# MEMBERS OF THE PUBLIC v ASTRAZENECA and BRISTOL-MYERS SQUIBB

## Onglyza advertisement in the Health Service Journal

**Two complaints were received about an advertisement in the Health Service Journal (HSJ) for Onglyza (saxagliptin), co-marketed by AstraZeneca UK and Bristol-Myers Squibb Pharmaceuticals. Onglyza was an add-on therapy for type 2 diabetics not controlled on metformin or a sulphonylurea alone.**

**In Cases AUTH/2426/8/11 and AUTH/2427/8/11 the complainant queried whether the placement of the advertisement was appropriate given that the HSJ was read by NHS managers in all roles and levels of seniority, and also by members of the public.**

**In Cases AUTH/2728/8/11 and AUTH/2429/8/11 the complainant stated that given its technical content, the advertisement should have appeared in medical and clinical publications only. The complainant queried whether it should have been placed in the HSJ.**

**The detailed response from AstraZeneca and Bristol-Myers Squibb is given below.**

**The Panel noted that the Code applied to the promotion of medicines to health professionals and to appropriate administrative staff. It required that promotional material should only be sent or distributed to those categories of persons whose need for, or interest in, the particular information could reasonably be assumed. Promotional material should be tailored to the audience to whom it was directed.**

**The Panel considered that the HSJ was a specialist professional title and was not aimed at the general public. The Panel did not accept that the advertisement was an advertisement to the public as alleged and considered that the publication was an acceptable vehicle for the advertisement of prescription only medicines. No breach of the Code was ruled.**

**The Panel noted that the journal was mainly read by administrative and general management personnel and by only a relatively small percentage of clinicians. The Panel noted that the title of the advertisement referred to Onglyza being 'an add-on alternative for your patients ...'. The Panel considered that the advertisement contained a considerable amount of clinical information and noted that only the acquisition cost of Onglyza compared with other treatments was stated. The advertisement, however, referred to the requirement for an initial assessment of renal function in patients with renal disease, together with periodical assessment thereafter, but the cost of this monitoring was not stated. The Panel thus did not consider that the advertisement included all the cost information that a manager would need.**

**The Panel considered that the reference to 'your patients' in the title, together with the content of the advertisement, was such that it was aimed at clinicians. It had not been tailored to the main audience of the HSJ. A breach of the Code was ruled which was appealed by AstraZeneca and Bristol-Myers Squibb.**

**The Appeal Board noted the companies' submission that the advertisement was aimed at an audience of those responsible for budgetary decisions which included a wide variety of management roles.**

**Although the Appeal Board considered that the heading might be more suited to clinicians it did not consider that the term 'your patients' was necessarily only appropriate in material aimed at clinicians. The content of the advertisement was broad and included information on efficacy, side effects, tolerability and acquisition costs, topics which would be of interest to the budgetary impact/payer audience that read the HSJ. The Appeal Board noted the companies' submission that the treatment costs, above and beyond acquisition costs, for all the other medicines referred to were broadly similar.**

**The Appeal Board was satisfied that the advertisement was sufficiently tailored to a significant proportion of the HSJ audience and in that regard the audience could reasonably be assumed to have an interest in it. The Appeal Board ruled no breach of the Code. The appeal was thus successful.**

Two complaints were received about a full page advertisement (ref 422UK11PM170/CZ006148-ONGL) for Onglyza (saxagliptin), co-marketed by AstraZeneca UK Limited and Bristol-Myers Squibb Pharmaceuticals Limited. The advertisement, which took the form of an advertorial, had been published in the Health Service Journal 4 August 2011. Onglyza was an add-on therapy for type 2 diabetics not controlled on metformin or a sulphonylurea alone.

**Cases AUTH/2426/8/11 and AUTH/2427/8/11**

**COMPLAINT**

The complainant queried whether the placement of the advertisement was appropriate given that the Health Service Journal was read by NHS managers in all roles and levels of seniority, and also by members of the public.

**Cases AUTH/2428/8/11 and AUTH/2429/8/11**

**COMPLAINT**

The complainant considered that the advertisement was a full blown technical advertisement that should appear in medical and clinical publications only. The complainant queried whether the advertisement should have been placed in the Health Service Journal.

When writing to AstraZeneca and Bristol-Myers Squibb, the Authority asked them to consider the requirements of Clauses 11.1 and 22.1.

