



Medicines & Healthcare products  
Regulatory Agency

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[gov.uk/mhra](https://www.gov.uk/mhra)

Ms Caroline Topping  
HM Coroner for the County of Surrey

27 February 2023

Dear Ms Topping,

**Report to Prevent Future deaths - Gavin Peter Pedleham**

Thank you for your report dated 30 December 2022 which was received on 10 January 2023. I would like to offer my sincere condolences to Mr Pedleham's family on their tragic loss.

The MHRA monitors the safety of all medicines to ensure that up-to-date information on the benefits and risks of a medicine is available for healthcare professionals and patients. The Summary of Product Characteristics (SmPC) for a medicine provides information for healthcare professionals (HCPs) about the medicine, including warnings and precautions of use in higher risk situations. The same information is provided to patients in a patient information leaflet, which is written in language that can be understood by the lay person and accompanies each medicine. However, this tragic event did not occur to a patient but to an unintended recipient, therefore, will not have seen the product information.

In 2019 we undertook a review of the benefits and risks for all opioid medicines in the treatment of non-cancer pain and risks associated with dependence and addiction and sought the advice of an Opioid Expert Working Group of the Commission on Human Medicines, the MHRA's advisory body. The Expert Working Group considered the positive benefit-risk profile of opioid-containing medicines and made recommendations for regulatory action to better support appropriate use of prescription opioids including morphine oral solutions like Oramorph.

An investigation into the potential for accidental exposure and accidental overdose has been undertaken. Oramorph oral solution contains morphine in strengths of either 10mg/ml or 20mg/ml. The patient information leaflet and labels include clear guidance on the correct use of Oramorph.

The leaflet states:

*This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.*

*Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else.*

The leaflet highlights that the oral solution should not be taken with alcohol. If it is diluted in a soft drink, then it should be consumed immediately.

This was a tragic accident which was not circumvented by the warnings and guidance clearly present in the product information. However, it is evident that the glass containing Oramorph was left unattended. Therefore, we will work with the Marketing Authorisation holders to update the product information to highlight the need to keep the medicine in a secure place and not leave any diluted Oramorph unattended.

We continually monitor for accidental deaths of opioid containing medicines and will take further prompt regulatory action when necessary.

Should you have any further questions, I should be pleased to assist.

Yours sincerely,

[Redacted signature]

[Redacted name]  
Chief Executive  
Medicines and Healthcare products Regulatory Agency

[Redacted contact information]