

CASE/0215/06/24

COMPLAINANT v AMICUS

Allegations about a company website

CASE SUMMARY

This case concerned allegations relating to:

- pages on Amicus's UK corporate website being out of date and their certification and recertification,
- the classification of projects including collaborative working, their documentation and transparency, and
- the disclosure of transfers of value (ToV).

There was an appeal by Amicus of two of the Panel's rulings in relation to the certification and recertification of the Programs webpage.

The outcome under the 2019 Code was:

Breach of Clause 20	Failing to meet the requirement to publicly disclose transfers of value made in connection with joint working
Breach of Clause 24.2	Failing to publicly disclose a transfer of value made in connection with joint working
No Breach of Clause 20	Requirement for joint working to fulfil certain criteria including the publication of outcomes

The outcome under the 2021 Code was:

Breach of Clause 5.1	Failing to maintain high standards
Breach of Clause 20.3 (x3)	Failing to meet the requirements for collaborative working in relation to the publication of summaries of the collaborative working agreement and outcomes
Breach of Clause 20.5 (x2)	Failing to publicly disclose a transfer of value made in connection with collaborative working
No Breach of Clause 2	Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry
No Breach of Clause 6.1	Requirement that information must be accurate, up-to-date and not misleading

No Breach of Clause 8.1 (x7) [Panel's ruling of one breach of Clause 8.1 overturned at appeal]	Requirement to certify promotional material
No Breach of Clause 8.3 (x11)	Requirement to certify non-promotional material
No Breach of Clause 8.5 (x10) [Panel's ruling of one breach of Clause 8.5 overturned at appeal]	Requirement to recertify material at intervals of no more than two years
No Breach of Clause 20.2	Requirement to meet certain criteria to be classified as collaborative working
No Breach of Clause 20.3 (x7)	Requirement for collaborative working to meet certain criteria in relation to the publication of summaries of the collaborative working agreement and outcomes
No Breach of Clause 20.5 (x3)	Requirement to publicly disclose transfers of value made in connection with collaborative working

**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 about Amicus Therapeutics UK Limited was received from a contactable complainant.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected.

First complaint submitted:

“Dear PMCPA,
As an HCP, I have come across a website by a company called Amicus Therapeutics. Their UK website is very bland but I did notice that it not only seems out of date but is trying to hide its donations or grants as collaborative working and make its transparency disclosure to ABPI opaque.
I understand that Amicus is a member of the ABPI.
Please find the complaints attached.
Please feel free to contact me for any further insights into the complaint.
I would like to remain anonymous whistle-blower.”

The complaint is shown as complaints 1-6 below as provided by the complainant and referred to above:

“Complaints against Amicus Therapeutics

Complaint 1 : Out of Date Website pages

[Screenshot of About Amicus webpage provided]

- NP-NN-UK-00031021 | April 2022
- Multiple web pages not updated or have been certified over 2 years ago.
- If recertified, no content updates have been provided for over 2 years
- Website contains Collaborative working summaries which have not been updated for over 2 years
- Copyright statement mentions 2024 ie website may have been updated without recertification.

[URLs for six webpages provided]

Complaint 2

Webpage certified prior to update

[URL for and screenshot of Modern Slavery Act Transparency webpage provided]

- Approved statement by board on 27th June 2023
- NP-NN-UK-00020223 has date March 2023.
- Copyright statement – again 2024.
- Misleading, not up to date or not certified final form.

Clause 20 Collaborative Working with Organisations – SI

[URL for and screenshot of transparency webpage provided]

- 'outcomes should be published by all parties as soon as possible and usually within six months of the project's completion, so that other NHS organisations and others can learn from and potentially replicate the initiative. Companies should publish the outcomes on their websites.'

Collaborative working with NHS has 4 summaries with not much details

Complaint 3:

Collaborative Working No Outcomes posted within 6 months

Project Duration Feb 22-Feb 23

[URL for and screenshot of Flash Mob Audit Executive Summary provided]

- NP-NN-UK-00030222
- No outcomes posted after 16 months. Breach of Clause 20
- Summary does not detail company amount spent or contribution from NHS

Complaint 4: Collaborative Working

Failure to post Outcomes

Project Duration 15 Dec 2022-15th May 2023

[URL for and screenshot of Fabry Disease Symptom Tracker App Executive Summary provided]

- As per NP-GA-GB-00011222 Dec 2022 summary
- No outcome posted after 13 months of end of project. Breach of Clause 20
- Summary does not detail NHS contribution to the collaborative working
- Summary does not detail company resource spent on project

Complaint 5

Failure to disclose collaborative working TOV

Clause 20.5 (x 3)

[Screenshot of Amicus Therapeutics 2022 disclosures on Disclosure UK provided]

- Two Institutions (2022) disclosed who received collaborative working
- [Named] University
- University Hospital [named locality] NHS Trust
- No disclosures in 2020 or 2021
- Four Collaborative working summaries available on company website.
- [named hospital] NHS Foundation Trust not disclosed
- Flash Mob Audit – [Named hospital] NHS trust not disclosed
- Fabry online education Programme with [Named hospital] Not Disclosed.

Complaint 6

Failure to provide summary of Collaborative Working

[Screenshot of 2022 TOV to named University on Disclosure UK provided]

- £23,332.66 to [named] University under 2022 disclosure as collaborative working has no summary on website.
- Breach of Clause 20.3

Summary of Complaints

- Website is out of date, misleading or not certified correctly
- Company does not seem to care about disclosure to ABPI
- 3 Collaborative workings not disclosed
- 1 disclosed collaborative working has no summary
- Multiple collaborative outcomes not posted
- Contribution of NHS not highlighted in available summaries
- Seems like collaborative working is just another tool to provide grants to NHS or worse inducement to prescribe
- Systematic failure of disclosure to ABPI
- Systematic failure to check current website
- Seems poor understanding of the code or purposeful ignorance on transparency.”

Second complaint submitted:

“Amicus Therapeutics Websites [URLs for six webpages provided] website out of date not certified after 2 years. Collaborative working does not have summaries posted on it after years of closure. Purposeful disregard to disclosureUK. Please see attached. Systematic failure of disclosure over 3 years.”

Additional information from the complainant:

“I have attached NP-GA-UK-00011219 Dated Feb 2020 ‘[Named hospital] Fabry App Joint Working Exec Summary’ which also seems to have the similar issues of non-disclosure on disclosure UK and non-disclosure of outcomes after several years after end of project.

I have also noticed that the company has now disclosed 4 additional collaborative workings under the 2023 disclosures amounting to £217,564.93. All 4 do not have any collaborative working linked adding to the misleading nature of these disclosures.

