

PHARMACIST v ASTELLAS

Frequency of telephone calls by representatives

The complaint concerned the frequency with which Astellas representatives contacted a pharmacist with regard to Betmiga (mirabegron), used in the symptomatic treatment of patients with overactive bladder syndrome.

Mirabegron had not been approved for use in the local publicly-funded pharmaceutical service but the pharmacist noted that he/she regularly got telephone calls from Astellas representatives asking how it could be approved. The pharmacist had not logged the times and dates of the calls, but he/she had been receiving them on a regular basis for two or more years. In the last month he/she had received possibly four such calls. The pharmacist stated that at the very least it was inconvenient and he/she personally found it intrusive and distressing.

The detailed response from Astellas is given below.

The Panel noted Astellas' submission that there had been no recorded calls in the company's customer relationship management system to anyone in the region in question, since November 2016.

The Panel noted, however, that three representatives had telephoned the pharmacist between January and April 2019 with queries about the local formulary in relation to mirabegron and enzalutamide. Details were provided including that representative 2 obtained the contact details from the relevant government webpage and contacted him/her as directed by that webpage. It appeared that the pharmacist stated that he/she did not talk to industry and ended the call.

Representative 3 had twice tried to contact the pharmacist (21 March and 3 April) to understand the process for applying for enzalutamide to be considered on the formulary and left voice messages on both occasions. The Panel noted that this was done despite the representative knowing about representative 2's interaction with the pharmacist and his/her position on speaking with industry.

The Panel noted that the three representatives, had telephoned the pharmacist four times between 16 January and 3 April 2019.

The Panel considered that if more than one representative from a company called the same health professional or other relevant decision maker, whether in relation to the same medicine or different medicines, particular care should be taken in relation to the number, timing of, and interval between calls made by those representatives to avoid inconveniencing the individual. The Panel noted Astellas' view that as it considered medicines were not promoted during the calls the interactions were not entered on the CRM system. The Panel did

not consider whether the calls were promotional or non-promotional but considered that it would be helpful if such calls were documented so that companies could assess such interactions in relation to the Code.

The Panel noted that representative 3 had tried to contact the pharmacist twice despite knowing his/her position on speaking with industry. The Panel noted Astellas' submission that the pharmacist was the single designated point of contact on the relevant formulary government webpage which the Panel noted provided a name and contact telephone number but no email or postal address. Nonetheless and on balance, the Panel considered that the pharmacist's wishes were not observed by representative 3 and a breach of the Code was ruled as acknowledged by Astellas. The Panel considered that representative 3 had failed to maintain a high standard of ethical conduct in this regard and a further breach of the Code was ruled as acknowledged by Astellas.

The Panel noted Astellas' submission that, *inter alia*, sales staff received additional training on the Code in 2017 and 2018, which specifically covered the requirements of the Code to observe arrangements in place at any particular establishment and to not cause inconvenience. A training presentation titled 'How should a representative behave?' stated, *inter alia*, that the timing and duration of calls must not cause inconvenience, that representatives must know and adhere to any local policies in place, the company's definition of a call vs a contact, and that call frequency must be no more than three per health professional per year.

The Panel noted its comments above and considered that it had no evidence before it that the representatives' briefing materials advocated any course of action which would likely lead to a breach of the Code in relation to calls and contacts with health professionals and other relevant decision makers, and observing the wishes of individuals and the arrangements in force in any particular establishment. The Panel therefore ruled no breach of the Code.

Noting its ruling of no breach of the Code above and in particular noting the content of the relevant government webpage the Panel did not consider that Astellas had failed to maintain high standards and so it ruled no breach of the Code.

The complaint concerned the frequency with which a pharmacist had been contacted by Astellas representatives with regard to Betmiga (mirabegron), used in the symptomatic treatment of patients with overactive bladder syndrome.

COMPLAINT

Part of the pharmacist's job was to manage the introduction of new medicines for the state-funded pharmaceutical service. The region in question was a self-governing jurisdiction which ran its own health service, which was similar to the NHS. However, it was not required to provide funding for medicines approved via the National Institute for health and Care Excellence (NICE) technology assessments.

