Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2024/00692**

29 November 2024

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 7 November. You wrote:

> *'I refer to the above subject and attach hereto Patient Information Leaflet [PIL] last revised October 2023.*
>
> *Your attention is drawn to the text highlighted on page 2, and reproduced below in indented italic text.*
> *Shingrix can be given at the same time as other vaccines such as unadjuvanted inactivated seasonal influenza vaccine, 23-valent pneumococcal polysaccharide vaccine, 13-valent pneumococcal conjugate vaccine, reduced antigen diphtheria tetanus acellular pertussis vaccine, or COVID-19*
> *mRNA vaccine. A different injection site will be used for each vaccine.*
>
> *I would be grateful if you could provide me - from MHRA records -with brief details of the studies undertaken to confirm the safety and efficacy of co-administration of Shingrix with the other five vaccines listed in the PIL.'*

MHRA Response

We can confirm that the Agency holds this information. However, the information is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain.

However, to be helpful, we have outlined below sources at which you can find the information you seek.

A brief description of the studies for these 5 vaccines can be found in the Summary of Product Characteristics. This is available on the MHRA products website at https://mhraproducts4853.blob.core.windows.net/docs/ef2a1eb0633b6b85fd7572dfebb3c945e93da837 and the relevant excerpt included below:

> *'Shingrix can be given concomitantly with unadjuvanted inactivated seasonal influenza vaccine, 23-valent pneumococcal polysaccharide vaccine (PPV23), 13-valent pneumococcal conjugate vaccine (PCV13), reduced antigen diphtheria-tetanus-acellular pertussis vaccine (dTpa), or coronavirus disease 2019 (COVID-19) messenger*

ribonucleic acid (mRNA) vaccine. The vaccines should be administered at different injection sites.

In five phase III, controlled, open-label clinical studies, adults ≥ 50 years of age were randomised to receive 2 doses of Shingrix 2 months apart administered either concomitantly at the first dose or non-concomitantly with an unadjuvanted inactivated seasonal influenza vaccine (N=828; Zoster-004), a PPV23 vaccine (N=865; Zoster-035), a PCV13 vaccine (N=912; Zoster-059), a dTpa vaccine formulated with 0.3 milligrams Al3+ (N=830; Zoster-042), or a monovalent COVID-19 mRNA-1273 50 micrograms booster vaccine (Original SARS-CoV-2 strain) (N=539; Zoster-091).

The immune responses of the co-administered vaccines were unaffected, with the exception of lower geometric mean concentrations (GMCs) for one of the pertussis antigens (pertactin) when Shingrix is co-administered with the dTpa vaccine. The clinical relevance of this data is not known.

The adverse reactions of fever and shivering were more frequent when PPV23 vaccine was co-administered with Shingrix (16% and 21%, respectively) compared to when Shingrix was given alone (7% for both adverse reactions). In adults aged 50 years and above, systemic adverse reactions that are very commonly reported (see Table 1 [of the SmPC]; such as myalgia 32.9%, fatigue 32.2%, and headache 26.3%), and arthralgia, uncommonly reported, following administration of Shingrix alone were reported with increased frequency when Shingrix was co-administered with a COVID-19 mRNA vaccine (myalgia 64%, fatigue 51.7%, headache 39%, arthralgia 30.3%). Concomitant use with other vaccines than those listed above is not recommended due to lack of data.'

Further sources of information already in the public domain that may be of interest are included below.

Shingrix powder and suspension for suspension for injection was originally licensed as a Centrally Authorised Product by the European Medicines Agency. Following the UK's exit from the EU, Shingrix was then licensed as a grandfathered product as PLGB 19494/0263 for Great Britain. For more information on the initial authorisation of Shingrix and the influenza study Zoster-004, please see the Public Assessment Report European Medicines Agency website here: https://www.ema.europa.eu/en/documents/assessment-report/shingrix-epar-public-assessment-report_en.pdf

The Green Book Chapter 28a on Shingles may be of interest, available online at https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

There is also a published study '*Co-administration of the adjuvanted recombinant zoster vaccine with other adult vaccines: An overview'* goes into more detail on each clinical trial. The authors of this article are listed as scientists from GSK, the company responsible for Shingrix. This is available online at https://www.sciencedirect.com/science/article/pii/S0264410X24001944#s0010

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.

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