ANONYMOUS v SANDOZ

Conduct of a representative

An anonymous health professional complained about the questions asked of the speakers by a Sandoz medical science liaison (MSL) at a Sandoz-sponsored meeting. Sandoz marketed the biosimilars Zessly (infliximab) and Hyrimoz (adalimumab).

The complainant explained that in February 2019, he/she attended an educational event run by Sandoz in Glasgow and connected to a venue in London via a video link. The event was advertised as non-promotional and health professionals spoke about diseases, treatment and therapeutic drug monitoring. The meeting ended with a multidisciplinary panel discussion from some of the remaining speakers. The purpose of the discussion was for attendees to ask the speakers more in depth questions. There were no questions from the audience so the Sandoz representatives asked questions. The complainant stated that he/she was concerned about the motive behind one of the named representative's questioning. The representative asked questions about switching and biosimilars such as how to do a successful switch, and then went on to mention therapeutic drug monitoring and how important it was. Upon discussions with his/her colleagues, the complainant had learned that Sandoz offered free therapeutic drug monitoring with some of its biosimilars. In that regard the complainant alleged that the representative had tried to influence the attendees into doing biosimilar switching and in turn switching to a Sandoz biosimilar due to the therapeutic drug monitoring offerings.

The detailed response from Sandoz is given below.

The Panel noted Sandoz's submission that it made funding available for therapeutic drug monitoring (TDM) services for its infliximab and adalimumab products on a reactive basis only. Its availability was not publicised and there was no proactive offer of the service. Sandoz submitted that while TDM was included as a topic on the agenda there was no mention at any time of Sandoz's involvement in the provision or funding of TDM services.

The Panel noted that the stated purpose of the meeting titled 'Biologics and co-morbidities in Autoimmune Disease: What can we learn from each other?' was to facilitate discussion around the approaches to patient management within the different therapy areas, to gain insight into co-morbidities and other challenges faced by health professionals who managed patients with autoimmune diseases and prescribed biologic therapies.

The Panel noted that the therapeutic drug monitoring presentation was delivered by an independent scientist and discussed drug levels in relation to infliximab and adalimumab, immunogenicity and measurement platforms. The presentation did not refer to funding or Sandoz's position on reactive funding. The Panel noted that other presentations during the day also referred to TDM, for example, the specialist gastro pharmacist's presentation on his/her role in biologics referred to TDM studies with infliximab and adalimumab. None of the presentations referred to Sandoz's position on reactive funding for TDM services for its biosimilars infliximab and adalimumab. The Panel noted that a nurse requested to change his/her presentation to 'How to implement biosimilars' which Sandoz agreed to; this presentation referred to infliximab and adalimumab but made no specific reference to Sandoz's biosimilars, Zessly and Hyrimoz.

The Panel noted that at the question and answer session at the end of the meeting, according to Sandoz, neither the panel nor the audience asked questions and thus the MSLs chairing the meeting asked a number of questions. The Panel noted that the MSL in question asked 4 questions and only the fourth question referred to therapeutic drug monitoring. The MSL's fourth question referred to a clinician who was '… really invested in things like TDM and levels and TNF …' and referred to the pressure across all specialities to use anti-TNF first line due to cost and queried whether, due to the potential for an immune shift, if it was always the best biologic to choose, finishing by asking the panel what practice they used to select a biologic and if they agreed with using anti-TNF first line due to its cost.

The Panel noted that the question at issue focussed on anti-TNF biologics and that there were many biosimilars within that class. The Panel did not consider on the evidence before it that the MSL in question had tried to influence attendees to switch to a Sandoz biosimilar due to its therapeutic drug monitoring offerings as alleged. In that regard, the therapeutic drug monitoring had not been referred to by the MSL as an inducement to prescribe and the Panel ruled no breach of the Code.

The Panel considered that the complaint solely concerned the questions asked by the MSL. Given its ruling and comments above the Panel considered that the fourth question which referred to therapeutic drug monitoring did not constitute a disguised promotional activity and no breach was ruled. Similarly given its comments and rulings above the Panel did not consider that either the company or the MSL had failed to maintain high standards in this regard and no breach of the Code was ruled including Clause 2.

An anonymous health professional complained about the questions asked of the speakers by a Sandoz medical science liaison (MSL) at a Sandoz-sponsored meeting. Sandoz marketed the biosimilars Zessly (infliximab) and Hyrimoz (adalimumab).