There has also been another executive summary NP-NN-UK-00020424 (attached) dated April 2024 named 'executive summary Pompe physiotherapy service'. This document has similar key data missing as to the amount or resources provided by each party and is deliberately written to hide than to disclose. Additionally, this project seems to be provision of a service rather than collaborative working. Please find both these documents attached to assist in the complaint.”

When writing to Amicus, the PMCPA asked it to consider the requirements of the following clauses of the 2021 Code:

Complaint 1: 8.1, 8.3, 8.5

Complaint 2: 6.1, 8.1, 8.3

Complaint 3: 20.2, 20.3

Complaint 4: 20.2, 20.3

Complaint 5: 20.5 (x3)

Complaint 6: 20.3

Complaint 7: 20, 24.2 (2019 Code) and 20.3, 20.5 (2021 Code)

Complaint 8: 20.3 (x4)

Complaint 9: 20.2

Overall: 5.1 and 2.

AMICUS' RESPONSE

The response from Amicus is reproduced below:

“Amicus Therapeutics UK Limited understands the PMCPA has received a complaint from an anonymous contactable complainant. The complaint relates to the approval of some content on the Amicus corporate website and the purpose and transparency of collaborative working projects, including transfers of value. Amicus Therapeutics UK Limited’s subsidiary in the UK (Amicus Therapeutics Operations Limited, ‘Amicus’) manages and enters into collaborative working arrangements with the NHS and is providing this response.

Amicus is a patient-focussed company that is committed to working collaboratively with the NHS to enhance patient care directly and indirectly. Indeed, it has been noted that collaborative working is incredibly beneficial for patients and the NHS in the area of rare disease including the rare diseases Amicus focuses on. We understand that collaborative working is built on trust and transparency, and Amicus is fully committed to being transparent about all the arrangements we enter into.

In addition, transparency concerning transfers of value, made in the course of collaborative working or otherwise, is taken seriously at Amicus. In line with these principles, Amicus has taken the complaint very seriously and has carried out a full review of the practices within the scope of the complaint.

Response to the Complaint

Amicus has adopted the headings used by the complainant in the slides provided with the 10 July letter (which consists of Allegations 1 - 6) and the bullet points contained in the letter of 25 July (consisting of Allegations 7 - 9).

In an attempt to limit duplication, this letter responds to the allegations regarding Amicus's website first, followed by allegations regarding the administration of collaborative working projects, and concludes with the response to allegations regarding disclosure of transfers of value. As a result, the response to Allegation 7 has been split into a response regarding collaborative working and a response regarding transfers of value.

A. The Website

ALLEGATION 1: Out of date website pages

The Allegation states that the Amicus UK corporate website ([URL provided] '**Website**') has multiple pages with a unique identifier code of NP-NN-UK-00031021 and date of preparation of April 2022 (the '**Webpages**'). The allegation is that this means the pages were certified over two years ago or if re-certified there were no content updates. In addition, the copyright statement on the pages is dated 2024, which it is alleged may mean they have been updated without recertification.

The transparency page of the Website contains summaries of collaborative working projects (as required by Clause 20.3 of the ABPI Code) ('**Executive Summaries**'), which it is alleged have not been updated within the last two years.

The CPM requested Amicus to consider Clauses 8.1, 8.3, 8.5 of the 2021 Code.

The enclosed copies of the Webpages demonstrate that the content is general corporate, non-promotional information. With respect to the Webpages, Clause 8.1 is not applicable. Clause 8.3 relates to certification of Executive Summaries while Clause 8.5 relates to recertification. Neither Clause 8.3 or 8.5 are applicable to the Webpages.

Further, all amendments made to the Webpages were examined, in line with the supplementary information to Clause 8.3.

The copyright notice on the Website is applied manually and is indicative of ownership of the content on Webpages [URL provided]. It is not relevant to certification or examination.

The Executive Summaries were certified and recertified within 2 years, where necessary. Please find enclosed the certification for the Executive Summaries that slide 3 of the complaint points to on the Website. In the order showing on slide 3:

- 'Fabry disease symptom tracker app' with the [named hospital] NHS Foundation Trust, certified on 9 December 2022
- 'Fabry Family Screening' with University Hospital [named locality] NHS Foundation Trust, certified on 4 November 2022
- 'Flash Mob Audit' with the [named hospital] NHS Foundation Trust, certified on 7 February 2022 and recertified on 12 December 2023
- 'Fabry Online Education Programme' with [named hospital] NHS Trust, certified on 7 February 2022 and recertified on 12 December 2023

A unique identifier code is stated on the Webpages as initially the pages were certified in our electronic approval system. It was later decided that as the Webpages did not require certification pursuant to the ABPI Code, examination and approval of changes would be performed 'offline'. However, the unique identifier code remained on the page. Amicus has formalised the process by which material related to this Website is examined and the unique identifier codes have been removed from the Webpages.

Amicus denies breaches of Clauses 8.1, 8.3 and 8.5 of the 2021 Code.

ALLEGATION 2: Webpage certified prior to update

The Allegation refers to the page of the Website that contains Amicus's UK Modern Slavery Act Statement 2023 (the '**Statement**'). The Allegation notes that (i) the Statement was approved by the board on 27 June 2023; (ii) the page states NP-NN-UK-00020223 March 2023; and (iii) the copyright statement is dated 2024. It is alleged that the webpage was certified prior to being updated and therefore it is misleading, not up to date or not certified in its final form. The CPM requested Amicus to consider Clauses 6.1, 8.1 & 8.3 of the 2021 Code.

As noted in the response to Allegation 1, a copyright notice is not relevant to certification or examination under the ABPI Code.

The Modern Slavery Act 2015 states that qualifying organisations must publish an annual statement setting out the steps they take to prevent modern slavery in their business and supply chains. This requirement does not fall within the remit of the ABPI Code. In addition, the Statement does not contain promotional material and does not require certification under Clause 8.1 and is not covered by any of the activities listed as requiring certification in Clause 8.3.

Clause 6.1 provides, amongst other things, that information must be accurate, balanced, fair, objective and unambiguous. It must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis. As discussed above, the ABPI Code does not apply to a Modern Slavery Act Statement on a corporate website,

but even if it did, the Statement would not be in breach of any of the criteria in Clause 6.1.

The Statement was examined pursuant to the supplementary information to Clause 8.3. The current content was examined by a senior compliance employee who is an appropriately qualified person. A unique identifier code is stated on the Webpage as initially the pages were certified in our electronic approval system. It was later decided, as certification is not required, that examination and approval of changes would be performed 'offline'. However, the unique identifier code remained on the page. This has been addressed as explained above in the response to Allegation 1.

Amicus denies breaches of Clauses 6.1, 8.1, and 8.3.

B. Collaborative Working

The CPM requested details of the pooling of skills, expertise and or resources for each collaborative working project mentioned in the complaint. [Document] identifies this information for each project.

