CASE AUTH/2451/11/11

MERCK SERONO v SANDOZ

Omnitrope patient support items

Merck Serono complained about a soft toy, water bottle and backpack offered as patient support items by Sandoz in relation to its product Omnitrope (somatropin).

Merck Serono did not consider that the items were related to the treatment of growth hormone deficiency. Merck Serono was unable to find scientific evidence that concluded that the items, either individually or as part of a package, were linked to improved adherence. Merck Serono was concerned that the backpack cost more than £6.

The detailed response from Sandoz is given below.

The Panel had to decide whether the provision of each item (the backpack, soft toy and water bottle) individually met the requirements of the Code regarding patient support items. The Panel considered that the supplementary information indicated that an acceptable patient support item need not necessarily be medical in nature but should be supplied for a clear specific purpose related to the disease in question.

The Panel recognised the difficulties with a child adhering to a treatment regime that involved daily injections. The Panel noted that the parent/carer testimonies discussed the use of rewards, or comforters. None referred to the soft toy at issue. The Panel noted the letters from endocrine specialists and considered that, on balance, these supported Sandoz's view that a toy such as the one at issue might be used as a comforter in the initial stages of growth hormone treatment injections to aid compliance. It could be argued that providing a soft toy for a child to cuddle when having an injection when such treatment was required every day would directly benefit patient care. On balance no breach of the Code was ruled.

Whilst accepting that hydration promoted good health, the Panel did not consider that provision of the water bottle as a patient support item was directly related to the condition under treatment, and ruled a breach of the Code in that regard.

With regard to the rucksack the Panel noted that Omnitrope had to be stored at 2-8˚C irrespective of whether the cartridge had been opened or not. The rucksack would not be appropriate for storing Omnitrope. The Panel was thus not satisfied that the rucksack in question was related to the treatment of growth hormone deficiency or otherwise directly benefitted patient care. A breach was ruled.

The Panel noted that the unit cost for each of the items at issue was £6 or less plus VAT and thus inexpensive as defined by the Code and no breach was ruled.

Merck Serono Limited complained about a soft toy, water bottle and backpack offered as patient support items by Sandoz Ltd in relation to its product Omnitrope (somatropin). Omnitrope was indicated for the treatment of a number of growth disturbances in infants, children and adolescents and hormone replacement therapy in adults.

The items in question were also referred to in Omnitrope promotional material (including exhibition stand posters, a display unit containing the items, leavepieces and a video).

COMPLAINT

Merck Serono alleged that Sandoz had breached Clause 18.2 of Code, the supplementary information to which stated 'Items which may be made available to patients … should be inexpensive and related to either the condition under treatment or general health. No item for use by patients must be given for the purpose of encouraging patients to request a particular medicine'.

Merck Serono did not consider that the items in question were related to the treatment of growth hormone deficiency. It had asked Sandoz to withdraw the items, all references to them and not to distribute them to patients on initiation of Omnitrope. In response, Sandoz claimed that the items supported adherence and were related to the condition under treatment and general health, therefore did not breach Clause 18.2.

Merck Serono had reviewed the references provided and undertaken its own literature search and was unable to find scientific evidence which concluded that the items, either individually or as part of a package, were linked to improved adherence.

Sandoz also stated '… the backpack aids adherence by allowing the patient to store and transport their GH [growth hormone] and supporting items from one destination to another, including repeat visits, ensuring that they have all the items they need to perform each injection on a daily basis regardless of their location'.

Merck Serono was concerned that the backpack in question (which did not have a built in cool bag component and would definitely cost more than £6) was used to transport Omnitrope which, according to its summary of product characteristics (SPC), required refrigeration. In addition, no cost data had been provided by Sandoz in response to Merck Serono's request. Merck Serono did not agree with the Sandoz response.

Merck Serono was not aware that other companies were providing these items as stated by Sandoz. No

other growth hormone company was demonstrating or referring to these items at the European Society for Paediatric Endocrinology conference which was held in Glasgow in September 2011.

RESPONSE

Sandoz explained that the complaint from Merck Serono and further correspondence had specifically related to three patient support items, the soft toy (termed the comforter or soft dog by Sandoz), the water bottle and backpack. There had been no written correspondence sent to Sandoz which related to '… promotional materials referring to these patient support items including the exhibition stand posters, a display unit containing the items, leavepieces and a video'. Sandoz therefore considered that it had not had an opportunity to discuss these items through inter-company dialogue so it would just focus on the specific items in question.

The patient support package (collectively known as the Sproutz) offered to patients prescribed Omnitrope comprised of support items which were designed to aid adherence and general health. The backpack, comforter (soft dog) and water bottle formed an integral part of the overall support package.

