CASE AUTH/3697/10/22 ***NO BREACH OF THE CODE***

COMPLAINANT v ASTRAZENECA

Presentations about influenza vaccination

CASE SUMMARY

This case was in relation to presentations at an AstraZeneca sponsored symposium.

The Panel ruled no breach of the following Clauses of the 2021 Code on the basis that:

- **within the context of the presentation the speaker's comment 'mismatch of the vaccine' was not inaccurate, incapable of substantiation, did not create a misleading impression and the general nature of the speaker's comments was such that the phrase in question did not disparage any pharmaceutical company or flu vaccines, and**
- **the complainant had not established that the presentations had not been copy approved or that the alleged misleading and unsubstantiated comments resulted from a failure, on AstraZeneca's part, to brief the speaker appropriately.**

No Breach of Clause 6.1	**Requirement that information must be accurate, up-to-date and not misleading**
No Breach of Clause 6.6	**Requirement that another company's medicines must not be disparaged**
No Breach of Clause 8.1	**Requirement to certify promotional material**
No Breach of Clause 9.1	**Requirement that all relevant personnel concerned with the preparation or approval of material or activities covered by the Code must be fully conversant with the Code and the relevant laws and regulations**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

An anonymous, contactable complainant raised concerns about two presentations at a symposium sponsored by AstraZeneca UK Limited.

COMPLAINT

The complainant submitted that they attended a flu congress entitled 'Options XI for the Control of INFLUENZA' in September 2022 and attended a symposium talk hosted by AstraZeneca that had several health professional speakers.

The complainant's concerns were:

1 The slides presented did not seem to have been copy approved. The complainant joined after the first few minutes and did not see a job bag code on any slide, especially the final one.

2 One of the speakers suggested the effectiveness of flu vaccines in 2021 was down to a 'mismatch' of strains. To the complainant's knowledge this was factually incorrect and, in fact, was disparaging against current flu vaccine producers and could lead to mistrust in current vaccines and industry partners. The complainant thought that this was strange given AstraZeneca itself produced flu vaccines. Whilst the speaker was free to air their own views, the complainant questioned, was AstraZeneca not responsible for briefing the speakers appropriately to ensure they do not say things that were incorrect, do not say things that were unsubstantiated and could bring the industry into disrepute?

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 6.1, 6.6, 8.1 and 9.1 of the 2021 Code.

RESPONSE

AstraZeneca submitted that it thought that the complainant was referring to the symposium entitled 'Active and Passive Immunoprophylaxis: Lessons from Flu and Recent Innovations to Protect Vulnerable Patients' which took place at the Options Congress in Belfast, September 2022. The symposium was sponsored by AstraZeneca. The Options Congress was an ISIRV (The International Society for Influenza and other Respiratory Virus Diseases) meeting. ISIRV was an independent and international scientific professional society promoting the prevention, detection, treatment and control of influenza and other respiratory virus diseases.

Two expert speakers presented slides during the AstraZeneca sponsored symposium. The speaker slides were examined as non-promotional materials by both the global medical affairs lead and the global nominated signatory within the dedicated materials review and approval tool, Veeva Vault PromoMats (VVPM) and, as such, there were no certificates for these materials. The global nominated signatory was a registered global signatory with the PMCPA and The Medicines and Healthcare products Regulatory Agency (MHRA) for the AstraZeneca Global business.

The approval codes and date of preparation were included on the first slide of each speaker slide deck; [named Professor] and [second named Professor]. Both experts were selected due to their expertise in respiratory disease, specifically influenza and COVID-19. One was a leading virologist and influenza expert and recognised for their work on severe acute respiratory syndrome (SARS) and H5N1. The other was a chief investigator on multiple COVID studies and had been an investigator on multiple other SARS-CoV2 trials. Since the complainant arrived a few minutes late, they might have missed the first slide being displayed, which included the approval code.

The speakers were briefed separately by two global medical affairs leaders alongside key members of the medical communications agency, who were supporting the AstraZeneca medical team, during teleconference meetings prior to the congress.

