Medicines & Healthcare products
Regulatory Agency

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

[redacted]

3rd November 2023

Dear [redacted]

FOI 23/750

Thank you for your information request, dated 6th October 2023, where you requested information relating to inclisiran.

1. Please can you send me copies of all the reports you have received via the Yellow Card scheme concerning inclisiran in the last five years?

   I can confirm that we hold this data however, we are unable to provide you with copies of individual Yellow Card reports as these are exempt from disclosure under Section 40 (personal information) and Section 41 (information provided in confidence) of the FOI Act. Supplying you with this information could lead to patient identification. Further to the use of Section 40 and 41, as outlined in our Privacy Policy, the MHRA will not share the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, unless we are required or permitted to do so by law. As this is personal data in relation to an individuals' health, this would be of detriment to them and may damage the engagement with the scheme.
   However, a summary of this information is available through our interactive Drug Analysis Profile for inclisiran. Each iDAP contains a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies:
   https://info.mhra.gov.uk/drug-analysis-profiles/dap.html?drug=./UK_EXTERNAL/NONCOMBINED/UK_NON_000084485576.zip&agency=MHRA

2. Please can you send me copies of all reports and/or investigations the MHRA has compiled, completed, begun or initiated in the last five years?

   I can confirm we hold relevant data however we are unable to provide you with a copy of the single report identified as being relevant as this is exempt from disclosure under Section 41 (information provided in confidence) of the FOI act.

   For reference, Leqvio (inclisiran) gained initial marketing authorisation via the centralised procedure on 9th December 2020 (EMEA/H/C/005333). With respect to the request for any relevant MHRA reports and/or investigations the only relevant record is a Commission on Human Medicines (CHM) paper which was prepared for the CHM

meeting held on 21st May 2020. This paper was prepared to facilitate CHM consideration of a new drug not previously licensed in the United Kingdom.

The contents of the paper are confidential on the grounds that it is comprised of information supplied in confidence in the form of European assessment reports which are not available in the public domain. These reports outline the European regulatory position following the day 80 assessments made as part of the centralised procedure timetable. The Commission endorsed the recommendations of the Rapporteurs that the product was not approvable at that time pending the response of the Applicant to the list of issues raised.

You may find it helpful to consult existing information in the public domain particularly the European Public Assessment Report published by the EMA following conclusion of the centralised procedure.

3. Please can you send me copies of all correspondence you have had with a) NHS England b) Department of Health and Social Care and c) NICE concerning inclisiran in the last five years?

   Having searched our records, we can confirm that we do not hold this information.

I hope the information provided is helpful, but 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 of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Safety and Surveillance

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