Medicines & Healthcare products Regulatory Agency

[redacted]

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MHRA Website

Our Ref: **FOI2026/00006**

30 January 2026

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 3 January. You wrote:

> *Dear Medicines and Healthcare Products Regulatory Agency, please provide me with the following parts of Module 4 of the CTD for zapomeran (Kostaive) mRNA COVID-19 vaccine which you recently approved:*
>
> *4.1 Table of Contents*
> *4.2 Study Reports (the actual results from nonclinical studies, including:*
> *Pharmacology, with special regard to the proposed mechanism of action.*
> *Pharmacokinetics (ADME - Absorption, Distribution, Metabolism, Excretion).*
> *Toxicology (acute, subchronic, chronic toxicity, genotoxicity, carcinogenicity, reproductive toxicity, etc.).*

MHRA Response

The Agency has completed its search for the information you have requested and we are able to confirm that we hold some of the information you have requested.

Under Section 14(1) of the FOI Act, public authorities are not obliged to comply with a request which is deemed vexatious. By way of clarification, it is the request which is treated as vexatious not the person making the request.

A request may be treated as vexatious, if the amount of time required to review and prepare the information for disclosure would impose a grossly oppressive burden on the organisation.

A vexatious request is assessed with reference to all the circumstances of an individual case. There are four broad themes to consider when looking at whether an FOI request is vexatious. These four themes are:

1. the burden (on the public authority and its staff);
2. the motive (of the requester);
3. the value or serious purpose (of the request); and
4. any harassment or distress (of and to staff).

These four broad themes are not a checklist, and they are not exhaustive they simply emphasise that a range of factors need to be considered when apply Section 14(1).

In this case, the Agency is treating your request as vexatious because the documents concerned are large in volume. In order to fulfil your request, we would be required to extract the following documentation (non-clinical study reports) for Kostaive powder for dispersion for injection (PL 47991/0019), which was granted a Marketing Authorisation on 02 January 2026:

Module 4.2.1 Pharmacology (total 664 pages)
- Primary Pharmacology (463 pages)
- Secondary Pharmacology (200 pages)
- Safety Pharmacology (1 page)

Module 4.2.2 Pharmacokinetics (total 2061 pages)
- Analytic Methods and validation reports (341 pages)
- Distribution (1644 pages)
- Metabolism (76 pages)

Module 4.2.3 Toxicology (total 6475 pages)
- Repeat-dose toxicity (3876 pages)
- Genotoxicity (total 601 pages)
    - *In Vitro* 363 pages
    - *In vivo* 238 pages
- Reproductive and Developmental Toxicity (total 1998 pages)
    - Fertility and Early Embryonic Development (1 page)
    - Embryo-fetal development (743 pages)
    - Prenatal and postnatal development, including maternal function (1254 pages)
- Local Tolerance (1 page)
- Other Toxicity studies (12 pages)

These documents would then need to be checked page by page to see if there is any information that should be redacted under one or more sections of the FOI Act. This would need to be assessed by a subject matter expert; doing so would remove them from their day-to-day duties of the preparation and publication of Public Assessment Reports of granted Marketing Authorisations. This in turn would have an impact on public and patient safety as well as an impact on the Agency obligation and commitment to transparency through established publication schemes. We would then need to consult with third parties on these documents to see if there are any objections to their release or any additional redactions that need to be made on their behalf.

We estimate that the work itemised above would place a disproportionate burden on staff in order to meet your request. Therefore, on this basis, the Agency has decided that Section 14(1) of the FOI Act applies on this occasion. We recommend that you restrict any future request to, for example, the non-clinical overview or specific sub-sections of Module 4 that you would like to be considered for release.

On this basis, the Agency has decided that Section 14(1) of the FOI Act applies on this occasion.

Please note that we have checked our records and have found that we do not hold the information ‘Module 4.1 Tablet of contents’ that you have requested for Kostaive powder for dispersion for injection (PL 47991/0019).

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information
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https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/