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 [...]

Vegetative Dystonie
3x ½ Tabl. Contergan
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
EMEA: 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- October 2008: withdrawn
EMEA: 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 commisioner 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)
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