FOI 23/572

Dear

Many thanks for your request for information, received on 04 August 2023, where you asked the following:

Re: Marketing authorisations PLGB 22407/0012 (120mg) and PLGB 22407/0013 (240mg) (Tecfidera; marketing authorization holder: Biogen Netherlands B.V.).
1. Any variation applications made by the holder of the above MA(GB)'s seeking an additional year of market exclusivity for either of the MA(GB)'s based on one or more new therapeutic indications, and if so made the date the application was made.
2. If a variation application has been made, any documents evidencing (i) whether the variation application has been granted by the MHRA, (ii) whether the market exclusivity period of the above marketing authorisations has been extended by an additional year, and (iii) the date of grant of the application.

Please find our response below:

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.

We now consider this request to be closed. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please email: info@mhra.gov.uk

After that, if you remain dissatisfied, you may write to the Information Commissioner at;
The Information Commissioner’s Office
Wycliffe House
Water Lane
Wilmslow

Cheshire
SK9 5AF