

SANDOZ v MERCK SERONO

Patient support item

Sandoz alleged that a rucksack with a removable cool bag, given as a patient support item by Merck Serono in association with Saizen (somatropin – a growth hormone used, *et al*, in children) was not related to the treatment of growth hormone deficiency and did not otherwise directly benefit patient care. Sandoz noted that Merck Serono had successfully complained about a rucksack it had provided (Case AUTH/2451/11/11) but then continued to use a similar item itself.

Merck Serono's detailed response is below.

The Panel noted that the rucksack was supplied with a self-contained cool bag which was attached to the outside of the rucksack. The Panel disagreed with Merck Serono's submission that the rucksack and cool bag constituted a single item; the cool bag had its own carrying handle and could be used independently.

The Panel noted Merck Serono's submission that the rucksack was required to contain additional equipment such as needles and a sharps bin; the company had placed a 0.45 litre sharps bin in the sample rucksack provided to the Authority. Although in the Panel's view the sharps bin provided was larger than required for weekend/holiday use, there was still plenty of room left in the rucksack for a child to pack almost all he/she would need for an overnight stay. The rucksack had a capacity of at least 10 litres. The cool bag had a capacity of approximately 2.5 litres and so the Panel queried whether it could have been designed to hold a small sharps bin, needles and the Saizen administration device.

The Panel considered that the rucksack and cool bag were two separate items. Reconstituted Saizen had to be stored at 2° - 8°C. The rucksack would not be appropriate for storing Saizen and was very much larger than needed to carry needles and a small sharps bin. The Panel did not consider that the rucksack was related to the treatment of growth hormone deficiency or otherwise benefited patient care. A breach of the Code was ruled.

During the consideration of this case the Panel was very concerned to note that although Merck Serono had successfully complained about the provision of rucksacks as patient support items by Sandoz, it had continued to provide rucksacks of its own despite inter-company dialogue. The Panel considered that such conduct demonstrated a cynical disregard for upholding the Code and the principles of self regulation, and requested that Merck Serono be advised of its concerns in this regard.

Sandoz Ltd complained about a Saizen (somatropin) patient support item provided by Merck Serono

Limited. Saizen was indicated for, *et al*, growth failure or disturbance in children and adolescents. The item at issue was a rucksack with a removable cool bag.

COMPLAINT

Sandoz referred to Case AUTH/2451/11/11 in which Merck Serono complained about the rucksacks which Sandoz had provided to patients being treated with its product Omnitrope (somatropin). Sandoz was ruled in breach of the Code. Since then Sandoz had been in inter-company dialogue with Merck Serono regarding the withdrawal of Merck Serono's rucksacks. Sandoz believed the continued use of the rucksacks breached Clause 18.2. Merck Serono successfully complained about a patient support item provided by Sandoz and had then continued to use a similar item itself. Sandoz alleged that such behaviour showed a cynical disregard for the Code and brought discredit to the industry. Merck Serono had claimed that as its rucksack had a built-in cool bag it did not breach Clause 18.2.

Sandoz noted that the cool bag could be detached from the rucksack leaving two separate items, a cool bag and a rucksack. Until the ruling in Case AUTH/2451/11/11, Sandoz also provided a cool bag and a rucksack, the only difference between the Merck Serono and Sandoz systems was that the cool bag supplied by Sandoz did not attach to the outside of the rucksack by Velcro but went inside the rucksack.

Sandoz submitted that material provided by Merck Serono demonstrated that both the medicine and device were carried in the cool bag and not the rucksack. As was applicable to the Sandoz system, the rucksack provided by Merck Serono was not appropriate for storing the medicine and a cool bag was provided for this purpose. Consequently there was no requirement for a separate rucksack.

Sandoz thus failed to understand how the rucksacks provided by Merck Serono did not also breach Clause 18.2 as they were not related to the treatment of growth hormone deficiency and did not otherwise directly benefit patient care.

RESPONSE

Merck Serono submitted that in Case AUTH/2451/11/11 one of the decisions the Panel made was whether the provision of the items in question from Sandoz individually met the requirements of the Code with regard to patient support items. Merck Serono submitted that its rucksack, which had an integral cool bag compartment, constituted a single individual item, was part of a patient support programme, was supplied for a clear and specific

purpose related to the disease, was inexpensive and directly benefited patient care, and as such did not breach Clause 18.2.

Merck Serono stated that Saizen had to be carried in a temperature controlled environment with one of three devices for administration, cool.click, easypod or one.click, together with ancillary equipment such as needles and a sharps bin.

Merck Serono submitted that the rucksack ensured that Saizen was maintained at a temperature of between 2° - 8°C when travelling for up to four hours in the cool bag section which was securely attached through two clips. The cool bag could be detached for ease of packing but both parts were designed to be used together with the body of the rucksack containing the additional equipment. A sharps bin was included in the rucksack provided as an example of how this section would be used.

Adherence was critical for successful treatment with growth hormone. The rucksack was to be used when a child slept away from home, either at weekends or on holiday, to maximise adherence and as such was directly related to the treatment of growth hormone deficiency. The rucksack was part of a wider patient support programme which included patient support nurses, a telephone helpline and an online resource providing support through a website.

Merck Serono submitted that the rucksack was an individual item which helped maximise adherence with growth hormone treatment, was part of a formal patient support programme and therefore complied with Clause 18.2.

PANEL RULING

The Panel noted that Clause 18.2 stated that health professionals might 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, Items Given to Patients, noted that the items should be, *et al*, related to either the condition under treatment or general health.

The Panel noted that the rucksack was supplied with a self-contained cool bag which was attached to the

outside of the rucksack by two clips and strips of Velcro. The Panel disagreed with Merck Serono's submission that the rucksack and cool bag constituted a single item supplied for a clear and specific purpose related to the disease. The cool bag had its own carrying handle and could be used independently.

The Panel noted Merck Serono's submission that the rucksack was required to contain additional equipment such as needles and a sharps bin; the company had placed a 0.45 litre sharps bin in the sample rucksack provided to the Authority. Although in the Panel's view the sharps bin provided was larger than required for weekend/holiday use, there was still, nonetheless, plenty of room left in the rucksack for a child to pack almost all he/she would need for an overnight stay away from home. The rucksack had a capacity of at least 10 litres. In the Panel's view this was not commensurate with the size of the sharps bin required. The cool bag had a capacity of approximately 2.5 litres and in that regard the Panel queried whether it alone could not have been designed to hold a small sharps bin, needles and the Saizen administration device.

The Panel considered that the rucksack and cool bag were two separate items. Reconstituted Saizen had to be stored at 2° - 8°C. The rucksack would not be appropriate for storing Saizen and was very much larger than needed to carry needles and a small sharps bin. The Panel did not consider that the rucksack was related to the treatment of growth hormone deficiency or otherwise benefited patient care. A breach of Clause 18.2 was ruled.

During the consideration of this case the Panel was very concerned to note that although Merck Serono had successfully complained about the provision of rucksacks as patient support items by Sandoz (Case AUTH/2451/11/11), it had continued to provide rucksacks of its own despite inter-company dialogue. The Panel considered that such conduct demonstrated a cynical disregard for upholding the Code and the principles of self regulation, and requested that Merck Serono be advised of its concerns in this regard.

Complaint received **16 April 2012**

Case completed **23 May 2012**