FOI 23/235 – GDP and GMP Inspections deficiency data

MHRA RESPONSE
21 April 2023

Dear

Thank you for your Freedom of Information (FOI) request dated 29th March 2023 where you asked for the following:

Please would it be possible to have deficiency data from GDP and GMP Inspections carried out in 2020, 2021 and 2022.

Ideally the data would be provided in electronic spreadsheet format (Excel or CSV file) similar to how the 2019 data was published on your website: https://www.gov.uk/government/statistics/good-manufacturing-practice-inspection-deficiencies (copy attached)

For each inspection we would like to see number of deficiencies of each category (critical, Major, Other) and the GMP / GDP chapter references cited, as well as the type of site inspected e.g., non-sterile, sterile, packaging, importer etc.

This information is exempt under Section 22 of the FOIA. Section 22 provides an exemption for information that is intended to be published in the future. We expect shortly to be able to publish these data online on the same webpage as mentioned in your request. In terms of the public interest, we do not perceive that there is a clear basis to release these data ahead of our formal publication. While we appreciate that, the data on deficiencies could be of interest to the public via indirectly improving GDP/GMP compliance, as this is a general request for release of a large dataset that requires collation we consider it more appropriate to publish this in the format previously used which is to make the data available in full (subject to appropriate redaction) on our website. We intend to re-instate this process annually. Should this not meet your needs please let us know.

Include if we have reliable an estimated publication date
We expect that these data will be published by x date:.

We consider exemption of these statistics under Section 22 in this case is:

- sensible;
- in line with accepted practices;
- and is
- fair to all concerned.

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 online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Yours sincerely
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