Department of Health & Social Care

From Nadine Dorries MP
Parliamentary Under Secretary of State for Patient Safety, Suicide Prevention and Mental Health

39 Victoria Street
London
SW1H 0EU

020 7210 4850

Our Ref: PFD-1197115

Mr Nigel Parsley
HM Senior Coroner, Suffolk
HM Coroner's Office
Beacon House
53-65 Whitehouse Road
Ipswich IP1 5PB

27th February 2020

Dear Mr Parsley,

Thank you for your letter of 18 November 2019 to Matt Hancock about the death of Deborah Michelle Headspeath. I am replying as Minister with responsibility for patient safety and I am grateful for the additional time in which to do so.

Firstly, I would like to say how very saddened I was to read the circumstances of Ms Headspeath's death. I can only imagine how devastating her death must be to those who loved and knew her. Please share my heartfelt condolences with her family and loved ones.

While the great majority of medicines prescribed online are done so appropriately and safely, we know there have been cases where a patient has been able to access particular types of medicine, or medicines on a scale that they would not likely be prescribed by their GP and that this has led to serious harm and, very sadly, death. It is deeply concerning that patients are being put at risk in this way and we must do all we can to prevent future tragedies.

The Department is working closely with the Care Quality Commission (CQC) and relevant professional regulators to look at how they can better regulate online prescribers and close the loopholes in legislation that allow a small number of online organisations to operate without the necessary oversight.

A UK-wide regulatory forum was established in 2017, chaired by the CQC, to consider the issues around online prescribing and to agree co-ordinated action to address regulatory gaps. The following measures have been taken by members of the forum:

- In November 2019, a range of healthcare regulators and organisations, co-authored and agreed principles of good practice in remote consultations and prescribing that are expected of UK regulated healthcare professionals when prescribing medication online[1]. The principles set out clear responsibilities and expectations for all prescribing healthcare professionals (doctors, nurses, pharmacists, dentists and opticians) and are underpinned by existing standards and guidance from both professional and system regulators. The principles make clear that prescribers of medication are expected to understand how to identify vulnerable patients and take appropriate steps to protect them; carry out checks to ensure medication is safe; and take responsibility for raising concerns when adequate patient safeguards are not in place. Serious or persistent failure to act in accordance with standards of practice within their professions may put at risk a healthcare practitioner's fitness to practice;

- Publication in November 2019 by the General Pharmaceutical Council (GPhC) of revised Guidance for Pharmacist Prescribers[2], to ensure that they provide safe and effective care when prescribing. This includes further examples of prescribing in different settings and strengthens the guidance in relation to online prescribing of high-risk medicines, such as opioids. The guidance sets out when prescribers should consider if extra safeguards are needed, for example, when prescribing antibiotics online or medicines likely to be abused or misused, such as opioids. Where there is concern that a GPhC registrant is not meeting the required professional standards they may face enforcement action, including removal from the register; and,

- Guidance from the General Medical Council (GMC) is available to doctors on remote consultations and prescribing[3], as well as advice on good practice[4]. The GMC is currently seeking the views of its members on remote consultations and prescribing to decide if changes are necessary to its guidance. The call for evidence closes on 18 February 2020.

The CQC has inspected all registered online providers and published the findings[5]. All online providers in England, registered with the CQC, now receive a quality rating following inspection. There is a range of enforcement action that the CQC can take if it identifies that providers are not meeting regulations.

I am aware that the CQC, GPhC and the GMC have each taken enforcement action against online prescribers and providers of prescription medicines online, where insufficient safeguards have been put in place or followed, and where checks have not been made to ascertain that the medicines supplied, such as opioids and other high-risk

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[1] https://www.pharmacyregulation.org/news/principles-good-practice-issued-protect-patients-online-0

[2] https://www.pharmacyregulation.org/news/gphc-launches-new-guidance-pharmacist-prescribers

[3] https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/remote-prescribing-via-telephone-video-link-or-online

[4] https://www.gmc-uk.org/ethical-guidance/ethical-hub/remote-consultations

[5] https://www.cqc.org.uk/publications/major-report/state-care-independent-online-primary-health-services

medicines, are clinically appropriate. As a result, there are recent examples of providers stopping the prescribing of high-risk medicines or ceasing to operate altogether.

In relation to your concern that online providers are changing their business model to circumvent regulatory scrutiny, the Department is working with the CQC and other regulators to understand what the options might be to address this.

Where a provider is outside the scope of CQC regulation, oversight might fall to other regulators, namely the GPhC and the Medicines and Healthcare products Regulatory Agency (MHRA), and I am assured that all three regulators are working collaboratively to share information where there are concerns about a provider.

I am advised that, at present, there is no single database that prescribers can use to ascertain whether medication is clinically appropriate for a patient, or whether a patient has access to medicines from another source. However, healthcare providers are legally obliged (under section 251(b) of the Health and Social Care Act 2012[6]) to share information about a patient where it will facilitate that patient's care and is in their best interests (there are certain circumstances where this does not apply, for example, if the patient objects to their data being shared). Health professionals must meet the standards set by their professional regulatory body. This includes accurate record keeping and where possible, the sharing of patient information with other health professionals to facilitate patient care. Regulators can take action when expected practice is not met.

