12th Pharmacovigilance Stakeholder Forum

Doctor's Vision

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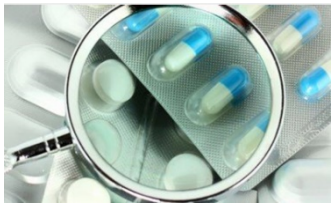
Where Are We?

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

Underreporting

Where Are We?

- **Reporting gaps** – 3 categories:

technology, education, the overall process[2]

- **Key actors** contributing to under-reporting of ADEs relate to lack of:

- standardized process

- training and education

- integrated health information technologies[2]

- **Patient characteristics** may affect ADR reporting by physicians to Regulatory Agencies[3]

Where Are We?

Underreporting

- **Seven deadly sins[4]:**

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. **IGNORANCE**[5] on how to describe the notification (believing that only serious and unexpected ADRs must be reported);
6. **INSECURITY**[5] 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. **INDIFFERENCE**[5] that is, lack of interest, time or other excuses related to postponing the notification of damage due to drug use.

Where Are We?

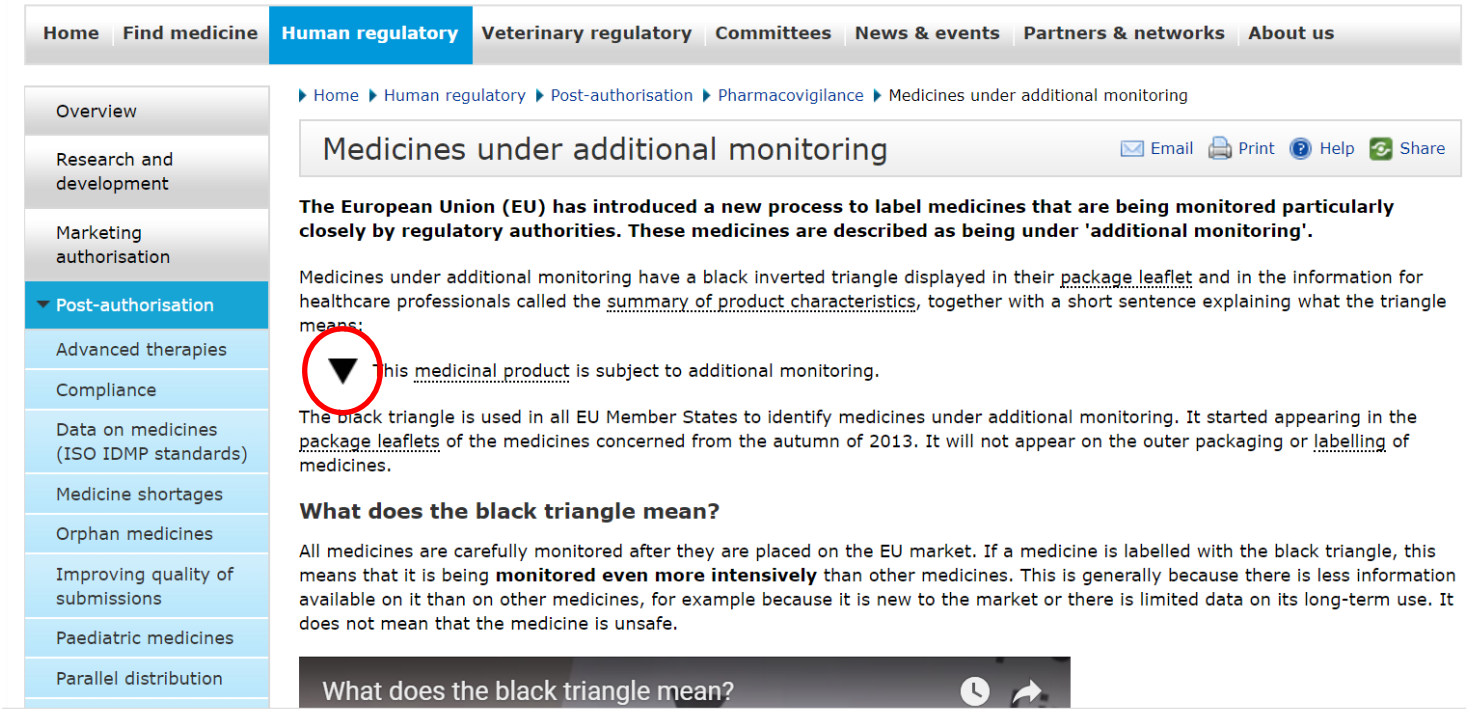
- **LACK OF TRAINING** in pharmacovigilance[5].

Where Are We?

Needs

- Further support **HCP education** around AE reporting[6]
- Further support around the **black triangle**

(ensure confidence in making reports and makes clear the importance and ultimate benefit to patients)[6]



Where Are We?

Needs

Strategy

- To improve **safety communication** strategies[7]

  - 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 information[7]

(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 communication[7]

Where Are We?

Needs

Strategy

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

Where Are We?

Needs

Strategy

➢ **Other interventions possible**[9]**:**

- **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** to[10]:

- 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)

References

1. WHO. http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/ Accessed 19 September 2018
2. Drug Saf (2016) 39:1117–1127
3. Int J Clin Pharm (2016) 38:80–87
4. Inman WHW. Assessment drug safety problems. In: Gent M, Shigmatsu I, editors. Epidemiological issues in reported druginduced illnesses. Honolulu, Ontario: McMaster University Library Press; 1976. p. 17-24
5. Rev. esc. enferm. USP vol.48 no.4 São Paulo Aug. 2014
6. ecancer 2018, 12:809
7. Communication on Safety of Medicines in Europe: Current Practices and General Practitioners' Awareness and Preferences (2017)
8. Completeness of Spontaneous Adverse Drug Reaction Reports Sent by General Practitioners to a Regional Pharmacovigilance Centre: A Descriptive Study (2016)
9. Int J Clin Pharm (2016) 38:80–87
10. A New Erice Report Considering the Safety of Medicines in the 21st Century. Published online: 17 August 2017
11. Drug Saf 2011; 34 (9)

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