Department of Health & Social Care

From Nadine Dorries MP
Minister of State for Patient Safety,
Suicide Prevention and Mental Health

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Mr Andrew J Cox
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21 May 2021

Dear Mr Cox

Thank you for your letters of 17 February and 8 March 2021 about the death of Katie Corrigan.

I would like to begin by saying how very sorry I was to read the circumstances of Mrs Corrigan's death and my deepest sympathies are with her family and loved ones.

While the great majority of medicines prescribed online are done so appropriately and safely, it is deeply concerning that patients, including Mrs Corrigan, have been able to access particular types of medicine, or medicines on a scale that they would not likely be prescribed by their GP, with serious, and sadly fatal, consequences. I would like to assure you that we are determined to do all we can to prevent such deaths from occurring again.

I welcome the action by the Care Quality Commission (CQC) and the General Pharmaceutical Council (GPhC) to investigate the online providers identified by your investigation of Mrs Corrigan's death. Where unsafe or criminal practice is identified it is essential that regulatory authorities take appropriate enforcement action within the range of enforcement powers available.

The Department continues to work with healthcare regulators (the CQC), and the Medicines and Healthcare products Regulatory Agency (MHRA)), and professional regulators (the General Medical Council (GMC) and the GPhC), and others, to explore how the regulation of independent online prescribers can be strengthened.

Since 2017, a UK-wide regulatory forum, chaired by the CQC and including the relevant regulatory bodies, has considered a number of issues around digital health care provision, including independent online prescribers. The group meets regularly and collaborates in taking action to safeguard patient safety.

I am aware that you have received responses from the CQC and the GPhC, providing detail on those actions that include the provision of new and strengthened guidance, as well as regulatory activity, including enforcement action.

You may also wish to note that in relation to suppliers of medicines at a distance, following the UK's departure from the European Union, the MHRA is considering, under powers in the Medicines and Medical Devices Act 2021, a replacement scheme of registration for suppliers of medicines at a distance which has been disapplied in Great Britain.

This is a complex issue and we recognise that there are remaining concerns about the ability of the regulatory framework to protect the public and improve the safety of online prescribing.

As you know, the CQC has identified proposals for legislative change to improve its ability to take action against independent online providers where there is unsafe practice and I can provide assurance that we will work with the CQC to consider these proposals carefully.

Conflicts of Interest

Turning to your concern about the potential for abuse in the relationship between a prescriber and a pharmacist, independent regulators of healthcare professionals have standards and guidance in place to ensure that financial arrangements between prescribing doctors and pharmacies are transparent and managed appropriately.

Guidance from the GMC is available to doctors on conflicts of interest[1], as well as guidance on good practice[2]. The GMC's guidance states that if a doctor, someone close to them, or their employer has a financial or commercial interest in an organisation providing healthcare, such as a pharmacy or dispensary, they must not allow that interest to affect the way they prescribe for, advise, treat, refer or commission services for patients.

With effect from April 2021, the GMC also has updated guidance on prescribing[3], which places emphasis on following the principles of good practice regardless of the medium through which a consultation is taking place, face to face or online.

We would expect all registered pharmacies and pharmacists in England to meet the regulatory standards set by the GPhC when dispensing any lawfully valid prescription.

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[1] Financial and commercial arrangements and conflicts of interest (gmc-uk.org)

[2] Good medical practice-english (gmc-uk.org)

[3] Good practice in prescribing and managing medicines and devices (gmc-uk.org)

The GPhC has advised you of its standards for registered pharmacies[4] and registered pharmacy professionals[5], as well as guidance for providing services at a distance, including on the internet[6]. In addition, I am advised that the GPhC has initiated an investigation to consider this matter further and will share any findings and a decision once the investigation concludes.

NHSEI Alert System

In relation to the effectiveness of NHS England and NHS Improvement's (NHSEI's) alert system in preventing people from obtaining prescription-only medicines improperly, my officials have brought your concerns to the attention of NHSEI.

As you may already be aware, NHSEI has a clear responsibility in providing systems oversight for the management and use of controlled drugs. NHSEI's Controlled Drugs Accountable Officers (CDAOs)[7] undertake this role within each geographical region across England. They provide assurance that all healthcare organisations, including pharmacies, adopt a safe practice for appropriate clinical use, prescribing, storage, destruction and monitoring of controlled drugs.

CDAOs facilitate the routes to share concerns, report incidents and take remedial action as well as highlighting good practice. This is shared with wider partners such as clinical commissioning groups (CCGs) and the Police through the Controlled Drugs Local Intelligence Networks (CDLINs). Details of all CDAOs in England are held on a national register, which is owned and published by the CQC: www.cqc.org.uk/content/controlled-drugs-accountable-officers.

