EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMA Q&A – practical transitional measures - November update

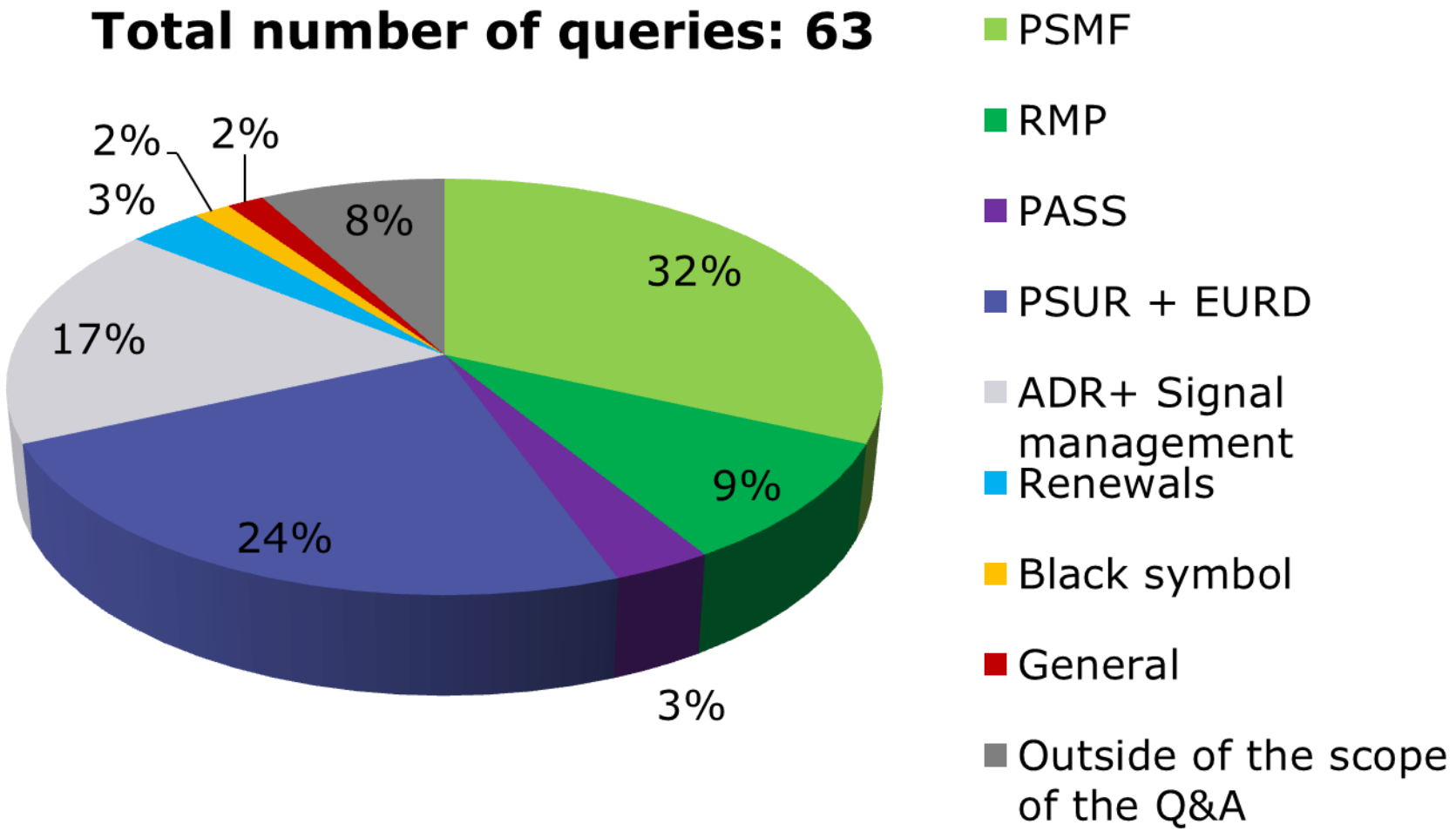
Stakeholders meeting – 8 November 2012

Presented by: Christelle Bouygues
Regulatory Affairs

Background

- Third update since 1st publication in May 2012 -> planned end November 2012
- Aim is to keep providing updated practical guidance on operational aspects of the new requirements of the PhV legislation
- Basis for the update:
  - Mailbox QandA-PV-legislation@ema.europa.eu
  - Frequently asked questions received through other routes (network, other mailboxes, etc)

