

Transparency & risk communication



Feedback from the Ditchley Group

**David H.-U. Haerry,
European AIDS Treatment Group**

www.eatg.org

david@haerry.org



European
AIDS Treatment
Group

Ditchley meetings



- Multidisciplinary group meeting since 2010
 - EMA, FDA, national regulators, other governmental agencies such as FPA, pharmaceutical industry, academics & patients
- Transparency, risk communication by regulators (raised in F. Boudier thesis)
- 1st meeting June 2010 at Ditchley Park, 2nd June 2012 Mayerling
- Lead by Ragnar Löfstedt, Kings College London and Frederic Boudier, Maastricht University

Key messages 2010



- There is no transparency evangelium
- Fish bowl model – data dumping – does not lead to better decision making or informed public but rather the opposite
- Any transparency initiative must be based on best communication science
- Transparency initiatives require evaluation
- Transparency initiatives have benefits and negative consequences
- Different nations will benefit from coordinating transparency initiatives

Discussions 2012



- Regulatory system damaged by lack of disclosure & transparency
- But will suggested measures work?
- What are the consequences?
- Who benefits?
- Are there alternatives suiting the sector better?
- Important to differentiate between transparency and communication
- Move to more transparent communication models is irreversible

National & European level measures



- Dedicated web portals
- Establishing the PRAC
- Introducing public hearings
- Disclosing agenda & meeting minutes
- Publishing RMP summaries & additional monitoring list
- New policies welcomed by all, but
 - Does the public still trust the regulator?
 - Or is there too much distrust in the system?
- How are trust, transparency & communication related?
- Issues re data transparency & transparency of decision making

Future topics



- Addressing rather than denying the political implications of moving to a more transparent environment
- Reinforce transparency dialogue & coordination between regulators (FDA & EMA)
- Strengthening neutral third parties (academics, PO)
- Retrieve more evidence of societal perceptions & preferences
- Develop methods to better understand risk
- Better present benefit/risk & risk/risk tradeoffs

Next meeting, thanks



- Stockholm June 2013
- Topics risk communication & transparency, latest EMA policies, Goldacre book review

Thanks

- Frederic Boudier, Ragnar Löfstedt
- Passionate participants