CASE AUTH/3648/5/22

COMPLAINANT v NOVARTIS

Promotion of Entresto

CASE SUMMARY

This case was in relation to allegations about a virtual meeting and a write up of the meeting, which the complainant alleged constituted disguised promotion of Entresto.

The Panel ruled a breach of the following Clause of the 2019 Code as Novartis' classified the meeting as non-promotional, noting the mention of Novartis' medicine on several slides by brand name (Entresto), non-proprietary name (sacubitril valsartan) and drug class (ARNI) and the strong, emotive messaging 'Don't let our heart failure patients die on suboptimal therapy' following discussions of treatment options which included Entresto:

Breach of Clause 9.1	**Failing to maintain high standards**

The Panel ruled no breach of the following Clauses of the 2019 Code as, in its view, health professionals, on the balance of probabilities, would be likely to assume that the meeting would include material on Novartis' medicines and therefore be promotional and it had not been established that the promotion of Entresto during the virtual meeting was not in accordance with the terms of its marketing authorisation:

No Breach of Clause 12.1	**Requirement that promotional material and activities must not be disguised**
No Breach of Clause 3.2	**Requirement to not promote a medicine for an unlicensed indication**

With regard to the meeting write up, the Panel considered that the material was promotional and ruled a breach of the following Clauses of the 2019 Code for failing to include the obligatory information:

Breach of Clause 4.1	**Failing to include up-to-date prescribing information**
Breach of Clause 4.3	**Failure to include non-proprietary name of the medicine immediately adjacent to the most prominent display of the brand name**
Breach of Clause 4.6	**Failing to include a clear, prominent statement as to where prescribing information could be found**
Breach of Clause 4.9	**Failing to include information about how to report adverse events**
Breach of Clause 9.1	**Failing to maintain high standards**

The Panel ruled no breach of the following Clause of the 2019 Code in relation to the meeting write up:

No Breach of Clause 2	Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry

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

COMPLAINT

An anonymous, contactable complainant complained about what they described as a promotional document that Novartis had organised and funded but had allegedly not ensured compliance with promotional requirements. The Code breaches were relevant to the 2019 Code. The complainant stated that Novartis and a healthcare organisation delivered the second Heart Failure Primary Care Leaders Network virtual meeting online in December 2020. This event was fully organised and funded by Novartis. The complainant provided a link to the landing webpage for the meeting.

The complainant alleged that the event was actually a promotional event as Novartis products were discussed (Entresto for heart failure) but this was not made clear anywhere on the page or agenda, which breached Clauses 12.1 and 9.1 as it was disguised promotion.

The complainant referred to the event write up on the bottom of the landing webpage, which opened up a 5 page summary document of the meeting (MLR ID: 102550 December 2020). The document mentioned from the outset that this was a Novartis heart failure meeting. The complainant stated on page 2 of this document, the following information was given:

> 'An active discussion followed [named speaker]'s talk, which began with a focus on LVSD (Left Ventricular Systolic Dysfunction) management. [named speaker] commented that the recommendation to commence ramipril followed by Entresto in symptomatic LVSD patients, for both those who have severe LVSD identified via an echocardiogram and those who do not, was developed for several reasons. Firstly, simple algorithms are more likely to be followed.
>
> Secondly, some GPs are reluctant to start patients on Entresto, preferring to begin with ramipril and move over to Entresto once they gain confidence. Thirdly, whilst NICE (National Institute for Health and Care Excellence) guidance recommends that Entresto should be given in cases of severe LVSD, the license is slightly wider than that.'

The complainant alleged there was no generic name given for Entresto (breach of Clause 4.3), no prescribing information or where to find prescribing information was given (breach of Clauses 4.1 and 4.6) and no adverse event reporting was given (breach of Clause 4.9). The clear licenced indication for Entresto was not provided (breach of Clause 3.2). High standards were not maintained (breach of Clauses 9.1 and 2). The complainant alleged that the write up document was a promotional piece about Entresto and that Novartis acted outside the boundaries and the spirit of the Code by not ensuring this document was correct in alignment with promotional requirements. The complainant referred to the agenda for this meeting which

they alleged failed to mention that this was a promotional event (breach of Clause 12.1) and provided a link to the agenda.