**RESPONSE TO BOTH COMPLAINTS**

Bristol-Myers Squibb responded on behalf of both companies and submitted that the Health Service Journal was a leading provider of NHS and private health care news and policy information which was only available to subscribers and not promoted to the public. Typical subscribers included primary and secondary care doctors, nurses, pharmacists, primary care trust (PCT) commissioners, medical directors and finance directors. Both companies had a policy to only advertise prescription only medicines in journals that were distributed to health professionals and appropriate administrative staff and therefore they believed this was an appropriate journal in which to place a payer orientated Onglyza advertisement.

The advertisement itself was designed specifically for that audience. In addition to describing where saxagliptin might be appropriately used and its safety and tolerability profile, the advertisement also compared the acquisition costs of Onglyza with other dipeptidyl peptidase-4 (DPP-4) inhibitors and pioglitazone. The companies considered that this information was appropriate to the Health Service Journal readership. The advertisement was certified specifically for inclusion in the Health Service Journal, with knowledge of, and consideration for, the potential audience, as required by the Code.

Bristol-Myers Squibb and AstraZeneca maintained that there had been no breach of Clauses 11.1 and 22.1 and that the advertisement complied with the letter and spirit of the Code.

**PANEL RULING**

The Panel noted that Clause 1.1 stated that the Code applied to the promotion of medicines to members of the United Kingdom health professions and to appropriate administrative staff. Clause 11.1 required that promotional material should only be sent or distributed to those categories of persons whose need for, or interest in, the particular information could reasonably be assumed. The supplementary information to Clause 11.1 stated that promotional material should be tailored to the audience to whom it was directed.

The Panel considered that the Health Service Journal was a specialist professional title and was not aimed at the general public. The Panel considered that the key factor was to whom the publication was aimed at rather than whether it could be purchased by the public. The Panel did not accept that the advertisement was an advertisement to the public as alleged and considered that the publication was an acceptable vehicle for the advertisement of prescription only medicines. The Panel therefore ruled no breach of Clause 22.1.

The Panel then considered whether the content of the advertisement was suitable for the readership of the journal. The audience profile breakdown submitted by Bristol-Myers Squibb and AstraZeneca showed that the journal was mainly read by administrative and general management personnel and by only a relatively small percentage of clinicians.

The Panel noted that the title of the advertisement referred to Onglyza being 'an add-on alternative for your patients …'. The Panel considered that the advertisement contained a considerable amount of clinical information and noted that only the acquisition cost of Onglyza compared with other treatments was stated. The advertisement, however, referred to the requirement for an initial assessment of renal function in patients with renal disease, together with periodical assessment thereafter, but the cost of this monitoring was not stated. The Panel thus did not consider that the advertisement included all the cost information that a manager would need.

The Panel considered that the reference to 'your patients' in the title, together with the content of the advertisement, was such that it was aimed at clinicians. It had not been tailored to the main audience of the Health Service Journal. The Panel therefore ruled a breach of Clause 11.1. This ruling was appealed by AstraZeneca and Bristol-Myers Squibb.

**APPEAL BY ASTRAZENECA AND BRISTOL-MYERS SQUIBB**

Bristol-Myers Squibb appealed on behalf of both companies and submitted that the basis of the ruling of a breach of Clause 11.1 was the imbalance between clinical and cost information and as such, the Panel considered it was not suitable for those who read the Health Service Journal. The Panel stated that '... the journal was mainly read by administrative and general management personnel

and by only a relatively small percentage of clinicians'. Within the current NHS environment, budgetary decisions were made by a wide number of management roles across the varied NHS structures including, *inter alia*, commissioners, primary care personnel and acute trust staff. In addition, many of these management roles were occupied by clinically qualified practitioners. In arriving at local formulary/protocol decisions the primary consideration was the clinical merit of the intervention and thereafter, where this had been met, the economic impact of the treatment. Several drug and therapeutics committees stated on their websites their role in assessing both the efficacy and safety of new medicines, as well the financial implications of their use. Furthermore, an advisory board which included members of NHS management - a director of finance, head of finance and commissioning performance, business services manager, associate director of primary care and pharmacists - advised that such personnel needed information on efficacy, safety and cost of a medicine to make a market access decision.

The advertisement was orientated to payers and provided appropriate clinical information to meet their needs ie an appropriate positioning of the medicine (suitable patients), a few facts that addressed the major safety concerns in this therapy area and a table outlining acquisition costs of the competing options.

