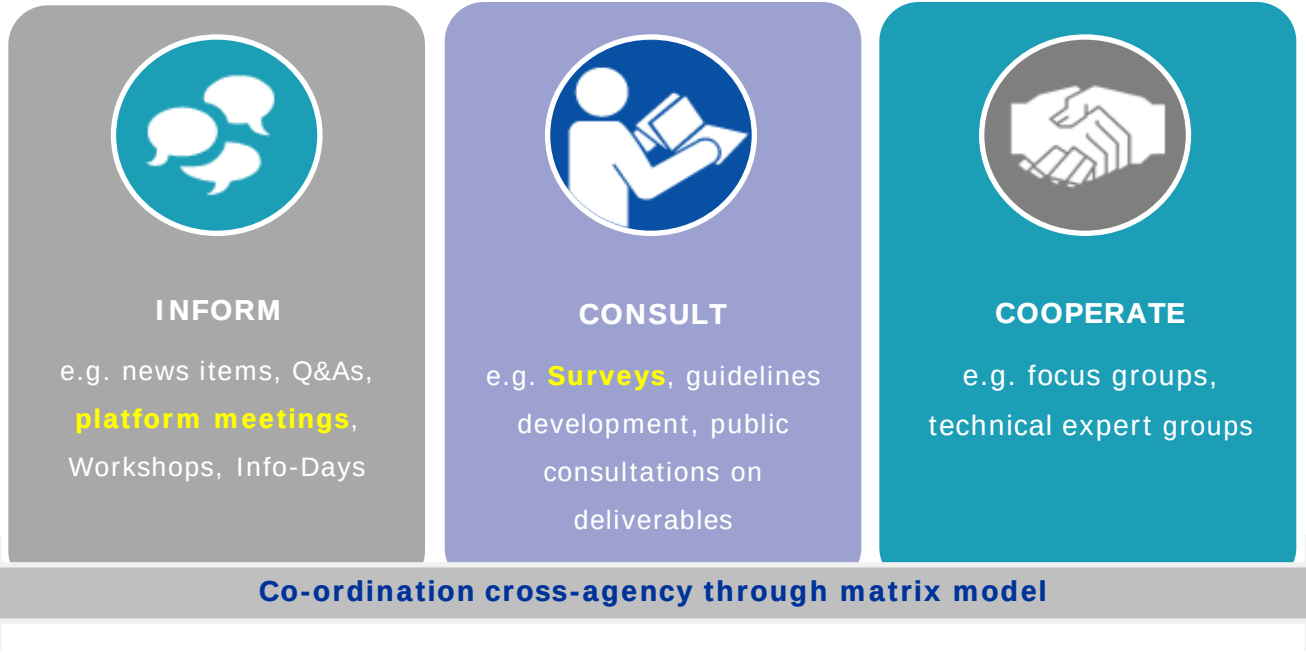
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA survey on ‘Centralised post-marketing authorisation procedures’ 2015

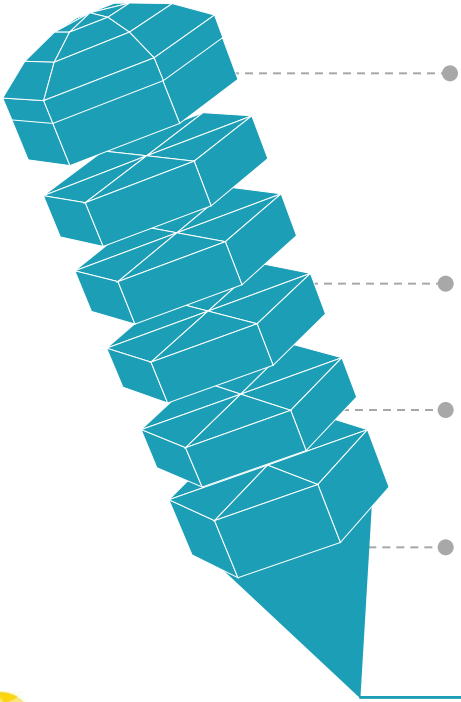
24 April 2015: Industry stakeholder platform meeting on the operation of the centralised procedure

Presented by Marie-Helene Pinheiro on 24 April 2015
Industry Stakeholders Liaison; Stakeholders & Communication Division

