

RETIRED HOSPITAL DOCTOR v SCHERING HEALTH CARE

Advertisement to the public about contraception

A retired hospital doctor complained about an advertisement for long-acting reversible contraception (LARC) placed by Schering Health Care in the Marks and Spencer magazine, Christmas 2006. The page was headed 'Advertisement Promotion' and 'Time for you to take control' and discussed contraceptive issues for working mothers. A highlighted box in the bottom right hand corner discussed four methods of LARC; intrauterine system (IUS), intrauterine device (IUD), implant or injection. All except the IUD released progestogen.

The complainant stated that she had never seen an advertisement for progestogens in the medical press which did not include warnings of side effects and special precautions. The advertisement at issue had no warning that progestogens were internationally recognised as carcinogenic and genotoxic.

The complainant was both surprised and alarmed to see the advertisement.

The Panel noted that the complainant had implied that the material was misleading with respect to the safety of LARC because it did not refer to warnings and side-effects related to progestogens. The Panel noted, however, that the material did not refer at all to the safety of LARC. There was no implication that such contraceptive methods had no side-effects. Readers were told that their doctor or family planning nurse could advise them on the most suitable method of contraception for them. On the basis of the complaint made the Panel ruled no breach of the Code.

A retired hospital doctor complained about an advertisement for long-acting reversible contraceptive methods placed by Schering Health Care Limited in the Marks and Spencer magazine, Christmas 2006. The page was headed 'Advertisement Promotion' and 'Time for you to take control' and discussed contraceptive issues for working mothers. A highlighted box in the bottom right hand corner discussed four types of long-acting reversible contraceptive methods; intrauterine system (IUS), intrauterine device (IUD), implant or injection. All except the IUD released progestogen.

COMPLAINT

The complainant stated that she had never seen an advertisement for progestogens in the medical press which did not include warnings of side effects and special precautions. The Marks and Spencer advertisement had no warning that progestogens were recognised by the International Agency for Research on

Cancer (IARC), part of the World Health Organization (WHO), as carcinogenic and genotoxic.

The complainant was both surprised and alarmed to see the advertisement.

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

RESPONSE

Schering Health Care submitted that the advertisement was not a 'promotional' piece for any specific product and did not mention any products by name. The heading 'Advertisement Promotion' was included at the insistence of Marks and Spencer to ensure compliance with the British Code of Advertising, Sales Promotion and Direct Marketing 2005 which stated that 'Marketers and publishers should make clear that advertisement features are advertisements, for example by heading them "advertisement feature"'. The piece was in fact a non-promotional health information piece.

Schering Health Care explained that the guidelines from the National Institute for Health and Clinical Excellence (NICE) on long-acting reversible contraception (LARC) recommended that all women should be offered long-acting reversible contraceptives as a choice when they came to consider their family planning needs and this was linked to clear public health goals aiming to reduce unwanted pregnancies. The NICE guidelines stated that in 2003/4 in the UK there was very low uptake of LARC at around 8% of contraceptive usage, compared with 25% for the oral contraceptive pill and 23% for the barrier method among women aged 16 to 49. Expert clinical opinion was that LARC methods might have a wider role in contraception and their increased uptake would reduce unintended pregnancy. In 2006, a survey of 100 women currently either taking the combined oral contraceptive pill or the progestogen only pill showed that between 24% and 88% were aware of different LARC methods and only 22% were aware of all four.

The material in question profiled LARC as recommended by the NICE guidelines. The article was written with the aim of informing consumers about the various methods of LARC available, so that they could then have an informed discussion with the relevant health professional. It was not a promotional piece. The piece did not just mention the progestogen implants, injections and IUS but mentioned all long-acting reversible methods of contraception including the

intrauterine device (IUD). The title 'Advertisement Promotion' was added by Marks and Spencer and was not part of the submitted piece which was a general information piece.

As it was unlikely that consumers would understand the methods implied by the term 'long-acting reversible contraception', there was a small informative section on each method of LARC. There was a clear statement at the bottom of the page that indicated where further information could be found (www.modernmotherhood.co.uk which was a non-promotional informative website which had detailed information available on all methods including any warnings, side effects and precautions) and a clear recommendation that a woman's doctor or family planning nurse could advise on the most suitable method of contraception for each woman.

Schering Health Care was not aware of any requirement nor any rational argument for the inclusion of the data published by the WHO/IARC (2005) in such a piece. These data concerned the carcinogenicity of estrogen-progestogen replacement therapy and combined oral contraceptives and concluded that the combinations were on the one hand carcinogenic to humans, but that at the same time, there was also convincing evidence for a protective effect of combined oral contraceptives against some other types of cancer. The IARC summarised that 'the overall net public health outcome could be beneficial' for combined oral contraceptives and hormone replacement therapy but that a rigorous analysis would be required to demonstrate this. The WHO regularly reviewed the safety of combined oral contraceptives and assessed the balance of risks and benefits of their use and it had determined that for most healthy women, the health benefits clearly exceeded the risks. Regardless of these findings, the results of WHO/IARC were not generalisable to LARC methods, none of which contained a combination of estrogen and progestogen. Therefore Schering Health Care did not accept that the inclusion of such data in this piece was either warranted or appropriate.

Schering Health Care noted that the Code allowed non-promotional information about prescription only medicines to be provided to the public provided that it was balanced, factual and not made for the purpose of encouraging members of the public to ask their doctors or other prescribers to prescribe a specific prescription only medicine. The material in question was a non-promotional health awareness campaign that highlighted LARC to raise awareness among women as this had been shown to be lacking. This was in line with the NICE LARC guideline that had been published recently with the aim of reducing unwanted pregnancies. The article was of a high standard, including a section by a well respected women's health specialist. The section on the methods available was non-promotional, balanced, fair and accurate and

directed women to appropriate places for further information such as a relevant health professional or a factual and balanced website that had extensive information on all methods available. No products were mentioned by brand name and there were no promotional claims made about any products. As such, no information such as prescribing information which included warnings of side effects and special precautions would be expected to be included with such a piece.

Schering Health Care submitted that the material complied with Clauses 20.2, 9.1 and 2 of the Code as a non-promotional health information piece that was of a high standard, was balanced, fair and accurate.

PANEL RULING

The Panel noted that the complainant had implied that the material was misleading with respect to the safety of LARC because it did not refer to warnings and side-effects related to progestogens. The Panel noted, however, that the material did not refer at all to the safety of LARC. There was no implication that such contraceptive methods had no side-effects. Readers were told that their doctor or family planning nurse could advise them on the most suitable method of contraception for them. On the basis of the complaint made the Panel ruled no breach of Clause 20.2. It thus followed that there was no breach of Clauses 2 and 9.1 and the Panel ruled accordingly.

During its consideration of this case, the Panel was concerned that the highlighted box of text which detailed the various LARC methods available gave more positive data about the IUS than the other methods and that in that regard the material was not balanced. Some women might be encouraged to ask their doctor or other health professional for an IUS. The Panel noted that Schering Health Care marketed an IUS - Mirena.

The Panel was further concerned that one part of the website www.modernmotherhood.co.uk which featured patient profiles only profiled women who had been successfully prescribed an IUS. 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 its concerns up as a separate complaint in accordance with Paragraph 17 of the Constitution and Procedure (Case AUTH/1936/12/06).

Complaint received **23 November 2006**

Case completed **16 February 2007**