The complainant went on to describe the working ways and compliance culture at Novartis as bad, alleging that staff were expected to be onsite in the office at all times leading to burnout and therefore compliance errors. The complainant further alleged that Novartis was not doing enough to improve the compliance culture by recruiting experienced medical signatories and building a dedicated signatory team. Thus, there was a constant battle to improve compliance standards. The complainant alleged that an audit of the company procedures should be considered by the PMCPA considering the clear lack of importance given to compliance.

When writing to Novartis, the Authority asked it to consider the requirements of Clauses 2, 3.2, 4.1, 4.3, 4.6, 4.9, 9.1 and 12.1 of the 2019 Code.

RESPONSE

Novartis stated that the complaint caused it concern and it had taken its content seriously. Novartis wanted to highlight that it was committed to operating in accordance with the required standards and meeting the relevant requirements and expectations.

'Heart Failure Primary Care Leaders Network' virtual meeting; a non-promotional meeting

Rationale behind the meeting

Novartis submitted that due to the challenges that arose from the COVID-19 pandemic, The British Society for Heart Failure (BSH) and the NHS highlighted the need for a primary point of contact for the management of heart failure patients in each locality.

Novartis had partnered with [named healthcare organisation] for several years on a variety of projects. The idea for the Heart Failure Primary Care Leaders' network was developed by Novartis in collaboration with the [healthcare organisation]. The Heart Failure Primary Care Leaders Network was a group of driven, like-minded experts working together to improve the journey for patients with heart failure (HF).

The network was open to PCN (Primary Care Nurses), Cardiovascular Leads, GPwERs (General Practitioners with Extended Role) and other Healthcare Professionals (HCPs) based in primary care (general practitioners, practice-based pharmacists, practice nurses) who were passionate about improving the Heart Failure patient pathway within their locality.

Organisation and funding of the meeting

This meeting was organised and fully funded by Novartis. The aim was to bring the Heart Failure Primary Care Leaders Network together virtually or face-to-face to provide an environment for sharing best practice and discussing HF patient management.

Planning for the meeting

Novartis stated that the parties were very thorough in planning for the meeting, with multiple calls being held between Novartis and the [healthcare organisation]. A contract was put in place between Novartis and the secretariat of the [healthcare organisation] in relation to the event

(copy provided). Novartis stated that the agreement covered the organisation and delivery of the meeting, as well as the communication strategy to drive awareness of the meeting externally.

Novartis created the agenda for the meeting in collaboration with the Chairs, the [healthcare organisation] President and Vice President. Both parties inputted into the selection of the speakers for the meeting. The parties selected [named speaker] due to his experience in creating a HF treatment pathway in Primary Care.

Meeting materials (including the event write up)

Details of the meeting were available on the [healthcare organisation's] website (link provided).

Health professionals were invited to the meeting via email by both Novartis and the [healthcare organisation] (copies of both invitations were provided), the agenda for the meetings was sent within the invitations.

The event write up was examined by Novartis before being displayed on the [healthcare organisation] website. As noted above, the agenda was also examined separately before dissemination via email invitations; and prior to being used on the [healthcare organisation] webpage. The [healthcare organisation] agenda webpage itself and the meeting description on the [healthcare organisation] website had not been examined by Novartis. However, having reviewed the [healthcare organisation] agenda webpage and the meeting description on the [healthcare organisation] website, Novartis was comfortable that these webpages were non-promotional in nature and met the requirements of the ABPI Code.

Endorsement of the meeting by the [healthcare organisation]

Novartis stated that the [healthcare organisation] endorsed the meeting and selected speakers in collaboration with Novartis, invited its members, hosted the write up on its website and allowed the [healthcare organisation] logo to be used in associated communications about the meeting.