With respect to the specific allegation that one of the speakers suggested the effectiveness of flu vaccines in 2021 was down to a 'mismatch' of strains, AstraZeneca thought this allegation was associated with the presentation of a slide entitled 'Vaccine uptake and effectiveness remain a challenge for the prevention of influenza' and included information related to vaccine uptake and vaccine effectiveness in the UK.

The information on this slide was factually correct, and up-to-date, and the data was fully substantiated by the two references from the GOV.UK website. [Named Professor] presented the information on the slide covering vaccine uptake in the different groups and vaccine effectiveness in a balanced way, including reference to vaccine development, vaccine hesitancy and prevalence of flu in the last 2 years. Specifically, the statement by [named professor] about the mismatch of vaccine to circulating strain was given as a possible explanation as to the low vaccine effectiveness in the >50 years old age group. In the backdrop that [named professor] was, personally, working in vaccine development and provided a balanced overview of the current environment, as well as recognising that developers should be doing better, their opinion about reasons for low efficacy should not be taken out of context and should not be considered disparaging of any of the current flu vaccine manufacturers.

AstraZeneca, therefore, strongly refuted a breach of Clauses 6.1, 6.6, 8.1 and 9.1 for the following reasons:

> Clause 6.1 – an up-to-date presentation of the available evidence was provided and there was no direct comparison made between flu vaccines. The information presented was based on an up-to-date and reputable source – UK Government data.
>
> Clause 6.6 – no pharmaceutical company products were disparaged evidenced by both the slides and the speaker transcript.
>
> Clause 8.1 – the information was reviewed and approved by a suitably qualified and experienced individual who was knowledgeable about the UK Code of Practice. The global nominated signatory was registered as a global nominated signatory for AstraZeneca Global business with the PMCPA and the MHRA.
>
> Clause 9.1 – the symposium was organised by the global medical affairs team and supported by a medical communications agency who were fully conversant with the ABPI UK Code of Practice. The external speaker presentation slides were submitted into the AstraZeneca materials review and approval system (VVPM), reviewed and approved by both the global medical affairs leader and the global nominated signatory, and the slides included the relevant job bag approval code and date of preparation.

AstraZeneca's response for additional information

The Panel requested screenshots of the Veeva job bags for the two speaker slide presentations. AstraZeneca confirmed there were no certificates because the non-promotional materials were examined and not certified. When the approval route in Veeva Vault PromoMats (VVPM) was selected as examination, the system did not generate a certificate. AstraZeneca stated that it would be helpful to understand how the provision of screenshots from VVPM would inform the PMCPA's decision on this case in relation to Clause 8.1, which is specific to certification of promotional materials. AstraZeneca stated that it would like to ensure that it

provided the necessary information in the format anticipated, and to help ensure other non-relevant information was appropriately redacted.

In response to the Panel's request for the qualifications of the global nominated signatory who approved the speaker slide presentations, AstraZeneca confirmed the nominated signatory was on the AstraZeneca global nominated signatory list, and at the time of its response this list held by the PMCPA and MHRA did not contain any Appropriately Qualified Persons (AQPs). In order to qualify to be included in this list, the qualifications the signatory must fulfil were either registered medical practitioner or UK-registered pharmacist. AstraZeneca requested that the PMCPA confirm what further details were required by the PMCPA in order to provide a ruling on this case.

In response to the request for further information by the Panel, AstraZeneca submitted that there were individual speaker briefings in August 2022 and additionally for both speakers in September 2022 during a slide rehearsal where the speakers were briefed that:

- the activity is intended and planned to be a non-promotional scientific exchange symposium
- all content must be prepared, reviewed and approved in advance of the meeting in accordance with relevant guidelines
- all content should be presented in an objective, balanced manner and should be accurate, scientific in tone, language and intent
- information should cover all available immunoprophylaxis options, and must be accurate, fair and balanced across the available options
- Where unlicensed medicines are being discussed, this must be made clear to the audience and is only for the purpose of sharing scientific information
- Where relevant, the regulatory status (e.g., emergency use authorization, conditional marketing authorization or temporary supply authorization) and the issuing authority and region/country (European Medicines Agency (EMA), Europe; Food and Drug Administration (FDA), US; MHRA, UK) must be made clear to the audience.

