

Chapter 7

Online purchasing of
pharmaceuticals

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Overview

What is new? This chapter focuses on the way people can now buy medicines (or products sold as such) on the internet. Products available online include many that are prescription-only or otherwise restricted in the UK and other countries. While in the past similar purchases might have been made via advertisements in magazines, mail order or in other unofficial ways, the internet brings a new dimension to the activity. Online purchase of pharmaceuticals can be linked to consumerisation and responsabilisation, the social phenomena and aspects of personalisation discussed in Chapters 1 and 2, since it involves both the exercise of consumer choice and the need for the purchaser to take more responsibility to verify that medications offered are what they purport to be, and in some cases to make their own decisions without consulting health professionals.

Which ethical values come into conflict as a result of this development? The major conflicts that occur are between the value of individuals being able to pursue their own interests in their own way and the values of efforts by the state to reduce harm, using public resources fairly and efficiently, and social solidarity.

What is the existing pattern of interventions like? As noted in previous chapters, there is no overall oversight of information on the internet, but the UK and other jurisdictions apply their laws to the information on it and how it is used. The most significant measures applying to online drug purchasing are service-specific licensing schemes that have been adapted from those originally applying to 'bricks and mortar' pharmacy services, which usually rely on the state's legal powers. Additionally there are some measures of the 'general governance' type applying to the online provision of pharmaceuticals, notably professional guidance and laws of tort or delict and fair trading. Advertising standards schemes also apply to selling medicines as they do to any other product.

What gaps or shortfalls are there in existing interventions? While recognising that the oversight regime applying to 'bricks and mortar' pharmacies in the UK and elsewhere is not free from shortcomings, we think the current arrangements create a possibility for serious harm to patients from pharmaceuticals (or products sold as such) purchased online. Protections for consumers are weak because suppliers may not follow the legislation that applies in the country they operate in, or they may be registered in countries with weak oversight powers and trade across national boundaries.

What types of intervention might possibly fill those gaps or remedy those shortfalls? Applying intervention measures to the internet is difficult, but possible options for reducing the risk of harms include: voluntary adoption of good practice; development or more extensive use of existing systems of redress; state or other third-party provision of high-quality information about risk; and further state intervention, for example in the form of increased inspection of premises or the closure of websites that are found to be operating illegally.

What types of intervention do we recommend, and why? We think the potential for harms from online drug purchasing justifies intervention requiring the state's legal powers, so we endorse the restrictions already in place on sellers in the UK. However, given the difficulties involved and the lack of evidence at this time of widespread harm being caused (and similar lack of evidence about potential benefits), we cannot justify recommending any further measures than currently exist to attempt to prevent the operations of websites from selling products without adherence to the restrictions in place. We recommend that governments should carefully monitor the incidence and extent of harms and benefits from this development to allow more informed judgments and evidence-based policy to be applied to this domain in future. We also recommend: (i) provision by public healthcare services of good information; (ii) voluntary adoption of good practice by providers; (iii) good professional medical practice adapted to this new development; and (iv) enforcement of legislation regarding the supply of antibiotics and state monitoring of antibiotic resistance.

Introduction

- 7.1 Buying pharmaceuticals over the internet has become increasingly common.²⁴⁹ The use of medicines, by its very nature, touches upon personal matters such as illness, despair, craving and addiction. These powerful motivational factors, combined with the transnational and comparatively regulation-free nature of the internet, provide the conditions for creating a very lucrative market for the sale of pharmaceuticals (or products sold as such).
- 7.2 Selling pharmaceuticals online takes a number of different forms. In some cases, people buy medicines from suppliers that are licensed by national regulatory authorities and provide products that are themselves licensed for sale. There are systems for registering and inspecting online pharmacies in various countries, including Great Britain (see Box 7.1). In other cases, people buy pharmaceuticals (or what are sold as pharmaceuticals) that are restricted or illegal in their own country, without a prescription or not under the authority of a pharmacist. Selling restricted medicines (which include some over-the-counter products) in the UK (and many other countries) without adhering to the applicable restrictions is illegal. However, people can easily purchase pharmaceutical products from websites and suppliers based in another country (the legality of such purchases depends on the substance bought). The suppliers may be operating legally or illegally in the country they are based in. The international nature of this trade contributes to making it difficult to assess, monitor and establish effective oversight measures.
- 7.3 The purchasing of pharmaceuticals online rather than face-to-face represents a significant shift in the way individuals interact with healthcare systems. It can be linked to consumerisation and responsabilisation, the social phenomena and aspects of personalisation discussed in Chapters 1 and 2, since it involves the exercise of consumer choice and the need for the purchaser to take more responsibility to verify that medications offered are what they purport to be and in some cases to make their own decisions without consulting health professionals. We noted in Chapter 2 (see Paragraph 2.14) that there had been a shift towards greater patient involvement in medical decision-making processes, and in some cases buying pharmaceuticals online can cut medical professionals out of the process altogether.

Box 7.1: Royal Pharmaceutical Society of Great Britain's online pharmacy registration scheme²⁵⁰

The Royal Pharmaceutical Society of Great Britain (RPSGB) has been the professional and regulatory body for pharmacists and pharmacy technicians in England, Scotland and Wales. At the time of writing, the RPSGB was in the process of separating its regulatory and professional roles, with a new General Pharmaceutical Council taking over as the regulatory body.

The RPSGB has established an online pharmacy registration scheme for companies based in Great Britain. If an online pharmacy meets the required conditions, the RPSGB provides its internet pharmacy logo with a registration number. The logo is then permitted for use with the facility for users to click on it to navigate to the RPSGB website where the registration of the internet pharmacy they have come from can be verified. The onus for compliance with the conditions of the scheme is on the registered pharmacy and not on any web design companies involved.

The situation in Northern Ireland is slightly different. Northern Ireland has not come under RPSGB's jurisdiction, nor will it for the new General Pharmaceutical Council. Rather, the Pharmaceutical Society of Northern Ireland (PSNI) fulfils an analogous function. Consequently, those pharmacies registered in Northern Ireland are not subject to the RPSGB's internet

²⁴⁹ Medicines and Healthcare products Regulatory Agency (2009) Risks of buying medicines over the internet, available at: <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/BuyingmedicinesovertheInternet/CON019610>.

²⁵⁰ Royal Pharmaceutical Society of Great Britain (2010) Internet pharmacy logo, available at: <http://www.rpsgb.org.uk/registrationandsupport/registration/internetpharmacylogo.html>.

pharmacy logo scheme, and the PSNI does not currently operate a similar scheme.²⁵¹

At the time of writing, draft legislation being considered by the European Parliament sought to amend Directive 2001/83/EC on the EU code relating to medicinal products for human use, by extending the Directive to cover pharmaceutical sales over the internet and to oblige Member States to set tougher sanctions against producers of fake medicines. The draft legislation aims to require national authorities to carry out frequent and unannounced inspections of premises of manufacturers, distributors and importers of active substances used as starting materials. A key provision is that licensed internet pharmacies would need to be authorised by national authorities and to display an official EU logo guaranteeing their authenticity, whose validity users could check in a centralised national website. How this proposed scheme would interact with, or supersede, the current RPSGB logo scheme is currently unclear.²⁵²

Benefits and harms

7.4 Some potential advantages and disadvantages of purchasing pharmaceuticals online were set out in Table 3.1.

Potential advantages

- Convenience;
- price competition;
- availability; and
- privacy.

Potential disadvantages

- Obtaining inappropriate or harmful medicines;
- adverse interactions with other medicines;
- limited or no opportunity for advice;
- risks from incomplete information about adverse effects and contraindications;
- increased danger of obtaining fake or low-quality medicines;
- no limits on quantity bought;
- possibility of increased antibiotic resistance arising from their misuse; and
- reduction in the quality of relationships with health professionals if health conditions not discussed.

These advantages and disadvantages apply to people purchasing for themselves as well as for others, including children, the elderly and other vulnerable groups.

Reasons people purchase pharmaceuticals online

7.5 People choose to buy online for reasons that include convenience, price, avoidance of embarrassment or being able to buy products that would not otherwise be available without prescription (or at all) in the purchaser's country. Some of the most commonly bought products (see Paragraph 7.18) are associated with conditions where social stigma is involved, suggesting that people might feel uncomfortable about talking to their doctor about their condition or about these pharmaceuticals. They might also think, correctly or otherwise, that such products would

²⁵¹ The PSNI has published a document outlining how internet pharmacies registered in Northern Ireland must operate. See: Pharmaceutical Society of Northern Ireland (2009) *Professional standards and guidelines for internet pharmacy services*, available at: <http://www.psnir.org.uk/documents/316/Standards+on+Internet+Pharmacy.pdf>.

