

From Maria Caulfield Parliamentary Under Secretary of State for Primary Care and Patient Safety

> 39 Victoria Street London SW1H 0EU



26 January 2022

Dear Mr McLoughlin,

Thank you for your letter of 29 September 2021 to Sajid Javid about the death of Mary Land. I am replying as Minister with responsibility for Patient Safety, and am grateful for the additional time allowed.

I would like to begin by expressing how saddened I was to read of the circumstances of Mary Land's death, and I offer my sincere condolences to her family and loved ones. The circumstances your report describes are concerning and it is essential that these are carefully explored to ensure the continued safety of these medical devices.

I have been made aware that the Medicine and Healthcare products Regulatory Agency (MHRA), the regulator of medical devices and medicinal products, has provided a response to your report explaining the actions it has taken in relation to this incident and the concerns raised. You will therefore be aware that following the outcome of the inquest into Mrs Land's death, Phillips Respironics has extended its investigation to look at the connection tubing and facemask. Phillips has also been asked by the MHRA to investigate the potential impact on performance of the breathing circuit of using a filter in the facemask. A final report of the investigation has been requested by the MHRA, and the MHRA will ensure that the investigation has been conducted in line with the relevant regulations and that any corrective action identified is taken.

In addition, MHRA will discuss with the British Thoracic Society and the National Institute for Health and Care Excellence whether an update is required to guidance relating to the management of COVID-19 patients and, specifically, ensuring that guidance on the prescribing and setting up of breathing circuits and use of filters is in line with breathing system device manufacturer's instructions.

MHRA have also reviewed the current International Organisation for Standardization standards for connectors used within a breathing circuits and have conducted a stakeholder engagement with the Association of Respiratory Nurses in order to seek feedback on the use of breathing masks, tubing and filters and the means of connecting them to make a complete breathing circuit

I am advised that the Mid Yorkshire Hospitals NHS Trust has taken learning from its own investigation of the circumstances around Mrs Land's death. This includes actions relating to the response to the device alarm. I am further advised that the Care Quality Commission (CQC) is satisfied with the Trust's action plan and will continue to monitor the Trust in line with its current regulatory approach.

Finally, it is vitally important that local organisations and system-level leaders reflect carefully on, and take learnings from, the circumstances of deaths related to the Covid-19 pandemic, such as that of Mrs Land, and I am grateful to you for bringing these concerns to my attention. It is right that there is an active and continuous process of learning, adapting and responding to the challenges of the Covid-19 pandemic and you will know that the Prime Minister has announced that there will be a full statutory inquiry into the Government's response to the Covid-19 pandemic, beginning in Spring 2022, to identify national learnings.

I hope this response is helpful.

MARIA CAULFIELD MP
PARLIAMENTARY UNDER SECRETARY OF STATE
FOR PATIENT SAFETY AND PRIMARY CARE