Department of Health

From the Lord O'Shaughnessy
Parliamentary Under Secretary of State for Health (Lords)

Our reference: PFD 1144474

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Ms L J Hashmi
HM Area Coroner, Manchester North
Coroner's Service,
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02 OCT 2018

Dear Ms Hashmi

Thank you for your letter of 8 August to the Department of Health and Social Care about the death of Mr Ian Paul Wolstenholme. I am responding as Minister with portfolio responsibility for medicines and I am grateful for the additional time in which to do so.

I was extremely saddened to read of the circumstances surrounding Mr Wolstenholme's death. If you have the opportunity, please convey my sympathies to his family.

I have noted carefully the matters of concern identified in your report. My officials have made enquiries with the Medicines and Healthcare products Regulatory Agency (MHRA), to which you also issued your report. Please accept this response on behalf of the MHRA.

The MHRA monitors the safety of medicines and endeavours 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 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.

Codeine is a weak opioid which is available in pharmacies under the supervision of a pharmacist or by prescription. Morphine is a prescription only medicine indicated for the treatment of severe pain. Pregabalin is indicated for neuropathic pain, epilepsy and generalised anxiety disorder, whilst methadone is indicated for

the treatment of opioid addiction. Each of these drugs carry a risk of dependence, addiction and tolerance.

The SmPC for each medicine (codeine, pregabalin and methadone), contain warnings concerning interactions with other medicines and advises healthcare professionals and patients that concomitant use of central nervous system depressants, can increase the risk of side effects. The SmPC and leaflet provides guidance for healthcare professionals and patients on dose control and advises that cessation of treatment should be undertaken gradually over a period of time. The MHRA endeavours to ensure that the patient information leaflet and labelling have clear and understandable information for patients and carers with clear direction to seek medical advice in the event of adverse reactions suggestive of tolerance, sedation or respiratory depression.

You will be interested to note that the MHRA is currently undertaking a review of the product information for all opioid medicines and will be seeking the advice of an Expert Working Group of the Commission on Human Medicines. The Expert Working Group will consider the benefit risk of opioid-containing medicines and make recommendations for regulatory action to better support appropriate use of prescription opioids, including educational initiatives to ensure awareness of risks for both patients and healthcare professionals.

In addition, the information in your report relating to the medicines involved in Mr Wolstenholme's death has been added to the MHRA's Yellow Card database that collates suspected adverse drug reactions to help monitor medicine safety (reference ADR 24340935).

My officials also sought the advice of the National Institute for Health and Care Excellence (NICE) on the matters of concern in your report. NICE advises that it has issued a guideline on '*Multimorbidity: clinical assessment and management*'[1] (NG56), and a guideline on '*Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes*'[2] (NG5). NICE has also published a key therapeutic topic on '*Multimorbidity and polypharmacy*'[3] (KTT18).
The guideline on multimorbidity (NG56) includes the following recommendations:

> *1.3.2 Consider using a validated tool such as eFI, PEONY or QAdmissions, if available in primary care electronic health records, to identify adults with multimorbidity who are at risk of adverse events such as unplanned hospital admission or admission to care homes.*
>
> *1.3.5 Consider an approach to care that takes account of multimorbidity for adults of any age who:*

[1] https://www.nice.org.uk/guidance/ng56/chapter/Recommendations

[2] https://www.nice.org.uk/guidance/ng5

[3] https://www.nice.org.uk/advice/ktt18

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- *are prescribed 10 to 14 regular medicines*
- *are prescribed fewer than 10 regular medicines but are at particular risk of adverse events*

Establish treatment burden by talking to people about how treatments for their health problems affect their day-to-day life, including the number and type of medicines a person is taking and how often, and any harms from medicines.

I am advised that NICE agrees that there is currently no guidance, national or otherwise, available to clinicians specifically on how best to approach the *prescribing of highly addictive and potentially harmful drugs alongside one another*. However, I can confirm that NICE has been commissioned to produce guidance on safe prescribing and withdrawal management of prescribed drugs associated with dependence and withdrawal. This work is due to start in early 2019.

I hope this information is helpful. Thank you for bringing your concerns to our attention.

JAMES O'SHAUGHNESSY