Differences in presentation slides

AstraZeneca submitted that the difference between the presentation slides provided with its response and those provided by the complainant was that when the 'viewable rendition' was extracted from VVPM, the software embedded the job bag number and expiry date on every page of the pdf downloadable version. If AstraZeneca extracted the 'source file', which was a PowerPoint slide deck, this information (job bag number and expiry date) was not added and was the same as the show reel. The job bag number (from the VVPM downloadable viewable rendition pdf) matched the job bag number included on the first slide for each presentation.

PANEL RULING

The Panel noted that the complaint concerned an AstraZeneca symposium at an 'Options for the control of influenza' meeting organised by the International Society for Influenza and other Respiratory Virus Diseases (ISIRV). The complainant alleged that the symposium slides did not appear to have been copy approved as no job codes were visible and referred to two photographs taken during the symposium, one slide from each of the two presentations. The Panel noted that the speaker presentation slides submitted by AstraZeneca included a job code and approval date on the first slide in each deck and also that the complainant had joined the

symposium a few minutes after the start and therefore may have missed seeing the job codes on the opening slides of the presentations.

The Panel noted the differences between the slides in the two photographs provided by the complainant and those submitted by AstraZeneca in relation to the job code and expiration date and also noted AstraZeneca's subsequent explanation in this regard, that the job code and expiry date had not been on the 'show reel' version used at the symposium which was the same as the source file reviewed and approved in AstraZeneca's electronic approval system.

The Panel noted that the requirement for a unique reference number (the job code) was included within the Quality Standards section of the Guidelines on Company Procedures Relating to the ABPI Code and related to materials requiring certification, although it noted that it was common practice for companies to also include a unique reference number on examined materials. The Panel noted AstraZeneca's submission that the speaker presentations had been examined as non-promotional material by a global medical affairs lead and a global nominated medical signatory whose qualifications met the requirements of the Code.

The Panel noted that the complainant had referred to copy approval but had not indicated whether or not they considered the presentations in question to be promotional or non-promotional and therefore whether certification or examination was appropriate. In the Panel's view, the narrow allegation concerned the principle of whether a copy approval mechanism had been used and therefore given AstraZeneca's submission that the presentations had been examined the Panel considered that it did not need to decide whether or not the material in question was promotional. The Panel noted that the complainant bore the burden of proof and had not alleged or provided any reasons to support an assertion that the material in question was promotional or needed to be certified. The Panel also noted AstraZeneca's submission that its approval system did not generate a certificate for materials that were examined, rather than certified. The Panel considered that it was good governance to have documentary evidence to demonstrate that material had been examined and was concerned that such evidence was not before the Panel. Nonetheless, the Panel considered that the complainant had not established that the presentations had not been copy approved as alleged. Further, the complainant had not alleged or established that examination was inappropriate. On the very narrow ground alleged, that the material had not been copy approved, the Panel therefore **ruled no breach of Clause 8.1**.

The Panel noted that the second limb of the complaint concerned statements made by the first speaker, in relation to the effectiveness of flu vaccines being down in 2021 due to a 'mismatch' of strains, which the complainant believed to be factually incorrect and disparaging to current flu vaccine manufacturers.

The Panel noted that the slide accompanying the statements in question was entitled 'Vaccine uptake and effectiveness remain a challenge for the prevention of influenza' and included two images; the first a bar chart showing vaccine uptake in England in 2021-2022 in specific populations, the second, a visual, showed adjusted influenza vaccine effectiveness in England for 2021–2022 in two age groups, 1-17 years (73%) and over 50 years (26%), and was referenced to the UK government report – Surveillance of influenza and other seasonal respiratory viruses in the UK in winter 2021 to 2022.

AstraZeneca provided the transcript for the relevant slide which indicated that the speaker used the data to explain some of the difficulties for the influenza prevention strategies, in particular

vaccine hesitancy and low vaccine uptake levels in some target populations as well as variations in vaccine effectiveness in different groups; this was around 70% in young adults and young people but only 26% in those over 50 years of age. According to the speaker, 2021-2022 was a bad year and the low level of effectiveness in those aged 50 years and over 'was to do with the circulating strains and the possibilities to vaccinate, and also the mismatch of the vaccine, possibly' as well as the low levels of influenza in the previous two years.

