



Department
of Health &
Social Care

*From the Lord Kamall
Parliamentary Under Secretary of State for Innovation (Lords)*

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[REDACTED]
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Simon Nelson
HM Assistant Coroner, Manchester West
HM Coroner's Court
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20 October 2021

Dear Mr Nelson,

Thank you for your letter of 24 June 2021 about the death of Amy Ganner. I am replying as Minister with responsibility for medicines, and I am grateful for the additional time allowed in order for me to do so.

Firstly, I would like to say how saddened I was to read of Amy Ganner's death and I offer my sincere condolences to her family and loved ones. The circumstances your report describes are very concerning and I am grateful to you for bringing these matters to my attention.

With regards to the concerns that you raise within your report, you may wish to note that the Medicines and Healthcare products Regulatory Agency (MHRA) undertook a review of opioid medicines and the risk of addiction and dependence in 2019, and sought advice from an Expert Working Group of the Commission on Human Medicines (CHM).

In April and June 2019, the Expert Working Group made recommendations, which were endorsed by CHM, and subsequently took forward a number of actions to better support appropriate use of prescription opioids, and to increase awareness of their risks amongst both healthcare professionals and patients.

As a result of these recommendations, the warnings on the risks of dependence, addiction, and tolerance in the product information for tramadol tablets, Zomorph modified release capsules and morphine sulphate oral solutions (amongst other opioid medicines) have been updated to contain consistent warnings on the risks of dependence, addiction, and tolerance. This information also encourages patients and healthcare professionals to discuss treatment regimens and plan for end of treatment. In addition, in May 2019 warnings that products 'Can cause addiction' and 'Contains opioid' were added to the packaging for opioid-containing medicines.

The MHRA communicated this in its bulletin, Drug Safety Update (DSU)¹ in September 2020, publicly available on the MHRA website and through the Yellow Card app. The DSU is also sent electronically to healthcare professionals, and direct subscribers. The individual representatives in the MHRA Patient Group Consultative Forum were also contacted by email to highlight the DSU article at the same time. The article also sets out how to report cases of dependence to the Yellow Card Scheme – which is a system for collecting and monitoring information on the safety of medicines. The bulletin is also published online.²

Further, the update provides information for healthcare professionals and a link to a safety leaflet, either from a web page³ or in PDF form, for patients that can be printed from the MHRA website⁴. This includes a warning that patients may develop tolerance and can experience withdrawal effects if they stop taking their medicine suddenly, and if this happens to discuss it with their doctor.

In order to increase awareness a press release was issued at the same time⁵ as a notification that explained the strengthened warnings in relation to the risk of dependence and addiction.

My officials have made the MHRA aware of your report and the circumstances of Ms Ganner's death and those details have been added to the MHRA's Yellow Card database [REDACTED]. The data held within the Yellow Card scheme is used to help monitor the safety of medicines and will help to build on the evidence base. The MHRA recognises the important safety concerns in your report and has taken action to try and ensure the risks associated with dependence, addiction and tolerance are minimised. The MHRA will ensure this issue remains under continuous monitoring to ensure these measures are effective.

Furthermore, I will speak to the MHRA about how to improve access to their information leaflets, to ensure this information is as widely available as possible.

¹ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/920770/Sept-2020-DSU-PDF.pdf

² <https://www.gov.uk/drug-safety-update/opioids-risk-of-dependence-and-addiction>

³ <https://www.gov.uk/guidance/opioid-medicines-and-the-risk-of-addiction>

⁴ <https://assets.publishing.service.gov.uk/media/5f6a078ed3bf7f7238f23100/Opioid-patient-safety-information-leaflet-v2-Aug2021.pdf>

⁵ <https://www.gov.uk/government/news/uk-regulator-strengthens-opioid-warnings>

In relation to the wider context and the increasing concern internationally and here in the UK about the overuse and misuse of opioids leading to a growing problem of dependence and addiction, I would like to outline the range of action that has been taken to protect patients from harm.

In 2017, the Government asked Public Health England (PHE) to conduct an evidence review to identify the scale, distribution and causes of prescription drug dependence, and what might be done to address it. PHE's report of the review was published in September 2019⁶, providing evidence for dependence on, and withdrawal from, prescribed medicines, with the aim of making sure that local healthcare systems build awareness and support to enhance clinician and patient decision making.

In support of this, NHS England and NHS Improvement (NHSEI) is co-ordinating a programme to implement the recommendations of the review, working closely with relevant health system partners. The programme covers five classes of medicines including benzodiazepines; Z-drugs; gabapentinoids; opioids, for chronic non-cancer pain; and antidepressants.

Finally, since October 2020, Primary Care Networks of GPs have been required to identify and prioritise patients, including patients using potentially addictive pain management medication, who would benefit from a structured medication review. You may also wish to note that further to the February 2020 update to the GP contract agreement 2020/21 to 2023/24, a Quality Improvement Module in the Quality and Outcomes Framework for general practice on preventing prescription drug dependency is in development.

I hope this response is helpful.

Yours,

A handwritten signature in blue ink, appearing to read 'Syed', written in a cursive style.

LORD KAMALL

⁶https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/940255/PHE_PMR_report_Dec2020.pdf