

PARAGRAPH 17/DIRECTOR V SCHERING HEALTH CARE

Advertisement to the public and a website

During the consideration of Case AUTH/1921/11/06 the Panel was concerned about an advertisement feature issued by Schering Health Care and published in the Marks & Spencer magazine, Christmas 2006. The advertisement was headed 'Time for you to take control' and was about long acting reversible contraception (LARC). A highlighted box of text described various LARC methods available. The first was the intrauterine system (IUS), which readers were told released 'progestogen where needed, so you only absorb a low dose of hormones' and was even more reliable than the pill. Comparable data, where appropriate, was not given for any of the other LARC methods referred to (implant, injection and intrauterine device (IUD)). The Panel was concerned that by giving more positive data about the IUS than the other methods the material was not balanced and some women might be encouraged to ask their doctor or other health professional to prescribe that method. The Panel noted that Schering Health Care marketed, Mirena (levonorgestrel), the only IUS available in the UK.

The Panel was further concerned about the content of the Schering Health Care website www.modernmotherhood.co.uk referred to in the advertisement. The home page featured a box 'The GP is in!' which linked readers to frequently asked questions about LARC and to the real life experiences of five mums. Each of the women profiled had been successfully prescribed an IUS. There were no profiles of women using any other method of LARC. The Panel was concerned that the website was not balanced and that its content would encourage readers to ask their doctor or other health professional to prescribe Mirena.

The Panel decided to take the matter up with Schering Health Care as a complaint (Case AUTH/1936/12/06) under Paragraph 17 of the Constitution and Procedure.

The Panel noted that the descriptions of the different LARC methods in the advertisement did not use the same parameters. The reliability of the IUS was compared with that of the pill when no equivalent data was given for the IUD, implant or injection. Similarly the progestogen level of the IUS was described as low whereas no description was given for the progestogen level in the implant or injection. The Panel considered that the content of the highlighted box would encourage women to ask for an IUS which, in effect, would be a request for Mirena. A breach of the Code was ruled.

The Panel considered that as the case studies on the

website only related to women using the IUS that section was not balanced. Schering Health Care should have ensured that each type of LARC was represented by case studies. The material would encourage women to ask for the IUS which in effect would be a request for Mirena. The Panel ruled a breach of the Code.

COMPLAINT

During the consideration of Case AUTH/1921/11/06 the Panel was concerned about an advertisement feature issued by Schering Health Care Ltd and published in the Marks & Spencer magazine, Christmas 2006. The advertisement was headed 'Time for you to take control' and was about long acting reversible contraception (LARC). A highlighted box of text gave details of various LARC methods available. The first method described was the intrauterine system (IUS), which readers were told released 'progestogen where needed, so you only absorb a low dose of hormones' and was even more reliable than the pill. Comparable data regarding progestogen absorption was not given for implants or injection and the comparative efficacy data versus the pill was not given for any of the other LARC methods (implant, injection and intrauterine device (IUD)). The Panel was concerned that by giving more positive data about the IUS than the other methods the material was not balanced and some women might be encouraged to ask their doctor or other health professional to prescribe that method. The Panel noted that Schering Health Care marketed an IUS, Mirena (levonorgestrel).

The Panel was further concerned about the content of the Schering Health Care website www.modernmotherhood.co.uk referred to in the advertisement. The home page featured a box 'The GP is in!' which linked readers to frequently asked questions about LARC and to the real life experiences of five mums. Each of the women profiled had been successfully prescribed an IUS. There were no profiles of women using any other method of LARC. The Panel was concerned that the website was not balanced and that its content would encourage readers to ask their doctor or other health professional to prescribe Mirena.

The Panel decided to take the matter up with Schering Health Care as a complaint (Case AUTH/1936/12/06) under Paragraph 17 of the Constitution and Procedure.

When writing to Schering Health Care the Authority asked the company to respond in relation to the requirements of Clauses 2, 9.1 and 20.2 of the Code.

RESPONSE

Schering Health Care submitted that the highlighted box of text gave details of the various LARC methods available together with a short description. The first method described was the IUS which readers were told released 'progestogen where needed, so you only absorb a low dose of hormones'. Readers were also told that the IUS was even more reliable than the pill. The fact that the IUS was situated within the uterus and released progestogen to the surrounding tissue where it had the majority of its effects was unique to that method (Mirena summary of product characteristics (SPC), French and Guillebaud 2003). It had not seemed relevant or appropriate to mention absorption of progestogen for other methods. Furthermore, although comparative efficacy data versus the pill was not given for any of the other LARC methods, other equally relevant positive aspects were highlighted for these methods. For example readers were told that the IUD was not affected by other medicines and that the implant could be used by women of any age. Therefore, positive data were indeed highlighted for the other LARC methods. Schering Health Care submitted that the material was balanced and women would not be encouraged to ask their doctor or other health professional for the IUS over and above any of the other LARC methods.

Schering Health Care submitted that with respect to the www.modernmotherhood.co.uk website, there were five case histories of mums who had been successfully prescribed the IUS. A facility was provided for women to write in with their own stories which would then be considered for inclusion on the site. However, no case histories were submitted. Therefore, unfortunately, although the rest of the website was of a high standard, balanced, fair and accurate, the lack of provision of additional case histories had left this section of the website only describing women who had been successfully prescribed the IUS. On the assumption that Schering Health Care did not anticipate receiving case studies from women as expected, this section of the website was removed.

Schering Health Care confirmed that Mirena was the only IUS available in the UK.

Schering Health Care submitted that in view of the above the 'Time for you to take control' advertisement satisfied the requirements of Clauses 2, 9.1 and 20.2 respectively as a non-promotional health information piece that was of a high standard, balanced, fair and accurate.

PANEL RULING

The Panel noted that in accordance with Clause 20.2 of the Code companies could make available information about prescription only medicines to the public either directly or indirectly. Such information must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product. Further, statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine. Particular care was needed when referring to types of medicine when there was only one medicine that met the description. In this regard the Panel noted that Mirena was the only IUS available in the UK.

The Panel noted that the descriptions of the different LARC methods in the advertisement did not use the same parameters. The reliability of the IUS was compared with that of the pill when no equivalent data was given for the IUD, implant or injection. Similarly the progestogen level of the IUS was described as low whereas no description was given for the progestogen level in the implant or injection. The Panel considered that the content of the highlighted box would encourage women to ask for an IUS which, in effect, would be a request for Mirena. A breach of Clause 20.2 of the Code was ruled. The Panel did not consider that the circumstances warranted a ruling of a breach of Clauses 2 or 9.1.

The Panel considered that as the case studies on the Schering Health Care website only related to women using the IUS that section was not balanced. The company should have ensured that each type of LARC was represented by case studies. The material would encourage women to ask for the IUS which in effect would be a request for Mirena. The Panel ruled a breach of Clause 20.2. The Panel did not consider that the circumstances warranted a ruling of a breach of Clauses 2 or 9.1.

Proceedings commenced 10 December 2006

Case completed 5 February 2007