EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Draft GVP Module XV
Safety communications

Joint PCWP/HCP WP
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Introduction

Safety communication refers to new or emerging information on an authorised medicinal product which has an impact on its benefit-risk

Aim: to facilitate informed decisions on the rationale use of medicines and to support risk minimisation behaviour.

- two-way process (see also Module X and XII)
- communication *vs* transparency
- complement to statutory product information
- need for coordination
- special focus in DHPC

Principles of safety communication

- Safety communication as part of risk assessment throughout the entire process
- Need to deliver clear messages to right audience at the right time
- Information on the risk to be put always in the context of the benefit
- Always address uncertainties
- Use of adequate quantitative measures
- Involve civil society (whenever possible)
- Effectiveness of communication to be measured

Target audiences

- Primary target audience: *patients and healthcare professionals*
- Media
- Health ministries, public and private health bodies
- Health technology assessment bodies
- Health insurance providers, etc

Content

- Clear and concise information
- New (emerging) important information
- Explain reason for its publication/dissemination
- Include any recommendations to patient/healthcare professionals
- Avoid advertisement, misleading, subjective, promotional information

Means of communication

Tools and channels:

- Direct healthcare professional communication (DHPC)
- Documents in lay language (e.g. Q&A)
- Press communication
- Website and web-based communications
- Inter-authority communication (LTT)
- Public enquiries
- Bulletins and newsletters
- Others (e.g. scientific journals, etc)

Direct healthcare professional communication (DHPC)

- Specific tool which involves both industry and regulators for the purpose of protecting public health.
- A direct healthcare professional communication (DHPC) is defined as a communication intervention by which important information is delivered directly to individual healthcare professionals by a marketing authorisation holder or by a competent authority, to inform them of the need to take certain actions or adapt their practices in the interest of public health.

Effectiveness of safety communication

- Safety communication is considered effective when the transmitted message is received and understood by the target audience in the way it was intended and appropriate action is taken

- adequate mechanisms to be in place to ensure effectiveness – it helps in making decisions on prioritisation and in adapting tools and practices (see Module XVI)

- For DHPCs – MAH to evaluate effectiveness of its dissemination

Coordination of safety announcements in the EU

- Good level of coordination – clear messages for patients and healthcare professionals

- Prior to the publication of a safety announcement, the Member States, the Agency or the European Commission shall inform each other not less then 24 hours in advance, unless urgent public announcements are required for the protection of public health [DIR Art 106a(2)]

- For active substances contained in the medicinal products authorised in more then one Member State, the Agency shall be responsible for the coordination between national competent authorities of safety announcements [DIR Art106a(3)]

Criteria for coordination

- Suspension, withdrawal or revocation of a marketing authorisation due to changes to the benefit-risk balance
- Start of finalisation of a safety referral or Union procedure for safety reasons
- Restrictions of indications (i.e. changes to summary of product characteristics section 4.1)
- Dissemination of a DHPC agreed by the Agency
- Other emerging safety concerns that may give raise to public or media interest (e.g. a publication of important safety findings in a (scientific) journal, safety related regulatory action taken in a Member State or in a country outside the EU.

Process for exchange and coordination

- EMA or MS will inform the network of any safety announcement prior to its publication (under embargo)

- Depending on the public health relevance, urgency, population affected and potential (media) interest, the EMA, in cooperation with reference/lead MS and MS concerned, may prepare in addition :
  - LTT or
  - EMA safety announcement (under embargo)

PRAC will also be consulted as well as CHMP and CMDh (Co-) Rapps

Exchange of safety information produced by third parties

- Safety information produced by third parties (e.g. scientific publications, MAH's communication, communications from non-EU regulatory authorities, etc) will be brought to the attention of the network

- Where necessary and after validation, the same process will apply

DHPC preparation- Process

- Draft DHPC and communication plan (for products authorised in more than 1 MS) to be referred to the PRAC

- Roles and responsibilities are defined depending on the medicinal product's route of authorisation:
  - centrally authorised medicines
  - medicines authorised through mutual recognition or decentralised procedure
  - nationally authorised products

Next steps

- Public consultation by 21st September 2012
- Comments by PCWP and HCP WP welcomed by 5th October 2012
- Finalisation expected by end 2012