CASE AUTH/3658/6/22 ***NO BREACH OF THE CODE***

COMPLAINANT v NOVARTIS

Allegations about an email regarding a promotional symposium for Mayzent (siponimod)

CASE SUMMARY

This case was in relation to an email distributed by a multiple sclerosis independent education provider about a Novartis promotional symposium.

The Panel ruled no breach of the following Clauses of the 2021 Code as:

- **the email had been certified**
- **the complainant had not established that reference to 'Mayzent for SPMS with Active Disease', within the particular material at issue, promoted Mayzent in a manner that was inconsistent with its SPC or was unqualified as alleged**
- **the complainant had not established that the material had not made clear that the webinar was only for health professionals.**

No Breach of Clause 2	**Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1	**Requirement to maintain high standards**
No Breach of Clause 8.1	**Requirement to certify promotional material**
No Breach of Clause 11.2	**Requirement not to promote a medicine in a manner that was inconsistent with its SPC**

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 who described themselves as a health professional complained about an email regarding a Mayzent (siponimod) Novartis promotional symposium distributed by a Multiple Sclerosis independent education provider.

COMPLAINT

The complainant alleged that the promotion of Mayzent was outside of the licensed indication and that the bespoke content on the website (link provided) had not been certified.

The complainant stated that the webpage at issue had timings for a promotional symposium organised by Novartis. The following text was populated on the webpage for the webinar:

'Mayzent for SPMS with Active Disease'.

The complainant alleged that Mayzent had a very specific licence and simply saying SPMS with active disease, without qualification of the actual licence, was outside the particulars of the summary of product characteristics (SPC). The complainant stated that the licence for Mayzent was:

> 'Mayzent is indicated for the treatment of adult patients with secondary progressive multiple sclerosis (SPMS) with active disease evidenced by relapses or imaging features of inflammatory activity (see section 5.1).'

The complainant alleged that the wording on the webpage did not qualify adult patients and there was no mention of relapses and imaging features etc. The standalone claim of medicine and indication mentioned was unqualified.

The complainant alleged that the webpage was not certified as there was no date of production or unique code noted on the page. There was no mention from the start that the webinar was only for health professionals. The complainant alleged breaches of Clauses 11.2, 5.1, 8.1 and 2.

When writing to Novartis**,** the Authority asked it to consider the requirements of Clauses 2, 5.1, 8.1 and 11.2 of the Code as cited by the complainant.

RESPONSE

Background

Novartis submitted that Mayzent (siponimod) was indicated for the treatment of adult patients with SPMS with active disease evidenced by relapses or imaging features of inflammatory activity. The anonymous complainant alleged unqualified and uncertified material was in the public domain, specifically in relation to a Novartis satellite symposium at a Multiple Sclerosis independent education provider event. Novartis strongly refuted any such allegation and addressed each allegation in turn.

Clause 8.1

The complaint alleged that the purportedly offending material had no job code, date or certification, and was thereby in contravention of the requirements under Clause 8.1 of the Code. However, Novartis submitted that the material clearly stated, in bold, the date of preparation and unique code in the standard Novartis UK format: UK | September 2021 | 151725. Furthermore, the material had been certified prior to the event by a final signatory on behalf of Novartis, in the appropriate manner in accordance with Clause 8.1. The individual certifying the material was a registered UK pharmacist and was not the person responsible for either developing or drawing up the material in question. The certificate was provided as evidence to support this position.

Accordingly, in light of the above, Novartis refuted a breach of Clause 8.1.

Clause 11.2

Novartis did not accept there had been any promotion beyond the marketing authorisation, nor was there any inconsistency with the particulars listed in Mayzent's SPC – Mayzent was indicated for active Secondary Progressive Multiple Sclerosis (SPMS).

In addition, Novartis made the following submissions:

Indication not explaining 'activity'

(i) The title '*Mayzent for SPMS with Active Disease*' was used for one of the sessions, lasting approximately five (5) minutes, which was within the promotional satellite symposium of forty (40) minutes duration. There was no intention, overt or otherwise, that the title was to be construed as a claim. In any event, the full indication was clearly cited in the webinar slides.

(ii) Mayzent's licensed therapeutic indication as stated in the SPC was *'for the treatment of adult patients with secondary progressive multiple sclerosis (SPMS) with active disease evidenced by relapses or imaging features of inflammatory activity'* (the '**Indication**'). In this context, 'activity' was a well understood and accepted term within MS to mean either relapse activity and/or magnetic resonance imaging (MRI) activity – both permissible under the Indication; Novartis submitted, therefore, that utilising the phrase '*Mayzent for SPMS with Active Disease*' was indeed in accordance with the terms of the marketing authorisation and, as such, was not inconsistent with the particulars listed in the SPC. This was further substantiated by the fact that:

a) The Lublin Criteria (Lublin *et al*, 2014) and the revised McDonald criteria (Thompson *et al*, 2018) defining the clinical course of MS were the most cited and widely accepted definitions of MS disease course. In these criteria, disease activity was determined by clinical relapses and/or MRI activity.

b) In clinical practice, relapses and imaging features of inflammatory activity were the two methods of identifying disease activity in MS. These definitions were used routinely in diagnosis of activity across the MS Spectrum (in Primary Progressive MS, Relapsing MS and Secondary Progressive MS) and to fulfil reimbursement criteria for other MS disease modifying therapies (NHS England Treatment Algorithm, updated 2019).

