

TEVA v PHARMASURE

Provision of a chocolate hamper

The Medicines and Healthcare products Regulatory Agency (MHRA) referred a complaint to the PMCPA that it had received from Teva UK about the provision of a chocolate hamper to a group of health professionals by a representative from Pharmasure.

Teva explained that, in December, its meeting for a clinical team at a named hospital, was briefly interrupted by a representative from Pharmasure dropping off a substantial high street chocolate hamper. The gift to the team was on behalf of Pharmasure.

Teva alleged that the gift was inappropriate as it was not inexpensive or relevant to the practice of medicine or pharmacy.

The detailed response from Pharmasure is given below.

The Panel noted Pharmasure's submission that its representative had promoted both supplements and prescription only medicines (POMs) to the fertility unit up until November 2017. When the chocolate hamper was delivered he/she solely promoted medicines to the unit but none were discussed during the visit. The Panel disagreed with Pharmasure's submission that this meant that the chocolate hamper was not provided in connection with the promotion of any medicines.

The Panel considered that whilst promotional activity in relation to supplements was not within the scope of the Code, if a representative promoting supplements called on the same health professionals to promote medicines then the Code would apply.

The Panel noted that a representative whose role was to promote medicines had given a chocolate hamper to a group of health professionals. The Code prohibited the provision of items to health professionals save for very limited circumstances. The chocolate hamper did not fit within the exemptions set out in the Code.

The Panel noted Pharmasure's submission regarding the relevance of UK law as at the time the company was not covered by the Code.

The Panel could only rule in relation to the Code. The prohibitions in the Code regarding the provision of items to health professionals etc although more restrictive than UK law, were not inconsistent with those requirements which allowed items that were inexpensive and relevant to the practice of medicine or pharmacy. Given the requirements of UK law the Panel did not consider it was unreasonable to rule that the provision of the chocolate hamper was unacceptable and in breach of the Code.

The Panel noted Pharmasure's estimation that representatives who promoted medicines had given chocolate hampers to up to 15 fertility units. Extra care and guidance was required when representatives promoted medicines and something not covered by the Code such as supplements. The Panel considered that the provision of the chocolate hamper by the representative who promoted medicines meant that Pharmasure had not maintained high standards. A further breach of the Code was ruled. The Panel considered that whilst it could be argued that the representative had not maintained a high standard and had failed to comply with the Code, this was due to the company's arrangements and in that regard the matter was covered by its ruling above. No further breach was ruled.

The Panel noted its ruling above regarding the provision of the hamper and considered that the arrangements brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel was concerned about the arrangements, however it noted that when the chocolate hampers were given the company was not on the list of non-member companies that had agreed to comply with the Code and accept the jurisdiction of the PMCPA. In the exceptional circumstances of this case, and on balance, the Panel decided not to report Pharmasure to the Code of Practice Appeal Board.

The Medicines and Healthcare products Regulatory Agency (MHRA) referred a complaint to the PMCPA that it had received from Teva UK Ltd about the provision of a chocolate hamper to a group of health professionals by a representative from Pharmasure. The MHRA forwarded the complaint to the Authority and the Authority invited Pharmasure to join the non-members' list and to respond to the complaint which it duly did.

COMPLAINT

Teva explained that on 14 December, two of its staff conducted a lunchtime presentation to a clinical team at a named private hospital. Teva provided details of those who had attended; they were all nurses, health professionals or clinical scientists. The meeting was briefly interrupted by the unscheduled arrival of a named representative from Pharmasure. The Pharmasure representative had visited only to drop off a substantial high street chocolate hamper for the team, which was handed over to the fertility centre manager. The gift was clearly not given in any personal capacity but on behalf of Pharmasure as it contained a compliments slip from the company.

Teva considered that the gift was inappropriate as it was not inexpensive or relevant to the practice of medicine or pharmacy.

When writing to Pharmasure to advise it of the complaint, the Authority asked it to bear in mind the requirements of Clauses 2, 9.1, 15.2 and 18.1 of the Code.

RESPONSE

In mitigation, Pharmasure firstly submitted that the majority of its promotional activity was in relation to supplements which fell outside the jurisdiction of the Code and where there was no equivalent constraint as to the giving of gifts. The chocolate hampers were intended for customers of these supplement products. Pharmasure explained that it took on a dedicated team of supplements sales people in January/February 2017. The company's medical representatives also sold Inofolic and subsequently Condensyl (both supplements) until November 2017, when they focussed solely on prescription only medicines (POMs).

