COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

Implementation of the Pharmacovigilance legislation
-
The views of physicians

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Standing Committee of European Doctors – CPME

- Founded in 1959, CPME has been promoting for more than half a century the highest standards of medical training and medical practice in order to achieve the highest quality of healthcare for all patients in Europe.

- We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

- We are concerned with the promotion of public health, the relationship between patients and physicians and the free movement of physicians within the European Union.

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CPME activities in the field of Pharmacovigilance

- CPME represented in the EMA HCP WP
- CPME General Assemblies (twice a year)
- CPME Working group on Pharmaceuticals (twice a year + webmeetings)
- Email communications
- Public consultations (EMA policy on publication of clinical trial data ; black symbol)

CPME Expectations on Pharmacovigilance (I)

- Better **reporting of ADRs by HCPs,** notably physicians

- Directive 2010/84 - Art. 102 :

*"The Member States shall take all appropriate measures to encourage **patients, doctors, pharmacists and other healthcare professionals to report suspected adverse reactions to the national competent authority;** for these tasks, organisations representing consumers, patients and healthcare professionals may be involved as appropriate"*

- Measures to properly **involve physicians** are essential

CPME Expectations on Pharmacovigilance (II)

Physicians need:

- Better **acces to PhV and safety data**
- Better **information and training**
- Better **use of technological advances**
- Better **involvement of associations of professionals**
- Better **feedback from authorities** to the reporting physicians

Reflections on communication achievements

- Communication of the EMA is **outstanding**

- Feedbacks from National Medical Associations:

  - **Finnish Medical Association (FMA)** “in Finland the EMA has not been very visible, however the national medicines agency FIMEA has keenly worked according to the EMA and the Directive mainstream”

  - **German Medical Association (GMA)** : Joint workshop BfArM and PEI; regular exchanges between the GMA, BfArM and PEI

  - **Danish Medical Association (DMA)** involved since 2009 in strengthening pharmacovigilance

The Danish Case (I)

- Since 2009, **two national action plans** on PhV in close collaboration between the Danish Health and Medicines Agency (SST) and the Danish Medical Association (DMA). The DMA is represented at the **Danish Medical Council on PhV**

- Measures to facilitate the reporting of adverse drug reactions by physicians:
  - Simple electronic reporting systems: http://laegemiddelstyrelsen.dk/en/topics/side-effects-and-trials/side-effects.aspx
  - Side effect managers
  - Feedbacks from SST to the industry and physicians
  - Direct feedbacks from SST to each reporting physician
  - Information campaigns

The Danish Case (II)

- Very positive outcome: **increase of the ADR reportings by physicians**
- But there is **still room for improvement:**
  - **Financial barriers** to the full implementation of the side effect manager;
  - **Work overload of physicians** – burnout situations -> reduce the reportings
- Further incentives are needed, but the Danish case is a good example to go forward and increase reporting of ADRs by physicians !

Thank you for your attention!

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