Growth hormone deficiency was a chronic condition and required patients to inject growth hormone daily. Sandoz submitted that adherence and concordance to growth hormone therapy could be poor and it had been suggested that non-adherence might be as high as 36% to 49%. The many causes of non-adherence fell into two overlapping categories, intentional and unintentional. Intentional non-adherence could be associated with perceptual barriers, for example patients' beliefs and preferences, and unintentional non-adherence with practical barriers, for example capacity and resources. It was these factors that influenced a patient's ability to adhere to the agreed treatment. Published guidelines recognised that interventions might help with non-adherence and while Sandoz appreciated that these interventions were not solely material or physical items, the concept that such items might improve adherence was well recognised in the field of endocrinology. A number of letters from endocrine key opinion leaders relating to this point were provided by Sandoz.

The comforter was an intervention provided to remove perceptual barriers to daily growth hormone treatment as the support item was designed to comfort and reduce the fear associated with daily injections and thus aimed to limit intentional non-adherence. The rucksack was designed to reduce the likelihood of those who were unintentionally non-adherent by removing the practical barriers related to growth hormone treatment as it provided patients with somewhere to store and transport their medication including the supplied cool bag, a validated cool bag required to store the medicine between 2-8˚C. The water bottle, while less related to adherence, supported the Water in School is Cool Campaign that was appointed by the Department of Health to research and develop the Food in Schools Water Provision guidance. This initiative specifically stated that 'drinking regularly throughout the day is vital not only for healthy bladders and bowels, but also for general health and wellbeing'. Sandoz therefore considered that the availability of the water bottle for patients being treated with Omnitrope gave patients the ability to keep hydrated throughout the day and ultimately supported their general health.

Sandoz also referred to some statements which had been posted on The Child Growth Foundation website by parents/carers of children receiving growth hormone replacement therapy. Sandoz submitted that these demonstrated the fear and pain associated with the growth hormone injections and the interventions parents used to help their child comply with treatment:

> 'Hi …, our son is nearly 4 and has been on treatment since May. Initially it was horrendous as we used the easy pod and he used to scream every night. We tried to give him it in his sleep as we are all distressed but then he was having trouble sleeping. We were told to hold him down but we couldn't cope so stopped treatment for a week and chose another device, Genotropin. We are now in a routine and he has this before his bath and we did give him a toy every night (cheap toys from pound shop) and this did the trick. I never thought we would be where we are now and even questioned if we should continue. But what choice do we have. … has grown 5cm in this short time. Keep with it. If you want any further advice or to talk via email I will happily forward my email. It may be worth considering another device as I think sometimes association of pain with the initial device is a hurdle. There is one device without a needle. We inject … in his bottom every night as his legs seemed to feel the pain more plus if your partner holds him they cannot see what is happening. …'.
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> 'Hi, my daughter although older (8yrs) has a special injection sweet jar, where after her injection she gets to choose 1 sweet, this stopped the tears almost immediately!! We think of it as reward rather than bribery and it works for her, also we involve her in choosing the sweets and make it very clear that they are for brave children. Good luck anything is worth a try, …'
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> 'Hi my son is now 8 (MPHD) and we started injections at 6. We chose the zomacton pen as it was needle free. Initially it caused problems - some bruising and bleeding and he was terrified of the injections - screamed and refused to cooperate. As a result for over a year we injected in his sleep. This worked for us as it was less stressful and I am pleased to say he is now over 50th centile, he started below the graphs. Now he self-injects every night and only asks for me to do it if he is unwell. I wanted to write because we certainly found it really difficult at first but he is now growing and self-injecting. We did not put any pressure on him we felt he had enough to cope with medically although we were very open and he took the decision when to start self-injecting. Hang in there it will get easier.'

Sandoz submitted that one further key point was that the patient support items should only be given to patients once they had been prescribed Omnitrope, they were not to be used as an incentive for the patient to choose Omnitrope over other available treatments. This decision should be based on the needs of the patient identified by the prescribing clinician after discussion with the parent or guardian as outlined in the National Institute for Health and Clinical Excellence (NICE) Guidance T1A88. In addition, Sandoz stated that it had evidence to show that similar items were provided by other growth hormone companies; a number of photographs of items on exhibition stands were provided.

Sandoz considered that the patient support items offered to patients that had been prescribed Omnitrope were related to the condition under treatment or general health as they provided the parent or carer with items to help ensure that their child adhered to their treatment. Sandoz considered that the materials in question were not in breach of Clause 18.2. As a company it was committed to supporting patients and through interaction and guidance from clinicians in this field considered that if these items were withdrawn by pharmaceutical companies this would have a detrimental effect on the overall treatment of children.

