EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Patients/Consumers Working Party (PCWP) and Healthcare Professionals Working Group (HCP WG) Joint Meeting :Reporting of adverse drug reactions by patients and consumers

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Adverse Reaction reporting by Patients and Consumers

- New Pharmacovigilance Legislation
  - Ensures that methods for reporting by patients and consumers are available
    - A standardised text shall be included in the patient information leaflet, expressly asking patients to communicate any suspected adverse reaction to his/her doctor, pharmacist, healthcare professional or directly to the national spontaneous reporting system
    - Requires to specify the different ways of reporting available (electronic reporting, postal address and/or others)
    - The Agency shall, in collaboration with the Member States, develop standard web-based structured forms for the reporting of suspected adverse reactions by healthcare professionals and patients

Adverse Reaction reporting by Patients and Consumers

- Electronic ADR reporting
  - Reflection paper on web-based reporting forms drafted with Project Team 3 (EMA and Member States)
    - This paper includes feedback received from the Healthcare Professional Working Group (HCPWG) and the Patients' and Consumers' Working Party (PCWP)

Adverse Reaction reporting by Patients and Consumers

- Reflection paper on web-based reporting agreed by:
  - Project Team 3: June 11 2012
  - Project Coordination Group June 20 2012
  - ERMS FG (European Risk Management Strategy Facilitation Group) 27 June 2012

Adverse Reaction reporting by Patients and Consumers

- Reflection paper on web-based reporting forms

- General recommendations, not legally binding. The recommendations proposed are intended to aid National Competent Authorities to implement web-based reporting forms within their territory.
- The recommendation for the minimum data elements for inclusion are agreed taking into account the support from the NCAs, the proposals from the PCWP and HCPWP, also to meet the needs of the legislative requirements and to support pharmacovigilance and signal detection.
- The minimum number of fields has been reduced as much as possible, in agreement with the Member States, but individual NCAs may wish to include other additional fields.

Health Care Professionals

Reporting by patients, consumers and health care professionals to National Competent Authority

National Competent Authority

EudraVigilance Human

Patients Consumers

Web-forms and ADR reporting by Patients/Consumers

- Administrative and patient details (contact details, age/age group, sex, weight, height)

- Reaction and medical info :
  - Reaction free text and further info free text
  - Outcome and any action taken
  - Dates
  - Medical history free text

Web-forms and ADR reporting by Patients/Consumers

- Medicinal product info:
  - Name
  - Batch number
  - Indication
  - Dose/strength
  - Route of admin
  - Dates
  - Other drugs
  - Action taken
  - Free text further info

ADR reporting by Patients/Consumers
Current status

- Patient/consumer reports in EudraVigilance between July 1st and End August 2012 for reports categorised as 'Non healthcare professional' [1]
  - Compared to the same period in 2011 there has been around a 157% increase
  - Compared to 2 month period before legislation came into force there was a 112% increase
- Of those reports via NCAs (not MAHs) in the current period, most refer to vaccines
- Mostly from Member States with already well established patient reporting (eg Netherlands/UK)
- [1] Using E2B field (A.2.1.4) for primary source=Lawyer or consumer/other non health professional

ADR reporting by Patients/Consumers
Next steps

- A further survey of the NCAS may be carried out to obtain further experience of how patient reporting has been implemented and also how web-based forms have been utilised for both HCP and patients/consumers

- Survey (along with information from QRD template) may also gather information on the different reporting mechanisms available in Member States

THANK YOU