The Panel noted that Clause 6.1 required, amongst other things, information to be balanced, fair, objective and unambiguous, based on an up-to-date evaluation of all the available evidence and not misleading. The Panel further noted that the government report Surveillance of influenza and other seasonal respiratory viruses in the UK in winter 2021 to 2022 indicated that while the provisional overall adjusted influenza vaccine effectiveness was 26% in adults aged 50 years and over, protection against different strains of influenza varied considerably; for the same population the adjusted influenza vaccine effectiveness for the A(H1N1)pdm09 strain was 76% (95% CI: 30% to 92%) but for influenza A (H3N2) was 28% (95% CI: -3% to 50%). The predominant strain of influenza A in England in 2021-2022 was influenza A(H3N2).

The Panel noted the allegation that the speaker's comments were disparaging against current flu vaccine producers and could lead to mistrust in current vaccines and the industry contrary to Clause 6.6 which required that the medicines, products and activities of other pharmaceutical companies must not be disparaged.

The Panel noted that the speaker's comments were general in nature and did not identify any influenza vaccines or pharmaceutical companies. The Panel noted that 'mismatch of the vaccine' was not given by the speaker as the sole reason for concerns about vaccine effectiveness but was listed as one of a number of reasons and was further qualified by use of the word 'possibly'. Noting its comments above, and in particular the government report, the Panel did not consider that in the particular circumstances of this case, the speaker's use of the phrase 'mismatch of the vaccine' was inaccurate, incapable of substantiation, created a misleading impression or disparaged any pharmaceutical company or flu vaccines as alleged. The Panel therefore ruled **no breach of Clauses 6.1 and 6.6**.

The Panel noted the allegation regarding AstraZeneca's responsibility to ensure its speakers were appropriately briefed to ensure speakers did not say things that were incorrect, unsubstantiated or could bring the industry into disrepute. It considered that it was well-established that Clause 9.1 required, amongst other things, that contracted individuals involved in the preparation of materials covered by the Code were fully conversant with its requirements and that companies ensured that any materials were consistent with the Code. In the Panel's view, it was critical that the briefing provided to speakers was clear and took account of the speaker's experience in, and understanding of, the Code.

The Panel noted that according to AstraZeneca, the symposium was organised by the global medical affairs team and supported by a medical communications agency who were fully conversant with the ABPI UK Code of Practice. Prior to the meeting, AstraZeneca and the agency verbally briefed the speakers individually and again during a slide rehearsal, that:

'• the activity was intended and planned to be a non-promotional scientific exchange symposium;
- all content must be prepared, reviewed and approved in advance of the meeting in accordance with the relevant guidelines;

- all content should be presented in an objective, balanced manner and should be accurate, scientific in tone, language and intent;
- information should cover all available immunoprophylaxis options, and must be accurate, fair and balanced across the available options;
- where unlicensed medicines are being discussed, this must be made clear to the audience and is only for the purpose of sharing scientific information;
- where relevant, the regulatory status (e.g. emergency use authorisation, conditional marketing authorisation or temporary supply authorisation) and the issuing authority and region/country (EMA, Europe; FDA, US; MHRA, UK) must be made clear to the audience.'

The Panel was concerned that no written briefing document was provided to the speakers. In its view the provision of a written briefing was good practice and helpful as it reinforced the importance of compliance with the Code and enabled speakers to refer back to the information.

The Panel noted that the complainant had linked the alleged misleading and unsubstantiated comments to a failure, on AstraZeneca's part, to appropriately brief the speaker, however, in light of its rulings of no breach above in relation to the speaker's comments and its comments regarding the verbal briefings, the Panel ruled **no breach of Clause 9.1**.

The Panel noted the complainant had raised the importance of briefing speakers appropriately to ensure that 'they don't say anything that is incorrect or unsubstantiated as this could bring the industry into disrepute', however, it had not been asked to consider the requirements of Clause 2 and thus made no comment in relation to that Clause. In any event, the Panel noted its ruling of no breach of Clause 9.1 above.

Complaint received **14 October 2022**

Case completed **28 September 2023**