A number of local initiatives to share patient care records are in place, though it is acknowledged that it will be some time before there is national coverage. Led by NHS England and NHS Improvement, five Local Health and Care Record Exemplars (LHCRE's[7]), covering 23.5 million people, are putting in place complete electronic patient records with joined-up IT systems to enable better coordinated and safer care. LHCRE's will enable data to be accessed by doctors, nurses and other health professionals as patients move between different parts of the NHS and social care system. LHCRE's will improve the monitoring and analysis of population health and inform the commissioning and delivery of services.

Public awareness of the risks that can be associated with obtaining medicines online is another key aspect to responding to this patient safety issue. The MHRA has led a number of public awareness campaigns, including a targeted and sustained campaign, #Fakemeds[8], which has run online and through social media for maximum coverage. In addition, the GMC is working with the GPhC and others to develop information for patients on how to stay safe when accessing medication and treatment online.

To assist patients to purchase medicines safely online, there is a European wide Distance Selling Logo to help the public identify websites that can legally sell medicines.

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[6] http://www.legislation.gov.uk/uksi/2015/1470/pdfs/uksiem_20151470_en.pdf

[7] https://www.england.nhs.uk/publication/local-health-and-care-record-exemplars/

[8] https://fakemeds.campaign.gov.uk/

Under the provisions of the *European Falsified Medicines Directive*[9], all Member States of the European Union (EU) are required to introduce national arrangements to register suppliers of medicines at a distance. For the UK this means that anyone based in the UK, wising to sell medicines online in the UK (or any European Economic Area country), must be registered with the MHRA and display a Distance Selling Logo on pages of the website offering medicines for sale, with a link to the MHRA's website. The MHRA is responsible for managing the UK list of online retailers that have registered to sell medicines to the public remotely.

The MHRA routinely monitors medicines being offered for sale on the internet and has taken enforcement action to remove illegally trading websites and to seize products.

Overall, this is a complex issue. However, I can provide assurance that the Department is working with healthcare regulatory partners to identify what more can be done to protect the public and improve the safety of the provision of medicines online.

Turning to the wider issues raised in your report, you explain that Ms Headspeath had a long-standing dependence on the opioid, codeine. We are very concerned about the recent increase in people addicted to opioid medicines and, in 2017, the Government asked Public Health England (PHE) 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] and made the following recommendations:

- Increasing the availability and use of data on the prescribing of medicines that can cause dependence or withdrawal to support greater transparency and accountability and help ensure practice is consistent and in line with guidance;

- Enhancing clinical guidance and the likelihood it will be followed;

- Improving information for patients and carers on prescribed medicines and other treatments, and increasing informed choice and shared decision making between clinicians and patients;

- Improving the support available from the healthcare system for patients experiencing dependence on, or withdrawal from prescribed medicines; and,

- Further research on the prevention and treatment of dependence on, and withdrawal from prescribed medicines.

The report acknowledged that work to tackle this issue has already started or is planned. For example, England's Chief Pharmaceutical Officer, Dr Keith Ridge, was asked by the Secretary of State for Health and Social Care, Matt Hancock, to review overprescribing in the NHS, problematic use of multiple medications concurrently, and how to help patients come off repeat prescriptions they no longer need.

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[9] https://ec.europa.eu/health/human-use/falsified_medicines_en

[10] https://www.gov.uk/government/publications/prescribed-medicines-review-report

In addition, we asked the National Institute for Health and Care Excellence (NICE) to develop guidance on the safe prescribing of drugs associated with dependence (such as opioids) and the careful management of withdrawing from these drugs[11]. NICE is also developing guidance on *Chronic pain: assessment and management*[12].

The MHRA is currently undertaking a review of opioid medicines and the risk of addiction and dependence. Following initial recommendations of an Expert Working Group, endorsed by the Commission on Human Medicines, in April 2019, we announced that all opioid medications will carry prominent addiction warnings on their labels. Furthermore, the MHRA is working with stakeholders to better support appropriate use of prescription opioids and provide better guidance and consistent information for healthcare professionals. In addition, a leaflet for patients is expected to be available in the coming months, either directly from pharmacists or online.

The MHRA continues to review other regulatory options to respond to concern about overuse or misuse of opioids and it has added the concerns within your report to its Yellow Card Scheme database[13], to help inform this review.

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

Yours, Nadine.

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[11] https://www.nice.org.uk/guidance/indevelopment/gid-ng10141

[12] https://www.nice.org.uk/guidance/indevelopment/gid-ng10069

[13] The Yellow Card Scheme is the UK system for collecting and monitoring information on suspected adverse drug reactions. Its aim is to provide an early warning that the safety of a product may require further investigation.