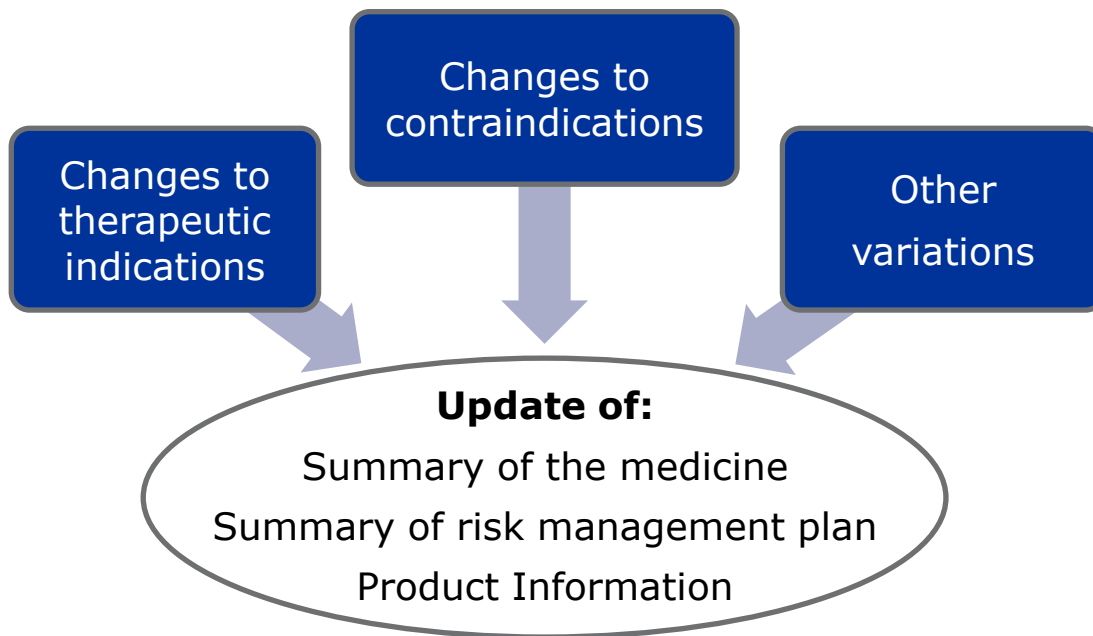
- Summary of the medicine's safety profile and measures to prevent or minimise its risks

Assessment report

- The full scientific evaluation



Post-authorisation Changes to existing information



Structure of RMP summaries (pilot phase)

- Overview of the disease & disease epidemiology
- Summary of benefits
- Summary of main safety concerns:
 - Important identified and potential risks and what is missing
- Summary of risk minimisation measures for each safety concern
- Planned post-authorisation development plan (safety and efficacy)



Summary of risk management plan

EMA/329000/2014

Plegridy
peginterferon beta-1a

Next tab »

This is a summary of the [European public assessment report \(EPAR\)](#) for Plegridy. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Plegridy.

For practical information about using Plegridy, patients should read the [package leaflet](#) or contact their doctor or pharmacist.

Expand all items in this list

- What is Plegridy and what is it used for?
- How is Plegridy used?
- How does Plegridy work?
- What benefits of Plegridy have been shown in studies?
- What are the risks associated with Plegridy?
- Why is Plegridy approved?
- What measures are being taken to ensure the safe and effective use of Plegridy?
- Other information about Plegridy

Name	Language	First published	Last updated
Plegridy : EPAR - Summary for the public	EN = English	31/07/2014	

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Name	Language	First published	Last updated
Plegridy : EPAR - Risk-management-plan (English only) summary	(English only)	31/07/2014	

This EPAR was last updated on 31/07/2014 .

More details are available in the summary of product characteristics

Summary of the risk management plan (RMP) for Plegridy (peginterferon beta-1a)

This is a summary of the risk management plan (RMP) for Plegridy, which details the measures to be taken in order to ensure that Plegridy is used as safely as possible. For more information on RMP summaries, see [here](#).

This RMP summary should be read in conjunction with the EPAR summary and the product information for Plegridy, which can be found on [Plegridy's EPAR page](#).

