Governing Pharmaceutical Technologies in the Age of the Internet

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Background

- The Internet provides a means to disseminate information about pharmaceutical products
- The Internet is a medium for sale and purchase of pharmaceuticals, across national borders
- What are the challenges for governance of drug prescribing?

Research Methods

- Two-year study

- Qualitative data

- Documentary analysis: literature, web sites and other Internet communication media

- 'Online ethnography' of web discussions

- Interviews with professionals, industry, regulators, consumers and support groups

A Model of Governance

- We can understand governance as a **system of rule (SoR)** that achieves compliance from stakeholders, through negotiation and alliances between **sources of authority** (Rosenau 1995)

- Governance is dynamic, forever evolving, and fluctuating between order and disorder as the environment changes (ibid: 18)

- Self-regulation and codes of practice are as important as legislation ('governance without government') (ibid: 15)

Governing the E-clinic

- We studied how consumption of pharmaceutical drugs was affected by the rise of the Internet as an information and commercial medium

- We identified three moments in the e-enabling of pharmaceutical consumption in the UK

Moment 1: Electronic Transfer of Prescriptions (ETP)

- Government pilot scheme, now to be rolled-out nationally
- E-enabled communication between prescribers, pharmacists and Prescriptions Pricing Authority
- Drugs may be collected or sent by courier to patient
- Technical fix: will not address accuracy of prescriptions and may not have great effect on efficiency

Moment 2: the E-pharmacy

- Now easy to buy pharmacy medicines (PMs) on the Internet
- Some high street pharmacy chains have online wings; some new e-pharmacies have been established
- In UK, pharmacists have adapted there code of practice to include online dispensing of PMs: a questionnaire completed by the consumer must be assessed by a qualified pharmacist
- Does not apply to prescription medicines

Moment 3: the E-clinic

- The E-clinic or online clinic can dispense prescription-only medicines (POMs)

- In the UK, MHRA has ruled that:

  – No information about drugs can be given before an assessment by a qualified prescriber as this would constitute marketing to consumers

  – Online assessment and diagnosis by a prescriber is judged acceptable under existing legislation

- Most prescriptions are for 'lifestyle' drugs

Governance Issues

- Small change to legislation required to permit ETP (e-signatures)
- E-pharmacies operate within pharmacy code of practice
- Online consultations judged equivalent to other distance-consultation
- Ban on advertising to consumers was stumbling block for UK e-clinics

Governing Pharmaceutical Advertising

- Direct-to-Consumer Advertising (DTCA) is permitted in US and New Zealand, but illegal in UK and EU

- UK ban is self- regulated by industry code-of-conduct and policed by MHRA

- Overseas web sites can promote (and sell) pharmaceuticals to UK nationals

The Status Quo and Challenges

- Internet does not respect national boundaries: information is easy to obtain

- Multinational pharmaceutical companies constrained by UK law: cannot give 'user-friendly' web information to the public

- Industry may supply web information about their products for healthcare professionals

The Regulator's View

- Internet is another medium alongside print and TV: ban on DTCA applies to UK web sites

- By negotiation, foreign companies encouraged to respect UK law on web materials aimed at UK consumers, but this cannot be enforced

The Industry's View

- Ban affects competitiveness of UK companies

- Industry supports concept of expert patient (informed consumer?)

- 'Patient Information Leaflet' and other permitted information is 'consumer-unfriendly; and should be augmented by consumer information

- Currently, the industry association is lobbying to alter law on DTCA

Patient Views

- Consumers divided:
  - Some patient support groups believe consumers need more and better information about pharmaceuticals and are working with industry
  - Many grassroots support groups use the Internet to get information and purchase PoMs
  - Consumer Association strongly opposed to lifting ban for safety reasons

The Future of DTCA?

- Challenge from Internet may make the law banning DTCA unworkable and unjust

- EU strongly opposed to lifting ban and efforts to allow more flexibility were rejected

- Possible compromise: industry and patient groups work to create impartial information

Conclusions 1

- Case studies suggest:
  - Governance 'system of rule' is highly dependent on self-regulation
  - Legislation used as last resort
  - Internet may pose a challenge that will change the balance between sources of authority, making new governance arrangements necessary to ensure compliance

Conclusions 2

- Compliance is key to future: will consumers force a change by their economic power?

- Internet de-stabilises centralised governance and makes alliances more important

- Model generalisable to other technologies e.g. human reproductive technology, environmental protection

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