



Department
of Health &
Social Care

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

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Ms Jacqueline Devonish
HM Area Coroner, Suffolk
HM Coroner's Office
Beacon House
53-65 Whitehouse Road
Ipswich IP1 5PB

27th February 2020

Dear Ms. Devonish,

I am writing to you in relation to the Prevention of Future Deaths report issued following the inquest into the death of Gemma Louise Macdonald.

Your report was issued to the Medicines and Healthcare products Regulatory Agency (MHRA), which brought the report to the attention of the Department. The matters of concern in your report and the circumstances of Gemma Macdonald's tragic death touch on issues that go beyond the scope of the MHRAs responsibilities and as Minister with responsibility for patient safety, I write to provide information on how those issues are being addressed across the health-system.

To begin, I would like to say how deeply saddened I was to read the circumstances of Gemma Macdonald's death. Gemma's death, at such a young age, must be extremely distressing to those who knew and loved her and I offer my most sincere condolences.

Your report explains that Gemma was able to obtain a significant quantity of aspirin and paracetamol online. I also note that morphine and phenoxymethylpenicillin, which are prescription-only medicines, were among the medicines taken by Gemma, though it is not clear from your report if these were obtained from Gemma's GP, or an online prescriber.

While the great majority of medicines bought online are done so appropriately and safely, we know that there have been cases where patients have 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. We are deeply concerned that patients are being put at risk in this way and we are determined to do all we can to prevent future tragedies.

The Department is working with healthcare regulatory partners across the health system to identify what more can be done to protect the public and improve the safety of medicines online.

In 2017, a UK-wide regulatory forum was established, chaired by the Care Quality Commission (CQC), to identify and consider issues around the provision of primary care services online 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 online¹;
- Publication in November 2019 by the General Pharmaceutical Council (GPhC) of revised Guidance for Pharmacist Prescribers², 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 General Medical Council (GMC) is currently seeking the views of its members on remote consultations and prescribing to decide if changes are necessary to its guidance^{3 4};
- The CQC has inspected all registered online providers and published the findings⁵. 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 advised 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 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.

Where a provider is outside the scope of CQC regulation, oversight might fall to other regulators, namely the GPhC and the MHRA, and the three regulators are working collaboratively to share information where there are concerns about a provider.

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>

In relation to the circumstances of Gemma's death, I am advised by the MHRA that in the UK, the legal provisions relating to the retail of medicines⁶ restrict the supply of non-effervescent paracetamol and aspirin tablets to 100 at any one time, and that quantities of more than 100 require a prescription. Where there is evidence that a provider has breached the Human Medicines Regulations 2012, the MHRA can, and will take enforcement action.

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, #Fakemed⁷, 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. Under the provisions of the *European Falsified Medicines Directive*⁸, all Member States of the European Union 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, wishing 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 online and has taken enforcement action to remove illegally trading websites and to seize products.

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 2012⁹) 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

⁶ <http://www.legislation.gov.uk/uksi/2012/1916/contents/made>

⁷ <https://fakemed.campaign.gov.uk/>

⁸ https://ec.europa.eu/health/human-use/falsified_medicines_en

⁹ http://www.legislation.gov.uk/uksi/2015/1470/pdfs/uksiem_20151470_en.pdf

(LHCRE's¹⁰), 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.

Overall, this is a complex issue. However, the Department will continue to work with healthcare regulatory bodies to improve patient safety in this area. Thank you for bringing these concerns to my attention.

yours,
Nadie.

NADINE DORRIES

¹⁰ <https://www.england.nhs.uk/publication/local-health-and-care-record-exemplars/>