Overview of disease epidemiology

Plegridy is used to treat the relapsing-remitting form of multiple sclerosis (MS). MS is a disease in which the body's immune system malfunctions and attacks parts of the central nervous system (the brain and spinal cord). This causes inflammation and destroys the protective sheath around the nerves, leading to progressive disability. Onset of MS is usually between the ages of 20 and 40 years, and rarely occurs in children or in adults 60 years and older. Approximately twice as many women than men have MS. About 85% of people with MS initially have the relapsing-remitting form, characterised by occasional flare-ups of the disease, called relapses, in between periods when the disease is inactive. About half of patients with MS relapses go on to develop progressive MS within 10 to 20 years after diagnosis. The total number of people with MS worldwide is estimated to be between 2 to 2.5 million, and approximately 93 of every 100,000 persons in Europe have MS.

Summary of treatment benefits

Plegridy is a medicine that contains the active substance peginterferon beta-1a. It is available as a solution for injection under the skin. The peginterferon beta-1a in Plegridy is a 'pegylated' interferon (a protein naturally produced by the body), which is removed from the body at a slower rate than other interferons, allowing the medicine to be given less often.

Plegridy was investigated in 1,516 patients in one main study, in which it was compared with placebo (a dummy treatment). Plegridy showed about a 30% reduction in the number of relapses in patients with relapsing-remitting MS compared with placebo, which is comparable to the effect of other MS



At the time of the authorisation

Summary of risk management plan

Summary of safety concerns

Important identified risks

Important potential risks

Risk	What is known
Cardiac (heart) disorders	Worsening of cardiac disease has been reported in patients receiving interferon beta. If patients develop heart problems, which can cause symptoms such as chest pain (angina), particularly after any activity; swollen

Missing information

Risk	What is known
Use in paediatric patients	Plegridy has not been studied in patients under 18 years of age.
Use in older patients	Plegridy has not been studied in patients over 65 years of age.
Effects on pregnancy and use in breastfeeding women	Treatment with Plegridy should not be started in pregnant patients. Patients who could get pregnant should use contraception during treatment with Plegridy. Patients planning to have a baby, or who become pregnant while using Plegridy, should tell their doctor to discuss possible treatment discontinuation. Patients wishing to breastfeed while using Plegridy should speak with their doctor first.

Preventability

Patients should not use peginterferon beta-1a if they are allergic to peginterferon beta-1a, interferon beta-1a, or any of the other ingredients of Plegridy. Patients should contact a doctor immediately if they experience symptoms of an allergic reaction. Peginterferon beta-1a should be discontinued if serious hypersensitivity reactions occur.

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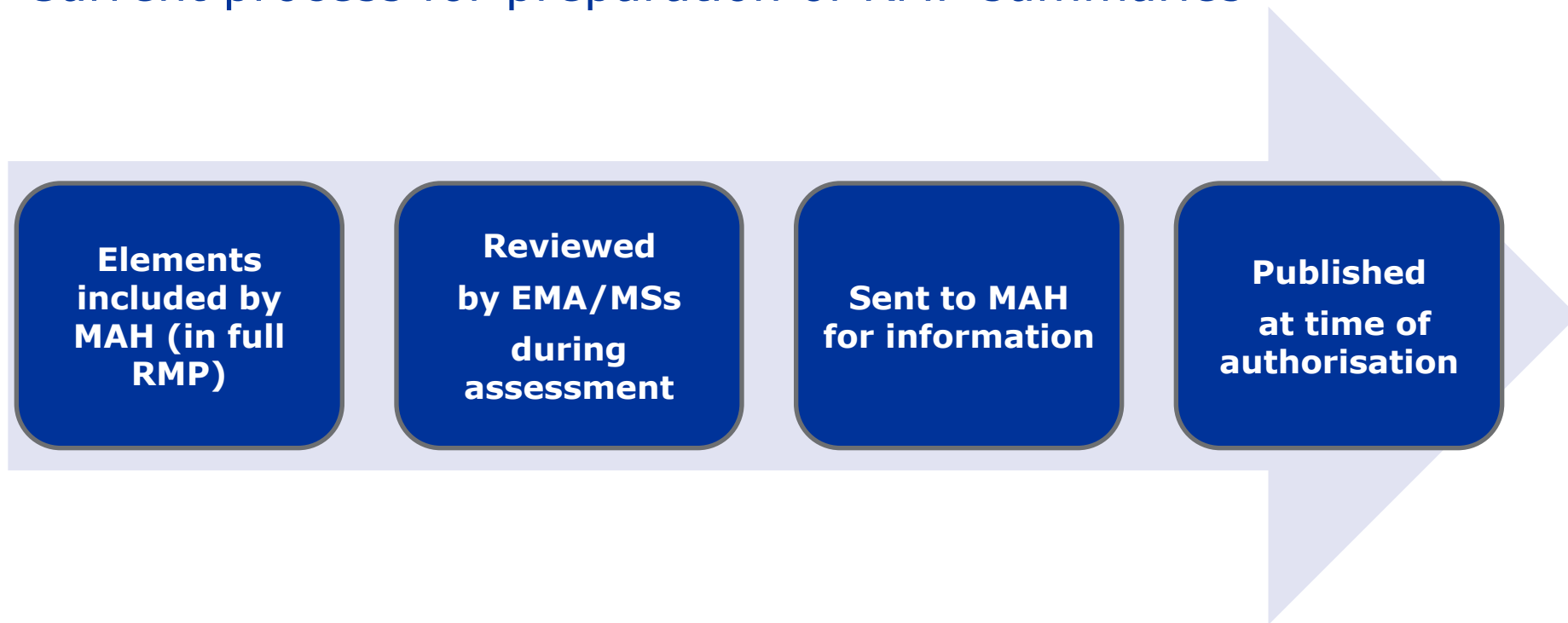
Patients should call a doctor immediately if they get yellowing of the skin or eyes (jaundice), itch all over the body, bruise easily or feel sick or vomit. These may be signs of a possible liver problem. Doctors may do blood tests from time to time to make sure that the patients liver and blood values are within the normal range.