Non-promotional meeting

The objectives of the meeting were stated in the Speaker Briefings (copies provided), and were summarised by Novartis as follows:

- to provide a forum for leaders in HF management from within primary care to:
    - discuss a variety of topics relating to HF management and service provision, with a particular focus on primary care specific guidance;
    - share best practice, challenges, and ideas; and
    - provide support and offer solution; and
- to encourage discussion between attendees as to how to improve patient engagement, to ensure optimal management.

Novartis stated that these objectives were clearly focused on supporting primary care leaders in the management of HF, and not to promote any particular medicine over another. It was not

stated on the agenda or the webpage that the meeting was promotional, because, according to Novartis, this event was a non-promotional meeting.

All of the speaker briefings (copies provided) explained that this was a non-promotional meeting as indicated by the phrase '*As this is a non-promotional meeting, there should be no focus on any singular medicine and all discussion must remain balanced and fair throughout*'. Novartis submitted that the Internal Meeting Approval (copy provided) clearly stated that this was a non-promotional meeting.

Novartis stated that from the agenda, the aim of the meeting was to discuss and share updates on HF management. The meeting sessions included a 'Chairpersons Address', 'Reflections of the [healthcare organisation] conference', a discussion on an independently developed HF treatment pathway adopted in a named area and two discussion sessions where attendees were able to contribute. The entire meeting was 2 hours, with the discussion sessions running for 50% of the time, to give delegates the opportunity to share ideas, challenges and best practice with peers and colleagues. Novartis stated that half of the meeting was fully dedicated to discussion which it felt supported the intent that this was set up as non-promotional educational meeting, organised in follow-up to the [healthcare organisation] conference to provide real value for the attendees.

Novartis' response to alleged breaches of the 2019 Code are given below.

Clause 12.1 of the 2019 Code:

Disguised promotion as agenda and webpage did not state that the meeting was promotional

Meeting Agenda:

The agenda for the session was available within the Speakers Briefing. As explained above, the agenda was also available in the email invitations sent by the [healthcare organisation] and Novartis, and also displayed on the [healthcare organisation] website.

It was not stated on the agenda or the webpage that the meeting was promotional, because this event was a non-promotional meeting for the reasons outlined above.

Event Write Up:

The 5-page event write up which the complainant specifically referred to, was produced by the [healthcare organisation's] secretariat and examined by Novartis before being certified and displayed on the [healthcare organisation] website. The write up included a section on a named area's HF algorithm. As a result, there were a few mentions of a broad range of medicines including SGLT2s, Dapagliflozin, Entresto, ARNi, NICE recommendations, use of Ramipril or ACEi's, Loop diuretics, ARBs, MRAs, Beta blockers and Thiazides too. There was no particular emphasis on any one product as the intention was to highlight and share current treatment guidelines as part of the wholistic discussion on the management of HF.

The complainant specifically referred to page 2 of the Meeting Write up which stated:

'An active discussion followed [named speaker]'s talk, which began with a focus on LVSD management. [Named speaker] commented that the recommendation to commence ramipril followed by Entresto in symptomatic LVSD patients, for both those who have severe LVSD identified via an echocardiogram and those who do not, was developed for several reasons. Firstly, simple algorithms are more likely to be followed. Secondly, some GPs are reluctant to start patients on Entresto, preferring to begin with ramipril and move over to Entresto once they gain confidence. Thirdly, whilst NICE guidance recommends that Entresto should be given in cases of severe LVSD, the license is slightly wider than that.'

These statements were describing the rationale behind the independently-created named area's HF pathway algorithm. For full context, the write up of [named speaker]'s session focused largely on the wider management of HF including investigations for breathlessness, diagnosing HF and treatments to consider in the algorithm. The section of the write up in the complaint had been specifically highlighted by the complainant, without the full context, and formed a very small proportion of the entire write up.