Analysis of Q&A PhV mailbox



Scope of 3rd update

- Pharmacovigilance system master file (PSMF) & PhV system summary
- Risk Management Plan (RMP)
- Post-Autorisation Safety Study (PASS)
- Periodic Safety Update Reports (PSUR) and European Union Reference Dates (EURD) list
- Product information and black symbol
- Adverse Drug Reaction reporting / signal management
- Literature monitoring
- Renewal

} NO update foreseen

PSMF & Pharmacovigilance system summary

- MA without yet a DDPS → Is it possible to introduce a new DDPS after 2 / 21 July 2012 ?
- MA with existing DDPS → Is there a need to maintain up-to-date the existing DDPS?
- Transfer of MA → Is it possible to introduce a new DDPS where one already exists?
- PSMF number → Is the PSMF number required in Module 1.8.1?

PSMF & Pharmacovigilance system summary

- Change in QPPV and introduction of PhV system summary → Is it one or two variations?
- Introduction of PhV system summary to MAs with and without DDPS → Is it one or two groups of variations?

Risk Management Plan (RMP)

- When will the RMP template be published ?
- New RMP format and content **mandatory** as of **10 January 2013**

Post-Autorisation Safety Study (PASS)

- Reference to newly published guidance on the format of non-interventional PASS **protocol**

  http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/10/WC500133174.pdf

- Guidance on the format of non-interventional PASS **abstract** and **final study results report** -> planned to be provided

  In the meantime, use the structure provided in the Commission implementing Regulation (Annex III).

Post-Autorisation Safety Study (PASS)

- Clarifications on **EU PAS register** (upgrade of the ENCePP E-Register)
  - Background for such requirement to register **non-interventional** PASS imposed and those initiated, managed or financed voluntarily
  - Technical guidance to register in EU PAS register / ENCePP E-Register

PSURs and EURD list

- Update with reference to the publication of the **1st EURD list** on 1st October -> binding 1st April 2013
- Reference to **new PSUR statements** agreed with EC to be introduced in the MA
  - **QRD update** in November -> for a roll-out with the November CHMP opinions
  - Publication of **guidance for implementation** of this 2012 QRD update

PSURs and EURD list

- Further clarifications on requirements for generics and WEU during the transitional period until the EURD list becomes binding
- Clarifications on the long-term DLPs
- Clarifications on PSUR requirement for a combination of active substance when only one substance is listed
- Clarifications on PSUR requirements for marketing autorisation applications under 'old' legal basis

Product information & black symbol

- Reference to Annex II / QRD template update **in November 2012**
- Reference to planned QRD update **in 2013**

ADRs

- Clarification that Q&A on implementation of electronic exchange of individual case safety reports (ICSRs) (EMA/46003/2011, v. 5.4), Vol 9A

  ⇨ NO longer relevant as replaced by the GVP modules published

Conclusions

- Each update is made in collaboration with the Member States / CMDh and with consultation of the EC
- Continue to address questions
- Likely to be more updates

THANK YOU

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Back-up slides

Annex II – PSUR statements

- **Periodic safety update reports**

[MAA with a substance NOT in EURD list or listed but different PSUR frequency]

<The marketing authorisation holder shall submit the first periodic safety update report for this product within {*specify number of months*} months following authorisation. Subsequently, the marketing authorisation holder shall submit periodic safety update reports for this product in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal.>

[MAA with a substance in EURD list + generics/WEU, PSURs required]

<The marketing authorisation holder shall submit PSURs for this product in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal.>

[Generics /WEU, PSURs not required]

<At the time of granting the marketing authorisation, the submission of periodic safety update reports is not required for this medicinal product. However, the marketing authorisation holder shall submit periodic safety update reports for this medicinal product if the product is included in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal.>