COMPLAINT

The complainant explained that in February 2019, he/she attended an educational event run by Sandoz in Glasgow and connected to a venue in London via a video link. The event was advertised as non-promotional and health professionals spoke about diseases, treatment and therapeutic drug monitoring. The meeting ended with a multidisciplinary panel discussion from some of the remaining speakers. The purpose of the discussion was for attendees to ask the speakers more in depth questions. There were no questions from the audience so the Sandoz representatives asked questions. The complainant stated that he/she was concerned about the motive behind one of the named representative's questioning. The representative in question had asked questions about switching and biosimilars such as how to do a successful switch, and then went on to mention therapeutic drug monitoring and how important it was. Upon discussions with his/her colleagues, the complainant had learned that Sandoz offered free therapeutic drug monitoring with some of its biosimilars. In that regard the complainant considered that the representative had tried to influence the attendees into doing biosimilar switching and in turn switching to a Sandoz biosimilar due to the therapeutic drug monitoring offerings.

When writing to Sandoz the Authority asked it to consider the requirements of Clauses 2, 9.1, 12.1, 15.2 and 18.1.

RESPONSE

Sandoz stated that the meeting in question, 'Biologics and Co-morbidities in Autoimmune Disease: What Can We Learn from Each Other?', was a medical educational, non-promotional event which it had initiated, organised and funded. The arrangements for the meeting were approved through the Sandoz internal compliance system and the event was hosted at two sites (Glasgow and London), with an audience and speakers at both sites. An audio-visual link between the two venues allowed the audience at either site to see and hear all presentations during the day. The event was run by the medical function, the only commercial involvement was on the day logistical support. The speakers were external health professionals and one scientist who all had relevant experience within the therapeutic areas being discussed. The chairs at both sites were Sandoz medical science liaisons (MSLs). A transcript of the question and answer session referred to by the complainant was provided.

The non-promotional meeting was intended to facilitate discussion around the approaches to patient management within the different therapy areas, and to gain insight into the co-morbidities and other challenges faced by health professionals who managed patients with autoimmune diseases and prescribed biologic therapies. Health professionals invited to the meeting were from dermatology, rheumatology and gastroenterology. There were a number of co-morbidities that spanned these different therapy areas, and there were already clinics set up jointly between the different specialities, although this approach was not consistently demonstrated. The objective of the meeting was to bring together doctors, nurses and pharmacists who worked in these therapy areas, to exchange information and best practice, with the aim of improving patient care.

Health professionals were told about the meeting initially by a 'Save the Date' item, which was sent out from November 2018, followed by an email or hard copy invitation distributed from January 2019, which included the proposed agenda. Both non-promotional items were certified and distributed by representatives and MSLs. The invitation offered the recipient further information by means of contacting the MSLs. The representatives' role in distributing the 'Save the Date' and invitation was limited to providing the item in a non-promotional interaction without any detailed discussion. More than 400 invitations were distributed across the relevant UK health professionals.

The agenda consisted of presentations by rheumatology, gastroenterology and dermatology consultants who provided an overview of the diseases in their specialty for which biologics were a treatment option, the assessment tools used to assess the diseases, the management and therapies used, and how they monitored response. This was followed by an overview of therapeutic drug monitoring (TDM) by a scientist employed as the clinical lead for laboratory immunology at a hospital trust. A specialist hospital pharmacist in gastroenterology then provided an overview of his/her role which included staff education, communicating with patients and interpreting the results of TDM.

There were a further 3 sessions by specialist nurses in dermatology, rheumatology and gastroenterology, who all had the initial brief to discuss their role in the clinic and managing co-morbidities and discuss a relevant case study. Two of the nurses presented on these topics. However, the specialist inflammatory bowel disease (IBD) nurse did not have time to prepare a presentation on the agreed topic ('Nurse experience of joined up approach in their trust') and so he/she proposed an alternative title and subject ('How to implement biosimilars') which he/she had previously presented (details provided). This change was proposed two weeks before the meeting in February. The medical team considered the suggestion and agreed that it was an acceptable alternative at this late stage. Although highly relevant to the attendees, the topic of biosimilars switching was not initially included in the agenda and its addition was due to the last minute request from the nurse. The team also suggested that the nurse provided information on the 'IBD Passport' which was an online resource founded by him/her.

