Department of Health & Social Care

The Rt Hon Andrew Stephenson CBE MP
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Mr Christopher Murray
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27 March 2024

Dear Mr Murray,

Thank you for your letter of 2 December 2023 about the death of Mr Steven Bowker. I am replying as Minister with responsibility for medicines and medicines regulation.

Firstly, I would like to say how saddened I was to read of the circumstances of Mr Bowker's death and I offer my sincere condolences to their family and loved ones. You have raised concerns of the dangers to patients in respect of the prolonged prescription and use of opiate medication and I am grateful to you for bringing these matters to my attention. Thank you for the additional time provided to the department to provide a response.

In preparing this response departmental official have made enquiries with NHS England and the Medicines and Healthcare products Regulatory Agency (MHRA).

I hope you will appreciate and understand, that the decision to prescribe a particular product is, rightly, a clinical one and should be based on the patient's medical needs. GPs and clinicians are expected to take into account regulatory and good practice guidance, appropriate local and national guidance on clinical, and cost effectiveness and treatment pathways of their respective Integrated Care Board (ICB). They are accountable for their prescribing decisions, both professionally and to their service commissioners. Similarly, the process of reviewing medication is one in which the GP or responsible clinician work together with the patient to decide on the most appropriate course of treatment. Prescribing clinicians should always satisfy themselves that the medicines they consider appropriate for their patients can be safely prescribed. This prescribing decision and any monitoring activity should be discussed and agreed with the patient.

In March 2023, NHS England published Optimising personalised care for adults prescribed medicines associated with dependence or withdrawal symptoms: framework for action. The framework sets out five actions for ICBs to consider to further reduce inappropriate prescribing of high-strength painkillers and other

addiction-causing medicines, like opioids and benzodiazepines. Sometimes these medicines may no longer be the most clinically appropriate treatment for patients – and in some cases can become harmful without intervention.

Several data resources provide insights to ICBs to foster improvement at the local level. Data from the English Dispensing Dataset (EPD) is available on an Opioid Prescribing Comparators dashboard (NHS Business Services Authority [BSA]). This dashboard can be used to review up-to-date data, highlight variation and support local work to reduce harm from the prescribing of dependence and withdrawal forming medicines, as well as equip users with the tools for ongoing monitoring. The dashboard will be continually reviewed and updated with more metrics and views. Data is also available on duration of treatment of opioids, as well as the number of patients prescribed a dependence forming medicine who have received a structured medication review (SMR). SMRs are designed to be a comprehensive and clinical review of a patient's medicines and detailed aspects of their health. They are delivered by facilitating shared decision-making conversations with patients aimed at ensuring that their medication is working well for them.

Each ICB should take a population health management approach using data on primary care prescribing and health inequalities to monitor implementation of the actions and foster improvement at the local level. This includes looking at data on access to services, patient experience feedback and outcomes for communities within the integrated care system (ICS) that often experience health inequalities.

The National Institute for Health and Care Excellence (NICE) is the independent body responsible for developing evidence-based guidelines for the National Health Service, following a rigorous process and extensive engagement with stakeholders and expert input to develop the scope of the guidelines. In April 2022, NICE published guideline Medicines associated with dependence or withdrawal symptoms: safe prescribing and withdrawal management for adults. This guideline covers general principles for prescribing and managing withdrawal from medicines such as opioids in primary and secondary care. However, it is important to note that NICE guidelines do not override a clinician's responsibility to make decisions appropriate to individual patients. NICE guidelines describe best practice, and the Government expects NHS commissioners to take them into account in designing services that meet the needs of their local populations.

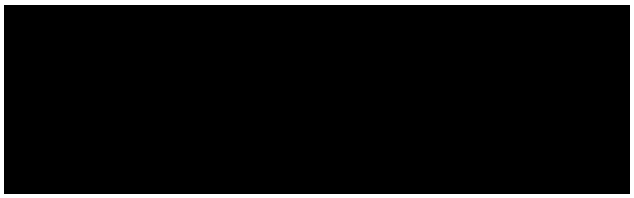
The MHRA regulates medicines amongst its other functions. The MHRA ensures that information about medicines marketed within the UK is available to patients, their families, and doctors, to inform them of the risks and benefits associated with treatment. This information is kept up to date during the lifecycle of the product and consists of the summary of product characteristics (SmPC) for prescribers and the patient information leaflet (PIL) for patients. The product information can be accessed on the MHRA website https://products.mhra.gov.uk/ and the PIL is supplied with each package of medicine.

The MHRA continuously monitors the benefits and risk of medical products on the UK market and takes action to reduce risks where appropriate. Due to some inconsistency in information on dependence to opioid medicines, in 2019, the MHRA launched a review of the risks of dependency and addiction to opioid medicines used in the

treatment of acute pain and established the Commission of Human Medicines' Opioid Expert Working Group. Following this review in December 2019, the Commission of Human Medicines made recommendations to update product information and guidance for healthcare professionals Opioids: risk of dependence and addiction - GOV.UK (www.gov.uk). All national licences authorised in the UK now include consistent information concerning dependence and addiction. These include guidance to involve patients in a conversation with their prescriber to plan for end of treatment and all labels for medicines containing opioids now state "can cause addiction, contains opioid".

I hope this response is helpful. Thank you for bringing these concerns to my attention and once again, please accept my sincere apologies for the delay in responding to your letter.

Yours sincerely,



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Minister of State Health and Secondary Care