Department of Health & Social Care

[redacted]
Parliamentary Under-Secretary of State for Health Innovation and Safety

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HM Coroner Sarah Bourke
Inner North London
St Pancras Coroner's Court,
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[redacted]

19th December 2025

Dear Ms Bourke,

Thank you for the Regulation 28 report of 6 August 2025 sent to the Secretary of State about the death of Jacob Matthew Wooderson**.** I am replying as the Minister with responsibility for prescribing.

Firstly, I would like to say how saddened I was to read of the circumstances of Mr Wooderson's death and I offer my sincere condolences to their family and loved ones. The circumstances your report describes are concerning and I am grateful to you for bringing these matters to my attention.

The report raises concerns over the need for regular monitoring of heart rate and blood pressure of patients taking Elvanse and the risk of unreliable heart rate and blood pressure readings taken by patients outside of consultations being used by clinicians, which may be higher for remote consultations. It also raises concerns about methods used in giving advice to patients who have ADHD, symptoms of which can include forgetfulness and problems with inattention.

In preparing this response, my officials have made enquiries with NHS England (NHSE), the National Institute for Health and Care Excellence (NICE) and the Medicines and Healthcare products Regulatory Agency (MHRA) to ensure we adequately address your concerns.

When MHRA authorises a medicine for use in the UK, it publishes a summary of product characteristics (SPC). This sets out a medicine's properties and conditions for safe and effective use by healthcare professionals. It is based on clinical trials and product research and is regularly updated as new data emerges. The SPC forms the basis for other guidance for prescribers such as the British National Formulary (BNF). The BNF is an evidence-based independent drug formulary used by health professionals as a source of key information on the selection, prescribing, dispensing and administration of medicines. NICE

develop clinical guidelines for selected topics which set out evidence-based recommendations for best practice in health and care.
First, regarding monitoring of heart rate and blood pressure (BP) of Elvanse patients, Guidance in the BNF and the SPC for Elvanse, available at Search Results - (emc), states that there is a need for baseline BP and heart rate monitoring, as well as before every change of dose and every 6 months. The recommendations in the NICE guideline - attention deficit hyperactivity disorder: diagnosis and management [NG87] - are consistent with the requirements for monitoring in the SPC and the BNF.

NICE also say the following in its Making decisions using NICE guidelines page: 'Healthcare professionals should take note of the contraindications, warnings, safety recommendations and any monitoring requirements for the medicine. These are explained in the SPC for the medicine, the British National Formulary (BNF) or British National Formulary for Children (BNFC).'

Recommendation 1.7.4 of guideline NG87, above, states 'an ECG is not needed before starting stimulants…..unless the person has any of the features in recommendation 1.7.5, or a co-existing condition that is being treated with a medicine that may pose an increased cardiac risk.' Recommendation 1.7.5 lists factors, symptoms and signs which may imply a cardiac history.

Regarding the monitoring of heart rate, the rationale for this is given in Evidence review D, section 1.9.1.3, Pages 87 to 89. Although the evidence of cardiac side effects is not strong, this may be because of a paucity of specific large studies. In the discussion (p89) the committee "agreed that it was important to monitor heart rate and blood pressure every 6 months and if there were important clinical changes the dose should be reduced and referral to a cardiologist may be necessary".

Further to this, recommendation 1.7.26, states that "During the titration phase, ADHD symptoms, impairment and adverse effects should be recorded at baseline and at each dose change on standard scales by parents and teachers, and progress reviewed regularly (for example, by weekly telephone contact) with a specialist". From a regulatory perspective, the MHRA may request the marketing authorisation holder to produce additional risk minimisation measures (aRMM) in addition to the product information. This is to ensure the safe and effective use of the medicine, to reduce or prevent the risk of an adverse event, or to reduce the severity or impact on the patient should an adverse event occur. The MHRA is responsible for reviewing and approving the aRMM.

Elvanse has aRMM as conditions to their licences to address safety concerns, identified in their risk management plan. This includes the risk of serious cardiovascular events (including arrhythmias, ischaemic cardiac events, cardiomyopathy, and sudden death). The aRMM of Elvanse for this risk includes the following educational materials for health care professionals:

- Checklist 1: lisdexamfetamine checklist before prescribing that supports health care professionals in the appropriate initiation of lisdexamfetamine. This includes a checklist of contraindications where symptomatic cardiovascular disease is evaluated together with family history of sudden cardiac/unexplained death, family history of ventricular arrhythmia, and patient's history and physical cardiovascular exam.

- Checklist 2: checklist for ongoing monitoring of lisdexamfetamine therapy that supports health care professionals in the monitoring of patients. This includes a checklist to monitor new cardiovascular findings or worsening thereof exertional chest pain, unexplained syncope, other symptoms suggestive of cardiac disease, and monitoring of changes in blood pressure and heart rate. It includes a reminder to document blood pressure and heart rate.
- Chart for ongoing monitoring of lisdexamfetamine therapy that supports the health care professional on keeping a record and monitoring different measurements of the patient including blood pressure and heart rate. In line with the summary of product characteristics (SmPC), the chart also reminds the health care professional that blood pressure and heart rate should be recorded at each adjustment of dose and then at least every six months.