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The doctor may do blood tests from time to time to make sure that a patient's blood count is within the normal range. Patients should speak with their doctor, pharmacist or nurse before injecting peginterferon beta-1a if they experience infections or bleeding. They may get worse while using peginterferon beta-1a.



Current process for preparation of RMP summaries





Outline

- Background on RMP summaries and pilot phase
- **Objectives of the analysis**
- Results
- Conclusions and way forward



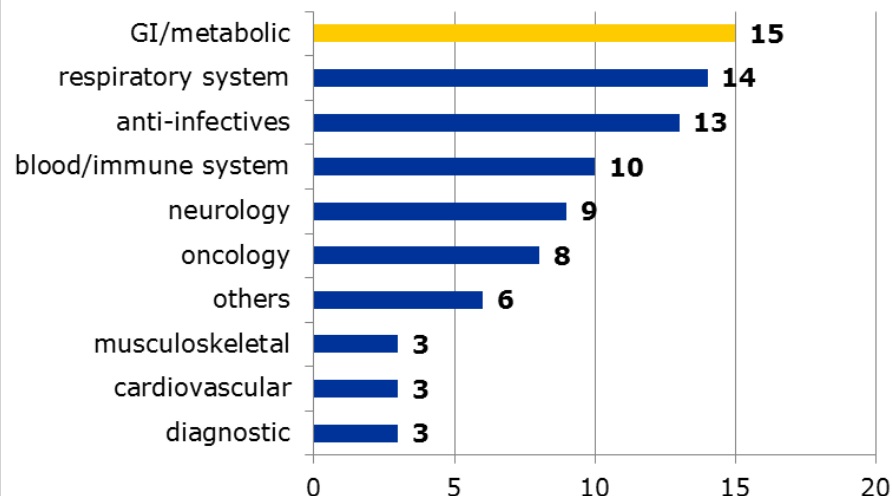
Objectives of the analysis

- Confirm external interest and usefulness of RMP summaries
- Define the audience
- Improve format and content - based on needs and expectations of audiences
- Streamline the process for preparation