For completeness, Amicus also provides the written agreement entered into for each collaborative working, and one joint working, project captured in the complaint.

ALLEGATION 3: Collaborative Working - No outcomes published within 6 months. Project Duration Feb 22-Feb 23

The complaint alleges that the Executive Summary of the collaborative working project of 'Flash Mob Audit' with the [named hospital] NHS Foundation Trust does not detail the company spend or contribution from the NHS. The complaint also alleges that no outcomes from the project have been published 16 months after the project ended. The CPM requested Amicus to consider Clauses 20.2 & 20.3 of the 2021 Code.

Clause 20.2 of the ABPI Code provides that collaborative working must demonstrate the pooling of skills, experience and/all resources from all parties involved. There must be a shared commitment to successful delivery and each party must make a significant contribution. This criteria is met for the 'Flash Mob Audit' project, as evidenced in the Agreement and the PID. There is, therefore, no breach of Clause 20.2.

Clause 20.3 requires that a summary of the collaborative working agreement is publicly available before the arrangements for the project are implemented. This requirement was met. It is acknowledged that the Executive Summary does not detail the company spend or contribution from the NHS. However, it is not a requirement of the ABPI Code that the Executive Summary contains this information and therefore there is no breach of the Code in this regard. Importantly, recently published ABPI guidance on collaborative working projects, *Accelerating transformation: How to develop effective NHS-industry partnerships June 2024* provides a framework for what should be included in the Executive Summary (page 31). The new guidance also does not require detail of the company spend or contribution from the NHS to be included in an Executive Summary and is thereby aligned with Amicus's SOP on Collaborative Working and the Code. The certification certificate for the Executive Summary is [provided].

Amicus is aware that the supplementary information to Clause 20 states that '*outcomes should be published as soon as possible and usually within six months of the project's completion, so that NHS organisations and others can learn from and potentially replicate the initiative. Companies should publish the outcomes on their website*'. Amicus's SOP on Collaborative Working includes a requirement of publication of outcomes on the Website within six months of completion of a project and the outcomes were published within six months of completion of the Flash Mob Audit project in multiple places. The project ran for 12 months from February 2022 until February 2023. Once complete, an abstract of the outcomes was: (i) submitted to the [named medical professional membership organisation] on 3 March 2023 and published in the [named medical publication] abstract supplement for the named medical professional membership organisation congress on 2 June 2023; (ii) presented as a poster at the [named medical professional membership organisation] annual meeting, 5-7 June 2023; and (iii) made available online ([named medical publication]) on 18 October 2023. However, in this instance the outcomes were not published on the Website.

The external publication of the outcomes demonstrates that the purpose of the requirement in the supplementary information to Clause 20, to ensure NHS organisations and others could learn and potentially replicate the initiative, has been fulfilled. The outcomes for the project have now been published on the Website and recent training emphasising the need to publish outcomes on the Website within six months of completion of a project has been undertaken by the team.

Amicus denies breaches of Clauses 20.2 and 20.3.

The complaint also states (on the slide between allegation 2 and 3) that the four Executive Summaries, available on the Website at the time of the complaint, did not have '*much detail*'. It is not clear if this slide/statement is part of an allegation, and the CPM has not asked Amicus to respond to a specific Clause in this regard, but it is addressed for completeness.

Neither the ABPI Code, nor guidance available at the time of production and certification of the Executive Summaries, specified what level of detail was to be included. Amicus believes that the amount of detail provided in the Executive Summaries met the objective sought of transparency regarding the projects taking place.

The certification certificates for the four Executive Summaries are [provided].

ALLEGATION 4: Collaborative Working Failure to post Outcomes Project
Duration 15 Dec 2022- 15 May 2023

The complaint alleges that the Executive Summary of the collaborative working project 'Fabry disease symptom tracker' entered into with the [named hospital] NHS Foundation Trust does not detail the company spend or contribution from the NHS. The complaint also alleges that no outcomes from the project have been published 13 months after the project ended. The CPM requested Amicus to consider Clauses 20.2 & 20.3 of the 2021 Code.

The criteria required by Clause 20.2 of the ABPI Code is met for the project, as evidenced in the Agreement and the PID, and set out in [document]. Therefore, there is no breach of Clause 20.2.

As noted in the response to Allegation 3, it is not a requirement of Clause 20.3 of the ABPI Code, that the Executive Summary contains detail of the company spend or the contribution from the NHS. Amicus has met the requirements of the Code. The certification certificate for the Executive Summary is [provided].

The outcomes for this project are not yet available. The project commenced on 15 December 2022, with an expected duration of 15 months, as detailed in the Executive Summary. The project was due to end in March 2024 but is ongoing due to staff illness, IT process delays and changes within the NHS Trust, which caused the project to be delayed. The outcomes will be published once the project has been completed.

Amicus denies breaches of Clauses 20.2 and 20.3.

ALLEGATION 6: Failure to provide summary of Collaborative Working

The Allegation states that, in 2022, Amicus disclosed a transfer of value to [named] University for a collaborative working project but no Executive Summary is available on the Website for this project. The CPM requested Amicus to consider Clause 20.3 of the 2021 Code.

The arrangement with [named] University was, in fact, for a studentship agreement (i.e a research grant supporting a PhD). The disclosure of the transfer of value in this regard is addressed in Section D. Please find enclosed the studentship agreement. There is no requirement under Clause 20.3, or elsewhere in the Code, for an Executive Summary to be published on the company website as regards research grants. As such, there is no breach of Clause 20.3.

Amicus denies a breach of Clause 20.3.

ALLEGATION 7 (part 1): Failure to publish outcomes for Joint Working ([named hospital] NHS Foundation Trust, Fabry App)

The complaint alleges that the outcomes relating to the Joint Working project 'Fabry App' with the [named hospital] NHS Foundation Trust have not been published on the Website. The CPM's letter of 26 July notes that the Executive Summary for this project, provided with the complaint, is dated February 2020 and therefore the 2019 Code was applicable at that time. The CPM requested Amicus to consider Clause 20 of 2019 Code and Clause 20.3 of the 2021 Code, which concern joint or collaborative working. The second part of Allegation 7 regarding transfers of value is addressed in section C below.

Clause 20 of the 2019 Code stated that joint working was acceptable where it is carried out in a manner compatible with the Code and benefited patients. The Agreement shows the project was established in accordance with the Code. As the 2019 Code was applicable at the time the project was initiated, Amicus is not clear what aspect of

Clause 20.3 of the 2021 Code the CPM would like Amicus to address. The supplementary information to Clause 20 of the 2021 Code that requires outcomes to be published is relevant to the project. However, the project has not yet completed and therefore no outcomes have been published on the Website. Nevertheless, the principle of transparency has been achieved in the interim as the contributors from the [named hospital] NHS Foundation Trust published a paper on the value of the Fabry App (based on interim results) in the [second named medical publication] in January 2024. Once the project is completed, the outcomes will be published on the Website.

