CASE AUTH/3685/8/22

COMPLAINANT v SANDOZ

Allegations in relation to an Omnitrope Cool Bag

CASE SUMMARY

This case was in relation to Sandoz's withdrawal of a cool bag from offered as part of a package deal for Omnitrope, a medicine requiring storage between 2 - 8°C, and its failure to act transparently in relation to the withdrawal.

The Panel ruled a breach of the following Clauses of the 2021 Code because:

- **the cost of the cool bag exceeded the cost limit of £10 excluding VAT, and**
- **in the Panel's view, it appeared that Sandoz had not acted transparently in relation to the withdrawal of the cool bags, as demonstrated by its failure to communicate proactively with relevant stakeholders**

Breach of Clause 19.2	**Providing an item for patient support that did not meet the Code definition of 'inexpensive'**
Breach of Clause 5.1	**Failing to maintain high standards**

The Panel ruled no breach of the following Clauses of the 2021 Code as it considered that the complainant had not established that the offer of the cool bag as part of the package deal overall was not fair and reasonable, nor that the cool bag was not relevant to the medicine and it considered that the rulings of breaches adequately covered the matters raised and an additional ruling of a breach of Clause 2 would be disproportionate in the particular circumstances of this case.

No Breach of Clause 19.1	**Requirement that no gift, pecuniary advantage or benefit may be supplied, offered or promised to health professionals or other relevant decision makers in connection with the promotion of medicines, or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine**
No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A contactable complainant who described themselves as a health professional complained about cool bags provided by Sandoz Ltd.

COMPLAINT

The complainant stated that they had been using Omnitrope (somatropin) for a number of years in their clinic. A few patients had reported that Sandoz had stopped providing cool bags for the storage of the medicine to patients. This medicine must be stored in the fridge and therefore the cool bag was an essential item for the correct use of the medicine. The complainant asked a Sandoz representative about the reason for stopping the supply of the cool bags and was informed that the cool bags were too expensive and the company therefore considered them in breach of the PMCPA rules. The complainant queried how Sandoz was able to provide such expensive cool bags for such a long time in breach of the Code. Were there any consequences for the company in doing so? Why had Sandoz not opted to provide a cheaper cool bag to the patients that would fit within the Code requirements? Why had Sandoz not communicated this issue to health professionals and patients rather than leaving patients without care? The complainant noted that it was the company's ethical and moral duty to ensure it complied with Code while ensuring that patients were cared for. This incident reflected the poor ethics and morale of Sandoz and therefore the complainant asked for it to be investigated.

When writing to Sandoz, the Authority asked it to consider the requirements of Clauses 19.1, 19.2, 5.1 and 2 of the 2021 Code.

RESPONSE

Sandoz stated that the complaint caused it concern and the company had taken its content seriously. Sandoz was committed to operating in accordance with the required standards and meeting the relevant requirements and expectations.

Background

Sandoz explained that Omnitrope (somatropin) was indicated for the treatment of infants, children and adolescents with growth disturbance due to, or associated with, various causes, and infants, children and adolescents diagnosed with Prader-Willi syndrome. It was also used as replacement therapy in adult patients with pronounced growth hormone deficiency. A copy of the Omnitrope SPC was provided.

There were three strengths of Omnitrope: 5mg, 10mg and 15mg. Omnitrope patients were currently provided with a starter pack that contained the following:

- SurePal Pen 5 device OR SurePal Pen 10 device OR SurePal Pen 15 device (the SurePal device was a reusable self-injection pen designed to support the daily administration of Omnitrope. The 5, 10 and 15 devices supported administration of the 5mg/1.5ml, 10mg/1.5ml and 15mg/1.5ml solutions for injection respectively).
- BD Microfine – 5mm pen needles.
- BD Needle safe clip.
- Sharps bin.
- Alcohol medical wipes.
- SurePal 5mg, 10mg, 15mg, How to use leaflet and FAQs respectively.
- 5mg, 10mg, 15mg starter kit carton respectively.
- How to use video leaflet.