This was an entirely independent website that provided practical information for health professionals and was thought to be a useful topic to present at the meeting.

The final part of the meeting was a multidisciplinary panel discussion and question and answer session, scheduled for 1 hour.

This agenda did not change from the planning stage, except for the change noted above. A copy of the agenda and the certificate were provided.

An MSL chaired each meeting (Glasgow and London) and a medical advisor also attended the London meeting as an observer. Both sites had two external agency staff to provide the audio-visual link between the two sites, film and record the session. A representative provided logistical support at each site due to the number of attendees (details provided). Sandoz provided details of who had attended each meeting together with a copy of the certified briefing material provided to the representatives before they attended the meeting.

Sandoz explained that the representative referred to by the complainant was an MSL who directly reported to the medical director. The MSL's role was entirely non-promotional. As stated above, the meeting was initiated, organised and funded by the medical function at Sandoz, and an MSL chaired the meeting at each location. This involved opening the meeting, providing 'housekeeping' information (eg timings), introducing the speakers and chairing the Q&A session, scheduled for the last hour of the meeting.

During the Q&A session at the end of the meeting, neither the panel nor audience asked any questions initially. In their role as meeting chairs, the MSLs asked the panel a number of questions. These were not briefed before the meeting or prepared in advance but were asked as a direct result of the presentations and discussions during the day. Stimulating debate and encouraging audience participation was an established practice by those who chaired meetings and the MSLs considered at the time that this was required of them, as on the agenda, there was an hour set aside for this discussion.

- Sandoz summarised the topic of each of the four questions asked by the MSL Glasgow, which Sandoz understood formed the basis of the complaint (to provide context) and provided the full transcript of the questions as they were asked at the meeting. They included a question on data package for approval and whether there was a justification to require data on neutralizing and non-neutralizing anti-bodies; a question on whether gastroenterologists were concerned that biosimilars might be launched with no data on gastroenterology indications; a question on likelihood of the National Institute for health and Care Excellence (NICE) guidelines becoming more aligned with EU requirements rather than current requirement for strict adherence to disease activity scores (DAS) before biologic prescription; and a question on how biologics were selected for first line use.

The MSL role was the field-based element of Sandoz's medical affairs department. It provided a non-promotional service to health professionals that facilitated interactions and scientific discussions on relevant therapy areas. The employee in question had been trained on the Code and participated in ongoing Code educational activities. His/her role profile and Code training certificates were provided.

Sandoz explained that TDM was increasingly seen as an important tool in the management of patients on biologic treatments, especially within gastroenterology. NHS Scotland funded TDM in patients on infliximab and adalimumab, but across the rest of the UK availability was variable. Pharmaceutical companies were a well-established source of funding for these services and in that regard Sandoz funded TDM services for its infliximab and adalimumab products on a reactive basis only. Its availability was not publicised and the service was not offered proactively. Only if requested or enquired about would the availability of the service be discussed. Further details on this were provided in a medical briefing and the terms of the TDM reactive provision of funding to trusts was also defined in a template contract agreement (copies provided).

While TDM was included as a topic on the agenda of the meeting, Sandoz's involvement in the provision or funding of TDM services was not discussed.

Sandoz noted that the complaint related specifically to the questions asked by an MSL set out above. It was clear from the questions that there was no basis for two of the complainant's central assertions: that the MSL asked the panel questions about switching and biosimilars such as how to do a successful switch and that he/she then went onto mention therapeutic drug monitoring and how important it was.

Sandoz stated that it had reviewed the questions to determine whether the MSL had tried to influence the attendees into doing biosimilar switching and in turn switching to a Sandoz biosimilar due to the therapeutic drug monitoring offerings as alleged.

The first question was a technical question, which related to regulatory data requirements. It was clear from the outset that the question applied equally to biosimilars and originators, and this was explicitly stated. There is nothing in the question which could be considered an attempt to influence attendees into switching to biosimilars. There was no mention of either any Sandoz product or therapeutic drug monitoring.

The second question related to the lack of data available for biosimilars in gastroenterology and how this might be a concern for professionals and patients. Since this was clearly a drawback in prescribing biosimilars it contradicted the assertion that the representative had tried to influence the attendees into biosimilar switching. No mention was made in this question of either any Sandoz product or TDM.

