European Commission Pharmacovigilance proposals: patient safety is at risk

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Florence Vandevelde
1960: Thalidomide

About 2,500 cases in Germany

- 1965: EU Directive 65/65/CE
  Marketing authorisation needed prior to commercialisation = gatekeeper
1970: DES (diethylstilbestrol)

- Used from 1950 to 1970 (1980 in France!)
- France: 160,000 children exposed
- Daughters: morphologic anomalies of uterus, cancer
- Complications during pregnancy
2004: rofecoxib (ex-Vioxx°)

- Used from 1999 to 2004; no therapeutic advance
- US: 30,000 strokes
- 2000: results of Vigor study: increased cardiovascular risks
- 2003: in France, post-MA study
- 2004: EMEA conclusions: no therapeutic advantage, probable increased risk... no withdrawal!
- 2004: 2nd study: withdrawal by the pharmaceutical company
2007: rimonabant (ex-Acomplia°)

- Authorised and used in Europe from June 2006 to October 2008
- Marketing autorisation refused in the US
- Increased neuropsychiatric risk (suicides)
- Risk management plan: loss of time!
- Withdrawn in 2008
In the 2000s
Multiplication of litigations

- Rofecoxib (Vioxx°)
- Olanzapine (Zyprexa°)
- SSRI (Seroquel°)
- Roziglitazone (Avandia°)

-> dissimulation of adverse drug reactions data
Three reasons to amend the proposals

1. Premature marketing authorisations
2. Dissimulation of adverse drug reactions data
3. Biased decision-making & secrecy
1. Premature marketing authorisations

*The illusion of “risk management systems” and of post-authorisation studies*

- Marketing authorisation: quality, efficacy, safety

- The EC aims to:
  - generalise Risk Management Systems;
  - favour authorisations with conditions, even with no public health justification

- **Risk Management Systems** = false “good idea”
  - Remove health authorities’ responsibilities;
  - EU citizens to become “guinea pigs”
1. Premature marketing authorisations

Our recommendations

• Marketing authorisation: quality, therapeutic progress, safety

• To preserve the meaning of marketing authorisation (protection)
• To help patients to recognise “intensively monitored” medicines

• Make RMS become proactive pharmacovigilance tools
2. Dissimulation of adverse drug reactions data (1)

The illusions of shifting “responsibilities” to pharma & of data “centralisation”

- National Centers (DRA)
- Regional Centers
- National database
- Eudravigilance
- European PhWP
- Pharmaceutical companies
- Clinical trials
- Health professionals (& patients)
2. Dissimulation of ADR data (2)

Our recommendations:

• Preserve and **strengthen Member States’ pharmacovigilance systems**

• Really encourage **patient notifications** to Regional or National pharmacovigilance Centres (not just a web portal)

• Guarantee **quality of Eudravigilance**: registration of data by the Member States’ pharmacovigilance systems

• More **transparency**:
  - Public access to National databases and to Eudravigilance
  - Patient leaflets adapted to users
3. Biased decision-making & secrecy (1)

Consequences of Health authorities’ financial and political dependence on pharmaceutical companies

- Current situation:
  - delayed decision-making process,
  - dissimulation of data

- Why? Conflict of interests ++
  - **Data interpretation** by pharma (PSURs)
  - **Hierarchy**: Marketing autorisation committees (directly funded by pharma companies fees + inherent conflict of interest) with more power than Pharmacovigilance systems
3. Biased decision-making & secrecy (2)

- **The EC proposals:**
  - **The end of** pharmacovigilance **public funding**
  - **Pharma companies** in charge of report follow-up and of their products **evaluation**
  - **PSURs:** more secrecy, not if “well-established use”
  - **Pharmacovigilance Risk Assessment Advisory Committee (Praac):**
    no authority, no autonomy, no resources
  - **Pharmacovigilance driven by MA Committees:**
    - CHMP (Committee for Medical Products for Human Use)
    - CMDh (Coordination group for Mutual recognition and decentralised procedures)
3. Biased decision-making & secrecy (2)

- **Our Recommendations**
  - **Maintain pharmacovigilance public funding**
  - **Health authorities** in charge of report follow-up and of evaluation on the basis of all available data
  - **PSURs:** list of individual cases; at least every 5 years
  - **European pharmacovigilance Committee**
    Same authority as CHMP; members independent from pharma and from MA committees
  - **Separate Pharmacovigilance from MA**
    - Creation of a Coordination group for risk assessment (equivalent to the CMDh)
3. Biased decision-making & secrecy

- Develop a **proactive pharmacovigilance** (clinical trials meta-analyses, post-authorisation observational studies run by Health authorities)

- More **transparency**:
  
  - of pharmacovigilance data (clinical data belongs to the public);

  - during every step of the decision-making process
Conclusion: Take home messages

Therapeutic progress: to avoid useless exposure

Marketing autorisation: last gate keeper (look out for RMS!)

Conflict of interests: pharma companies, MA committees

Quality of pharmacovigilance data: strengthen role and responsibilities of pharmacovigilance centres (look out for industry bypassing!)

Independency: public funding, separating Marketing Autorisation from pharmacovigilance

Proactivity

Transparency: clinical data belongs to the public, health authorities are to be held accountable