Conflict of Interest of Experts in Europe: impact on public health

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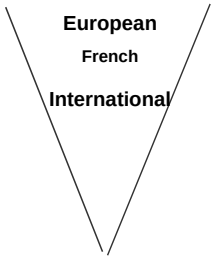
Prescrire on conflict of interest

- La revue *Prescrire*: a French continuing education journal for health professionals
- A non-profit organization: *Association Mieux Prescrire* (AMP)
- An English edition: *Prescrire International*

➡ Globalisation of conflict of interest reflects globalisation of drug markets

➡ Supporting Medwatcher's campaign and discussing joint actions

Speech in 3 parts



1- Management of conflict of interest by European Health Authorities
-> one national case (France)

2- ICH: a clear abuse of power

3- Proposals for getting things right

Part 1- Management of conflict of interest by European Health Authorities

1- EU Commission

Transparency rules

- Regulation for access to public documents
- Regulation governing European Medicines Agency
- Ombudsman and Court of Justice

EU Commission

When pharma laws are drafted by EU Commission

- New laws are influenced by **groups of experts**

Example: Biotechnology expert group dominates drafting
- 20 industry representatives, 6 academics
- no-one from public health groups independent of industry

EU Commission

- Partnership with **fake patient groups**

EU Commission wants to be seen as patient friendly

Example: European Patients' Forum (EPF) heavily sponsored by big pharma

EU Commission

- **State lobbying**

Example: EU law on chemicals (REACH) to control chemicals imported and manufactured in the EU

Final draft was weakened by EU and US lobbies

Secrecy of EU lobbies

➡ **EU Commission has failed to ensure transparency and accountability of expertise**

2- European Medicines Agency (EMEA) and conflicts of interest

- There is a binding law: Art 63 of Regulation 726/2004
- "*experts shall have no financial or other interests in the pharmaceutical industry which could affect their impartiality…*" but conflicts of interest only available on request
- "*experts shall declare, at each meeting, interests which could be considered to be prejudicial to their independence with respect to the items on the agenda…*"

EMEA (European Agency)

In practice:
EMEA management board in bed with front groups

- 2 representatives belonging to industry-sponsored patient groups
- Alzheimer Europe: 24% funding from big pharma
- European Federation Neurological Associations: partly funded by Merck Serono

EMEA (European Agency)

In practice:
Poor management of conflict of interest for market approval and pharmacovigilance Committees

- no transparency on management of conflicts of interest
- no information related to specific meetings
- no information on the way "conflicted" experts are excluded

EMEA (European Agency)

Example:
Prescrire's inquiry into a case of distorted drug evaluation

- Erlotinib case: a gefitinib me-too with serious adverse effects
- First EMEA refused use in advanced prostate cancer
- Roche appeal the decision: another group of experts finally approved this clinical use
- But 3 out of 4 had conflicts of interest with Roche

DISCLOSING CONFLICTS OF INTEREST IS NOT ENOUGH

EMEA (European Agency)

Example:
Influence of EU member states' health authorities

- The nimesulide case: a nonsteroidal anti-inflammatory being reviewed for liver toxicity
- Experts assigned by countries where nimesulide is heavily used voted for keeping the drug on the market
- They pretended that withdrawing nimesulide would have led patients to use more risky drugs

In short EMEA fails to fully apply the binding EU laws on conflicts of interest

3- EU member states' health agencies: no better than EMEA at controlling conflicts of interest

- There is a binding EU law regulating conflicts of interest: similar to that of EMEA
- Art 126b of Directive 2004/24/EC

A national example: France

- French **drug regulator** (Afssaps): conflicts of interest disclosed annually with much delay
- 2 categories of conflicts of interest : minor or major
- Minor = less than 5000 euros interest in a drug company marketing the product being evaluated

No evidence minor conflicts of interest protect from bias!

Market approval and pharmacovigilance meetings

- No detailed information on conflicts of interest at each meeting
- In 2006
  24% of conflicts of interest = occasional communication supported by drug companies
  20% = participation in clinical trials
  8% = sustained financial links with companies
  12% = experts failed to send declarations of conflicts of interest

No independent body for auditing conflicts of interest
No recognition of expertise as Publications and Research

French health technology assessment agency

- Conflicts of interest in poorly updated database with no link to relevant committees
- Same problem with Clinical Guidelines from this Agency: no declaration of conflicts of interest available

Legislative breakthrough

- Obligation for academics and physicians to disclose conflicts of interest when communicating with the public and media
- Campaigning was needed for the law to be published
- Unfortunately this law is not properly applied

Part 2- ICH: a clear abuse of power

International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use

Claimed Objectives

- Set regulatory standards for evaluating efficacy, safety and quality of medicines
- Avoid duplication of research

ICH has been behind the trend towards faster approval of drugs worldwide since 1990

Part 2- ICH: a clear abuse of power

ICH = structurally unable to serve patients' interests

- Key members = FDA + EMEA + MHLW + representatives of brand-name pharma of the 3 biggest markets (USA Europe Japan)
- IFPMA provides ICH secretariat
- No voting representative from developing countries, generics industry, public health advocacy, medical profession or consumers

Part 2- ICH: a clear abuse of power

Influence of ICH on Regulatory guidelines

Example:
Pharmacovigilance under the influence of ICH guidelines

- ICH recommendations on pharmacovigilance, although not legally binding, have been adopted by EMEA and its licensing committee
- Content and terminology of periodic safety update reports
- ICH gives recommendations for managing the database on adverse drug reactions (Eudravigilance)
- Eudravigilance cannot be accessed by the public

Part 2- ICH: a clear abuse of power

ICH = worse than conflicts of interest

Institutional Abuse of Power

Part 3 - Proposals

1- Improving transparency at the EU Commission

- Conflicts of interest of Experts advising legislators: **transparency**, **fairness** needed
- **Public access** to **obligatory register of experts**
- Elimination of expert group controlled by industry
- Elimination of patient groups sponsored by industry

Part 3 - Proposals

2- Improving transparency and accountability of Drug Regulatory Agencies

- Ensuring **transparency of management of conflicts of interest** at **each meeting**
- **Excluding experts with** major or minor **interest** from regulatory decisions
- Providing **publicly accessible database of conflicts of interest**
- **Paying experts** on public money and giving them academic recognition for ensuring independence

Part 3 - Proposals

3- Public money needed

- governments to fund regulatory work exclusively on **public money**
- governments to **increase funding of research** on public money

4- Education on conflicts of interest

- healthcare professionals
- the public and the media

3- Proposals

5- Democratizing ICH

- Exposing the abusive influence of this industry-driven organization
- Demanding that WHO rules over ICH
- Demanding that all pharma industries, patients, health professionals, UN member states have equal votes

Conclusion

A lot of opportunities to work together !

Any questions?