NHS England

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Dr Fiona Wilcox
HM Senior Coroner
Inner West London
Westminster's Coroner's Court
65 Horseferry Road
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13th February 2019

Dear Dr Wilcox,

Re: Regulation 28 Report to Prevent Future Deaths – Jennifer Anne Lacey, died on 4th June 2018.

Thank you for your Regulation 28 Report concerning the death of Jennifer Anne Lacey on 4th June 2018. Firstly, I would like to express my deep condolences to Ms Lacey's family.

The regulation 28 report dated 24 October 2018 concludes Ms Lacey's death was a result of cardiorespiratory failure triggered by consumption of tramadol and alcohol and that a conclusion was reached that Ms Lacey took her own life.

Following the inquest, you raised the following concerns in your Regulation 28 Report to NHS England:

1. *The such potentially dangerous and addictive drugs are so freely available over the internet.*
2. *That they can be prescribed without any contact with the patients' regular medical practitioner or access to the patients' medical records.*
3. *The such prescriptions of such potentially dangerous and addictive drug may be being filled in UK pharmacies without any further checks.*

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 NHS England's role, we have a clear responsibility in providing systems oversight for the management and use of controlled drugs, including tramadol. NHS England's Controlled Drugs Accountable Officers (CDAOs)[1] undertake

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

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

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[2] - 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.

Linked to this, the CQC inspected every company in England that provided online primary care services. Its findings were published in March 2018 in '*The state of care in independent online primary health services*'[3]. 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 CQC's inspectors asked included, how the service makes sure the identity of the patient is authenticated and that their NHS GP is kept informed of any treatment. These issues are important for NHS England 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. NHS England 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.

[2] 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.
[3] https://www.cqc.org.uk/publications/major-report/state-care-independent-online-primary-health-services

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. 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 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.

NHS England 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 would will be better placed should you wish to understand the 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

Professor Stephen Powis
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NHS England