Considering all the information above, Novartis refuted all breaches of Clause 12.1; the meeting was not a disguised promotional event.

Clause 3.2 of the 2019 Code:

Not stating the Entresto indication

Clause 3.2 stated the promotion of a medicine must be consistent with the marketing authorisation. This meeting was non-promotional, so Clause 3.2 did not apply.

Although Novartis did not accept that the meeting was promotional, in the alternative, Clause 3.2 did not mandate stating the licensed indication on all materials, it only indicated that the medicine must be promoted according to its licensed indication. Entresto (sacubitril/valsartan) was indicated in adult patients for the treatment of symptomatic chronic heart failure with reduced ejection fraction (HFrEF). HfrEF was an interchangeable term used with LVSD (Left Ventricular Systolic Dysfunction). This was general knowledge in the Heart failure therapy area as could be seen on the website of a named patient group website.

In the meeting, Entresto/ARNi was mentioned in relation to a named area's HF pathway and the CaReMe HF Algorithm (available within the following link: https://www.britishcardiovascularsociety.org/resources/careme). In both the pathway and the guideline, ARNI was being used for the treatment of HFrEF or LVSD and this use was fully within the licensed indication. It was difficult to have a discussion on HF management without discussing treatment guidelines and algorithms. Therefore, Novartis refuted any breaches of Clause 3.2.

Clause 4.1 of the 2019 Code

Provision of Prescribing Information

The meeting was not promotional as explained above, so there was no requirement to provide prescribing information in the event materials. Novartis did not accept a breach of Clause 4.1.

Clause 4.3 of the 2019 Code:

No generic name given for Entresto

Clause 4.3 also applied to promotional material. As the meeting was not promotional, this clause did not apply.

Although Novartis did not accept that the meeting was promotional, in the alternative, on the slide where Entresto was first discussed, the non-proprietary name (sacubitril/valsartan) was stated right next to the first mention of Entresto.

The event write up did not mention the non-proprietary name, as it was not a promotional document. Novartis did not accept any breaches of Clause 4.3 on this point.

Clause 4.6 of the 2019 Code

Prominent statement stating where the Prescribing Information can be found

The meeting was not promotional, as explained above, so there was no requirement to state where prescribing information could be found within the event materials. Novartis did not accept a breach of Clause 4.6.

Clause 4.9 of the 2019 Code

No adverse event reporting included

Clause 4.9 stated that all promotional material must include the adverse event reporting statement. This meeting was not a promotional meeting as explained above. As the meeting was not promotional, Novartis submitted that the requirement to include the adverse event reporting statement did not apply.

Clauses 2 and 9.1 of the 2019 Code:

Novartis considered it appropriate to address the alleged breaches of Clauses 2 and 9.1 in relation to the materials which formed the main subject matter of the complaint, as well as the more general comments made regarding Novartis' compliance culture.

Applicability to the materials mentioned in the complaint

Novartis stated that the meeting was non-promotional and none of the clauses cited had been breached as Clauses 3.2, 4.1, 4.3, 4.6 and 4.9 only applied to promotional meetings and associated materials. Therefore, high standards were maintained as this activity was not disguised promotion as explained above. Novartis submitted that the pharmaceutical industry had not been brought into disrepute either, as the aim of the meeting was to bring the Heart Failure Primary Care Leaders Network together to provide an environment for sharing best practice and offering ideas within the primary care setting. To the extent that Novartis' position was accepted by the PMCPA, Novartis stated that there could be no associated breaches of Clauses 2 and 9.1.

