Global consumption and the challenge to pharmaceutical governance in the United Kingdom

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Analysis of governance, based on research into the views of stakeholders, can show the ways in which systems for regulation of technology evolve in the face of changes such as globalisation

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The globalisation of production and consumption challenges the ways in which potentially harmful yet essential technologies such as pharmaceuticals are governed. In modern liberal democracies, governance (a term whose Greek root implies control) depends not only on law and regulation but also on successfully engaging a wide range of interests within society—industry, professionals, and the public—as responsible and accountable. With the emergence of the internet, consumers' access to information and opportunities to purchase goods online may destabilise the established processes regulating prescription drugs.

Technology, governance, and globalisation

For democratic societies, the challenge of governance is to balance and reconcile the differing interests of the state and of individuals in an effort to sustain the continuity, security, and cultural integrity of the state and the liberty and rights of individuals.¹ Governance systems can be established in the absence of legal or political authority and often depend on voluntary and consensual processes. A good example is the governance of professions, such as the medical profession, which have applied self regulation and codes of conduct alongside legal frameworks.

Scientific and technological developments such as nuclear power, genetic engineering, food safety, and pharmaceutical innovation all demand regulation for reasons of public health, safety, and security.^{2–4} These developments require policy makers and professionals to balance a paternalistic responsibility for others against individual freedoms and rights and the commercial interests of industry. New technologies

gradually acquire regulatory frameworks as policy makers assess and weigh different interests among innovators, professionals, consumers, and ethicists. For drugs, national governments determine how they may be supplied and consumed. The Medicines and Healthcare Products Regulatory Authority (MHRA) controls the marketing of pharmaceuticals and regulates the sale of pharmacy and prescription only medicines in the United Kingdom, while permitting individuals to import medicinal products other than controlled substances for their own use.⁵

Globalisation threatens governance, requiring control mechanisms to become either more inclusive or less comprehensive.⁶ In a global economy without barriers to trade across borders, the internet offers both an information resource for potential consumers and a commercial medium for suppliers to trade in commodities.⁷

Our research on the regulation of pharmaceutical consumption in the UK explores how globalisation of information and communication technologies (in particular, the internet) poses challenges for national systems of governance. We gathered data from “stakeholders” with interests in governance changes, using in-depth face to face and telephone interviews with respondents from UK government agencies, pharmacies and e-clinics, the pharmaceutical industry, and consumer groups and email interviews with consumers set up through internet health forums, plus documentary analysis of paper based and web based materials, including government publications. We concluded that globalisation of information has created two critical challenges for pharmaceutical regulation: online “e-pharmacy,” which circumvents the traditional gatekeeping of pharmaceutical consumption by health professionals, and challenges to European bans on direct to consumer advertising arising from consumers' access to transnational industry websites.^{8,9}

Globalisation and the growth of e-pharmacy

The pharmacy profession dispenses prescription only medicines and pharmacy medications within a governance context of legislation and its professional self regulatory code of practice.¹⁰ Categorisations of drugs as “over the counter” or prescription only medicines vary from country to country and anomalies (exploited by travellers) occur, so that drugs such as melatonin are available in one country as pharmacy medicines or food supplements and only by prescription in others.¹¹

The internet offers a means for UK residents to purchase drugs from an overseas e-pharmacy or from a handful of outlets registered in Britain that have sprung up in the past few years. We interviewed

A hundred years ago, local pharmacies had no competition from the internet, and governance was more straightforward

consumers of a range of pharmaceuticals, including lifestyle drugs such as sildenafil (Viagra) and orlistat (Xenical), who had used e-pharmacy to obtain pharmaceuticals and other products. They considered this an appropriate way to obtain drugs, especially when they did not wish to approach their general practitioner.

In legal British and American e-pharmacies, pharmacy medicines are dispensed after the customer completes an online questionnaire, which is assessed by a registered pharmacist. The Royal Pharmaceutical Society of Great Britain updated its code of practice in 2003 to accommodate e-pharmacy, arguing that a remote patient is nothing new: pharmacists are often required to dispense medicines to family and friends on a patient's behalf, and this way of working can be replicated online by using questionnaires and emailed advice as a means of communication.¹⁰

For prescription only medicines, e-pharmacies require some form of online consultation with a doctor. During our research, the MHRA confirmed that it considers this kind of interaction between patient and doctor as an acceptable medium for diagnosis, and it had agreed to UK pharmacies using this approach to sales of prescription only medicines. To overcome regulations on advertising, the MHRA requires that e-pharmacies based in the United Kingdom do not provide details of the available prescription only medicines before an online consultation. According to the director of one UK e-pharmacy, compliance with these MHRA guidelines has cost it business in the global market but has increased trust among consumers.

Globalisation and consumer advertising

Prescription only medicines can be marketed to the public in the United States and New Zealand, but in European Union countries direct to consumer advertising of prescription only medicines is explicitly banned, and healthcare professionals worry that such advertising may pressure prescribers to meet patients' requests for specific drugs.^{12 13} The internet has created an ambiguity for regulators: like the websites of many commercial organisations, pharmaceutical companies' websites describe the products the companies manufacture. Do these descriptions amount to marketing, and where does legitimate information about a drug become advertising? Given the global reach of a website authored in a country where direct to consumer advertising is legal, does this contravene advertising regulations elsewhere?

