EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Follow-up on Medication Error Action Plan

PCWP/HCPWP joint meeting 25 February 2014, London

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An agency of the European Union

Medication errors - background (1/2)

- Medication errors resulting in harm have a major public-health impact
- Medication error refers to any unintended error in the prescribing, dispensing or administration of a medicinal product while in the control of the healthcare professional, patient or consumer, according to Good Pharmacovigilance Practices (GVP).
- New pharmacovigilance legislation requires
  - Reporting of ADRs associated with medication errors to EudraVigilance [DIR 2010/84/EU amending DIR 2001/83/EC, Recital (5) and (17), Article 1(11) and 101(1)]
  - Member States to liaise with national patient safety organisations [Directive 2001/83/EC Article 107a (5)]

DIR Recital (5) and (17)

- *The definition of the term 'adverse reaction' should be amended to ensure that it covers noxious and unintended effects resulting not only from the authorised use of a medicinal product at normal doses, but also from medication errors and uses outside the terms of the marketing authorisation, including the misuse and abuse of the medicinal product.*
- *Member States should operate a pharmacovigilance system to collect information that is useful for the monitoring of medicinal products, including information on suspected adverse reactions arising from use of a medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, including overdose, misuse, abuse and medication errors, and suspected adverse reactions associated with occupational exposure.*

DIR Article 107a(5)

- *Member States shall ensure that reports of suspected adverse reactions arising from an error associated with the use of a medicinal product that are brought to their attention are made available to the EudraVigilance database and to any authorities, bodies, organisations and/or institutions, responsible for patient safety within that Member State.*
- *Member States shall also ensure that the authorities responsible for medicinal products within that Member State are informed of any suspected adverse reactions brought to the attention of any other authority within that Member State. These reports shall be appropriately identified in the forms referred to in Article 25 of Regulation (EC) No 726/2004, i.e. standard web-based structured forms for the reporting of suspected adverse reactions by healthcare professionals and patients.*

Medication errors - background (2/2)

- **EMA Workshop on medication errors** held in London, 28 February – 1 March 2013
  - Attended by regulators, national patient safety agencies, patient and healthcare professional representatives, academia and the pharmaceutical industry
  - Outcomes of workshop:
    - Medication errors are a global concern
    - Medication errors need to be addressed in the broader context of patient safety
    - Need for collaboration and synergies to be leveraged with different stakeholders
  - Workshop report published on EMA website:

    http://www.ema.europa.eu/docs/en_GB/document_library/Report/2013/05/WC500143163.pdf

Key recommendations from workshop

- Systematic assessment and prevention of the risk of medication errors during the product life-cycle
- Establishment of collaborative relationships between national patient safety authorities, national regulators, the EMA and the European Commission
- Active engagement and capacity building with patient consumer groups and healthcare professionals to improve safe medication practices
- Harmonisation and further development of terminologies and definitions at EU and international level
- Development of new methods to identify medication errors from a patient safety and pharmacovigilance perspective through data pooling and analysis
- Support to research into safe medication practices

...based on these recommendations

- It is recognised that many initiatives linked to patient safety will be local/national
- EU actions should focus on the regulatory role to
  - Complement/facilitate Member State activities or
  - Directly improve medicines regulation
- Aim is to **support availability of tools to the EU network**:
  - To make optimal use of existing regulatory tools (improve risk minimisation and prevention trough better and clearer product information)
  - Comply with legislation (reporting cases of medication errors causing harm nationally and at EU level for better learning)

→ **Specific actions were proposed to Heads of Medicines Agencies (HMA) that respect these criteria**

HMA meeting 28 November 2013

- HMA agreed with the deliverables to be completed over the next 21 months (Jan 2014 – Sep 2015) and Member States to provide input via existing development frameworks:
  - **Governance structure for the implementation of the pharmacovigilance legislation**
    - Project Team 1* for good practice guide (technical) for reporting errors
    - Project Team 2# for good practice guide (scientific) for risk minimisation
  - **SCOPE** (EC's Joint Action) for awareness campaign and communication toolbox
  - **MedDRA Points to Consider (PTC) Expert** Group on best use of terminologies
- **For all deliverables, collaboration with EC's Patient Safety & Quality of Care Working Group (PSQCWG) is foreseen**

*Project Team 1: Collection of key information on medicines
#Project Team 2: Better analysis and understanding of data and information

