[redacted]
National Medical Director
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Ms Caroline Beasley-Murray,
Senior coroner,
Essex and Thurrock Coroner's Service,
Essex County Council,
County Hall,
Chelmsford
CM1 1QH

7th May 2021

Sent by e-mail: [redacted]

Dear Ms Caroline Beasley-Murray

Re: Regulation 28 Report to Prevent Future Deaths – Joseph James Gingell. 24th May 2019

Thank you for your Regulation 28 Report dated 17th February 2020 concerning the death of James Joseph Gingell on 24th May 2019. Firstly, I would like to express my deep condolences to Mr Gingell's family.

The regulation 28 report concludes Joseph James Gingell's death was a result of mixed drug toxicity with alcohol. Following the inquest, you raised concerns in your Regulation 28 Report to NHS England and NHS Improvement (NHSE&I) regarding:

(1) The drugs found in Mr Gingell's system are known to have toxic effects when taken in excessive amounts in conjunction with other medication.

(2) Permitting the patient to "self certify" without any checks can allow abuse of the system by those most vulnerable who have addiction problems.

(3) Permitting the patient the option of not having a GP informed removes an otherwise effective safeguard.

We are grateful you have brought this to our attention and we also share these concerns. Firstly, it is important to set out that providers of controlled drugs based in England must comply with legislation which is enforced by healthcare regulators such as Care Quality Commission (CQC), the Medicines and Healthcare products Regulatory Agency (MHRA) and the General Pharmaceutical Council (GPhC). In addition, all healthcare professionals are subject to their respective codes of professional conduct and these are enforced by, for example, the General Medical Council (GMC) for doctors.

With regards to NHSE&I's role, we have a clear responsibility in providing systems oversight for the management and use of controlled drugs, including tramadol. NHS

E&I's Controlled Drugs Accountable Officers (CDAOs)[1] undertake this role within each geographical region across England. They provide assurance that all healthcare organisations, including pharmacies, adopt a safe practice for appropriate clinical use, prescribing, storage, destruction and monitoring of controlled drugs.

CDAOs facilitate the routes to share concerns, report incidents, and take remedial action as well as highlighting good practice. This is shared with wider partners such as Clinical Commissioning Groups and the Police through the Controlled Drugs Local Intelligence Networks (CD LINs). Details of all CDAOs in England are held on a national register, which is owned and published by the CQC: www.cqc.org.uk/content/controlled-drugs-accountable-officers.

The sale or supply of controlled drugs outside of the legislative framework is the responsibility of the Home Office, and NHSE&I does not have powers to stop illegal supply of dependence forming drugs with toxic potential. However, we can and do take this into account in the provision of NHS services. NHSE&I expects all NHS providers to follow the NICE guidance on *Coexisting severe mental illness (psychosis) and substance misuse: assessment and management in healthcare settings*[2] which directs people to consider the use of drugs, prescribed or otherwise when providing clinical care.

However, we are aware of cases where coroners have highlighted an online consultation with a doctor, issue of a prescription and supply of medicines, as having contributed to a death. We recognise further work is needed to ensure patient safety where consultations are given online.

As a result, in April 2017, the National Quality Board[3] - jointly chaired by NHS England and CQC - held a workshop focusing on online providers of primary care services and online prescribing. The workshop identified a number of challenges for the system including gaps in the current regulatory framework to protect patients from harmful practice. Following the workshop, the CQC established a UK-wide forum to review the regulatory landscape for online prescribing. As well as CQC, the group includes Healthcare Inspectorate Wales (HIW), Healthcare Improvement Scotland (HIS), The Regulation and Quality Improvement Authority (RQIA) (Northern Ireland), Medicines and Healthcare products Regulatory Agency (MHRA), the General Medical Council (GMC), General Pharmaceutical Council (GPhC) and Nursing and Midwifery Council (NMC). This group now meets regularly. The CQC remains concerned that citizens are able to source medicines with the potential for harm from providers who structure their business in such a way as to be outside the scope of registration with the CQC or GPhC.

We are working with other health regulators who have a greater role in responding to this challenge. Relevant UK agencies, such as the CQC and MRHA, have worked collaboratively to review the healthcare framework and, importantly, identify gaps to

1 https://www.england.nhs.uk/contact-us/privacy-notice/how-we-use-your-information/safety-and-quality/controlled-drugs-accountable-officer-alerts-etc/

2 https://www.nice.org.uk/guidance/cg120

3 The National Quality Board is a national cross organizational board comprising the clinical leaders of national arms-length bodies across health care, social care and public health. It is jointly chaired by NHS England and Care Quality Commission

ensure patients are protected from loopholes – notably, for example, where some companies have deliberately configured themselves to avoid regulation by CQC - within and outside the UK system.

Linked to this, the CQC inspected every company in England that provided non-NHS online primary care services. Its findings were published in March 2018 in 'The state of care in independent online primary health services'[4]. Providers were assessed against five key areas: whether they were safe, caring, effective, responsive to people's needs and well-led. The CQC also reviewed the provider's registered location, its systems and policies, examined how it delivered care, and analysed information it held against the provider including, where available, feedback from people who have used or have come into contact with the service.

