Medicines & Healthcare products
Regulatory Agency

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

[redacted]

08 December 2023

Dear [redacted]

Re: FOI 23/736

Thank you for your request for information dated 04 October 2023. We have provided our answers beneath each of your questions, as listed below.

Biogen sought, and obtained in June 2022, an indication extension in the UK with respect to its UK(GB) MA for Tecfidera. We kindly request that the MHRA:

1. Confirms why the additional year of market exclusivity was not granted in the UK;

Tecfidera 120 mg and 240 mg gastro-resistant hard capsules (PLGB 22407/0012-0013) were originally granted Marketing Authorisations in the European Union, including the UK, via the centralised procedure, on 30 January 2014. The licences were grandfathered to Great Britain (GB) licences on 01 January 2021.

This PLGB retains the benefit of the remaining data and marketing exclusivity periods from which it benefitted immediately before IP completion day. The data and marketing exclusivity would therefore expire 8 and 10 years, respectively, after the date on which the Commission Implementing Decision took effect (3 February 2014).

A variation to extend the therapeutic indication for Tecfidera to include treatment of relapsing remitting multiple sclerosis (RRMS) paediatric patients from 13 years of age and over, was granted by MHRA on 14 June 2022.

Pursuant to the Human Medicines Regulations 2012, as amended: *"The ten-year period [for market exclusivity] shall be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their*

authorisation, are held to bring a significant clinical benefit in comparison with existing therapies".

However, as the variation to extend the therapeutic indication was granted in GB on 14 June 2022, it was therefore obtained after the point at which it could have affected the marketing exclusivity date.

2. Provides copies of:

a. the variation assessment report relevant to the indication extension to the Tecfidera GB marketing authorisation; and

The variation was granted via the European Commission (EC) Decision Reliance Procedure, taking into account the assessment of the EMA. Therefore, please refer to the European public assessment report (EPAR) for the variation.
https://www.ema.europa.eu/en/documents/variation-report/tecfidera-h-c-2601-ii-0073-epar-assessment-report-variation_en.pdf

We hold a short assessment for the variation on our files, but this pertains mainly to assessing the information in the updated Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) and does not include a full assessment of the data or any reference to the Marketing Protection period.

b. any scientific advice requested by Biogen in relation to this June 2022 indication extension; and

Scientific advice meetings are considered to be commercially sensitive, and as such we cannot confirm or deny whether we have received any request for scientific advice by Biogen in relation to this variation. We consider this information to be exempt under Section 41(2) (Information provided in confidence) and Section 43(3) (Commercial interests) of the Freedom of Information (FOI) Act.

Section 41 is an absolute exemption, and no consideration of the public interest is required, except to state that we would consider confirming or denying whether we have received any requests for scientific advice would be an actionable breach of confidence. Section 43 is a conditional exemption and requires a consideration of the public interest. We have considered the public interest and cannot see any public interest argument that outweighs the commercial harm in disclosing information regarding the company's position with regards to seeking scientific advice.

c. any correspondence between Biogen (or its authorised representatives) and the MHRA between 1 January 2022 and 1 September 2023 with respect to the June 2022 therapeutic indication extension of Tecfidera and any application for an additional year of market exclusivity.

We confirm that we hold the requested correspondence, and we consider this information to be exempt under Section 41(1) (Information provided in confidence) and Section 43(2) (prejudice to commercial interests) of the FOI Act.

Section 41 is an absolute exemption, and no consideration of the public interest is required, except to state that we consider disclosure of correspondence regarding this matter would be an actionable breach of confidence. Section 43 is a conditional exemption and requires a consideration of the public interest. We have considered the public interest and cannot see any public interest argument that outweighs the commercial harm in disclosing information regarding the company's position on the indication extension and any application for an additional year of market exclusivity.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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 online via an electronic form:
https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or

by writing to:
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,
HQA FOI Team

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