Amicus denies a breach of Clause 20 of 2019 ABPI Code and of Clause 20.3 of the 2021 Code.

ALLEGATION 8: Summaries for 2023 Collaborative Working Projects

The complaint alleges there are four transfers of value for collaborative working projects under the 2023 disclosures (ref 4183628-31) but that all four ‘*do not have any collaborative working linked adding to the misleading nature of these disclosures*’. The CPM requested Amicus to consider Clause 20.3 of the 2021 Code (x4).

For clarity, the payment which shows as ‘[Named regional] NHS Group’ is for the ‘Fabry disease symptom tracker app’ project with [Named hospital] NHS Foundation Trust, which is part of the Named regional] NHS Group. The payment to the [Named hospital] NHS Foundation Trust was for both the ‘Flash Mob Audit’ and ‘Fabry Online Education Programme’ projects, and the payment to University Hospital [named locality] NHS Foundation Trust was for the ‘Fabry Family Screening project’. The payment to the University of [named locality] is, in fact, an investigator initiated study. The disclosure of the transfer of value in this regard is addressed in Section D below.

The requirements of Clause 20.3 of the Code are met for each project and, thereby, the principle of transparency complied with. An Executive Summary is published on the Website for each collaborative working project referred to. The certification certificate for each Executive Summary is [provided]. Amicus has provided the Agreement and PID for each project which show the relevant criteria to constitute permissible collaborative working is met and the pooling of resources are also listed in [document].

Amicus denies any breach of Clause 20.3 (x4).

ALLEGATION 9: Nature of project with [named hospital] NHS Foundation Trust

The complaint alleges that the Executive Summary ‘Pompe physiotherapy service’ (NP-NN-UK-00020424) dated April 2024 has key data missing as to the amount or resources provided by each party and is deliberately written to ‘*hide rather than to disclose*’. The complaint states that the project seems to be provision of a service rather than collaborative working. The CPM requested Amicus to consider Clause 20.2 of the 2021 Code.

Amicus has provided the Agreement and PID for this project, which show the relevant criteria for collaborative working, pursuant to Clause 20.2, are met. The pooling of resources is listed in [document].

As set out in Allegation 3, the ABPI Code does not specify that the amount or resources provided by each party is to be included in the Executive Summary. Amicus has met the requirements of the Code in this regard and there is no breach. The certification certificate for the Executive Summary. The Executive Summary was certified on 12 April 2024.

The complaint alleges that the arrangement is a provision of a service rather than collaborative working. However, the collaborative working project consists of various tasks to improve a physiotherapy service that has been inherited by [named hospital] NHS Foundation Trust, rather than Amicus providing the service. The PID for the project clearly sets out that the project is to develop the inherited physiotherapy service. The aims are: to improve efficiency; patient outcome measures and overall patient experience; to demonstrate the value of an enhanced physiotherapy service; and to improve the coordination for care for patients living with rare diseases. Further, in line with the principles of collaborative working, the PID clearly sets out the benefits to NHS, the patient and Amicus, and the contributions each party will make to the project. In any event, it is permissible, pursuant to the supplementary information to Clause 20.2, for a collaborative working project to include services.

Amicus denies a breach of Clause 20.2.

C. Disclosure of Transfers of Value

Transparency reporting is taken very seriously at Amicus. The CPM requested details of Amicus's arrangements for disclosing transfers of value in relation to collaborative working projects. Please find the relevant SOP enclosed.

ALLEGATION 5: Failure to disclose Collaborative Working Transfers of Value from 2020 - 2022

The complaint alleges that there were no disclosures of transfers of value for collaborative working projects commenced in 2020 or 2021 and that payments relating to the following projects were not disclosed in 2022:

- Fabry disease symptom tracker with [named hospital] NHS Foundation Trust
- Flash Mob Audit with [named hospital] NHS Foundation Trust
- Fabry Online Education Programme with [named hospital] NHS Foundation Trust

The CPM requested Amicus to consider Clause 20.5 of the 2021 Code (x 3).

Clause 20.5 requires that transfers of value made by companies in connection with collaborative working must be publicly disclosed annually giving in each case the financial amount or value and the name of the recipient.

In 2020, Amicus made one transfer of value as regards joint working pursuant to the 2019 ABPI Code. This was to the [named hospital] NHS Foundation Trust for the 'Fabry App' project and is dealt with under Allegation 7 part 2 as the CPM specifically requested a response regarding the 'Fabry App' joint working project under the 2019 Code to Allegation 7.

Amicus made no transfers of value for Collaborative Working projects during 2021. Therefore, no disclosures were made.

In relation to 2022, as explained in response to Allegation 4, the Collaborative Working project with [named hospital] NHS Trust has experienced delays. On account of such delays, no payments were made in 2022.

Amicus denies breaches of Clause 20.5 of the 2021 Code in relation to the years 2020 and 2021 and as regards Collaborative Working with [named hospital] NHS Trust in 2022

As regards transfers of value made in the two collaborative working projects with the [named hospital] NHS Foundation Trust in 2022 (Flash Mob Audit and Fabry Online Education Programme), all transfers of value made directly to the [named hospital] NHS Foundation Trust have been correctly disclosed. However, in reviewing the complaint, Amicus has realised that, for these projects, payments made to the same third-party vendor were not disclosed. These payments were not direct transfers of value to a healthcare organisation but, rather, were fees that Amicus paid to a third party for services performed on behalf of Amicus as part of the collaborative working projects. Nevertheless, Amicus recognises that Clause 20.5, and the corresponding supplemental information, require all sums incurred as part of collaborative working to be disclosed even when there is no direct transfer of value to a healthcare organisation (*'the amount spent on collaborative working projects is made public irrespective of whether the value is transferred to a healthcare organisation etc. or some other funding model is used'*). While the payments were correctly identified as payments relating to a collaborative working project within the Amicus financial system, the manual step required to transcribe the payment as a collaborative working transfer of value for the purpose of disclosure was missed. How Amicus will address this mistake is set out in section D.

Amicus admits two breaches of Clause 20.5 in relation to the Flash Mob Audit and Fabry Online Education Programme projects with the [named hospital] NHS Trust.

ALLEGATION 7 (part 2): Failure to disclose transfers of value for Joint Working ([named hospital] NHS Foundation Trust, Fabry App)

The complaint alleges that the transfer of value relating to the Joint Working project 'Fabry App' with the [named hospital] NHS Foundation Trust has not been disclosed. The CPM's letter of 26 July notes that the Executive Summary for this project, provided with the complaint, is dated February 2020 and therefore the 2019 Code was applicable at that time. The CPM requested Amicus to consider Clauses 20 and 24.2 of 2019 Code and Clause 20.5 of the 2021 Code, which concern disclosure of transfers of value.

