CASE AUTH/3490/3/21

VOLUNTARY ADMISSION BY BRITANNIA

Failure to publish details about certain trials

In its response to Case AUTH/3355/5/20, Britannia Pharmaceuticals Ltd voluntarily admitted that it had failed to publish details about certain investigator-led trials.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Britannia.

Britannia stated that it had undertaken an internal review of all investigator-led trials (interventional and non-interventional) funded by the company and acknowledged that these investigator-led trials were not appropriately disclosed.

The detailed response from Britannia is given below.

The Panel noted Britannia's submission that it had disclosed the transfers of value for the payments as medical and educational goods and services (MEGS).

Whilst the Panel noted Britannia's submission that it should have disclosed the trial results at issue, the Panel did not have enough information before it to consider whether that was so. The Panel considered that failure to have the required documentation including in relation to its payments for the majority of the trials and being unable to determine if and which trial results were required to be disclosed by Britannia meant that the company had failed to maintain high standards and a breach of the Code was ruled. Although the Panel was extremely concerned about Britannia's lack of documentation, it considered that, on balance, it did not have sufficient information to be able to rule a breach of Clause 2 of the Code which was a sign of particular censure and was reserved for such use. The Panel therefore ruled no breach of that clause.

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VOLUNTARY ADMISSION

Britannia stated that it had undertaken an internal review of all investigator-led trials (interventional and non-interventional) funded by the company; its findings were provided.

Britannia acknowledged that the investigator-led trials listed were not appropriately disclosed to the ABPI and therefore voluntarily admitted breaches of Clauses 13.3 and 13.1.

When writing to Britannia, in addition to Clauses 13.3 and 13.1, the Authority asked it to also consider the requirements of Clauses 9.1 and 2 of the Code.

RESPONSE

Britannia stated that it acknowledged a voluntary admission within its response to Case AUTH/3355/5/20.

Britannia stated that it undertook an internal review of all investigator-led trials to collate a response for Case AUTH/3355/5/20 in February 2021. The internal review highlighted that all investigator-led trials funded by Britannia had historically been processed as medical and education goods and services (MEGS); the payments had been disclosed albeit by way of the transfer of values disclosure. However, the studies themselves had not been disclosed on the company's website or the Clinical Trial Registries and Databases in accordance with Clauses 13.1 and 13.3.

During the internal review conducted in February 2021, Britannia reviewed its clinical trial standard operating procedures (SOPs) and recognised that they were not active. Britannia had several SOPs (previously provided in Britannia's response to Case AUTH/3355/5/20) relating to clinical trials in force until 2018; these were created and administered by the Phase 2 and Phase 3 Clinical Trials Team.

When these trials completed and certain individuals left the business, their duties were absorbed by other team members (excluding the administration of investigator led research), and the SOPs concerning investigator-initiated research were made obsolete.

Britannia stated that it was committed to ensuring that these SOPs and processes were developed and implemented by 30 April 2021. As previously committed to the Panel in its response to Case AUTH/3355/5/20, Britannia would not consider any further studies for funding until these SOPs and processes were effective.

In summary, Britannia stated that it was evident from the findings that there were failings internally regarding the approval and disclosure of the investigator-led trials funded by Britannia. Britannia acknowledged that these investigator-led trials were not appropriately disclosed and therefore admitted breaches of Clauses 2, 9.1, 13.1 and 13.3.

In response to a request for further information, Britannia submitted that it was currently attempting to reconcile study details with the relevant study centres and was awaiting responses. An initial email was sent to key contacts identified by the company in June 2021 requesting further information regarding the studies, followed by a second email in July 2021. Unfortunately, Britannia had only received one response to date and details were provided.

Britannia stated that it had provided funding to an overseas disease association for a study which was yet to commence therefore the details had not been published as yet. The grant was paid in 2019, and the MEGs contract was provided in 2020. Currently Britannia was complying (sic) a contract with legal, compliance and pharmacovigilance oversight to ensure it had all the appropriate processes in place.

Additionally, as per Britannia's commitment to the Panel in April 2021, the company had implemented a SOP for Investigator Initiated Research Trials detailing the receipt, review,

approval, tracking and management of Britannia-supported Investigator Initiated Research Trials. Relevant employees were notified of the SOP and their acknowledgements recorded.

PANEL RULING

The Panel noted that the dates of the payments ranged between 2017 and 2019 for eight of the trials and was unknown for the ninth trial. The Panel decided to consider the case under the 2019 Code as the requirements of Clauses 2, 9.1, 13.1 and 13.3 were the same in the 2016 Code as in the 2019 Code.

The Panel noted Britannia's submission that it had disclosed the transfers of value for the payments which Britannia had allocated as medical and educational goods and services (MEGS).

The Panel noted that Britannia had voluntarily admitted breaches of Clause 13.1 which stated that companies must disclose details of clinical trials in accordance with the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature. The relevant supplementary information stated that this clause required the provision of details about ongoing clinical trials (which must be registered within 21 days of initiation of patient enrolment) and the results of completed trials for medicines licensed for use and commercially available in at least one country. Further information was to be found in the current Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases and the current Joint Position on the Publication of Clinical Trial Results in the Scientific Literature, both at www.ifpma.org.en/ethics/clinicaltrials-disclosure.html. Companies must include on the home page of their website, information as to where details of their clinical trials could be found.

The company also admitted a breach of Clause 13.3 which stated that companies must publish the summary details and results of non-interventional studies of marketed medicines in a manner consistent with their parallel obligations with respect to clinical trials. The Panel noted that it appeared from the limited information provided by Britannia that all of the trials at issue were investigator-led trials (interventional and non-interventional) funded by the company and that Britannia stated that it had not disclosed the required details about the studies.

The Panel noted Britannia's submission that it had only received one response to date with regard to one of the nine trials at issue in an attempt to reconcile study details with the relevant study centres. In relation to that trial, the Panel noted that Britannia had provided funding in 2019 to an overseas disease association for a study that was yet to commence therefore the details had not been published as yet. The Panel noted that as there were no details to be disclosed there could be no breach of the Code in that regard. The Panel was, however, concerned about what appeared to be a long delay between providing the funding and the study commencing.

The Panel noted that Britannia had admitted breaches of Clauses 13.1 and 13.3. There was no specific information provided about each study including whether it was an interventional study or a non-interventional study. The Panel therefore could not be certain which study fell into which clause. Nor was there information before the Panel with regard to whether the remaining eight trial results required disclosing nor the identity of the sponsor, be that Britannia or someone else who would be responsible for such disclosure. The Panel therefore made no ruling in relation to Clauses 13.1 and 13.3.

Whilst the Panel noted Britannia's submission that it should have disclosed the trial results at issue, the Panel did not have enough information before it to consider whether that was so. The Panel considered that failure to have the required documentation including in relation to its payments for the remaining eight trials and being unable to determine if and which trial results were required to be disclosed by Britannia meant that the company had failed to maintain high standards and a breach of Clause 9.1 was ruled. Although the Panel was extremely concerned about Britannia's lack of documentation, it considered that, on balance, it did not have sufficient information to be able to rule a breach of Clause 2 of the Code which was a sign of particular censure and was reserved for such use. The Panel therefore ruled no breach of that clause.

Voluntary admission received **15 March 2021**

Case completed **8 August 2021**