Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

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1st August 2017

Dear Ms Galloway

Regulation 28 Report concerning Aaron John Peter McCaffrey

Thank you for your letter of 16th June 2017 in which you asked the MHRA to provide a response to the Regulation 28 Report to Prevent Future Deaths following the inquest into the death of Mr Aaron John Peter McCaffrey. Your report identified one matter of concern which falls within the remit of the MHRA.

> ***The concern is that there is no apparent limit on the amount of loperamide medication that can be purchased from a single store.***

The MHRA as a regulatory agency has a responsibility to ensure that medicines are efficacious and acceptably safe, that guidance on the use of a medicine is appropriately described in the authorised product information (Summary of Product Characteristics for healthcare professionals, labelling and patient information leaflet), and that the legal classification of a medicine is appropriate to the level of professional supervision required for safe access.

Loperamide is available as a General Sale List (GSL) medicine and as a Pharmacy medicine under the supervision of a pharmacist. There are no restrictions on the numbers of packs which can be purchased. Pack sizes of up to 12 tablets/capsules are available GSL and larger packs are available in pharmacies. One of the criteria for Prescription Only classification is that a medicine is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health. We do not consider that there is sufficient evidence that this criterion applies to loperamide. We have checked the report of the Advisory Council on Misuse of Drugs on Diversion and Illicit Supply of Medicines (DISM) from December 2016 and this has no mention of loperamide. The DISM report is available following this link:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/580296/Meds_report-_final_report_15_December_LU__2_.pdf

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In particular, we have reflected on whether restricting the amount which can be purchased would have deterred a determined individual from obtaining such large quantities as in Mr McCaffrey's case. On the evidence available to date, we consider that the benefit of access in retail outlets for those patients who use this medicine responsibly, outweighs the harms which may come to the very small number of individuals who deliberately misuse these medicines.

Turning to the medical cause of death, we note that this was hypoxic brain injury, multiple cardiac arrests and loperamide overdose. As part of an EU-wide review the cardiac toxicity of loperamide was assessed in March 2017. The EU Pharmaceutical Risk Assessment Committee (PRAC) considered that there was the potential for loperamide in doses significantly in excess of the maximum therapeutic dose to cause cardiac problems. As a result of that review the product information is being updated for all loperamide-containing products to advise patients not to exceed the labelled dosing instructions along with warning statements about the risk of cardiac effects in overdose.

As part of the PRAC update to include the cardiac warnings we are writing to the marketing authorisation holders who have not updated their Summary of Product characteristics (SmPCs) and Patient Information Leaflets (PILs). We will also publish an article in the MHRA's Drug Safety Update Bulletin to alert healthcare professionals to the risks.

We will keep this issue under review and will consider whether any further regulatory action is needed in the light of any new evidence.

Yours sincerely,

Jane M. Rawe

[redacted]
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