In response to the request for further information Sandoz provided copies of materials referring to the three items at issue, the backpack, soft toy and water bottle. The company stressed again that it did not consider that it had an opportunity to discuss the exhibition stand panels, leavepieces and DVD through inter-company dialogue with Merck Serono as these items were only raised in the correspondence to the PMCPA and not to Sandoz.

The patient support package offered by Sandoz was only given to patients once they have been prescribed Omnitrope. The decision of which growth hormone to use was based on the needs of the patient identified by the prescribing clinician after discussion with the parent or guardian as outlined in the NICE Guidance T1A88. The Omnitrope support package was subsequently provided to patients either by the nurse from the homecare company or by the health professional, primarily the endocrine specialist nurse.

PANEL RULING

The Panel noted that Clause 18.2 stated that health professionals may be provided with items which were to be passed on to patients and which were part of a formal patient support programme, the details of which had been appropriately documented and certified in advance as required by Clause 14.3. The items provided must be inexpensive and directly benefit patient care. The supplementary information to Clause 18.2 Patient Support Items stated, *inter alia*, inexpensive meant one costing the donor company no more than £6 excluding VAT. Examples were included such as a pedometer as part of a scheme to encourage exercise, perhaps for obese patients.

Merck Serono referred to the supplementary information to Clause 18.2 Items Given to Patients which stated that items which may be made available to patients, for example, by completing a request card enclosed with a medicine, should be inexpensive and related to either the condition under treatment or general health. Sandoz described the items as patient support items but also referred to their acceptability in relation to items given to patients and general health.

When responding to the request for additional information Sandoz was clear that the items at issue were patient support items, referring to them as such three times. The Panel considered them accordingly in relation to the requirements for patient support items.

The Panel had to decide whether the provision of each item (the backpack, soft toy and water bottle) individually met the requirements of the Code regarding patient support items. The Panel considered that use of a pedometer as part of a scheme to encourage exercise, one of the examples in the supplementary information of an acceptable patient support item, indicated that such items need not necessarily be medical in nature but should be supplied for a clear specific purpose related to the disease in question. The Panel had not been supplied with all of the material describing the patient support programme and its use other than photographs of some of the materials, a poster, reply paid card and a pen training DVD, and one of each of the three items at issue.

The Panel noted from Sandoz's submission that the items at issue in this case, the backpack, soft toy and water bottle, formed part of the overall support package. It appeared that Sandoz also supplied a cool bag about which there was no complaint.

The Panel recognised the difficulties in ensuring that a child adhered to a treatment regime that involved daily injections. The Panel noted that the parent/carer testimonies provided by Sandoz discussed the use of rewards, including sweets and toys as rewards or comforters. None referred to the soft toy at issue. The Panel noted the letters from endocrine key opinion leader specialists provided by Sandoz. The Panel considered that, on balance, these supported Sandoz's view that a toy such as the one provided by Sandoz might be used as a comforter in the initial stages of treatment with growth hormone injections to aid compliance in children. It could be argued that providing a soft toy for a child to cuddle when having an injection when such treatment was required every day would directly benefit patient care. On balance no breach of Clause 18.2 was ruled.

In relation to the provision of the water bottle, the Panel noted that a letter from a clinical nurse specialist in endocrinology stated that hydration was essential to promote good health 'especially when [a child was] growth hormone deficient'. Sandoz had not submitted any clinical evidence that hydration was particularly important in patients with growth hormone deficiency. Whilst accepting that hydration

promoted good health, the Panel did not consider that provision of the water bottle as a patient support item was directly related to the condition under treatment, and ruled a breach of Clause 18.2 in that regard.

With regard to the rucksack the Panel noted that Omnitrope had to be stored at 2-8˚C irrespective of whether the cartridge had been opened or not. The rucksack would not be appropriate for storing Omnitrope. It appeared that Sandoz provided a cool bag for that purpose. The Panel was thus not satisfied that the rucksack in question was related to the treatment of growth hormone deficiency or otherwise directly benefitted patient care. A breach of Clause 18.2 was ruled.

The Panel noted that Sandoz had submitted invoices that indicated that the unit cost for each of the items at issue was £6 or less plus VAT and was thus inexpensive as defined by the supplementary information to Clause 18.2. No breach of Clause 18.2 was ruled in that regard.

The Panel noted that Merck Serono had referred to Omnitrope promotional material (including exhibition stand posters, a display unit containing the items, leavepieces and a video) which contained reference to the patient support items at issue. Sandoz submitted that these items were not raised during inter-company dialogue, so did not refer to them in its response to the Authority. The Panel noted that the rulings of breaches of the Code regarding the patient support items above would apply to any other material that referred to the water bottle or rucksack. The question of whether or not inter-company dialogue had taken place was thus irrelevant in this regard.

Complaint received **3 November 2011**

Case completed **17 January 2012**