

FOI 23/004

20th January 2023

Dear

Thank you for your Freedom of Information Request to MHRA. We received your request on the 3rd of January so we determined that the deadline for us to reply is 31st January 2023.

We have reviewed our files and information held by the British Pharmacopoeia in order to address your three questions. Please find our responses to each of your questions below.

1. Please provide a copy of monograph 2993 contained in the European Pharmacopoeia prior to the 2018 Elaboration.

The 2018 elaboration of the Nilotinib Hydrochloride Monohydrate monograph was the first time it was included in the European Pharmacopoeia (EP). Consequently, there was no monograph contained in the EP prior to the 2018 elaboration. The draft monograph was published by EDQM in October 2017 for public comment in Pharmeuropa 29.4 (you may access this online at https://pharmeuropa.edqm.eu/app/Archives/content/Archives-37189/Pharmeuropa_29.04E.pdf - you will need to register (free) for access). Following this stage and finalising of the monograph by the expert group (including consideration of any comments received) the monograph was adopted at the 161st session of the European Pharmacopoeia Commission (EPC), as you stated in your letter. The monograph was subsequently published in Supplement 9.8 of the EP and was effective from 1 July 2019 (<https://www.edqm.eu/en/-/outcome-of-the-161st-session-of-the-european-pharmacopoeia-commission-1>).

2. Please provide materials submitted by Novartis (and/or its affiliates and/or representatives) in support of the 2018 Elaboration.

We can confirm that the British Pharmacopoeia does not hold this information. Any materials to support monographs elaborated by the EP through the P4 procedure are sent directly to and held by the European Directorate for the Quality of Medicines and Healthcare (EDQM) who act as Secretariat for the EP.

As the UK National Pharmacopoeia Authority (NPA), the BP participates in EP processes by nominating experts to the working groups and participating in the EPC sessions. According to the rules of the procedure of the EP (https://www.edqm.eu/en/d/69229?p_l_back_url=%2Fen%2Fsearch-edqm%3Fq%3Drules%2Bof%2Bprocedure), sessions of the EPC and Expert Groups are private and the BP is not permitted to share the working documents and reports produced and held by EDQM as these may contain commercial data that is owned by a manufacturer and provided to EDQM in confidence. To request access to this information please contact the EDQM directly (<https://www.edqm.eu/en/contact-the-edqm>).

3. Please provide copies of correspondence between Novartis (and/or its affiliates and/or representatives) and EDQM and/or BPC relevant to the 2018 Elaboration.

We have reviewed the relevant email and data files for any communications between Novartis (and/or its affiliates and/or representatives) and the BP regarding the elaboration of monograph 2993. From these searches we can confirm the BP did not receive any correspondence from Novartis (and or its affiliates and/or associates) regarding this monograph.

To request correspondence between Novartis (and/or its affiliates and/or representatives) and EDQM, please contact the EDQM directly (<https://www.edqm.eu/en/contact-the-edqm>).

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

If you remain dissatisfied following any internal review, you may ask the Information Commissioner (ICO) to decide on whether or not we have interpreted the FOIA correctly in dealing with the request and subsequent internal review. 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 ICO's address is:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Service Centre