



# Transparency of European medicines regulation

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# European Medicines Agency

- Transparency of stakeholders
- Transparency of safety information

# Patient & consumer groups at the EMA: Financial disclosure & transparency

- European patient and consumer groups are involved in management and scientific committees at EMA
- All experts working with the EMA are asked to disclose their income sources
- In 2010, research from Corporate Europe Observatory: patient representatives at the EMA made misleading or incomplete declarations of interests
  - Failed to identify that the patient organisation they were representing received funding from pharmaceutical companies

# Patient & consumer groups at the EMA: Financial disclosure & transparency

- HAI Europe survey of corporate sponsorship of the 23 patient and consumer groups working with EMA
- Findings
  - 2/3 of the groups received funding from the pharmaceutical industry and industry associations
  - < 50% of the groups met the EMA's financial reporting guidelines
- Conclusions
  - The EMA appears to have failed in the monitoring and enforcement of its guidelines on financial transparency

*“All financial interests of patients’ and consumers’ organisations were disclosed to the Agency as required by the transparency criteria... The Agency does not take any steps itself to disclose the financial statements of patient and consumer organisations”* EMA response reported in SCRIP (2010)

# Patient & consumer groups at the EMA: Financial disclosure & transparency

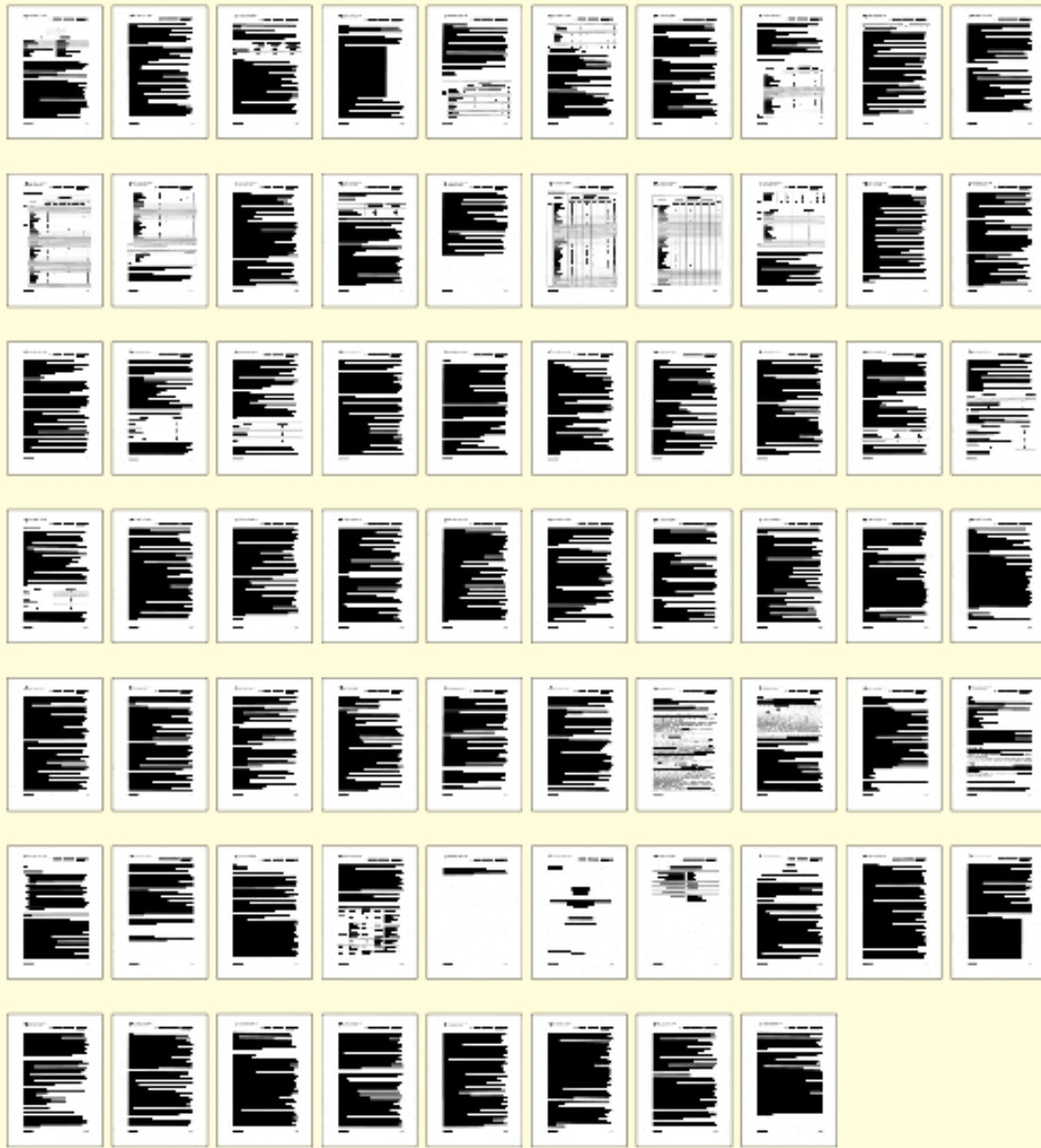
Why is financial transparency important?

- A qualitative and quantitative evidence base from which to assess potential conflicts of interest
- Any competing interest could influence the decision making process around medicines regulation

# Safety information at the EMA: European Public Assessment Report

- Medicines are authorised on the basis of the results of studies carried out by the manufacturer
- An European Public Assessment Report (EPAR) summarises the grounds for granting market authorisation
- Criticisms include:
  - Lack of data
    - Not all studies in the EPAR state the number of patients allocated to each treatment arm
  - Lack of information about approval process
    - Number of votes in favour and against authorisation, reasons for minority opposition, decisions of other licensing bodies
  - Delay in making EPAR's available

# A picture is worth more than 1000 words



Assessment report for *rimonabant* (Swedish DRA report)

Indication: obesity

Only 3 pages out of 68 were readable

Drug was withdrawn from the market for safety concerns

# Safety information at the EMA: European Public Assessment Report

- Why is it important that the EPAR be complete, accurate and transparent?
  - Healthcare professionals: to know the size of effect of newly licensed medicines for prescribing reasons
  - Researchers: to use data in the EPARs for meta-analysis and access data that may never be published in journals
  - Consumers: to understand and monitor the drug approval process
- Access to detailed information about authorised medicines:
  - Allows for independent analysis
  - Promotes greater public trust in regulatory decisions



# Safety information at the EMA: Adverse reaction reports

- EMA collects information on suspected adverse reactions to medicines from authorities in Member States and from drug companies
- In 2008, an Irish citizen asked EMA for reports on suspected serious adverse reactions to a treatment for acne after his son committed suicide in 1997 while using the medicine
- EMA refused his access to information requests:
  - Transparency rules do not apply to adverse reaction reports
  - Circulation of data might be misleading or unreliable

# Safety information at the EMA: Adverse reaction reports

In 2010, EU Ombudsman ruled that EU transparency rules apply to all documents held by EMA

- Because the EMA's work has a direct impact on the health of European citizens *"it is of the utmost importance for the EMA to give the widest possible access to documents"*
- Suggested that the EMA provide explanations to make data more understandable by the public

# Recent transparency initiatives at EMA

- Electronic declarations of interest
- New policy to handle conflicts of interest among scientific committee members and experts (2011)
  - Members of the management board are exempt from this policy
- New transparency policy (2010)
  - Still protect commercial confidentiality to the detriment of the public's right to know