In addressing the second concern, about ensuring advice given to patients with ADHD is understood and remembered, the national shared care protocol states that a shared decision making approach should be used, including discussing the benefits and risks of the treatment with the patient and/or their carer and obtaining and documenting their consent. This should include a patient information leaflet (PIL), which are required by law to be provided with each supply of the medication.

The PIL is not intended to replace the discussion with prescribers about the benefits and risks of treatments, but it aims to provide patients with information on using the medicine safely. The PIL information is in line with the SPC text and specifically warns patients about the monitoring required prior to taking Elvanse and during the therapy (including measuring blood pressure and heart rate), it informs patients of the possible side effects including the cardiovascular ones, and urges them to see a doctor straight away if they have an uneven heartbeat, chest pain or abnormal heart rhythm, life threatening irregular heart rhythm.

The problems of forgetfulness and problems with inattention in people with ADHD are well understood; and clinicians would be expected to take this into account in communicating with and providing information to their patients. Additionally, there are examples of easy read leaflets produced by 3rd parties to overcome this issue.(For example, https://youthmed.info/wp-content/uploads/2024/10/Lisdexamfetamine-Junior-Parent.pdf).

NICE has emphasised section 1.9 in NG87 is relevant here – 1.9.2 “Be aware that the symptoms of ADHD may lead to people having difficulty adhering to treatment plans”. There are also some relevant recommendations in the NICE guideline on medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence [CG76]. In particular, recommendations 1.1.24 “Offer patients information about medicines before the medicines are prescribed” and 1.1.28 “Do not assume that the patient information leaflets (PILs) that patients receive with their medicines will meet each patient's needs. Address concerns that patients may have after reading the standard PILs. PILs contain information for patients on how medicines should be used. It is a legal requirement that this information is included on the label or within the packaging of a medicine.”

Regarding the third concern, about the reliability of readings taken by patients, supported self-monitoring is the direction of travel supported by NHSE and follows the principle set out in the government’s Ten-Year Health Plan (10YHP). Heart rate and BP are two of the most commonly self-monitored biometrics thanks to the accessibility and affordability of digital

home monitoring devices. These form an important part of routine care for millions of people, bringing care into their home.

NHSE note that data can be unreliable when collected by a health care professional. An example is the phenomenon of 'white coat hypertension' where some patients have high blood pressure when they see a doctor, but home measurements are normal. In hypertension NHSE have moved towards using home measurements in preference to clinic measurements for most patients.

Although NICE guideline 1.8.9 does not explicitly mention home monitoring of heart rate and blood pressure, it is the opinion of NICE consultant clinical advisors that good practice would be to arrange for these measurements to be made, either remotely or in person. This is supported by a recent review (Comparative cardiovascular safety of medications for attention-deficit hyperactivity disorder in children, adolescents, and adults: a systematic review and network meta-analysis - PubMed).

Regarding online consultations more generally, we are aware that when used appropriately, online prescribing provides a valuable route for patient access, but additional safeguards are necessary when prescribing certain items online. In February 2025, the General Pharmaceutical Council (GPhC) published updated guidance for online pharmacies and prescribers which can be accessed here: Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet.

I do want to assure you that the Department is committed to ensuring that improving convenience and choice via private and online prescribing does not inadvertently reduce safety or quality of care. We are currently seeking views on how we can continue to ensure that the medicines people need are available conveniently and promptly, whilst maintaining the UK's high standards of medicine regulation, prescribing and use via a public call for evidence, which can be accessed here: Private (non-NHS) prescribing: call for evidence document - GOV.UK

Ultimately, decisions about what medicines to prescribe are made by the doctor or healthcare professional responsible for that part of the patient's care, and prescribers are accountable for their prescribing decisions. Prescribers must always satisfy themselves that the medicines they consider appropriate for their patients can be safely prescribed and that they take account of appropriate national guidance on clinical effectiveness – as detailed for ADHD management and Elvanse specifically in the above paragraphs. Prescribers are supported by specialist professional bodies (e.g. Royal Colleges) and held to account professionally by professional regulators, such as the General Medical Council (GMC).

The General Medical Council (GMC) is the regulator of all medical doctors, physician assistants (PAs), and physician assistants in anaesthesia (PAAs) (still legally known as anaesthesia associates and physician associates) practising in the UK. It sets and enforces the standards all doctors, PAs, and PAAs must adhere to. The GMC is independent of Government, directly accountable to Parliament and is responsible for operational matters concerning the discharge of its statutory duties The GMC is responsible for ensuring that doctors, PAs, and PAAs have the necessary skills and knowledge to join its UK registers. All doctors, PAs and PAAs must register with the GMC, and meet the expected standards set out in the GMC's *Good medical practice* to work in the UK: https://www.gmc-uk.org/professional-standards/professional-standards-for-doctors/good-medical-practice.

Doctors must also hold a licence to practice. *Good medical practice* states that doctors must propose, provide or prescribe drugs or treatment based on the best available evidence, and only when they have adequate knowledge of the patient's health and are satisfied that the drugs or treatment will meet their needs. Failure to uphold and adhere to the principles within *Good medical practice* and related guidance will put a professionals' registration with the GMC at risk.

If a concern is raised about a professional's fitness to practise, the GMC has a statutory duty to investigate and take action to safeguard the health and well-being of the public where necessary.

I hope this response is helpful. Thank you for bringing these concerns to my attention.

Yours sincerely,

Parliamentary Under-Secretary of State
for Health Innovation and Safety