The third question was about the differences between NICE and the EU approach to treatment pathways. There was no mention of biosimilar, any Sandoz product or TDM.

The final question was the only one which referred to TDM. In this question, the representative commented on the appeal of anti-TNF biologics as a first line treatment due to their 'cheapness' and queried whether that was always best, noting that 'it might not always be the best biologic to go to'. On consideration of this question, the complainant's interpretation was not supported.

Sandoz addressed the elements of the complaint individually.

> '…trying to influence the attendees into doing biosimilar switching…'

The question did not specifically mention either biosimilars or originators.

The question focused on anti-TNF biologics. There were many available biosimilars in this class. However, a reference to anti-TNF biologics clearly could not be taken to refer exclusively to biosimilars and not originators. Reference was made to the 'cheapness' of anti-TNF biologics. While their price could be in part attributed to the availability of biosimilars, anti-TNF biologics were comparatively 'cheap' as a class, including originators.

Moreover, the representative in this question queried whether the practice of using this class, which contained a comparatively high number of biosimilars, as a first line treatment was in fact the correct course. This directly contradicted the complainant's contention that the representative had tried to influence the attendees into doing biosimilar switching.

> '…and in turn switching to a Sandoz biosimilar….'

As above, there was no support for the assertion that any attempt was made to influence attendees into switching to any biosimilar. No reference was made to any Sandoz product. Sandoz noted that it was not the only manufacturer of anti-TNF biosimilars, and so referring to anti-TNF biologics was not a disguised reference to Sandoz products.

> '…due to the therapeutic drug monitoring offerings.'

The final question asked by the representative was the only question, which mentioned TDM. The reference was brief and incidental ('[name] who's really invested in things like TDM …') and could not be considered an inducement to change prescribing or other behaviour.

Sandoz similarly refuted any contention that the mere mention of TDM in the question was improper. As noted above, TDM was a topic on the agenda for the meeting, and a presentation was made by an independent specialist. There was no mention, at any time, of Sandoz's involvement in the provision or funding of TDM services. The fact that the complainant stated that it was upon discussion with his/her colleagues that he/she learned that Sandoz offered free therapeutic drug monitoring, further reinforced that this was not discussed or mentioned during the meeting.

With regard to Clause 12.1, Sandoz submitted that there was no promotional content or any information that could be deemed disguised promotion in any of the presentations or as part of the Q&A session. Sandoz products were not mentioned. There was no reference to Sandoz's funding for TDM or encouragement to switch to Sandoz biosimilars. Sandoz did not consider that either the materials used during the meeting, or its intent, were promotional. The presentations were created by the external speakers (and only reviewed and certified by Sandoz to ensure they were in line with the requirements of the Code). The Q&A, as demonstrated by the transcript provided, had no promotional content.

The conduct of all Sandoz attendees demonstrated a high standard of ethical conduct and complied with all relevant requirements of the Code. Representatives were only involved in a logistical capacity, and there was no specific mention of any Sandoz-branded products. Sandoz submitted that the transcript made clear that the MSLs maintained a high standard of ethical conduct, and it did not consider that the complainant had provided any evidence that this was not the case. The company denied a breach of Clause 15.2.

Sandoz stated that there was no pecuniary benefit offered, promised or implied to the attendees as an inducement to prescribe. The complainant alleged that TDM was mentioned in such a way as to influence the attendees to switch to Sandoz biosimilars on the basis of the free TDM service offered. The only mention of TDM from the MSLs was in passing, as one of the things that a specialist in the field was 'invested in'. The inclusion of a presentation on TDM was unrelated to service provision. That Sandoz could fund TDM was not mentioned. The fact that the complainant learnt that Sandoz did offer free TDM upon discussion with his/her colleagues reinforced that this was not discussed or mentioned during the meeting. The provision of TDM by the company was clearly defined and was offered as part of a package deal as has been described.

Sandoz submitted that high standards were maintained at all times in the preparation and execution of the meeting. The objective to promote a better understanding of the three therapy areas was clear from the outset. The totality of evidence provided supported this assertion. The company denied a breach of Clause 9.1.

The meeting in question was a non-promotional, educational meeting with the sole aim of providing relevant education and cross specialism perspectives for health professionals working in auto-immune diseases. The meeting had not brought discredit upon, or reduced confidence in, the industry.

