

ANONYMOUS v ALLERGAN

Alleged inappropriate payments to health professionals

An anonymous, non-contactable complainant alleged that Allergan had made large payments to doctors to endorse Botox and other products.

The detailed response from Allergan is given below.

The Panel noted that the complainant could not be contacted for any more information; he/she had provided no detail as to when or to whom the allegedly large payments had been made. The Panel noted Allergan's reference to policies and procedures which it submitted provided a framework which ensured that its relationships with health professionals were appropriate and transparent. On the basis of the information before it, the Panel considered that there was no evidence to support the complainant's allegation. No breach of the Code was ruled.

COMPLAINT

An anonymous complainant, who was initially contactable but later could not be contacted at the email address provided, contacted the Authority and simply stated 'large payments made by Allergan to top doctors to endorse Botox and other products'.

When writing to Allergan, the Authority asked it to respond in relation to Clauses 2, 9.1 and 18.1 of the Code.

RESPONSE

Allergan submitted that it operated within a framework of policies and procedures which set out to ensure that such activities did not occur. Allergan stated that its code of conduct outlined its commitment to integrity and ethical conduct and stated that any interaction with a health professional: served an appropriate and ethical business purpose; did not interfere with the health professional's independent medical judgment and did not violate local law, regulation or company policy or procedure. The code identified that there were risks inherent in Allergan's interactions with health professionals and that Allergan must ensure that such interactions were ethical and complied with company policies and procedures.

Allergan's global Anti-Bribery and Anti-Corruption policy aimed to ensure that all business activities carried out by, or on behalf of, Allergan were in line with all applicable legal and ethical requirements regarding anti-bribery and anti-corruption. The policy prohibited the offer or payment of any money or item of value with the intention of inappropriately influencing the recipient or obtaining an improper advantage. It required that all payments or transfers of value were for a legitimate reason and appropriately documented including relevant contracts and should not be excessive.

Allergan stated that its regional Commercial Compliance Principles Policy applied across the Europe, Middle East & Africa (EAME) region and was designed to ensure continued compliance with all applicable laws, rules and regulations and the Allergan Code of Conduct, by laying down key principles and minimum compliance standards applicable to Allergan commercial activities within the region. It provided general standards with regards to consultancy services with health professionals, including:

- There must be a clear business need for the engagement of the health professional
- Health professionals must be selected based on their qualifications, experience and expertise, as well as their ability to provide a service of value and not on their status as a user of Allergan products
- The business need would dictate the duration and the intensity of the engagement
- Services should not be conditional upon a requirement of the consultant to prescribe, supply, sell or administer any Allergan pharmaceutical or medical device product
- Compensation payable should be based on the nature of, and commensurate to, the services provided, and should be paid based on services actually provided
- All engagements with health professionals should be recorded in the form of an approved written agreement.

Allergan's regional Healthcare Professional Consultancy Procedure set the standards for establishing written consultancy agreements with health professionals acting as consultants for, or on behalf of, Allergan. In particular, the document set out fair market value rates for consultancy agreements which were used by the UK company to ensure that payments were appropriate. The regional procedures determined the specific fair market values and UK specific standard operating procedures (SOPs) and policies linked into these regional procedures.

Allergan further explained that UK/Ireland specific SOPs and policy documents covering meetings, hospitality and copy approval were in place to cover the basic principles to follow in relation to meetings organised by Allergan which took place in the UK or Ireland, or meetings organised by Allergan which involved attendance by UK/Irish health professionals at venues outside of the UK/Ireland.

The SOPs and policies provided guidance on logistical arrangements, hospitality (subsistence), and consultant payments. The same principles applied to meetings that Allergan supported but had not necessarily organised eg payment of speaker fee or for exhibition space.

Moreover all interactions with health professionals requiring engagement for speaking, training or advisory boards were subject to internal review and approval procedures covered by the SOPs noted above.

In addition to the internal policies and procedures, since 2013 Allergan disclosed transfers of value as required by the Code and intended to report in 2016 any transfer of value made in 2015 on an individual named basis, dependent on obtaining the relevant consent.

Allergan submitted that in 2012 it paid £264,775.32 to 206 consultants, averaging £1,285.32 per consultant. In 2013 it paid £558,439.75 to 384 consultants, averaging £1,454.27 per consultant and in 2014 it paid £837,300.45 to 514 consultants, averaging £1,628.99 per consultant.

Allergan submitted that an increase in payments was in line with Allergan operating in new therapy areas and the approval of new indications for existing products.

The complaint referred to payments being made in order to gain endorsement of Allergan products. As discussed above, Allergan policies and procedures precluded this kind of activity. Allergan submitted that it conducted training workshops on certain products, either because of the highly technical nature of their use (eg the VYCROSS range of dermal fillers) and/or because its product was the only one with a specific indication (eg Botox indications for chronic migraine and overactive bladder). In these cases Allergan entered into a consultancy agreement with a health professional, who would be an experienced prescriber/user of its products and would typically be a key opinion leader. The training concentrated on Allergan products. It was possible that the complainant was confusing those events, which were run in order to educate on the safe and effective use of Allergan products, with the endorsement of Allergan products by health professionals. All materials associated with those training events clearly identified the nature of the event so as not to leave any doubt for attendees.

Allergan was asked to consider whether payments to doctors had been the subject of internal concerns or complaints such as whistleblowing. As evidenced by the policies and procedures that it had in place, Allergan submitted that hopefully it was clear that

payments to health professionals had been the subject of review and oversight by the company. Allergan's records indicated that there had been no whistleblowing complaints related to payments made to UK health professionals.

Allergan noted that the anonymous complaint was vague and contained no specific examples which Allergan could attempt to defend. There appeared to be two points to consider; that payments to UK health professionals were large and that they were made to encourage the endorsement of its products. On both counts, on the basis of the detailed and adequate procedural documents outlined above, robust internal review and approval procedures being in place, and the fact that Allergan openly declared transfers of value as required by the relevant Code, the company strongly refuted the allegations and denied breaches of Clauses 18.1, 9.1 and 2.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure for the Prescription Medicines Code of Practice Authority, stated that anonymous complaints would be accepted but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant could not be contacted for any more information.

The Panel noted that in this case the complaint consisted of a single allegation with no detail as to when or to whom the allegedly large payments had been made. The Panel noted Allergan's submission including its reference to policies and procedures which provided a framework which ensured that its relationships with health professionals were appropriate and transparent. On the basis of the information before it, the Panel considered that there was no evidence to support the complainant's allegation that Allergan had paid doctors large amounts of money to endorse Botox and other products. No breach of Clauses 2, 9.1 and 18.1 were ruled.

Complaint received	16 December 2015
Case completed	21 January 2016