EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Patient and Consumer organisations Training session: Reporting side effects of medicines

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An agency of the European Union

Side effect reporting by Patients and Consumers

- New Pharmacovigilance Legislation- July 2012
  - ➢ Ensures that methods for reporting by patients and consumers are available
    - Information in the patient information leaflet provided with medicine, asking patients to report any side effect to their healthcare professional or directly to the national spontaneous reporting system
    - Different ways of reporting available (electronic reporting, postal address and/or others)

Health Care Professionals

National Competent Authority

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

Patients Consumers

Web-forms and ADR reporting by Patients/Consumers

- Administrative and patient details (contact details, age/age group, sex, weight, height)- Can report for oneself or on behalf of someone else eg your child.

- Side effect and medical info :
  - Side effect description
  - Outcome (eg side effect improved) and any action taken (eg side effect was treated by doctor)
  - Dates side effect occurred
  - Medical history free text

Web-forms and ADR reporting by Patients/Consumers

- Medicinal product info:
  - Name
  - Batch number (if known)
  - What was medicine used for (treated condition)
  - Dose/strength
  - Route of administration (eg injection, tablet)
  - Dates medicine was taken
  - Other medicines taken at same time
  - Action taken (eg was medicine stopped?)
  - Free text further info

ADR reporting by Patients/Consumers
Current status

- Patient/consumer reports in EudraVigilance between July 1st and end August 2012 [reports categorised as 'Non healthcare professional' [1]]
  - 157% increase compared to the same period in 2011
  - 112% increase compared to 2 month period before legislation came into force

Of those reports via NCAs (not MAHs) in the current period, most refer to vaccines (reported by parents)

- 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 Medicines agencies in Member States may be carried out to obtain further experience of how patient reporting has been implemented

- Information on the different reporting mechanisms available in Member States will be published through product information templates

THANK YOU