FOI 24/215

FOILicensing <FOILicensing@mhra.gov.uk>
Tue 02/04/2024 18:43
To [redacted]
Dear [redacted]

Thank you for your request of 1 March 2024:

> *In a "shingles" leaflet from Public Health Scotland it states:-*
>
> *"All medicines (including vaccines) are tested for safety and effectiveness by the Medicines and Healthcare Regulatory Agency (MHRA)."*
>
> *Can you confirm that the MHRA tests all medicines and vaccines for safety and effectiveness?*
>
> *How much of the MHRA budget is spent on "testing"?*
>
> *How many testing facilities or labs does the MHRA own and operate.*

Regarding your email request under the Freedom of Information Act (FOIA), MHRA assesses all new medicinal products for safety and efficacy before they are granted a marketing authorisation. This comprises of an assessment of the benefit/risk for each medicinal product before it is authorised for use in the UK. Assessment is based on the quality, non-clinical and clinical data submitted by an applicant (typically a pharmaceutical company) from pharmaceutical development studies, quality testing, non-clinical studies and clinical studies that have been conducted. With regards to testing for the safety and efficacy of medicinal products, MHRA does not run its own clinical trials and does not own or operate any clinical trial sites.

For further information about how we regulate medicines in the UK, please see the below link:
https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about

MHRA carries out independent laboratory testing of vaccines and blood products for the UK in its role as the UK Official Medicines Control Laboratory (OMCL). This testing focusses on biological quality of the product, and in addition this independent assessment also confirms that the manufacturer has reported on its wide-ranging tests on the product. Batches of vaccine that meet the specifications in the approval are issued a NIBSC certificate allowing the manufacturer to market them in the UK for use before the batch expiry date.

Testing is carried out from one MHRA laboratory site in the UK.

The total budgeted spend for 23/24 for the assessment and testing activities above, including pay and overhead costs, is £36,846,310.

For further information on the independent batch release testing process:
https://nibsc.org/control_testing/batch-release.aspx

With regards to the current available Shingles vaccines, Shingrix and Zostavax, further information on these is available through the Summaries of Product Characteristics (SmPCs) and the Patient Information Leaflets (PILs) available on the MHRA website. Links to these are provided below:
https://products.mhra.gov.uk/search/?search=Shingrix&page=1

https://products.mhra.gov.uk/search/?search=zostavax&page=1

Both these products were authorised through centralised procedures, further information on the assessment of these products is provided in the Public Assessment Reports (PARs) published by the European Medicines Agency (EMA). Links to these are provided below:
https://www.ema.europa.eu/en/medicines/human/EPAR/shingrix
https://www.ema.europa.eu/en/medicines/human/EPAR/zostavax

If you have a query about the information provided, please reply to this email.

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

Yours sincerely,
FOI Team