All patients prescribed Omnitrope would receive a starter pack at treatment initiation. Sandoz offered the starter pack via a package deal at one price that included the medicine (Omnitrope), the device and the offer of additional homecare support, such as dispense and delivery and nurse device training, if required.

Prior to withdrawal in April 2022, a cool bag was also included in a starter pack. The starter pack therefore included an insulated cool bag containing six cool packs in addition to the items described above. Sandoz offered the starter pack with a cool bag in it to patients, as explained in the previous paragraph.

Sandoz further explained that Omnitrope was a 'cold chain' medicine. It should be stored and transported refrigerated at a temperature of 2˚C – 8˚C (SPC, Section 6.4). The cool bag assisted patients in transporting their medicine at the required temperature. Initially, the rationale for providing the cool bag was to assist patients taking home their first dose from hospital. Over time, however, it became clear that patients might wish to transport their medicine in other circumstances, including, for example, travelling to and from further hospital visits, travelling between parents' homes where a child's parents were separated, or travelling for work or leisure.

Sandoz provided the Authority with a physical cool bag.

Sandoz stated that the withdrawal of the cool bag was communicated via a briefing document internally and a subsequent template email was provided to communicate this externally on a reactive basis only. Copies were provided.

Clause 19.1

Sandoz highlighted that the cool bag, as part of the starter pack, was provided to the patient after the decision to prescribe Omnitrope had been made. The cool bag was not provided to health professionals or other relevant decision makers in connection with the promotion of Omnitrope or as an inducement to prescribe. The supplementary information to Clause 19.1 stated that Clause 19.1 did not prevent the offer of package deals. Therefore, Sandoz considered that there had been no breach of Clause 19.1.

Clause 19.2

In 2022 the cost of the cool bag to Sandoz was net £13.66. The cost of the item had changed over the years from 13.91 EUR prior to 2019, to £13.66, thereafter.

Before removal from the starter pack, cool bags were included in the starter pack which was received by every patient prescribed Omnitrope. As explained above, they directly benefitted patient care by assisting patients to keep their medication at the correct storage temperature when being transported.

From the time that it was introduced, the starter pack was considered as one medical pack which, when provided as part of a package deal, was an acceptable benefit relevant to the medicine purchased, therefore, Sandoz believed that the value of the starter pack, as such, including the cool bag, was exempt from the Code limit for patient items (£10 from 2019).

After an internal assessment around governance of Sandoz's homecare programs/package deals, sufficient ambiguity was raised around the classification of the cool bag. Therefore, during the re-certification of the starter pack in 2022, a Sandoz final medical signatory flagged that the cool bag might be considered as a patient support item, and, if so, the price was above the net £10 upper limit for the cost of a patient support item as set out in the supplementary information to Clause 19.2. Due to the ambiguity around classification and the value of the item Sandoz made the decision to remove the cool bag from the starter pack in April 2022. Since the cool bag was not certified in 2022 because of its removal from the starter pack, the most recent certification for the starter pack that included the cool bag was in March 2020.

Sandoz noted that the complainant was clearly disappointed that the cool bags were withdrawn. When the cost of the cool bag was raised as a possible issue, it was Sandoz's view that the right thing to do was to remove it from the starter pack and withdraw the item. Before the withdrawal, Sandoz also investigated whether it would be possible to source an alternative cool bag which was less expensive but was unable to source a product that was considered of sufficient quality to replace the cool bags that were previously used.

Before withdrawing the cool bags, Sandoz also considered whether the withdrawal would have an impact on patient care. Although Sandoz believed that the cool bag was an appropriate item that benefited patient care, it concluded that it was not an indispensable item so the impact of withdrawal would not be unacceptable. Although Sandoz was aware that patients found cool bags useful items for support, and indeed their absence from the starter packs had been noted by patients and health professionals alike, Sandoz decided that withdrawal was a necessary action. Sandoz was currently assessing whether the company could re-introduce the cool bags with regard to the relevant Code provisions.