Applicability to complainant's general comments

Novartis noted that the complainant lodged this complaint as a 'concerned healthcare professional', but they also understood how pharmaceutical companies undertook reviews of materials and had a strong opinion on how this should work. The complainant had made comments and vague allegations about the working practices and Compliance culture within Novartis. Whilst no evidence of the Compliance culture being substandard had been provided by the complainant, Novartis addressed the complaints by describing the working ways and compliance below:

- Signatories at Novartis were highly experienced professionals. As required by the ABPI Code, Novartis Signatories were either Registered Medical Practitioners or Pharmacists fully registered in the UK. All new Signatories were required to undergo a detailed Final Signatory Assessment, regardless of prior Signatory experience with other pharmaceutical companies. The Final Signatory Assessment was composed of multiple-choice questions, scenarios, ABPI Code knowledge checks and an oral viva. The Final Signatory that signed-off the materials at issue, was a Registered Medical Doctor with several years of experience and an excellent track record within the Cardiovascular Therapy Area.

- After being registered as a Final Signatory for Novartis, the Signatory must keep their knowledge up-to-date. The Novartis Code Club had been running for some time. It was designed to update Associates on relevant PMCPA cases and enabled a better understanding and interpretation of the PMCPA Code and the impact of ABPI Code complaint decisions on the company's activities. The Novartis ABPI Code Club organised ABPI hot topics sessions quarterly. These sessions were developed collaboratively by an external Compliance Expert and the Novartis UK Compliance Team with the objective of sharing key learnings and findings from recent PMCPA cases, with opportunities for Novartis signatories to discuss and review Code case findings. At the time of the response, two ABPI hot topic sessions had taken place already; the meetings were interactive and well-attended.

- The internal training system at Novartis was also used to update Signatories and the wider organisation on new SOPs, Policy/SOP changes/updates, ABPI Code, etc.

On these grounds, Novartis strongly refuted the notion that the compliance culture was of concern or below industry standard as the complainant alleged. Novartis' view was that its internal policies procedures and training, in this regard, exceeded industry standards. As such, this aspect of the complaint was completely without merit with regard to Clauses 9.1 and 2.

This complaint followed a spate of recent complaints against Novartis across the last couple of months (10 complaints had been received and addressed or were currently being addressed). These complaints were largely similar in structure and similarities had been noted by the teams working on Novartis' responses. Based on these similarities, Novartis urged the PMCPA to establish whether any or all of the recent complaints against Novartis had originated from the same (or closely connected) source(s). Novartis further encouraged the PMCPA to undertake further engagement with the complainant health professional, to satisfy itself that the complainant was acting within the spirit of the Code and their own professional obligations.

PANEL RULING

The Panel noted the complaint referred to a 'Heart Failure Primary Care Leaders Network' virtual meeting and its write up summary document. Noting the event took place in 2020, the Panel considered the complaint under the 2019 Code.

'Heart Failure Primary Care Leaders Network' virtual meeting

The Panel noted Novartis' submission that the event at issue was developed in collaboration with a healthcare organisation and that the network was open to primary care health professionals passionate about improving the heart failure patient pathway in their locality; Novartis organised and fully funded the meeting.

The Panel noted Novartis' submission that the meeting was non-promotional and the objectives of the meeting were clearly focused on supporting primary care leaders in the management of heart failure (HF), and not to promote any particular medicine over another. The briefing documents stated the objectives of the meeting to be:

- to provide a forum for leaders in HF management from within primary care to:
    - discuss a variety of topics relating to HF management and service provision, with a particular focus on primary care specific guidance;
    - share best practice, challenges, and ideas; and
    - provide support and offer solutions; and
- to encourage discussion between attendees as to how to improve patient engagement, to ensure optimal management.

The Panel noted that the email invitations were sent from both Novartis and the [healthcare organisation] and included prominent logos of both organisations, a description of the objective of the meeting, the agenda and a statement 'This educational meeting is organised and fully funded by Novartis and is endorsed by the [healthcare organisation]'. This statement also appeared on the [healthcare organisation] agenda and meeting description webpages in small italics font at the bottom of the page.

In relation to the allegation that the event was disguised promotion as Entresto for heart failure was discussed and this was not made clear anywhere on the page or agenda, the Panel noted Novartis' submission that it was not stated on the agenda or the webpage that the meeting was promotional because the event was non-promotional.

