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Ms Lydia Brown
H.M Assistant Coroner for Exeter and
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Room 226 County Hall
Topsham Road
Exeter
Devon
EX2 4QD

10<sup>th</sup> October 2018

Dear Ms Brown

Re: Regulation 28 Report to Prevent Future Deaths - Karl James Willis, date of death 06/12/2017

Thank you for your Regulation 28 Report (Report) dated 24 August 2018 concerning the death of Karl Willis on 06/12/2017. Firstly, I would like to express my deep condolences to Karl's family.

Your Report concludes Karl Willis' death was a result of aspiration pneumonitis secondary to amitriptyline and morphine toxicity.

Following the inquest you raised concerns to NHS England regarding the (i) toxic effects of amitriptyline when taken in excessive amounts or in conjunction with other medications. (ii) Permitting a vulnerable patient to 'self-certify' information on a questionnaire to enable them to obtain access to such medication without checks being made on the accuracy of the patient's answers, and (iii) permitting the option for patients to refuse information to be passed to their GP.

It may be helpful if I first explain that NHS England is formally known as the NHS Commissioning Board (Board) in legislation (Section 9 Health & Social Care Act 2012 amending Sections 1G & 1H of the NHS Act 2006).

The Board's functions and duties are set out in that legislation and include a duty in respect of commissioning arrangements for NHS services. These include commissioning primary care services (including general practice and pharmacy), managing the NHS performer's lists and maintaining the pharmaceutical list.

We have responsibility for ensuring that GPs work within the terms of their contract and pharmacies adhere to their Terms of Service which are outlined in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013). The Board can take action such as issuing breach notices and requiring action or withholding payments in certain circumstances.

I recognise your concerns around the availability of some prescription only medication through the internet, however, when this arises outside the NHS (on a private basis in England or abroad), the Board has limited powers to influence.

In relation to your specific points, amitriptyline is medication which has well known side effects including sedation and in overdose, it can have cardio-toxic effects. As an antidepressant, it is less commonly used because of these side effects, but its use is still widespread in clinical practice as a medication that in comparatively low doses is effective in managing pain and anxiety symptoms. It is a licensed medication that by law requires a medical prescription before it can be obtained. It is not a licensed as a controlled drug under the misuse of drugs legislation.

In the case of Karl, the prescription was obtained on a private basis through the internet. The 'consultation' was in the form of an online questionnaire which would have informed the prescribing clinician about relevant past medical history, but as you have indicated, it is dependent on how accurately a patient submits their response. The use of a questionnaire for patients to 'self-certify' their medical history carries risks that the treating doctor would not be aware of the full extent of a patient's past medical history. It is why there is much work being done in the NHS to connect NHS services to the patient's summary care record so clinicians can access a summary of the patient's main conditions.

To be eligible to provide NHS care, all GPs working in England have to be included on the NHS England 'Performer list'. The Performer List regulations give the Board responsibility for assuring the quality of GPs providing NHS services in England, The Board has no powers to take action against a clinician who only practices privately, although such doctors do need to maintain their registration with the General Medical Council (GMC).

In choosing to access private health care, a patient is stepping outside the NHS, as a result, the Board has no jurisdiction over private consultations and none of the Board's powers relating to community pharmacy, prescriptions or regulation would apply.

It remains a patient's right to choose to seek private treatment even where this would be detrimental to their health. There is a wider question on whether an online prescriber should be able to prescribe all/certain medications but this is not in the Board's control.

You finally highlight the concern that Karl was given an option to refuse to have the details of his consultation with the private on-line provider to be shared with his own GP. We have checked the website for the provider which has been involved in this case and note that it is recommended that information is shared with a patient's own GP. As you will appreciate, whilst most often in a patient's best interest for information to be shared, the bar at which it is appropriate for confidentiality to be breached is set high and in the tragic circumstance of Karl Willis, there would have been no legal justification to have breached his confidentiality and informed his GP or anyone else involved in his care.

Thank you for bringing this important patient safety issues to my attention and we hope our response has addressed your concerns. Please do not hesitate to contact me should you need any further information. Yours sincerely,

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Professor Stephen Powis National Medical Director NHS England