Secondly, Pharmasure noted that each hamper cost £37.50 (inc VAT) and would have comprised little more than a festive treat for each member of a team of 10. However, the company accepted that the gift was not relevant to the practice of medicine and might not have been an appropriate expression of Christmas spirit.

Pharmasure stated that the representative had visited the hospital in question to follow up on a nurse ultrasound training discussion with one of the nurses and to organise a meeting with the team at the unit. He/she also took the opportunity to drop off the chocolate hamper for the team; it was intended to be shared between the 10 or so personnel at the unit as a Christmas treat. No other items were provided. The box contained a printed Pharmasure compliments slip, upon which was written 'Merry Christmas'.

Pharmasure stated that it purchased 74 hampers which were intended for employees, suppliers and the supplements sales team. Between 4 and 6 hampers were given to each sales person which erroneously included the medical representatives. Pharmasure estimated that its medical representatives gave hampers to up to 15 fertility units.

Pharmasure submitted that it was embarrassed by the incident and it took the procedural implications of it seriously. The company acknowledged the breach and that on the prescription side of the business there was not an adequate control system in relation to these gifts.

Pharmasure stated that it had begun a full review and overhaul of its promotional processes which it would complete within 3 months; it would not engage in further promotional activity during that period. The company undertook to establish a sound compliance approval system for promotional activity linked to its medicines in order to avoid breaches of the Code in future.

In response to a request for further information Pharmasure submitted that its POM sales representatives had sold supplements to fertility units for several years as well as promoting POMs. As Pharmasure's business was focussed on fertility treatment it was difficult for its sales team to always avoid promoting supplements in units where they might also promote POMs.

Pharmasure submitted that in November 2017 it formally asked its POM representatives to cease promoting supplements, leaving that responsibility to its supplements sales team. The reality, however, was that there had to be a transition period where the POM sales team continued to respond to queries and follow-ups for supplements until the supplements team were established in these units.

Pharmasure accepted that the representative at issue was officially a POM representative when the chocolate hamper was given. However, Pharmasure submitted that when the chocolate hamper was delivered, no products were discussed and the representative had promoted supplements to this unit during the previous year.

Pharmasure did not consider that the giving of the chocolate hamper brought discredit upon or reduced confidence in the pharmaceutical industry. None of the examples in the supplementary information relating to Clause 2 applied to this complaint, except possibly 'inducement to prescribe'. Pharmasure stated, however, that it was highly unlikely that a few bars of chocolate would induce a fertility unit to change its prescribing of high value, specialised gonadotrophin products and, for this reason, it did not believe the last example applied in this instance. Pharmasure denied a breach of Clause 2.

Pharmasure agreed that high standards must be maintained at all times and when it reviewed the supplementary information to Clause 9.1 it considered that it had not promoted POMs in a way that was unsuitable or in bad taste and it denied a breach of that clause.

Pharmasure submitted that its representatives were trained to maintain high ethical standards; they acted with integrity, honesty and provided accurate, balanced information. The fact that the representative in question had recently officially changed responsibility from promoting supplements and POMs to promoting POMs only contributed to confusion on the day. In that respect, Pharmasure submitted that it might be considered that the provision of a gift, albeit modest, did not comply with the relevant requirements of the Code. Pharmasure noted that there was no supplementary information to Clause 15.2.

Pharmasure submitted that the chocolates were not provided in connection with the promotion of any medicines. The unit in question had been previously visited by the representative at issue many times in connection with supplements and the very recent change to his/her responsibility to promoting only POMs did not negate his/her history with the unit.

Pharmasure submitted that there was no reference to any product on the chocolates or given alongside the chocolates. None of the supplementary information to Clause 18.1 appeared to apply to small gifts of chocolates.

Pharmasure confirmed that the representative at issue was a POM representative and that he/she had promoted two supplements as well as three POMs to the particular unit in this case during 2017.

With regard to the other units that received the chocolate hamper, Pharmasure submitted that the same confusion applied but all units concerned were units where supplements had been consistently promoted and that there was no promotion of any products when the chocolate hampers were given.

