CASE AUTH/3377/9/20

EMPLOYEE v BRITANNIA

Misleading promotion of Apo-go Pump

An employee from Britannia Pharmaceuticals Limited complained that the company's promotion of Apo-go (apomorphine) had been misleading.

Apo-go was indicated for the treatment of motor fluctuations in patients with Parkinson's disease who were not sufficiently controlled by oral anti-Parkinson medication.

The complainant stated that the marketing department sent a communication stating that 'Apo-go Pump' was non-compliant with the summary of product characteristics (SPC). The branding for Britannia's product had been incorrect/non-compliant for years; the complainant stated that Britannia should have advertised Apo-go as an infusion and not a pump.

Britannia had misled its customers and partners and the complainant was shocked that this was not picked up sooner. How could a company promote a product when it could not get the medicine's name correct?

The detailed response from Britannia is given below.

The Panel noted Britannia's submission that on 13 August 2020, it was brought to its attention that the Apo-go Pump branding historically used by the company was inconsistent with the SPC. From evidence provided by Britannia, it appeared that the issue had been flagged during a recent MHRA inspection.

The Panel noted that Apo-go was supplied as a pre-filled pen for injection, in ampoules to be used for infusion or injection and in pre-filled syringes as a solution for infusion.

The Panel noted that various summaries of product characteristics (SPCs) for injection or infusion stated that the products could be administered as a continuous subcutaneous infusion by minipump and/or syringe-driver. The SPCs further stated that the choice of which minipump and or syringe-driver to use would be determined by the physician in accordance with the particular needs of the patient. Apo-go was not supplied as a pump.

The Panel therefore considered that use of the APO-go pump logo and reference to the product as Apo-go pump was misleading and inconsistent with the particulars listed in the products' summary of product characteristics and breaches of the Code were ruled in relation to all of the affected material as acknowledged by Britannia.

The Panel noted its rulings above and that it appeared that the misleading description of Apo-go pump appeared to have been used for a long time and had not been identified by

the company. The Panel noted its comments and rulings above and considered that Britannia had failed to maintain high standards and a breach of the Code was ruled as acknowledged by the company.

The Panel was very concerned about the company's submission that its current certification system was not providing the oversight it required but further noted that Britannia stated that it sought to have fully implemented this certification system by the end of 2020, to provide the clarity and oversight of all active and inactive materials. The Panel noted that it appeared that whilst some affected material was withdrawn immediately, a number of materials, which included the misleading description and logo, were not withdrawn. The company briefing about the withdrawal of materials stated that materials featuring the Apo-go pump logo, which were designed to aid patients and health professionals, would be updated as a priority, and the current materials would be withdrawn when the company had replacements. The Panel noted that the company briefing stated that the logo was being reworked and it appeared that materials would take seven weeks to be re-issued (third week of October). Whilst the Panel was mindful of the importance of such materials for patients, it was concerned to note the length of time that the materials in question had been available. The Panel noted its comments and rulings above and considered that Britannia had failed to maintain high standards in this regard and a breach of the Code was ruled.

An employee from Britannia Pharmaceuticals Limited complained that the company's promotion of Apo-go (apomorphine) had been misleading.

Apo-go was indicated for the treatment of motor fluctuations in patients with Parkinson's disease who were not sufficiently controlled by oral anti-Parkinson medication.

COMPLAINT

The complainant stated that the marketing department sent out a communication stating that 'Apo-go Pump' was non-compliant with the summary of product characteristics (SPC). The branding for Britannia's product had been incorrect/non-compliant for years; the complainant stated that Britannia should have advertised Apo-go as an infusion and not a pump.

The complainant stated that what was even more concerning was that Britannia had raised a similar concern with Ever Pharma last year. Ever Pharma had promoted the use of Decepton pump when the actual wording was Decepton solution for infusion/injection in cartridge. This complaint was led by the Britannia leadership team and was one of the points that a senior employee was rather displeased [about]. Did the management team think that the rules did not apply to Britannia?

The complainant was concerned that Britannia had misled its customers and partners and was shocked that this was not picked up sooner. How could a company promote a product when it could not get the medicine's name correct? How was the branding initially created? What were the checks in place to ensure compliance? Had Britannia approached the PMCPA and admitted its mistake with a voluntary admission? Would Britannia communicate this rectification to its customers? The complainant stated that he/she suspected that this incorrect branding was created when a senior employee was in the marketing function. If that was the case, no one would be held accountable.

When writing to Britannia, the Authority asked it to consider the requirements of Clauses 3.2, 7.2 and 9.1 of the Code.

RESPONSE

Britannia stated that on the 13 August 2020, it was brought to its attention that the Apo-go Pump branding historically used by the company was inconsistent with the SPC.

