# THE PUBLIC IMPACT OF COMMUNICATION

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# Today's session

1- What is benefit/ risk (and risk/risk) communication ?

2- Background example of Vioxx and its impact

2- Brief introduction to case

# Why does Benefit/Risk Communication matter so much?

*Up to the early 1990's* – consensual style regulation in Europe. Decisions were made behind close doors.

*In the 1990's* – Series of regulatory failures:

- BSE (UK and Europe)
- Dioxin (Belgium)
- Tainted Blood (France)

Risk debate and Medicines:

- MMR –UK
- **Vioxx/Cox2 inhibitors**
- Avandia…
- Mediator –France

# As a result the communication context is changing

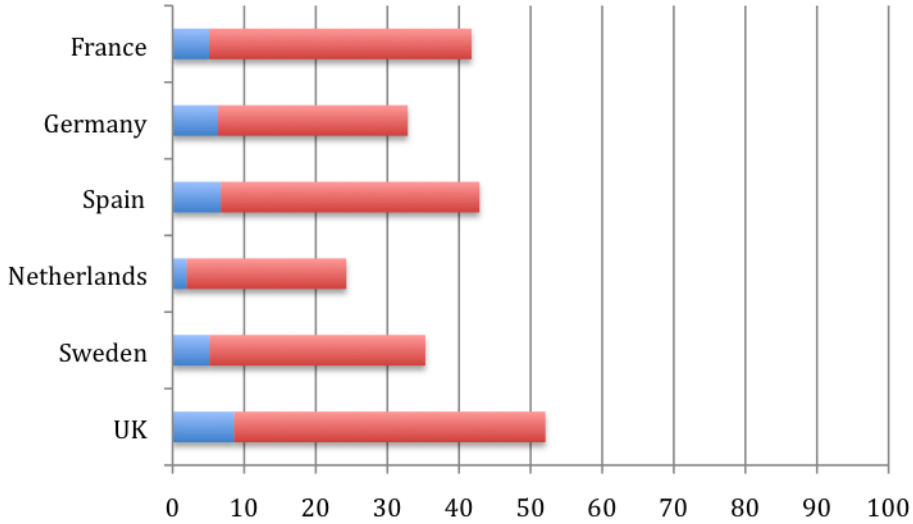
1. Greater public and stakeholder participation
2. Greater consideration for environmental and social values
3. Greater transparency in regulatory strategies and decisions
4. More accountability of the regulator
5. Greater use of precaution
6. The role of Science is downplayed, as scientific results are increasingly under scrutiny - scientists seen as just another stakeholder
7. The role of Media is enhanced

# EU policy trends in Pharma sector

- Maintaining dedicated **web portals** (e.g. safety-data on ADRs)
- **Publishing documents** (e.g. PSURs, RMPs and lists of monitored medicinal products)
- Introducing **public hearings**.
- Disclosure policy at **new PRAC**.
- Disclosing committee-**meeting minutes** (e.g. CHMP and PRAC)
- Public **workshops** (e.g. EMA's November 2012 & 2013 consultations.
- Proposals to **proactively release data** (e.g. EMA by 2014)

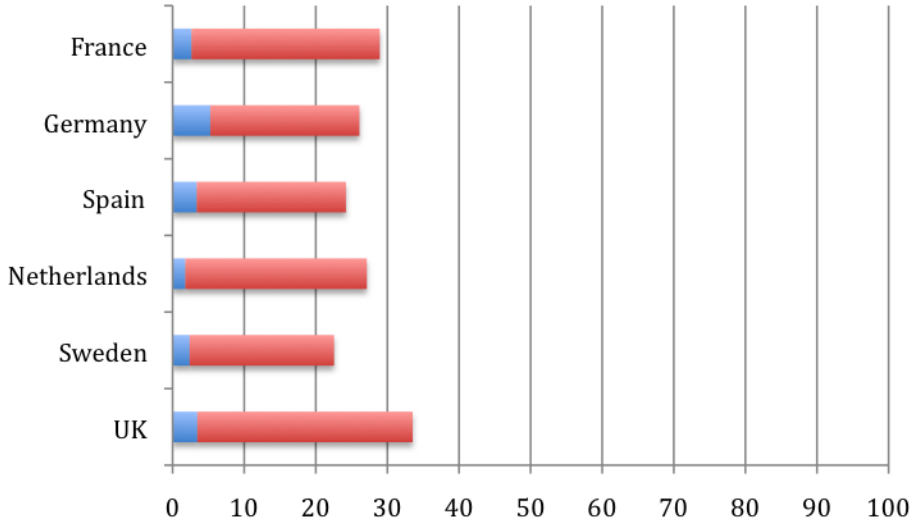
# *Are European regulators viewed as effective communicators?*

*Bouder et al. 2014*




**NHS [or equivalent]**

Figure: Bar chart showing respondents (%) (N=5,648) answers to the question: "How effective do you consider the NHS [or equivalent] is at providing members of the general public with information on medicines such as a health alert about a flu outbreak?" Blue shading signifies very effective. Red shading signifies fairly effective.




