

12th Pharmacovigilance Stakeholder Forum

Doctor's Vision

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Pharmacovigilance (WHO)¹



“the science and activities relating to the

- detection
- assessment
- understanding
- prevention

of **adverse effects** or any other **drug-related problem**”

Pharmacovigilance



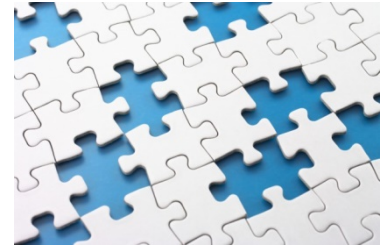
Systematic monitoring of the process of pre-market review and post-market surveillance

Identifies previously unrecognized adverse events or changes in the patterns of these effects, the quality and adequacy of drug supply

Where
Are
We?



Underreporting



Where
Are
We?

- **Reporting gaps** – 3 categories:
technology, education, the overall process²
- **Key actors** contributing to under-reporting of ADEs relate to lack of:
 - standardized process
 - training and education
 - integrated health information technologies²
- **Patient characteristics** may affect ADR reporting by physicians to Regulatory Agencies³



Underreporting



➤ **Seven deadly sins⁴:**

1. **Complacency** (believing that serious ADRs are well documented when the drug is released in the market);
2. Fear of getting involved in a **lawsuit** (legal process);
3. **Guilt** for having been responsible for the damage observed in the patient;
4. **Ambition** of group and publish case series or financial benefit;
5. **IGNORANCE⁵** on how to describe the notification (believing that only serious and unexpected ADRs must be reported);
6. **INSECURITY⁵** about reporting suspicions of ADR (belief that there should be notification only if there is certainty that the damage was caused by the use of specific medication);
7. **INDIFFERENCE⁵** that is, lack of interest, time or other excuses related to postponing the notification of damage due to drug use.

Where
Are
We?



➤ **LACK OF TRAINING** in pharmacovigilance⁵.





➤ Further support **HCP education** around AE reporting⁶

➤ Further support around the **black triangle**
(ensure confidence in making reports and makes clear the importance and ultimate benefit to patients)⁶



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Medicines under additional monitoring

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The European Union (EU) has introduced a new process to label medicines that are being monitored particularly closely by regulatory authorities. These medicines are described as being under 'additional monitoring'.

Medicines under additional monitoring have a black inverted triangle displayed in their package leaflet and in the information for healthcare professionals called the summary of product characteristics, together with a short sentence explaining what the triangle means:

 This medicinal product is subject to additional monitoring.

The black triangle is used in all EU Member States to identify medicines under additional monitoring. It started appearing in the package leaflets of the medicines concerned from the autumn of 2013. It will not appear on the outer packaging or labelling of medicines.

What does the black triangle mean?

All medicines are carefully monitored after they are placed on the EU market. If a medicine is labelled with the black triangle, this means that it is being **monitored even more intensively** than other medicines. This is generally because there is less information available on it than on other medicines, for example because it is new to the market or there is limited data on its long-term use. It does not mean that the medicine is unsafe.

What does the black triangle mean?



- To improve **safety communication** strategies⁷
 - information comes from the National Competent Authorities or another preferred sender, such as a professional body



- Collaboration with **authors of the most preferred channels** for keeping up to date on safety information⁷

(both hardcopy or electronic format, the medicines reference books and national clinical guidelines; point-of-care and email were the generally preferred methods, while mobile phone text and social media were not highly rated).



- Some **country-specific preferences** can be considered for successful safety communication⁷





- Only **one out of eight** ADR reports from GPs was **'well-documented'**⁸ (provided good level of information)



- Regard information required to accurately assess **drug causality** and about **drug-induced diseases**⁸



- **Under/post graduate** education⁸



- Important **challenge** for pharmacovigilance: , too many mandatory criteria could discourage reporting of ADRs and lead to a loss of signal ⁸



➤ **Other interventions possible⁹:**

- **Group informative talk** on Pharmacovigilance
- **Accompanying** physicians during clinical visits
- **Reminders** to medical staff.

(During general visits and in the later review of clinical records, the pharmacist identified those patients in which the physician detected an ADR in the clinical record but it had not been reported to IPC)

- **Feedback** to medical staff.

(to inform physicians on the number of identified and reported ADRs every week, during clinical visits)

- Improving **accessibility** to the ADRs **report format**





➤ Pharmacovigilance must transform itself to be **more flexible and dynamic** to¹⁰:

- support clinicians in making **accurate diagnoses**, both of diseases and adverse effects

- help patients, jointly with their healthcare professionals, to make **informed choices** about their **therapeutic options**

- to ensure that **information** about medicinal products is transparent, accurate, accessible, relevant and timely

- help determine **the best treatment options** and policies within mass treatment programmes that will have maximum public health impact in resource-poor settings

- to have **broader considerations** in mind, such as **drug-environment interactions** (with possible consequent effects on animals and humans)

Where
Are
We?

Needs

Strategy

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