As the UK regulator of pharmaceutical consumption, the MHRA has declared that pharmaceutical websites that are not intended exclusively for healthcare professionals may not publish details of their products beyond technical data on use and drug interactions.¹⁴ According to a respondent from the MHRA, voluntary self regulation by the pharmaceutical industry has ensured that, at least on their UK websites, pharmaceutical manufacturers do not flout UK legislation. Our respondent accepted that UK consumers could access fuller information from websites originating overseas, over which the MHRA has no legal control. This, she argued, was acceptable, as it represented a "pull" rather than a "push" in relation to

accessing drug information, a distinction also made by a respondent from the Royal Pharmaceutical Society.

The pharmaceutical industry self regulates its advertising, with companies informing on competitors who infringe the code of practice. Recent guidelines from the European Federation of Pharmaceutical Industries and Associations restricted online information for patients to technical data but permitted sites to provide further information for health professionals.¹⁵ Some transnational companies erect "Chinese walls," asking Europeans not to visit the pages on their websites that are aimed at US consumers and contain more overt marketing. Our data suggest that although companies do not wish to "rock the boat" by overtly advertising to consumers on their websites, a groundswell of opinion supports liberalisation. Respondents from the industry were hopeful that the ban on advertising would be lifted in the longer term, arguing that technical data could not adequately inform patients. We learnt of collaboration between the pharmaceutical industry and patient support groups, using non-industry websites to provide more comprehensive information to patients about drugs. A respondent from a patient group told us how pharmaceutical companies sponsored her group's website: detailed information about prescription only medicines on these non-commercial sites does not transgress rules on direct to consumer advertising.

Flexibility in the face of challenge

Our study indicates that global information and communication technology threatens existing pharmaceutical regulation. However, processes of governance are fluid and responsive, as shown in the two aspects of pharmaceutical consumption we reported here. In relation to the emergence of a global market in pharmaceuticals enabled by the internet, UK governance agencies have been conservative, underplaying the challenge while adapting existing regulations to address the emergent practices. A respondent from the NHS Modernisation Board argued that because internet access was low among the older age groups, who consume most prescription only drugs, use of overseas e-pharmacies was not an important problem in the United Kingdom. Meanwhile, the MHRA recognised the "online consultation" as a legitimate interaction between patient and doctor, thus enabling UK internet pharmacies to supply prescription only drugs to consumers.

Similarly, pharmacy stakeholders have subtly adapted their guidelines to permit the operation of UK internet pharmacies, protecting their members against competition from overseas outlets. The industry supports continued regulation as a way to prevent piracy of their copyright on pharmaceutical products. The broad outline of governance remains intact, leaving consumers free to purchase from overseas outlets, accepting that regulation across national borders is hard to police.

Sustaining existing bans on direct to consumer advertising in the face of the globalisation of communication may be less straightforward, with stakeholders taking more extreme positions. Respondents from industry, the pharmacy profession, and some consumer interests all doubted the viability of current

Summary points

Governance of technologies such as pharmaceutical medications is achieved by legislation and by consent among different interests

Globalisation challenges systems of governance as markets and consumption cross national frontiers

The rise of e-pharmacy in the United Kingdom has been achieved without adapting legislation and has sustained existing systems of governance

The internet challenges European Union bans on direct to consumer advertising

Alliances between the pharmaceutical industry and consumer groups may affect future regulation

strict controls on consumer-oriented information as the internet extends its global reach. On the other hand, both Which? (the consumers association, a self proclaimed protector of patients against commercial exploitation) and medical professionals voice anxiety over relaxing these regulations, as this could create a market for prescription only medicines and allow pressure by patients for particular drugs.

At present, regulators strongly support the status quo on direct to consumer advertising, but as a consequence of new information and communication technology they may have to readjust the balance of arguments concerning safety, consumer protection, and the public good; professional claims to authoritative knowledge; commercial interests; and citizens' rights to information and autonomy. The differing positions of governments around the world on this issue may exacerbate the tensions in this aspect of pharmaceutical governance.

The adaptability of UK regulations in relation to an emergent e-pharmacy may reflect in part the ultimate power of consumers to choose whether or not to purchase drugs online: where there is demand a market

will emerge, and consumers may accept a degree of regulation to protect their rights. When it comes to accessing pharmaceutical information, both sides of the provider-consumer partnership are involved. Different stakeholders have interests in ensuring dependable information is available to consumers. The future shape of governance of pharmaceutical information may depend more on alliances between the pharmaceutical industry and patient groups than on consumer sovereignty.¹⁶

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Just lucky

As a junior doctor at Westminster Hospital in 1991 before it closed, I treated an elderly man who had been a glider pilot during the second world war. He was involved in "Operation Market Garden" in September 1944, the basis for the film *A Bridge Too Far*. As proceedings unfolded, he found himself having to swim across the Rhine to escape capture. This was one of many heroic stories I heard from elderly people that enticed me towards geriatric medicine.

I recently discharged a man from my clinic who had survived the sinking of the *Lancastria* in the Bay of Biscay in June 1940. Two weeks after the evacuation of the British Expeditionary Force at Dunkirk there were still allied troops in France. Many had managed to reach St Nazaire by 17 June and were shuttled out to various ships in the Loire estuary. By 1 pm that day, there were an estimated 6000 troops on board the *Lancastria*,

with many others arriving in the next few hours. At 3 50 pm, however, the *Lancastria* was attacked by enemy dive bombers. She sank within 20 minutes, with only 2447 survivors. I was amazed to hear that more people lost their lives as a result of this disaster than in the sinkings of the *Titanic* and *Lusitania* combined.

I am so often reminded in my day to day work of the courage and sacrifice of all those who served their country during the second world war. I smiled recently when I saw the use of the sinking of the *Titanic* in an advertisement in the *BMJ* and remembered the brave chap in my clinic. He said he was just lucky.

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