Mirabegron had not been approved for use in the local publicly-funded pharmaceutical service but the pharmacist noted that he/she regularly got telephone calls from Astellas representatives asking how it could be approved.

When the pharmacist first answered those calls he/she would have explained that he/she did not see people from the industry due to a very heavy workload and that companies could not request the local approval of a medicine. The pharmacist had not logged the times and dates of the calls, but he/she had been receiving them on a regular basis for two or more years. In the last month he/she had received possibly four telephone calls from representatives. The representatives had sometimes stated that a particular colleague had asked them to contact him/her. The calls were described as inconvenient, intrusive and distressing.

When writing to Astellas, the Authority asked it to consider the requirements of Clauses 9.1, 15.2, 15.4 and 15.9 of the 2016 Code.

RESPONSE

Astellas explained that the company consisted of three separate business units - oncology, urology and specialist brands. Each business unit had its own marketing team, field-based representatives, sales managers and a shared market access team. Each business unit worked independently and shared a common customer relationship management (CRM) system to record calls and contacts.

The CRM system showed no current account plans for any business unit for the relevant region as it had not been identified as a priority for any part of the business. However, there was limited activity by Astellas on this account between 2012 and November 2016, with no activity such as calls or contacts made on the pharmacist. There had been no recorded activity in the form of calls on anyone in this account, since November 2016. The only recent activity recorded for individuals other than the pharmacist was in regard to 'contacts', where individuals had attended meetings or congress supported by Astellas.

Activity of the urology business unit

In January 2019, the representative (representative 1) who covered the region in question, received sales data for November 2018 that indicated a number of prescriptions for mirabegron had been written. He/she knew that the local formulary was being updated and wondered whether mirabegron

had now been included. He/she checked the relevant government website but could not see mirabegron on the list so, as directed by instructions on the website, he/she telephoned to enquire. In the telephone conversation which took place in January 2019, representative 1 introduced him/herself and asked whether mirabegron had been added to the formulary. The pharmacist asked how the representative had obtained his/her contact details and the representative explained he/she had followed the directions on the website. The pharmacist stated that the website details were not intended for people outside the region; representative 1 apologised and asked how he/she should contact the individual who replied, 'You don't'. Representative 1 then asked who he/she should contact, to which the pharmacist responded that representative 1 should 'Google it'. Representative 1 then thanked the pharmacist for his/her time and ended the telephone call and made no further contact. The pharmacist never stated that he/she did not engage directly with representatives or direct representative 1 to someone else who might be able to respond to his/her enquiry. As mirabegron was not promoted during the call and the conversation was purely an investigatory telephone discussion to understand process, Astellas submitted that there was no requirement to record the interaction in the CRM system.

Activity of the oncology business unit

On 26-27 November 2018, three members of the oncology business unit attended the British Association of Urological Nurses (BAUN) meeting. At this meeting, an oncology nurse from the region approached the stand to discuss another Astellas medicine, enzalutamide (Xtandi), stating that it was not on the formulary, he/she did not know why and that it might be beneficial to patients if it was added. One of the members of the oncology business unit present at BAUN (representative 2) then had a follow-on conversation with the nurse in January 2019 during which the latter recommended that the representative contact the pharmacy team and referred to the pharmacist.

Representative 2 obtained the contact details via the government website referred to above and, seeing the instruction on the website, telephoned on 21 January 2019. Representative 2 introduced him/herself and referred to the oncology nurse by name to which the pharmacist responded, 'I don't talk to Industry' and put down the telephone. No promotion took place during this interaction and thus the call was not recorded in the CRM system. Representative 2 had no further contact with the pharmacist.

