FOI 24/324 - CPAP Machine (Case Ref: SO54493)

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Wed 01/05/2024 17:08

To [redacted]

FOI 24/324

Dear [redacted]

Thank you for your information request of 3 April 2024. Your request is:

I hope you are well. One of our constituents has written to our office as he was recently supplied with the Phillips CPAP machine by the NHS to treat his sleep apnoea. I understand that the machine has been banned from sale in the US and that the MHRA have required healthcare practitioners to assess the risk of stopping or continuing use, on an individual patient basis.

I also understand that the MHRA undertook a Risk Benefit Analysis in February 2024 to assess the continuing use of the CPAP machine while awaiting repair or replacement. The findings stated that the known risks of the sudden discontinuation of treatment were higher than the potential risks posed by the degradation issue. Consequently, the Patient Safety Alert advises that patients should continue using the affected machines unless advised otherwise by their patient care provider.

However, our constituent remains concerned that the machine is being issued to residents of the UK and has requested for the data collected from this analysis to be passed onto him. I have been unable to find a published copy of the report online, hence I am requesting that it is passed onto our office via an FOI request.

Our constituent is also concerned that many individuals are being provided with the CPAP Machine without being made aware of its potential harm. Would you be able to assure our constituent that physicians are required to inform patients of the potential side-effects of using this course of treatment for their sleep apnoea?

We have been considering your request under the Freedom of Information Act 2000 (FOIA). To progress your request further, we need to ask you to provide us with more specific details about the information you are seeking.

We will explain where your request is not clear and provide advice about how you may clarify your request by describing the information you wish to receive.

The request refers to a Risk Benefit Analysis undertaken by the MHRA in February 2024. The MHRA has not conducted the stated assessment. The assessments carried out by the MHRA in relation to the CPAP foam degradation issue are described in the National Patient Safety Alert published on this matter:
https://assets.publishing.service.gov.uk/media/60d33fd58fa8f57ced82c703/Philips_Foam_NaPSA_update.pdf

Please can you clarify which data you are requesting. This will be dealt with as a new request and we will proceed to determine whether the information may be disclosed.

Further to your second question regarding physicians requirement to inform patients about the potential side effects of the CPAP machines, one of the actions included in the National Patient Safety Alert is that healthcare professionals should “Contact affected patients and have a risk–benefit conversation about continued use.” As part of the risk element of this discussion, the healthcare professional should be discussing any potential risks associated with continued use.

We will now close this request. In accordance with the Information Commissioner's guidance, when we receive this clarification from you, this will be dealt with as a new request.

The Information Commissioner's guidance can be found here:

https://cy.ico.org.uk/for-organisations/foi/freedom-of-information-and-environmental-information-regulations/interpreting-and-clarifying-requests/

Please contact us with any queries, quoting the reference number at the top of this email.

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
Telephone 020 3080 6000 gov.uk/mhra

From: [redacted]
Sent: Wednesday, April 3, 2024 4:59 PM
To: Executive.Office <Executive.Office@mhra.gov.uk>
Subject: FOI request - CPAP Machine (Case Ref: SO54493)