ANONYMOUS HEALTH PROFESSIONAL v PHARMACOSMOS

Symposium invitation

An anonymous, non-contactable complainant who described themselves as a health professional complained about an invitation to a Pharmacosmos symposium at a European congress to take place in Vienna, February 2013. The invitation asked 'Can we optimize treatment with single high dose intravenous iron in IBD [inflammatory bowel disease] patients? – *New data from clinical trials'.* Pharmacosmos marketed Monofer (iron as iron (III) isomaltoside 100) and CosmoFer (iron dextran)). Both products were for the intravenous treatment of iron deficiency and both could be administered as total dose infusions.

The complainant stated that the material was supposed to be new and therefore he/she did not understand how it could be discussed or promoted until published and licensed.

The detailed response from Pharmacosmos is given below.

The Panel noted that the front page of the flyer featured a headline banner which read 'Invitation'. The reader was then invited to save the date for the Pharmacosmos symposium followed by the statement 'Can we optimize treatment with single high dose intravenous iron in IBD patients? - *New data from clinical trials.*' The background picture was of someone adjusting the flow of an intravenous drip. The reverse featured similar details about the date, time and location of the symposium above corporate information about Pharmacosmos and referred to treatment options with maximum efficacy, convenience and safety for patients and professionals. Readers were invited to visit the corporate website for more information.

Although the Panel noted that it was confined to considering the content of the flyer it further noted that discussion or promotion of medicines based on unpublished clinical data was not universally prohibited as implied by the complainant. The use of data, be it published or otherwise, to promote an unlicensed product or indication was prohibited by the Code, however the legitimate exchange of medical and scientific information was allowed in limited circumstances.

The Panel noted that as submitted by Pharmacosmos the new data from clinical trials to be discussed at the symposium was about Monofer, however that was not stated or implied anywhere on the flyer. The flyer referred to single high dose intravenous iron in IBD patients. The Panel noted that Monofer and, in limited circumstances CosmoFer, could be administered as a single total dose infusion. The Panel considered that the flyer did not directly or indirectly refer to either medicine and thus was not promotional as implied by the complainant. The requirement to include prescribing information did not apply and no breach of the Code was ruled. As a consequence of its finding that the flyer was not promotional the Panel made other rulings of no breach of the Code.

An anonymous, non-contactable complainant who described themselves as a health professional complained about a double sided, A5 invitation to a Pharmacosmos symposium at the 8th Congress of ECCO (European Crohn's and Colitis Organisation) to take place in 14-16 February 2013. The invitation asked 'Can we optimize treatment with single high dose intravenous iron in IBD [inflammatory bowel disease] patients? – *New data from clinical trials*'. Pharmacosmos marketed Monofer (iron as iron (III) isomaltoside 100) and CosmoFer (iron dextran)). Both products were for the intravenous treatment of iron deficiency and both could be administered as total dose infusions.

COMPLAINT

The complainant stated that he/she had just transferred to a London hospital and the invitation was in the department. However, the material was supposed to be new and therefore the complainant did not understand how it could be discussed or promoted until published and licensed.

When writing to Pharmacosmos A/S, the Authority asked it to respond in relation to Clauses 3.1, 3.2, 4.1, 9.1 and 2 of the Code.

RESPONSE

Pharmacosmos stated that as the complaint was both anonymous and general, it was difficult to investigate any specific aspect of the matter. The complaint did not specify which aspect of the invitation gave cause for concern, other than that the data might not be within the product licence. Since the invitation did not identify a specific product in any capacity, it was not practical for the reader to identify a product licence against which the comments should be made.

Pharmacosmos submitted that twenty of the approved symposium flyers were given to each of its UK representatives in early October following its UK sales conference. Pharmacosmos would attend the ECCO conference. The Pharmacosmos symposium was open to all conference attendees it was an official part of the agenda and as such was a legitimate occasion for scientific exchange regarding treatments and products. Information about the symposium and all industry symposia was available from the conference organizer's website. Pharmacosmos noted that Clauses 3.1 and 3.2 related to promotional activity (or activity that was deemed to be promotional).

