



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Publication of Risk Management Plan (RMP) summaries:

Analysis of the experience of the 1-year pilot phase

PCWP meeting – November 2015



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
- **Complements** other information on medicines:
 - Product information (summary of product characteristics – SmPC – and package leaflet)
 - Summary of the medicine (EPAR summary)
 - Assessment report

RMP summary – pilot phased implementation

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

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

Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Slow heartbeat (bradycardia)	In studies to license the medicine most cases of slow heartbeat did not require any treatment and resolved.	Heart rate and blood pressure should be measured before starting treatment with Intuniv and then every week while the dose is being adjusted. When the right dose has been established, heart rate and blood pressure should be measured at least every 3 months for the first year and then at least twice a year.
Fainting (syncope)	In clinical studies most cases of fainting did not require treatment and resolved. However, fainting suddenly can result in a fall and injury.	Heart rate and blood pressure should be measured before starting treatment with Intuniv and then every week while the dose is being adjusted. When the right dose has been established, heart rate and blood pressure should be measured at least every 3 months for the first year and then at least twice a year.

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Process for preparation of RMP summaries during pilot phase

Company includes elements for RMP summary in full RMP

Draft RMP summary prepared by EMA

Draft RMP summary reviewed by EMA/member states

RMP summary sent to company for information

RMP summary published at time of authorisation

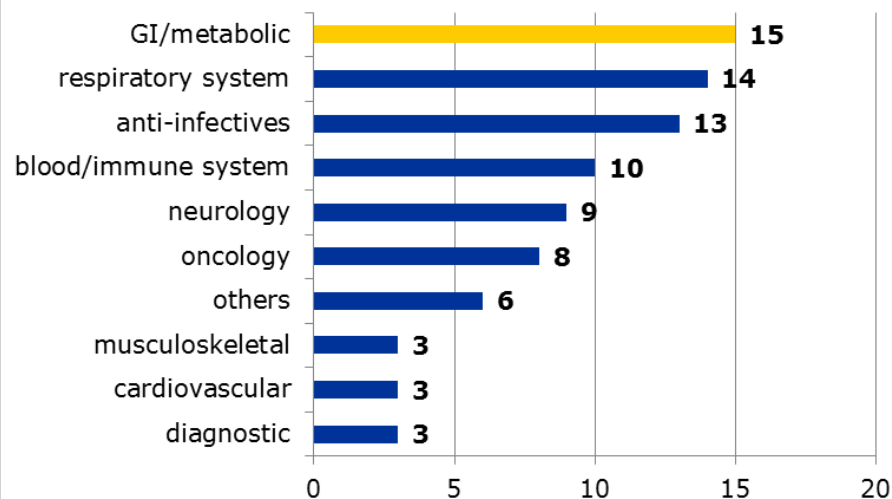
Objectives of the analysis

- 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

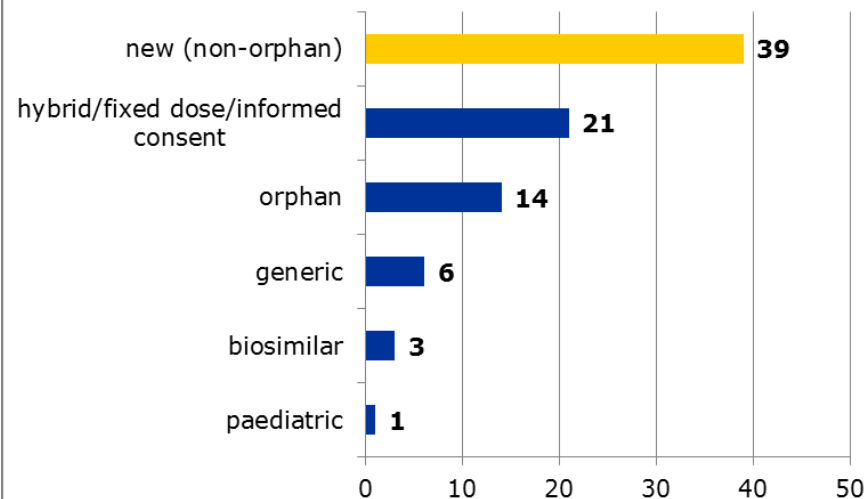


84 RMP summaries published so far

RMP summaries *per* therapeutic area

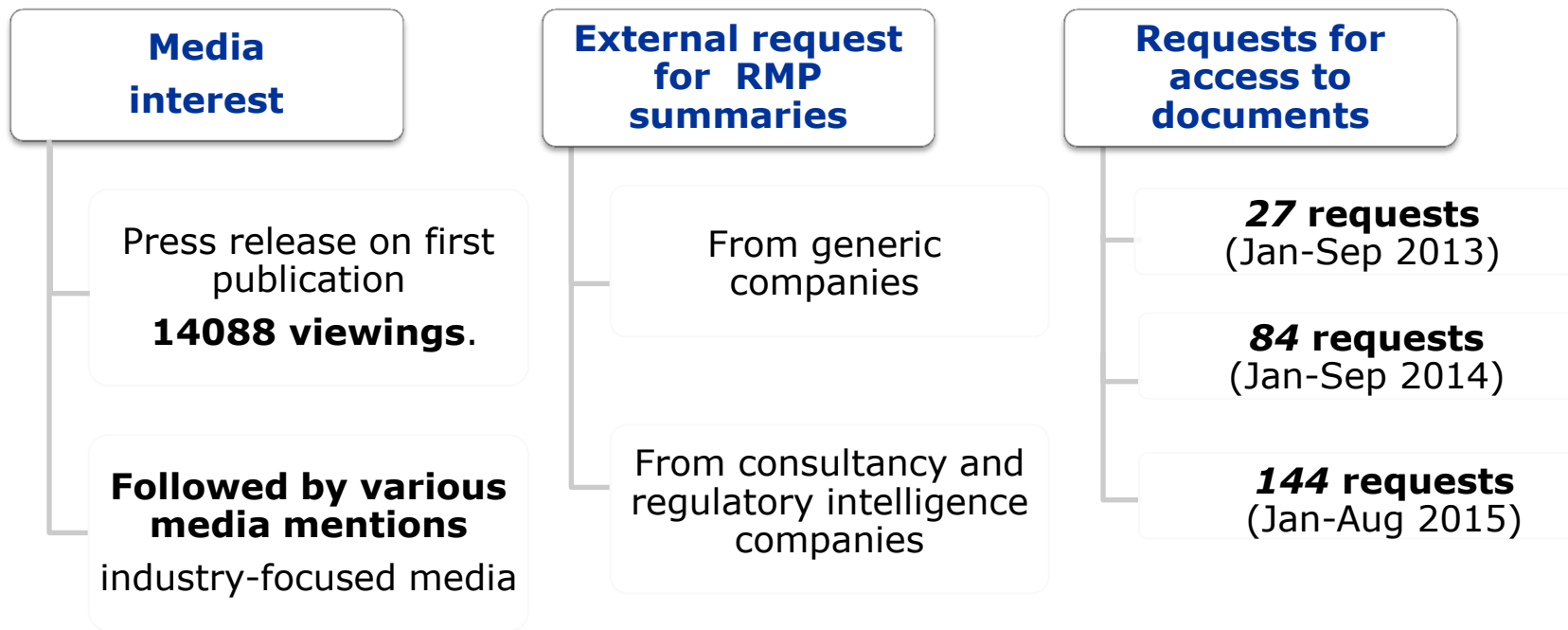


RMP summaries by type of application



