

CASE AUTH/3407/10/20

FERRING/DIRECTOR v PHARMASURE

Promotion of Meriofert/breach of undertaking

Ferring Pharmaceuticals Ltd alleged that Pharmasure Limited had breached its undertaking in that it continued to display on its UK website, promotional claims for Meriofert (menotrophin) which had been ruled in breach of the Code in Case AUTH/3227/7/19.

Meriofert was used to induce ovulation in women undergoing assisted reproduction techniques such as *in vitro* fertilization (IVF). Ferring marketed Menopur (menotrophin for injection) which was similarly used to induce ovulation in women undergoing fertility treatment.

The detailed response from Pharmasure is given below.

The Panel noted that in Case AUTH/3227/7/19 Ferring had complained about claims in a Meriofert detail aid but noted that similar claims were included on the Pharmasure UK website. A number of claims in the detail aid were ruled in breach of the Code and Pharmasure provided its undertaking in acceptance of those rulings.

In Case AUTH/3227/7/19, the Panel considered that claims that Meriofert produced a 'Higher mature oocyte yield than Menopur' and that it 'Contains predominantly placental hCG' were misleading and not capable of substantiation, in breach of the Code; in the context in which they appeared they gave an overall implication of clinical superiority and readers were not provided with sufficient information to properly assess the claims and form their own opinion of Meriofert vs Menopur. The claims now at issue (Case AUTH/3407/10/20) ie that Meriofert had been shown to produce more mature oocytes than Menopur and about the placental hCG content and purity of Meriofert vs Menopur appeared on the company's website beneath an emboldened heading 'What is the difference between Meriofert and Menopur (menotrophin)?'. These claims were slightly different to those claims previously considered but, in the Panel's view, they continued to imply overall superiority and as acknowledged by Pharmasure, were sufficiently similar to have been covered by the company's original undertaking to cease using such claims forthwith.

The Panel considered that by leaving claims on its website which were closely similar to claims which had been ruled in breach of the Code, Pharmasure had failed to comply with its undertaking given in Case AUTH/3227/7/19. A breach of the Code was ruled.

The Panel noted that a form of undertaking and assurance was an important document which underpinned self-regulation. It was very important for the reputation of the industry that companies complied with undertakings. The Panel considered that Pharmasure had failed to comply with its undertaking given in Case AUTH/3227/7/19 and had thus brought discredit upon, and reduced confidence in, the industry. A breach of Clause 2 was ruled.

Ferring Pharmaceuticals Ltd alleged that Pharmasure Limited had breached its undertaking in that it continued to display on its UK website, promotional claims for Meriofert (menotrophin) which had

been ruled in breach of the Code in Case AUTH/3227/7/19. Pharmasure had provided the requisite undertaking and assurance in acceptance of those rulings in June 2020.

Meriofert was used to induce ovulation in women undergoing assisted reproduction techniques such as *in vitro* fertilization (IVF). Ferring marketed Menopur (menotrophin for injection) which was similarly used to induce ovulation in women undergoing fertility treatment.

COMPLAINT

Ferring submitted that from June 2020 it had regularly monitored the Pharmasure website and, in that regard, it provided seventeen screenshots taken at intervals between 23 June and 26 October 2020. [A further two screenshots were also provided, 8 April and 10 June, which were taken before the undertaking in Case AUTH/3227/7/19 had been received].

Ferring stated that the contents of the website had not changed since it submitted the original complaint (Case AUTH/3227/7/19) in July 2019. Ferring noted that the website included the claims detailed below which were ruled in breach by the PMCPA and referred to allegations 1 and 2 in Case AUTH/3227/7/19.

Website text heading:

‘What is the difference between Meriofert and Menopur (menotrophin)?

1. Clinically, in a long down-regulation stimulation protocol for IVF, Meriofert has been shown to produce two more mature oocytes than Menopur with a shorter period of stimulation.
2. In another study, a higher proportion of mature oocytes were obtained with significantly less gonadotrophin being administered during a shorter period of stimulation.’

Ferring submitted that claims 1 and 2 above were similar to those ruled in breach of the Code in Case AUTH/3227/7/19. Ferring referred to the claim at issue in allegation 1 of that case: ‘Higher mature oocyte yield than Menopur’.

3. ‘The LH activity in Meriofert is predominantly from placental hCG whereas Menopur’s LH activity comes from pituitary hCG

These two types of hCG are different in terms of half-life and the effect on the receptor.

4. Meriofert has a higher purity than Menopur.’

Ferring submitted that claims 3 and 4 above were similar to those ruled in breach of the Code in Case AUTH/3227/7/19. Ferring referred to the claim at issue in allegation 2 of that case: ‘[Meriofert] Contains predominantly placental hCG’.

Ferring alleged that these were serious matters, in breach of Clauses 29 and 2.

As the complaint was about an alleged breach of undertaking, it was taken up by the Authority in the Director’s name as the Authority was responsible for ensuring compliance with undertakings.

RESPONSE

Pharmasure submitted that it received the Panel's findings for Case AUTH/3227/7/19 on 10 June 2020. The undertaking was submitted on 17 June and the company conducted a thorough recall of all material used by its sales team, such that they could no longer, even inadvertently, use material containing the claims found to be in breach.

