



EU Pharmaceutical Policy

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International Society of Drug Bulletins

Europe and drug control

A long history

- Thalidomide disaster
1961
- 65/65/EEC
Article 5
The authorisation shall be refused if [...] it proves that the proprietary medicinal product is harmful in the normal conditions of use, or that its therapeutic efficacy is lacking [...]



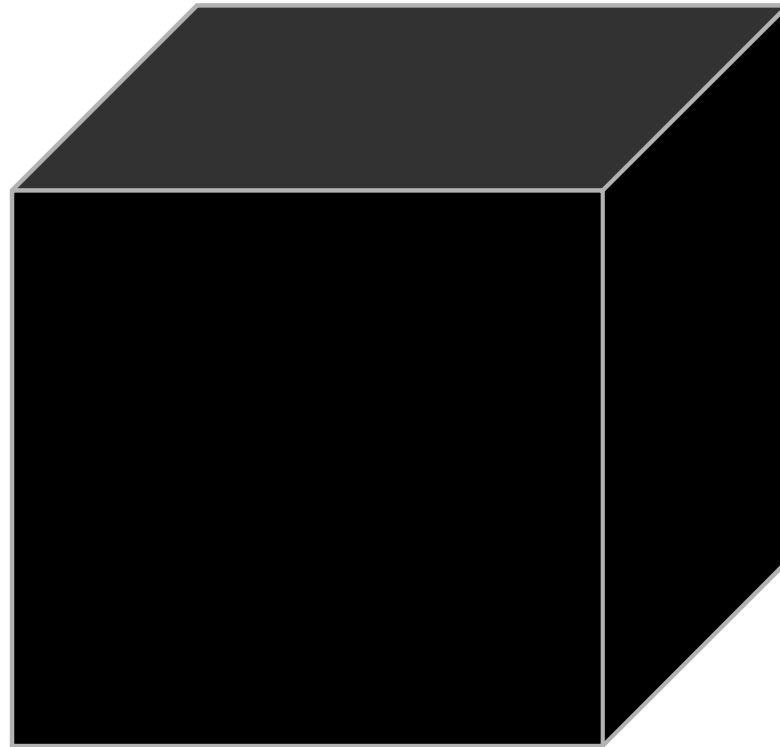
Transparency: EMEA

- EPAR improved, but still not sufficient
- Upon request from any interested person, the Agency shall **make available the assessment report of the medicinal product** by the Committee for Proprietary Medicinal Products and the reasons for its opinion in favour of granting authorization, after deletion of any information of a commercially confidential nature.

Regulation (EEC) No 2309/93 Article 12 (4)

- **Minority votes**
- **Access to Conflict of interest statements**

Transparency: Mutual recognition



EMEA: Vigilance an orphan?

- The first system to control drug risks was established 1 ½ years after the licensing procedures were started.
- Many problems still exist
- ... and may become worse

Money talks?

- EMEA is funded largely directly by the pharmaceutical industry.
- Rapporteurs get money
 - competition
- Under the auspices of DG Enterprise
 - competing interests

EMA: Quality of decisions

- 2006: Rimonabant (Acomplia®) licensed
- Questionable efficacy
- Anxiety and suicidal thoughts
- Never allowed in the US
- July 2007: Manage the risk?
- June-Aug 2008: 5 suicides in studies (1 placebo)
- October 2008: withdrawn

EMA: Conflict of interest / competing interests (COI)

- Top secret in the beginning
- Now a bit more transparency
www.emea.europa.eu/htms/aboutus/experts.htm
- Declaring COI enough?

Competing interests (COI) in Scientific advisory groups (SAG)

- Erlotinib in pancreatic cancer:
“Overall, from a clinical perspective, the toxicity observed for the combination compares unfavourably with the very small effect observed on clinical efficacy endpoints.” 7 July 2006 = **NO**
- “On the issue of balance of observed effect and toxicity there was considerable divergence of views.”
30 Nov 2006 = **YES**
- No new data
- 2 of 4 experts with COI (1 of which undeclared)

DG Enterprise: Out of balance

G 10 High level group 2000-2002

- 1 Enterprise commissioner and 1 industry minister
- 1 Health commissioner and 4 health ministers
- 4 Pharmaceutical industry people
- 1 Public health insurer
- Proposals for “competitive innovative-based industry”
 - DTCA
 - Quicker drug approvals
 - Switch Rx drugs to OTC

DG Enterprise: Out of balance Pharmaceutical Forum 2005 - 07

- 5 industry organisations
- 1 industry funded “patient organization”
- 2 professional organisations
- 1 consumer organisation
- 2 Public health insurers
- **Proposals**
 - DTCA again, now called “information”
 - Lousy self-made patient information
 - “Ensure timely access to valuable innovation”
 - Restrict price control

Counterfeits

- High tech solutions
- Confusion with substandard drugs
- Generics (IP)

Fake medicines

Tackling the threat to patient safety

INSIDE:

Putting patients first

Parallel trading

Track and trace technology

Illegal online pharmacies

Strengthening supervision

Patient safety is at the heart of the European commission's plans to tackle the rise in fake medicines, writes Günter Verheugen



Public information on fake medicines is essential, argues BEUC's Monique Goyens



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Counterfeits

What's needed?



- Safe supply chains
- Reducing prices
- Social insurance coverage
- Crack down dangerous internet sales at the source
- Public education about safe sources

Role of EU-Commission

Info to patients:

- Higher turnover through influencing patients

Pharmacovigilance:

- Longer patent life through earlier approvals
- Keep dangerous drugs on the market through “risk management”

Counterfeits:

- Secure profits for expensive brands