As a direct result of this discovery, all relevant promotional materials were identified and placed on hold within Britannia's warehouse to prevent employees ordering any additional stock; this was actioned on the 14 August 2020. The matter was escalated to the senior leadership team and following internal discussions with all stakeholders it became apparent that the same logo was used on other materials of relevance to health professionals and patients.

Britannia stated that in late August 2020 the promotional materials affected were withdrawn from use, and a business-wide briefing (copy provided) was issued to all employees for transparency; this detailed the reason for withdrawal and the agreed internal action plan.

A list of the promotional materials (six items) withdrawn from use was provided.

As part of the company's internal action plan, Britannia placed any company websites which featured the historical logo 'under maintenance' until it was able to recertify them; the sites thus could not be accessed or the content viewed.

Britannia stated that to ensure it could continue to support its patients and health professionals it was decided not to immediately withdraw the affected materials which directly related to the use of the Crono Pump III and those materials which supported patients. If such materials were withdrawn, there was a risk that patients might struggle with their treatment or suffer from unnecessary consequences from substandard support and care.

For transparency, details of the eleven patient and health professional materials that had not yet been withdrawn to ensure that the company could continue to support its patients were provided; Britannia was in the process of creating a new logo, materials and recertifying these materials, as per the briefing to all employees.
Britannia stated that it was committed to abiding by the Code and it took its compliance responsibilities seriously.

Britannia stated that there was a project to implement an industry standard certification system, the company recognised that its current certification system was not providing the oversight it required. Britannia stated that it sought to have fully implemented this certification system by the end of 2020, this would provide the company with the clarity and oversight of all active and inactive materials.

As outlined in the internal briefing issued to all employees and contracted services, Britannia would withdraw all current patient and health professional materials, recertify and reissue by 16 October 2020. Patient safety was of paramount importance to Britannia and it wished to ensure that they were supported throughout this transition of materials.

In summary, Britannia acknowledged that Clauses 3.2, 7.2 and 9.1 had been breached.

PANEL RULING

The Panel noted Britannia's submission that on 13 August 2020, it was brought to its attention that the Apo-go Pump branding historically used by the company was inconsistent with the SPC. From evidence provided by Britannia, it appeared that the issue had been flagged during a recent MHRA inspection.

The Panel noted that Apo-go was supplied as a pre-filled pen for injection, in ampoules to be used for infusion or injection and in pre-filled syringes as a solution for infusion.

The Panel noted that both the APO-go PFS 5mg/ml Solution for Infusion in Pre-filled Syringe and APO-go Ampoules 10mg/ml Solution for Injection or Infusion SPCs stated that the products could be administered as a continuous subcutaneous infusion by minipump and/or syringe-driver. The SPCs further stated that the choice of which minipump and or syringe-driver to use would be determined by the physician in accordance with the particular needs of the patient. Apo-go was not supplied as a pump.

The Panel therefore considered that use of the APO-go pump logo and reference to the product as Apo-go pump was misleading and inconsistent with the particulars listed in the products' summary of product characteristics and breaches of Clauses 7.2 and 3.2 were ruled in relation to all of the affected material as acknowledged by Britannia.

The Panel noted its rulings above and that it appeared that the misleading description of Apo-go pump appeared to have been used for a long time and had not been identified by the company. The Panel noted its comments and rulings above and considered that Britannia had failed to maintain high standards and a breach of Clause 9.1 was ruled as acknowledged by the company.

The Panel noted that the complainant had queried why this had not been picked up sooner, whether Britannia would communicate this rectification with customers, and referred to the checks in place to ensure compliance. The Panel was very concerned about the company's submission that its current certification system was not providing the oversight it required but further noted that Britannia stated that it sought to have fully implemented this certification system by the end of 2020, to provide the clarity and oversight of all active and inactive materials. The Panel noted that it appeared that whilst some affected material was withdrawn immediately, a number of materials, which included the misleading description and logo, were not withdrawn. The company briefing about the withdrawal of materials stated that materials featuring the Apo-go pump logo, which were designed to aid patients and health professionals, would be updated as a priority, and the current materials would be withdrawn when the company had replacements. The Panel noted Britannia's submission that this was to ensure that the company could continue to support its patients and reduce the risk that patients might struggle with their treatment or suffer from unnecessary consequences from substandard support and care. The Panel noted that the company briefing stated that the logo was being reworked and it appeared that materials would take seven weeks to be re-issued (third week of October). Whilst the Panel was mindful of the importance of such materials for patients, it was concerned to note the length of time that the materials in question had been available. The Panel noted its comments and rulings above and considered that Britannia had failed to maintain high standards in this regard and a breach of Clause 9.1 was ruled.

Complaint received	**10 September 2020**
Case completed	**18 February 2021**