Subsequently, in March 2019, representative 2 discussed this interaction with representative 3. Representative 3 had previous experience of working with the region and had met the pharmacist on one occasion over 10 years ago. Representative 3 telephoned on 21 March 2019 in order to understand the process for applying for a medicine to be considered for the formulary; he/she left a short, polite voice message introducing him/herself. As he/

she did not hear back, representative 3 made one follow-up call on 3 April 2019, again leaving a short, polite voice message on the answerphone stating that he/she wished to understand how enzalutamide might be submitted to the formulary; the message also stated that if the pharmacist preferred to speak with a company medical advisor instead of the representative then the representative could facilitate this. No products were promoted in either message and no further contact was made. Again, these telephone messages were not recorded in the CRM system.

Clause 15.4

Astellas submitted that it did not consider that the actions of representatives 1 and 2 were contrary to the requirements of Clause 15.4. Each representative only contacted the pharmacist once and when, as a result of these interactions, they knew his/her position on speaking to the industry they did not contact him/her again.

In relation to representative 3, he/she was in a difficult position in that the pharmacist appeared to be the only person who could provide information on how medicines could be placed on the local formulary.

However, representative 3 attempted to contact the pharmacist despite knowing that he/she had told representative 2 that he/she did not 'talk to industry'. Thus, Astellas considered that the wishes of the individual were not observed, and despite the best of intentions, the calls made by representative 3 caused inconvenience, contrary to the requirements of Clause 15.4. Astellas therefore acknowledged a breach of that clause. Astellas apologised for the inconvenience caused and had taken steps to ensure that no further contact was made with the individual.

Clause 15.2

As outlined in statements from each of the three representatives, the relevant government website directed enquiries about the formulary to the pharmacist as the single designated contact, therefore it was not unreasonable for each representative to assume that that individual should be contacted in order to understand whether a medicine was on the formulary, or to understand how a medicine could be placed on it.

Representatives 1 and 2 each contacted only once and did not try to do so again once his/her position in relation to the industry was indicated. With this in mind, Astellas did not consider that either representative had failed to maintain high standards and it thus denied any breach of the Code in that regard.

Astellas submitted that representative 3 did not deliberately try to be obtrusive or cause inconvenience. However, as noted above he/she tried to contact the pharmacist despite knowing that he/she did not talk to industry. In that regard, and in that exceptional circumstance, Astellas considered that representative 3 had failed to maintain high standards, in breach of Clause 15.2.

Clause 15.9

Astellas stated that as the region was not a priority for any of the business units, there was no briefing or instruction to staff specifically on the local arrangements.

Astellas trained all new and existing staff on the importance of high standards of the Code including Clause 15. Ethics and Compliance standards were also captured in job descriptions and annual objectives.

Code training was provided as part of the initial training course and Code updates via the company learning management system. Field-based personnel were reminded about calls and contacts standards on incentive scheme documentation and briefing materials. Further, sales staff training on the Code in 2017 and 2018 specifically covered the requirements of Clause 15.4.

Astellas did not consider that any sales force briefing documents had advocated, either directly or indirectly, any course of action, which would be likely to lead to a breach of the Code. Thus, Astellas denied a breach of Clause 15.9.

Clause 9.1

Given the briefing referred to above, Astellas considered that it had provided extensive briefing to its sales force in order to ensure that there was a clear and robust understanding of the requirements of the Code, including those noted in Clause 15.4 and thus it did not consider that it had failed to maintain high standards; the company denied a breach of Clause 9.1.

PANEL RULING

The Panel noted the allegation about the number of times the pharmacist had been contacted by Astellas representatives regarding how mirabegron could be approved for use in the local publicly-funded pharmaceutical service despite explaining when first contacted that he/she did not see people from the industry.

The Panel noted that Clause 15.4 stated that representatives must ensure that the frequency, timing and duration of calls on health professionals and other relevant decision makers in hospitals and NHS and other organisations, together with the manner in which they were made, did not cause inconvenience. The wishes of individuals on whom representatives wished to call and the arrangements in force at any particular establishment, must be observed. The supplementary information to this clause stated, *inter alia*, that 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 to follow up a report of an adverse reaction, a visit which was requested or a call which was made in order to respond to a specific enquiry which might be additional to those three calls.

The Panel noted Astellas' submission that there had been no recorded calls in the company's CRM system on anyone in the region in question, including the pharmacist, since November 2016.

