EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

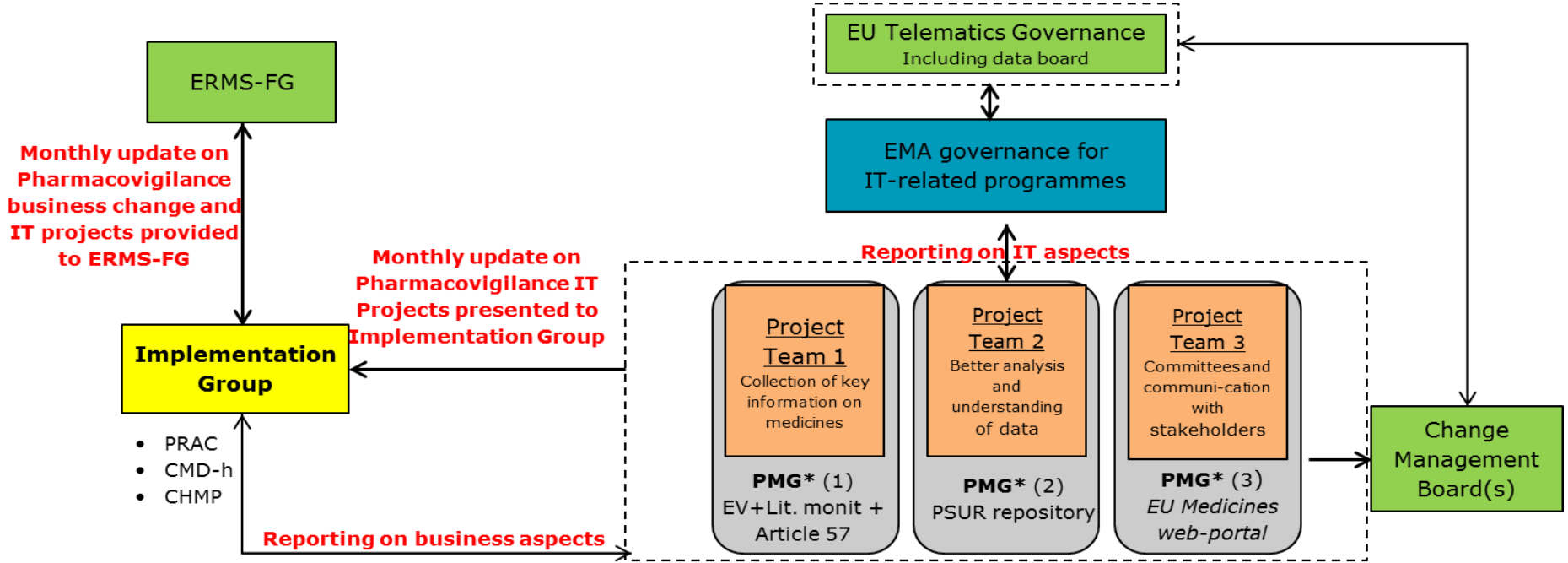
EU network pharmacovigilance governance

7th Industry Stakeholder Platform

Presented by Peter Arlett on 4 April 2016
Head of Pharmacovigilance Department

Current structure

- The current Pharmacovigilance governance structure was adopted at the HMA meeting in November 2014 to deliver robust governance from an integrated business and IT perspective.



Status in 2016: from implementation to operation

Implementation: to do

- The new Eudravigilance sytem, with the EV functionalities audit scheduled in Q3 2016 and move to centralised reporting in Q3 2017;
- Implementation of PSUR repository mandatory use as of 13 June 2016;
- Launch of the PRAC public hearings (anticipated Q3 2016)
- Launch of the full-scope EU Medicines Web-portal – for development beyond 2016.

Operation: to do

- Implementation of recommendations from the SCOPE Joint Action that requires coordination at EU level;
- Oversight of the performance of the EU system and measure its impact;
- Follow up on a major process improvements (including guidelines and templates);
- Focus on stakeholder engagement and communications;
- Support innovation through real-world evidence of medicines.

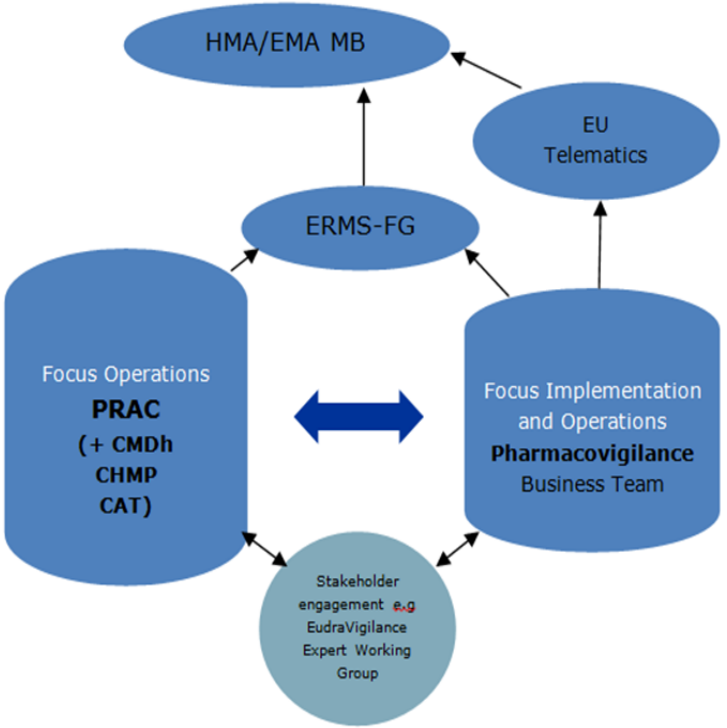
New governance for 2016 and beyond: principles

Principles:

- EU pharmacovigilance delivers positive impact for health and innovation
- Reduce the number of structures – deliver efficiency and effectiveness
- EU network partnership underpinning collaboration and engagement with stakeholders
- Optimise the capacity within the system building on SCOPE Joint Action
- Bring together good practice for all medicines however they are authorised
- Business leadership for communications and technology supporting pharmacovigilance
- Look forward and meet the challenges to come

EU Pharmacovigilance network governance in 2016

- EU Network has revised the current structure and streamlined the governance driven by effectiveness and efficiency;
- The operations will be overseen by PRAC (in collaboration with CHMP, CMDh, CAT) and the implementation and key operational issues will be supported by a dedicated pharmacovigilance business team
- Starts April 2016



Industry interface

- Quarterly industry platform meetings with EU associations
- Engagement at conferences and association meetings
- EudraVigilance Expert Working Group
- PSUR Repository Advisory Group
- [Article 57 Implementation Working Group]
- ……..

Thank you for your attention

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