**From:** FOILicensing
**Sent:** 12 January 2024 16:13
**To:** MHRA Customer Services; FOILicensing
**Cc:** [redacted]
**Subject:** FW: FOI 23/983 and 23/981

**Categories:** FOIs

Hi all,

[redacted]

Many thanks,
[redacted]

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**From:** FOILicensing <FOILicensing@mhra.gov.uk>
**Sent:** Friday, January 12, 2024 4:11 PM
**To:** request-1059615-225d1324@whatdotheyknow.com
**Cc:** request-1059616-6280b9be@whatdotheyknow.com
**Subject:** FOI 23/983 and 23/981

Dear [redacted]

Thank you for your correspondence of 14 December 2023, where you requested the following information:

***FOI 23/983:***
*All emails received or sent since 1 January 2020 which contain any of the following word or word combinations in either the subject line or the body of the email:*
*"frameshift" "frame shift" "frameshifting" "frame shifting" "frameshifts" "frame shifts"*

*The relevant paper is: https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.nature.com%2Farticles%2Fs41586-023-06800-3&data=05%7C02%7CFOILicensing%40mhra.gov.uk%7C4dbf01fcaff14fdf8af608dc01489974%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638386658568976871%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=MI0hDbeY1yJfdyPDJK23uIFPeQoF58Mp98GCcI9QfJw%3D&reserved=0*

***FOI 23/981:***
*All emails received or sent since 1 January 2020 up till the current date by any authors of the paper cited below who are named as being linked to the MRC Toxicology Unit, University of Cambridge, Cambridge, which contain any of the following word or word combinations in either the subject line or the body of the email:*

*"frameshift" "frame shift" "frameshifting" "frame shifting" "frameshifts" "frame shifts"*

*The relevant paper is: https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.nature.com%2Farticles%2Fs41586-023-06800-3&data=05%7C02%7CFOILicensing%40mhra.gov.uk%7C4dbf01fcaff14fdf8af608dc01489974%7Ce527ea5c*

[redacted]

*62584cd2a27f8bd237ec4c26%7C0%7C0%7C638386658568976871%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=MI0hDbeY1yJfdyPDJK23uIFPeQoF58Mp98GCcI9QfJw%3D&reserved=0*

Our response:
Unfortunately, we estimate that compliance with this 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 and we are therefore refusing your request.

There is also a further reason why we consider that section 12 applies. This is section 12(4)(d) which with the 'Fees Regulations 2004' says:

Freedom of Information Act 2000
Exemption where cost of compliance exceeds appropriate limit. (4)The Minister for the Cabinet Office may by regulations provide that, in such circumstances as may be prescribed, where two or more requests for information are made to a public authority—(a)by one person, or (b)by different persons who appear to the public authority to be acting in concert or in pursuance of a campaign, the estimated cost of complying with any of the requests is to be taken to be the estimated total cost of complying with all of them.

The Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004
Estimating the cost of complying with a request – aggregation of related requests 5.—(1) In circumstances in which this regulation applies, where two or more requests for information to which section 1(1) of the 2000 Act would, apart from the appropriate limit, to any extent apply, are made to a public authority— (a)by one person, or (b)by different persons who appear to the public authority to be acting in concert or in pursuance of a campaign, the estimated cost of complying with any of the requests is to be taken to be the total costs which may be taken into account by the authority, under regulation 4, of complying with all of them. (2) This regulation applies in circumstances in which– (a)the two or more requests referred to in paragraph (1) relate, to any extent, to the same or similar information, and (b)those requests are received by the public authority within any period of sixty consecutive working days.

Although we consider that the time needed to retrieve the information for each request alone would exceed 24 hours, we also consider that these two requests should be aggregated. The requests were received on the same day and cover the same over-arching theme of frame shifting.

In order to locate all emails containing the authors and keywords that you have stated, we would have to search the email accounts of numerous members of staff of the agency (and members of staff who have left the agency) including those that work in Clinical Trials and in licensing of biological products, as well as senior agency staff. We anticipate that searching numerous email accounts and retrieving relevant emails would far exceed 24 working hours.

We would advise you to refine your request, perhaps to ask if we hold information relating to a specific issue that you are interested in, perhaps for a specific product.

Please note that the role of the Medicines and Healthcare products Regulatory Agency (MHRA) is to ensure that medicinal products authorised in the UK meet acceptable standards of safety, quality and efficacy at the time of first authorisation and thereafter. We have authorised the use of COVID-19 vaccines following a rigorous review of their safety, quality, and efficacy. Furthermore, independent batch release testing is undertaken on all COVID-19 batches before they are released to patients, ensuring all batches meet the required specifications. The identity of the drug substance in the drug product is critical for the drug product specifications, which is a requirement for the release of the vaccine.

[redacted]

We now consider this request closed. If you do submit a refined request, this will be a new request and the 20 working days statutory time limit will begin from the date your refined request is received.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

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

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

Yours sincerely,
FOI Team