When considering the impact on patient care the withdrawal could have, Sandoz also reviewed how the cool bag was used by patients. When looking at the information Sandoz had on Omnitrope use, the company noted that, over time, the number of Omnitrope patients that got their first dose delivered to their home via homecare had increased. Third party homecare providers delivered Omnitrope to patients via cold-chain transport and once it was delivered to the patient, it could be kept in their fridge at home. Therefore, the need for patients to transport their first dose of Omnitrope had reduced and so not all patients necessarily needed to use the cool bag. As a result, Sandoz also considered whether the provision of cool bags in all starter packs was appropriate from an environmental perspective. Sandoz aimed to drive sustainability through its operations and so another factor that contributed to the decision to withdraw the cool bags was a desire to reduce wastage. But as explained above, Sandoz was currently assessing alternatives to provide the cool bag to patients in need taking into account sustainability aspects as well.

Sandoz accepted that the cost of the cool bag was greater than £10. If the Panel considered that the cool bag could not be provided as part of a package deal and/or that the £10 limit for items for patient support applied, then Sandoz admitted that Clause 19.2 had been breached.

Clause 5.1

Sandoz stated that it took its responsibility in following the Code very seriously. Controls were in place to ensure that external and internal requirements were duly followed. When the ambiguity around classification and the price of the cool bag was flagged by a medical signatory during the certification process in 2022, Sandoz decided to remove the cool bag from the starter

pack and entirely withdraw them. Currently, Sandoz was also conducting a compliance review on items and services provided through homecare to assess whether the approval process and oversight around these programs could be strengthened.

In Sandoz's view, even if the Panel took the view that there had been a breach of Clause 19.2, that should not automatically lead to a finding that high standards had not been maintained. Further, the actions taken by Sandoz as described above demonstrated the high standards applied by Sandoz once the ambiguity around classification of the cool bag was raised.

Clause 2

The actions of Sandoz in relation to this matter had not brought discredit upon, or reduced confidence in, the pharmaceutical industry. Sandoz took prompt action to withdraw the cool bags after a potential lack of compliance with the Code was raised.

Conclusion

Sandoz stated that it would welcome guidance from the PMCPA on the correct classification of the cool bags. If the Panel considered that the cool bag could not be provided as part of a package deal and/or that the £10 limit for items for patient support applied, then Sandoz conceded that Clause 19.2 had been breached. Whilst there might have been one breach, high standards had been maintained and the actions of Sandoz were not considered to have brought discredit on, or reduced confidence in, the pharmaceutical industry.

PANEL RULING

The Panel noted Sandoz's submission that the cool bag, as part of a starter pack, was provided to the patient after the decision to prescribe Omnitrope had been made and that it was offered via a package deal at one price that included the medicine (Omnitrope), the device, the cool bag and the offer of additional homecare support, such as dispense and delivery and nurse device training, if required. The Panel did not have before it the contract covering the package deal. The Panel noted that the decision was taken by Sandoz to remove the cool bag from the starter pack after an internal assessment around governance of Sandoz's homecare programs/package deals raised sufficient ambiguity around the classification of the cool bag and it was flagged during re-certification of the starter pack in 2022, that the cool bag might be considered as a patient support item.

The Panel noted that Sandoz consistently referred to the items within the package deal as a starter pack. The Panel noted that starter packs were described in the supplementary information to Clause 21.1 as small packs designed to provide sufficient medicine for a primary care prescriber to initiate treatment in such circumstances as a call out in the night and the provision of such packs were not permitted. In the Panel's view, it was clear that the items in the package deal referred to by Sandoz were not a starter pack as set out in the relevant supplementary information, they did not include a small medicines pack and the nature of the medicine/therapy area would not necessitate the need for urgent administration.

The Panel noted that up until 1 July 2021, the 2019 Code or previous Codes applied to the provision of the cool bag and between 1 July 2021 and April 2022, when the cool bags were withdrawn, the 2021 Code applied. In this regard, the Panel noted that when notified of the complaint, Sandoz was advised that previous versions of the Code might apply.

