

ANONYMOUS, NON-CONTACTABLE HEALTH PROFESSIONAL v MERCK SERONO

Terms of trade

An anonymous, non-contactable complainant, who described him/herself as a consultant gynaecologist, complained about terms of trade offered by Merck Serono in association with the purchase of Gonal-F (follitropin alfa) and Ovitrelle (choriogonadotrophin alfa). The complainant alleged that the company would be willing to off-set the price of Gonal-F and Ovitrelle by reducing the cost of equipment and providing other business support services to the complainant's clinic. If the complainant did not buy Gonal-F he/she would have to pay the full price for any of Merck Serono's equipment he/she wanted to purchase, and for Ovitrelle. The complainant stated that he/she was surprised by this proposition, especially as in the past the price of his/her medicines had not been linked to the purchase price of equipment or sponsorship and support.

The detailed response from Merck Serono is given below.

The Panel noted that according to Merck Serono there would be no offers linking its medicines and its equipment. The Panel further noted Merck Serono's submission that it would not link the price of prescription medicines or the purchase of fertility products to sponsorship and support.

The complainant had not provided evidence to demonstrate on the balance of probabilities that Merck Serono had linked the price of its medicines to the cost of equipment or to any sponsorship and/or support. The Panel therefore ruled no breaches of the Code including Clause 2.

An anonymous, non-contactable complainant, who described him/herself as a consultant gynaecologist, complained about terms of trade offered by Merck Serono in association with the purchase of Gonal-F (follitropin alfa) and Ovitrelle (choriogonadotrophin alfa). Gonal-F and Ovitrelle were both indicated, *inter alia*, for use in in vitro fertilisation (IVF) techniques.

COMPLAINT

The complainant alleged that managers from Merck Serono had informed him/her that they would be willing to off-set the price of Gonal-F and Ovitrelle by reducing the cost of their laboratory equipment and providing other business support services to the complainant's clinic. If the complainant did not buy Gonal-F he/she would have to pay the full price for any of Merck Serono's laboratory equipment he/she wanted to purchase, and for Ovitrelle.

The complainant stated that he/she was surprised by this proposition, especially as in the past the price of his/her medicines had not been linked to the purchase price of laboratory equipment or sponsorship and support.

The complainant understood from colleagues in other clinics that they had had the same type of 'offers' extended to them.

When writing to Merck Serono, the Authority requested that it consider the requirements of Clauses 2, 9.1, 18.1, 19.1 and 19.2.

RESPONSE

Merck Serono submitted that it was difficult to conduct a comprehensive investigation as the complainant did not identify a specific manager or clinic, nor a timeframe during which the alleged interaction took place.

Merck Serono stated that various staff were interviewed and/or contacted about the complaint and to understand if any submission for exceptional requirements for pricing proposals was approved and for details about any interaction that could have led to the complaint. No further information or evidence of an interaction that could have led to the complaint came to light.

Merck Serono stated that it currently sold and distributed fertility technology products (such as laboratory equipment) and prescription medicines. This part of the business was organised into one fertility business franchise with managers who worked with fertility technology products and prescription medicines and interacted with NHS and private fertility clinics. However, commercial offerings and contracts for the procurement, supply or pricing of fertility technology products or prescription medicines were separate.

Merck Serono explained that currently all prescription products were made available to the NHS via tenders. Fertility technology products might occasionally be made available to the NHS via separate tenders, but in general Merck Serono would be asked by the NHS trust to provide a written quote for the relevant fertility technology products.

Merck Serono stated that when it worked with private clinics it had two guidance documents on pricing - one related to pricing for its prescription medicines and the other related to pricing for fertility technology products. Merck Serono stated that it did not currently have any other pricing modules for private clinics.

The pricing guidance was the only financial offers Merck Serono had. The company did not currently have, nor had it had to date, any financial offers available to its customers whereby the price of Gonal-F and Ovitrelle (or any other prescription medicines) were offset by a reduction in the price of any of the fertility technology products or by the provision of business support services, including sponsorship and support.

Merck Serono submitted that its fertility team was last trained on the pricing guidance in October 2018 at the quarterly fertility team meeting. Merck Serono submitted that the pricing guidance was comprehensive and no other instructions or direction on pricing was provided.

With regard to Clauses 18.1, 19.1 and 19.2, Merck Serono stated that it had a strict policy in relation to sponsorship, grants and medical education services. This was governed by a policy called 'Appropriate Interactions between Medical and Commercial Functions' which did not allow commercial functions to be involved in any decisions relating to grants and sponsorships. All requests received by Merck Serono's commercial teams must be sent to the medical team which independently reviewed each request and also operated with a budget independent of the budget operated by commercial teams. In addition, the internal approval system did not allow staff working in commercial functions to enter or approve any such requests.

Merck Serono thus refuted any claims that it would ever link the price of its prescription medicines or the purchase of its fertility technology products to sponsorship and support.

Merck Serono stated that it took compliance with the Code very seriously. The company was committed to full compliance with the Code and to maintaining the highest ethical standards in all of its commercial activities. The company submitted that this complaint was not founded, and it denied breaches of Clauses 2 and 9.1.

In summary, Merck Serono submitted that it had investigated the matter to the best of its ability based on the limited information provided and it sincerely regretted that the complainant did not provide further details. Its investigation did not lead the

company to believe that any manager or employee of the fertility team did not comply with the pricing guidance, or with the company's policy in relation to sponsorship, grants and medical education services, or with the Code. The company considered that its explanation and supporting documentation provided clear evidence as to why it had not breached the Code, and more particularly had not breached Clauses 2, 9.1, 18.1, 19.1 or 19.2.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure for the Prescription Medicines Code of Practice Authority stated that anonymous complaints would be accepted but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant had provided little detail to support his/her allegations and could not be contacted for more information.

The Panel noted Merck Serono's submission that its prescription products were made available to the NHS via tenders. Occasionally separate tenders might be used for fertility technology products. Further the commercial offerings and contracts for procurement, supply or pricing of fertility technology products and prescription medicines were kept separate.

The Panel noted that according to Merck Serono there would be no offers linking its medicines and its laboratory equipment. The Panel further noted Merck Serono's submission that it would not link the price of prescription medicines or the purchase of fertility products to sponsorship and support.

The complainant had not provided evidence to demonstrate on the balance of probabilities that Merck Serono had linked the price of its medicines to the cost of the laboratory equipment or to any sponsorship and/or support. The Panel therefore ruled no breach of Clauses 2, 9.1, 18.1, 19.1 and 19.2.

Complaint received **9 October 2018**

Case completed **21 November 2018**