

David Place  
Assistant Coroner for the City of Sunderland

[REDACTED]

7 May 2024

Dear Mr Place

**Re: Regulation 28 Report to Prevent Future Deaths: Mr Jason Brown**

Thank you for sending us your Regulation 28 report regarding the death of Mr Jason Brown. We are sorry to hear about this sad death and we would like to pass on our sincere condolences to Mr Brown's family.

You have raised a concern that, due to a special container status, zuclopenthixol dihydrochloride 2mg tablets (Clopixol®) must be dispensed in its own special container, as a full pack of 100 tablets (original pack dispensing), and that this can endanger the safety of a patient with known suicide risks, including previous overdose attempts.

The General Pharmaceutical Council (GPhC) has a statutory purpose to protect patients by setting and upholding the standards for registered pharmacies and the standards for pharmacy professionals, to ensure that registered pharmacies are safe to provide services, and that pharmacy professionals are fit to practise. We do not have a direct role in relation to the licensing, status or pack size of medicines. These would be matters for the Medicines and Healthcare Products Regulatory Agency (MHRA), the Department of Health and Social Care and the medicines manufacturer. However, we do have a role in supporting professionals to meet our standards and to dispense safely, taking account of relevant national policy and guidelines.

As detailed in your report, Clopixol® 2mg tablets are manufactured in a pack size of 100, and this is classed as a Special Container in the Drug Tariff. This means that if a prescription is received for 28 tablets, then the pharmacy is directed to dispense a full pack of 100 and will be paid for a pack of 100. This can cause a disparity between the information that a prescriber holds regarding what has been prescribed, and the actual number of tablets a patient has received.

According to the Summary of Product characteristics (SmPC) for Clopixol® 2mg tablets, the manufacturer (Lundbeck) directs that the tablets are stored in the original container in order to protect from light. This further reinforces the messaging to the pharmacy to store and dispense the Clopixol® 2mg in the original container.

Community Pharmacy England (CPE), formerly PSNC, produced a factsheet in June 2020 with regards to dispensing special containers. There are two particularly relevant points in this guidance.

The first directs the pharmacy to dispense the original pack:

“Where the quantity of a product ordered by the prescriber does not coincide with that of an original pack size and the product is considered a special container (as a complete pack or sub-pack size), contractors are required to supply the special container or combination of containers nearest to the quantity ordered and endorse the prescription form with the number and size of these containers”.

And the second indicates that for a small number of cases the exact quantity should be dispensed:

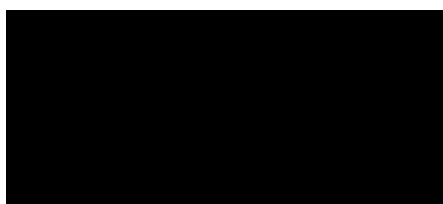
“Exceptions to the rules around quantity to supply for special containers. In a small number of cases, where there is an over-riding clinical requirement to dispense the exact quantity ordered rather than the nearest complete pack or sub-pack size (for example, if the drug is required to be packaged into a weekly compliance aid or if there is a risk that the patient may misuse the drug), pharmacists would need to assess the clinical appropriateness of splitting the pack to dispense the exact quantity bearing in mind the impact on the stability of the drug once removed from its original packaging. There may be patient safety issues to consider if a pharmacist decides to dispense the exact quantity ordered (if not a multiple of the sub-pack size). For example, if a hygroscopic drug is not stored and used correctly, exposure to moisture could affect the integrity of the drug by potentially decreasing its stability and/or efficacy”.

This indicates the need for a pharmacist to use their professional judgement when there is an over-riding clinical requirement to dispense the exact quantity. This would involve assessing the risk of doing so for the individual patient, balancing against the relevant storage requirements or other relevant guidance.

Going forward, we will consider whether there are any communications we can issue to the pharmacy professions to raise awareness, including about the exceptions to the rules around quantity to supply for special containers.

We hope this information is helpful. If you should require any further information, please do not hesitate to contact me.

Yours sincerely,

A large black rectangular redaction box covering the signature of the Chief Executive and Registrar.

  
**Chief Executive and Registrar**