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03 May 2022

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Mr Jeremy Chipperfield
Senior Coroner for County Durham and Darlington
HM Coroner's Office
PO Box 282
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Dear Mr Chipperfield

Re: Ms Claire COPELAND, deceased (around 17 June 2021)
Boots Pharmacy, Station Yard, Consett, County Durham, DH8 5YB
Inquest date: Friday 04 March 2022
Regulation 28 Report to Prevent Future Deaths (dated 08 March 2022)

Further to the inquest into the death of Claire Copeland that concluded on 04 March 2022, I am writing on behalf of Boots UK Limited ('**Boots**') in reply to the Regulation 28 Report to Prevent Future Deaths ('the **Report**') dated 08 March 2022.

This response addresses (in turn) the four matters of concern highlighted within Section 5 of the Report which, taken together, were held to constitute 'arrangements' with no fail-safe provisions ensuring continuity of care in the event of a failed prescription delivery, namely:

1. **Arrangements … rely upon delivery of a physical prescription document**

The prescription in question for Ms Copeland was for methadone oral solution, a Schedule 2 Controlled Drug, the supply of which from a community pharmacy is governed by the Human Medicines Regulations 2012 and the Misuse of Drugs Regulations 2001 (as amended).

Schedule 2 Controlled Drugs can be prescribed via the NHS Electronic Prescription Service; however, methadone and other treatments for managing substance dependency are prescribed in instalments. The prescribing of such medication in instalments must be effected using a designated prescription form (FP10MDA). There is currently no electronic equivalent for this form, so the paper prescription remains the only legal mechanism for instalment prescribing for the treatment of addiction in England.

To comply with the regulations, a community pharmacist must receive an appropriate FP10MDA form before making a supply of methadone for the treatment of addiction. The Human Medicines Regulations 2012 do not permit the making of an emergency supply of a Schedule 2 Controlled Drug under Sections 224 or 225 (those governing emergency supply).

2. **Arrangements … allow that delivery be neither witnessed nor confirmed**

This would be within the power of individual treatment clinics or the service commissioners, who could require all clinics posting FP10MDA forms to use recorded in-person delivery and also put in place an administrative system to monitor for failed deliveries of prescription forms.

There are no steps that Boots can take independently to address this concern, but Boots will support individual treatment clinics that seek confirmation of receipt.

3. **Arrangements … lack effective mechanism immediately to detect failed delivery**

Patients have a free choice regarding the community pharmacy that they attend for the dispensing of their prescriptions. It is therefore not possible for pharmacies to detect any failed deliveries.

However, Boots will encourage clinics to contact the pharmacies to confirm receipt where FP10MDA forms are posted to try and avoid the risk of future failed deliveries.

4. **Arrangements … lack mechanism to remedy failed delivery**

As noted under (1) above, the supply of a Schedule 2 Controlled Drug from community pharmacies is governed by the Human Medicines Regulations 2012 and the Misuse of Drugs Regulations 2001 (as amended). A pharmacy is not permitted in law to provide medication (including an emergency supply), where there is a failed delivery of an FP10MDA form, unless a replacement paper FP10MDA form is provided.

Community pharmacies typically provide dispensing services, including the dispensing of methadone for the treatment of addiction, for more hours each week than clinics are available. When a problem with an FP10MDA form (including a missing prescription) is detected outside of clinic hours, there is no route for a pharmacist to contact one of its prescribers (who will be familiar with the patient's medical history) and request an urgent replacement prescription.

Boots will remind its pharmacists that, where any problems regarding FP10MDA forms are reported outside of clinic hours, patients must be directed to the Accident & Emergency team at a local hospital, so that an appropriate prescriber can review the patient's circumstances and consider providing an interim prescription, pending the clinic reopening.

Reflection on the death of Ms Copeland

Given the seriousness of the incident involving Ms Copeland and the tragic circumstances which prevailed in this case, Boots has taken the opportunity to reflect carefully on any different actions that could be taken at individual pharmacy level and from a Company-wide perspective to help prevent recurrence.

Ms Copeland's clinic (Human Kind) was closed on Saturday 12 June 2021 when she arrived at the Boots pharmacy in Consett, expecting to collect her medication. On reflection, the pharmacist has considered whether direct contact with the Accident & Emergency team at the local hospital (to explain the unique circumstances and ascertain whether they would review the patient's prescription needs) could have addressed the lack of other 'out-of-hours' support for Ms Copeland. As a Company, we have taken the opportunity to renew our focus on Controlled Drug Stewardship, with the development of a dedicated resource to support all our pharmacy teams' understanding of the need for compassionate, person-centred care when managing supplies of Controlled Drug medication.

I hope this letter provides the necessary assurance that Boots has duly noted the gravitas of the concerns raised during the course of the inquest into Ms Copeland's death, reflected on the circumstances of this sad case and shared its insights appropriately. As a founder member of the (external) Community Pharmacy Patient Safety Group, Boots has liaised with its Chair so that further dissemination of our insights from this case can be effected, using an anonymised case study format, at its next meeting.

Yours sincerely

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Dr [redacted]
Deputy Superintendent Pharmacist – Quality & Governance
Boots UK Limited