The Panel noted, however, that three representatives had tried to telephone the pharmacist between January and April 2019 with queries about the local formulary in relation to mirabegron and enzalutamide.

Representative 1 contacted the pharmacist once on 16 January as directed by the relevant government website to ask if mirabegron had been added to the formulary and made no further contact when informed that he/she did not engage directly with representatives of pharmaceutical companies.

Representative 2, from a different business unit, contacted the pharmacist on 21 January in relation to enzalutamide at the recommendation of an oncology nurse. The representative obtained contact details from the relevant government webpage and contacted him/her as directed by that webpage. It appeared to the Panel from Astellas' submission that the pharmacist stated that he/she did not talk to industry and put down the telephone before enzalutamide was mentioned.

The Panel noted that representative 3 had tried twice to contact the pharmacist (21 March and 3 April) to understand the process for applying for enzalutamide to be considered on the local formulary and left voice messages on both occasions. The Panel noted that this was done despite representative 3 being aware of representative 2's interaction with the pharmacist and his/her position on speaking with industry.

The Panel noted that the three representatives telephoned the pharmacist four times between 16 January and 3 April 2019 with queries about the company's medicines and the local formulary. The Panel noted Astellas' submission that the relevant government website directed enquiries about the formulary to the pharmacist as the single designated contact, therefore it was not unreasonable for the representatives to assume that the individual should be contacted in order to understand whether a medicine was on the formulary, or to understand how a medicine could be placed on the list.

The Panel considered that if more than one representative from a company called the same health professional or other relevant decision maker, whether in relation to the same medicine or different medicines, particular care should be taken in relation to the number, timing of, and interval between calls made by those representatives to avoid inconveniencing the individual. The Panel noted Astellas' view that as it considered medicines were not promoted during the calls the interactions were not entered on the CRM system. The Panel did not consider whether the calls were promotional or non-promotional but considered that it would be helpful if such calls were documented so that companies could assess such interactions in relation to Clauses 15.2 and 15.4 of the Code.

The Panel noted Astellas' submission that representatives 1 and 2 had each contacted the pharmacist once; no further contact was made once they knew the pharmacist's position on speaking to industry. The Panel noted that representative 3, however, had tried to contact the pharmacist twice despite knowing his/her position on speaking with industry. The Panel noted Astellas' submission that the individual was the single designated point of contact on the relevant government webpage which the Panel noted provided a name and contact telephone number but no email or postal address. Nonetheless and on balance the Panel considered that the pharmacist's wishes were not observed by representative 3 and a breach of Clause 15.4 was ruled as acknowledged by Astellas. The Panel considered that representative 3 had failed to maintain a high standard of ethical conduct in this regard and a breach of Clause 15.2 was ruled as acknowledged by Astellas.

The Panel noted that Clause 15.9 stated, *inter alia*, that briefing material must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code.

The Panel noted Astellas' submission that field-based personnel were reminded about calls and contacts standards on incentive scheme documentation and briefing materials and that sales staff received additional training on the Code in 2017 and 2018, which specifically covered the requirements of Clause 15.4 to observe arrangements in place at any particular establishment and to not cause inconvenience. The Panel noted that a training presentation titled 'How should a representative behave?' stated, *inter alia*, that the timing and duration of calls must not cause inconvenience, that representatives must know and adhere to any local policies in place, the company's definition of a call versus a contact, and that call frequency must be no more than three per health professional per year.

The Panel noted its comments above and considered that it had no evidence before it that the representatives' briefing materials advocated any course of action which would likely lead to a breach of the Code in relation to calls and contacts with health professionals and other relevant decision makers, and observing the wishes of individuals and the arrangements in force in any particular establishment. The Panel therefore ruled no breach of Clause 15.9.

Noting its ruling of no breach of Clause 15.9 above and in particular noting the content of the relevant government webpage the Panel did not consider that Astellas had failed to maintain high standards in this regard and ruled no breach of Clause 9.1.

Complaint received 10 April 2019

Case completed 2 October 2019