²⁵² See: Watson R (2010) EU prepares to tackle counterfeit drugs *British Medical Journal* **340**: c2425; Rankin J (2010) MEPs want crack down on counterfeit medicines *EuropeanVoice.com* 27 April, available at: <http://www.europeanvoice.com/article/2010/04/meps-want-tough-action-on-counterfeit-medicines/67795.aspx>; European Parliament (2010) Medicinal products for human use: Prevention of the entry into the legal supply chain of falsified medicinal products (amend. Directive 2001/83/EC).

not be prescribed by a doctor, or they might have been refused them in the past. The internet offers the possibility of obtaining medication that is not provided by the public healthcare system in the purchaser's country or by their insurance scheme. It may also offer the chance of obtaining the medication at a lower cost than through other channels.²⁵³

Potential harms to health

- 7.6 Along with such benefits, however, serious harms can also result from buying pharmaceutical products online (see Box 7.2). Owing to the relatively recent development of this practice, we have not found systematic evidence about either benefits or harms. One author concludes: "...we simply do not have sufficient evidence whether, and under which conditions, online prescribing of relatively safe drugs... actually creates more harm than benefit, or vice versa."²⁵⁴ But not all online purchases are of 'relatively safe' drugs, and the possibility of serious harm can be inferred from the history of pharmaceuticals before today's standards of testing and licensing were developed.
- 7.7 Buying online from a website that is not a registered pharmacy offers no opportunity for a healthcare professional to assess whether the medicine is safe and appropriate for the individual concerned, or to advise on how the medication should be taken. The information about medicines available on some websites can be incomplete, even where it might be factually accurate.²⁵⁵ Prescription errors by doctors are of course far from unknown: findings vary, but studies in the last ten years indicate an error rate in prescribing of between 7 and 12% but that many of those errors are corrected by pharmacists, nurses or other doctors.²⁵⁶ But not consulting with a healthcare professional can increase the risk of reaching either an incorrect diagnosis of the condition or the inappropriate pharmaceutical (either in form or dosage) being selected. There is no opportunity to talk to a healthcare professional about managing a condition, and there may be an increased risk of attempting to treat symptoms rather than their underlying cause. There have, for example, been instances of people delaying consultation with a health professional while self-treating with pharmaceuticals purchased via the internet.²⁵⁷
- 7.8 Furthermore, the international access to pharmaceuticals provided by the internet may lead to confusion about medicine names and labels. For example, a medicine as ubiquitous as paracetamol is known throughout the world by a variety of different names. In the USA, for example, it is called acetaminophen,²⁵⁸ but is often known simply through a brand name such as Tylenol,²⁵⁹ while in Israel paracetamol is often known through another brand name, Acamol.²⁶⁰

²⁵³ Although we note that it has been suggested that economic considerations are less likely to be primary motivating factors for people who live "in a regulated drugs market where final drug prices are negotiated", such as in Europe. Orizo G, Schulz R and Domenighini S *et al.* (2009) Cyberdrugs: A cross-sectional study of online pharmacies characteristics *European Journal of Public Health* **19**(4): 375–7. People in the USA, for example, pay approximately 60% more for brand-name pharmaceuticals than those in Great Britain or Switzerland and two-thirds more than Canadians. Bostwick JM and Lineberry TW (2007) Do cheap internet drugs threaten the safety of the doctor–patient relationship? *Expert Opinion in Drug Safety* **6**(1): 10.

²⁵⁴ Eysenbach G (2001) Online prescriptions of pharmaceuticals: Where is the evidence for harm or for benefit? A call for papers – and for reflection *Journal of Medical Internet Research* **3**(1): e1.

²⁵⁵ Clauson KA, Polen HH, Boulos MN and Dzenowagis JH (2008) Scope, completeness, and accuracy of drug information in Wikipedia *The Annals of Pharmacotherapy* **42**(12): 1814–21.

²⁵⁶ See: Dorman T, Ashcroft D, Heathfield H *et al.* (2009) *An in-depth investigation into causes of prescribing errors by foundation trainees in relation to their medical education – EQUIP study*, available at: http://www.gmc-uk.org/FINAL_Report_prevalence_and_causes_of_prescribing_errors.pdf_28935150.pdf; Shah SNH, Aslam M and Avery AJ (2001) A survey of prescription errors in general practice *The Pharmaceutical Journal* **267**: 860–2.

²⁵⁷ Veronin MA and Clauson KA (2007) Internet pharmacy drugs delay treatment for congestive heart failure *Journal of the American Pharmacists Association* **47**(4): 436.

²⁵⁸ Bradley N (1996) British Medical Journal should use "paracetamol" instead of "acetaminophen" in its index *British Medical Journal* **313**: 689.

²⁵⁹ MedlinePlus (2010) Acetaminophen, available at: <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a681004.html#combo-names>.

²⁶⁰ Israeli Ministry of Health (2008) Acamol, available at: <http://www.health.gov.il/units/pharmacy/trufot/alonim/4062.pdf>.

- 7.9 There is also the potential for adverse reactions, or adverse interactions with other products. We have heard in our consultation that the increased privacy that online purchasing offers also means that healthcare professionals are concerned that they might prescribe medicines without knowing about other products the patient is taking that they have bought for themselves online.²⁶¹
- 7.10 The internet also facilitates access to antibiotics without a prescription.²⁶² It is known that self-medication using antibiotics takes place in all countries, but currently there is limited evidence as to the extent that antibiotics are actually purchased over the internet, without prescription, for this purpose.²⁶³ Increased use of antibiotics is a case of individual behaviour that can damage public health by increasing antibiotic resistance in the population as bacteria develop the ability to survive exposure. We return to this risk in our recommendation in Paragraph 7.48.
- 7.11 Finally, and perhaps most dangerously, the authenticity, safety and quality of products are harder for purchasers to ascertain if registered pharmacies are not used (whether 'bricks and mortar' or internet pharmacies).²⁶⁴ Although the risk of obtaining fake products from registered pharmacies cannot be completely ruled out, buying from outlets that are not registered pharmacies increases the risk that products could be fake, contain dangerous substances or the wrong dose of the expected substance.²⁶⁵ They could also be new drugs that have not yet been tested appropriately or approved. The Medicines and Healthcare products Regulatory Agency (MHRA) reported in 2008²⁶⁶ that the World Health Organization (WHO) estimated fake medicines to comprise more than 10% of the global medicines market.²⁶⁷ In 2009, a group comprising Pfizer, the MHRA, the RPSGB, The Patients Association and HEART UK launched a campaign to inform the public of the risks involved in purchasing fake medicines from unlicensed suppliers operating over the internet.²⁶⁸ It has also been estimated that 62% of medicines purchased over the internet are fake.²⁶⁹ Of course we recognise that it was possible to obtain medicines by mail order or from other unregistered sources before the internet: but, for reasons described in Chapter 5, the distinctive features of the internet – the combination of search facilities and large amounts of information – are likely to make unlicensed pharmaceutical products more accessible than in the past.

²⁶¹ Although we note that there is also the risk of this problem with 'conventional' practices, for example if primary care doctors and hospitals or other healthcare providers do not communicate about patients' medicines. See: O'Dowd A (2009) GPs and hospitals do not communicate adequately about patients' medicines *British Medical Journal* **339**: b4450.

²⁶² Mainous AG, Everett CJ, Post RE, Diaz VA and Hueston WJ (2009) Availability of antibiotics for purchase without a prescription on the internet *Annals of Family Medicine* **7(5)**: 431–5.

²⁶³ *Ibid.*

²⁶⁴ Liang BA and Mackey T (2009) Searching for safety: Addressing search engine, website, and provider accountability for illicit online drug sales *American Journal of Law and Medicine*, **35(1)**: 125–84.

²⁶⁵ Harms are further discussed in Montoya ID (2008) The root cause of patient safety concerns in an internet pharmacy *Expert Opinion on Drug Safety* **7(4)**: 337–41.

²⁶⁶ Medicines and Healthcare products Regulatory Agency (2008) *Medicines and medical devices regulation: What you need to know*, available at: <http://www.mhra.gov.uk/home/groups/comms-ic/documents/websitesresources/con2031677.pdf>.

