Medicines & Healthcare products Regulatory Agency

MHRA

Ms Alison Mutch
Senior Coroner, Greater Manchester South
[redacted]

27 July 2021

Medicines & Healthcare products Regulatory Agency

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Canary Wharf
London
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[redacted]

gov.uk/mhra

Dear Ms Mutch,

Regulation 28 report into the death of Ian Hall

Thank you for your report under Regulation 28 following the inquest into the tragic death of Mr Ian Hall.

We note that one of the concerns that you raise is incorrect dispensing of a product in a pharmacy and your report states it is unclear how amitriptyline rather than atenolol had been dispensed in the community. The MHRA is responsible for the assessment of the labelling of all licensed medicines to ensure that the statutory information required to appear is clear, legible and easily assimilated by those who select and administer medicines.

It would be helpful to know which particular amitriptyline and atenolol products the pharmacy held at the time Mr Hall was supplied with amitriptyline instead of his prescribed atenolol. Without this, it is difficult to be certain whether and to what degree the medicines packaging may have contributed to the mis-selection in the pharmacy.

The primary purpose of medicines labelling is the unambiguous identification of the medicinal product contained within the packaging. We have issued best practice guidance to the pharmaceutical industry which includes amongst other things, a need to ensure that medicines which may be stored together or used concomitantly by patients are well differentiated from each other by the judicious use of colour to reduce the likelihood of medication error.

We also issued an article in our 2018 Drug Safety Update (DSU) bulletin to remind healthcare professionals on the need for continued vigilance for these sorts of errors https://www.gov.uk/drug-safety-update/drug-name-confusion-reminder-to-be-vigilant-for-potential-errors. That guidance highlighted a known confusion between atenolol and amiodarone (another antihypertensive) but confusion between atenolol and amitriptyline has not been reported to us previously.

The MHRA will review the packaging of these medicines and if we consider on assessment that improvements could be made we will contact any pharmaceutical manufacturers who supply these medicines and seek changes so that the likelihood of future errors of this nature may be reduced.

For your information, Ian Hall's case has been recorded on our adverse drug reaction database with the Yellow Card reference number [redacted].

Yours sincerely

Dr [redacted]
Chief Executive
Medicines and Healthcare products Regulatory Agency

[redacted]