**The Government**

Figure: Bar chart showing respondents (%) (N=5,648) answers to the question: "How effective do you consider the government is at providing members of the general public with information on medicines such as a health alert about a flu outbreak?" Blue shading signifies very effective. Red shading signifies fairly effective.

# *Who is trusted and who is not?*

*Bouder et al. 2014*

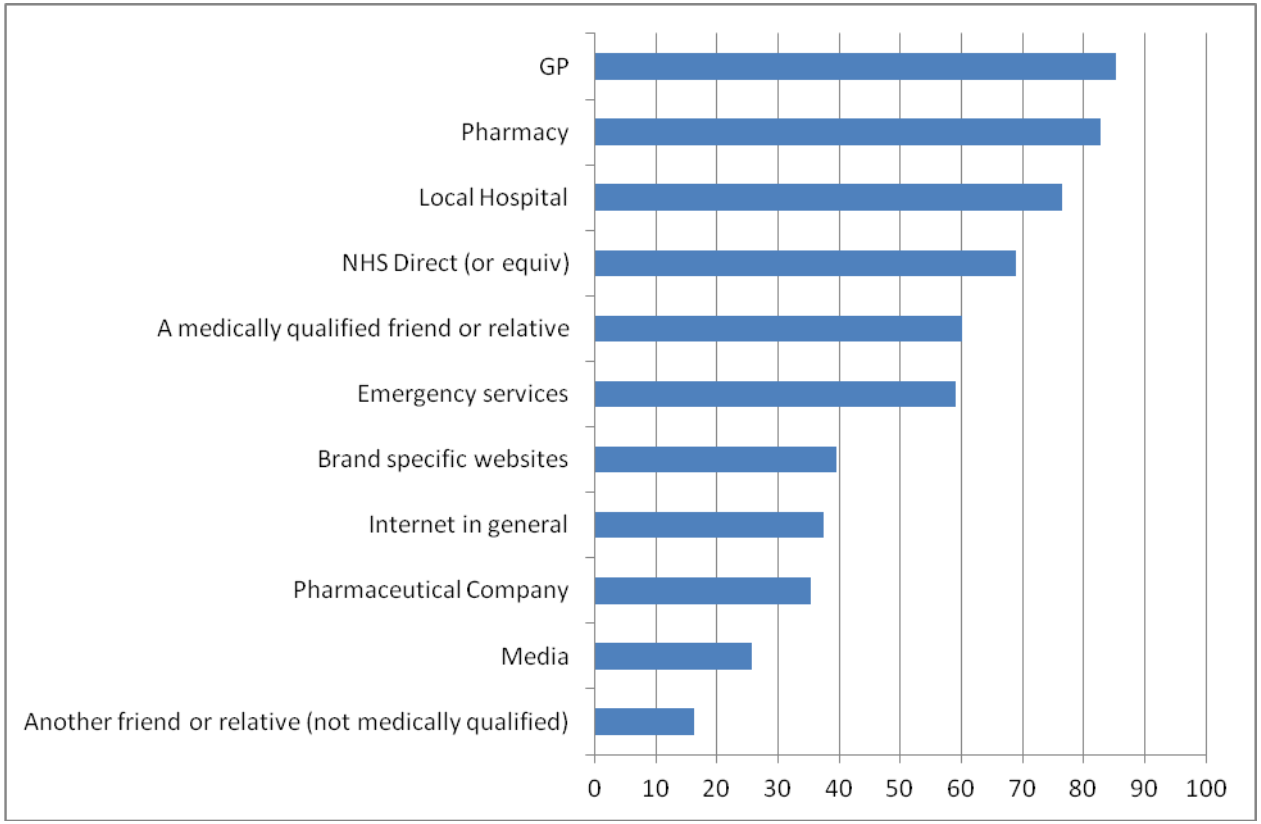



Figure: Bar Chart showing how trustworthy respondents (%) (N=5,648) felt a predetermined list of sources of information are in (a) providing them with advice about medicines or communicating health alerts (blue shading) and; (b) providing them with advice on the side effects associated with specific medicines (red shading). The bar chart represents the % of respondents that chose very or fairly trustworthy for each source of advice.

# What can we learn from advancements in decision sciences?

‘(…)Interactively sharing risk and benefit information with the public to enable people to make informed independent judgments’ (*FDA Risk Communication Advisory Committee*)

# Science of communication

**Psychometrics**

Starr 1969; Fischhoff et al. 1979, Slovic 1987 etc.