²⁶⁷ We note that the proportion in developing countries is far higher than in developed countries and recent research suggests that the majority of fake medicines are produced in developing countries such as China, India and Russia. See: Royal Pharmaceutical Society of Great Britain (2008) Millions risk health buying drugs online, available at: <http://www.rpsgb.org/pdfs/pr080110.pdf>; European Alliance for Access to Safe Medicines (2008) *The Counterfeiting Superhighway*, available at:

http://v35.pixelcms.com/ams/assets/312296678531/455_EAASM_counterfeiting%20report_020608.pdf.

²⁶⁸ 'Get Real, Get A Prescription' campaign (2009) Over 7 million UK adults may be gambling their lives with fake medicine, <http://www.rpsgb.org.uk/pdfs/pr091103.pdf>.

²⁶⁹ Mayor S (2008) More than half of drugs sold online are fake or substandard *British Medical Journal* **337**: a618.

Box 7.2: Evidence of harm from buying pharmaceuticals online

There is currently little systematic evidence of widespread harm from pharmaceuticals bought over the internet. For example, in 2007 it was reported that the US Food and Drug Administration (FDA) did not have accurate figures on 'adverse events' resulting from these purchases.²⁷⁰ Numerous cases have been reported in the media,²⁷¹ and the FDA cites the case of a man in the USA, with a family history of heart disease, who died as a result of taking Viagra bought online without examination by a doctor. There is also the much publicised case of Ryan Haight, who died in 2001 from an overdose of Vicodin acquired via the internet (see also Box 7.3). The Senate Report that accompanied the Ryan Haight Online Pharmacy Consumer Protecting Act 2007 lists eight incidents in relation to the online purchase of prescription controlled substances that are described as a consequence of "ease of access to the Internet, combined with lack of medical supervision".²⁷²

A survey in the UK, published in *GP* magazine, reported that one in four general practitioners said they had treated patients for adverse reactions to medicines bought online, while a further 8% suspected they had treated side-effects of internet-bought drugs.²⁷³ However, the survey did not ask whether the pharmaceuticals that caused these reactions were purchased from abroad or from unregistered outlets, or whether the reactions were the result of fake drugs, a failure in the instructions provided, or an interaction with another medication.

One of the reasons why it is hard to obtain evidence of the scope of harms is that privacy is an important motivation for people to buy pharmaceuticals online. As already noted, the desire to deal with conditions that can be considered embarrassing, such as erectile dysfunction (see Paragraph 7.5) is an important consideration in this method of purchase. So adverse reactions are unlikely to be commonly reported if people perceive the consequences of revealing the incident to be socially or psychologically detrimental, even in the face of potentially significant health problems. Reporting the incident not only reveals the underlying condition about which there may have been embarrassment originally, but also that the customer bought a product online, possibly illegally and perhaps without due safeguards.

²⁷⁰ Easton G (2007) Clicking for pills *British Medical Journal* **334**: 14–5. The FDA itself states that it is "impossible to accurately quantify adverse event rates" for pharmaceuticals purchased via the internet, due to the limited number of reports the FDA's postmarketing surveillance system receives in general. See: Food and Drug Administration (2009) Buying medicines and medical products online FAQs, available at:

<http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm134631.htm>.

²⁷¹ See: BBC News Online (21 April 2009) *Internet drug warning after death*, available at: <http://news.bbc.co.uk/1/hi/wales/8010210.stm>. See also Liang BA and Mackey T (2009) Searching for safety: Addressing search engine, website, and provider accountability for illicit online drug sales *American Journal of Law and Medicine*, **35**: 125–84, which highlighted the following examples: Booker J (2008) Action urged on internet drugs *New Zealand Herald* 30 September, available at: http://www.nzherald.co.nz/marlborough/news/article.cfm?l_id=132&objectid=10534908&pnum=1; Griffin D and Fitzpatrick D (2008) Widow: My husband died from online drugs *CNNhealth.com*, available at: <http://edition.cnn.com/2008/HEALTH/05/21/online.drugs/index.html> 22 May; Solomon S (2007) BC woman killed by fake drugs bought online, *National Review of Medicine* 30 July, available at: http://www.nationalreviewofmedicine.com/issue/2007/07_30/4_policy_politics_13.html; Marshall M (2008) Online pharmacies: Dangerous prescription? *CBS NEWS* 31 May, available at: <http://www.cbsnews.com/stories/2008/05/31/earlyshow/health/main4142407.shtml>; Paul R (2007) Illegal internet pharmacies pose a growing threat *Drug Topics* 20 August, available at: <http://drugtopics.modernmedicine.com/drugtopics/article/articleDetail.jsp?id=450106&searchString=MarkMonitor>; Barnet A (2003) Deadly cost of the trade in online prescription drugs *The Observer* 10 August, available at: <http://www.guardian.co.uk/society/2003/aug/10/health.drugs>.

²⁷² Senate Report Number 110–521, p5, available at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_reports&docid=f:sr521.pdf.

²⁷³ The research reflected the answers received from a survey of 420 GPs in the UK. See: Moberly T (2009) One in four GPs report online drug concerns *GP* 16 April, available at: <http://www.healthcarerepublic.com/search/GP/news/898287/One-four-GPs-report-online-drug-concerns/?DCMP=ILC-SEARCH>.

- 7.12 Several studies have examined the quality of pharmaceuticals bought online. The WHO, during the course of its investigative activities in a number of countries,²⁷⁴ found that medicines purchased over the internet from illegal sites that conceal their physical address were fake in over 50% of cases.²⁷⁵ A study by the European Alliance for Access to Safe Medicines reported that 62% of prescription products ordered from the internet were fake, substandard or unapproved generic medicines.²⁷⁶ In 2005 the Office of Compliance in the US FDA's Center for Drug Evaluation and Research commissioned a study to "determine the quality of a select group of pharmaceutical products purchased via the internet from foreign sources".²⁷⁷ The authors of the study purchased 20 pharmaceutical samples from eight different websites and one sample of each drug product manufactured in the USA from a local supplier. The study concluded: "Two of 20 samples failed [United States Pharmacopeia standards] for quality attributes. The additional analytical methods found 11 of 20 samples had different formulations when compared to the U.S. product. Seven of the 20 samples arrived in questionable containers, and 19 of 20 had incomplete labelling. Only 1 of the 20 samples had final packaging similar to the U.S. products."²⁷⁸
- 7.13 To note such risks with products bought online is not to deny that there can be many problems in the method of providing drugs to patients through a face-to-face consultation, where harm can be caused by factors such as errors in diagnosis and prescription, wrong doses, ineffective medicines, and the pharmaceutical companies' influence on doctors' prescribing practices, including a tendency to 'medicalise' all ills. Some may argue that 'empowering' the consumer in this domain can help to correct these familiar problems, as it has in other areas where paternalism has been challenged by consumerism.

Extent of use and the type of products purchased

- 7.14 The proliferation and expansion of internet pharmaceutical outlets is the result of a combination of factors: increasing internet access and use, new technology facilitating online purchase of goods, many people's increasing familiarity with internet purchasing, the availability of 'lifestyle drugs',²⁷⁹ and the convenience and privacy that the internet can afford for some types of purchase.
- 7.15 Indeed, online purchasing of pharmaceuticals is a natural extension of some of the other forms of increasing online delivery of healthcare services discussed in this report, namely the recording of health information using online personal health records (Chapter 6) or telemedicine (Chapter 8), and is underlain by the same information communications technology. This technology makes possible the remote prescribing of medication – using online methods rather than requiring a face-to-face visit to the doctor – to order prescribed medicines that can be delivered. There are now a number of online clinics in the UK and elsewhere whose doctors are permitted to prescribe certain pharmaceuticals following an online consultation with a patient ('e-prescribing').²⁸⁰

²⁷⁴ Information supplied by the World Health Organization.

²⁷⁵ World Health Organization (2010) *Medicines: Counterfeit medicines fact sheet No 275*, available at: <http://www.who.int/mediacentre/factsheets/fs275/en/index.html>.

²⁷⁶ European Alliance for Access to Safe Medicines (2008) *The counterfeiting superhighway*, available at: http://v35.pixelcms.com/ams/assets/312296678531/455_EAASM_counterfeiting%20report_020608.pdf.

