CASE AUTH/2423/7/11

PHARMACOSMOS v VIFOR PHARMA

Ferinject leavepiece

Pharmacosmos A/S complained about a Ferinject (ferric carboxymaltose solution for injection/ infusion) leavepiece issued by Vifor Pharma UK. Ferinject was indicated for the treatment of iron deficiency when oral preparations were ineffective or could not be used.

The detailed response from Vifor is given below.

The claim 'Mastering the art of iron therapy' appeared as a strapline immediately beneath the product logos on the front page and inside flap of the leavepiece. Pharmacosmos alleged that the claim was that Ferinject was a best-in-class product. As this was non-specific and all-embracing, in the absence of any meaningful best-in-class data, it was misleading in breach of the Code.

The Panel considered that the strapline would be seen as a claim for Ferinject. The Panel noted that to 'master' an art meant to be extremely skilled or accomplished. The Panel considered that the strapline implied that Ferinject had a non-specific special merit compared with other iron therapies. The Panel considered that the claim was misleading in that regard and ruled a breach of the Code.

The claim 'Ferinject reduces time spent in clinics' appeared as a heading to two graphics which detailed administration times based on practical clinic times (including set-up and infusion). The first graphic showed that eight Ferinject patients could be treated in 4 hours compared with one Cosmofer (iron dextran) patient. The second graphic showed that two and a half Ferinject patients could be treated in 75 minutes compared with one Monofer (iron isomaltoside) patient.

Pharmacosmos alleged that the time comparisons were simplistic, without scientific rationale and based solely on the products' summaries of product characteristics (SPCs) with no practical assessment and no direct comparison between the products. There appeared to be an arbitrary 15 minutes administration time added to that quoted in the SPC for actual administration of the product. Only one arbitrary dose (1000mg) was compared instead of a range of doses. Given that Cosmofer and Monofer could be given in higher doses than Ferinject, Pharmacosmos noted that some patients treated in one visit with either Cosmofer or Monofer would require two visits if treated with Ferinject. Patient weight was also an important parameter that had been left out of the comparison. Patients weighing < 67kg would need two visits to receive the 1000mg dose used in the comparison.

The Panel noted that the graphic depicting Ferinject vs iron dextran showed that eight patients could be treated with Ferinject 1000mg in the four hours that it would take to treat one patient with iron dextran 1000mg. The other graphic showed that two and a half Ferinject 1000mg patients could be treated in the time that it took to treat one patient with the same dose of iron isomaltoside. The Panel further noted that both parties acknowledged that there were numerous factors which contributed to the time a patient spent in the clinic. Vifor had attempted to minimise this subjectivity by, *inter alia*, adding what appeared to be an arbitrary 15 minutes set up and tidy up time to the times otherwise calculated from the relevant SPCs. The Panel considered that the depicted absolute differences between the two products were not accurate. A breach of the Code was ruled.

Pharmacosmos A/S complained about the promotion of Ferinject (ferric carboxymaltose solution for injection/infusion) by Vifor Pharma UK Limited. Ferinject was indicated for the treatment of iron deficiency when oral preparations were ineffective or could not be used.

The material at issue was a six-page gatefolded leavepiece (ref 0090A/FER/2011) entitled, 'Benefits of Ferinject in managing iron deficiency anaemia in inflammatory bowel disease (IBD)'. The inside pages appeared to be designed as a single landscape page.

1 Claim 'Mastering the art of iron therapy'

The claim appeared as a strapline immediately beneath the product logos on the front page and inside flap of the leavepiece.

COMPLAINT

Pharmacosmos alleged that the claim was that Ferinject was a best-in-class product. As this was non-specific and all-embracing, in the absence of any meaningful best-in-class data, it was misleading in breach of Clause 7.2.

Pharmacosmos was concerned that Vifor had failed to recognise that this was a promotional claim.

RESPONSE

Vifor submitted that 'Mastering the art of iron

therapy' was an internationally recognized introductory statement which had been used for many years. It was clearly a strapline and not a claim about the product. It did not state or imply any superiority or 'best-in-class' and thus did not require substantiation. It was simply intended to start a discussion between the representative and the health professional on the challenges and 'art' of managing the complexity of iron therapy. Vifor denied a breach of Clause 7.2.

PANEL RULING

The Panel considered that, contrary to Vifor's submission, the strapline 'Mastering the art of iron therapy', in association with the product logo, would be seen as a claim for Ferinject. The Panel noted that to 'master' an art meant to be extremely skilled or accomplished. The Panel did not consider that the strapline implied that Ferinject was a best-in-class product *per se* but it did imply a non-specific special merit for the medicine compared with other iron therapies. The Panel considered that the claim was misleading in that regard and ruled a breach of Clause 7.2.

2 Claim 'Ferinject reduces time spent in clinics'

The claim appeared as a heading to two graphics which provided details of administration times based on practical clinic times (including set-up and infusion). The first compared Ferinject with iron dextran (Cosmofer) and the second compared Ferinject with iron isomaltoside (Monofer). The first graphic showed that eight Ferinject 1000mg patients could be treated in 4 hours compared with one iron dextran 1000mg patient. The second graphic showed that two and a half Ferinject 1000mg patients could be treated in 75 minutes compared with one iron isomaltoside 1000mg patient. Cosmofer and Monofer were Vitaline Pharma UK products (Vitaline Pharma was the UK subsidiary of Pharmacosmos).

COMPLAINT

Pharmacosmos alleged that the claim and accompanying graphics were biased comparisons based on selective parts of the relevant summaries of product characteristics (SPCs) and not head-to-head comparisons based on clinical facts. The comparisons were overly simplistic and considered only one dose and omitted important parameters such as patient weight and maximum doses of the medicines compared. In addition, the SPC data had been arbitrarily altered. Pharmacosmos was not aware of any evidence to support the claim and the supporting graphics and alleged that they were inaccurate, unfair and selective in breach of Clause 7.2.

