

About CQC

1. The Care Quality Commission (CQC)¹ is the independent regulator of health and adult social care in England. Our purpose is to make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage these services to improve.

Introduction

2. We welcome this opportunity to offer written evidence to the Public Bill Committee considering the Online Safety Bill. Our founding legislation was based on an assumption that services were delivered at physical locations in England. As health and care services have evolved we are increasingly seeing online services delivered from overseas, which cannot be regulated.
3. One of the key aims of the Bill is to make provision for and in connection with the regulation of internet services. It rightly addresses the need for policy change to increase user safety online, improve law enforcement's ability to tackle illegal content online, and to improve society's understanding of the harm landscape. This includes imposing duties in relation to content which is illegal, harmful to children, or 'legal but harmful' to adults.
4. The online healthcare landscape is evolving quickly and we cannot predict future harms, therefore legislation must be future-proofed as far as possible. We anticipate the issues and evidence highlighted in this briefing will only get worse and encourage consideration of the long-term impact of failing to act. Online research by YouGov, commissioned by the General Pharmaceutical Council (GPhC)², found that 1 in 4 adults say they are likely to use online pharmacies in the future.

Summary

5. We welcome the move to protect internet users from content that may lead to physical or psychological harm.
6. Figures published this year by the NHS Business Services Authority (NHS BSA)³ showed that online pharmacy dispensing has quadrupled in five years. The ease with which people can now access treatment online, often without oversight from their GP, can make this an attractive option to people. However, as remote care and the internationalisation of healthcare rapidly accelerates, there are also greater associated risks.
7. In the majority of cases involving deaths and harm linked to independent online prescribing services, a prescription has been acquired from a non-UK provider, and regulators such as CQC and GPhC have been unable to act because of regulatory gaps and legislative barriers.
8. We would like to see changes to legislation to bring into the scope of our registration online providers that are based outside England yet are lawfully providing treatment to patients in

¹ <https://www.cqc.org.uk/>

² [New safeguards for people seeking medicines online | General Pharmaceutical Council \(pharmacyregulation.org\)](#)

³ [Online pharmacy dispensing quadruples in five years, NHS data show - The Pharmaceutical Journal \(pharmaceutical-journal.com\)](#)

England. Enforcement against providers domiciled in England is done through English courts. Any extension of regulation outside England would need a corresponding set of enforcement levers, which may need to include some 'powers to disrupt' online activity.

Reason and urgency

9. The pandemic has had a significant impact on how care is accessed and delivered, with more people accessing digital healthcare services. We are keen to support innovation and welcome greater patient choice, but as the independent regulator for quality of care in England we want to be able to intervene where we are seeing unsafe or criminal practice and take the appropriate action to keep people safe and prevent future deaths and harms.
10. We continue to receive information about cases involving deaths and harm linked to non-UK based online providers. In these cases, an unsafe prescription from a non-UK based provider has been acquired by a patient in England and we have been unable to act because of regulatory gaps.
11. For example, last July we were informed that an inpatient at a psychiatric unit was able to acquire amitriptyline online and, as a result of overdosing, was admitted to ITU. The Medicines and Healthcare products Regulatory Agency (MHRA) previously attempted to take action against the website and were quickly met with legal challenge - the website's services were reinstated on the grounds that no offence was caused within existing medicines regulations. The service user had acquired the drug from an online provider based in a country independent of the European single market, limiting any external country from taking meaningful action against them.
12. In the same year, we were made aware of a service user who was able to purchase a plethora of prescription-only drugs online, without GP oversight, and died of prescription drug overdose. The drug, Zopiclone, which the individual took in sufficient doses to cause their death, was acquired from several non-UK based online provider websites known to UK regulators, but that either sit outside our jurisdiction or are operating illegally.
13. We have also had occasions of England-based providers actively circumventing regulation. For example, we know of some providers that have set up shell companies based in Romania to employ doctors that can lawfully prescribe to English patients. In one case, a woman who was treated for anorexia was able to order three months' worth of prescription slimming pills from an online doctor site. The drugs were prescribed by a Romanian doctor contracted through a shell company, based in Romania, that was set up by a doctor that had been struck off in the UK. This specific case was included in a BBC Panorama investigation⁴ which aired in 2018, exposing safety concerns relating to websites using doctors from companies based outside England and perceived gaps in regulation.
14. *The Pharmaceutical Journal*⁵ published recent analysis of GPhC online pharmacy inspection reports which revealed that, for a third of reports where online pharmacies are failing, the pharmacy in question had links to prescribing services based outside of the UK (most commonly in Romania). This enabled them to avoid regulation by the CQC. The same report

⁴ [Safety concerns over websites selling prescription drugs - BBC News](#)

⁵ [Online pharmacy boom prompts concern over patient safety - The Pharmaceutical Journal \(pharmaceutical-journal.com\)](#)

showed that, for one such pharmacy which uses a Romania-based online prescribing service, 95% of prescriptions dispensed were for opioids and z-drugs⁶.

