FOI 23/116

14th March 2023

Dear

Thank you for your information request, dated 9th February 2023, regarding the Philips Respironics Dreamstation CPAP machines. We are sorry to hear of the illness your client has experienced, and hope that her health is improving.

Further to your requests, please see our response below to your questions.

1. The number of people, if any, in the UK who have suffered adverse effects attributable to or associated with the use of Philips Respironics CPAP machines

The MHRA has received approximately 90 unique reports of suspected foam degradation issues associated with the issue discussed in NatPSA/2021/005/MHRA. This includes reports from patients, professional users and regulatory reports received from Philips. A number of these reports indicate suspected harm occurring. While all of these events are under investigation by both Philips Respironics and the MHRA, the evidence gathered to date has not established that the reported harm can be associated with the device at this time. The MHRA continues to monitor the situation and will ensure that all incidents reported to us are investigated thoroughly.

2. The nature of the adverse effects, illnesses associated.

The types of injuries associated with these reports include:

Adverse/Allergic reaction

Asthma

Blood/Fluid Loss

Cancer

Chest Pain

Cognitive Changes

Dizziness

Dry Mouth

Eye Pain

Renal Impairment

Depression

Dry Eye(s)

Fall

Headache

Infection

Inflammation

Pain

Respiratory affect

Unexpected deterioration

To our knowledge, none of these reported injuries have resulted in a patient death/ We would like to reiterate that at this time none of these reported injuries have been confirmed as having been caused by the use of Philips Respironics CPAP machines, however investigations into these incidents are still ongoing.

With regards to your remaining questions.

3. The name of the Trusts that have reported adverse effects from the use of the CPAP machine and

4. How many cases of adverse effects/illnesses have been reported by each Trust?

Unfortunately, this information is exempt from release under sections 40 and 41 of the FOI act:

Section 40 – Personal information: Section 40 protects personal data, the disclosure of which would breach one or more of the data protection principles. The Agency is satisfied that disclosure here would breach the first data protection principle, in particular the requirement of fairness on the basis that disclosure would not be reasonably expected by the people mentioned in the information.

Section 41 – Information provided in confidence: information provided to us in confidence, with the expectation that it will not be released, is exempt from disclosure under the FOI Act. Information will be covered by Section 41 if: it was obtained by the authority from any other person; its disclosure would constitute a breach of confidence; a person or organisation could bring a court action for that breach of confidence; and that court action would be likely to succeed.

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If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

If you have a query about the information provided, please reply to this email

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner’s Office

Wycliffe House

Water Lane

Wilmslow

Cheshire

SK9 5AF

Yours sincerely,

FOI Team

Safety and Surveillance Group