CASE AUTH/1945/1/07

VOLUNTARY ADMISSION BY NOVARTIS

Promotion prior to grant of marketing authorization

Novartis voluntarily advised the Authority that an advertisement for amlodipine/valsartan (Exforge) currently in development, which appeared in Hospital Doctor and Doctor on 9 and 11 January, was in breach of the Code. Whilst the product had received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP), a UK marketing authorization had not been granted at the time.

Novartis reassured the Authority that the advertisement was not placed by the UK company, nor was it aware of its inclusion in the journals in question until after publication. Those responsible from Novartis' parent company in Basle had been reprimanded and reminded of the company's policies and of the UK company's commitment to comply with the Code. Steps had been taken to ensure that the advertisement would not reappear in UK journals.

Novartis apologised for the breach of the Code and reassured the Authority of its commitment to prevent any further occurrence.

The Director decided that as the matter related to the promotion of a medicine prior to the grant of its marketing authorization it was sufficiently serious for it to be taken up and dealt with as a complaint under the Code.

The Panel was very concerned at the publication of the advertisement given that the agency involved was said to have had extensive experience of publishing in the UK. The Panel noted that the advertisement promoted the amlodipine/valsartan combination prior to the grant of the UK marketing authorization for Exforge. Thus the Panel ruled a breach of the Code as acknowledged by Novartis.

The Panel noted the action taken by Novartis but considered that high standards had not been maintained. A further breach of the Code was ruled. On balance the Panel did not consider the circumstances warranted a ruling of a breach of Clause 2 of the Code which was used as a sign of particular censure.

Novartis Pharmaceuticals UK Ltd voluntarily advised the Authority that an advertisement feature which appeared in Hospital Doctor, 9 January 2007 and Doctor, 11 January was in breach of the Code.

COMPLAINT

Novartis noted that this feature included information on an amlodipine/valsartan combination (Exforge) currently in development by Novartis. Whilst this product had received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP), a UK marketing authorization had not been granted at the time.

Novartis reassured the Authority that this advertisement feature was not placed by the UK company, nor was it aware of its inclusion in the journals in question until after their publication. Those responsible from Novartis' parent company in Basle had been reprimanded and reminded of the company's policies and of the UK company's commitment to comply with the Code. Active steps had also been taken to ensure that this feature would not appear again in UK journals.

Novartis apologised that this breach of Clause 3.1 of the Code had arisen and reassured the Authority of its commitment to prevent any further occurrence.

The Director decided that as the matter related to the promotion of a medicine prior to the grant of its marketing authorization it was sufficiently serious for it to be taken up and dealt with as a complaint under the Code. Novartis was asked to respond in relation to Clauses 2, 3.1 and 9.1.

RESPONSE

Novartis submitted that Exforge received a UK marketing authorization on 17 January 2007. The UK company found out about the two advertisement features in question through someone telephoning its medical information department to ask about the licence status of the product. The UK company was not aware of the placement of the advertisement feature and instigated an urgent investigation to ascertain its origin and to prevent, if possible, its reappearance.

The advertisement came from an agency working on behalf of Novartis' parent company in Basle. It appeared that there had been basic errors within a team of individuals who should have been fully aware of Novartis' procedures and of the Code having had extensive experience of supporting the company and of publishing in the UK. The team involved had been severely reprimanded and reminded of Novartis' policies and of the seriousness of this breach of the Code. Following formal investigation by the agency, disciplinary action would be taken against those involved. Reassurances had also been sought from the agency of the steps that had been taken to ensure that no repetition of these events could occur.

Novartis apologised that these events had occurred and that despite the best efforts of the company both in

the UK and Basle it had been let down by an agency working on its behalf. As a result the UK company had been unknowingly involved in the promotion of a product ahead of the grant of the marketing authorization. Novartis accepted that this was a breach of Clause 3.1.

Novartis hoped however that the urgency with which this issue had been managed by the UK company and brought to the Authority's attention was some reassurance of the robustness of the UK company's procedures and its commitment to the Code.

Novartis advised that the Medicines and Healthcare products Regulatory Agency was also informed of these events on 17 January.

PANEL RULING

The Panel was very concerned at the publication of the advertisement given that the agency involved was said to have had extensive experience of publishing in the UK. The Panel noted that the advertisement feature promoted the amlodipine/valsartan combination prior to the grant of the UK marketing authorization for Exforge. Thus the Panel ruled a breach of Clause 3.1 of the Code as acknowledged by Novartis.

The Panel noted the action taken by Novartis but considered that high standards had not been maintained. A breach of Clause 9.1 of the Code was ruled. On balance the Panel did not consider the circumstances warranted a ruling of a breach of Clause 2 of the Code which was used as a sign of particular censure.

Proceedings commenced	**18 January 2007**
Case completed	**28 February 2007**