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The key legal and regulatory issues impacting online pharmacies in the UK

Once treated with caution, online pharmacies are developing into mainstream eHealth offerings with a growing consumer following. Raj Gathani and Brian Kelly of Covington & Burling LLP examine certain key legal and regulatory issues that affect online pharmacies in the UK¹.

Online pharmacies are businesses that sell or supply medicines to consumers remotely over the internet. Their growth in the UK over recent years may be attributed to a variety of factors, including the following:

- the rise in ‘online doctor’ websites, whose offering often includes a prescription dispensing and delivery aspect. These sites usually operate solely in the private sector, so they would not provide services reimbursable by the National Health Service (‘NHS’);
- the fact that many traditional ‘bricks and mortar’ pharmacies (including both high street chains and independent pharmacies) are developing their presences online. Some of these providers have created sophisticated web platforms

that, for example, enable patients to coordinate repeat prescriptions between their GP and pharmacy; and

- the increasing popularity of electronic prescriptions. This means patients can nominate a pharmacy to receive prescriptions electronically from a doctor’s surgery. As a result, the physical proximity of the pharmacy to the patient or prescriber becomes less significant, opening the marketplace to online operators.

The expansion of this sector has not been free of controversy. In 2016, the Medicines and Healthcare products Regulatory Agency (‘MHRA’) reportedly shut down 4,760 websites selling medicines without a licence². In 2017, the Care Quality Commission (‘CQC’), England’s health and social care regulator, sanctioned a number of online

doctor-pharmacy platforms for providing unsafe services to patients³. The CQC investigations revealed that certain providers had failed to meet necessary legal and regulatory standards for the sale or supply of medicines, including, for example, ensuring the suitability of making a supply and obtaining necessary information from the patient.

Key requirements

Consistent with the position across the EU, UK businesses selling any class of medicine over the internet (whether or not they are ‘pharmacies’) must: (i) register with the MHRA; (ii) only sell products that have a valid marketing authorisation in the destination Member State; and (iii) display certain mandatory information, including the common EU logo⁴. Under UK law, an entity may only sell

continued

or supply prescription-only medicines and so-called 'pharmacy medicines'⁵ to consumers if it is a registered pharmacy, operating from registered pharmacy premises and under the supervision of a registered pharmacist⁶. Amongst other things, this means online pharmacies must have an underlying site for staff to prepare, assemble, label and supply medicines under appropriate supervision. The premises should meet certain requirements and be subject to regulatory inspection. Existing 'bricks and mortar' pharmacies that are already registered do not need a separate permission to operate online.

The registration and regulation of pharmacies and pharmacists is the responsibility of the General Pharmaceutical Council ('GPhC')⁷. Amongst other requirements, the GPhC expects pharmacies to comply with its 'Standards for Registered Pharmacies'⁸ as well as its 'Distance Services Guidance'⁹. These guidelines have a significant impact on providers operating online¹⁰. We discuss some of the main considerations below.

Suitability of supplying a medicine

Before dispensing or supplying a medicine, pharmacists should consider its suitability for the customer/patient. This duty is not discharged simply because a doctor has chosen to prescribe or recommend a product. To perform the necessary assessment, a pharmacist may require information from the patient (e.g., to confirm their age or capacity, check certain symptoms or ensure the patient is not pregnant). The pharmacist may also require additional information from the prescriber, if any (e.g., confirming a particularly high dose or the intention to use the product 'off label').

These requirements create particular requirements for online pharmacies because of the remote nature of the service¹¹. A pharmacist may often need to know more than what the patient has submitted online. There is a risk that consumers have chosen the online route to obtain medication inappropriately and to that end have provided incomplete or incorrect information. Particular issues may arise where patients choose to use the pharmacy on a one-off basis, as this risks creating

knowledge gaps in terms of medical history or other medications taken.

In effect, the GPhC requires that online pharmacies develop an infrastructure so that pharmacists may meet their professional obligations despite the remote nature of the service¹². There must be a mechanism to obtain necessary information and communicate with patients or prescribers throughout the dispensing and supply process. This includes a facility to refuse to make a supply if necessary. This requirement may affect the way in which online pharmacies structure the contractual relationship with consumers. Particularly so, because of the general expectation that consumers should provide payment at the time they request medicines, which is often before the time the pharmacist has made a suitability assessment.