²⁷⁷ Westenberg BJ, Ellison CD and Fussner AS *et al.* (2005) Quality assessment of internet pharmaceutical products using traditional and non-traditional analytical techniques *International Journal of Pharmaceutics* **306**: 56–70.

²⁷⁸ *Ibid.*

²⁷⁹ The term 'lifestyle drug' is generally considered to refer to "drugs taken to satisfy a non-medical or non-health-related goal". Some people include sildenafil, orlistat and anti-baldness drugs in this classification. Lifestyle drugs are also sometimes referred to as 'lifestyle medicines'. See: Gilbert G, Walley T and New B (2000) Lifestyle medicines *British Medical Journal* **321**: 1341–4; Flower R (2004) Lifestyle drugs: Pharmacology and the social agenda *Trends in Pharmacological Sciences* **25(4)**: 182–5.

²⁸⁰ The RPSGB/General Pharmaceutical Council does not have any jurisdiction over these online clinics unless they also operate as a pharmacy. See Box 7.1 and Paragraph 7.25.

- 7.16 As we noted in Chapter 5, the incidence of internet use is lower among the elderly (one of the largest groups of pharmaceutical users) than among the young and middle-aged, but even so internet use by the elderly has grown markedly and seems likely to continue to do so. We know that the number of people who buy pharmaceuticals online has increased and the number of websites is growing.²⁸¹ But it is currently hard to quantify how many people buy medicines online, the volume bought and their authenticity.²⁸² That difficulty arises from the nature of the product and the fact that internet pharmacies, especially ‘rogue’ websites, “open and close with high frequency, often have several URLs for one company, and may only be transiently listed on select search engines”.²⁸³
- 7.17 Nevertheless, some estimates have been made of the extent of online purchasing. In 2003, the UK National Audit Office reported that 1% of UK respondents to a survey claimed to have bought prescription medicines over the internet.²⁸⁴ More recently, in 2008, the RPSGB reported that approximately two million people in Great Britain were regularly purchasing pharmaceuticals online (both with a prescription from registered UK pharmacies and without prescriptions from other websites).²⁸⁵ A recent survey commissioned by Pfizer, the MHRA, RPSGB, The Patients Association and HEART UK found that 15% of the British adults asked had bought a prescription-only medicine online without a prescription.²⁸⁶ For the USA, a 2006 study found that searching for information on prescription or over-the-counter drugs was the fifth most popular health topic searched for, and a 2004 study found that 4% of Americans had purchased prescription medications online.²⁸⁷ Within the EU, mail-order trade in medicines has been found to be “by and large marketed through the internet”. In the Netherlands, the market share of internet pharmacies is still small: there are reported to be about ten “serious” mail-order pharmacies in operation, although their operations are expanding.²⁸⁸ In Germany, approximately seven million people buy from mail-order pharmacies, and mail-order sales account for approximately 8–10% of total pharmaceutical sales.²⁸⁹
- 7.18 In developed countries, online pharmacies supply so-called ‘lifestyle drugs’,²⁹⁰ such as for weight loss, hair loss or erectile dysfunction. There is likely to be less demand for therapeutic medication in countries with “high social security coverage” (such as France) given that the price of the relevant pharmaceutical may actually be higher than in domestic pharmacies.²⁹¹ RPSGB has identified the most popular purchases online (or at least products being sold as such) as Prozac (an antidepressant), Viagra (for erectile dysfunction), Valium (a tranquiliser), Ritalin (a psychostimulant), Serostim (a synthetic growth hormone) and Provigil (a

²⁸¹ Medicines and Healthcare products Regulatory Agency (2009) Risks of buying medicines over the internet, available at: <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/BuyingmedicinesovertheInternet/CON019610>; Levaggi R, Orizio G, Domenighini C *et al.* (2009) Marketing and pricing strategies of online pharmacies *Health Policy* **92**: 187–96.

²⁸² Levaggi R, Orizio G, Domenighini C *et al.* (2009) Marketing and pricing strategies of online pharmacies *Health Policy* **92**: 187–96.

²⁸³ Liang BA and Mackey T (2009) Searching for safety: Addressing search engine, website, and provider accountability for illicit online drug sales *American Journal of Law and Medicine* **35**: 125–84.

²⁸⁴ National Audit Office (2003) *Safety, quality, efficacy: Regulating medicines in the UK*, p26, available at: http://www.nao.org.uk/publications/0203/safety_quality_efficacy_reg.aspx.

²⁸⁵ Royal Pharmaceutical Society of Great Britain (2008) Millions risk health buying drugs online, available at: <http://www.rpsgb.org/pdfs/pr080110.pdf>.

²⁸⁶ ‘Get Real, Get a Prescription’ campaign (2009) Over 7 million UK adults may be gambling their lives with fake medicine, available at: <http://www.rpsgb.org/pdfs/pr091103.pdf>.

²⁸⁷ Fox S (2006) *Online health search*, available at: http://www.pewinternet.org/~media/Files/Reports/2006/PIP_Online_Health_2006.pdf.pdf; Fox S (2004) *Prescription drugs online*, available at: http://www.pewinternet.org/~media/Files/Reports/2004/PIP_Prescription_Drugs_Online.pdf.pdf.

²⁸⁸ Seeberg-Elverfeldt NJ (2009) Mail-order trade in medicines in Europe: a guide for legislators to protect consumers *European Journal of Health Law* **16**: 351–66.

²⁸⁹ *Ibid.*

²⁹⁰ Glover-Thomas N and Fanning J (2010) Medicalisation: The role of e-pharmacies in iatrogenic harm *Medical Law Review* **18(1)**: 28–55.

²⁹¹ Mahé E, Saiag P, Aegerter P and Beauchet A (2009) Shopping for psoriasis medicine on the internet *Journal of the European Academy of Dermatology and Venereology* **23**: 1050–5.

psychostimulant).²⁹² A study in the USA has also shown that antibiotics are commonly available online without prescription.²⁹³

Current system of interventions

- 7.19 The current response to internet supply of pharmaceuticals (and products sold as such) in the UK and many other countries mainly involves attempts to adapt and apply the service-specific legislative framework that had been developed for control of medicinal products before the internet came to be used for the supply of these products. Measures involving state-specific legal powers regulate the advertising, supply and sale of medicines, and registration of pharmacies and professionals. There are also guidance and verification schemes specifically designed for internet pharmacy services. Some measures of the 'general governance' type described in Chapter 4 (see Box 4.1) also apply to this area, including professional standards and laws such as the common law of negligence, product liability law and the consumer regime. The main type of intervention in the UK that does not rely on the state-specific legal power is the advertising standards regime, which applies to advertising medicinal products as it does to any other product. Box 7.3 summarises the pattern of interventions in the USA.
- 7.20 However, national-level legislation relating to online sale of pharmaceuticals often has limited impact given that websites and suppliers can be located in different countries from consumers and therefore in a different jurisdiction (see also Paragraph 5.24). State regulatory agencies are restricted by the legislative and policy frameworks within which they practice. Laws can be hard to enforce in this domain because new websites can be created rapidly or move jurisdiction and it is hard to track the products they deliver. For example, research by the FDA in the USA highlighted the difficulty internet users can have in identifying the origin of the pharmaceuticals they are purchasing. The FDA's research reported that, of 11,000 websites purporting to be Canadian internet pharmacies, only about 1,000 actually sold pharmaceuticals, and of them less than 25% were registered or hosted by companies or individuals in Canada.²⁹⁴

Box 7.3: Online pharmacies in the USA: a comparison

The provision of medicines in the USA is controlled by a mix of state and federal regulation. Federal legislation requires prescriptions "be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."²⁹⁵ This requirement has been interpreted as meaning that prescriptions must be made "in accordance with a standard of medical practice generally recognized and accepted in the United States".²⁹⁶ The Drug Enforcement Administration is responsible for ensuring that controlled substances are used in compliance with Federal law.²⁹⁷

Unlike in the UK, where existing legislation was adapted to license online supply of pharmaceuticals by adding a new registration scheme, the USA enacted specific legislation for control of online pharmacies.

The much-publicised death of the teenager Ryan Haight in 2001 from an overdose of the painkiller Vicodin (see also Box 7.2), after buying the drug online,²⁹⁸ was one of the factors leading to increased legislative control of online pharmacies at the federal level in the USA, in the form of the Ryan Haight Online Pharmacy Consumer Protection Act 2008 ('The Ryan Haight

²⁹² Royal Pharmaceutical Society of Great Britain (2008) Millions risk health buying drugs online, available at: <http://www.rpsgb.org/pdfs/pr080110.pdf>.