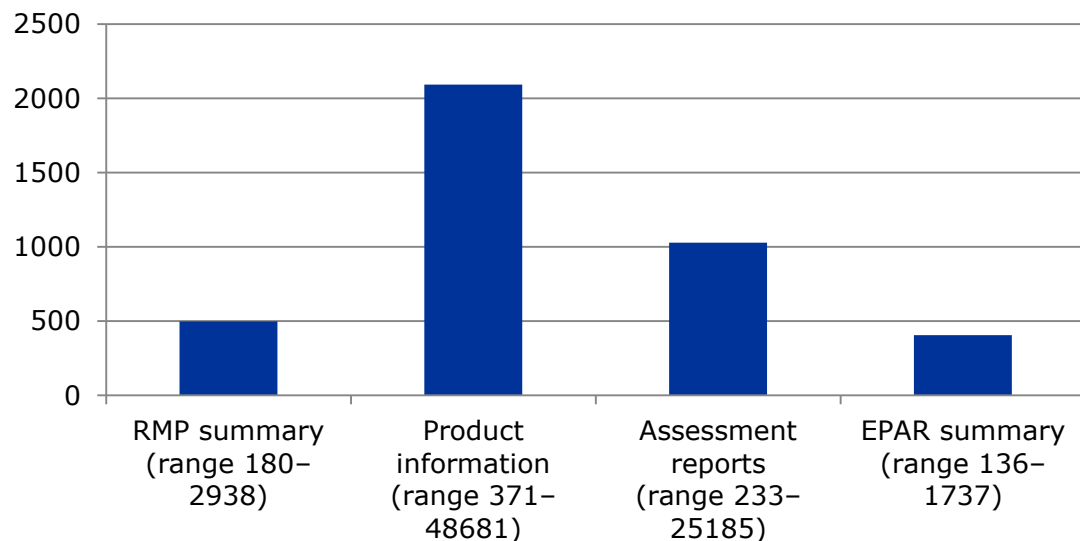
Results from pilot testing

Suggested interest



Suggested interest

Median downloads of different communication materials for 45 new medicines



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



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 on usefulness for industry (generic companies compared to innovators)
- Some suggestions for improvement of the template



Conclusions

- Information on RMP summaries adds value and complements existing information:
 - Interest from stakeholders has been seen
 - Up-to date 'living' document
 - Information is otherwise fragmented or soon outdated

Way forward – refocused audience

- Wide interest from different audience groups - each with different needs and expectations of the document.
- Improvements needed to current format and content - so they meet these needs and become a useful information resource for the different users.
- 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.

Way forward – content and structure

Template simplification

- Presentation and layout to be simplified - unnecessary information removed.
- information to be further contextualised - to clearly explain the purpose of the RMP and how it relates to other information, in particular the product information.
- Plain-language approach to be used.
 - Plain-language approach includes organising information logically (and giving priority to action points), breaking information into digestible chunks, and using layout that improves readability of a document
 - However, this does not mean that technical terms should be avoided.

Way forward – content and structure

Template simplification

- RMP summary to describe all risk information present in the full RMP
- Information should be directly relevant to risk and risk reduction and should not duplicate 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 transposed from the full RMP
- 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
- Living document

Next steps

- RMP summary template update – Part of the full RMP template (Part VI) and aligned with EU Guidance (GVP Module V 2.0)
- Implementation as of 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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