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Department
of Health

Your Ref: 61026

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From the Lord O'Shaughnessy
Parliamentary Under Secretary of State for Health (Lords)

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08 JAN 2018

Dear Ms Hashmi,

Thank you for your Report dated 30 October to the Department of Health about the death of Ms Jane Allison Powell. I am responding as Minister with responsibility for medicines regulation and I apologise for the slight delay in doing so.

I was very saddened to read of the circumstances surrounding Ms Powell's death. Please pass my condolences to her family and loved ones. I appreciate this must be a very difficult time for them.

You ask for clarity on what action has been, or is being, taken to address the ease with which individuals can obtain large amounts of medication (including 'prescription only') over the internet.

In preparation of this response, my officials have liaised with the Medicines and Healthcare products Regulatory Agency (MHRA) and the General Pharmaceutical Council (GPhC).

It might be helpful if I first provide some background to the legal controls on the retail sale, supply and advertisement of medicinal products in the UK.

Under medicines legislation, it is unlawful for medicinal products for human use to be marketed, manufactured, imported from a third country, distributed and sold or supplied in the UK except in accordance with the appropriate licences or exemptions. The UK has three legal classes of authorised medicines:

- General sale list medicines are suitable for sale and normal use without supervision or advice from a pharmacist or doctor;
- Pharmacy (P) medicines can only be obtained from a pharmacy and are sold or supplied under the supervision of a pharmacist; and
- Prescription only medicines (POM) must be prescribed by an authorised healthcare professional, for example a doctor, dentist, or independent prescriber.

Doctors may also supply medicines direct to patients – for example, where they personally administer a medicine such as a vaccine, or where they are able under specific NHS arrangements to supply prescribed medicines to their patients as part of an NHS dispensing service

A UK registered pharmacy may have a presence on the internet; however, the requirements of legislation apply equally to both UK internet pharmacies and bricks-and-mortar premises. A POM cannot be advertised directly to the public.

These legal controls apply equally to medicines for human use sold or supplied via the internet or e-mail transactions. Some POMs are ‘Controlled drugs’ (such as benzodiazepines) and their availability to patients can be subject to additional control under the Misuse of Drugs Act 1971, which is administered by the Home Office.

These restrictions do not apply to countries outside UK jurisdiction where medicines may be classified and regulated differently. For example, in the US and other countries some medicines that would be POMs in the UK are available without prescription.

Medicines legislation does not prohibit the remote prescribing of POMs by a qualified prescriber. However, prescriptions must meet the usual requirements set out in medicines legislation.

Additionally, there are no formal restrictions on an individual importing medicines into the UK provided they are strictly for use by that person or a member of their immediate family.

The GPhC operates the Internet Pharmacy Logo, which helps members of the public identify if a website is being operated by a legitimate pharmacy in the UK.

In addition, under provisions in the European Falsified Medicines Directive (FMD), Member States have been required to introduce national arrangements to register suppliers of medicines at a distance. This has involved the establishment of a national website and the adoption of a common EU logo. All websites supplying medicines at a distance are required to display the EU logo and provide a hyperlink to



Department of Health

the national website of the Member State in which the person offering to sell medicines at a distance is established. These provisions took effect across the EU on 1 July 2015 and the MHRA is responsible for UK registrations.

The UK's registration scheme for the online retail selling of a medicine is set out in the Human Medicines Regulations 2012.

Other provisions in FMD relating to sales of medicines at a distance require all EU Member States to make non-prescription medicines available online – some Member States allow POMs to be supplied electronically.

In terms of guidance, the GPhC has produced “Guidance for registered pharmacies providing pharmacy services at a distance including on the internet”. The General Medical Council has issued guidance to doctors on good practice concerning prescribing where they are not in face-to-face contact with the patient.

The MHRA has serious concerns about the availability of medicines being offered via the internet. Medicines purchased from websites, particularly websites based overseas, cannot be guaranteed to meet set standards of quality, safety and efficacy and the MHRA advises patients not to purchase medicines in this way.

