Department of Health & Social Care

From the Lord Kamall
Parliamentary Under Secretary of State for Innovation (Lords)

39 Victoria Street
London
SW1H 0EU
Tel: 020 7210 4850

Our Ref: PFD 1381869

D Hocking
Assistant Coroner
for the area of Leicester City and South Leicestershire
Her Majesty's Coroner's Office
Town Hall
Town Hall Square
Leicester
LE1 9BG

30 August 2022

Dear Mrs Hocking,

Thank you for your letter of 21 October 2021 about the death of Jamie O'Connor. I have been asked to reply as Minister with responsibility for Medicines and am grateful for the additional time allowed for me to do so.

I was sad to read of the circumstances of Jamie O'Connor's death. I and my department offer our sincere condolences to his family and loved ones. The circumstances described in your report are very concerning, so I am grateful to you for bringing these matters to my attention.

I should make it clear that in preparing this response, Departmental officials have enquiries with the Medicines and Healthcare products Regulatory Agency (MHRA), General Pharmaceutical Council (GPhC), NHS England and NHS Improvement, as well as the Care Quality Commission.

I am advised that in the UK, medicines (for human use) are subject to strict legal controls under the Human Medicines Regulations 2012. The legislation provides for schemes to authorise medicinal products and to license their manufacture and distribution.

Medicines are classified in one of three categories:

- Prescription only (POM); or
- Pharmacy; or
- General Sales list products.

POMs (including those that are also subject to control under Misuse of Drugs Regulations), should only be dispensed against a prescription from a relevant healthcare provider – including private prescriptions - and can be issued electronically. Relevant providers include doctors registered in the European Economic Area member state, as well as pharmacists that are independent prescribers.

The MHRA has reviewed the supply of POMs to Mr O'Connor exchange information with the relevant regulators, CQC and GPhC. Enquiries revealed that the medicines were supplied in accordance with a prescription issued by an appropriate healthcare provider and consequently, no breach of regulatory requirements in the Human Medicines Regulations 2012 appear to have happened.

The Department is working with other healthcare regulators including the General Medical Council and their equivalents in Scotland, Wales and Northern Ireland in the area of digital healthcare provision. As a result, a review of the UK's legislative position was undertaken and gaps identified. These included cases involving inappropriate prescribing and a lack of checks with the patient's GP before prescribing. There were also concerns about the absence of pharmacy records of medicines dispensed by other pharmacies. The Department and healthcare regulators are also working together to review prescribing by private prescribers in relation to controlled drugs.

An Expert Working Group of the Commission of Human Medicines, which is the MHRA's independent scientific advisory body, examined the risk of dependence and addiction to opioids. Dihydrocodeine is an opioid medicine authorised for the treatment of acute pain. In April 2019, warnings were added to the packaging to highlight that the medicine contains an opioid and to warn about the risk of addiction. In 2020, further warnings were added in the product information, the Summary of Product Characteristics for healthcare professionals and the patient information leaflet, about the risk of addiction.

Further to this, on 23 September 2020 an article was published in the MHRA's electronic drug safety bulletin for healthcare professionals, Drug Safety Update[1] (DSU) highlighting the risk of addiction and the potential for overdose which could be fatal. A separate patient leaflet[2] is linked to the DSU, which was recently updated in August 2021 following user-testing to ensure that patients can access the messages. This leaflet also highlights the issue of tolerance, where a patient may consider that the medicine is not having the same effect as before, and therefore feels the need to take more than directed. Pharmacies have been encouraged to provide a link to this patient leaflet on their websites to increase awareness of these warnings. The MHRA continues to review the safety and access to the opioid medicines and will take any necessary regulatory action as laid in the Human Medicines Regulations 2012.

In addition, the UK has a Yellow Card Scheme for collecting and monitoring information on suspected adverse drug reactions (ADRs). The Scheme is run by the MHRA and relies on voluntary reporting of suspected ADRs by health professionals and patients. There is also a legal obligation for pharmaceutical companies to report serious ADRs associated with their drugs. The purpose of the Scheme is to provide an early warning that the safety of a product may require further investigation. My officials have advised that Jamie O'Connor's case has been added to the Yellow Card database.

As more people use the internet to research health issues, there have been more patients going online to buy prescription medicine. The guideline about advertising and promotion of medicines in the UK is set out under the Human Medicines Regulations 2012 (Part 14). Advertising of medicinal products has a broad definition under the Regulations and is considered to be anything which is designed to promote their prescription, supply, sale or consumption. These legal requirements are set out in the MHRA Blue Guide[3].

Any website for consumers, registered in the UK or aimed at a UK audience, which provides a treatment service is required to comply with the law on advertising of medicines. While websites may promote their treatment service, which may lead to the prescription and supply of a POM, they must not promote specific POMs to the public. This is prohibited by Regulation 284, which guards against the issue of an advertisement to the public likely to lead to use of a POM. The regulation aims to protect public health by ensuring that appropriate management of a condition for an individual

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[1] https://www.gov.uk/drug-safety-update/opioids-risk-of-dependence-and-addiction
[2] https://assets.publishing.service.gov.uk/media/5f6a078ed3bf7f7238f23100/Opioid-patient-safety-information-leaflet-v2-Aug2021.pdf
[3] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956846/BG_2020_Brexit_Final_version.pdf

consumer is undertaken via joint consideration between prescriber and patient in a professional consultation, taking into account a potential range of medical factors and a relevant range of therapeutic options.

Appendix 6 of the Blue Guide[4] provides guidance for treatment service providers that outlines how to promote a service (and professional consultation) without breaking the law by promoting specific POMs to the public. If a complaint is received, the decision on whether a particular communication complies with the Regulations will be taken by the MHRA on a case-by-case basis, having regard to the circumstances of the particular case. Completed investigations are published on the Government's website[5].

General principles for services such as online clinics or pharmacies include advising that they make information available on a particular condition and its management, which may include a factual and balanced overview of the range of therapeutic options. Website homepages and any linked social media content should focus on medical conditions and the service provided. Casual browsers should not be presented with information on POMs. Further pages about a condition may set out non-promotional information on specific medicines if presented as a fair overview of options.

The MHRA also works closely with other regulators to ensure that the public are protected from the advertising of POMs. This work can involve the issuing of guidance for advertisers to uphold high standards, and joint enforcement or working closely on investigations and complaints. These bodies include, but are not limited to - the Advertising Standards Authority, CQC, and the professional bodies for healthcare professionals. The General Pharmaceutical Council (GPhC) is the professional body for upholding high standards from the pharmacy profession, including those professionals who operate distance-selling businesses. GPhC guidance[6] outlines how pharmacy websites should be arranged so as not to enable a consumer to choose a POM and its quantity before an appropriate consultation with a prescriber has taken place.

I hope this response addresses the concerns raised in your PFD report. Please do contact my department if any further clarification is required. I do hope we can learn from the sad death of Jamie O'Connor to prevent such tragedies in the future.

Yours sincerely,

LORD KAMALL

[4] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956859/Appendix_6.pdf
[5] https://www.gov.uk/government/collections/advertising-investigations-by-mhra
[6] https://www.pharmacyregulation.org/sites/default/files/document/guidance_for_registered_pharmacies_providing_pharmacy_services_at_a_distance_including_on_the_internet_april_2019.pdf