Pharmasure submitted that it was a small company focussed on a specialist niche; in order to be able to efficiently access potential customers throughout the UK it had recently trained its supplements team to be able to sell POMs and its POMs representatives were again also selling supplements.

PANEL RULING

The Panel noted that Paragraph 5.3 of the Constitution and Procedure stated that a complaint from a pharmaceutical company would be accepted only if the Director is satisfied that the company concerned has previously informed the company alleged to have breached the Code that it proposed to make a formal complaint and offered inter-company dialogue at a senior level in an attempt to resolve the matter, but that this offer was refused or dialogue proved unsuccessful.

The Panel considered that whilst inter-company dialogue had not occurred in this particular case, the case preparation manager had accepted the complaint as it had been received via the MHRA. Teva had originally submitted the complaint to the MHRA as Pharmasure was not on the list of non-member companies that agreed to abide by the Code and accept the jurisdiction of the PMCPA. On being notified of the complaint, Pharmasure had agreed to join the list.

The Panel noted that Clause 18.1 of the Code required that no gift, pecuniary advantage or benefit might be supplied, offered or promised to members of the health professions 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 provision of Clauses 18.2 and 18.3. Clause 18.2 permitted patient support items and Clause 18.3 permitted the provision of inexpensive notebooks, pens and pencils for use at certain meetings.

The Panel noted Pharmasure's submission that the representative at issue had promoted both supplements and POMs to the fertility unit up until November 2017. When the chocolate hamper was delivered he/she solely promoted medicines to the unit but none were discussed during the visit. The

Panel disagreed with Pharmasure's submission that this meant that the chocolate hamper was not provided in connection with the promotion of any medicines.

The Panel further noted that the Code covered the promotion of medicines (Clause 1.3). Whilst promotional activity in relation to supplements was not within the scope of the Code, if a representative promoting supplements called on the same health professionals to promote medicines then the Code would apply.

The Panel noted that a representative whose role was to promote medicines had given a chocolate hamper to a group of health professionals. The Code prohibited the provision of items to health professionals save for very limited circumstances. The chocolate hamper did not fit within the exemptions set out in the Code.

The Panel noted Pharmasure's submission regarding the relevance of UK law as at the time the company was not covered by the Code.

The Panel could only rule in relation to the Code. The prohibitions in the Code regarding the provision of items to health professionals etc although more restrictive than UK law, were not inconsistent with the requirements of UK law which allowed items which were inexpensive and relevant to the practice of medicine or pharmacy. Given the requirements of UK law the Panel did not consider it was unreasonable to rule that the provision of the chocolate hamper was unacceptable and in breach of Clause 18.1 of the Code.

The Panel noted Pharmasure's estimation that representatives who promoted medicines had given chocolate hampers to up to 15 fertility units. Extra care and guidance was required when representatives were promoting medicines and something not covered by the Code such as supplements. The Panel considered that the provision of the chocolate hamper by the representative who promoted medicines meant that Pharmasure had not maintained high standards. A breach of Clause 9.1 was ruled. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 15.2. Whilst it could be argued that the representative had not maintained a high standard and had failed to comply with the Code, this was due to the company's arrangements. The Panel considered that the matter was covered by its ruling of a breach of Clause 9.1 and therefore ruled no breach of Clause 15.2.

The Panel disagreed with Pharmasure's submission that none of the examples in the supplementary information relating to Clause 2 applied to this complaint except possibly inducement to prescribe and it was highly unlikely that a few bars of chocolate would induce a fertility unit to change its prescribing habits. The Panel noted that the list of examples in the supplementary information to Clause 2 was not exhaustive. The Panel noted its ruling of Clause 18.1 above and considered that the arrangements brought discredit upon, and reduced

confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel was concerned about the arrangements however it noted that at the time the chocolate hampers were given the company was not on the list of non-member companies that have agreed to comply with the Code and accept the jurisdiction of the PMCPA. In the exceptional circumstances of this case, and on balance, the Panel decided not to report Pharmasure to the Code of Practice Appeal Board for it to consider in accordance with Paragraph 8.2 of the Constitution and Procedure.

The Panel noted that Pharmasure recently decided that all of its representatives would promote both supplements and medicines. The company needed to be certain that it instructed representatives carefully to ensure compliance with the Code.

Complaint received **4 January 2018**

Case completed **27 March 2018**