Clause 20 of the 2019 ABPI Code states that '*Transfers of value made by companies in connection with joint working must be publicly disclosed*'. Clause 24.2 of the 2019 ABPI Code confirms that transfers of value made to healthcare organisations for joint working in accordance with Clause 20 must be disclosed.

As part of our review, Amicus has identified the transfer of value for this joint working was not included in the 2020 disclosure report as the payment was not correctly transcribed from the financial system into the spreadsheet for reporting to Disclosure UK. How Amicus will address this mistake is set out in section D.

No further payments have been made for this project since 2020 and therefore there have been no transfers of value to disclose pursuant to Clause 20.5 of the 2021 Code.

Amicus admits a breach of Clause 20 of the 2019 Code.

Amicus denies a breach of Clause 20.5 of the 2021 Code and Clause 24.2 of 2019 ABPI Code.

D. Applicability of Clauses 5.1 & 2 of the 2021 Code

Clause 5.1 states that high standards must be maintained at all times. As set out above, and evidenced with the documents enclosed, Amicus has established systems and processes to meet our obligations under the ABPI Code as regards the requirements of, and documentation to support, collaborative working.

However, it is recognised that a manual step in the reporting of transfers of value process has given rise to mistakes. Our review has shown that all payments made in the context of collaborative working were correctly coded in the financial system as required by the SOP. However, a manual step is required where the relevant information must be extrapolated from the financial system and transcribed into the relevant category in the disclosure report. Unfortunately, mistakes in this manual step resulted in the three breaches of clause 20.5 that Amicus admits (Allegation 5 and 7). This manual step is also why the research investigator initiated study with the University of [locality] (Allegation 8) and the studentship agreement at the University of [locality] (Allegation 6), and two other payments made in 2023 that were not raised as part of the complaint, were miscategorized as collaborative working. In these regards, the fact transfers of value had been made to certain organisations were publicly disclosed and were transparent. However, Amicus has amended Disclosure UK to correctly categorise the payments. In order to prevent future mistakes, enhancements to the current process are under consideration, including the potential to increase use of automation, use of checklists and additional cross-checking between departments. Enhanced training on the SOP for the team responsible for disclosure and further oversight will be implemented in advance of the next disclosure cycle. While Amicus does not believe that the mistakes made are 'systematic failure' as alleged, we will learn from the mistakes in order to meet the high standards we strive to maintain.

The complaint makes some serious allegations about Amicus, which Amicus strongly denies. These include that Amicus does not seem to care about disclosure to ABPI, that collaborative working is being used as a tool to provide grants to the NHS or as an inducement to prescribe, that a systematic failure to check the current website is occurring and that Amicus has a poor understanding of the code or purposeful ignorance on transparency. Amicus strongly denies these claims and is disappointed that anyone would consider this to be the case. Amicus hopes the CPM and Panel understand the company approach and underlying intent from the explanations

provided in this response and agrees that these allegations are unfounded. In the absence of truth about these serious allegations, Amicus does not believe that the manual mistake identified during its review, should be considered as '*such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry*'. Amicus notes that a ruling of a breach of clause 2 '*is a sign of particular censure and is reserved for such circumstances*' and strongly refutes the facts of the complaint warrant a ruling of a breach of clause 2.

Conclusion

Amicus hopes the CPM and the Panel are reassured by the comprehensive nature of this response, that it reflects the thoroughness of Amicus's review and that Amicus takes all allegations of non-compliance extremely seriously."

PANEL RULING

Although this complaint was general in nature, the Panel considered it under three limbs:

1. allegations relating to pages on Amicus's UK corporate website being out of date and their certification and recertification,
2. allegations concerning the classification of projects including collaborative working, their documentation and transparency, and
3. the disclosure of transfers of value (ToV) on the ABPI portal.

The Panel referred to the PMCPA Constitution and Procedure, which stated that the complainant had the burden of proving their complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties.

Allegation 1: Out of date webpages

The complainant alleged that six webpages on Amicus's corporate website had not been updated or had been certified more than 2 years ago, or if recertified no content had been updated for more than 2 years. The complainant further alleged that the 2024 copyright statement indicated that the website may have been updated without being recertified.

Amicus had been asked to consider Clauses 8.1, 8.3 and 8.5 of the 2021 Code.

The Panel noted that each of the six webpages cited by the complainant:

- (a) used the same template header and footer,
- (b) displayed the same job code (NP-NN-UK-00031021) and date of preparation (April 2022), and
- (c) contained a copyright statement dated either 2023 or 2024.

The Panel reviewed the six webpages and noted the following substantive content:

- a) Contact page
Comprised Amicus's name, address and contact telephone number for general enquiries along with details of how to submit a medical information request or report an adverse event in the UK and in Ireland.

b) About us page

Comprised a blue banner stating 'About Amicus' below which were two blue boxes (one stating 'Belief Statement' and the other 'Who We Are') that both appeared to link to separate pages.

c) Beliefs page

Comprised a headline 'Our passion for making a difference unites us' below which were two blue boxes (one stating 'Belief Statement' and the other 'Who We Are') that both appeared to link to a separate page. Underneath was a brief description of the background to Amicus's three fundamental beliefs which were shown as separate boxed statements:

- We believe..... In the Fight to Remain at the Forefront of Therapies for Rare and Orphan Diseases
- We believe..... In Our Future to Build Long-term Value for Our Stakeholders
- We believe..... In Each Other to Foster Teamwork and Respect for Each Individual's Contribution

d) Programs page

Comprised a blue banner stating 'Programs' and below, in blue, the headline 'Our Science and Technology' followed by an image of a gloved hand holding a test tube and a pipette. The accompanying text, headed 'Science that's powered by passion', stated:

'We are leveraging our innovative technology platforms to develop treatments for human genetic diseases. The scientists researching these methods are dedicated to finding enhanced treatments for patients suffering from these rare diseases. Their passion fuels progress as we work to deliver meaningful benefits. We are proud to take this bold approach towards these developments, in the hope of offering healing beyond disease.'

With extraordinary patient focus, Amicus Therapeutics is committed to advancing and expanding a robust pipeline of cutting-edge, first- or best-in-class medicines for metabolic diseases.'

A blue box at the bottom appeared to link to a separate webpage inviting viewers to 'Explore Our Pipeline'.

e) Transparency page

Comprised a blue banner stating 'Transparency' below which was the title 'Patient Organisation Support' and text explaining how and why Amicus worked with patient and advocacy organisations. A paragraph detailing that the company published a list of its financial support followed, together with links to the UK data for the years 2016 to 2022. A link to 2022 data relating to Patients and Members of the Public was also provided in this section.

