CASE AUTH/3725/1/23

COMPLAINANT v NOVARTIS

Allegations about out-of-date prescribing information

CASE SUMMARY

This case was in relation to outdated prescribing information on two documents, hosted on a Novartis website. The complainant also alleged that the presence of documents with different versions of the Entresto (sacubitril/valsartan) prescribing information showed a lack of due care for patient safety.

The outcome under the 2021 Code was:

Breach of Clause 2	**Bringing discredit upon, and reducing confidence in, the pharmaceutical industry**
Breach of Clause 5.1 (x3)	**Failing to maintain high standards**
Breach of Clause 12.1 (x2)	**Failing to include up-to-date prescribing information**

No Breach of Clause 8.5 (x2)	**Requirement that material must be recertified at intervals of no more than two years**

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

FULL CASE REPORT

A complaint was received from an anonymous, non-contactable complainant about Novartis Pharmaceuticals UK and the versions of the Entresto (sacubitril/valsartan) prescribing information on materials available on its website for health professionals and other relevant decision makers. Entresto was indicated in adult patients for treatment of symptomatic heart failure with reduced ejection fraction.

COMPLAINT

The complainant described themselves as a health professional based in the north of the UK. They stated they were directed to view the Novartis website by a company representative and were shocked to see that the documents available to download compromised the safety of patients. The website contained various documents to download for Entresto. It also contained the Entresto prescribing information for Great Britain and Northern Ireland dated October 2022. A document available to download from this website, titled 'The Affinity Care Heart Failure pathway', contained Entresto prescribing information dated May 2021 and did not contain the Northern Ireland prescribing information. Another document also available to download from this website, called 'Treatment Algorithm for Guideline-Directed Medical Therapy Including Novel Therapies', contained an Entresto prescribing information from June 2020 and did not contain

the Northern Ireland prescribing information. The complainant stated that they were deeply shocked to see various documents on this website had different versions of the Entresto prescribing information, which they considered showed a lack of due care for patient safety. The complainant noted particularly that, if these documents were used in isolation, they would lack the latest safety information for Entresto – which could seriously harm patient safety. The patients treated by the complainant were often frail and vulnerable and the complainant stated that they could not compromise patient safety because this company was 'too lazy' to update its documents. The complainant requested that the PMCPA take action on Clauses 2, 5, 8, 12 and 15.

When writing to Novartis, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 8, 8.5 and 12.1 of the 2021 Code. The PMCPA did not ask Novartis to respond to the complaint in relation to Clause 15, as it was deemed that there was insufficient information within the complaint to show that there may have been a breach of the Code in that regard and the complainant was non-contactable. This was in accordance with Paragraph 5.1 of the Constitution and Procedure.

RESPONSE

Novartis stated that the complaint caused the company great concern, as patient safety was of paramount importance and was fundamental within the industry and Novartis had therefore taken its contents very seriously.

The complaint alleged that Novartis had committed several breaches of the Code in the context of incorrect or outdated prescribing information on Novartis' 'HCP portal' (a website intended for a UK healthcare professional audience and NHS relevant decision makers only, contained information pages on Novartis medicines) (**'Novartis HCP Portal'**) concerning two materials:

(**A**) 'The Affinity Care Heart Failure Pathway'

(**B**) 'JACC [Journal of the American College of Cardiology] Treatment Algorithm for Guideline-Directed Medical Therapy Including Novel Therapies'

Both materials were downloadable from the Novartis HCP Portal, the allegations of which Novartis addressed in its response under the headings below.

Novartis was asked to address Clauses 2, 5.1, 8, 8.5 and 12.1 of the Code in its response.

1 Background

A webpage within the Novartis HCP Portal titled, 'Formulary & Business Case support: Cardio-renal metabolism', contained multiple materials and resources to download that were designed to help support with clinical decision making through the provision of international guidelines and NHS best practice sharing. The relevant access to the website and disclaimers were in place (on entering the HCP portal and at the top of the page) to ensure the site was viewed by healthcare professionals only and an alternative link was provided for the general public.

Below the description at the top of the page, there were links to the most up to date prescribing information, which were visible and compliant with the Code as the prescribing information could

be accessed via one direct click of the link provided (e.g., For ENTRESTO (sacubitril/valsartan) prescribing information click here).