(iii) Prescribing information was provided and contained all information required according to Clause 12.2 of the Code, including the full licensed therapeutic indication.

Not using 'Adult'

(iv) SPMS, a specific phenotype of MS, followed an initial relapsing remitting course. It was an adult onset phenotype with a median time to SPMS diagnosis of 21.4 years from MS onset (95% CI 20.6 to 22.2 years) and median age of SPMS diagnosis of 53.7 years (95% CI 53.1 to 54.3 years) for adult-onset MS (Koch *et al*, 2010). Between 3% and 10% of patients with MS present under 16 years of age (Boiko *et al*, 2002), 98% of which present with a relapsing–remitting course and the remaining 2% presented primary progressive MS (Renoux, *et al*, 2007). Patients with childhood-

onset MS took over 10 years longer to reach secondary progressive disease phase compared to adults. The estimated median time from childhood-onset MS to secondary progression was 28 years, and the median age at conversion to secondary progression was 41 years (Renoux, *et al*, 2007, Alroughani & Boyko, 2018).

(v) Based on the meeting target audience, the webinar topic of SPMS: difficult discussion in progressive disease, and the above explanation of SPMS, it was clear that this was a meeting focused on adult patients.

No mention from the start that this webinar was only for health professionals.

(vi) The organisation holding the event was an independent education provider for clinicians, specialist nurses and professions allied to medicine. The training programme focused on both disease management and service transformation. Each priority condition was led by an Academic Faculty of practicing clinicians who operated within a separate disease-focused academy; the academy in question provided expert training in MS for health professionals.

(vii) The mailout for the meeting was distributed by the academy to raise awareness for the live webinar which was held in September 2021. The mailout was part of the academy's standard communication with its members and was sent out independently of Novartis.

(viii) The live webinar contained two sessions: a Novartis-sponsored session (which Novartis had no input or control over; merely funded) and a Novartis satellite symposium which was promotional, organised and funded by Novartis. This was clearly communicated within the paragraph:

> *'This webinar has received sponsorship from Novartis Pharmaceuticals UK limited. The first session in the webinar is designed and delivered by the [academy] and sponsored by Novartis Pharmaceuticals UK limited; the sponsor has had no input into the educational content or organisation of this session. The second session is a promotional satellite symposium that is organised and funded by Novartis Pharmaceuticals UK limited. This promotional satellite symposium is for UK Healthcare Professionals only.'*

The above paragraph was displayed as the first slide of the Mayzent Webinar slides at the promotional satellite symposium, making it clear who the target audience was before the symposium actually began.

The above paragraph was also displayed twice in the mailouts; once at the beginning (in the second paragraph), and again below the agenda of the Novartis promotional satellite symposium.

(ix) In the aforementioned paragraph, it was made expressly clear that the Novartis promotional satellite symposium was for 'UK Healthcare Professionals only'; there could be no doubt as to the target audience.

Accordingly, Novartis refuted any purported breach of Clause 11.2 of the Code, as the information provided at the time was in accordance with the SPC at all times.

Clause 5.1

Novartis submitted that the intention was to make health professionals aware that the symposium was taking place. Furthermore, all information presented was accurate, fair, balanced, referenced and capable of substantiation; and the material was certified according to the ABPI Code of Practice.

Novartis refuted any breach of Clause 5.1 and submitted that high standards had been maintained at all times.

Clause 2

Regarding a potential breach of Clause 2, Novartis saw no evidence that the material could bring discredit upon, or reduce confidence in, the pharmaceutical industry. Novartis did not accept a breach of Clause 2.

Novartis satellite symposium

Regarding attendee details and speaker selection, speakers were selected based on their professional experience (including speaker experience, professional positions, publications, and clinical trial experience). In addition, they were also selected based on their suitability and experience on the subject of the symposium; in this case, their experience of using Mayzent. The Chair and speaker selections were reviewed and approved internally by Medical. A full list of attendees was also provided.

In summary, the complaint raised a number of issues related to the advertising and promotion of Mayzent. Novartis' position was that there had been no breaches of Clauses 2, 5.1, 8.1 and 11.2 of the Code.

PANEL RULING

The Panel noted that the material at issue appeared to be an email distributed by the independent academy inviting recipients to a webinar titled 'SPMS: difficult discussions in progressive MS'.