I am advised by NHSEI that on occasion, CDAOs share information about individual patients with relevant partners to support the safe management and clinical use of controlled drugs, including codeine. Circumstances where this may occur include where there is a credible concern that someone may be accessing controlled drugs inappropriately from several clinical services. I am further advised that information provided about individual patients is in line with the Caldicott principles[8], and the individual's freedom to choose how they access healthcare is balanced with the need for patient safety and public protection.

Controlled drugs regulations

Turning to the comments in your report about controlled drugs regulations, as your report identifies, decisions on the scheduling of controlled drugs under the relevant legislation are

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[4] standards_for_registered_pharmacies_june_2018_0.pdf (pharmacyregulation.org)

[5] standards_for_pharmacy_professionals_may_2017_0.pdf (pharmacyregulation.org)

[6] Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet (pharmacyregulation.org)

1 https://www.england.nhs.uk/contact-us/privacy-notice/how-we-use-your-information/safety-and-quality/controlled-drugs-accountable-officer-alerts-etc/

8 The Eight Caldicott Principles — The UK Caldicott Guardian Council (ukcgc.uk)

taken by the Home Office. This is done with the provision of advice from the Advisory Council on the Misuse of Drugs. Any decisions must weigh up the risks of misuse, abuse and diversion, against not impeding legitimate use within healthcare. This Department works closely with health system leaders to provide evidence of safety and risk associated with medicines to help inform such decisions.

You highlight in your report that you have been advised that a change in the status of codeine linctus from a pharmacy medicine to a prescription-only medicine is needed.

I can confirm that the MHRA, the independent medicines regulator in the UK, is keeping the legal status of codeine, including codeine linctus, under review and will consider all sources of evidence and information relating to this issue.

In the last year, there has been increased police activity and enforcement action by the GPhC in relation to codeine linctus and its misuse in the preparation of a street drug. There is active engagement between this Department and the Home Office, and with relevant stakeholders including the MHRA, the CQC and the GPhC on this issue.

Categories of medicines where there is a risk of addiction, such as opioids, should only be supplied online if appropriate safeguards are in place to make sure they are clinically appropriate for patients. The GPhC has strengthened its guidance[9] to UK online pharmacies which clearly states that the selling and supplying of medicines online carries risks that need to be appropriately managed to protect patient safety. Not taking appropriate steps to follow these guidelines can lead to failure to meet the standards of registered pharmacies, which can result in enforcement action.

Opioids

In relation to the wider context to this issue and the increasing concern internationally and here in the UK, about the overuse and misuse of opioids leading to a growing problem of dependence and addiction, I would like to outline the range of action that has been taken to protect patients from harm.

In 2017, the Government asked Public Health England to conduct an evidence review to identify the scale, distribution and causes of prescription drug dependence, and what might be done to address it. PHE's report of the review was published in September 2019[10], providing evidence for dependence on, and withdrawal from, prescribed medicines, with the aim of making sure that local healthcare systems build awareness and support to enhance clinician and patient decision making.

In support of this, NHSEI is co-ordinating a programme to implement the recommendations of the review, working closely with relevant health system partners. The programme covers five classes of medicines including benzodiazepines; Z-drugs; gabapentinoids; opioids, for chronic non-cancer pain; and antidepressants.

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

[10] Prescribed medicines review: summary - GOV.UK (www.gov.uk)

The MHRA recently reviewed the risk of addiction and dependence with opioid medicines, as a result of which, all opioid medications now carry prominent front-of-pack warnings that the product contains opioids and may cause addiction. In addition, warnings on the risk of dependence in product information have been strengthened and harmonised. The MHRA has also worked closely with stakeholders and Trades Associations to develop an additional, user-tested, safety information leaflet for distribution directly to patients at pharmacies and on the MHRA government website.

In addition, from October 2020, Primary Care Networks of GPs are required to identify and prioritise patients, including patients using potentially addictive pain management medication, who would benefit from a structured medication review[11]. You may also wish to note that further to the February 2020 update to the GP contract agreement 2020/21 to 2023/24[12], a Quality Improvement Module in the Quality and Outcomes Framework for general practice on preventing prescription drug dependency is in development.

I hope this response is helpful. Thank you for bringing these concerns to my attention.

NADINE DORRIES

MINISTER OF STATE FOR PATIENT SAFETY, SUICIDE PREVENTION

[11] Report template - NHSI website (england.nhs.uk)

[12] Criteria for registration as a pharmacy technician in Great Britain (england.nhs.uk)