FOI 23/295 – information on Covid-19 vaccines reviewed by MHRA Advertising Standards and Outreach Unit, excluding materials produced by pharmaceutical companies

REQUEST AND MHRA RESPONSE 26 April 2022

"I refer you to the 2021 Annual Report of your Advertising Standards & Outreach Unit, Vigilance and Risk Management of Medicines Division, Published 17th March 2022 and entitled "Delivering High Standards in Medicines Advertising Regulations".

In section 3. Of this document, which is headed "Vetting advertising before issue" it says:

*"We also reviewed information disseminated on COVID-19 vaccines given a temporary supply and conditional authorisations,"* 

Under the requirements of the Freedom of Information Act 2000 I am requesting that you send me copies of, or specific and direct electronic links to, each such item of information which has been reviewed by the MHRA Advertising Standards Unit in 2019, 2020, 2021, 2022 and 2023

I am also asking for the MHRA to tell me exactly why the MHRA Advertising Standards and Outreach Unit reviewed each item of information and what sets of regulations, standards or guidelines the Unit used to review each item of information and assess its suitability for dissemination.

Please note that this FOIA request does not apply to the review of materials produced by pharmaceutical companies.

However, it applies to all information reviewed which was produced by the UK Government, all UK devolved governments and all governmental departments or agencies (including, but not restricted to, the NHS, the UKHSA, the MHRA, the DHSC)"

Thank you for your information request, dated 19 April 2023, where you asked for copies of, or links to, items of information disseminated on Covid-19 vaccines given a temporary supply and conditional authorisations reviewed by MHRA Advertising Standards Unit for the period 2019–23.

You stated that the request did not apply to review of materials produced by pharmaceutical companies, but that it applied to all information produced by UK

Government, devolved Governments and all Government departments or agencies.

I can confirm that we do not hold the information that you have requested. You may find the following clarifications useful.

Vetting of advertising before issue, as quoted in your information request and as cited in the 2021 Annual Report 'Delivering High Standards in Medicines Advertising Regulation', is a supervisory function performed by the MHRA on behalf of Health Ministers in relation to advertisements proposed for use only by Marketing Authorisation Holders of specific medicinal products. This scrutiny activity is conducted to help ensure that these companies produce material for their products that is compliant with Part 14 (Advertising) of the Human Medicines Regulations 2012.

Further information on this activity is outlined in chapter 8 of the MHRA Blue Guide on the Advertising and Promotion of Medicines in the UK. The Blue Guide outlines the scope of vetting in relation to activity by Marketing Authorisation Holders and may include checking of their proposed non-promotional activity as well as promotional.

Your information request also asked about why each item may be reviewed and what sets out the regulations, standards or guidelines the Unit used to review each item and assess suitability for dissemination. I can confirm that the Blue Guide provides this overview in relation to the activity of vetting company material for specific medicinal products prior to use (see again chapter 8 [The Role of the MHRA] and also chapters 3 [The Legislative Framework] and 4 [General Rules]). I can confirm that all official Government material in support of public-health campaigns that you are asking about is considered to be outside the scope of Part 14 (Advertising) of the Human Medicines Regulations 2012. The MHRA therefore plays no part in review of this information before issue in the context of these Regulations.

I understand that the MHRA has previously advised you in correspondence of its view that materials disseminated by Government bodies in support of a public-health campaign are not caught by the definition of an advertisement for a medicine (as defined in regulation 7 of the above Regulations) because they are not 'designed to promote the prescription, supply, sale or use' of a specific medicine or medicines. Their purpose is rather to promote public health by encouraging people to seek appropriate medical intervention, such as uptake of vaccination against COVID-19.

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, Healthcare Quality and Access