Below the opening paragraph, which included the time and date of the webinar, was the statement:

> *'This webinar has received sponsorship from Novartis Pharmaceuticals UK limited. The first session in the webinar is designed and delivered by the [academy] and sponsored by Novartis Pharmaceuticals UK limited; the sponsor has had no input into the educational content or organisation of this session. The second session is a promotional satellite symposium that is organised and funded by Novartis Pharmaceuticals UK limited. This promotional satellite symposium is for UK Healthcare Professionals only.'*

The Panel noted Novartis' submission that the organisation holding the event was an independent education provider for clinicians, specialist nurses and professions allied to medicine. Each priority condition was led by an Academic Faculty of practicing clinicians who operated within a separate disease-focused academy; the academy in question provided expert

training in MS for health professionals. The email for the meeting was distributed by this academy. The Panel noted that the Novartis certificate for the email gave the audience as 'Physician, Pharmacist, Nurse, Other Healthcare Stakeholder'.

The Panel noted that the email included information about the webinar and below this was information about the Novartis promotional satellite symposium which included the title: 'MAYZENT ▼ (siponimod) patient identification and onboarding: UK Real world experience', followed by the Novartis logo and the agenda which included 'Mayzent for SPMS with Active Disease'. Beneath details of the speakers for the Novartis symposium was, amongst other things, the job code 'UK September 2021 151725', a link to Mayzent prescribing information and a 'Register' tab.

The Panel noted that the allegations appeared to be in relation to the email from the academy only (mailing reference 151725) and not the meeting itself, or any other material related to the meeting; thus the Panel made its rulings solely on the mailing at issue.

With regard to the allegation that the mailing was not certified, the Panel noted Novartis' submission that it was certified ten days prior to the webinar. Whilst it was not clear what date the complainant received the mailing in question, the Panel considered that he/she had not established that it was not certified as alleged and **no breach of Clause 8.1** was ruled.

Regarding the allegation that the mailing promoted Mayzent outside of its licensed indication, the Panel noted that section 4.1 (therapeutic indications) of the Mayzent SPC stated 'Mayzent is indicated for the treatment of adult patients with secondary progressive multiple sclerosis (SPMS) with active disease evidenced by relapses or imaging features of inflammatory activity'.

The Panel noted that the mailing in question referred to 'Mayzent for SPMS with Active Disease'.

Whilst noting Novartis' submission that prescribing information was provided, which included the full licensed indication, the Panel considered that claims in promotional material must standalone and could not rely on qualification in the prescribing information.

In this regard, the Panel noted Novartis' submission that 'activity' was a well-understood and accepted term within MS to mean either relapse activity and/or MRI activity. According to Novartis, in clinical practice, relapses and imaging features of inflammatory activity were the two methods of identifying disease activity in MS and Novartis submitted that this was further substantiated by widely-accepted criteria; the Lublin criteria and the revised McDonald criteria.

The Panel further noted Novartis' submission that SPMS was an adult-onset phenotype with a median time to SPMS diagnosis of 21.4 years from MS onset and median age of SPMS diagnosis of 53.7 years for adult-onset MS and that the estimated median time from childhood-onset MS to secondary progression was 28 years, and the median age at conversion to secondary progression was 41 years. Noting the content of the mailing, which made no reference to children and was focused on SPMS, and Novartis' submission regarding the clinical course of this disease, in the Panel's view, the mailing at issue did not give the impression that Mayzent could be used in children.

The Panel noted that the Mayzent SPC stated that treatment with siponimod should be initiated and supervised by a physician experienced in the management of MS. Whilst it might have

been helpful to include the full indication within the mailing, the Panel considered that the complainant had not established that reference to 'Mayzent for SPMS with Active Disease', within the particular material at issue, meant that the mailing promoted Mayzent in a manner that was inconsistent with its SPC, as alleged, and **no breach of Clause 11.2 was ruled**.

Whilst the Panel disagreed with Novartis' submission that the statement 'Mayzent for SPMS with Active Disease' was not a claim, the Panel considered that the complainant had not established that this claim, within the particular material at issue, was unqualified as alleged and **no breach of Clause 5.1** was ruled in that regard.

In relation to the allegation that there was no mention from the outset that the webinar was only for health professionals, the Panel noted Novartis' submission, with regard to the recipients of the email, the statement near the top of the email, 'this promotional satellite symposium is for UK Healthcare Professionals only' and the information in the attendee report provided by Novartis. The Panel considered that the complainant had not established that the material had not made clear that the webinar was for health professionals only and the Panel ruled **no breach of Clause 5.1** in that regard.

The Panel noted its comments and rulings of no breaches above and consequently ruled **no breach of Clause 2**.

Complaint received **13 June 2022**

Case completed **19 June 2023**