FOI 23/065

Dear

We have been reviewing our records for FOI request handling and have seen that you did not receive a response to your request of 26 January 2023. We sincerely apologise for the delay in responding to you. We should have communicated the response to you sooner, and while we do not hold some of the information you asked for, we are directing you to some published information where further context and explanation may be found.

We do not hold the information you have asked for in your first two questions below:

- What is the total quantity of imported pharmaceuticals that failed UK quality testing in the years 2020, 2021 and 2022? What was the total amount of pharmaceuticals imported to the UK during these years?

- What was the total quantity of imported pharmaceuticals from India that failed UK quality testing in the years 2020, 2021 and 2022?

Regarding the second of these questions, we can advise that batch testing is the responsibility of the Importer.

For your third question, we can direct you to published procedures under section 21 of the FOIA:

- What is the UK's procedure when it identifies a pharmaceutical product that has failed quality testing? Is it destroyed? Will the government notify the country/company that it imported the item from?

We can advise here that the UK has a procedure related to recalls and defects, this can be initiated via the company and/or healthcare professionals and patients who have identified a quality issue. Details of the procedure are available on this link:

https://www.gov.uk/government/publications/a-guide-to-defective-medicinal-products

We can also advise that responsibilities with regards to Importation can be found in the GMP guide, Annex 21:

https://ec.europa.eu/health/document/download/e2ddfe65-7b4e-4765-b71b-4681772d2949_en

Once again, we apologise for the delay in responding to your FOI request. You are welcome to contact us if you would like to discuss your request further.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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

MHRA Customer Experience Centre
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Medicines and Healthcare products Regulatory Agency
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