The companies noted that the Panel was concerned that the advertisement did not include all of the financial information that a manager would require, in that there was no reference to the cost of renal monitoring. These data were not included as renal monitoring applied to all of the referred treatment options as part of the National Institute for Health and Clinical Excellence (NICE) guideline on the routine management of type 2 diabetics, which stated that a renal assessment should be conducted at least annually. As this cost already existed within the existing care pathway, managers did not require this information when considering alternative therapeutic options for their diabetes patients – the key requirement was acquisition cost, which was included.

With regard to the Panel's comment that the use of 'your patients' indicated that the advertisement was solely directed to clinicians, AstraZeneca and Bristol-Myers Squibb submitted that this interpretation of 'ownership' of patients was too narrow within the context of the NHS; everyone working within a local health economy took responsibility for any patient within their organisation and managers would consider them to be 'their patients' too.

AstraZeneca and Bristol-Myers Squibb submitted that the advertisement had been developed in accordance with the Code. The companies provided a copy of an advisory board report exploring NHS priorities and agendas in diabetes, a supporting letter from an NHS manager from a PCT and examples of other recent advertisements from the Health Service Journal that contained both clinical and payer focus.

**COMMENT FROM THE COMPLAINANT IN CASES AUTH/2426/8/11 AND AUTH/2427/8/11**

The complainant stated that he sympathized with most of the points raised by the NHS manager but had a different view around perceptions of the composition of the Health Service Journal's readership and as the facts of the journal's readership had already been reviewed in these cases, these differences in perception were moot.

**COMMENT FROM THE COMPLAINANT IN CASES AUTH/2428/8/11 AND AUTH/2429/8/11**

The complainant stated that the letter from the NHS manager provided by Bristol-Myers Squibb and AstraZeneca was irrelevant to his complaint as the author dealt with how he wished things to be.

The complainant stated that this process was a palaver and that most complaints were company to company and the system was geared to that.

The complaint stated that this case was obvious, the Health Service Journal never carried this type of advertising. The readership profile was available from its marketing department.

The complainant considered that the complaints procedure was designed to put off ordinary complainants, the sanctions were a wet lettuce slap and confirmed his view, whatever the outcome, that self regulation was not in the public interest.

**APPEAL BOARD RULING**

The Appeal Board noted that Clause 11.1 required that promotional material should only be sent or distributed to those categories of persons whose need for, or interest in, the particular information could reasonably be assumed. The supplementary information to Clause 11.1 stated that promotional material should be tailored to the audience to whom it was directed.

The Appeal Board noted the companies' submission that the advertisement was aimed at an audience of those responsible for budgetary decisions which included a wide variety of management roles.

The Appeal Board noted that the Health Service Journal was a subscription journal with a wide readership. The audience profile data in relation to 'Areas of purchasing responsibility' indicated that 18% of readers had a role in purchasing medicines and 71% had a training, educational or learning responsibility. The job role data indicated 28% of readers were in 'Management and best practice' roles; 26% in 'Policy and politics'; 24% in 'Commissioning'; 19% in 'Primary care' and 17% in 'Acute care'. The majority of subscribers were in a management or senior role.

The Appeal Board noted the companies' submission that although the heading to the advertisement 'Onglyza … is an add-on alternative for your patients with type 2 diabetes not controlled on metformin or a sulphonylurea (SU) alone' had been used for different advertisements in other journals the content of the advertisement at issue was designed specifically for the Health Service Journal audience and had only ever appeared in that journal.

Although the Appeal Board considered that the heading might be more suited to clinicians it did not consider that the term 'your patients' was necessarily only appropriate in material aimed at clinicians. The content of the advertisement was broad and included information on efficacy, side effects, tolerability and acquisition costs and in the Appeal Board's view these topics would be of interest to the budgetary impact/payer audience that read the Health Service Journal. The Appeal Board noted the companies' submission that the treatment costs, above and beyond acquisition costs, for all the other medicines referred to were broadly similar.

The Appeal Board was satisfied that the advertisement was sufficiently tailored to a significant proportion of the Health Service Journal audience and in that regard the audience could reasonably be assumed to have an interest in it. The Appeal Board ruled no breach of Clause 11.1. The appeal was thus successful.

**Complaint received Case AUTH/2426/8/11 and AUTH/2427/8/11** **8 August 2011**

**Complaint received Case AUTH/2428/8/11 and AUTH/2429/8/11** **9 August 2011**

**Cases completed** **16 November 2011**