A similar section concerning healthcare practitioners and healthcare organisation disclosures with a link to Disclosure UK followed, together with third section titled 'Collaborative working with the NHS'. This latter section explained Amicus's rationale for working collaboratively with the NHS and provided links to the Executive Summaries for four collaborative working projects.

f) Careers page

Comprised a blue banner stating 'Join the Amicus Team', beneath which was a section relating to its culture that sought 'to deliver the highest quality therapies for persons living with these diseases' along with sections related to diversity and benefits. The final section related to leadership being 'committed to delivering meaningful benefits to the rare disease community'. A blue box at the bottom invited visitors to 'View Open Positions'.

The Panel considered the content of each of the six webpages and whether they required certification as alleged.

Clause 8.1 stated, amongst other things, that promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified.

Clause 8.3 listed materials that required certification in advance in a manner similar to that provided for by Clause 8.1. The supplementary information to Clause 8.3 stated that material issued by companies which is not required to be certified under the Code should be examined by a signatory or an appropriately qualified person, who need not be a signatory, to ensure that it does not contravene the Code or the relevant statutory requirements.

Amicus submitted that the webpages had initially been certified in its electronic approval system with the job code included. It was later decided that certification was not required and changes to the webpages would be approved via "offline" examination. Amicus acknowledged that the original job codes and date of preparation had remained on the webpages despite this change in approval process but that these had now been removed. It also submitted that the copyright statement was not relevant to certification or examination under the ABPI Code.

In the Panel's view, the complainant's reference to the copyright statements formed part of their allegation that the webpages in question had been updated without being recertified.

Certification of the Contact, About Us, Beliefs, Transparency and Careers webpages

In the Panel's view, the content of four of the webpages (the Contact, About Us, Beliefs and Careers webpages) consisted of general corporate information. The Transparency page contained descriptions of Amicus's engagement with patient organisations, healthcare professionals, healthcare organisations and the NHS, with links to collaborative working executive summaries. While the Beliefs and Careers pages included aspirational statements and references to Amicus's commitment to rare and orphan diseases, the Panel did not consider that any of these webpages contained promotional claims, referred to specific medicines or otherwise sought to encourage the use of Amicus's products.

The Panel considered that none of these five webpages (the Contact, About Us, Beliefs, Transparency and Careers webpages) amounted to promotional material under the Code and therefore were not covered by Clause 8.1. **No breach of Clause 8.1** was ruled for each of those five webpages.

The Panel further did not consider these five webpages fell under the list of materials requiring certification as specified in Clause 8.3. Additionally, the Panel noted Amicus's submission that the webpages had been examined and, given the complainant bore the burden of proof, the

Panel did not consider it had been established that the webpages had not been appropriately examined. The Panel therefore ruled **no breach of Clause 8.3** in relation to each of the webpages.

The Panel considered that, as these five webpages were not deemed promotional and did not fall under the list of material requiring certification under Clause 8.3, the requirement to recertify did not apply and **no breach of Clause 8.5** was ruled in relation to each of the five webpages.

Certification of the Programs webpage

Although no specific medicines were referred to on the Programs webpage, the Panel nonetheless considered that the statements it contained were very positive about Amicus's medicines. The Panel took account of statements that included terms such as "cutting-edge", "first- or best-in-class", and "healing beyond disease". The Panel concluded that the overall impression created, on balance, went beyond general corporate messaging and in its view, this webpage required certification under Clause 8.1. Amicus submitted that the page was no longer managed through its electronic approval system and the Panel therefore concluded that the version available at the time of the complaint had not been recertified within the two-year period required by Clause 8.5. On balance, the Panel ruled **a breach of Clauses 8.1 and 8.5** in relation to the Programs webpage. The webpage did not fall under the list of materials requiring certification as specified in Clause 8.3 and therefore **no breach of Clause 8.3** was ruled.

Certification of the collaborative working summaries in the Transparency webpage

The complainant further alleged that the collaborative working summaries, which appeared on the Transparency webpage, had not been updated for over two years.

Clause 20.3 required material relating to collaborative working to be certified in accordance with Clause 8.3, while Clause 8.5 required recertification at intervals of no more than 2 years.

In response to this allegation, Amicus submitted certificates relating to each Executive Summary which indicated the:

- Fabry Disease Symptom Tracker Executive Summary had been certified in December 2022.
- Fabry Family Screening Executive Summary had been certified in November 2022.
- Flash Mob Audit Executive Summary had been certified in February 2022 and recertified in December 2023.
- Fabry Online Education Programme Executive Summary had been certified in February 2022 and recertified in December 2023.

The Panel considered recertification was not yet required for any of these executive summaries at the date of the complaint (June 2024) and the Panel therefore ruled **no breach of Clause 8.3 and Clause 8.5** in relation to each summary of the collaborative working agreement.

Allegation 2: Modern Slavery Act Statement

The Panel noted that the complainant and Amicus had provided different versions of the Modern Slavery Act statement. The complainant had provided a screenshot of the final section of the 'Modern Slavery Act Transparency' webpage which indicated that the statement had been

approved in June 2023. The corresponding section in the Amicus version differed in content and format.

The version provided by Amicus (which was the full webpage):

- included substantively different content in the corresponding section to the complainant's version,
- showed the statement approval date as December 2021,
- had a blue banner at the top, with the title 'Modern Slavery Act Transparency', beneath which was the heading 'UK Modern Slavery Act Statement 2021', and
- included several paragraphs explaining the purpose of the statement and the steps Amicus had taken to ensure it complied with its legal obligations.

The Panel considered the publication of a Modern Slavery Act Statement was a statutory obligation which did not fall within the scope of the Code. However, it did not appear to the Panel that the complaint related to the *wording* of the statement. Instead, the allegations were about the webpage's job code and date of preparation predating the date of the content. The complainant also alleged that the 2024 copyright statements suggested that the webpage was not up-to-date, or was not certified in its final form, and was misleading.

On that basis, the Panel decided to consider the allegations by reference to the material provided by the complainant.

The Panel noted that, in addition to setting out the requirements for 'certification', Clause 8 and its supplementary information also included detailed procedural requirements and a reference to the phrase 'final form'. Although not defined in the Code, 'final form' was a descriptive term for material to which no subsequent amendments will be made.

Having carefully considered the submissions of the parties, the Panel concluded the webpage did not contain any material that rendered it promotional, thus requiring certification, and therefore ruled **no breach of Clause 8.1**.

Amicus submitted that, following initial certification of the material at issue, changes to the webpage had been examined 'offline' by an appropriately qualified person. In this instance the Panel did not consider that the complainant had established that the webpage had not been examined, nor that the webpage fell under the list of materials requiring certification in **Clause 8.3** and it ruled **no breach**.

