From Minister Karin Smyth MP Minister of State for Health



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| Our ref: | |
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Miss I Thistlethwaite
HM Assistant Coroner
Rutland and North Leicestershire area
HM Coroner's Office
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LE3 8RA

08 August 2024

Dear Miss Thistlethwaite,

Thank you for the Regulation 28 report of 4 June 2024 sent to the Department of Health and Social Care about the death of Mr Nigel Walter Dixon. I am replying as the Minister with responsibility for medicines regulation.

Firstly, I would like to say how saddened I was to read of the circumstances of Mr Dixon's death, and I offer my sincere condolences to their family and loved ones.

The report raises concerns over how Mr Dixon was able to obtain large quantities of online from an illicit suppler, without the knowledge of Mr Dixon's GP. I share the desire to learn from Nigel's death and it is essential that we do all we can to reduce the risks to patient safety from online supply of illicit medicines.

In preparing this response, Departmental officials have made enquiries with the Department for Science, Innovation and Technology (DSIT), the Medicines and Healthcare products Regulatory Agency (MHRA), and the General Pharmaceutical Council (GPhC), as the independent regulators of medicine and pharmacy, respectively.

Enforcement action against illicit trade of medicines

| The GPhC regulates pharmacists, pharmacy technicians and pharmacies in Great Britain | | |
|--|--|--|
| The company | is not a business registered with the | |
| GPhC and operates outside the UK jurisdiction. As | s such, this matter falls to the MHRA. | |

The MHRA, acting on behalf of the Secretary of State for Health and Social Care, is responsible for the regulation of all medicines and medical devices in the UK by ensuring they work and are safe. This includes applying the legal controls on the retail sale, supply and advertising of medicines which are set out in the Human Medicines Regulations 2012. These regulations apply equally to medicines advertised, sold, or supplied via the internet.

The MHRA and its Criminal Enforcement Unit also actively seeks to identify individuals involved in unlawful activity and, where appropriate, prosecute those who put public health at risk. The efforts of the MHRA and its partners in this regard, have led to increasing levels of medicines being seized, significant custodial sentences for offenders, the forfeiture of criminal profits and considerable disruption to the illegal trade online. In 2023, the MHRA and its partners seized more than 15.5 million doses of illegally traded medicines with a street value in excess of £30 million. It also disrupted more than 15,000 links to websites and social media pages selling medical products to the public illegally.

However, the sale and supply of unregulated medicinal products is a global problem. Online portals play a significant role in transnational medicines crime and many websites proliferate across the internet. Currently, there is no legal mechanism for UK law enforcement to seize control of illicit domains or compel registrars to suspend them when domains are registered beyond the reach of UK jurisdiction. The website referenced in the Regulation 28 notice falls into this category, being registered outside of the UK.

The MHRA can confirm that the website in question is subject to an active criminal investigation, and that arrests had been made prior to the issuing of the Regulation 28 Report. The MHRA has also issued multiple formal requests to the registrar (the company that manages the website's domain name) to suspend the website, which has thus far been unsuccessful. Other MHRA efforts to minimise the risk this website poses to the public have included:

- Delisting from the UK's major search engine providers, meaning the offending website has been removed from standard search results.
- Website added to British Telecom's parental blocking list, rendering it barred to customers with active parental controls.
- Website details passed to anti-cybercrime partners in the internet industry for further attempts at takedown.
- Request sent to the registry (the provider of domain name registry services and internet infrastructure) for takedown.

Through a combination of public empowerment, technological innovation, traditional methods of law enforcement and close collaboration with partners, the MHRA is constantly working to develop new and innovative ways to tackle the online trade in illegal medicines. Some of these future criminal countermeasures will include:

- Enhanced collaboration with search engines and UK internet service providers (ISPs) aimed at blocking harmful content through targeted ISP-filtering.
- Collaboration with the Office of Communications (Ofcom) to explore fresh
 preventative opportunities presented by the Online Safety Act (further details
 below), which will create new rules for social media companies and search engine
 providers.
- Boosted collaboration with UK Border Force, allowing the MHRA to grow its operational footprint at the border and increase the seizure rates of illegally trafficked medicines.
- The use of cutting-edge technology to identify, track and seize the proceeds of crime, including cryptocurrency.
- Rollout of a web-based online pharmacy checker that will allow users to search if a website or social media listing has been deemed fraudulent by the MHRA.
- Implementation of a web-based reporting scheme allowing users to report suspicious websites, online marketplaces, and social media listings to the MHRA.
- Continued commitment to enhancing collegiate working across internet infrastructure community, including private sector and international law enforcement partners.

DSIT has also taken steps to tackle criminal activity online. The Online Safety Act (the 'Act') received Royal Assent in October 2023. The Act will require search services and platforms that facilitate user-to-user interactions to take robust action to protect their users from harm and illegal content and activity.

Under the Act, user-to-user platforms such as online marketplaces are required to put in place systems to reduce the risk their services are used for sales of illegal drugs and other 'priority offences'. Search services will also have duties to reduce the risk that users will encounter content amounting to priority offences in search results or when they click on them. Offences designated as 'priority offences' reflect the most serious and prevalent illegal content and activity, such as the sale of illegal drugs or weapons and the promotion or facilitation of suicide.

Ofcom is the independent regulator of the Act's regime and is taking a phased approach to implementation. The illegal content safety duties in the Act are expected to take effect in early 2025. Ofcom will have robust powers to take enforcement action against companies who do not comply with their new duties and protect users from harm.

Following the change of government, DSIT will be considering the issues raised in the report very carefully in deciding how to move forward in ensuring greater online safety.

Improving communication between secondary care and community pharmacy

Whilst the primary concern of the report is the illicit supply of medicines, the report also identifies concerns in the communication between secondary care and the community pharmacy charged with dispensing Mr Dixon's prescriptions. The Discharge Medicines Service (DMS) is an essential service provided by all community pharmacy contractors in England, which enables hospitals to refer discharged patients to community pharmacies for support. By referring patients to community pharmacy on discharge with information about medication changes made in hospital, community pharmacy can better support patients to improve outcomes and prevent harm, making sure the patient and primary care prescriber do not inadvertently continue with legacy medicine regimes.

Although there is currently no contractual requirement for NHS trusts to participate in the DMS, it is recommended that clinical staff refer eligible patients to community pharmacy into the DMS in the interests of patient safety and in line with their professional responsibility. NHS England has been actively promoting this service to hospital chief pharmacists, to further facilitate its implementation and will introduce improved IT to improve the interoperability between the two settings to remove existing barriers preventing Trusts from fully engaging with the service. If the University Hospitals of Leicester NHS Trust had completed a DMS referral via their chosen IT provider (such as PharmOutcomes - as referenced) the community pharmacy team would have been made aware that morphine treatment had ceased in hospital which would have flagged that any legacy prescriptions should not be dispensed. As noted in the report the Trust have committed to make improvements to reduce the risk of similar reoccurrence in future

Mr Dixon's case sadly demonstrates the dangers of purchasing illicit medicines online and the importance of robust enforcement of the law. I am assured that the swift action of the MHRA and the strengthening of regulation around online content will help prevent similar incidences and give enforcement agencies greater powers to tackle and remove online content concerning illicit drugs and medicines.

I would like to take the opportunity to thank you for highlighting these matters of concern, and for giving us the opportunity to respond. I hope this response is helpful.

Yours sincerely,

KARIN SMYTH MP

MINISTER OF STATE FOR HEALTH