The Panel noted that Clause 19.1 of the 2021 Code stated that 'No gift, pecuniary advantage or benefit may be supplied, offered or promised to health professionals or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, subject to the provisions of Clauses 10.4 and 19.2'. The supplementary information to Clause 19.1, Package Deals, stated, amongst other things, that 'Clause 19.1 does not prevent the offer of package deals which are commercial arrangements whereby the purchase of a particular medicine is linked to the provision of certain associated benefits as part of the purchase price, such as apparatus for administration, the provision of training on its use or the services of a nurse to administer it. … The transaction as a whole must be fair and reasonable and the associated benefits must be relevant to the medicine involved'. The requirements of Clause 18.1 of the 2019 Code were closely similar to Clause 19.1 of the 2021 Code including in relation to package deals.

The Panel noted that Clause 19.2 of the 2021 Code stated that health professionals may be provided with materials and items for patient support which are to be passed on to patients, the details of which must be appropriately documented and certified in advance as required by Clause 8.3. The items provided must be inexpensive and directly benefit patient care. They may bear the name of the company providing them but must not be product branded unless the name of the medicine is essential for the correct use of the item by the patient. The supplementary information describes an 'inexpensive' item for patient support to mean one that has cost the donor company no more than £10, excluding VAT. The perceived value to the health professional and the patient must be similar.

The Panel noted that patient support programmes were not a discrete activity classification under the 2021 Code. They were, however, referred to in Clause 18.2 of the 2019 Code which stated that health professionals may be provided with items which are to be passed on to patients **and which are part of a formal patient support programme**, the details of which have been appropriately documented and certified in advance as required by Clause 14.3. The items provided must be inexpensive and directly benefit patient care. They may bear the name of the company providing them. They must not be given out from exhibition stands. They must not be given to administrative staff unless they are to be passed on to a health professional. The relevant supplementary information defined inexpensive as one that cost the donor company no more than £10 plus VAT.

Whilst the Panel noted that Clause 18.2 of the 2019 Code only referred to items being provided as part of a formal patient support programme, Sandoz did not state that the cool bag was part of such a formal programme. Clause 19.2 of the 2021 Code did not require items to be provided as part of a formal support programme. Nonetheless, in both instances, the item to be provided to health professionals to be passed on to patients was required to be inexpensive. In view of the similarity in the requirements of the 2019 and 2021 Codes, in this regard, and the narrow nature of the allegation, the Panel decided to consider the case under the 2021 Code.

The Panel noted that the complaint concerned the cool bag alone rather than the broader offerings within the package deal. With regard to the cool bag itself, the Panel considered that, in general terms, the Code did not prohibit such an item being offered as part of a package deal. In relation to the supplementary information to Clause 19.1, the only requirement was that the benefit was relevant to the medicine and the package overall was fair and reasonable. The Panel noted that Omnitrope had to be stored at 2-8˚C, irrespective of whether the cartridge had

been opened or not, and the Panel therefore considered that a cool bag was relevant to the use of the medicine.

The Panel noted, however, that the cool bag differed from the other items in the package deal in that ownership of the cool bag passed directly to the patient/carer and although directly relevant to the medicine, was potentially of general long-term utility. The Panel considered that given the ultimate recipients, patients and carers, it was particularly important to ensure that items for patient support provided by pharmaceutical companies as part of a package deal complied with all the relevant requirements of the Code. In the Panel's view, such provision had to comply with both the supplementary information to Clause 19.1, Package Deals, and Clause 19.2, including the financial limit. To allow otherwise would permit companies to circumvent the requirements of Clause 19.2, including the financial limit in the Code in relation to the provision of physical items for patients and carers for patient support when provided as part of a package deal. In this regard, the Panel noted that it was not unacceptable for a package deal to consist of one item.