2 Novartis Response to the Specific Complaints

A. Claim – 'The Affinity Care Heart Failure pathway' document does not contain Northern Ireland prescribing information'

Novartis stated that Affinity Care was a Primary Care Group comprising of 5 practices over 8 sites within the Bradford district. A pathway guideline was developed by Affinity Care for the 'Management of Heart Failure with Left Ventricular Systolic Dysfunction'. Novartis did not input into the creation or development of this pathway guideline but had permission from Affinity Care to share it as a downloadable resource for HCPs on the Novartis HCP portal. The content of which did not go through Novartis' internal signatory process. Entresto was mentioned in the material, therefore prescribing information was added in order to comply with the Code.

The material in question contained prescribing information (PI) for the UK dated May 2021. The UK PI was created to cover the entire UK which included Northern Ireland (NI) and Great Britain (GB). Novartis confirmed that the PI dated May 2021 was in alignment with the current approved up-to-date EU (NI) summary of product characteristics (SPC) and GB SPC. Novartis stated this was the version of the PI which was available via the link at the top of the website. Novartis also confirmed that Novartis' internal standard operating procedure required all prescribing information related to its products to be split into GB and NI respectively by the end of 2022 and consequently be updated, which the company was currently in the process of doing.

Novartis stated that it therefore refuted the complainant's claim that the prescribing information was not suitable for Northern Ireland and that patient safety was compromised as the prescribing information on this material was consistent with the latest EU (NI) SPC and GB SPC and did not omit any relevant safety information and was suitable in terms of use in its geographic location, i.e. the UK (GB and NI).

As previously mentioned, a link to the most up to date prescribing information could be found at the top of the webpage above the downloadable materials. In light of the above, Novartis' opinion was that there was no breach of Clauses 5.1, 8, 8.5 and 12.1 of the Code.

B. Document – 'JACC Treatment Algorithm for Guideline-Directed Medical Therapy Including Novel Therapies'

Novartis stated that this resource could be downloaded by health professionals from the Novartis HCP Portal. It was published by the JACC and outlined a treatment algorithm for the management of patients with Chronic Heart Failure with Reduced Ejection Fraction. As previously mentioned, the most current and up to date prescribing information for Entresto (sacubitril/valsartan) could be found at the top of the webpage, it was clearly visible and was accessible via one direct click of the link.

2020 vs 2021 MLR ID sign off

The 'JACC Treatment Algorithm for Guideline-Directed Medical Therapy including Novel Therapies' contained outdated prescribing information and therefore did not contain the SPC update information (listed below). These included:

- Addition of a new Posology and Administration (section 4.2) that splitting and crushing of the tablets is not recommended.
- Addition of a new Warning and precaution (section 4.4) for 'psychiatric disorders': 'Psychiatric events such as hallucinations, paranoia and sleep disorders, in context of psychotic events, have been associated with sacubitril/valsartan use. If a patient experiences such events, discontinuation of sacubitril/valsartan treatment should be considered.'
- Addition of hallucinations (frequency 'rare' ≥1/10,000 to <1/1,000), paranoia (frequency 'very rare' <1/10,000) and sleep disorders (frequency 'rare'≥1/10,000 to <1/1,000) in the adverse drug reaction section (section 4.8).
- Clarification of Interactions with other medicinal products and other forms of interactions (section 4.5) to clarify that lithium is not recommended with sacubitril/valsartan. If the combination proves necessary, careful monitoring of serum lithium levels is recommended.

'Splitting and crushing of the tablets is not recommended'. This information was missing from the outdated prescribing information; however, Novartis did not feel that this statement would compromise the safety of patients or put the majority of patients taking Entresto at risk.

Hallucination, paranoia and sleep disorders were assessed internally (by Novartis) as 'low clinical impact' as these events were typically not serious, were reversible and manageable by drug discontinuation and routine medical care. Novartis decided to continue to monitor these events through routine pharmacovigilance.

Novartis stated that it used a third-party vendor/marketing company ('the Agency') to build the Novartis HCP Portal. In order to ensure materials were removed that contained out of date prescribing information, Novartis liaised with the Agency to pull all active materials in question from the webpage so Novartis could internally update and re-approve the materials accordingly. This was in line with Novartis' internal standard operating procedures (SOPs) for updating prescribing information.

