LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

GVP Module XV

Safety communication

Jane Ahlqvist Rastad
Juan Garcia Burgos

- This Module provides guidance to marketing authorisation holders, competent authorities in Member States and the European Medicines Agency on how to communicate and coordinate emerging safety information in the EU

- It mainly focuses on:
  - Principles of safety communication
  - Means of safety communication (with particular consideration to DHPC, including process for preparation)
  - Coordination of safety announcements within EU

GVP Module XV

- Module released for consultation in July 2012
- Comments received from:
  - Patients' organisations
  - Regulatory authorities
  - Learned societies
  - Industry and industry associations
- Overall positive and constructive feedback

Feedback received

- Patients' organisations:
  - European Organisation for Rare Diseases (EURORDIS)
- Regulatory authorities:
  - Medicines Evaluation Board (CBG- MEB)
  - Danish Health and Medicines Authority (DKMA)
  - Estonian State Agency of Medicines (Ravimiamet)
  - Medicines and Healthcare Products Regulatory Agency (MHRA)
- Healthcare professionals and learned societies:
  - Standing Committee of European Doctors (CPME)
  - European Industrial Pharmacists Group (EIPG)
  - Royal Pharmaceutical Society

Feedback received (2)

- Industry and industry associations:
  - European Federation of Pharmaceutical Industries and Associations (EFPIA)
  - Association of the European Self-Medication Industry (AESGP)
  - European Generic Medicines Association (EGA)
  - European Association of Biotechnology Industries (EuropaBio)
  - German Pharmaceutical Industry Association (BPI)
  - Association of the Austrian pharmaceutical industry (PHARMIG)
  - Gilead Sciences International Limited
  - Novartis
  - Pfizer
  - Zentiva

Introduction

- Scope has ben further clarified:
  - Safety communication – broad term
  - Module focuses on 'emerging safety information'
- Reference to Module XI (public participation) and Module XII (continuous pharmacovigilance)
- Recommendation for two-way interaction in designing safety communication

Principles of safety communication

- Reinforce the need to address uncertainties - balance the usefulness of early communication if uncertainties are not properly addressed
- Need to complement with relevant follow-up communication (e.g. resolution/ updated recommendations)
- Safety communication to address both prescribers and CT investigators on any safety concern at the same time.

Means of safety communication

- 'Tools' and 'channels' used indistinctly

- Specific consideration and guidance (for preparation) is given for DHPC:
  - Due to central importance of DHPCs in targeting healthcare professionals
  - Because of the level of coordination required between marketing authorisation holders and competent authorities in their preparation

- Introduce specific reference/description of 'EU Medicines web portal' as key tool to communicate safety in EU

Coordination of safety announcements

- No major comments/changes to be incorporated
- Largely discussed with MSs prior to consultation
- Extend criteria for coordination so that it is fully in line with legal scope of article 107 (to cover restricted indication, restricted populations and new contraindications)
- Role of industry and stakeholders recognised as part of the process.
- Any safety announcement should be provided to the concerned MAH prior to its publication

Processing of DHPCs

- Simplification
- More precise guidance on roles and responsibilities
- Flowchart illustrating the process to be added
  - For CAPs and referrals, DHPC submitted to the Agency
  - For MR or decentralised procedure, DHPC submitted to Reference MS(which will coordinate with Concerned MSs)
  - For purely NAPs, DHPC submitted to MSs where the product is authorised

Processing of DHPCs

- The PRAC should always be consulted on draft DHPCs related to a safety concern being discussed at the PRAC and the DHPC should form part of the PRAC assessment

- Final DHPC to be circulated within EU regulatory Network as part of 'coordination of safety announcements'

- Next steps:
  - Implementation of additional specific comments, finalisation and publication by end of 2012

- Acknowledgements:
  - To stakeholders for the useful, constructive comments received
  - To contributing authors:
    - Ingebjørg Buajordet
    - Priya Bahri
    - Federica Castellani
    - Nacho Mbaeliachi