The purpose of the flyer was to inform physicians attending the conference that Pharmacosmos would hold a scientific symposium at the conference. There was no intention to distribute the flyer more widely and so Pharmacosmos had not regarded this as a promotional piece *per se*. There was no reference on the flyer to a *specific* product and no mention of any product name. While Pharmacosmos recognised these were not the only determinants of promotion, these were key considerations when reviewing this item in combination with the intention that it would only be given to health professionals known to be attending ECCO. Indeed, there would be little value in providing the flyer to those who would not attend ECCO because the symposium was part of the main conference and could not be attended by any physician who was not registered for the conference. It was unclear how the flyer ended up on a hospital department noticeboard; Pharmacosmos assumed it was placed there by a well-meaning colleague of the complainant.

Pharmacosmos submitted that there was nothing in the title of the symposium, 'Can we optimise treatment with single high dose intravenous iron in IBD patients? – *New data from clinical trials*', which would indicate use of any particular product. Pharmacosmos noted that Monofer was already licensed for high dose intravenous use in IBD and that the presentation was intended to be about Monofer data. However, Monofer and its licence status were not directly identifiable from the flyer.

Pharmacosmos submitted that as the complaint had been received six weeks before the symposium was due to be held the presentations were not written and thus had not been submitted to Pharmacosmos for review. However, a copy of the symposium agenda was provided. Neither the agenda nor any other material about the symposium had been given to any UK health professionals.

Given all the circumstances, Pharmacosmos denied breaches of Clauses 3.1 and 3.2.

Pharmacosmos and other companies made a number of products related to intravenous iron therapy, the majority of which were suitable for use in patients with IBD. On that basis Pharmacosmos stated that the invitation did not identify any specific product. Pharmacosmos would not normally add obligatory information to meetings invitations unless the invitation text specifically named or indicated a specific product. An Appeal Board ruling had made it clear that a reference to a class of treatment was not promotional *per se* unless a specific treatment was identifiable (Case AUTH/2482/2/12).

Given that the material did not promote a specific medicine, there was no requirement for prescribing information to be included. Pharmacosmos thus denied a breach of Clause 4.1.

Pharmacosmos was grateful that the concerns had been raised and for the opportunity to comment; further it denied breaching Clauses 2, and 9.1 of the Code.

PANEL RULING

The Panel noted that the front page of the 2 page flyer featured a headline banner which read 'Invitation'. The reader was then invited to save the date for the Pharmacosmos symposium followed by the statement 'Can we optimize treatment with single high dose intravenous iron in IBD patients? - *New data from clinical trials.*' The background picture was of someone adjusting the flow of an intravenous drip. The reverse featured similar details about the date, time and location of the symposium above corporate information about Pharmacosmos and referred to treatment options with maximum efficacy, convenience and safety for patients and professionals. Readers were invited to visit the corporate website for more information.

The complainant's concern was that new material could not be discussed or promoted until it was published or licensed and in this regard the Panel noted that it was confined to considering the content of the flyer. The Panel noted that discussion or promotion of medicines based on unpublished clinical data was not universally prohibited as implied by the complainant. The use of data, be it published or otherwise, to promote an unlicensed product or indication was prohibited by Clauses 3.1 and 3.2, however the discussion of such data might be permitted in those limited circumstances set out in the supplementary information to Clause 3, Marketing Authorisation, regarding the legitimate exchange of medical and scientific information.

The Panel queried whether the flyer had been distributed solely to physicians attending the conference as submitted by Pharmacosmos. The target audience on the relevant job bag form was described simply as 'gastro clinicians' and each UK representatives had been provided with twenty although the Panel did not know how they were briefed to use them and how many had been distributed.

The Panel firstly had to decide whether the flyer was promotional. The Panel noted that as submitted by Pharmacosmos the new data from clinical trials to be discussed at the symposium was about Monofer, however that was not stated or implied anywhere on the flyer. The flyer referred to single high dose intravenous iron in IBD patients. The Panel noted that, in limited circumstances, both Monofer and CosmoFer could be administered as a single total dose infusion. The Panel considered that the flyer did not directly or indirectly refer to either medicine and was thus not promotional Monofer as implied by the complainant. The requirement to include prescribing information did not apply and thus no breach of Clause 4.1 was ruled. Noting its finding that the flyer was not promotional the Panel also ruled no breach of Clauses 3.1 and 3.2. The Panel consequently ruled no breach of Clauses 2 and 9.1.

Complaint received **20 December 2012**

Case completed **6 February 2013**