Llywodraeth Cymru
Welsh Government

ATISN 15673

17 November 2021

Dear

ATISN 15673 – Ventilators

Thank you for your email of 10 November to the Welsh Government requesting information under the Freedom of Information Act (2000). I am sorry to read that you are dissatisfied with our earlier response to your original request (ATISN 15418). Your original request included a number of open ended requests, such as:

“Any documentation and correspondence between the Welsh Government/NHS Shared Services and the Health Boards regarding these devices since the arrangement with Philips began, prior to the recall.”

There were more than 6,065 documents that were captured using relevant key words relating to your original request. It was also determined that on average it would take 46 seconds to decide if each document fell in scope of your request. As a result it would take 77.45 hours to complete your request. This does not include additional searches that would also be required for email exchanges among policy officials, which would increase this time further. Therefore it was determined that your request would exceed the appropriate limit for a freedom of information request. The removal of point eight of your original request does not bring the request within the relevant limit as these are documents held by Healthcare Inspectorate Wales.

I am sorry to read of the distress you are experiencing as a result of the recall of this medical device. I appreciate that it must be a very difficult time for you. We expect the NHS in Wales to support you through this process and clinical teams should be contacting all patients that are affected. The devices are manufactured by the company Philips and are procured on behalf of health boards in Wales by the NHS Shared Services Partnership. Although the Welsh Government approves contracts over a certain value, the Welsh Government does not generally procure medical devices and did not procure the medical devices that you are writing about. These are responsibilities of the NHS in Wales. I understand you have already contacted the NHS Shared Services Partnership, which will have details of the contractual arrangements.

Your email of 10 November makes a new request concerning recorded information of the following nature:

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- To advise if there have been any internal assessments of the toxins that patients may have been exposed to stemming from the Philips recall and the subsequent damage that may have been done to patients using these devices?

- If guidance has been issued to Health Boards regarding the treatment of people exposed to these toxins? If not, can you explain when this process will begin?

The regulation of medical devices is a matter for the Medicines and Healthcare products Regulatory Agency (MHRA). With regard to the recall of the devices you describe, the Welsh Government has not received any assessment of the devices' toxicity. Furthermore, no guidance has been issued by the Welsh Government to the NHS in Wales regarding the treatment of exposure to any toxins released by the devices in question. The MHRA, as a UK body, has issued a National Patient Safety Alert to the NHS in Wales which described the required action relating to the devices and summary of the biological safety risk assessment but does not include the treatment of toxicity. This can be found at:

National Patient Safety Alert: Philips ventilator, CPAP and BiPAP devices: Potential for patient harm due to inhalation of particles and volatile organic compounds (NatPSA/2021/005/MHRA) - GOV.UK (www.gov.uk)

I understand that you have already raised your dissatisfaction with the handling of your original request with the Information Commissioner's Office.

I hope this information is helpful.

Yours sincerely,