CASE AUTH/1843/6/06

ANONYMOUS v SERONO

Representative call rates

An anonymous complainant complained about call rates for Serono representatives and provided a copy of 'Activity Standards and Definitions', updated 1 January 2006. The call targets were split into four different therapy areas, reproductive health, multiple sclerosis, myalgic encephalomyelitis and dermatology. Details of the call rates which were described as minimum requirements over an average period were provided. The frequency for a cycle from September to December for doctors was three times in one therapeutic area and twice in another. The complainant stated that the document detailed the minimum level of activity expected. The activity levels were per cycle and there were three cycles per year.

The Panel noted Serono's submission that the document provided by the complainant had been altered. Nonetheless both the original document supplied by Serono and that provided by the complainant included for some therapy areas the statement 'For Sept-Dec 04' which thus implied that the stated call frequency, eg 3 calls for some doctors in rheumatology, was for that period of time only, thus resulting in the possibility of 9 calls a year based on 3 cycles per year. Serono submitted that the statement 'For Sept-Dec 04' had been a typographical error; the statement should have read 'As agreed with Manager'. The Panel noted that other supporting documents and the training on the Code had made the requirements of the Code clear with regard to call rates. The 'Activity Standards and Definitions' document, however, had to stand alone. The inclusion of the typographical error had given the wrong impression about call rates. A breach of the Code was ruled.

An anonymous complainant complained about the call rates Serono required of its key account managers (KAMs). A copy of 'Activity Standards and Definitions', updated 1 January 2006, sent with the complaint had a definitions section followed by a section on 'Activity – Target Levels'. The call targets were split into four different therapy areas, reproductive health, multiple sclerosis, myalgic encephalomyelitis and dermatology. The call rates which were described as minimum requirements over an average period were provided. The frequency for a cycle from September to December for doctors was 3 times in one therapeutic area and twice in another. The tables set out daily call rate, daily contact rate, coverage per cycle, frequency per cycle for various

target groups in relation to activity with doctors, nurses and others.

COMPLAINT

The complainant stated that the document detailed the minimum level of activity expected of all of Serono's KAMs. The activity levels were per cycle and there were three cycles per year.

When writing to Serono, the Authority asked it to respond in relation to Clause 15.4 of the Code.

RESPONSE

Serono stated that the document sent by the complainant was an out of date document which was revised in January 2006 from a previous version in 2004 (a copy of which was provided) and was superseded by additional documentation including: December 2005 Standard Operating Procedures (SOP), January 2006 Cycle meeting booklet, January 2006 ABPI presentation, January 2006 individual performance objectives detailing activity standards and Serono 2006 policy statements.

The updated document sent to the Authority was amended by the sender; Serono provided a copy of the original document.

The SOP applicable and relevant during the period (dated 21/12/05) clearly stated under the heading 'ABPI Code of Practice – Key points from the Code (2006)', that the number of calls on a doctor should not exceed three in one year. All KAMs were extensively briefed and trained on these SOPs and the new 2006 Code during business unit meetings and the Serono business cycle meeting in January 2006. All employees had completed the ABPI Wellards on-line training and validation course on the 2006 Code, where the level of calls was discussed and was confirmed to all sales staff.

The document at issue clearly stated that Serono did not believe in a call rate culture.

The tables under 'Activity – Target Levels' listed daily call rates, contact rates, both of which were 'As agreed with manager'. The frequency per cycle bullet point

in the table clearly showed the cycle to be 'For Sept – Dec 04'. The inclusion of this on the updated document was a typing error and should have been removed and replaced with the aforementioned 'As agreed with Manager'. The revised table was issued on 17 January 2006.

The call volume listed was the per annum rate, which was also confirmed by the performance objective document (provided) that clearly showed the amount of calls permissible and how it was personally discussed with the KAM during their performance objectives in January and July of each year. This was further confirmed with the opening statement in bold type face above the tables that stated 'Cycle Call volume – As agreed per cycle with manager and on an individual basis'.

Serono stated that it did not have a call rate culture of seeing any health professional 12 times per year.

The 2006 cycle booklet issued and discussed with KAMs on 17 January clearly showed that activity levels were to be only 3 unsolicited calls per annum. The table in the multiple sclerosis section clearly showed that the level of call rate activity permitted by Serono was and always had been only 3 calls per year in line with the 2006 Code.

Serono's portfolio included several complex products and services and therefore the calls on any health professional were by necessity segmented into three categories: KAM initiated calls (3 per annum); customer requested calls (as requested) and group meetings (as requested and authorised).

Serono had recently conducted a thorough revision of all policies and procedures with the SOPs being revised from the December 2005 versions to become more detailed and robust. These were now in force.

There were now policy statements related to all areas of the Code for quick reference by all employees regarding meetings, patient groups, contact with health professionals and a series of statements detailing the many aspects of the 2006 Code. The current certified statement on contact with health professionals, that showed that the level of contact allowable remained within the new 2006 Code parameters, was provided.

All KAMs from late 2005 had been fully briefed both as groups and as individuals on the level of contact permissible and at no time was there any confusion relating to this.

Serono submitted in summary that the document upon which the complaint was based had been altered. The original document entitled 'Activity Standards and Definitions' updated January 2006, was an out of date document superseded immediately after issue by many other clearly defined pieces that made it very clear that KAMs were not permitted to make an unsolicited call on a health professional more than 3 times in a year. There had been no confusion about this from any of the sales staff, particularly with the detailed briefings all staff had received in relation to the Code which reinforced this position. The sales director and managers alike enforced this with vigour and ensured that these were included within individual performance objectives.

PANEL RULING

The Panel noted that Clause 15.4 of both the 2003 and the 2006 Codes stated, inter alia, that representatives must ensure that the frequency, timing and duration of calls on health professionals, administrative staff in hospitals and health authorities and the like, together with the manner in which they were made, did not cause inconvenience. The supplementary information to Clause 15.4 of the 2006 Code stated, inter alia, that the number of calls made on a doctor or other prescriber and the intervals between successive visits were relevant to the determination of frequency. The number of calls made on a doctor or other prescriber by a representative each year should not normally exceed three on average. This did not include attendance at group meetings, a visit requested by a doctor or other prescriber or a call made to respond to a specific enquiry or a visit to follow up a report of an adverse reaction, all of which were additional to the three visits. The reference to 'other prescriber' in the supplementary information was newly introduced in 2006; the supplementary information to Clause 15.4 in the 2003 Code referred only to doctors.

The Panel noted Serono's submission that the document provided by the complainant had been altered. Nonetheless both the original document supplied by Serono and that provided by the complainant included for some therapy areas the statement 'For Sept-Dec 04' which thus implied that the stated call frequency eg 3 calls for target group A doctors in rheumatology, was for that period of time only, thus resulting in the possibility of 9 calls a year based on 3 cycles per year. Serono submitted that the statement 'For Sept-Dec 04' had been a typographical error; the statement should have read 'As agreed with Manager'. The Panel noted that other supporting documents and the training on the Code had made the requirements of the Code clear with regard to call rates. The 'Activity Standards and Definitions' document, however, had to stand alone. The inclusion of the typographical error had given the wrong impression about call rates. A breach of Clause 15.4 was ruled.

During its consideration of this case the Panel noted that the 'Activity Standards and Definitions' document should state how long a cycle was. If the cycle was a year then this should be stated. With regard to the call rates for nurses and others, if these groups included prescribers then the supplementary information to Clause 15.4 needed to be followed.

Complaint received	1 June 2006
Case completed	15 August 2006