

# VOLUNTARY ADMISSION BY PROCTER & GAMBLE

## Promotion of Intrinsa to the public

Procter & Gamble voluntarily admitted promoting Intrinsa (testosterone transdermal patch), a prescription only medicine (POM), to the public. As the matter related to a serious breach of the Code, it was taken up and dealt with as a formal complaint under the Code in accordance with the Constitution and Procedure.

Procter & Gamble stated that an Intrinsa advertisement was placed in the journal 'Wellbeing', which was published in association with the Royal College of Obstetricians and Gynaecologists and Wellbeing of Women, a UK registered charity, in the belief that as the journal was distributed to health professionals, it was solely for their use. However, the health professionals in turn made copies available to patients, typically by placing it in their waiting rooms.

Procter & Gamble and the publisher had agreed to send every recipient of the journal materials to over sticker the Intrinsa advertisement so that patients could no longer see it. The charity had confirmed that it would not distribute any further copies of the journal in the current form.

The Panel considered that from the full title, 'Wellbeing for Women, Mothers & Babies 2007', it should not have been a surprise to Procter & Gamble that the journal was intended for the public. It was not a publication aimed at health professionals. The Panel was extremely concerned that Procter & Gamble had not established the full details about the intended audience and that the advertisement had not been certified. Intrinsa, a POM, had been promoted to the public. A breach of the Code was ruled as acknowledged by Procter & Gamble. High standards had not been maintained and a further breach of the Code was ruled in that regard. The Panel noted Procter & Gamble's actions once the mistake had been discovered including instructions to over sticker the advertisement. However, on balance, the Panel considered that the seriousness of the errors reduced confidence in the pharmaceutical industry and thus a breach of Clause 2 of the Code, which was reserved to indicate particular censure, was ruled.

Procter & Gamble Pharmaceuticals UK Limited voluntarily admitted promoting Intrinsa (testosterone transdermal patch), a prescription only medicine (POM), to the public.

Paragraph 5.4 of the Constitution and Procedure stated that the Director should treat such an admission as a complaint if it related to a serious breach of the Code. Promotion of a POM to the public was regarded as a serious matter and the Director accordingly decided

that the admission must be treated as a complaint.

## COMPLAINT

Procter & Gamble stated that an Intrinsa advertisement (ref INT-UK3063) appeared in a journal which might be read by patients. The advertisement, developed for use in journals intended for health professionals, was placed in the June 2007 edition of 'Wellbeing' in the mistaken belief that the journal was intended solely for health professionals; the publisher had stated that the content, including all advertisements, was subject to the editorial control of a senior fellow of the Royal College of Obstetricians and Gynaecologists (RCOG). Indeed, the vast majority of articles were sourced from members of the RCOG. However, although 100,000 copies of the journal were distributed directly to members of the RCOG, they then made it available in their surgeries for patients to read typically by placing it in their waiting rooms.

The journal was produced in association with the RCOG and Wellbeing of Women, a UK registered charity that raised money for research into health issues that solely affected women.

Procter & Gamble agreed with the publisher that it would write to every recipient of the journal (copy letter provided) wherein it would provide materials to over sticker the Intrinsa advertisement so that it was no longer visible to patients. No further distribution would take place by the publisher until the Intrinsa advertisement had been over stickered. Wellbeing of Women had confirmed that it would not distribute any further copies of the journal in the current form.

Procter & Gamble had not been contacted by consumers with regard to this issue. Procter & Gamble was monitoring the situation closely and it would tell any consumer that contacted the company that the advertisement should not have been placed in the journal and that it was doing all it could to prevent any further disclosure.

The publication of the advertisement in such a journal was obviously a very regrettable error; steps had already been taken internally to tighten the approval process for placing print advertisements in journals, and appropriate follow-up action concerning the person involved was being taken.

Procter & Gamble had written similarly to the Medicines and Healthcare products Regulatory Agency (MHRA).

When writing to Procter & Gamble the Authority asked it to respond in relation to Clauses 2, 9.1 and 20.1 of the Code.

## RESPONSE

Procter & Gamble fully understood that POMs must not be promoted to the general public, as stated in Clause 20.1 and thus acknowledged that the publication of the advertisement in the journal at issue constituted a breach of Clause 20.1.

Procter & Gamble submitted that regrettably, the advertisement in question was that which was examined by the PMCPA at the audit (Cases AUTH/1902/10/06 and AUTH/1903/10/06) and was found to lack certification by the final signatories. Further actions taken following the findings of the audit would be described in the company's response to the PMCPA audit report.

Procter & Gamble recognised that the special nature of medicines and the professional audience to which the material was directed required that the standards set for the promotion of medicines were higher than those which might be acceptable for general commodity advertising.

Procter & Gamble submitted that the advertisement in question was developed for use in journals intended solely for health professionals and had been pre-vetted by the MHRA. Procter & Gamble therefore believed that it was of the required high standard for advertising to health professionals. As described above, Procter & Gamble had erroneously believed that the publication in question would be distributed only to health professionals.

Procter & Gamble took immediate action with the publisher to determine the facts, and following this, immediately informed both the MHRA and the PMCPA. Procter & Gamble had worked diligently with the publisher to ensure appropriate follow-up action to minimise exposure of this advertisement to the public. Via the publisher, Procter & Gamble had sent correspondence to the same mailing list used for the original journal. The 100,000 copies produced for distribution were actually distributed to approximately 3,500 recipients. Each one received sufficient material to over-sticker 30 copies of the advertisement. A free telephone number was also provided in case of questions. Procter & Gamble therefore considered that it had exhibited high standards in handling this situation when it came to its attention and thus denied a breach of Clause 9.1.

Procter & Gamble would never intentionally breach the Code or UK Advertising Regulations, it strove to

operate in a responsible, ethical and professional manner as demonstrated by its actions when this error came to its attention. Patient safety and/or public health was not prejudiced at any time by the publication of this advertisement in the journal.

Procter & Gamble acknowledged the seriousness of this case, however given the circumstances, and immediate follow-up actions, it submitted that this did not warrant a breach of Clause 2.

## PANEL RULING

The Panel noted that the Intrinsic advertisement had appeared in the Wellbeing journal which was produced in association with the RCOG and Wellbeing of Women, a UK charity that raised money for research into health issues solely effecting women. The full title of the journal was 'Wellbeing for Women, Mothers & Babies 2007'. Procter & Gamble submitted that the publisher had told it that the journal was subject to the editorial control of a senior fellow of the RCOG and had assumed that it was therefore intended solely for a health professional audience. Procter & Gamble had subsequently discovered that once distributed to physicians, they might, in turn, make copies available in their surgeries for patients to read.

The Panel considered that from the title it should not have been a surprise to Procter & Gamble that the journal was intended for the public. It was not a publication aimed at health professionals. The Panel was extremely concerned that Procter & Gamble had not established the full details about the intended audience and that the advertisement had not been certified as required by Clause 14. Intrinsic, a POM had been promoted to the public. A breach of Clause 20.1 was ruled as acknowledged by Procter & Gamble. High standards had not been maintained and a breach of Clause 9.1 was ruled. The Panel noted Procter & Gamble's actions once the mistake had been discovered including instructions to over-sticker the advertisement. However, on balance, the Panel considered that the seriousness of the errors reduced confidence in the pharmaceutical industry and thus ruled a breach of Clause 2, which was reserved to indicate particular censure.

**Complaint received** 20 August 2007

**Case completed** 19 September 2007