The Panel noted the agenda included two key discussion topics: 'Exploring what we can do in Primary Care (The [named area] HF pathway)', scheduled for 15 minutes followed by a discussion, and 'How are we engaging with our HF patients?'.

The first key topic, presented by the [named speaker], looked at a local NHS guideline on non-acute breathlessness, followed by the [named area] Heart Failure pathway which included flow chart illustrations for 'Structured Investigation of Breathlessness', 'Managing of LVSD: detection & diagnosis', 'Managing of LVSD: management', 'LVSD Management: Covid-19 Addendum', 'Sequence of Symptomatic LVSD Medicine Management'.

The Panel noted that the latter three slides referred to Entresto by brand name within the treatment pathway flow chart illustrations; each slide stated at the bottom that 'Novartis had no involvement in the creation of this pathway'.

The Panel noted that Entresto was also referred to within two boxes to the right of the treatment pathway flow chart on the slide titled 'Managing of LVSD: management'. The section titled 'Medication switches' stated for ramipril: 'Issues with ACEI cough: Ramipril should be discontinued and switch to Entresto. If issues with renal decline or angioneurotic oedema then Entresto should NOT be started; seek advice'. The slide also included a prominent red filled box on the bottom right of the slide which stated:

'All those with LVSD should be offered:

Ramipril moving to Entresto

- Bisoprolol +/or Ivabradine to optimize HR
- Sinus rhythm 50-65bpm
- AF 80-110bpm
- Spironolactone/Eplenerone 50mg
- Systolic Blood Pressure should not be consistently <110mmHg
- Creatinine<200umol or NO increase >50% from baseline
- Potassium >5.5mmol.'

The Panel noted the 'Summary and Take-Home Messages' included, amongst other things, the bullet point 'Don't let our heart failure patients die on suboptimal therapy' followed by 'Let them live on the best we can do!' in bold.

The open discussion forum section appeared to contain a further three slides. Firstly, was a slide titled 'Five Pillars of HfrEF therapy in international guidelines', referenced to Seferović *et al*, 2020 and Meara E, *et al*. 2020, which referred to multi-mechanistic therapy to reduce mortality with numerous drug classes: ARNI, ACEi or ARB, MRA, β blocker and Dapaglifozin (with or without T2D). The next slide was titled 'Lifetime benefits of comprehensive disease-modifying drug therapies in patients with Heart Failure with Reduced Ejection Fraction A comparative analysis of three randomised controlled trials: EMPHASIS-HF, PARADIGM-HF and DAPA-HF' and appeared to compare conventional therapy (ACE/ARB and β blocker) with comprehensive therapy (ARNI, β blocker, MRA and SGLTi). The third slide illustrated the CaReMe guideline which included in the flow chart the option to offer sacubitril valsartan if ejection fraction was less than 35%.

The internal meeting approval document provided by Novartis listed in the selection of external speakers that the speaker had 'recently changed their local HF pathway and is willing to share this with the group as an example of best practice'.

The Panel noted the [named area] HF and CaReMe guidelines were presented during the meeting, with the [named area] HF pathway discussed in more detail having been mentioned in the speaker briefings, agenda and invitations. Novartis provided no details of other treatment guidelines and thus it was unclear to the Panel whether the pathways were selected due to their favourable positioning of Entresto/ARNIs or not. The Panel was not an investigatory body and it judged complaints on the evidence provided by both parties.

The Panel considered that if a company-organised meeting discussed its medicines, the company should consider how this would not be defined as promotion under the Code.

The Panel noted Novartis' medicine had been mentioned on several slides by brand name (Entresto), non-proprietary name (sacubitril valsartan) and drug class (ARNI), and considered that the meeting constituted promotion, bearing in mind the broad definition of promotion. This was further compounded by the strong, emotive messaging displayed within the take-home slides 'Don't let our heart failure patients die on suboptimal therapy' following discussions of treatment options which included Entresto. The Panel, noting the arrangements for the meeting in that it was classified as non-promotional, considered that high standards had not been maintained in this regard and a **breach of Clause 9.1** was ruled.

