
Risk Management, New Drug
Assessment and the adequacy of
Health Protection
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Risk Management and Drug Regulation

- Pre-market risk-benefit assessment
- Alternative to withdrawal
- Basis for re-marketing

Explanations for Risk Management

- Technically defensible regulatory tool maximising overall benefits of innovative pharmaceuticals to patient populations
- regulatory capture or corporate bias towards commercial interests of industry
- response to patient demand (can this be assumed to be independent of industry?)

Lotronex case study - creation of expectation

- Manufacturer claims IBS affects 20% population - others estimate 5%
- Manufacturer claims highly efficacious, but placebo 40-50%; lotronex 10-20% more
- FDA granted accelerated review status as significant therapeutic advance
- several cases of ischaemic colitis (IC) in trials - manufacturer claimed not due to drug - drug approved by FDA

Lotronex case study - emergence of risks

- Cases of severe constipation and IC requiring hospitalisation linked to drug within 6 months marketing (June 2000)
- Manufacturer - acute, transient, self-limiting
- By Sep 2000 deaths reported
- Manufacturer withdrew drug 28 Nov 2000

Lotronex case study - risk management strategy

- Despite severe ADRs up to Nov 2000, marketing continued with a medication guide about its risks
- After withdrawal, FDA accepted company risk management plan to re-approve drug - identifying risk factors for patient likely to develop IC. - but risk factors elusive
- FDA Adv Comte vote for re-approval despite 7 deaths, over 100 hospitalisations (incl 50 surgeries)

Lotronex case study - patient demand

- After withdrawal, Lotronex Action Group (LAG) & Int Found for Funct Gastro-int Disorders lobby for re-approval
- Individual IBS patients testified willingness to take the drug risks
- LAG & FDA requested compassionate availability but ruled out by manufacturer for commercial reasons
- Hence, re-marketing approval with risk management strategy

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- Expectation
- Risks & benefits
- Risk-benefit Management Strategy
- Patient Demand

Conclusions

- While true that patients and patient groups sometimes lobby for early availability, maintenance of marketing or re-marketing of some drug innovations, the risk management conditions are not necessarily what patients want, but heavily influenced by manufacturer demands
- What some patients lobby for is not necessarily in the interests of public health