**Intuition and rationality**

Kahneman and Tversky 1974; Slovic 2001

**Trust**

Renn and Levine 1991; Lofstedt 2005

# Risk perception drivers

- Natural – Technological
- Voluntary – Involuntary
- Familiar – Non Familiar
- Control – Non Control
- High Frequency/Low Consequence Risk VS Low Frequency/High Consequence Risk
- Child – no child
- Reproduction

# Trust- No Trust

# Fairness, competence, efficiency

(Renn and Levine 1992)

**"Well I would rather have a med approved then not, but they are definitely in cahoots with the drug companies."**


**"They try to do a good job but I don't think they have enough resources to take care of all of it."**

# Risk perception and pharma

| Product / Perception | Low | Moderate | High | Dread |
|---|---|---|---|---|
| Vitamin pills | X | | | |
| Acupuncture | X | | | |
| Aspirin | | X | | |
| Valium | | X | | |
| Antibiotics | | X | | |
| Cancer chemotherapy | | | X | |
| Diet medicines | | | X | |
| Depression and anxiety medicines | | | X | |
| AIDS therapies | | | X | |
| DNA technology | | | | X |

# Media and perception

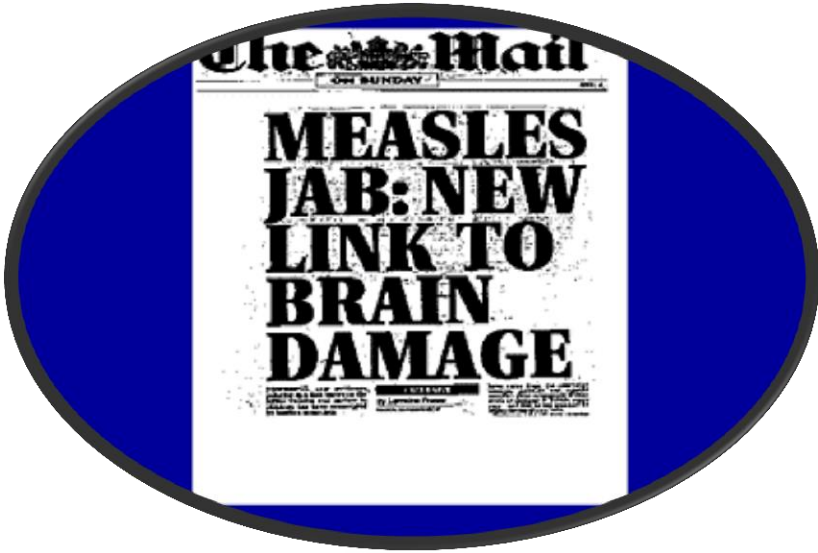
## Risk amplification/attenuation

(Kasperson & Kasperson 1988; Pidgeon et al. 2003

Information passes from sender to receiver

Intermediate stations  of a communication chain (individuals; medias; NGOs etc.) change the message

Ripple effects, may amplify (or attenuate)perceptions



# Example: Cox2 Inhibitors

Pain relief sometime presented as ‘super aspirin’

Non-steroidal anti-inflamatory drug (NSDAID), reducing the risk of ulceration /stomach bleeding

Withdrawal (11/04) after concerns for increased ‘vascular events’

Amplification: intense media coverage and US senate hearing (11/04), UK House of Commons (04/05)…

# What was the problem with Vioxx 2004 withdrawal (Löfstedt 2007)

Manufacturer seen as presenting a biased picture (Bowe 2005) publishing only results that suits them + aggressive DTC

“Whistle blower” factor within FDA: Should the product have been been taken earlier?

Regulator‘s ambiguity : ‘’Vioxx was no less risky than  having poor diet”. Then why being so precautionary?

# Lessons from Vioxx/Cox2 inhibitors

The Cox-2 inhibitor crisis has thrust pharmaceutical regulation into the post-trust era of risk communication: pharma industry less credible actor, and regulators questioned.

Improving public impact?

- Science-based : being clearer about benefit/risks but also risk /risk
- Proactive and well articulated message
- Test for trust
- Associating oneself with more-trusted actors

# Effective communication of benefit and risks

# Key variables

(Löfstedt 2005; Bouder and Löfstedt 2008; Bouder 2010)

- State of scientific knowledge
- Balancing of the message
- Frequents dialogues ?
- Confrontation ?
- Lawyers?
- What neutral third parties say
- NGOs/patients

# Practical case: Diclofenac

- Diclofenac – NSAID, authorised for relief of pain and inflammation
- Reason for review:

  Previous reviews (2005, 2006 and 2012) have suggested an increased relative risk of arterial thromboembolic events, sometimes greater than commonly prescribed NSAIDs and certain COX-2-inhibitors.
- Risk issue:

  There is a small risk of heart attack or stroke in patients taking systemic diclofenac regularly, especially at high doses and for long periods.