The MHRA's advice is issued with a view to protecting patient health; as you will be aware, there have been cases in the UK where individuals have purchased medicines online that have led to severe adverse reactions and death. Consequently, the MHRA is working to ensure that there is proper guidance to support the safe purchase of medicines over the internet, which it hopes will reconcile the increasing trend towards electronic commerce, including the growth of legitimate pharmacies trading online, with the protection of individual patient safety and public health.

The MHRA is taking a range of action in this area. It routinely monitors medicines being offered for sale on the internet and enforcement action can be taken immediately against wrong-doing based in the UK. The MHRA investigates reports of illegal activity taking place on a website and, where appropriate, takes enforcement action against suppliers who operate outside the legal requirements. Considerable illegal activity takes place outside of UK jurisdiction and websites identified overseas are referred to the relevant country for appropriate action. However, many set up their operations from countries where there is little, or no, regulatory control. The MHRA therefore works closely with the EU and other

international regulatory authorities to ensure that, wherever possible, offending websites are amended to reflect the law.

The MHRA, working with the internet service industry and other stakeholders, has closed thousands of websites, including websites based overseas, and brought into compliance hundreds more.

In addition, the MHRA has investigated cases where POMs have been supplied to members of the public from websites without a prescription and the involvement of a qualified healthcare professional. A number of individuals have been successfully prosecuted by the MHRA for selling medicines illegally over the internet.

An example of international collaboration to tackle the illegal online supply of medicines is demonstrated by Operation Pangea.

This international initiative to target illegal internet trade in pharmaceutical products was instigated by the MHRA in April 2006. It started as the UK Internet Day of Action and has grown annually into an International Week of Action. It is the largest internet-based enforcement action of its kind to date. It is coordinated by INTERPOL and carried out with the assistance of police, the World Customs Organisation, and law enforcement agencies/drug regulatory agencies across the world.

The latest Operation Pangea (Pangea X) was carried out recently and resulted in more than 1.3 million units of medicines and devices seized with an estimated value of just over £4 million.

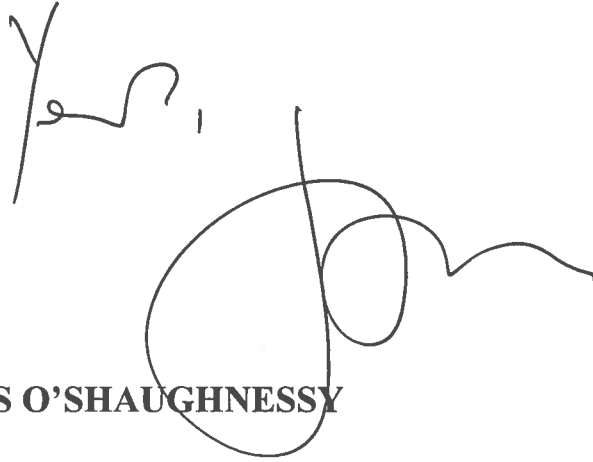
In terms of raising awareness among the public and healthcare professionals, in August 2016, the MHRA launched the FakeMeds campaign, aimed at reducing online purchases of falsified, unlicensed and counterfeit medicines and medical devices. Channels used to promote the campaign include broadcast and print media, the gov.uk website and social media, as well as relevant partnership networks. The success of the campaign is being assessed through awareness of, and consumer behaviour towards, online purchasing of falsified products ultimately leading to reduced negative impact on public health.

With regard to the sad death of Ms Powell, I am advised that from the information provided in your Report, it is not possible to determine if Ms Powell obtained medicines online legitimately, or from a website operating illegally. The MHRA has requested information from Greater Manchester Police on the evidence held in this case relating to the purchase and supply of medicines from websites and will investigate further once it has received those details.



Department
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I hope this reply is helpful. Thank you for bringing the circumstances of Ms Powell's death to my attention.



JAMES O'SHAUGHNESSY