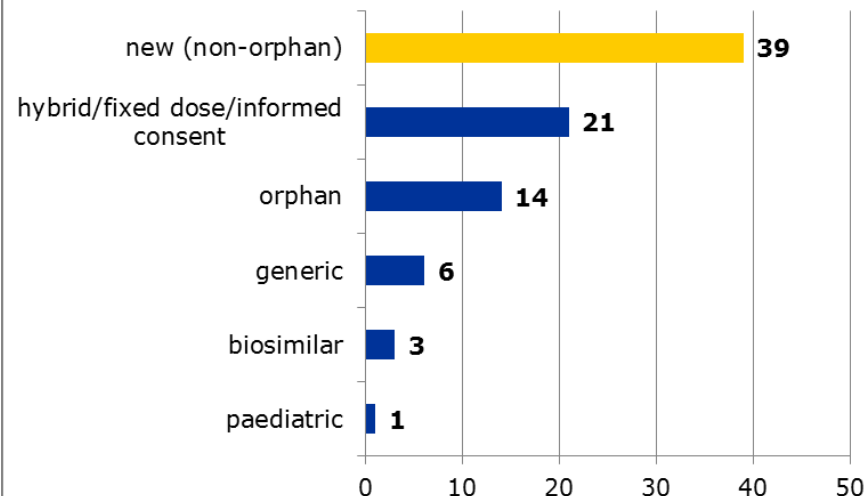


84 RMP summaries published so far

RMP summaries *per* therapeutic area



RMP summaries by type of application



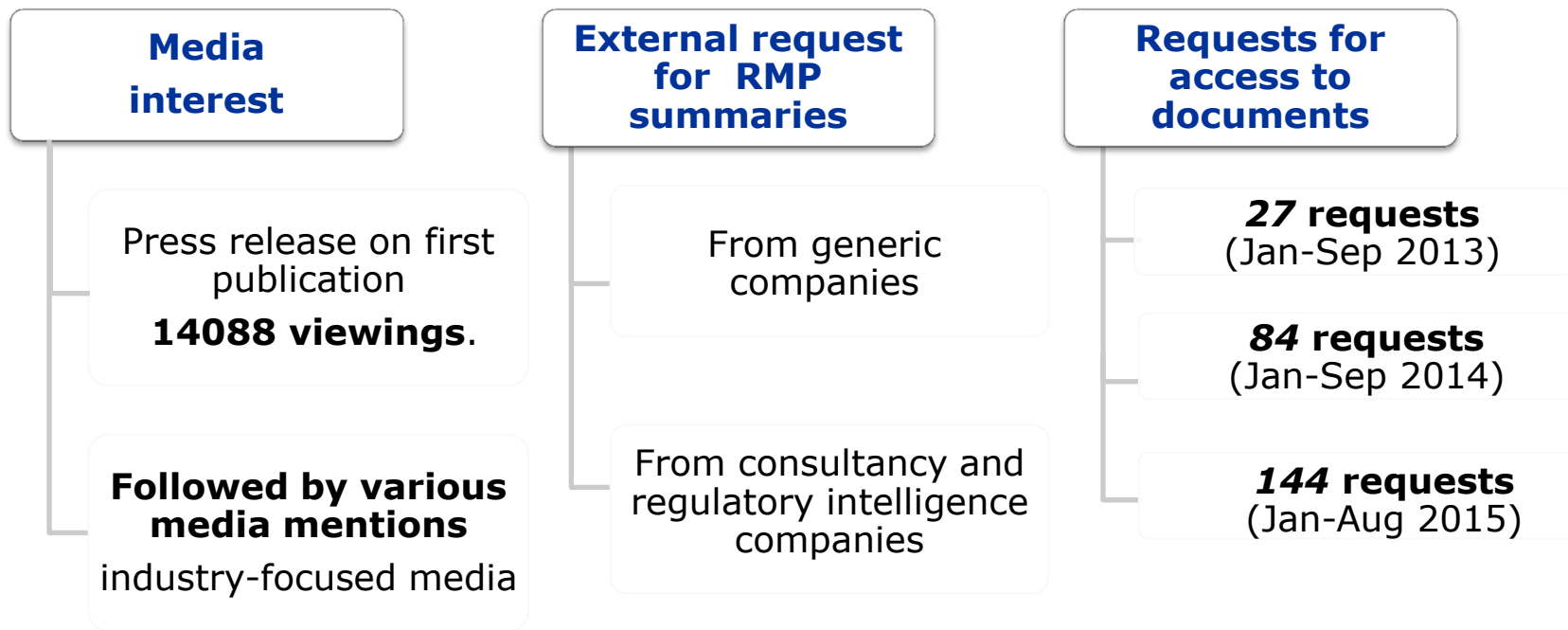


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Results from pilot testing

Suggested interest





Suggested interest

Example of downloads from EMA's website

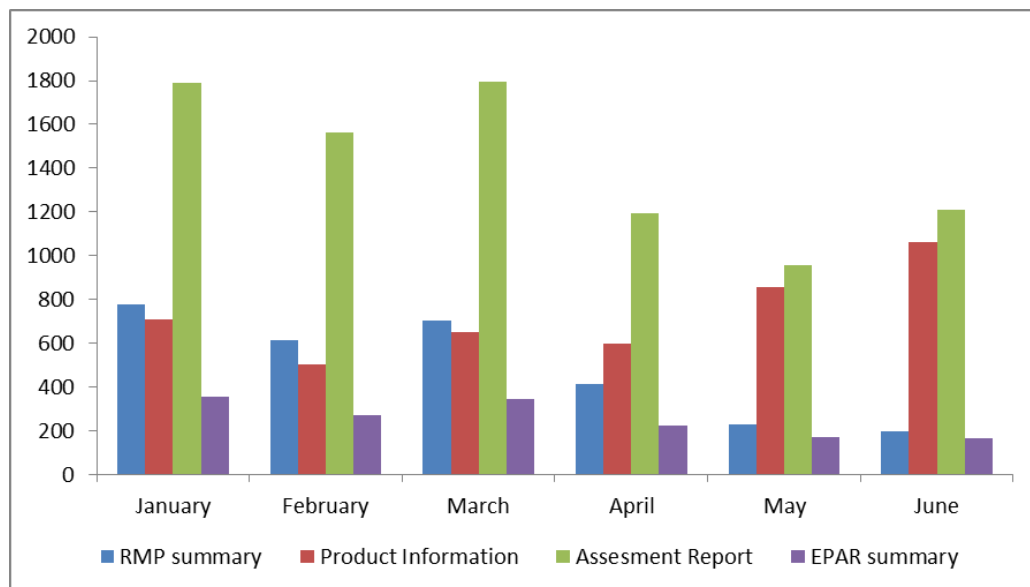
