

FOI 23/500

MHRA RESPONSE
27 JULY 2023

Dear

Thank you for submitting FOI request 23/500:

6238434	<i>Copy of all documents related to INSP GMP/IMP 11059/56091-0020 for the 12-April-2018 inspection of MANDEVILLE MEDICINES located in AYLESBURY , UNITED KINGDOM</i>
6238435	<i>Copy of all documents related to INSP GMP/IMP 47794/28762-0019 for the 12-April-2018 inspection of PHARMARON UK LIMITED located in RUSHDEN , UNITED KINGDOM</i>
6238436	<i>Copy of all documents related to INSP GDP 11387/104681-0003 for the 11-April-2018 inspection of GUY'S AND ST THOMAS' NHS FOUNDATION TRUST located in LONDON , UNITED KINGDOM</i>
6238437	<i>Copy of all documents related to INSP GDP 31753/376326-0006 for the 11-April-2018 inspection of NEWPORT PHARMACY (BOLTON) LIMITED located in BOLTON , UNITED KINGDOM</i>
6238438	<i>Copy of all documents related to INSP GDP 40746/5240180-0006 for the 11-April-2018 inspection of LIGHTHOUSE PHARMACY LIMITED located in CLACTON-ON-SEA , UNITED KINGDOM</i>
6238439	<i>Copy of all documents related to INSP GDP 47587/16266617-0003 for the 11-April-2018 inspection of VYGORIS LIMITED located in LONDON , UNITED KINGDOM</i>
6238440	<i>Copy of all documents related to INSP GDP 47587/16266617-0004 for the 11-April-2018 inspection of VYGORIS LIMITED located in LONDON , UNITED KINGDOM</i>
6238441	<i>Copy of all documents related to INSP GDP 48751/17684095-0001 for the 11-April-2018 inspection of VIRGIN ATLANTIC AIRWAYS LIMITED located in CRAWLEY , UNITED KINGDOM</i>
6238442	<i>Copy of all documents related to INSP GDP 48851/18245709-0001 for the 11-April-2018 inspection of COLLEGE PHARMACY LIMITED located in ROCHESTER , UNITED KINGDOM</i>
6238443	<i>Copy of all documents related to INSP GDP 51568/18245709-0002 for the 11-April-2018 inspection of COLLEGE PHARMACY LIMITED located in ROCHESTER , UNITED KINGDOM</i>
6238444	<i>Copy of all documents related to INSP GDP 627/18231460-0001 for the 11-April-2018 inspection of CENTAUR SERVICES LIMITED located in STOKE-ON-TRENT , UNITED KINGDOM</i>
6238445	<i>Copy of all documents related to INSP GDP 627/18231460-0002 for the 11-April-2018 inspection of CENTAUR SERVICES LIMITED located in STOKE-ON-TRENT , UNITED KINGDOM</i>

6238446	<i>Copy of all documents related to INSP GDP 963/609029-0004 for the 11-April-2018 inspection of PHOENIX HEALTHCARE DISTRIBUTION LIMITED located in GLASGOW , UNITED KINGDOM</i>
6238447	<i>Copy of all documents related to INSP GMPBL 21463/40742-0016 for the 11-April-2018 inspection of MANCHESTER UNIVERSITY NHS FOUNDATION TRUST located in MANCHESTER , UNITED KINGDOM</i>
6238448	<i>Copy of all documents related to INSP GDP 33185/460900-0002 for the 10-April-2018 inspection of MARIE STOPES INTERNATIONAL located in LONDON , UNITED KINGDOM</i>
6238449	<i>Copy of all documents related to INSP GDP 41968/7384037-0003 for the 10-April-2018 inspection of NEW PARK ENTERPRISES LIMITED located in HARROW , UNITED KINGDOM</i>
6238450	<i>Copy of all documents related to INSP GDP 45236/12941047-0004 for the 10-April-2018 inspection of PURECARE LIMITED located in LONDON , UNITED KINGDOM</i>
6238451	<i>Copy of all documents related to INSP GDP 48730/17654421-0001 for the 10-April-2018 inspection of MARINE FIRE SAFETY LIMITED located in GODSTONE , UNITED KINGDOM</i>
6238452	<i>Copy of all documents related to INSP GDP 49159/18202702-0001 for the 10-April-2018 inspection of SELTFAR LIMITED located in LONDON , UNITED KINGDOM</i>