²⁹³ Mainous AG, Everett CJ, Post RE, Diaz VA and Hueston WJ (2009) Availability of antibiotics for purchase without a prescription on the internet *Annals of Family Medicine* **7(5)**: 431–5.

²⁹⁴ Krebs B (2005) Few online 'Canadian pharmacies' based in Canada, FDA Says *Washington Post* 14 June, available at: <http://www.washingtonpost.com/wp-dyn/content/article/2005/06/14/AR2005061400254.html>.

²⁹⁵ 21 US Code of Federal Regulations § 1306.04(a).

²⁹⁶ *United States v. Moore*, 423 U.S. 122, 96 S.Ct. 335, 46 L.Ed.2d 333 (1975).

²⁹⁷ See: <http://www.justice.gov/dea/agency/mission.htm>. 'Controlled substances' in the USA are those substances or their analogues (i.e. similar chemical structure or effect) included in the relevant Schedules of the Controlled Substances Act 1970.

²⁹⁸ National Association of Boards of Pharmacy (2009) *State of the internet: NABP position paper on the continued proliferation of rogue internet drug outlets*, available at: <http://www.nabp.net/assets/State%20of%20the%20Internet.pdf>.

Act'). This amended the US Controlled Substances Act 1970 and Controlled Substances Import and Export Act by adding several new provisions to prevent the illegal distribution and dispensing of controlled substances by means of the internet. The Act made it a violation of the Controlled Substances Act 1970 for a medical practitioner to issue a prescription for a controlled substance over the internet without having performed at least one face-to-face consultation (with some exceptions). However, performing one such consultation was not necessarily deemed sufficient to demonstrate a "legitimate medical purpose".²⁹⁹

The Ryan Haight Act also provides a specific definition for the term 'online pharmacy', which is "a person, entity, or internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet".³⁰⁰

The Verified Internet Pharmacy Practice Sites (VIPPS), an information and verification website, is operated by the National Association of Boards of Pharmacy. To qualify under the scheme, a pharmacy must "comply with the licensing and survey requirements of their state and each state to which they dispense pharmaceuticals" and comply with VIPPS criteria.³⁰¹ These criteria include patient rights to privacy, authentication and security of prescription orders, adherence to a recognised quality assurance policy, and provision of consultation between patients and pharmacists.

UK legislation on the selling of pharmaceuticals

- 7.21 In the UK, medicines are divided by the Medicines Act 1968 into three broad categories: (1) those that can be sold from a wide range of premises such as supermarkets, provided those premises can be closed to exclude the public (i.e. they are lockable) and the medicines are pre-packed (that is, 'general sale list' medicines such as ibuprofen); (2) those that can be obtained only from registered pharmacy premises by or under the supervision of a pharmacist; and (3) those that can be obtained only with a prescription from a healthcare professional. The first two categories here are referred to as 'over-the-counter' medicines. Restrictions over which drugs can be prescribed only by a medical practitioner, which can be obtained only from a pharmacist and which can be sold from other sources vary from one country to another.
- 7.22 The Medicines Act 1968 (albeit now superseded in many of its provisions by EU legislation) requires medicines to be licensed before they can be legally supplied in the UK, and the MHRA is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. Additionally, some medicines fall under the provisions of the Misuse of Drugs Act 1971, which places further restrictions on supply.
- 7.23 A number of medicines can be legally supplied from a registered online pharmacy, including not only over-the-counter medicines (categories (1) and (2) above) but also prescription-only medicines, provided certain conditions – as specified in Box 7.1 – are met. The laws mentioned above apply equally to online pharmacies as they do to more conventional pharmacies or healthcare clinics. The legality of internet pharmacies selling pharmaceuticals to people based in another country from that where the pharmacy is based has been tested at the EU level (see Box 7.4).

²⁹⁹ US Federal Register (2009) *Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. Interim final rule with request for comments* 74(64): 15595–625.

³⁰⁰ 21 US Code of Federal Regulations § 1300.04(h), available at: <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&qgn=div5&view=text&node=21:9.0.1.1.1&idno=21>.

³⁰¹ National Association of Boards of Pharmacy (2009) VIPPS accreditation, available at: <http://www.nabp.net/indexvipps2.asp>.

Box 7.4: Internet pharmacies: an EU case study

Within the EU, the legality of internet pharmacies, specifically the cross-border trade in pharmaceuticals, was tested in the *DocMorris* case of 2003.³⁰² The case concerned the provision of prescription and non-prescription pharmaceuticals in Germany by the DocMorris company, which was established in the Netherlands but did much of its trade in Germany.³⁰³ DocMorris was taken to the European Court of Justice (ECJ) by the regional court of Frankfurt following an accusation of illegal practice by the German Association of Pharmacists.³⁰⁴ Pharmaceuticals could be ordered from the company in several ways, including telephone, fax and online. Some products offered by the company were 'prescription-only' in either Germany or the Netherlands; DocMorris' approach was "[to apply] the stricter classification of that prevailing in the Netherlands and that in the country of residence of the customer and would only supply prescription-only medicines on production of the original prescription".³⁰⁵

The ECJ considered several issues, including: (i) which law to follow in cross-border practice;³⁰⁶ and (ii) whether German legislation prohibiting the mail-order sale of pharmaceuticals authorised for sale only in pharmacies contravened Article 28 of the EC Treaty (which provides for the free movement of goods within the European internal market). The Court held that where a pharmaceutical product was not authorised in a specific country, it could not be supplied there: "Article 28 could not be used to circumvent the system of national marketing authorisations".³⁰⁷

The ECJ also held that while Member States could impose a more restrictive regulatory environment on some products than other nations, such as that pertaining to pharmaceuticals, this regulation must be executed with due regard to Article 28 of the EC treaty. The court found that, while the German legislative prohibition on the mail-order sale of pharmaceuticals initially appeared to violate Article 28, the need to provide individual advice and to verify prescriptions provided a sufficiently persuasive argument for the Court to find that the prohibition was lawful under Article 30, which allows for restrictions on the grounds of public health. The Court held:

*"Article 30 EC may be relied on to justify a national prohibition on the sale by mail order of medicinal products which may be sold only in pharmacies in the Member State concerned in so far as the prohibition covers medicinal products subject to prescription. However, Article 30 EC cannot be relied on to justify an absolute prohibition on the sale by mail order of medicinal products which are not subject to prescription in the Member State concerned."*³⁰⁸

Prior to the *DocMorris* judgment, most EU Member States rejected mail-order trading in medicines. That is no longer the case.³⁰⁹ However, the judgment contained no safety standards: these were included in the Council of Europe's *Resolution on good practices for distributing medicines via mail order which protect patient safety and the quality of the delivered medicine*.³¹⁰

- 7.24 Legislation mostly relates to the supplier rather than the purchaser. UK medicines legislation does not restrict the importation of medicines for personal use purchased online. But 'controlled drugs' (see below) are subject to the additional requirements of the Misuse of Drug Regulations 2001 which limit the importation if medicines falling into this category.

³⁰² Case C-322/1 *Deutscher Apothekerverband eV v 0800 DocMorris NV and Jacques Waterval* [2003], available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62001J0322:EN:HTML>.

³⁰³ Catalán J (2004) Internet medicine sales and the need for homogenous regulation *International Journal of Medical Marketing* **4**(4): 342–9.

³⁰⁴ Mäkinen MM, Rautava PT and Forsstrom JJ (2005) Do online pharmacies fit European internal markets? *Health Policy* **72**: 245–52.

³⁰⁵ Pickering G (2007) *Internet Pharmacy in the European Union*, available at: http://www.reedsmith.com/db/documents/Internet_Pharmacy_article.pdf.

³⁰⁶ Mäkinen M Rautava PT and Forsström JH (2005) Do online pharmacies fit European internal markets? *Health Policy* **72**: 245–52.

³⁰⁷ Pickering G (2007) *Internet pharmacy in the European Union*, available at: http://www.reedsmith.com/db/documents/Internet_Pharmacy_article.pdf.

³⁰⁸ Case C-322/1 *Deutscher Apothekerverband eV v 0800 DocMorris NV and Jacques Waterval* [2003], available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62001J0322:EN:HTML>.