Pharmacosmos stated that it was unclear whether this was a claim that health professionals spent less time in clinics or that the patient did. However, the claim appeared as a heading above a graphical representation of patients demonstrating that eight Ferinject patients could be seen/treated in the time it took to see/treat a single iron dextran patient or two and a half Ferinject patients when comparing to iron isomaltoside.

The time comparisons were incredibly simplistic and without scientific rationale and based solely on the products' SPCs with no actual assessment of time taken in a practical setting and no direct comparison between the products. The calculation appeared to have arbitrarily added 15 minutes administration time to that quoted in the SPC for actual administration of the product. Only one arbitrary dose (1000mg) was compared instead of a range of doses. The comparisons ignored the fact that Cosmofer and Monofer could be given in higher doses than Ferinject which could have a massive impact on the comparison as some patients handled in one visit with either Cosmofer or Monofer would require two visits if treated with Ferinject. The weight of the patient was also an important parameter that had been left out of the comparison. Patients weighing less than 67kg would need two visits to receive the 1000mg dose used in the comparison.

Pharmacosmos stated that assuming the claim was based on time saved by the health professional, the graphical claim implied that six [*sic*] Ferinject patients could be seen in the time it took to see a single iron dextran patient. This assumed that there was no other clinical or administrative consideration to make in respect of any of the patients; perfect scheduling and that all patients would receive the same dose of product under equivalent conditions. There was no head-to-head assessment in any sense other than the SPC comparison. Again, one arbitrary dose (1000mg) was considered and the fact that Cosmofer could be given in higher doses than Ferinject was ignored.

In inter-company correspondence, Vifor had stated that the claim and supporting graphic represented time spent in clinic by patients. It was difficult to see where the time saving actually occurred as it assumed that the time in the treatment room receiving iron treatment was the only consideration when in reality there were numerous factors to consider in respect of travel time, number of visits, waiting time, concomitant illnesses, time waiting at the pharmacy, etc.

RESPONSE

Vifor submitted that the key issues appeared to be whether the claim 'Ferinject reduces the time spent in clinics' was inaccurate, unfair and selective. Any comparison of intravenous irons would inevitably involve a certain amount of subjectivity as the respective dosage intervals, test dose necessity and observation period requirements varied extensively. This was exacerbated by variations in individual physician and clinic practice with respect to patient set up and appointment times, etc. In this respect, Vifor supported the assertion that *'…* there were numerous factors to consider in respect of travel

time, number of visits, waiting time, concomitant illnesses, time waiting at the pharmacy, etc, etc …'. However, it was clearly impractical to produce a comparison containing all the possible variations in product choice, haemoglobin levels, test dose necessity, observation period, appointment times, patient set up times, patient weight, travel time, number of visits, concomitant illnesses, pharmacy waiting time, etc.

Vifor submitted that it had therefore tried to minimise this subjectivity by referencing the respective SPCs as the most objective reference source available and adding 15 minutes for each product for set up time, individual practice variations, etc. In many ways this mitigated against Ferinject as no test dose was required and so its set up time was usually shorter. Nonetheless, in order to ensure that the comparison was as objective, fair and accurate as possible the standardised value of 15 minutes was used for all products.

The administration times were therefore taken directly from the SPC as stated by the complainant and compared Section 4.2 of the product SPCs at issue. Section 4.2 of the Ferinject SPC stated minimum 15 minutes for 1000g and the diagram showed 30 minutes. As mentioned above, a 15 minute 'set up' and 'tidy up' time was assumed for each patient. The 15 minutes was the same for all products even though the observations for iron dextran were much higher in reality as the product had a test dose requirement before it could be administered. Vifor acknowledged that there would be differences in patients' weights etc but, again, in order to standardise the comparison, the graphic referred to demonstrated 1000g as this was a common dose and was given according to all the relevant SPCs.

Clearly this issue was open to interpretation. However, it was clear that the central claim 'Ferinject reduces the time spent in clinics' could be substantiated as it was administered in 15 minutes whereas all of the comparator products required much longer administration periods. A reasonable person could therefore extrapolate that this would result in a reduction in the time spent in clinics.

Vifor contended that the leavepiece in question was accurate, fair and as objective as possible and was therefore not in breach of Clause 7.2.

PANEL RULING

The Panel noted that the graphic depicting Ferinject vs iron dextran showed that eight patients could be treated with Ferinject 1000mg in the four hours that it would take to treat one patient with iron dextran 1000mg. The other graphic showed that two and a half Ferinject 1000mg patients could be treated in the time that it took to treat one patient with the same dose of iron isomaltoside. The Panel further noted that both parties acknowledged that there were numerous factors which contributed to the time a patient spent in the clinic. Vifor had attempted to minimise this subjectivity by, *inter alia*, adding what appeared to be an arbitrary 15 minutes set up and tidy up time to the times otherwise calculated from the relevant SPCs. The Panel did not agree with Vifor's submission that the addition of this arbitrary figure ensured that the claim was as 'objective, fair and accurate as possible'. In any event the graphics and accompanying text did not refer to the additional 15 minutes.

The Panel noted that the graphics depicted, in absolute terms, the number of patients who could be treated with Ferinject 1000mg in a set time vs the number of patients who could be treated with other intravenous iron preparations. The data to calculate the differences had included the addition of an assumed 15 minutes for set up and tidy up. The Panel considered that the depicted absolute differences between the two products were thus not accurate. A breach of Clause 7.2 was ruled.

Complaint received **27 July 2011**

Case completed **31 August 2011**