Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

Dear [redacted]

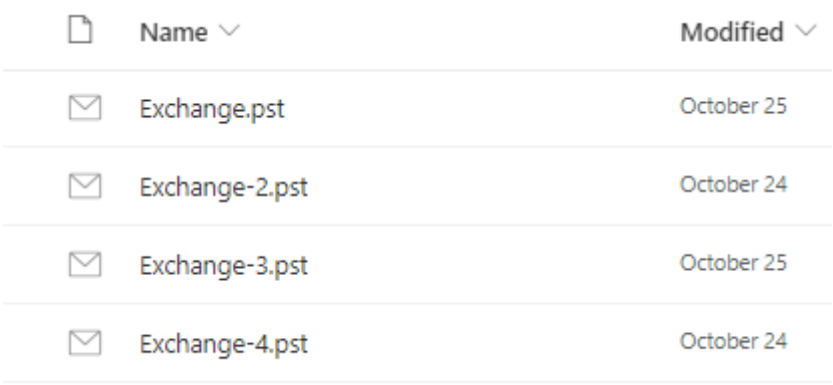
Many thanks for your refined request for information, dated 28 November, where you requested the following:

1. a list of the communications which you have identified, without the attachments.
2. a Consolidated Assessment Report - the full table of contents for this report.

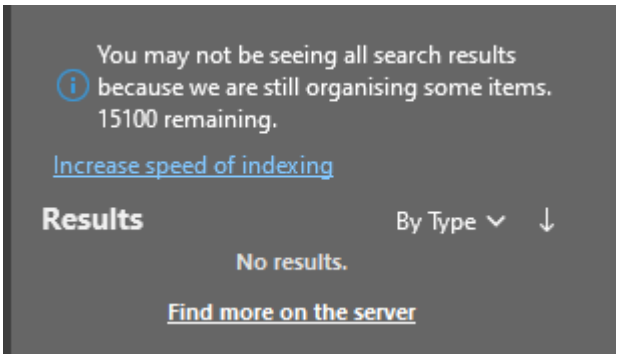
Please note that in your previous request for information (23/731), you requested copies of all communications between the MHRA and Pfizer between the period 1 October 2020 and 30 March 2021, that record discussions on the Pfizer/BioNTech Covid-19 vaccine (BNT162b2) manufactured by Process 2. In our search for the requested communications, we did not obtain or compile a list of communications, therefore we do not hold the information requested in Part 1 above.

To clarify, the Section 12 refusal was issued in 23/731 due to the time it would take to locate, retrieve and extract the requested information. We identified two email accounts of previous members of staff which we expected would hold information on Process 1 and 2. The email account file size of one of these accounts was 39 gigabytes and the other account was therefore, expected to be of a similar size.

The first screenshot illustrates the 4 PST files which were located in relation to your original request 23/731. The process of mailbox recovery and download-upload when combined with the estimated time to review the individual emails to see if they are relevant to the request, crossed the estimate for Section 12. Please note, during handling of 23/731 difficulties were encountered when downloading these files due to their size. Please also note, that an internal review is a step available to you in relation to 23/731 provided this is received by Wednesday, 3 January 2024.



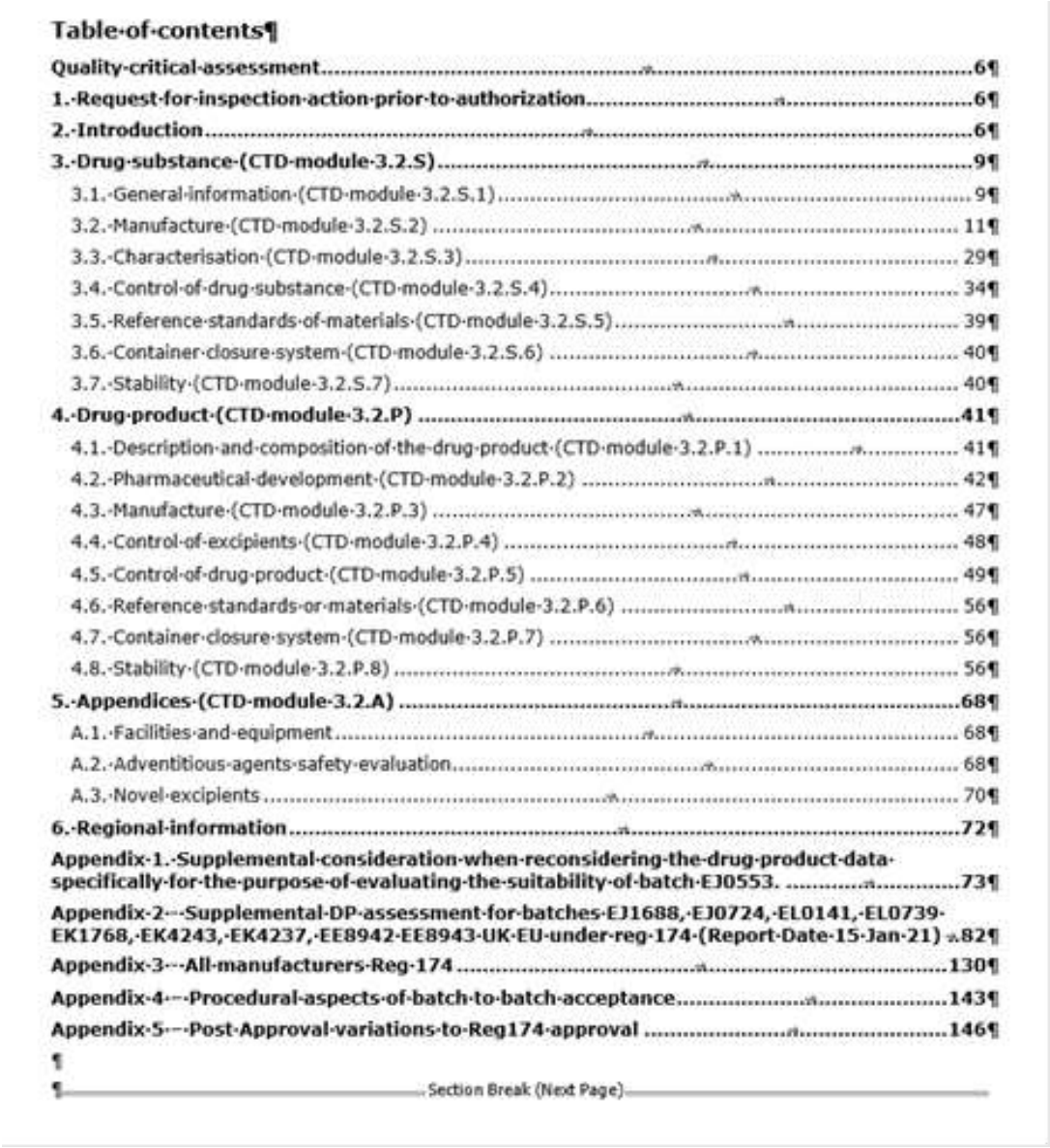
From prior experience, the search functionality for recovered mailboxes is often disrupted and this was confirmed on re-downloading the first PST file [see second screen shot].



Please see overleaf for part 2 of your request.

Part 2 of your request

This information is held, please find the table of contents below, as requested.



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We trust you will find this information of use. However, if you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content 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 in writing to:
Information Commissioner's Office,
Wycliffe House,
Water Lane,
Wilmslow,
Cheshire,
SK9 5AF

Yours sincerely,

HQA FOI Team