³⁰⁹ Seeberg-Elverfeldt NJ (2009) Mail-order trade in medicines in Europe: a guide for legislators to protect consumers *European Journal of Health Law* **16**: 351–66.

³¹⁰ Council of Europe (2007) *Resolution ResAP(2007)2 on good practices for distributing medicines via mail order which protect patient safety and the quality of the delivered medicine*, available at: http://www.coe.int/t/information/society/documents/Goodpractices_en.pdf.

Oversight of the supply of medicines in the UK

- 7.25 Medicines of the second and third types described in Paragraph 7.21 can only be legally supplied only by registered healthcare professionals, including pharmacists. All retail pharmacies in the UK,³¹¹ including those providing internet services, must be registered with the RPSGB/General Pharmaceutical Council (the new regulator that was coming into operation at the time of writing) or with the Pharmaceutical Society of Northern Ireland, and broadly similar arrangements apply in many other countries. Anyone who breaches these rules is guilty of an offence, and courts may impose an injunction to forbid someone from further breaches of those rules. Any further breach would constitute contempt of court, for which severe penalties apply.
- 7.26 The MHRA, the agency mentioned above, is responsible for preventing others from selling or supplying medicines of the second and third types.³¹² The MHRA also monitors internet sites that are known to be selling prescription-only medicines and performs checks to see whether such sites are based in the UK. If they are, and they are not registered pharmacies, the MHRA can prosecute those concerned. Where the sites are based overseas, the MHRA refers them to the relevant regulatory body in their country of origin. In 2007, research found 570 websites hosted in the UK selling medicines,³¹³ yet at the time of writing there were only 116 internet pharmacies registered with the RPSGB, suggesting a notable disparity between the number of internet suppliers and those that were licensed.
- 7.27 The RPSGB/General Pharmaceutical Council maintains an inspectorate of some 26 people which, among other duties, aims to enforce the provisions of the Medicines Act 1968 that relate to the retail sale and supply of human medicines.³¹⁴ The inspectorate works by investigation, education, advice and enforcement.³¹⁵ It performs both routine visits to premises and specific investigations stemming from complaints made against pharmacies and pharmacists. Every three years it routinely visits registered pharmacy premises, including those of internet pharmacies.
- 7.28 In addition to the usual rules that apply to ‘bricks and mortar’ pharmacies, the RPSGB/General Pharmaceutical Council demands professional standards for registered pharmacies trading on the internet. The standards include:
- the website having details of the pharmacy (ownership, address, registration of pharmacist), and how to make a complaint;
 - data security and encryption;
 - respect for patient choice (avoiding ‘prescription direction’);
 - provision of information/clinical assessment;
 - security of delivery arrangements;
 - records of supplies; and
 - special care with regard to high volumes of prescriptions to overseas patients.³¹⁶

³¹¹ The use of the title ‘pharmacy’ is legally limited to registered pharmacies, hospitals and health centres (s78 Medicines Act 1968). Those using such a title in an unauthorised manner in the UK may be committing a criminal offence and therefore be liable to prosecution. See: Royal Pharmaceutical Society of Great Britain (2009) Internet pharmacy logo, available at: <http://www.rpsgb.org/pdfs/iplfaq.pdf>.

³¹² The MRHA reported that during 2009/2010 it completed 16 prosecutions, with a conviction rate of 73%. See: MRHA (2010) *Annual statistics 2009–10*, available at: <http://www.mhra.gov.uk/Publications/Corporate/AnnualReports/CON087861>.

³¹³ The Pharmaceutical Journal (2007) One in five online pharmacies operates from the UK *The Pharmaceutical Journal* **279**: 197.

³¹⁴ Royal Pharmaceutical Society of Great Britain (2010) Inspectorate, available at: <http://www.rpsgb.org/protectingthepublic/inspectorate/>.

³¹⁵ *Ibid.*

³¹⁶ Royal Pharmaceutical Society of Great Britain (2009) *Professional standards and guidance for internet pharmacy services*, available at: <http://www.rpsgb.org.uk/pdfs/coepsqintpharm.pdf>.

UK professional oversight

- 7.29 Only certain qualified and registered people (such as a doctor, dentist, nurse or midwife) are allowed to prescribe prescription-only medications in the UK. Practitioners who prescribe in an irresponsible way may have their prescribing rights revoked.³¹⁷ Additional restrictions apply if the medicine concerned is a 'controlled drug' within Schedule 2 or 3 of the Misuse of Drugs Act 1971.³¹⁸ The person writing the prescription must have an address within the UK, so an online clinic or pharmacy based overseas cannot legally employ a staff-doctor to write prescriptions for Schedule 2 and 3 drugs for UK patients.³¹⁹
- 7.30 The *RPSGB Code of ethics for pharmacists and pharmacy technicians* sets out standards of conduct, practice and performance expected of pharmacists and pharmacy technicians, and failure to comply with the requirements of the Code can result in de-registration. The *Professional standards and guidance for internet pharmacy services* expands on the principles of the Code of Ethics to set out the professional responsibilities for pharmacists and pharmacy technicians who are involved in the sale and supply of medicines via the internet.³²⁰ Significantly, the standards state that patients are entitled to expect the same quality of pharmaceutical care irrespective of whether the service is provided online or face-to-face in the pharmacy's premises.³²¹ For over-the-counter medicines, this standard means that advice on safe use should be available and that suppliers should be aware of the possibility of abuse of the product in question. For provision of prescription-only medicines, the standards require, among other things, ensuring the clinical appropriateness of the prescription for the patient and advising the patient to consult a local pharmacy whenever a prescription indicates that their interests would be better served by a face-to-face consultation.³²²

Direct-to-consumer advertising of pharmaceuticals

- 7.31 As noted in Chapter 5 (Paragraph 5.41), direct-to-consumer advertising of pharmaceuticals is prohibited in the EU but companies are permitted to include information about their products on their own websites (Box 7.5 gives more details). However, there has been some discussion over whether proposed changes to EU law, which seek to allow certain information regarding pharmaceuticals to be provided directly to the general public, would in effect allow advertising, rather than 'information'.³²³
- 7.32 Search engine advertising policies also have an important effect on direct-to-consumer advertising. We note that Google's policies for promotion of pharmacies and prescription drugs depend on the country in which the search takes place. The company "requires online pharmacy websites targeting ads to the United Kingdom to target only the UK and to be

³¹⁷ Appelbe G and Wingfield J (2005) *Dale and Appelbe's pharmacy law and ethics*, 8th edition (London: Pharmaceutical Press), pp189–90.

³¹⁸ Some prescription medicines contain drugs that are controlled under the Misuse of Drugs legislation. These medicines are called 'controlled medicines'. They are categorised into five schedules corresponding to their therapeutic usefulness and misuse potential. Schedule 1 has the highest level of control, but drugs in this group are virtually never used in medicines. Schedule 5 has a much lower level of control. See: NHS Choices (2009) 'What is a controlled medicine (drug)?', available at: <http://www.nhs.uk/chq/Pages/1391.aspx?CategoryID=73&SubCategoryID=100>.

³¹⁹ The prescriber must also comply with certain other rules that apply when writing prescriptions for Schedule 2 and 3 drugs. The prescription must be written in ink (or otherwise indelible), signed and dated, and the address of the person issuing it must be specified. It must also specify the name and address of the person for whom it is issued, the dose, strength and total quantity.

³²⁰ Royal Pharmaceutical Society of Great Britain (2009) *Professional standards and guidance for internet pharmacy services*, available at: <http://www.rpsgb.org/pdfs/coepsqintpharm.pdf>.