Ensuring safe and effective supply

Online pharmacies should consider how to ensure they provide patients with appropriate information and advice (e.g., on the correct use or administration of the medicine)¹³. Patients should have the opportunity to ask questions about a medicine, including once they receive it. In a face to face setting, pharmacists can meet these requirements in a single conversation. In a remote context, providers will often use a combination of techniques (e.g., providing additional written information when customers select the product and/or with the delivered item; not dispatching certain products until the pharmacist has spoken to the patient by telephone and potentially only using specially trained staff to deliver certain products).

Medicines supplied online are subject to more scrutiny than conventional e-commerce products. As such, a pharmacy's legal and professional obligations do not end once products have been dispatched. Pharmacies have a responsibility to ensure medicines are delivered safely and to the correct person¹⁴. This will involve confirming that carriers stick to specified storage conditions, particularly for temperature-sensitive items. Other practical considerations include whether another person could take delivery of a medicine should the patient be unavailable. Providers would need to

assess the risk of people other than the intended recipient using the product (particularly children). Depending on the type of product, patient confidentiality might also be a relevant issue (e.g., for contraceptive medicines).

Transparency and consumer choice¹⁵

Consumers have the right to choose the pharmacy that provides their medication. The identity of the pharmacy must be clear to consumers, who should consent to receiving medication from that provider. Relationships between a pharmacy and a prescribing service must be transparent and should not restrict or exert undue influence over patients' choices. Over the past few years, this has become a particularly hot topic in the industry. In 2013, the British Medical Association as well as two pharmacy industry bodies (the PSNC and Pharmacy Voice) issued guidelines on protecting patient choice. In October 2015, NHS England wrote to GPs and pharmacies, expressing its concerns about relationships between prescribers and pharmacies.

This area raises issues for some online healthcare platforms, particularly those that provide an all in one offering encompassing prescribing and dispensing. Companies must balance providing a timely and cost-effective service without compromising a patient's right to choose suppliers. This might also impact commercial aspects of the platform, including pricing services/ medicines or how best to structure the relationship with the consumer.

Broader legal and regulatory considerations

Aside from the requirements of industry regulators, there are a number of broader legal and regulatory issues that providers may need to consider, particularly as the business model evolves in the future.

Use of assistive technologies

eHealth tools, such as online symptom checkers, are growing in sophistication and popularity. The question for some internet pharmacies is how much to integrate these technologies into the process of selling and dispensing medicines. The law prohibits selling prescription-only or 'pharmacy' medicines 'by means of an automated

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machine¹⁶. This seems to rule out fully automated systems (e.g., where a pharmacy website recommends, sells and dispatches a pharmacy medicine, without the involvement of a pharmacist).

Short of this, there seems to be scope for pharmacies to use assistive technologies in their practices. For example, these could be at the clinical assessment stage (e.g., highlighting that the medicine requested online may be inappropriate for the patient). Intelligent technologies could also assist pharmacists to develop more personalised ways of counselling patients, by assessing information entered online.

Cross border dispensing

Operating over the internet opens possibilities to trade across borders. Doing this with medicinal products raises a number of complex legal issues. Many of these go beyond the scope of this article. However, the following general observations are perhaps worth noting:

- Non-prescription medicines: In a 2003 ruling the European Court of Justice ('ECJ') held that it was unlawful for an EU Member State to prohibit cross border sales of non-prescription medicines to consumers over the internet. That is so long as: (i) the product had a valid marketing authorisation and held a non-prescription classification in the country of destination; and (ii) the seller was a registered

pharmacy in an EU Member State¹⁷.

- Prescription-only medicines: Since 2011, EU law has, subject to certain safeguards, provided for prescriptions written in one Member State to be dispensed in another (e.g., for a patient travelling or living overseas)¹⁸. In the UK, this includes dispensing certain electronic prescriptions from another EEA country¹⁹. That said, supplying a prescription-only medicine over the internet remains unlawful in a number of EU Member States. However, where this practice is permitted, a 2016 ECJ ruling suggests that pharmacies should be free to compete on price²⁰.