Interaction between EMA and industry stakeholders



Survey objectives



Enhance industry stakeholders' understanding of the EU medicines regulatory framework and enrich EMA's understanding of issues that are pertinent from an industry perspective;

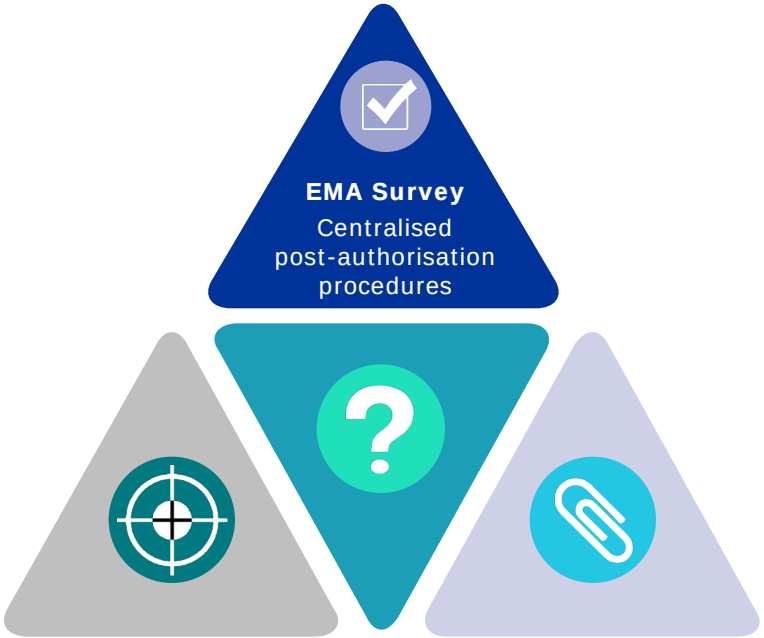
Encourage direct feedback from MAHs on certain post-marketing authorisation procedures (Type IB/II/PSURs);

Enable continuous improvement of processes and guidance related to centralised procedures;

Further increase transparency in interactions between EMA and industry stakeholders.

What do we aim to achieve?

Survey scope & structure



SCOPE

- *Post-authorisation marketing authorisation*
- *Type IB/II/PSURs*
- *Aims at sampling at least 10% of annual number of applications; period 01/04/15 – 30/09/15*
- *Once notification/opinion received*

QUESTIONS

- *~25 questions per procedure type*
- *10 minutes to complete*

SUBJECT MATTER

- *Pre-submission/Validation/Evaluation phase*
- *Qualitative aspects*
  EMA Guidance /Committee Reports/RSI/ Recommendations etc…
- *General aspects*
  Communication/ Interaction (satisfaction/timeliness/communication channels)

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EMA Survey on centralised post-authorisation procedures

PSURs (CAPs)

Evaluation phase

*** 20. Please rate the following statement**

	Strongly disagree 1	2	3	4	Strongly agree 5
The conclusions/regulatory actions were justified in the report	○	○	○	○	○

*** 21. Please rate the following statement**

	Strongly disagree 1	2	3	4	Strongly agree 5
The assessment report was clear on which issues needed an immediate response	○	○	○	○	○

*** 22. Where applicable, the comments to the product information were sent early enough to facilitate discussion during the procedure**

▼

*** 23. When did you receive your CHMP opinion?**

▼

Prev Next

Response rate status

EMA

47 Procedures completed (IB/PSURs (CAPs))

INDUSTRY

10 Procedures completed

Your input is key! **Click!**

- *To ensure survey results are representative and to enable a productive and open dialogue, high response rates are needed.*
- *Please continue to engage.*
- *For queries related to the survey, contact us at: EMACentralisedSurvey@ema.europa.eu*

Expected timeframe & reporting

Post-authorisation survey

01. *Monitor response rates (on-going);*

02. *Analyse survey results (October 2015);*

03. *Present survey results at the next centralised platform meeting (November/December 2015 – tbc);*

04. *Publish survey report on centralised post-marketing authorisation procedures (end of 2015).*

Initial MAA survey

01. *Kick-off preparatory work on a survey focusing on initial centralised evaluation (Summer 2015);*

02. *Launch survey on initial centralised evaluation (q1 2016).*

Special thanks & acknowledgements

EFPIA
For their input to scope and survey objectives

Thank you for your attention

Further information

EMACentralisedSurvey@ema.europa.eu — For queries related to the survey on post-authorisation procedures

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