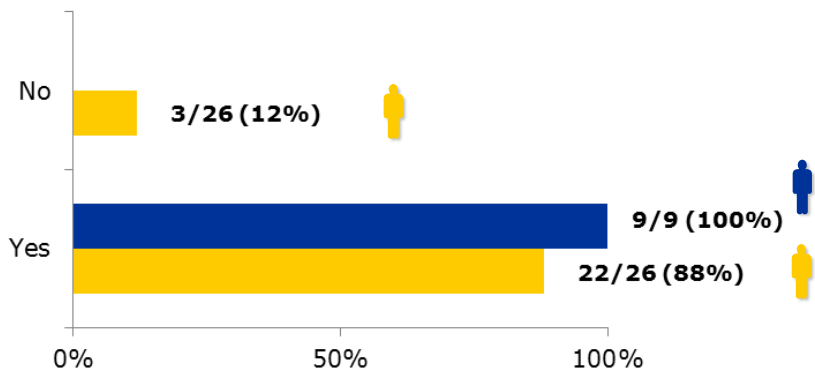


Illustration of the number of downloads of the different communication materials for one of the products in the pilot

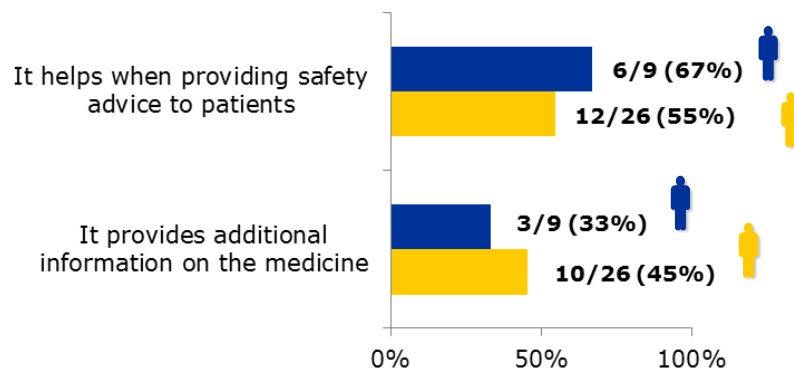


Healthcare professionals' interest in RMP summaries

Would you be interested in reading the RMP summary of medicines you may prescribe/use?



If yes, could you please state why?



