Baxter

By email: [redacted]

Your Ref: HJS/ljm

14 December 2018

[redacted]

Prescription Medicines Code of Practice Authority
7th Floor, Southside,
105 Victoria Street
London SW1E 6QT

Dear Mrs [redacted]

Case AUTH/3101/9/18: Disclosure of clinical trial results

Following my letter from 11 October 2018 to you concerning the Disclosure of clinical trial results, I would like to inform you that Baxter has been contacted recently by both [redacted] UK and [redacted] Pharmaceuticals UK who informed me that they received a letter from the PMCPA on this similar matter.

Included with the Baxter response from 11 October was a list of 19 studies where Baxter was identified as the sponsor of the study. These studies were registered in the EU Clinical Trials Register. Seventeen (17) of these studies were marked as completed, but did not report results as required by the 2012 EC guideline 2012/c302/03. Although the sponsor in the EU Clinical Trials Register was identified as Baxter most of the products mentioned were either sold to another company or the Baxter business owning these products has been spun off from Baxter. I informed you that the Baxter Vaccines business (studies 3 – 17) with all its rights and responsibilities was sold to [redacted] in 2014. The Baxter/Baxalta business (studies 1 and 2) with all it rights and responsibilities was spun off from Baxter in 2015 as an independent company Baxalta, which was subsequently acquired by [redacted]

Both [redacted] UK and [redacted] Pharmaceuticals UK informed Baxter that they have ownership of only some of the products as mentioned above.

As all Baxter/Baxalta staff left Baxter with the spin off in 2015 and all assets were moved to its new owners, it has proven difficult for Baxter to obtain the correct information. Following contact with [redacted] Legal Department we have been provided with additional clarifications and information.

Concerning studies 3 and 5-16 with the verocell technology or pandemic flu portfolio we have been informed that these products were sold in 2015 to the US company [redacted] Inc.

With respect to study 4 with the FSME IMMUN vaccine this product was acquired by [redacted] and recently confirmed by [redacted] UK that this is indeed the case.

Baxter

In study 17 the Lyme Borreliosis vaccine was assessed. This is a [redacted] product as has recently been confirmed by [redacted] Pharmaceuticals UK.

Consequently, based on our analysis, Baxter believes that for studies 3-17 identified in its search conducted on 9 October 2018, Baxter cannot be held responsible for not posting the results on the EU Clinical Trials Register (EUCTR).

Studies 1 and 2 were conducted with EPOMAX. EPOMAX was trademarked to [redacted] Pharmaceutical in 1993, and Baxter co-developed/partnered with [redacted] to conduct studies with the product, however, at some point [redacted] Pharmaceuticals dissolved as a company. This project was discontinued by Baxter some 10 years ago.

Besides the 2 studies mentioned on the list (2004-000676-13, conducted in Slovakia, estimated end date in 2006, and 2004-000673-57, conducted in Austria, end date of 12 July 2006), Baxter identified a 3rd study with Epomax, study 2004-000678-30, sponsor Baxter Healthcare S.A., Switzerland and conducted in Czech Republic, estimated end date in 2006.

With respect to studies 1 and 2 as well as the recently identified study 2004-000678-30, none of the studies were conducted by a UK company or had any UK involvement. Baxter therefore believes that these studies do not come within the scope of the UK Code. Nevertheless, Baxter will continue to undertake every effort to report the results of these studies.

On behalf of Baxter, I would like to sincerely apologise for the misunderstanding and any inconvenience which it may have caused the PMCPA.

Six paper copies of this letter with attachment will be mailed to you. In addition, the letter will be sent to you by e-mail to [redacted]

I hope to have informed you herewith sufficiently.
In case you would like to further discuss or have additional questions I can be contacted either by e-mail: [redacted] or on my mobile phone: [redacted] or [redacted]

[redacted]

[redacted] UK, Ireland & Nordics Cluster.

Enc.

Baxter

By email: [redacted]

Your Ref: HJS/ljm

11 October 2018

[redacted]

Prescription Medicines Code of Practice Authority
7th Floor, Southside,
105 Victoria Street
London SW1E 6QT

Dear Mrs [redacted]

Case AUTH/3101/9/18: Disclosure of clinical trial results

I herewith confirm receipt of your letter to Mr [redacted] dated 28 September. Baxter received this letter by mail on Tuesday 2 October 2018. Due to a typographical error in the e mail address of Mr [redacted] the letter was not received by him by e mail. The correct e mail address is [redacted] Please note the underscore between first and last name.

In your letter, you refer to the online publication from Goldacre *et al.* in the British Medical Journal on 12 September 2018 entitled 'Compliance with requirements to report results on the EU Clinical Trials Register: cohort study and web resource.' This study assessed the compliance rates with the European Commissions' requirement that all trials on the EU Clinical Trials Register (EUCTR) post results within 12 months of completion. The paper lists the study sponsors with the highest proportion of trials reported as well as the sponsors with the highest portion of trials not reported.

In the paper, Baxter is listed in 'Table 4 |Sponsors with highest proportions of trials reported' in the lower rank of the table. Table 4 mentions the total number of trials on the EUCTR, the number of due trials, the number of due trials with results published and the percentage reported. For Baxter, the numbers are respectively 61, 28, 16 and 57.1%. This means that 28 16 12 trials have not been reported within the time frame of 12 months. The publication does not mention the individual studies with EudraCT Number.

The 2016 version of the ABPI Code of Practice in clause 13.1 requires 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.

Based on the above you have decided that Baxter may have breached the ABPI Code of Practice for the Pharmaceutical Industry and thus decided to take the matter up as a complaint.

Baxter has queried the EU Clinical Trials Registry on 09 October 2018 keywording: Baxter, status=completed and results status=trials without results. This search identified 136 possible trials. These trials were checked one by one identifying the sponsor being Baxter, which resulted in 19 trials, 7 more than identified in the publication by Goldacre *et al.* Two of these trials, numbers 18 and 19 (see table provided) were identified as still ongoing, which was internally confirmed with the person responsible for these studies in Baxter.

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With respect to the remaining 17 studies the sponsor of these studies has been identified as Baxter/Baxalta or Baxter Vaccines.
The Baxter Vaccines business (studies 3 – 17), however, with all its rights and responsibilities was sold to [redacted] in 2014.
The Baxter/Baxalta business (studies 1 and 2) with all it rights and responsibilities was spun off from Baxter in 2015 as an independent company Baxalta.

Based on our analysis Baxter believes that for none of the studies identified in its search conducted on 09 October 2018 Baxter can be held responsible for not posting the results on the EU Clinical Trials Register (EUCTR).

Six paper copies of this letter with attachment will be mailed to you. In addition, the letter will be sent to you by e-mail to [redacted]

I hope to have informed you herewith sufficiently.
In case you would like to further discuss or have additional questions I can be contacted either by e-mail: [redacted] or on my mobile phone: [redacted]

Yours sincerely,

[redacted]

[redacted] UK, Ireland & Nordics Cluster.