During due diligence internal checks, it was noted that the prescribing information of the material was not up to date and the Agency was contacted immediately via email prior to the PMCPA contacting Novartis about the complaint. The error was noticed was on 19 January 2023, and Novartis informed the Agency immediately on the same day. The PMCPA notified Novartis about the complaint on 20 January 2023. Novartis stated that this demonstrated that Novartis was dedicated to ensuring that its materials were in line with the spirit and letter of the Code. The relevant email chain was provided to demonstrate this communication.

Novartis stated that immediate actions were taken to remove the assets from the webpage prior to the complaint being made. Novartis was made aware of the complaint via the PMCPA on 20 January 2023, however the company acted on 19 January 2023 to contact the Agency after an internal review of the HCP Portal and downloadable materials. This demonstrated Novartis'

ability to act in an agile manner both compliantly and accordingly and within the remit of the Code.

Once the discrepancy was noticed, the Agency was promptly asked to remove all affected material pending PI updates. This was a missing element of the update that came through in 2021. Again, the Agency was notified to remove all materials with old prescribing information, but unfortunately due to human error, this specific material was missed during the round of updates in 2021.

Therefore, Novartis agreed with the complainant regarding a potential breach of Clause 5.1 High Standards and Suitability and a breach of Clause 12.1 Prescribing Information and Other Obligatory Information.

With regard to Novartis' internal SOP regarding Promotional and Non-Promotional Materials (including Items of Medical Utility), Section 4. Principles, Additional Requirements for Promotional Materials, para 5. stated 'Materials for use in Great Britain (GB) and Northern Ireland (NI) must be approved separately in accordance with the individual regulatory requirements.'

Changes to prescribing information triggered the following process:

- Regulatory Affairs inform Medical Affairs and the Brand team of any changes to the PI.
- Medical Affairs conducts an assessment to determine if changes to the material and PI were required and the timelines for doing so. If changes were not required, then the material could continue to be used until expiry. If changes were required, the Owner must either re-submit the material for review or order the withdrawal and destruction of the material.
- The assessment and subsequent actions (i.e., submission for re-approval or destruction) of all current materials must be completed within 10 working days of receipt of approved SPC by Regulatory Affairs and must be documented in FUSE.

Novartis stated that the above information demonstrated that it had a robust and detailed process for updating prescribing information of its products. Therefore, Novartis did not agree with the complainant's assertion that the company was 'too lazy to update its documents'.

Clauses 8 and 8.5: Certification and Examination

Novartis stated that it had completed the review and approvals of the materials containing the updated prescribing information for the 'Affinity Care Heart Failure Pathway' but due to human error it was missed regarding the prescribing information for the 'JACC Treatment Algorithm for Guideline-Directed Medical Therapy Including Novel Therapies' guideline. In both circumstances, the materials were reviewed by a Final Medical Signatory, and both had the corresponding approval certificates respectively.

This demonstrated that Novartis' process for the re-approval of materials was in situ, however, on this occasion the Final Medical Signatory and the Agency missed that the prescribing information was not up-to-date.

Novartis stated that it had a robust process in place to manage the withdrawal and re-approval of Promotional and Non-Promotional Materials, Examination and Certification. The Promotional

and Non-Promotional Materials (including Items of Medical Utility) local SOP contained a specific section to manage changes in prescribing information and how the process should be conducted correctly to a compliant standard.

The process of updating PI was as below:

- New PI signed off by Final Medical Signatory.
- Communication to wider team and all active materials to be withdrawn/destroyed in a systematic process.
- The prescribing information of such materials needs to be updated.
- The materials required re-approval and re-certification by a Final Medical Signatory.
- Briefing sent to wider team to explain update to the PI.

Given that each material in question had an audit trail and the relevant certificate signed by a Final Medical Signatory demonstrated that Novartis' internal process was compliant with both internal SOPs and the Code, Novartis refuted breaches of Clauses 8 and 8.5 on the basis that this mistake was made due to human error during the prescribing information update.

Summary in relation to Document B

In summary, the complaint had raised issues related to one of the materials in question 'JACC Treatment Algorithm for Guideline-Directed Medical Therapy Including Novel Therapies'. Novartis accepted that Clauses 5.1 and 12.1 had been breached due to an outdated PI. However, Novartis ultimately believed it had a low clinical impact for the majority of patients taking Entresto.

A decision to remove assets prior to the complaint being made demonstrated Novartis' commitment in terms of compliance and adherence to the Code. Additionally, internal SOPs demonstrated a clear process on how the update of prescribing information should be conducted within the company.