Providing services to the NHS

Currently, most online pharmacies in the UK operate solely in the private sector. Yet the ability to dispense prescriptions reimbursed by the NHS can allow businesses to broaden their customer base and significantly increase revenues. Online providers who intend to provide NHS services encounter additional layers of legal and regulatory complexity.

To provide pharmaceutical services to the NHS, a pharmacy must be GPhC-registered as well as 'on the pharmaceutical list' (in other words a registered NHS pharmacy contractor). NHS market entry rules mean that joining the 'pharmaceutical list' can be very difficult. Because of this, the numbers of pharmacies providing NHS services has effectively been restricted. However, changes to the rules in 2013

created a lower threshold to NHS market entry for distance selling pharmacies, including those that operate exclusively online. As a result, recent years have seen an increase in the numbers of new, internet-only pharmacies serving the NHS in England. That said, these businesses are subject to certain legal requirements that have a significant effect on the way they operate. We discuss some of these below:

- An internet pharmacy that has used the 'distance selling' route to gain entry to the pharmaceutical list may not: (i) operate out of premises that are on the same site or in the same building as an NHS GP²¹; nor (ii) dispense an NHS prescription in a face to face context²².
- The pharmacy must, for at least 40 hours per week, ensure it is able to offer 'essential services' (such as dispensing NHS prescriptions) to any customer in England that requests them²³. In effect, this means that an online pharmacy with an NHS contract must, with reasonable promptness, dispense any NHS prescription presented to it. An internet-only NHS pharmacy therefore cannot restrict itself to dispensing certain types of medicine (e.g., those with a high profit margin or only non-temperature sensitive products). Nor can such a pharmacy only serve patients in a particular area or region.

1. This article should be read in conjunction with, 'Online Doctors: an evolving sector and a developing regulatory landscape,' written by the same authors and published in the October 2017 issue of Digital Health Legal.

2. See, 'Unregulated sale of antibiotics online risks creating untreatable superbugs,' published in The Independent on 11 March 2017 and available at: <http://www.independent.co.uk/life-style/health-and-families/health-news/uk-medicines-regulator-mhra-completely-impossible-illegal-online-pharmacies-antibiotic-resistance-a7623546.html>

3. Strictly, CQC is not a pharmacy regulator. CQC's investigations focussed on platforms that provided online GP consultation and prescription services, which is an activity that falls under its purview.

4. Article 85C of Directive 2001/83/EC, which is reflected in Part 12 of the UK Human Medicines Regulations 2012.

5. This is a certain legal class of non-prescription medicines that may only be supplied out of a pharmacy and not from general retail stores.

6. Regulation 220 of the Human Medicines Regulations.

7. In England, Scotland and Wales.

8. Available at: https://www.pharmacyregulation.org/sites/default/files/standards_for_registered_pharmacies_september_2012.pdf

9. 'Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet,' available at: https://www.pharmacyregulation.org/sites/default/files/guidance_for_registered_pharmacies_providing_pharmacy_services_at_a_distance_including_on_the_internet_april_2015.pdf

10. In addition to these, the GPhC encourages registered pharmacies operating online to display a standardised 'Registered Pharmacy' logo.

11. As highlighted in Principles 1.1, 4.2 and 4.4 of the Distance Services Guidance.

12. Principles 1.1 and 4.2 of the Distance Services Guidance.

13. Principle 4.4 of the Distance Services Guidance.

14. Principle 4.3 of the Distance Services Guidance.

15. Principle 4.1 of the Distance Services Guidance.

16. Regulation 222 of the Human Medicines Regulations 2012.

17. Case C-322/01 (Deutscher Apothekerverband eV v. 0800 DocMorris NV).

18. Directive 2011/24/EU on the application of patient's rights in cross border healthcare.

19. Regulation 219A of the Human Medicines Regulations 2012.

20. Case C-148/15 (Deutsche Parkinson Vereinigung eV v. Zentrale zur Bekämpfung unlauteren Wettbewerbs eV).

21. Regulation 25.2(a) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

22. Regulation 25.2(b)(ii) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

23. Regulation 25.2(b)(i) and Schedule 4 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.