The Panel noted its view above that the meeting was promotional. However, the Panel considered that promotional material did not need to be labelled as such, provided it was not disguised and the identity of the pharmaceutical company or their involvement was obvious. The Panel considered it was clear from the agenda and website that the meeting at issue was organised by Novartis and that the [named area] HF pathway would be discussed. In the Panel's view, health professionals, on the balance of probabilities, would be likely to assume that the meeting would include material on Novartis' medicines and therefore be promotional. The Panel did not consider, on balance, that the promotional nature of the meeting had been disguised. **No breach of Clause 12.1** was ruled.

Meeting write up

The Panel noted that the meeting write up was examined by Novartis before being displayed on the [healthcare organisation] website and was titled 'Novartis Heart Failure Primary Care Network Virtual Meeting'.

The Panel noted the section on Entresto referred to by the complainant was within the 'What we can do in primary care to improve the HF pathway?' section and stated:

> 'An active discussion followed [named speaker]'s talk, which began with a focus on LVSD management. [named speaker] commented that the recommendation to commence ramipril followed by Entresto in symptomatic LVSD patients, for both those who have severe LVSD identified via an echocardiogram and those who do not, was developed for several reasons. Firstly, simple algorithms are more likely to be followed. Secondly, some GPs are reluctant to start patients on Entresto, preferring to begin with ramipril and move over to Entresto once they gain confidence. Thirdly, whilst NICE guidance recommends that Entresto should be given in cases of severe LVSD, the license is slightly wider than that.'

Novartis' submitted that the write up included a section on the [named area] HF algorithm as a result, there were mentions of a broad range of medicines which included mentions of SGLT2s, Dapagliflozin, Entresto, ARNi, NICE recommendations, use of Ramipril or ACEi's, Loop diuretics, ARBs, MRAs, Beta blockers and Thiazides. The Panel noted the section referred to by the complainant formed a small proportion of the write up; Novartis submitted there was no particular emphasis on any one product as the intention was to highlight and share current treatment guidelines as part of the wholistic discussion on the management of HF.

The Panel noted later within the same section was a discussion on Dapagliflozin, which was not a Novartis product, being a 'cutting-edge treatment' and discussed its 'significant benefits'.

In the Panel's view, whilst the section on Entresto formed a small part of the write up and there appeared to be a more positive section on Dapaglifozin, the Panel, nonetheless, queried whether the section that referred to the recommendations for Entresto use in heart failure and, in particular, clarified Entresto's license as being 'slightly wider than that' of NICE guidance could be seen as anything other than promotional.

The Panel, noting that the write up at issue contained promotional information about Entresto, considered the requirements of the Code in relation to promotional material would thus apply in that regard. The Panel considered the write up on the [healthcare organisation's] website had promoted Entresto without the obligatory information for promotional material. The Panel ruled **a breach of Clauses 4.1 and 4.6** with regard to the lack of provision of prescribing information. The Panel noting the non-proprietary name for Entresto had not been included within the write up ruled **a breach of Clause 4.3**. The Panel considered the omission of the adverse event reporting statement meant that Novartis had failed to meet the requirements of Clause 4.9 and **a breach of Clause 4.9** was ruled.

The Panel did not consider the complainant had established that the promotion of Entresto was not in accordance with the terms of its marketing authorisation nor that it was inconsistent with the particulars listed in its SPC; the Panel **ruled no breach of Clause 3.2** accordingly.

The Panel noted its comments and rulings of the Code above and considered that Novartis had failed to maintain high standards. A **breach of Clause 9.1** was ruled.

The Panel noted that Clause 2 was a sign of particular censure and reserved for such use. The Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of **Clause 2** and **ruled no breach** accordingly.

Complaint received **15 May 2022**

Case completed **30 May 2023**