Medicines & Healthcare products
Regulatory Agency

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

[redacted]

30 May 2024

MHRA reference: FOI2024/00084

Dear [redacted]

Thank you for your information request, which we received on 1 May. You asked for:

> *"The MMR II vaccine [Merck] was introduced into the UK market/vaccination schedule in November 1988, please provide a copy of the Product Licence issued allowing the vaccine on to the market at that time."*

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

We confirm that we hold the information you have asked for, and we are disclosing this information in full.

We can confirm that the MMR vaccine (PL 00025/0078) was granted 17/08/72. The MMR vaccine was introduced to routine vaccine programmes in the UK, in 1988 and it was subsequently superseded by MMRII.

We can also confirm that a variation to change the strain from Rubella virus strain duck-cell adapted HPV-77 to Rubella virus strain Wistar RA 27/3 was granted 01/09/87. At the same time, the manufacturer also modified the buffers (excipients) used to further promote product stability. As a result of these changes, the company **changed the product name from MMR to MMR II**. The PL number remained PL 00025/0078. We have provided the product licence issued in 1972 for PL 00025/0078). We have also provided the variation application form which supported the product name change.

On 04/06/1992, the MAH submitted for a renewal of the product licence of MMR-II under the Extension Directive with a new Product Licence number of PL

Medicines & Healthcare products
Regulatory Agency

00025/0292. This was granted on 24/03/1995. We have also provided the renewal documents for PL 00025/0292.

The licence for PL 00025/0078 was cancelled in September 1995.

Section 40(2)
I can confirm that the only material we have redacted is within the attached document. These redactions concern personal data: this information is withheld as it falls under the exemption in sections 40(2) and 40(3)(a)(i) of the FOIA, which relates to the personal data of which the applicant is not the data subject. Section 40(2) of the FOIA provides that personal data relating to other persons is exempt information if disclosure would breach the Data Protection Act 1998 (DPA). We consider that disclosure of this information is likely to breach the first data protection principle in Schedule 1 to the DPA, which relates to the fair and lawful processing of personal data. Therefore, we have concluded that this information is exempt from disclosure under section 40(2) read in conjunction with section 40(3)(a)(i) of the FOIA

Advice and assistance
Please note, there is also an EPAR to the current version of Merck's MMRVaxPro which may be of interest to you:
https://www.ema.europa.eu/en/documents/scientific-discussion/m-m-rvaxpro-epar-scientific-discussion_en.pdf

And, a general guide on MMR vaccination:
MMR for all: general guide - GOV.UK (www.gov.uk)

We hope this information is useful for you. This concludes our response to your request.

If you have a query about this response, please contact us at foi.request@mhra.gov.uk

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Healthcare, Quality and Access Group
Medicines and Healthcare products Regulatory Agency

Medicines & Healthcare products
Regulatory Agency

Appeal rights

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

If you remain dissatisfied with the outcome of the internal review, you 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 a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: 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

Re-use of our information