FOI 24/196

FOILicensing <FOILicensing@mhra.gov.uk>
Mon 25/03/2024 14:16
To [redacted]

Dear [redacted]

Thank you for your request, dated 26 February 2024, asking the following questions:

"- How has the role of the MHRA changed since BREXIT?

- How has the structure of the MHRA as an organisation changed since BREXIT.

- When did these changes take effect?

- Why were these changes necessary?

- How has communication between MHRA and the NHS changed since BREXIT.

Please provide details.

- How has communication between MHRA and the pharmaceutical industry (CROs and pharmaceutical companies) in and outside the UK changed since BREXIT?

Please provide details.

- How has communication between MHRA and pharmaceutical manufacturers in and outside the UK changed since BREXIT?

Please provide details.

- In what ways have the requirements of Marketing Authorisation Holders (MAHs) in the UK changed?

Comment on changes related to ICSR and PSMF too.

- In what ways have you changed the requirements of Marketing Authorisation Holders (MAHs) outside the UK should they wish to market their products in the UK?

- How has the role of the Qualified Person Responsible for Pharmacovigilance (QPPV) changed in the UK?

- How has the role of the Qualified Person Responsible for Pharmacovigilance (QPPV) from outside the UK changed?

- How has communication between MHRA and the EU system changed?

Please specify.

- How has the licensing procedure for approved drugs changed in the UK?

- *How have requirements for pharmacovigilance activities of medicinal products authorized in the UK changed if they are to be marketed in the rest of the EU and outside the EU?*

- *Comment on overall changes to regulatory framework in the UK comparing pre and post-BREXIT.*

- *Add any further comments you may have that would be useful for the purpose of this research."*

You have mentioned the Freedom of Information Act (FOIA) in your request; however, we should explain that the FOIA provides the public with access to the recorded information which public authorities hold about their activities.

Questions which ask for views, opinions or commentary are not valid under Section 8 of the FOIA, unless those views are already held in recorded form at the time that the request is made. There is no requirement for a public authority to create new information in order to respond to a request. As some of your question ask for views and commentary rather than recorded information, in particular asking us to compare processes from before and after the UK's withdrawal from the European Union, there is no requirement for us to respond where these fall outside the scope of the FOIA.

We have included a link to the Information Commissioner's website, where you can find guidance about what is and is not in scope of the FOIA, and advice on how to word an effective information request. You can access this guidance at: https://ico.org.uk/your-data-matters/official-information/

However, we do hold some relevant information which sets out the new processes which came into effect; as this information is already published (and so exempt under section 21 of the FOIA), we are providing links to this information here:

https://www.gov.uk/government/collections/new-guidance-and-information-for-industry-from-the-mhra

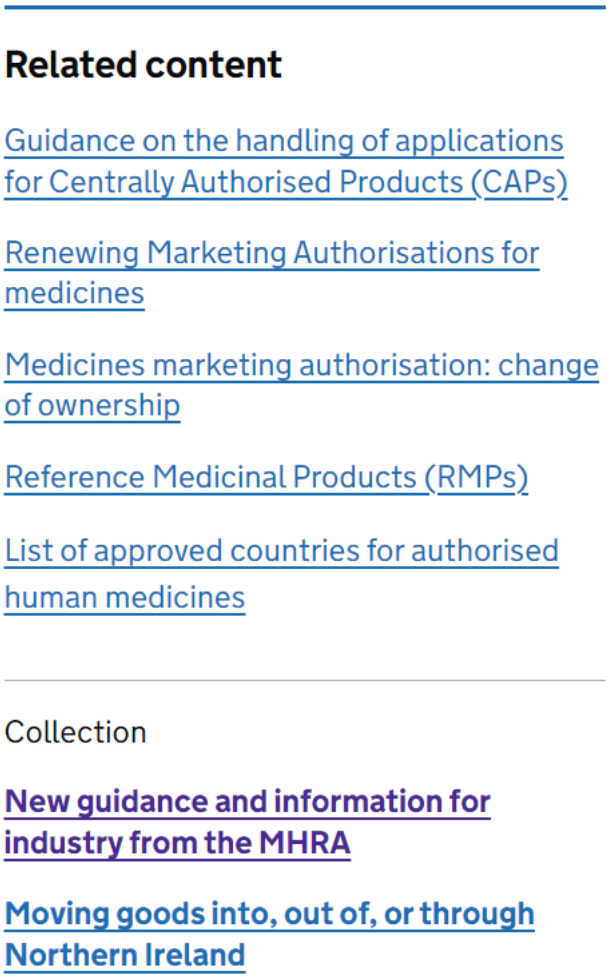
https://mhrainspectorate.blog.gov.uk/2020/12/23/post-transition-pharmacovigilance-requirements-for-uk-authorised-products-thursday-22-october-2020/

https://mhrainspectorate.blog.gov.uk/2021/01/29/pharmacovigilance-requirements-for-uk-authorised-products-13-january-2021/

https://www.gov.uk/government/publications/guidance-on-pharmacovigilance-procedures/guidance-on-pharmacovigilance-procedures

https://www.gov.uk/guidance/converting-centrally-authorised-products-caps-to-uk-marketing-authorisations-mas-grandfathering-and-managing-lifecycle-changes

From this page above, a further series of guidance is available. The links are on the right-hand side of the page:



You may also be interested in the MHRA Corporate and Delivery Plans for the time period, and the European Medicines Agency's guidance on the UK's withdrawal from the European Union:

https://www.gov.uk/government/publications/mhra-corporate-plan-2018-to-2023

https://www.gov.uk/government/publications/the-medicines-and-healthcare-products-regulatory-agency-delivery-plan-2021-2023

https://www.ema.europa.eu/en/about-us/history-ema/brexit-united-kingdoms-withdrawal-european-union

Further information on the current role of MHRA, our corporate governance and independent advisory bodies is available via the link below:

https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about

Information on our senior leadership structure is available via the link below:

https://assets.publishing.service.gov.uk/media/6527ccb22548ca000dddf1c8/MHRA_Senior_leadership_structure_Oct_23.pdf

Information on obtaining a marketing authorisation and post authorisation activities in the UK are provided below:

https://www.gov.uk/government/collections/medicines-licensing-and-applications

We hope that this is useful for you.

Yours sincerely,

FOI Team

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

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: info@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