Attendees gave very positive feedback and noted the value of this type of event.

Sandoz reiterated that the meeting was an educational, non-promotional, medical meeting, which sought to bring together different specialties, where there were a number of co-morbidities that required joint working with the ultimate aim of providing better care for patients. There was no intention or evidence that the meeting was set up to promote any of Sandoz products, or to tell the delegates about reactive funding of TDM from Sandoz to try and persuade them to prescribe a Sandoz product.

Maintaining the highest standards of compliance was very important to Sandoz and it took any complaints seriously and had used this as an opportunity to rigorously examine its practices.

PANEL RULING

The Panel noted Sandoz's submission that it made funding available for TDM services for its infliximab and adalimumab products on a reactive basis only. Its availability was not publicised and there was no proactive offer of the service. Sandoz submitted that while TDM was included as a topic on the agenda there was no mention at any time of Sandoz's involvement in the provision or funding of TDM services.

The Panel noted that the stated purpose of the meeting titled 'Biologics and co-morbidities in Autoimmune Disease: What can we learn from each other?' was to facilitate discussion around the approaches to patient management within the different therapy areas, to gain insight into co-morbidities and other challenges faced by health professionals who managed patients with autoimmune diseases and prescribed biologic therapies. The Panel noted that the meeting was scheduled to start at 9am and finish at 5pm and, according to the agenda, the day began with 3 presentations in each of rheumatology, dermatology and gastroenterology including an overview of the diseases and their management and therapies for which biologics were a treatment option. There followed an Overview of Therapeutic Drug Monitoring followed by a presentation on the role of the specialist gastro pharmacist in biologics and 3 sessions by specialist nurses in dermatology, rheumatology and gastroenterology respectively to discuss their role and a relevant case study. The latter nurse changed the content of his/her presentation at a late stage to 'How to implement biosimilars'. The day concluded with the multi-disciplinary panel discussion and Q&A.

The Panel noted that the therapeutic drug monitoring presentation was delivered by an independent scientist and discussed drug levels in relation to infliximab and adalimumab, immunogenicity and measurement platforms. The presentation did not refer to funding or Sandoz's position on reactive funding. The Panel noted that other presentations during the day also referred to TDM, for example, the specialist gastro pharmacist's presentation on his/her role in biologics referred to TDM studies with infliximab and adalimumab. None of the presentations referred to Sandoz's position on reactive funding for TDM services for its biosimilars infliximab and adalimumab. The Panel noted that, as referred to above, a nurse requested to change his/her presentation to 'How to implement biosimilars' which Sandoz agreed to; this presentation referred to infliximab and adalimumab but made no specific reference to Sandoz's biosimilars, Zessly and Hyrimoz.

The Panel noted that at the question and answer session at the end of the meeting, according to Sandoz, neither the panel nor the audience asked questions and thus the MSLs who were chairing the meeting asked a number of questions. The Panel noted that the MSL in question asked 4 questions and only the fourth question referred to therapeutic drug monitoring. The MSL's fourth question referred to a clinician who was '... really invested in things like TDM and levels and TNF ...' and referred to the pressure across all specialities to use anti-TNF first line due to cost and queried whether, due to the potential for an immune shift, if it was always the best biologic to choose, finishing by asking the panel what practice they used to select a biologic and if they agreed with using anti-TNF first line due to its cost.

The Panel noted that the question at issue focussed on anti-TNF biologics and that there were many biosimilars within that class. The Panel did not consider on the evidence before it that the MSL in question had tried to influence attendees to switch to a Sandoz biosimilar due to its therapeutic drug monitoring offerings as alleged. In that regard, the therapeutic drug monitoring had not been referred to by the MSL as an inducement to prescribe and the Panel ruled no breach of Clause 18.1 of the Code.

The Panel considered that the complaint solely concerned the questions asked by the MSL. Given its ruling and comments above the Panel considered that the fourth question which referred to therapeutic drug monitoring did not constitute a disguised promotional activity and no breach of Clause 12.1 was ruled. Similarly given its comments and rulings above the Panel did not consider that either the company or the MSL had failed to maintain high standards in this regard and no breach of Clauses 15.2 and 9.1 were ruled. The Panel consequently ruled no breach of Clause 2.

Complaint received **18 March 2019**

Case completed **18 September 2019**