The Panel noted the broad nature of the complainant's allegation querying whether the provision of the cool bag was in accordance with the Code. In relation to the package deal provisions, and noting its comments above, the Panel noted that the complainant bore the burden of proof and considered that they had not provided any evidence to establish that the offer of the cool bag as part of the package deal overall was not fair and reasonable, nor that the cool bag was not relevant to the medicine. Indeed, both parties appeared to agree that the cool bag was relevant to the medicine. Accordingly, the Panel ruled **no breach of Clause 19.1 of the 2021 Code**.

The Panel noted its comments above about the applicability of the supplementary information to Clause 19.1 and Clause 19.2 in relation to items for patient support and package deals. The Panel noted that Sandoz's response indicated that it had originally considered that items provided under a package deal were exempt from the cost limit set within the Code for patient items which had been queried by a signatory. The Panel noted the requirements for Clause 19.2 of the 2021 Code and its supplementary information, as set out above. The Panel noted that, according to Sandoz, the cost of the cool bag had changed over the years from 13.91 EUR, prior to 2019, to £13.66, thereafter, and in 2022 the cost of the cool bag to Sandoz was net £13.66. Noting that this exceeded the cost limit of £10 referred to in the supplementary information to Clause 19.2, the Panel ruled **a breach of Clause 19.2 of the 2021 Code** in relation to its provision from 1 July 2021.

The Panel noted the complainant's view that the cool bag was an essential item for the correct use of the medicine and that Sandoz should consider supplying a cheaper version rather than leaving patients without care. In its response Sandoz stated that it had considered the impact on patient care before withdrawing the cool bags and had concluded that while they were an appropriate item that benefited patient care, they were not an indispensable item so the impact of withdrawal would not be unacceptable. In the Panel's view, the cool bags were part of a discretionary commercial arrangement and, as such, there was no duty on Sandoz to provide them.

The Panel noted that the complainant had queried why Sandoz had not communicated the withdrawal of the cool bags to health professionals and patients rather than leaving patients without care. The complainant referred to hearing about the cessation of supply of the cool bags from patients and that, subsequently in an interaction with a Sandoz representative, they

had been told that the supply of cool bags had been stopped because they were too expensive and the company considered they were in breach of PMCPA rules. The Panel noted Sandoz's submission about the internal governance review of its homecare programs and package deals, its assessment of the impact on patients of ceasing to supply the cool bags and copies of internal and reactive external communications in relation to this decision.

According to Sandoz, once it became aware of the ambiguity of the status of the cool bag and the potential for its cost to be in breach of the Code, the company had investigated the possibility of sourcing a cheaper variant but was not able to source an alternative cool bag of sufficient quality. The Panel noted that Sandoz's assessment of the impact on patient care undertaken prior to the withdrawal had indicated that an increasing number of patients received their first dose of Omnitrope via a third party temperature-controlled homecare delivery service and therefore that the need for patients to transport their first dose in a cool bag from the hospital to their home had reduced. The Panel noted that sustainability concerns had also been a factor in Sandoz's decision to withdraw the cool bags from the package deal.

Turning to the communication of this decision, the Panel noted that Sandoz had briefed its sales team and had provided an email template for representatives to use externally with health professionals, however, this was for reactive use only in response to enquiries. The Panel had no information before it relating to communication between the company and purchasers of the package deal. It appeared that Sandoz had not communicated proactively with either purchasers of the package deal about its decision to withdraw the cool bags or health professionals prescribing Omnitrope. It appeared that the complainant was initially informed by their patients. In the Panel's view, it appeared that Sandoz had not acted transparently in relation to the withdrawal of the cool bags, as demonstrated by its failure to communicate proactively with relevant stakeholders. In this regard, the Panel considered that Sandoz had failed to maintain high standards and **a breach of Clause 5.1** was ruled.

The Panel considered that the rulings of breaches adequately covered the matters raised and an additional ruling of a breach of Clause 2 would be disproportionate in the particular circumstances of this case. A ruling of a breach of Clause 2 was used as a sign of particular censure and reserved for such use. The Panel, on balance, ruled **no breach of Clause 2**.

Complaint received **18 August 2022**

Case completed **22 August 2023**