³²¹ *Ibid.*

³²² *Ibid.*

³²³ See: European Commission (2009) Information to Patients, available at: http://ec.europa.eu/pharmaforum/information_en.htm; British Medical Association (2008) *Response to the European Commission consultation regarding the legal proposal on information to patients*, available at: http://www.bma.org.uk/images/BMAresponsepatientinformation_tcm41-176194.pdf; British Medical Association (2009) *BMA response to the European Commission proposal for a directive on information to the general public on medicinal products subject to a medical prescription*, available at: http://www.bma.org.uk/images/bmareponseeuiinformationtopatientproposal2009_tcm41-183021.pdf.

registered with the Royal Pharmaceutical Society of Great Britain (RPSGB). These ads will not be displayed in other countries. Additionally, ad campaigns for online pharmacies and related services in the UK cannot promote specific prescription drugs.³²⁴ Similarly, Google requires that online pharmacy websites targeting advertisements to Germany must target only Germany, must be licensed by the competent regional health authority and sign an online pharmacy policy compliance declaration provided by Google.³²⁵ In the USA, online pharmacies must be accredited by the National Association Boards of Pharmacy VIPPs program (see Box 7.3) and may target advertisements at the USA and its territories only in order for Google to accept them, and online pharmacies in Canada must be accredited by the Canadian International Pharmacy Association and may target Canada only.³²⁶ Given Google's powerful market position, the policies it adopts for online pharmacies and the extent to which it can enforce them are likely to be important in determining the efficacy of the formal regulatory arrangements described earlier, although it has been reported that some search engines have problems in restricting 'rogue' online pharmacies from advertising through their systems.³²⁷

Box 7.5: Direct-to-consumer advertising of pharmaceuticals

Direct-to-consumer advertising of prescription-only pharmaceuticals means advertising targeted at patients/consumers, rather than physicians. It is legal in only two developed countries: New Zealand and the USA. However, as noted earlier, pharmaceutical companies are permitted to post information about their products on their own websites in the UK and elsewhere (see Paragraph 5.41). Direct-to-consumer advertising of prescription-only pharmaceuticals is a contentious issue and is the subject of much debate.³²⁸

Advertisements for over-the-counter medicines aimed at both consumers and healthcare professionals are permitted in the UK,³²⁹ subject to certain conditions,³³⁰ but direct-to-consumer advertising of prescription-only pharmaceuticals is currently prohibited in the EU.³³¹ In the UK, advertising medicines is governed by the Medicines Act 1968 and the statutory instruments implementing EU Directives.³³² There are some exceptions to the direct-to-consumer ban, for instance for the promotion of certain vaccine campaigns.³³³ As described earlier, the MHRA is responsible for ensuring compliance with the legislation.

Advertising prescription-only pharmaceuticals to health professionals is permitted in the UK. Such advertising, along with the provision of information to the public about prescription-only medicines, is subject to the general advertising standards regime described in Chapter 5 and is

³²⁴ Google (2010) What is Google's policy for online pharmacy ads?, available at: <http://adwords.google.com/support/aw/bin/answer.py?hl=en&answer=7463>. Online pharmacies can be advertised in the UK, but not specific prescription products, as mentioned above.

³²⁵ *Ibid.*

³²⁶ Google (2010) Google Adwords Help – advertising policies – prescription drugs and related content, available at: <http://adwords.google.com/support/aw/bin/answer.py?hl=en&answer=7463>.

³²⁷ Whitney L (2009) Rogue pharmacies still a problem for search engines *cnet news* 19 August, available at: http://news.cnet.com/8301-27083_3-10303655-247.html.

³²⁸ General Accounting Office (2002) *Prescription drugs – FDA oversight of direct-to-consumer advertising has limitations*, p1, available at: <http://www.gao.gov/new.items/d03177.pdf>.

³²⁹ Exemptions also apply for advertisements for non-prescription medicines aimed at the prevention of neural tube defects, treatment of sprains and strains, treatment of rheumatic or non-serious arthritic conditions, and vaccination campaigns approved by Health Ministers.

³³⁰ The Proprietary Association of Great Britain, a national trade association for manufacturers of over-the-counter medicines and food supplements, operates a self-governing system to which members must adhere. See: Proprietary Association of Great Britain (2009) *Medicines Advertising Codes Summary Version*, p3, available at: <http://www.paqb.co.uk/advertising/PDFs/advertisingcode.pdf>. All advertising in the UK must also adhere to the usual advertising standards codes administered by the Advertising Standards Authority, as described in Chapter 5.

³³¹ Directive 2001/83/EC on the Community code relating to medicinal products for human use (as amended) OJ L311/67.

³³² The Medicines (Advertising) Amendment Regulations 1994 (as amended, primarily in 1999, 2004 and 2005). Association of the British Pharmaceutical Industry, Medicines Healthcare products Regulatory Agency and Prescription Medicines Code of Practice Authority (2005) *Memorandum of understanding between the association of British pharmaceutical industry, The Prescription Medicines Code of Practice Authority and the Medicines and Healthcare Regulatory Agency*, p1, available at: http://www.pmcpa.org.uk/files/sitecontent/Memo_of_understanding.pdf.

³³³ Mullins CD and Palumbo FB (2002) The development of direct-to-consumer prescription drug advertising regulation *Food and Drug Law Journal* 57(3): 423–43.

also controlled on a self-governing basis for members of the Association of the British Pharmaceutical Industry (ABPI)³³⁴ by the Prescription Medicines Code of Practice Authority. Breaches often come to light through reports from competitors, and sanctions for breaches of the Code (some 88 cases out of 101 complaints in 2005)³³⁵ include public censure, requiring companies to issue a “corrective statement” or suspension/expulsion from the ABPI.³³⁶

Compensation

7.33 To obtain compensation for harm caused by pharmaceuticals bought online, the consumer in the UK must turn to the general law of contract, negligence, or product liability. Under the law of contract, the consumer can recover the cost of the drug if it fails to meet agreed or implied terms of sale. Under the law of negligence,³³⁷ a consumer harmed by a negligent misstatement or a negligently supplied drug (for example where the wrong drug or dosage is supplied) can sue for compensation reflecting physical injuries and associated pain, suffering and loss of earnings caused by the pharmacist’s conduct, but discomfort on its own is not sufficient as a basis for claiming compensation. If no physical injury is suffered, the consumer can recover for psychological harm only if it amounts to a recognised psychiatric illness, and general anxiety is not sufficient to sustain a claim. Under product liability legislation,³³⁸ a consumer who suffers more than £275 of damage (excluding the cost of the product which can only be recovered in contract law) can sue the manufacturer, or in some instances the supplier, if the product was not as safe as consumers can be argued to be generally entitled to expect. The consumer is not required to prove the manufacturer or supplier was ‘at fault’, but if the consumer has been contributorily negligent, compensation will be reduced. The complications that arise when suppliers are based overseas were described earlier in Paragraphs 5.34–35.

Softening the ethical dilemmas

7.34 The major conflicts that occur in this case study are between the ethical value of individuals being able to pursue their own interests in their own way and the values of efforts by the state to reduce harm, using public resources fairly and efficiently, and of social solidarity (see Chapter 3). Buying pharmaceuticals on the internet (with a prescription if one is needed) from a licensed online pharmacy offers benefits to consumers, including convenience, privacy and possibly cost savings. It may be particularly suitable for some people with long-term stable conditions. But we have already noted that people may be desperate or vulnerable when they make purchases, and if individuals buy medicines that are ‘prescription-only’ in their country of residence without a prescription, or over-the-counter products from websites that are not licensed pharmacies, there is potential for serious harm. Those possibilities of harm include:

- adverse reactions;
- adverse interactions with other products obtained in consultation with a health professional or otherwise;
- no opportunity for a health professional to assess whether the medicine is safe and appropriate for the individual, or to advise on how the medication should be taken; and
- difficulty in ascertaining the authenticity, safety and quality of the products supplied.

³³⁴ The ABPI is the trade association for companies in the UK producing prescription medicines.

³³⁵ Prescription Medicines Code of Practice Authority (2007) Code of practice FAQ, available at: <http://www.pmcpa.org.uk/?q=fagsaboutcodeofpractice>.

³³⁶ Prescriptive Medicines Code of Practice Authority (2009) Sanctions, available at: <http://www.pmcpa.org.uk/?q=sanctions>.

³³⁷ The pharmacist’s conduct is negligent if, in the view of the courts, it displays an unreasonable lack of care. Typically, when dealing with health professionals, the courts have regard to the views of the profession. If a reasonable body of professionals (not necessarily a majority) regard the conduct as reasonable, no negligence will be found (provided the court considers the view is based on logical and reasonable grounds). See also Box 4.1.