The Panel considered the impression created for viewers of the webpage who may not be familiar with the nuances of the Code. The Panel considered the purpose of the webpage and the Modern Slavery Act Statement, which was dated, were clear and unambiguous. In the Panel's view, these formed the substantive content of the webpage and the Panel did not consider that a conflicting date in the footer of the webpage was likely to adversely impact a viewer's understanding of the Modern Slavery Act Statement or otherwise mislead them as alleged. Nor had it been established that the substantive content was not up-to-date. The Panel therefore ruled **no breach of Clause 6.1**.

Allegation 3: Collaborative Working – Flash Mob Audit

Publication of outcomes

The complainant alleged Amicus had failed to publish the outcomes of the 'Flash Mob Audit' collaborative working project on its website within six months of completion, which was the time period set out in the supplementary information to Clause 20.

The Flash Mob Audit project ran from February 2022 until February 2023 and therefore, to comply with the supplementary information, the outcomes were required to be published within six months, by August 2023.

The Panel acknowledged that the outcomes:

- (a) had been submitted to a named medical professional membership organisation in March 2023,
- (b) had been published in a named medical publication for a named medical professional membership organisation congress in June 2023,
- (c) were presented at the annual meeting in June 2023, and
- (d) were published online in a named medical publication in October 2023

but that Amicus had not published the outcomes on its website.

The Panel disagreed with Amicus' submission that the external publication of the outcomes fulfilled Clause 20 and its supplementary information. While the Panel considered that it may be acceptable for a company to signpost to where the outcomes could be found externally, this was not the situation in the present case. The supplementary information to Clause 20, Collaborative Working with Organisations, included that companies should publish the outcomes of collaborative working "*as soon as possible and usually within six months of the project's completion, so that other NHS organisations and others can learn from and potentially replicate the initiative. Companies should publish the outcomes on their websites*".

The Panel considered that enabling other NHS organisations to learn from, and potentially replicate, collaborative working initiatives was a central principle behind collaborative working. The Panel concluded that Amicus's failure to publish outcomes on its website did not comply with the spirit of the Code, nor with the supplementary information to Clause 20. The Panel therefore ruled a **breach of Clause 20.3**.

Executive Summary

The complainant alleged that the executive summary for the Flash Mob Audit did not detail the company financial contribution or the contribution from the NHS.

The Panel noted that Clause 20.3 required companies to "*have a summary of the collaborative working agreement publicly available before the arrangements are implemented*". While neither Clause 20 nor its supplementary information set out what should be included in the summary, the supplementary information listed a number of points to be included in the written agreement, including an outline of the financial arrangements along with the roles and responsibilities of each party.

The Panel considered that although these related to the written agreement, the purpose of the summary was to reflect the key aspects of the arrangements bearing in mind the principle of transparency. The Panel noted guidance published by the PMCPA, in the form of a Q&A, stated the following:

“Do the financial arrangements for joint working need to be included in the Executive Summary?

Yes. Joint working is a form of 'collaborative working', which requires the publication by the company of a summary of the collaborative working agreement. The agreement should include an outline of the financial arrangements. Clause 20 and its supplementary information provide more details on collaborative working.”

The Panel observed that the summary for the Flash Mob Audit contained the following information:

- the name of the project,
- the name of the NHS Trust the collaborative working project was with,
- the commencement date and expected duration, and
- the aim of the project, its expected outcomes and key deliverables.

However, there was no information on the contributions made by the company or the NHS, whether financial or non-financial.

In the Panel's view, on balance, the summary did not adequately summarise the collaborative working arrangement, including the nature of the financial arrangements or roles and responsibilities of the parties. The Panel ruled a **breach of Clause 20.3** in this regard.

The Panel noted that Clause 20.2 required collaborative working arrangements to demonstrate the pooling of skills, experience and/or resources from all parties involved, with each party making a significant contribution and a shared commitment to delivery.

Although the case preparation manager had raised Clause 20.2, the Panel acknowledged that there was no allegation that the collaborative working arrangements did not pool skills, experience and/or resources. The complaint appeared to be limited to the adequacy of the published executive summary, which the Panel had already ruled upon above. The Panel therefore made no ruling in relation to Clause 20.2.

Allegation 4: Collaborative Working – Fabry Disease Symptom Tracker

Publication of outcomes

This allegation related to Amicus's alleged failure to publish the outcomes of 'Fabry Disease Symptom Tracker App' collaborative working project on its website within six months.

According to Amicus, the Fabry Disease Symptom Tracker App project commenced in December 2022, had an expected duration of 15 months, and was due to end in March 2024. However, due to staff illness, the project had not completed and remained ongoing at the time of the complaint.

The Panel took account of the fact that the supplementary information to Clause 20.3 included that companies should publish the outcomes of collaborative working as soon as possible and usually within six months of the project's *completion*. While the Panel considered that, in the spirit of transparency, it would have been helpful to have added a note to the summary, the

project had nonetheless not been completed at the time of the complaint. The Panel therefore ruled **no breach of Clause 20.3**.

Executive Summary

Amicus had provided the collaborative working agreement and project initiation document for the Fabry Disease Symptom Tracker App but noting that the complaint was limited to the Executive Summary published on the company's website the Panel restricted its consideration to that document.

With regard to the allegation that the Fabry Disease Symptom Tracker App Executive Summary did not detail the company financial contribution or the contribution from the NHS, the Panel noted that, similar to the Flash Mob Audit summary above (Allegation 3), the information provided was limited to:

- the name of the project,
- the name of the NHS Trust the collaborative working project was with,
- the commencement date and expected duration, and
- the expected outcomes of the project and key deliverables.

The Panel considered that this did not adequately summarise the collaborative working arrangement, particularly in relation to the nature of the financial arrangements or roles and responsibilities of the parties. For the same reasons as set out above in Allegation 3, the Panel ruled a **breach of Clause 20.3** and made no ruling in respect of Clause 20.2.

Allegation 5: Failure to disclose collaborative working Transfers of Value on Disclosure UK

The Panel decided to consider this allegation in relation to each of the calendar years to which the following allegations related:

- (a) In 2020, Amicus made no Transfers of Value (ToV) disclosures in relation to collaborative working.
- (b) In 2021, Amicus made no ToV disclosures in relation to collaborative working.
- (c) In 2022, Amicus disclosed ToVs to two institutions for collaborative working despite four executive summaries for collaborative working projects being available on Amicus's website.

The complainant provided a screenshot of Amicus's disclosed ToV for 2022 on Disclosure UK.

No ToV disclosures in 2020

Amicus accepted that one ToV was made in 2020 in respect of a Fabry App joint working project and that this had not been disclosed on Disclosure UK due to an error. The Panel addressed the failure to disclose this ToV under Allegation 7 below, under the 2019 and 2021 Codes.

No ToV disclosures in 2021

Amicus submitted that it made no ToV for collaborative working in 2021. Given the complainant bore the burden of proof and they had not provided evidence of collaborative working projects in 2021, the Panel ruled **no breach of Clause 20.5**.