Pharmasure stated that, unfortunately, it missed the content on its website, meaning that no changes in the website content were made following the undertaking given. The claims would definitely have been removed had this not been overlooked. Pharmasure stated that this was completely unintentional and its fault. The claims in question were taken down from the website within minutes of receiving this complaint. Pharmasure stated that it could accept that it had breached the undertaking, but that it had not deliberately done so.

Pharmasure stated that in mitigation, the findings of Case AUTH/3227/7/19, its undertaking, the recall and withdrawal of materials found in breach were carried out during lockdown. At that time, Pharmasure had only a skeleton staff working; sales, marketing and the vast majority of administrative staff were on furlough as a result of the Covid 19 pandemic.

Pharmasure stated that it was very surprised that Ferring monitored and took screen shots of the website for over three months before it complained to the PMCPA. Since the claims were the subject of a previous ruling, measures should have been taken to have them removed as soon as they were noted. Pharmasure stated that had it been informed when Ferring first noticed, it would have prevented the claims it was so concerned about being available to view for at least a further three months.

Pharmasure stated that it respected the role of the PMCPA and understood the benefits to the public, the medical profession and the industry of having well-regulated promotion of medicines. Pharmasure noted that it had agreed to abide by the Panel's rulings and, especially following a ruling of a series of breaches and administrative charges related to the complaint for which it gave the undertaking in question (Case AUTH/3227/7/19), it made no sense whatsoever to have deliberately breached that undertaking.

Pharmasure provided a copy of the certificate for the information on the website and details about its signatory and his/her qualifications. The webpage in question remained unchanged from its original certification on 24 October 2018 until this complaint was received on 28 October 2020.

Pharmasure stated that it was embarrassed and disappointed to find itself in this situation and apologised unreservedly for the mistake.

PANEL RULING

The Panel noted that in Case AUTH/3227/7/19 Ferring had complained about claims in a Meriofert detail aid (ref UK/201809/00001/01) issued by Pharmasure but noted that similar claims were included on the Pharmasure UK website (ref UK/201810/00005/01).

The Panel in that case noted that it did not rule on any claims as they appeared on the website and only ruled in relation to the specific claims within the detail aid as referred to by Ferring.

The Panel noted that the Panel in Case AUTH/3227/7/19 had considered that a number of claims in the Meriofert detail aid were in breach of the Code. Those rulings were accepted by Pharmasure and it provided a signed undertaking on 17 June 2020 that use of the detail aid, and any similar material would cease forthwith. In its undertaking the company noted that the detail aid had last been used on 31 March 2020.

In Case AUTH/3227/7/19, the Panel considered that the claim that Meriofert produced a 'Higher mature oocyte yield than Menopur' was misleading and not capable of substantiation, in breach of the Code; in the context in which it appeared it gave an overall implication of clinical superiority and readers were not provided with sufficient information to properly assess the claim and form their own opinion of the therapeutic value of Meriofert vs Menopur. The claims now at issue (Case AUTH/3407/10/20) ie that Meriofert had been shown to produce more mature oocytes than Menopur and that a higher proportion of mature oocytes were obtained with Meriofert than with Menopur, appeared on the company's website beneath an emboldened heading 'What is the difference between Meriofert and Menopur (menotrophin)?' and were referenced to Lockwood *et al* (2017) and Alviggi *et al* (2013) respectively. The claims were slightly different to the claim previously considered but, in the Panel's view, they continued to imply overall superiority and as acknowledged by Pharmasure, were sufficiently similar to have been covered by the company's original undertaking to cease using such claims forthwith.

In Case AUTH/3227/7/19, the Panel also considered that the claim that Meriofert 'Contains predominantly placental hCG' was misleading and could not be substantiated, in breach of the Code; in the context in which it appeared it gave an overall implication of clinical superiority and readers were not provided with sufficient information to form their own opinion of its therapeutic impact. The claims now at issue (Case AUTH//3407/10/20) about the placental hCG content and purity of Meriofert vs Menopur also appeared under the same emboldened heading as above. In the Panel's view, and again as acknowledged by Pharmasure, although the claims were slightly different to that previously considered, they were sufficiently similar such that they were covered by the original undertaking to stop using such claims forthwith.

The Panel noted its comments above and considered that by leaving claims on its website which were closely similar to claims which had been ruled in breach of the Code, Pharmasure had failed to comply with its undertaking given in Case AUTH/3227/7/19. A breach of Clause 29 was ruled.

The Panel noted that a form of undertaking and assurance was an important document which underpinned self-regulation. Companies had to give an undertaking that the material in question and any similar material, if not already discontinued or no longer in use would cease forthwith and give an assurance that all possible steps would be taken to avoid similar breaches of the Code in future (Paragraph 7.1 of the Constitution and Procedure). It was very important for the reputation of the industry that companies complied with undertakings. Noting the extreme importance of undertakings and the reference at the outset in the previous case to similar claims on the Pharmasure website, the Panel did not accept the Covid 19 pandemic and lockdown as mitigation in this case. The Panel considered that Pharmasure had failed to comply with its undertaking given in Case AUTH/3227/7/19 and had thus brought discredit upon, and reduced confidence in, the industry. A breach of Clause 2, a sign of particular censure, was ruled.

Complaint received

26 October 2020

Case completed

19 February 2021