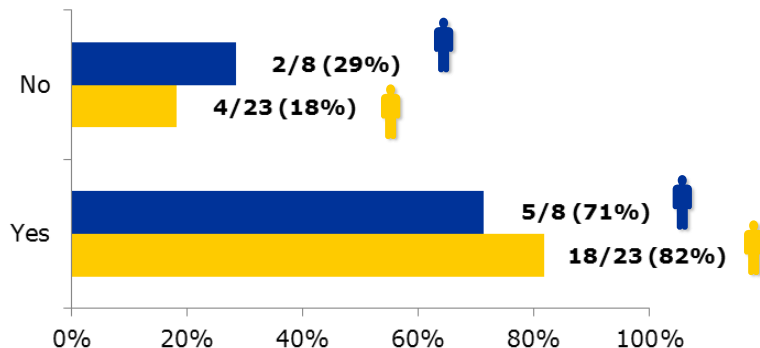
Healthcare professionals' organisations



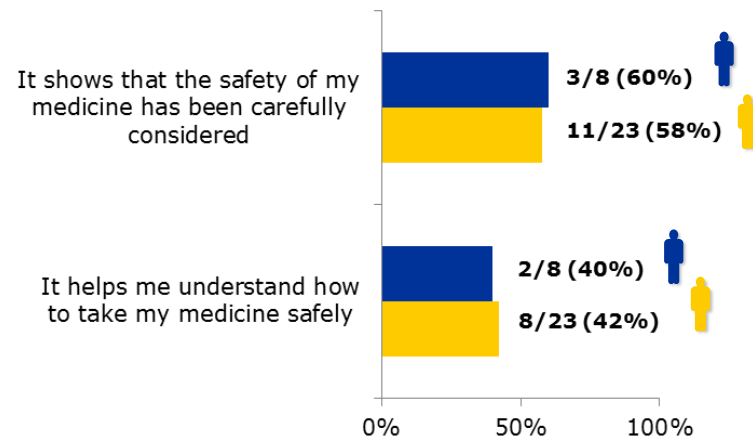
Individual healthcare professionals

Patients' and consumers' interest in RMP summaries

If you were taking this medicines, would you be interested in reading the RMP summary?



If yes, could you please state why?



Patient and Consumers' organisations



Individual patients

Feedback from industry

- *Do you think that making summaries of RMP publicly available is useful, taking into consideration the information on medicines already available?*
- *Request for feedback on current format & content/any missing information/any proposal for improvement?*
- *Request for feedback on proposed criteria for updates*



Feedback from industry

Limited analysis which does not allow to draw firm conclusions: few responses from individual companies and not an overall position from the different associations consulted

- In general industry welcomes transparency
- Package leaflet is the most relevant information for patients
- The audience of RMP summaries can be fine-tuned
- Mixed views regarding usefulness for industry
- Some suggestions for improvement of the template



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Conclusions

- Information on RMP summaries adds value and complements already existing information:
 - Interest from stakeholders has been seen
 - Up-to date 'living' document
 - Information is otherwise fragmented or soon outdated
- Companies will be able to use the RMP summary when submitting a RMP for a generic product, as the RMP summary of the reference medicinal product will contain the elements they need for submission.



Conclusions

- Need to revise template – format, content and structure simplification
- Need to implement process simplification
- Need to start publishing updates and back-log

Way forward – Proposed target audience

- Refocus the audience:
 - Documents will not be written in lay language
 - However, information will still be clearly written and presented, but using technical terms as necessary
 - For patients, priority given to 'Package Leaflet' and 'EPAR summary' as primary source of information
 - However, RMP summary remains a secondary source of information, for those patients who want to know more about their medicines

Way forward – Content & Structure

Template simplification

- RMP summary to describe all risk information in the full RMP
- Information should be directly relevant to risk and risk reduction and should avoid duplication of information described elsewhere.
 - However, the RMP summary should continue to be presented in the context of the medicine's benefit
- Template simplification by mapping it to the full RMP, allowing information to be easily extracted from the main document
- Transparency by maintaining post-authorisation development plan

Way forward – Process simplification

- Simplify process, as much as possible, and minimise resource investment
- Fully integrated in the preparation and publication of EPARs
- Consistency on the way information on RMPs is published at EU level

Way forward – Proposed criteria for updates

In revised GVP Module V

- The RMP summary will be updated when important changes are introduced into the full RMP
- Changes will be considered important if they relate to the following:
 - New important risks or important changes to a known risks
 - Inclusion or removal of 'additional risk minimisation measures'
 - Major change to the pharmacovigilance plan

Next steps

- Template update - in parallel to update of the full RMP template and GVP Module V
- Full implementation in 2016, once new template is published
- Further research to measure:
 - The uptake of RMP summaries by different audiences
 - Acceptability of RMP summaries
 - Impact of RMP summaries



Thank you for your attention

Further information

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