Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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London
E14 4PU

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MHRA Website

[redacted]

Our Ref: **FOI2026/01455**

19 November 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 22 October. You wrote:

> *Please provide only the principal final or operative record for each item below:*
>
> *1. MHRA states that it received the final DART study report in January 2021, did not undertake a separate assessment, and recognised the EMA's scientific evaluation. Please provide the record documenting MHRA's decision to recognise that evaluation and any recorded conclusion about its effect on the GB authorisation, benefit–risk assessment, or advice on pregnancy and breastfeeding. If no such decision or conclusion was recorded, please confirm that expressly and identify the recorded policy or procedure under which the evaluation was recognised.*
> *2. Your response identifies the EMA CHMP assessment report as the principal paper considered by the UK expert working group for PLGB 53632/0008. Please provide the principal final record of the UK working group's conclusion and any recorded UK-specific considerations or sign-off preceding the grant on 5 December 2022. If the published minutes and grant letter are the complete operative record, please confirm this.*
> *3. The grant letter lists four post-authorisation measures for use in children aged 6 months to 4 years. For each measure, please provide the principal final record showing whether it was fulfilled and MHRA's conclusion on the material submitted. If a measure remains outstanding or was changed, please provide its latest recorded status or decision.*
>
> *I am seeking identified decision and close-out records, not drafts or a general search of correspondence. If one item would exceed the appropriate cost limit, please process the others and advise how to narrow that item.*
>
> *Separately from the FOI request, I would welcome an explanation of where responsibility for the GB benefit–risk decision lay when MHRA relied on EMA or European Commission work after the UK's EU transition ended. What checks and continuing oversight did MHRA itself undertake in these two cases?*

MHRA Response

The Agency has completed its search for the information you have requested. Please find our response to each of your questions below:

1. MHRA states that it received the final DART study report in January 2021, did not undertake a separate assessment, and recognised the EMA's scientific evaluation. Please provide the record documenting MHRA's decision to recognise that evaluation and any recorded conclusion about its effect on the GB authorisation, benefit–risk assessment, or advice on pregnancy and breastfeeding. If no such decision or conclusion was recorded, please confirm that expressly and identify the recorded policy or procedure under which the evaluation was recognised.
The Centralised Procedure grandfathering application for PLGB 53632/0002 included the 'baseline submission' as of 31 December 2020 and all variations approved by EMA between 01 January 2021 and 16 April 2021. The submission included the DART study. MHRA approved this application on 22 April 2021. Please find attached the grant letter for this, which constitutes the MHRA's decision to recognise the EMA evaluation.

2. Your response identifies the EMA CHMP assessment report as the principal paper considered by the UK expert working group for PLGB 53632/0008. Please provide the principal final record of the UK working group's conclusion and any recorded UK-specific considerations or sign-off preceding the grant on 5 December 2022. If the published minutes and grant letter are the complete operative record, please confirm this.
The final record of the expert working group's conclusion is the published minutes, which are available here:
18_November_2022.pdf

The Public Assessment Report provides details of the MHRA assessment of the procedure:
4be8e89c9460839c2f6e291b9f32d9e2ccd5c5f5

3. The grant letter lists four post-authorisation measures for use in children aged 6 months to 4 years. For each measure, please provide the principal final record showing whether it was fulfilled and MHRA's conclusion on the material submitted. If a measure remains outstanding or was changed, please provide its latest recorded status or decision.
For PAM 1, it was agreed that the data could be submitted as part of PSUR 4. A redacted copy of PSUR 4, covering the period 19 June 2022 to 18 December 2022, was previously disclosed by the MHRA under FOI 23/474 and is publicly available on GOV.UK at the following link:
FOI_23-474_PDF_attachment__4_.pdf

PAM 2 and PAM 3 were fulfilled as the information was submitted to MHRA on 03 February 2023 and 05 January 2023, respectively. We do not hold a principal final record of approval for these commitments such as a grant letter.

PAM 3 was to clarify if people aged 6 months to 4 years can be included in the UK study of post-authorisation vaccine effectiveness (study WI255886), providing an updated protocol, or make a new proposal for studying vaccine effectiveness in this population in the UK (within one month of approval). In response to this, the company made a new proposal to utilise study C4591014. The final report for study C4591014 was subsequently submitted and the submission approved.

PAM 4 was fulfilled as the information was submitted to MHRA on 03 May 2024. Please find attached the MHRA grant letter regarding the fulfilment of PAM 4.

Please note that some of the information in the grant letters that we have provided is being exempt from release. We consider that the information is exempt under Section 40(2) of the FoI Act.

Section 40(2)
We are unable to provide you with some of the information requested as it constitutes personal data of someone other than yourself and as such, it is being withheld in accordance with section 40(2) of the Freedom of Information Act.

Section 40(2) exempts information in response to a request if it is personal data belonging to an individual other than the requester and it satisfies one of the conditions listed in the legislation. In this case the condition contained in section 40(3A)(a) applies - that disclosure would breach one of the data protection principles, specifically that “Personal data shall be processed lawfully, fairly and in a transparent manner...”.

We do not consider that disclosing this information is necessary or justified in order to satisfy your information request and the requirements of the FoI Act. In relation to this request, we consider that there is no strong legitimate interest that would override the prejudice to the rights and freedoms of the data subject.

Personal data are subject to UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018.

MHRA maintains the following policy on disclosure of personal information:
"All personal information held in MHRA records is regarded as confidential. Information will not normally be disclosed to third parties without the consent of the person concerned. Information may normally be disclosed without consent to meet statutory requirements; to comply with a court order; to prevent duplication of payments from public funds; or where there is a compelling public interest in making the disclosure."

All disclosures made by MHRA, in order to be considered authorised must be able to demonstrate that at least one of the above criteria apply.

Regarding your general question about regulatory oversight of Centrally Authorised Products post-Brexit, please refer to our published guidance regarding the grandfathering and reliance processes:
[Withdrawn] Converting Centrally Authorised Products (CAPs) to UK Marketing Authorisations (MAs), 'grandfathering' and managing lifecycle changes - GOV.UK

International Recognition Procedure - GOV.UK

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
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:
https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/