Medicines & Healthcare products Regulatory Agency

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United Kingdom
gov.uk/mhra

[redacted]

21 September 2023

Dear [redacted]

FOI 23/559: PIPs for Tecentriq, Bavencio and Imfinzi

Thank you for your information request, dated 31 July 2023, in which you requested:

1) Details of the Paediatric Investigation Plans (PIPs) that have been agreed (with either the EMA or the MHRA, with respect to either initial MA applications or Type II variations) for the medicinal products Tecentriq, Bavencio and Imfinzi.

2) An indication of which of those agreed PIPs has been completed.

3) A copy, preferably an electronic copy, of the statement indicating compliance with an agreed PIP (i.e., a statement according to regulation 58A(2)(a) of the Human Medicines Regulations 2012) for each completed PIP.

Please find the MHRA response below:

Tecentriq (atezolizumab)

1) Tecentriq (PLGB 00031/0908 and PLGB 00031) was authorised by MHRA for Great Britain (GB, consisting of England, Scotland and Wales) on 01 January 2021. The products were originally European Union (EU) Centrally Authorised Products (CAPs), authorised on 20 September 2017, that have been converted to GB Marketing Authorisations (‘grandfathering’).

Please note that adopted PIPs (prior to 01 January 2021) were agreed via the European Medicines Agency (EMA) and are available from the EMA website. Please also refer to the EMA website for Tecentriq (atezolizumab) European-PIPs post 01 January 2021.

An application for a full product specific waiver for all subsets of the paediatric population for the PIP for Tecentriq (MHRA-100131-PIP01-21) was received by the MHRA. A Final Decision was issued to Roche Product Limited on 10 November 2021 and the outcome was published on 17 December 2021; an electronic link to the published final decision with details of the waiver is available at:

https://cms.mhra.gov.uk/pip/mhra-100131-pip01-21

2) The MHRA has granted a full product specific waiver for the Tecentriq PIP (MHRA-100131-PIP01-21. The PIP requirements are therefore considered completed.

3) As the current MHRA (MHRA-100131-PIP01-21) and EU-PIP ([EMEA-001638-PIP02-21 (P/0384/2021)], are for a full product specific waiver, no compliance check is required, that is, a compliance statement is not applicable.

Bavencio (avelumab)

1) Bavencio (PLGB 11648/0262) was authorised by MHRA for Great Britain (GB, consisting of England, Scotland and Wales) on 01 January 2021. The product was originally a European Union (EU) Centrally Authorised Product (CAP), authorised on 18 September 2017, that has been converted to a GB Marketing Authorisation ('grandfathering').

As before, please note that adopted PIPs (prior to 01 January 2021) were agreed via the European Medicines Agency and are available from the EMA website. Please also refer to the EMA website for Bavencio European-PIPs post 01 January 2021.

An application for MHRA-100238-PIP01-21-M01, to modify the PIP for Bavencio (avelumab), was received by the MHRA. A Final Decision was issued to Merck Serono Ltd on 29 July 2022 and the outcome was published on 27 September 2022. An electronic link to the Final decision and details of the modified PIP is available at:
https://cms.mhra.gov.uk/pip/mhra-100238-pip01-21-m01-update

2) The MHRA-PIP for Bavencio (MHRA-100238-PIP01-21-M01) has not yet been completed (please refer to the electronic link above for details).

3) The Published information for PIPs on the website quoted in (1) above will state if any measures in the PIP were subject to a compliance check (either partial or full). Note that full or partial compliance checks are not statements of compliance as they are separate procedures which are not published. Compliance checks are usually requested by companies and the outcomes issued directly to company concerned with the product and PIP.

A statement of compliance according to Regulation 58A(2)(a) of the Human Medicines Regulations 2012, is issued directly to companies with the grant letter, at the time of their marketing authorisation or variation/extension applications and only when the relevant PIP is fully completed. If companies have not been issued with a compliance statement and the PIP is completed, then this statement can be requested as a variation request on the MHRA portal. As MHRA-100641-PIP01-22-M02 measures are not fully completed, no UK-PIP compliance statement can be issued/has been issued.

Imfinzi (durvalumab)

1) Imfinzi (PL 17901/0327) was authorised by MHRA for Great Britain (GB, consisting of England, Scotland and Wales) on 01 January 2021. This product was originally a European Union (EU) Centrally Authorised Product (CAP), authorised on 21 September 2018, that has been converted to a GB Marketing Authorisation ('grandfathering').

As before, please note that adopted PIPs (prior to 01 January 2021) were agreed via the European Medicines Agency and are available from the EMA website. Please also refer to the EMA website for Imfinzi (durvalumab) European-PIPs post 01 January 2021.

An application to modify the PIP for Imfinzi (durvalumab) MHRA-100641-PIP01-22-M02 was received by the Agency. A Final Decision was issued to AstraZeneca UK Limited on 21 April 2023 and the outcome was published on 14 August 2023. An electronic link to the Final decision and details of the modified PIP is available at:

https://cms.mhra.gov.uk/system/files/2023-08/mhra-100641-pip01-22-m02-update.pdf

2) The proposed date of completion of the MHRA-PIP for Imfinzi (durvalumab) is 31 August 2023.

3) The Published information for PIPs on the website quoted in (1) above will state if any measures in the PIP were subject to a compliance check (either partial or full). Note that full or partial compliance checks are not statements of compliance as they are separate procedures which are not published. Compliance checks are usually requested by companies and the outcomes issued directly to company concerned with the product and PIP.

A statement of compliance according to Regulation 58A(2)(a) of the Human Medicines Regulations 2012, is issued directly to companies with the grant letter, at the time of their marketing authorisation or variation/extension applications and only when the relevant PIP is fully completed. As MHRA-100641-PIP01-22-M02 measures have not yet been confirmed to be fully compliant, no UK-PIP compliance statement can be issued/has been issued.

We now consider this FOI request closed.

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 2 months of the date you receive this response and addressed to: info@mhra.gov.uk, quoting reference FOI 23/559.

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, and Cheshire, SK9 5AF.

Yours sincerely,

The FOI Team,
Healthcare, Quality and Access