3 Conclusion

Novartis stated that it took its responsibilities under the Code extremely seriously and invested significant resources to ensure its associates developed a deep understanding of the requirements of the Code. Even with robust oversight, and high standards, human errors would inevitably occur over the course of many thousands of items being reviewed and Novartis welcomed the opportunity for these to be highlighted to the company so that it might correct these promptly and review and further refine its processes as a result.

Taking all the variables into consideration, Novartis accepted that the prescribing information was not updated due to human error and accepted Clauses 5.1 and 12.1 in respect of Document B. However, Novartis believed a breach of Clause 2 would be a severe finding in the context of a genuine administrative error within the company's internal compliance and approval processes given the volume of materials that currently needed updating. As flagged above, Novartis also refuted the alleged breach of Clauses 8 and 8.5.

PANEL RULING

The complaint was in relation to outdated prescribing information on two documents, hosted on a webpage of a Novartis website (the 'Novartis HCP Portal'). The Panel referred to these documents as follows, for consistency with Novartis' response:

- **Document A:** 'The Affinity Care Heart Failure Pathway'.
- **Document B:** 'JACC Treatment Algorithm for Guideline-Directed Medical Therapy Including Novel Therapies'.

The Panel noted the complainant's observation that the two documents contained outdated prescribing information for Entresto, differing from that provided on the webpage itself:

- Prescribing information in Document A was dated May 2021.
- Prescribing information in Document B was dated June 2020.
- Prescribing information on the webpage itself was dated October 2022.

In the Panel's view, Novartis was not sufficiently clear about the date of the prescribing information on the webpage itself. When commenting on Document A, Novartis submitted the prescribing information on Document A dated May 2021 was in alignment with the current approved up-to-date EU (Northern Ireland) summary of product characteristics (SPC) and Great Britain SPC, stating this was the version of the prescribing information which was available via the link at the top of the website. While the prescribing information dated October 2022 had been provided, Novartis was not explicitly clear that this was the version on the webpage at the time of the complaint, as alleged by the complainant. In any event, the Panel noted that the complaint concerned the version of prescribing information on Document A and Document B.

The Panel noted the complainant's concerns that the presence of different versions of Entresto prescribing information showed a lack of due care for patient safety, especially if these documents were used in isolation meaning they would lack the latest safety information for Entresto.

Version of prescribing information

The Panel noted the general principle that prescribing information (defined by Clause 12.2) must be up-to-date and must comply with Clauses 12.1 and 12.2 of the Code. The Panel noted the content of prescribing information as listed in Clause 12.2 and that some changes to an SPC might not need to be reflected in the prescribing information.

The Panel addressed each document in turn.

Document A

The Panel noted that Document A contained Entresto prescribing information dated May 2021 (MLR ID: 129646). This was a single prescribing information for the UK, whereas the October 2022 version had separate prescribing information for Great Britain and for Northern Ireland. The Panel noted the only difference between the two versions appeared to be the new marketing authorisation numbers for Great Britain (which were not present in the May 2021 version).

The Panel noted that, while Novartis stated that the most up-to-date prescribing information could be found via a link at the top of the webpage, Clause 12.1 of the Code required that the

prescribing information must form part of the promotional material and must not be separate from it. Noting Document A was downloadable, the Panel considered Document A therefore required up-to-date prescribing information.

The Panel noted Novartis' submission that Document A was removed from the webpage on 20 January 2023 after it had identified that the prescribing information was not up to date on 19 January 2023, the day before receiving notification of this complaint.

The Panel disagreed with Novartis' submission that the May 2021 prescribing information was suitable for use in both Great Britain and Northern Ireland. Clause 12.2 of the Code required that one of the features of prescribing information that must be present in all material was the number of the relevant marketing authorisation. The Panel noted that the PMCPA Brexit Guidance (issued February 2021) stated that pharmaceutical companies should update the marketing authorisation number and holder in promotional material as soon as possible after 1 January 2021, and by no later than 1 January 2023. This was reflected in the Supplementary Information to Clause 12, Arrangements for Changes to the Marketing Authorisation Number and the Marketing Authorisation Holder Name and Address Following Changes Resulting from the UK Leaving the EU which noted that from 1 January 2021 until 1 January 2023 a complaint that the prescribing information for a previously centrally approved medicine does not have, amongst other things, the new marketing authorisation number as required by Clause 12.2 (vii) will not be considered in breach of that clause providing certain conditions were met.