Having reviewed your request, we estimate that compliance with the request, would exceed the appropriate costs limit under S.12 Freedom of Information Act 2000. Public authorities are not obliged to work past the appropriate costs limit under section 12(1) of the Freedom of Information Act 2000.

This is because your request covers 19 inspection reports, and we also considered the time expended in relation to another of your requests made 31/05/23 (FOI 23/386), which also included 19 inspection reports—and was a request made in a 60 working day period as 23/500 (the present request).

We have reached our conclusion based on previous precedents set in relation to the location, retrieval, and extraction of inspection reports.

We are obliged to offer guidance as to what would be manageable under the costs limit in terms of refinement, however, given that the 60 working day period is soon to expire, we simply suggest re-submitting the full request, no sooner than 23 August 2023. However, there are particular reports in the list that you require more urgently, please let us know.

If you do submit a refined request, the we will treat it as a substitute request to your original request and the 20 working day statutory time limit will begin from the date your refined request is received. In the absence of a refined request, we will send an official response to your original request, engaging the costs limit exemption under section 12(1) of the Freedom of Information Act 2000 within the 20 working day limit.

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/>

Or

by writing to:
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely
MHRA Customer Service Centre
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

FURTHER ENQUIRY
3 AUGUST 2023

Good day, FOI Team. I have a few questions regarding FOI requests, as I am not familiar with the regulations. Is there a specific number of requests allowed per 60 working day period? How is the cost limit assessed - is it by number of requests, type of requests, or something else? I just want to make sure that going forward I abide by the regulations.

FURTHER MHRA RESPONSE
16 AUGUST 2023

Regarding your questions concerning Freedom of Information (FOI) requests, specifically:

“Is there a specific number of requests allowed per 60 working day period? How is the cost limit assessed - is it by number of requests, type of requests, or something else?”

The cost limit in section 12 of the FOI Act is about the time needed to retrieve the information that's been asked for from our systems. The FOI Act allows that a request can be refused where that request would take longer than 24 working hours to determine whether we hold the information, find that information, retrieve it, and extract it from our records. The Act also allows that requests made in a 60-day period from the same requester or organisation which ask for similar information can be 'aggregated' together and to total time needed for those requests added together. So once a requester has reached the 24 hour limit for retrieval for the requests they've already made in a 60 day period, the time needed for any new requests will be added to that if it is still within the same 60 day period. If this would mean that retrieval for the new request would take the total time for all requests over 24 hours, then the time needed for the new request will be 'aggregated' with the time already spent on the previous requests, and the new one will be refused using section 12.

Based on previous experience, we set a limit on inspection reports of no more than 20 requested in a 60-day period, to avoid triggering Section 12.

Please also be aware that outside Section 12 considerations, the time taken to redact, review, and make redactions irreversible, also requires resource. So with regard to particularly large requests, such as requests for more than 20 inspection reports or for reports that are lengthy, Section 14 may also be triggered (concerning vexatious requests). Further information on the use of Section 12 and Section 14 of the FOI Act is available from the Information Commissioner's Office, see link below: [When can we refuse a request for information? | ICO](#)

When submitting a request to MHRA, you may want to consider, for example, which reports are most needed and whether you require an inspection report in its entirety or just certain sections of that report. Please note, we have no issue releasing redacted reports to assist companies with, for example, their GMP compliance training because we perceive an over-arching benefit to the public interest in relation to an improvements in site compliance and an indirect benefit to patient safety.

Many thanks and kind regards,

HQA FOI Team