Development frameworks

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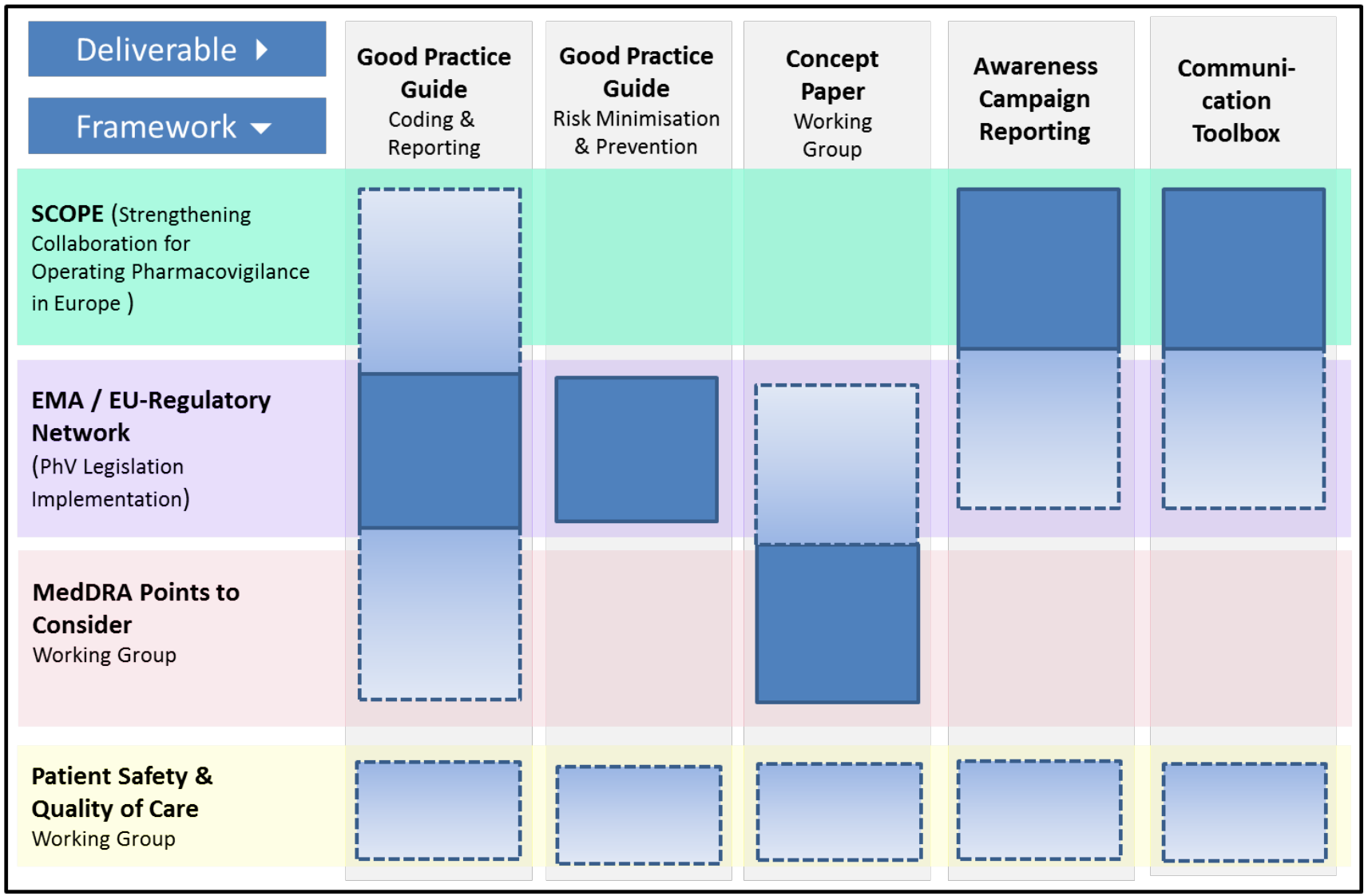
HMA Medication Errors Action Plan 2014-2015



Collaboration with EC's PSQCWG

- Objectives of collaboration
  - To facilitate implementation of EU legislative requirements on medication errors
  - To understand national processes of reporting and learning from patient safety incidents
- PSQCWG consultation on deliverables produced by Project Team 1 and 2 and MedDRA PTC WG on patient safety aspects (reporting, learning, risk prevention and minimisation, etc.)
- PSQCWG consultation on draft recommendations for data sharing between national patient safety organisations (reporting and learning systems where in place) and pharmacovigilance centres building on the RLSS report
- Interested PSQCWG members could also input at drafting stage

→ Collaboration is currently formalised (feed-back mid March 2014)

Next steps

- Agree Member States' Rapporteurs and EMA Co-Rapporteurs for the 2 good practice guides, and align with Project Team 1 and 2 work plan
- Draft concept paper for inclusion of medication error aspects in work plan of the MedDRA PTC expert group currently under review by MedDRA MSSO
- Align deliverables developed with SCOPE work plan (March 2014)
- Publication of final action plan with milestones on EMA website (March/April 2014)
- PCWP/HCPWP input via public consultation