The Panel noted that this complaint was received after 1 January 2023 and that Novartis confirmed in its submission that Document A was not taken down from the webpage until 20 January 2023. The Panel noted that Document A was available to download from the Novartis HCP Portal and did not contain up-to-date Entresto prescribing information. The Panel, therefore, ruled **a breach of Clause 12.1**.

Document B

The Panel noted the allegation that Document B contained out-of-date prescribing information for Entresto, dated June 2020.

The Panel noted that, while Novartis stated that the most up-to-date prescribing information could be found via a link at the top of the webpage, Clause 12.1 of the Code required that the prescribing information must form part of the promotional material and must not be separate from it. The Panel noted that Document B was downloadable and therefore required up-to-date prescribing information.

The Panel noted that Novartis had provided, as part of its submission, a copy of the certificate for Document B with the June 2020 prescribing information (110879) and a copy of Document B with the May 2021 prescribing information (110879-1) but no corresponding certificate. The Panel noted that Novartis did not clarify which of these had been available on the website at the time of the complaint, but the complainant alleged that it was the older of the two (June 2020 prescribing information). The Panel noted that, regardless of which of the two versions was present on the website at the time of the complaint, the document should have been updated with the October 2022 version of the prescribing information.

The Panel noted Novartis' acknowledgement that it had identified that the prescribing information on Document B was not up to date and had contacted a third-party agency on 19

January 2023, the day before receiving notification of this complaint, to remove it from the webpage.

The Panel noted that the version of Document B available to download from the Novartis HCP Portal did not contain the most up-to-date Entresto prescribing information and the Panel, therefore, ruled **a breach of Clause 12.1**, as acknowledged by Novartis.

Certification

In relation to the failure to update materials, the Panel noted that Novartis had been asked to comment in relation to 'Clause 8 and in particular Clause 8.5'. Novartis had referred to both Clause 8 and Clause 8.5 in its response and commented generally on certification. The Panel therefore made it rulings in relation to Clause 8.5, given no other sub-clause had been identified.

Clause 8.5 referred not only to the content of the certificate but also required that 'material which is still in use must be recertified at intervals of no more than two years to ensure that it continues to conform with the relevant regulations relating to advertising and the Code'. In the Panel's view, Clause 8.5 did not require that relevant materials be recertified only once at intervals of two years; two years was the maximum period that could elapse before material was recertified. Circumstances might require recertification more frequently.

The Panel considered the documents provided by Novartis, in particular the certificates for Document A, Document B and the webpage. The Panel noted the certificates were dated as follows:

- Document B – 18 March 2021
- Document A – 9 June 2021
- Webpage – 3 March 2022.

The Panel noted the broad nature of the allegation in relation to certification and considered that the application of Clause 8.5 was unclear in the circumstances of this case. The Panel considered that the concerns about failure to update the materials published on the website with the relevant prescribing information might be more appropriately considered under Clause 8.1. As Clause 8.1 had not been raised in this case, the Panel decided to consider this matter under Clause 5.1 (the requirement to maintain high standards).

The Panel noted that the failure to update and recertify Document A and Document B with new prescribing information, on multiple occasions, indicated that high standards had not been maintained. The Panel therefore ruled **a breach of Clause 5.1 in relation to each document**.

Noting its ruling of a breach of Clause 5.1 in relation to certification above, the Panel based its ruling in relation to Clause 8.5 on the narrow ground of whether the maximum time interval had lapsed. Noting the complaint was received in January 2023 and that two years had therefore not yet lapsed since any of the materials had been certified, on this narrow ground, the Panel ruled **no breach of Clause 8.5 in relation to each document**.

Clause 5.1 and Clause 2

The Panel noted the complainant's concern that the presence of different versions of the prescribing information could harm patient safety, and their criticism of Novartis' failure to

update its materials. The Panel noted the differences between the three versions of the Entresto prescribing information.

The Panel noted the only difference between the October 2022 prescribing information and the May 2021 prescribing information appeared to be the new marketing authorisation numbers.