One of the questions CQCs inspectors asked during these inspections included how the service makes sure the identity of the patient is authenticated and requested that where a treatment might have the potential to affect safe care or decrease the ability of the patient's GP to provide safe and effective care that the patient's NHS GP is kept informed of any treatment, with the exception of sexual health services. These issues are important for NHSE&I and we will ensure that NHS online consultations provide a safe and secure way for patients to discuss their health concerns with an appropriate clinician connected to their own GP practice and place centred around their needs. NHSE&I has adopted a robust system of quality assurance, safety and security standards so that patients and clinicians can feel confident in using online consultations.

These services will continue to be regulated by CQC and we understand that they are progressing plans to help increase public understanding of the quality and safety of online services in England by rating providers as 'outstanding', 'good', 'requires improvement' or 'inadequate', as used on other healthcare services.

In the UK, the MHRA are responsible for the legal provisions relating to the supply of medicines online which include;

- All categories of medicines (GSL, P and POMs) may be sold online – provided all other legal requirements in medicines regulations are met – for example, Prescription Only (POM) and Pharmacy (P) medicines may only be legally sold or supplied to the public through registered pharmacy premises, by or under the supervision of a pharmacist and POMs may only be sold or supplied in response to a prescription from an authorised healthcare professional (such as a doctor, dentist, or certain trained nurses and pharmacists). [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 sales from bricks-and-mortar premises and sales online.Medicines legislation does not prohibit the remote prescribing of POMs by a qualified prescriber however prescriptions must meet the usual requirements set down in medicines legislation.

- 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.

The EU's Falsified Medicines Directive (FMD), introduced national arrangements to register suppliers of medicines at a distance. This required Member States to establish a national website and adopt the EU Common logo. The Human Medicines Regulations 2012 were amended and MHRA was responsible for managing the UK list of online retailers that registered to sell medicines to the public remotely. The scheme was disapplied in GB from 1 January 2021 and powers sought in the Medicines and Medical Devices Bill to introduce a new system. The Bill has since been granted Royal Assent and MHRA plan to consult with stakeholders on what system would best suit UK market.

The MHRA is working with partner healthcare regulators including the Care Quality Commission, the General Pharmaceutical Council, the General Medical Council, Public Health England, NHS England and partners in Scotland, Wales and N Ireland to review the UK legislative framework on digital healthcare provision and, importantly, identify gaps.

In addition to action to remove illegally trading websites and seizing products, the MHRA recognises that reacting to threats also involves alerting patients and has run a number of public awareness campaigns including a targeted and sustained campaign named #Fakemeds which was developed with the assistance of supporting research and was run online and through social media for maximum coverage.

The Yellow Card Scheme is the UK system 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 ADR reports to their drugs. The purpose of the Scheme is to provide an early warning that the safety of a product may require further investigation.

In addition to this:

- The GMC has issued guidance[5] for all healthcare professionals with prescribing responsibilities. It sets out the shared high level principles of good practice expected of everyone when consulting and or prescribing remotely from the patient.

- NHSE&I provides advice[6] to patients on the dangers of buying medicines on-line.

- The GPhC provides guidance to GB internet based pharmacies on providing pharmacy services online and operates a voluntary internet pharmacy logo scheme

[5] 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

[6] https://www.nhs.uk/nhs-services/prescriptions-and-pharmacies/pharmacies/dangers-of-buying-medicines-online/

to provide reassurance to patients and the public that they are purchasing medicines online from registered pharmacies who have to meet GPhC standards.

In the wider context of this issue, Public Health England published in 2019 a Prescribed medicines review[7]. This reported on the evidence for dependence on, and withdrawal from, prescribed medicines with the aim of making sure that local healthcare systems build awareness and support to enhance clinician and patient decision making. In support of this NHSE&I are co-ordinating a programme to implement the review recommendations working closely with relevant Arm's Length Bodies (ALBs) to ensure cross system improvements. The programme covers five classes of medicines including:

- Benzodiazepines;
- Z-drugs;
- Gabapentinoids;
- Opioids, for chronic non-cancer pain; and
- Antidepressants.

With regard to this case, and based on the information provided within the Regulation 28, it appears that this death was not the result of services provided by NHS, but from services outside of the NHS. It is unclear where this doctor or company were registered and the site from which the deceased obtained the consultation, prescription and medication. Nevertheless, the provision of remote consultations and the supply of medicines through distance selling remains a concern.

NHSE&I remains committed to improving the safety of controlled drugs and online prescribing. We will continue to work across the system with key partners nationally, regionally and locally to ensure patient safety. We would also suggest that contact is made directly with the CQC and MRHA who would be better placed should you wish to understand their work in this area further.

Thank you for bringing these important patient safety issues to my attention and please do not hesitate to contact me should you need any further information.

Yours sincerely,

[redacted]

[redacted]
National Medical Director
NHS England and NHS Improvement

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