³³⁸ s.5 Consumer Protection Act 1987

- 7.35 Taken without caveats, the value of each individual to be able to pursue their own interests in their own way could imply that people should be free to purchase pharmaceuticals online without restriction despite the harms listed above. But though we fully acknowledge (see Paragraph 7.13) that face-to-face prescribing is far from free from risk or error, we think the potential for very serious harms from online purchasing justifies some state activity to prevent this and to impose certain restrictions on sellers (see recommendation in Paragraph 7.40).³³⁹
- 7.36 UK law does not prevent people from purchasing many pharmaceuticals (both over-the-counter and many prescription-only drugs) for personal use from suppliers based in the UK or overseas. Placing further legal restrictions on buyers purchasing online would be justifiable if the level of harm were sufficiently serious (following the proportionality principle set out in Chapter 4). But given the lack of firm evidence about the balance of harms and benefits of online pharmaceuticals purchasing to which we have already referred, we cannot at present justify recommending further legal restrictions on buyers.
- 7.37 As in the previous two cases, our recommendations attempt to soften or reduce the dilemmas arising from potential conflicts between the ethical values referred to above. Specifically we would like to see government monitoring of the incidence and extent of harms and benefits from the online purchasing of pharmaceuticals to allow more informed judgments and evidence-based policy to be applied to this domain in future. We also recommend: (i) provision by public healthcare services of high-quality information to help potential purchasers; (ii) voluntary adoption of good practice by providers; (iii) good professional medical practice adapted to this new development; and (iv) enforcement of legislation regarding the supply of antibiotics and state monitoring of antibiotic resistance.

Assessing the harms

- 7.38 **We recommend that the responsible bodies, which in the UK are currently the Government Health Departments and the Medicines and Healthcare products Regulatory Agency, should monitor and assess the incidence and extent of harms caused as online purchasing continues to become more common. Such monitoring will enable more informed judgments and evidence-based policy to be applied to this domain in future.**

Quality control systems

- 7.39 Current systems for classifying pharmaceuticals as over-the-counter, pharmacy-only and prescription-only in the UK and other countries have certain well-known and much-discussed shortcomings that go beyond the remit of this report. Nevertheless, we recognise the value of state-operated quality-control processes that aim to protect people from harm.
- 7.40 **We endorse attempts to mirror in the online selling of pharmaceuticals the quality-control processes that exist in some countries for more traditional pharmacies. An example of this is the registration and internet logo scheme for online pharmacies based in Great Britain by the pharmacies regulator (see Box 7.1).**

State provision of information

- 7.41 The state can also aim to prevent harm through providing information about the risks of purchasing pharmacy-only products, or what are sold as such, from an unregistered supplier or purchasing prescription-only medicines without a prescription. A number of professional and regulatory bodies already provide information on the risks and benefits of purchasing

³³⁹ The question has been raised as to whether professional protectionism might be at play here: we do not find this to be the case.

pharmaceuticals online.³⁴⁰ But we doubt whether many potential users of websites that offer pharmaceutical products are aware that they can ascertain that a website in Great Britain has the logo of the pharmacies regulator (and it is being legitimately used).

- 7.42 **We recommend that all relevant public healthcare service websites should include clear and prominent information about the risks of buying pharmaceuticals online (or products sold as such) and about how to identify a registered online pharmacy. We also recommend that private providers of healthcare and online personal health records direct their patients/users to registered online pharmacies if they wish to use the internet to purchase pharmaceuticals.**

The doctor-patient relationship

- 7.43 We have already noted that healthcare professionals are concerned that they might prescribe medicines without knowing about other pharmaceuticals the patient is taking that they have bought for themselves online.
- 7.44 **In line with the value we place on efforts by the state to reduce harm, we recommend that organisations responsible for the training of healthcare professionals and professional standards (such as medical schools, Royal Colleges and the General Medical Council in the UK) should train and advise healthcare professionals to be aware of the possibility that their patients may have bought pharmaceuticals online without disclosing this information, as well as how to address this situation, for example in clinical assessments and the questions they ask of their patients.**
- 7.45 If people cause themselves harm after taking pharmaceuticals, or products sold as such, without a prescription or from an unregistered website, they may require healthcare and thus costs to healthcare providers may result. We cannot in this report take a general position on whether public healthcare services should provide unconditional care for those who have self-inflicted harms.
- 7.46 **At this time, given the lack of evidence for the scale of harm, we conclude that the solidarity principle underlying the NHS in the UK should mean that the healthcare service should not make any distinction between caring for people whose health problems are caused by taking pharmaceuticals bought online (or products sold as such), and those caused by other self-inflicted harms. We think a similar principle should apply to comparable healthcare systems in other countries.**

Antibiotic resistance

- 7.47 Going beyond the level of the individual as consumer and patient, we have already noted that increased taking of antibiotics as a result of availability on the internet (overriding the restrictions on access and on sale imposed by many countries)³⁴¹ has the potential to have a serious long-term negative impact on public health in the form of increased antibiotic resistance. This potential harm brings our ethical value of individuals being able to pursue their own interests in their own way into stark contrast with the value we place on social solidarity (see Chapter 3) and of state action to reduce harm at a collective level. At present we lack evidence of the extent of antibiotic resistance that can be attributed to online purchasing that bypasses existing

³⁴⁰ See, for example: Food and Drug Administration (2009) Buying prescription medicine online: A consumer safety guide, available at: <http://www.fda.gov/Drugs/ResourcesForYou/ucm080588.htm>; Food and Drug Administration (2009) Buying medicines and medical products online FAQs, available at: <http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismAndDrugPreparedness/ucm134631.htm>; Medicines and Healthcare products Regulatory Agency (2010) Risks of buying medicines over the internet, available at: <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/BuyingmedicinesovertheInternet/CON019610>.

³⁴¹ The UK already makes it illegal for suppliers based in the country to sell antibiotics without a prescription or, in certain circumstances, following consultation with a licensed pharmacist, and this restriction applies equally to online pharmacies.

restrictions, so we are not in a position to justify the adoption of more coercive measures to tackle the problem, but we consider that such evidence needs to be collected given the potential seriousness of increased antibiotic resistance at a population level.

- 7.48 **Countries worldwide should attempt to set and enforce regulations regarding the supply of antibiotics in their jurisdictions (we note restrictions on such supply vary widely and are entirely lacking in some countries). Governments and international health organisations should assess and monitor whether online availability is associated with any increases in antibiotic resistance in order to allow for evidence-based policy making in this area.**

Future impact

- 7.49 Widening choice through more online purchasing of pharmaceuticals may bring future benefits in the form of cost reduction, improved access to effective treatments or the adoption of new and better products or prescribing technologies. However, online purchasing of pharmaceuticals also involves potential risks, some of them serious. Many of those risks are to individuals, but as we have seen there are potential population-level risks as well, notably that of increased antibiotic resistance.
- 7.50 The impact of online selling of pharmaceuticals, or products sold as such, on the pharmaceutical industry has yet to be seen. Pharmaceutical companies report that they are taking action to prevent the supply of products that mimic their own or do not respect their patents. Some have concerns that in the world of online sales it will become more difficult to enforce patents and that incentives for developing new products may be weakened, creating a different kind of potential collective risk. Taxes might also be avoided.³⁴²
- 7.51 Given recent trends, online purchasing and online prescribing of pharmaceuticals seems likely to grow. A world where ever more people are online, combined with an increasingly global market for pharmaceuticals, the lack of restrictions on pharmaceutical purchases in some countries, and the expected increase in telemedicine (see Chapter 8), make it probable that online provision of such products will continue to increase. A world of greater international mobility may also contribute to increased online purchasing of pharmaceuticals, for example when patients who have had treatment abroad wish to buy or import their medicines from another country, once they return home,³⁴³ and corresponding challenges for healthcare providers, for example in how to verify the authenticity of the medicines provided by the patient if they were asked to administer them. Furthermore, it is possible and even likely that, as today's adults who are familiar with internet purchasing become tomorrow's elderly (the sub-population who use pharmaceuticals the most), they will be more able and willing to obtain pharmaceuticals online than today's elderly group, provided that the format of the internet does not change in a way that creates difficulties for that group.

³⁴² We note that the Pharmaceutical Package under review in the European Union at the time of writing, as described earlier, included proposals aimed at strengthening EU legislation to tackle fake medicines. See: European Commission (2010) EU pharmaceutical package, available at: http://ec.europa.eu/enterprise/sectors/pharmaceuticals/human-use/package_en.htm.

³⁴³ One commentator has suggested that some Members of the European Parliament see the draft Directive on patients rights' in cross-border healthcare (*Proposal for a Directive of the European Parliament and of the Council 2008/0142 on the application of patients' rights in cross-border healthcare*) as a mechanism to promote patients' access to treatments and medicines that they might not be able to access under their home systems (personal communication).