The Panel noted the following differences between the October 2022 prescribing information and the June 2020 prescribing information:

- Absence of the new marketing authorisation numbers for Great Britain.
- Addition of the words 'Splitting or crushing of tablets is not recommended' to the 'Dosage & administration' section.
- Addition of information about psychiatric disorders to the 'Warnings/Precautions' section and addition of hallucinations (rare), sleep disorders (rare) and paranoia (very rare) to the 'Undesirable effects' section.
- Change of wording in the 'Interactions' section relating to interactions between sacubitril/valsartan and lithium.
- Change of URL for the Novartis patient safety information tool in the adverse events reporting statement (although the old URL redirected to the new URL and so was still functional).

The Panel, bearing in mind Entresto's indication for certain patients with heart failure, was very concerned about Novartis' view of the clinical significance of the changes. The Panel noted Novartis' submission that the omission of the statement about splitting or crushing tables would not compromise the safety of patients or put the majority of patients taking Entresto at risk. In the Panel's view, Novartis' comment acknowledged that the omission might put some patients at risk. The Panel queried Novartis' assessment that the new psychiatric disorders listed in the Undesirable effects and Warnings/Precautions section were 'low clinical impact' as they were 'typically not serious, [were] reversible and manageable by drug discontinuation and routine medical care'. The Panel noted that Novartis had not commented on the significance of the changes to the 'Interactions' section.

The Panel considered that the patient population for Entresto was likely to include older and vulnerable patients who would be likely to experience other issues that would cause them to crush or split tablets. The Panel considered that the addition of the psychiatric disorders not only to the 'Undesirable effects' section but also to the 'Warnings/Precautions' section indicated their significance from a patient safety perspective.

Regarding the change of wording in the 'Interactions' section, the Panel noted that the wording in the June 2020 prescribing information regarding lithium interactions stated '… this combination is not recommended. If the combination proves necessary, careful monitoring of serum lithium levels is recommended'. In the October 2022 prescribing information, this statement was retained but additional information had been provided about the type of interaction. The Panel was particularly concerned that a new statement ('If a diuretic is also used, the risk of lithium toxicity may be increased further') was included in the October 2022 prescribing information, the omission of which in the June 2020 prescribing information could have significant implications for patient safety.

The Panel noted that Novartis disagreed with the complainant's critical description of its failure to update its materials. The Panel, however, considered that relevant emails dated 19 and 20

January 2023 revealed a certain lack of urgency regarding removal of the material at issue from the website. Whilst emails dated 19 January requested that links be removed from the website, no clear deadlines were given. It was only upon notification of the PMCPA complaint on 20 January that an email asked for certain material to be taken down 'now'. That urgency was not apparent was of particular concern given the nature of the May 2021 SPC update. Further, in the Panel's view, the Brexit guidance and relevant Supplementary Information to Clause 12 as described above meant that at the very least implementation of changes in relation to the marketing authorisation numbers ought to have been front of mind. In this regard, the Panel noted Novartis' submission that its standard operating procedure required all prescribing information related to its products to be split into Great Britain and Northern Ireland, respectively, by the end of 2022 and consequently be updated.

Taking into account the above, the Panel considered Novartis had failed to maintain high standards and **a breach of Clause 5.1** was ruled, as acknowledged by Novartis.

The Panel noted that Clause 2 was a sign of particular censure and was reserved for such use. The supplementary information to Clause 2 included prejudicing patient safety as an example of an activity that was likely to be in breach of this clause. In the Panel's view, the omission of information about not splitting or crushing tablets, the wording about psychiatric disorders, and the interactions information relating to lithium and diuretics from the prescribing information present in Document B had the potential to impact patient safety. That, as submitted by Novartis, the failure to withdraw Document B from the website to allow for the May 2021 prescribing information update was human error did not lessen the seriousness of the matter. The Panel was particularly concerned about the length of time for which Document B had been available on the website with out-of-date prescribing information. The Panel considered that it was crucial that health professionals and others could rely upon the pharmaceutical industry for accurate and up-to-date information about their medicines. Bearing in mind its comments above, the Panel considered that Novartis had reduced confidence in, and brought discredit upon, the pharmaceutical industry. The Panel ruled **a breach of Clause 2**.

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The Panel had concerns regarding Novartis' comment that 'the content of [Document A] did not go through [Novartis'] internal signatory process', although a certificate was provided as part of Novartis' submission. As an item that was being used promotionally, Clause 8 required that it must be certified to ensure that it complied with the Code. The Panel noted, however, that this did not form part of the allegation and so did not rule on this matter.

Complaint received **10 January 2023**

Case completed **18 March 2024**