Medicines & Healthcare products Regulatory Agency

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United Kingdom
gov.uk/mhra

Liliane Field
Assistant Coroner for London Inner south

24 November 2025

Dear Liliane Field,

CEC 236182 – Prevention of future deaths Reg 28 Paula Doreen Hughes.

We are very sorry to hear of the death of Paula Doreen Hughes and extend our sympathies to her family.

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health and Social care with responsibility for ensuring medicines meet appropriate standards of quality, efficacy and safety. The Human Medicines Regulations 2012 lays out the conditions of the licencing and marketing of a medicine.

In response to your concern, 1(1), the use of paracetamol and accidental overdose is a safety concern, especially in relation to the many trade names of non-prescription and prescription medicines containing paracetamol. Therefore the Human Medicines Regulations 2012, contain a number of conditions for the presentation of these medicines to highlight the presence of paracetamol in a medicine.

Schedule 25, Part 4 of the Human Medicines Regulations, sets out statutory labelling requirements for paracetamol medicines to highlight the presence of paracetamol in that product. Paragraph 14 states that, except where the name of the product includes the word “paracetamol” and appears on the outer and immediate packaging, the words **“contains paracetamol”** should be displayed.

Paragraph 15 states that, the labelling must highlight paracetamol on the front face of the carton or label and should also contain the warning: **“Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor”**, which must appear adjacent to either the directions for use or the recommended dosage.

Further to this, if the product contains a leaflet, paragraph 16 states, if the product contains paracetamol, unless the product is wholly or mainly intended for children twelve years old or

younger, the words **“Do not take anything else containing paracetamol while taking this medicine”** and (a) and (b) highlights that the warning **“Talk to a doctor at once if you take too much of this medicine, even if you feel well”** and if the product does not contain a leaflet then the words **“Talk to a doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage”** should be displayed.

Additional conditions are in place for children aged 12 years or younger, including the colour of the product, packaging presentations (blisters, child resistant enclosures), and adaptations of the above warnings for parents.

For those medicines containing paracetamol which are prescribed to a patient, the statutory warnings should be added to the prescribing label which is applied to the box by the pharmacist. These are highlighted in the BNF (warning label 30, BNF Issue 90).

The regulations (Schedule 8) also set out material which must accompany any application for the marketing of a medicine. The Summary of Product Characteristics (SmPC) as referenced in part 2, for healthcare professionals, provides a summary of the clinical particulars in the use of a medicine, including the recommended maximum daily dose. In addition, particulars in reference to overdose are provided. This includes the potential dose over which liver damage may occur and potential risk factors which may elevate the risk of overdose, including medical history, concomitant medicines or alcohol intake. A summary of the symptoms of overdose and management are also provided.

The market authorisation holders are obligated under the Human Medicines Regulations to continually review the safety of their medicines and to inform the MHRA of any serious adverse reactions. The MHRA continues to monitor the safety of all medicines and if necessary, will take advice from our independent experts on recommended regulatory action.

The MHRA provides a list of the SmPCs and patient leaflets for all medicines at the following: MHRA Products | Home. Additional resources on product information and the treatment of overdose are available from the BNF, the electronic medicines compendium (eMC), the National Poisons Information Service and NHS, Paracetamol for adults: painkiller for pain and high temperature - NHS.

The Human Medicines Regulations and the BNF highlight the information that is required in general and electronic prescriptions.

We have liaised with NHSE with regard to the ability of the prescribing system to dispense two concurrent medicines containing paracetamol and we understand they will incorporate learning from this incident into the commissioning of the ePRaSE tool.

Yours sincerely,

[redacted]

[redacted]
Chief Safety Officer

Medicines and Healthcare products Regulatory Agency
[redacted]