Department of Health & Social Care

[redacted]
Minister of State for Health (Secondary Care)

39 Victoria Street
London
SW1H 0EU

Our ref: [redacted]

HM Coroner Christopher Long
Coroner's Court
2 Faraday Court
Faraday Drive
Preston
Lancashire
PR2 9NB

By email: [redacted]

28 March 2025

Dear Mr Long,

Thank you for the Regulation 28 report of 10 January 2025 sent to the Secretary of State about the death of Ava Grace Hodgkinson**.** I am replying as the Minister with responsibility for medicines regulation, pricing and supply.

Firstly, I would like to say how saddened I was to read of the circumstances of Ava's death, and I offer my sincere condolences to her family and loved ones.

The report raises concerns over the requirement to supply medication in accordance with the prescription, as set out in the Human Medicines Regulations 2012, which prevent a pharmacist from issuing different strengths of prescribed medication without an amended prescription, even when the same dosage could be achieved.

Currently, for most prescriptions, there is clear separation between the function of prescribing and dispensing – this is primarily for patient safety. It provides for a second clinical check on suitability, dose and interactions, and ensures prescribers have clarity about the medication being supplied to the patient.

The Human Medicines Regulations 2012 (HMRs 2012) require dispensing to be "in accordance with a prescription", with some very limited exceptions e.g. Serious Shortage Protocols (SSPs) and more recently introduced original pack dispensing (OPD). This means that in practice, community pharmacists must supply the exact product, quantity, strength and formulation according to what has been originally prescribed.

If the exact product isn't available, there are obvious benefits from pharmacists being able to supply to patients with an alternative straight away – patients are able to start their treatment sooner, patient journeys are reduced and there is a positive impact on the efficient use of GP Practice and pharmacy staff time. However, there are also patient safety risks. For example, if formulations or dosage regimes change, then patients may get confused

and not take their medicines as intended and the prescriber will not have a clear view of what their patient is taking. There are also supply chain implications – it could affect suppliers' ability to predict future demand that is primarily based on historic orders and/or have the unintended effect of creating a shortage of the alternative. The pharmacist may not always be aware of the wider supply situation of any product. For example, if a lower strength was supplied in place of the higher strength due to a shortage, it could mean that stock of the lower dose is rapidly depleted at an increased rate in order to match the required dosage. Serious Shortage Protocols (SSP) are developed with oversight from DHSC's Medicines Supply Team to ensure that any substituted alternative product can adequately support the increased demand.

Nevertheless, I am committed to my officials exploring new flexibilities. There has been a recent programme of engagement, since December 2024, as part of which my officials have discussed possibilities with stakeholders such as GP representatives, pharmacy bodies and patient groups. The stakeholder feedback has been sufficiently positive that the Government is minded, subject to the normal machinery of Government clearance processes, to proceed to a formal, public consultation.

Any proposed new flexibilities would need amendments to the HMRs 2012 – and a public consultation on such changes is a requirement of the Medicines and Medical Devices Act 2021 and would need to be joint with the Department of Health in Northern Ireland. The consultation will seek wider views than those already canvased on if, and the circumstances in which, it may be appropriate to grant pharmacists the flexibility to supply an alternative dose and formulation to that specified in a prescription written by a prescriber. My expectation at this stage is that consideration will be given to whether or not the flexibilities should be limited to cases of immediate clinical need where it is impractical to obtain a prescription for the alternative medicine without undue delay. I am confident that a solution can be found to granting new flexibilities that will receive patient, professional, NHS and pharmacy businesses' support.

Subject to the normal clearances, my officials aim to publish this by summer 2025.

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

Yours sincerely,

[redacted]

Minister of State for Health and Secondary Care