15. Our main concern at this time is non-UK online providers lawfully prescribing to people in England⁷ and the ease of access to schedule 4 and 5 controlled drugs⁸, and other medicines online, from non-NHS providers. There is evidence which indicates that the majority of current risks in online healthcare stem from this area and we continue to receive coroners' reports highlighting the risk of future death and serious harm. We firmly believe that this should be actively mitigated and that the escalation of these harms is inevitable as internet use expands.
16. Our ability to take action against non-UK providers directly is limited as our current enforcement powers and legal processes do not work across borders. There are obvious challenges in serving summonses overseas; feasibility of proceedings where they don't attend; and overseas enforcement of court judgments.
17. Other regulators, such as the GPhC, also acknowledge this risk and updated their guidance for online pharmacies this year⁹. In the guidance they specify that pharmacy owners must "not work with online providers who circumvent, or try to circumvent, the regulatory oversight put in place within the UK to ensure patient safety". We work closely with the GPhC on issues relating to online health services and share concerns about the potential for harm to the public from providers who structure their business deliberately to be outside the scope of registration with the CQC or the GPhC.
18. Given the upwards trajectory of online healthcare and the risk it poses to service users in England, we think new powers are needed to disrupt the business practises of unscrupulous providers, to act as a deterrent and drive wider behavioural change. Gaps in legislation prohibit us from having a meaningful right of action against non-England based individuals or organisations online. It also prevents us from championing good care where we see it.
19. Our focus to date has been on prescribing activities, however, the online healthcare landscape is evolving quickly and we cannot predict future harms. We are already seeing online healthcare expand into other sectors, such as the mental health and dental sector.

Conclusion

20. We welcome the move to increase user safety online, improve law enforcement's ability to tackle illegal content online, and to improve society's understanding of the harm landscape. The risks we are highlighting are of indirect harm, where someone harms themselves or another person as a result of content.

⁶ The National Institute for Health and Care Excellence (NICE) defines Z-drugs as non-benzodiazepine hypnotics, developed to overcome some of the adverse effects of benzodiazepines (such as next-day sedation, dependence, and withdrawal). Like benzodiazepines, they are also GABA receptor agonists. The two z-drugs available in the UK are zolpidem, and zopiclone.

⁷ EEA and Swiss registered clinicians can issue legally valid EEA/Swiss prescriptions in relation to England. Therefore, any non-UK provider employing EEA/Swiss doctors can lawfully prescribe to patients in England.

⁸ [List of most commonly encountered drugs currently controlled under the misuse of drugs legislation - GOV.UK \(www.gov.uk\)](https://www.gov.uk)

⁹ [Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet \(pharmacyregulation.org\)](https://www.pharmacyregulation.org)

21. Our regulatory activity has led us to identify a gap in primary legislation that means we do not have powers to protect the public by taking enforcement action against non-UK based online providers offering regulated activities to people in England, where we suspect harm may be caused. We believe that the regulatory loopholes in online care need to be addressed to prevent further avoidable deaths.
22. We have been sharing our growing concerns and recommendations surrounding this issue with DHSC on an ongoing basis. Given the nature of this Bill and its fundamental intention to both protect internet users from content that may lead to physical or psychological harm and improve society's understanding of the harm landscape, we wanted to take the opportunity to bring this important issue to Parliament's attention also.
23. We would ultimately like to bring into scope of our registration, online providers that are either based outside England, or have set up a shell company that is based outside England, yet are lawfully providing treatment (including prescribing activities) to patients in England. This would assist in closing the regulatory gaps that we know some non-UK online providers are exploiting. It would require them to register with us in order to lawfully treat people in England - if they do not register, they will be committing a criminal offence in England. Primary legislation changes would allow us to take action where we found businesses based outside England to be failing to meet the fundamental standards. This will involve making it difficult for them to lawfully conduct business in relation to people in England. Until these changes are made, avoidable deaths will continue.

For more information

If you have any queries regarding this briefing please contact Zara Azam, Senior Parliamentary and Stakeholder Engagement Officer at zara.azam@cqc.org.uk or the CQC parliamentary team at parliamentaryaffairs@cqc.org.uk