

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

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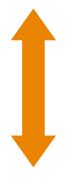
#### Side effect reporting by Patients and Consumers

- 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 (<u>electronic reporting</u>, postal address and/or others)



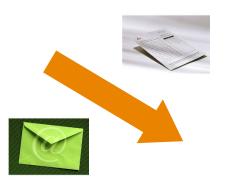


**Health Care Professionals** 





Patients Consumers





National Competent Authority



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







#### 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 1<sup>st</sup> and end August 2012 [reports categorised as 'Non healthcare professional' <sup>1</sup>]
  - > 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)
- 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