

Department of Health & Social Care

> Pharmacy and Eye Care Team Department of Health and Social Care 39 Victoria Street London SW1H 0EU United Kingdom

Mark Koziol Chairman, The Pharmacists' Defence Association Old Fire Station 69 Albion Street Birmingham B1 3EA

27 February 2024

Dear Mark,

Pharmacy Supervision Consultation

Thank you for your letter dated 23 February asking for clarity as to what is meant by the below paragraph taken from the Explanatory Note at the end of the draft statutory instrument, which was published alongside the pharmacy supervision consultation on 7 December 2023.

Extract:

"Additionally, if a prescription only or pharmacy medicine has been dispensed and is ready for sale or supply at or from a registered pharmacy, a pharmacist anywhere in the United Kingdom will be able to authorise any member of the pharmacy staff to undertake the final supply of that medicine in the pharmacist's absence – or where the pharmacist is treated as being absent because they are unavailable or not in a position to intervene (for example, because they are providing clinical services to a patient) (article 7(4))."

You have asked for clarity for the benefit of your membership as to what is meant by "a pharmacist anywhere in the United Kingdom", as this has raised a concern that this is a move toward remote supervision. The explanatory note describes the effect of the legislation in more common language. This extract relates specifically to proposal 2, which is to allow the handing out of pre-checked and bagged medicines to patients in the absence of a pharmacist. We can confirm that the highlighted text is meant to indicate the territorial extent of the new provision, and not imply any form of remote supervision. This section of text refers to the checked and bagged items provision, which unlike the great majority of the other proposals, will apply in Northern Ireland as the authorisation can be to non-registered members of staff.

This proposal is designed to allow medicines that have been appropriately checked by a pharmacist and bagged to be handed out in the temporary absence of a pharmacist (for example, when the pharmacist is not interruptible in a consultation room or temporarily absent from the premises). The law will still require each retail pharmacy to have a Responsible Pharmacist (RP), who is physically on the registered premises, subject to any statutory exceptions in the rules or regulations under section 72A of the Medicines Act 1968, responsibility for which has now passed from Government to the regulators. As you know, there will be consultation before any changes to the current absence exception. 'Remote supervision' will remain, as it is now, unlawful by operation of the common law, as described in Annex B of the consultation document. And as is the case now, each RP will remain personally responsible for the safe and effective running of each retail pharmacy, so far as concerns the sale or supply of medicines at or from that pharmacy. This goes back to section 72A(1) of the Medicines Act 1968, and nothing we are doing changes that.

This part of the Medicines Act 1968 is designed to be high level and enabling, and to allow for pharmacy regulators and professional bodies to set the detail. This is why we provided for a transition period so the General Pharmaceutical Council (GPhC), and Pharmaceutical Society of Northern Ireland (PSNI) could run their consultations on rules and regulations for the RP and standards for RPs, Superintendent Pharmacists and Chief Pharmacists – as a basis for implementing any new rules on absence safely into practice. We will be engaging with the regulators to ensure that the timing of any implementation of the proposed supervision changes is staged appropriately in the light of these other workstreams.

The Explanatory Note has no legal force and is intended to give a concise and clear statement of what the SI does for the lay reader. We can certainly review this and given how it has been misinterpreted, we will be making drafting changes post-consultation.

Your sincerely,

Alette Addison



Deputy Director - Pharmacy and Eye Care Services

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