Two ToV disclosures in 2022

In relation to the two disclosures made in 2022, Amicus submitted that:

- a) the disclosure to an academic institution, relating to a research grant supporting a PhD student, had been incorrectly categorised as collaborative working. The Panel considered this matter as part of Allegation 6 below because that was a more specific allegation about this collaborative working project.
- b) the disclosure relating to the Fabry Family Screening collaborative working project was one of the four collaborative working executive summaries cited in Allegation 1e and already dealt with by the Panel above.

Similarly, the other Executive Summaries cited by the complainant also formed part of Allegation 1e and related to the following collaborative working projects:

- (a) the Fabry Disease symptoms tracker,
- (b) the Flash Mob Audit, and
- (c) the Fabry Online Education Project.

Fabry Disease symptoms tracker

This project was also the subject of Allegation 4 above. The Panel accepted Amicus's submission that because the Executive Summary had been certified in December 2022 and the work had been delayed; no payment had been made in 2022. The Panel noted that the written agreement had been signed off in January 2023. On that basis, the Panel ruled **no breach of Clause 20.5**.

Flash Mob Audit and the Fabry Online Education Projects

The Panel noted both projects were undertaken with the same NHS Foundation Trust and that the Executive Summaries were certified in February 2022. The complainant's screenshot of Amicus's 2022 Disclosure UK entries showed only two ToV for collaborative working to healthcare organisations, neither of which corresponded to the NHS Foundation Trust participating in the above projects.

In its response to the PMCPA, Amicus maintained that all payments made directly to the NHS Foundation Trust had been correctly disclosed. However, payments which were not a direct ToV to the healthcare organisation (but which were payments to a third party vendor for services provided in connection with the collaborative working projects) had not been disclosed as required by Clause 20.5.

The Panel accepted that the ToVs made indirectly to the NHS Foundation Trust in 2022 in respect of the Flash Mob Audit and Fabry Online Education collaborative working projects had not been disclosed in accordance with Clause 20.5 at the time of the complaint. In respect of

each of the two collaborative working projects, the Panel therefore ruled **a breach of Clause 20.5**, as acknowledged by Amicus.

Allegation 6: Failure to provide collaborative working summary

This allegation concerned a ToV disclosed against an academic institution in 2022 which had been classified on Disclosure UK as collaborative working but for which no executive summary had been published.

The Panel took account of Amicus's submission that the ToV in fact related to a research grant, supporting a PhD student, which had been categorised incorrectly as collaborative working during compilation of its disclosure report. The Panel limited its ruling to the requirements for collaborative working. The matter regarding the incorrect disclosure category was addressed in the section relating to high standards below.

Having considered the written agreement and limited information before it, the Panel considered it had not been established that the arrangement constituted collaborative working. It followed that the requirements of Clause 20 did not apply and therefore the Panel ruled **no breach of Clause 20.3**.

Allegation 7: Failure to publish outcomes of Fabry App Joint Working Project or disclose ToV on Disclosure UK (2019 Code applies)

Publication of outcomes

The complainant alleged that Amicus had failed to publish the outcomes of its joint working project 'Fabry App' on its website several years after the end of the project.

The Panel noted the written agreement indicated the project would commence in February 2020 and expire in February 2021 but that changes could be made by consensus of all parties. In view of the date of the project, Amicus had been asked to respond to the complaint in relation to Clause 20 of the 2019 Code, which required the written agreement to include information regarding the planned publication of any data or outcomes and also in relation to Clause 20.3 of the 2021 Code.

The Panel took account of the following:

- The 2019 Code itself did not stipulate a specific timeline within which outcomes must be published (unlike the 2021 Code which came into force on 1 July 2021).
- There was no transition period for the 2021 Code (other than for companies wishing to continue with ongoing Medical and Educational Goods and Services, where there was a transition period until 31 December 2021).

In its response, Amicus submitted that at the time of the complaint (July 2024), the project had not completed and therefore no outcome had been published on its website but that it would be published once the project completed. It stated that interim outcomes had been published by the contributing NHS Foundation Trust, in a second named medical publication in January 2024.

While the Panel considered that, in the spirit of transparency, it would have been helpful to have added a note to the summary to this effect, the project was not complete at the time of the complaint. The Panel considered that if outcomes (interim or final) were not published on its

own website, to comply with the spirit of the Code, companies' websites should include a prominent signpost to where the outcomes could be found.

On the basis that the project had not concluded when the 2019 Code was in force, the Panel ruled **no breach of Clause 20 of the 2019 Code**.

On the basis that the project remained ongoing at the time of the complaint, the Panel ruled **no breach of Clause 20.3 of the 2021 Code**.

Disclosure of Transfers of Value

As noted above in Allegation 5 above, the complainant alleged that there had been no disclosure made on Disclosure UK for any 2020 ToV in relation to the Fabry App joint working project.

Amicus accepted that one ToV was made in 2020 and that, due to an error in transcribing from its financial system into a spreadsheet for reporting to Disclosure UK, this had not been disclosed on Disclosure UK as required by Clause 20 and Clause 24.2 of the 2019 Code. The Panel ruled a **breach of Clause 20 and Clause 24.2 of the 2019 Code**.

The Panel noted Amicus's submission that no payments had been made in respect of the project since 2020 and therefore there were no ToV to disclose in the years since. Given the ongoing nature of the project and, in the absence of evidence to the contrary, it had not been established that any further ToVs had been made. The Panel therefore ruled **no breach of Clause 20.5 of the 2021 Code**.

Allegation 8: 2023 Disclosures for four collaborative working projects

This allegation concerned four ToVs for collaborative working, under the 2023 disclosures on Disclosure UK, for which it was alleged that no Executive Summaries had been published.

The Panel noted that three of the payments related to four collaborative working projects: the Fabry Disease Symptom Tracker, Fabry Family Screening, Flash Mob Audit and the Fabry Online Education Programme.

Amicus submitted that one payment provided to an NHS Foundation Trust reflected a combined payment for the Fabry Family Screening and Flash Mob Audit projects. While the Panel noted this was contrary to the requirements of Clause 28.3, which required payments to healthcare organisations to be disclosed on a per activity basis, the allegation related to the publication of summaries for collaborative working.

The Panel noted the four collaborative working projects were the same as those at issue in Allegation 1e above where it was alleged that the published Executive Summaries for the projects had not been updated for over two years. On the basis that the complainant's evidence in Allegation 1e demonstrated that Executive Summaries *had* been published for the collaborative working projects connected to the three ToV disclosed, the Panel ruled **no breach of Clause 20.3 in relation to each collaborative working project**.

The Panel noted that, according to Amicus, the fourth disclosed ToV payment made to an academic institution was an investigator-initiated study which had been incorrectly categorised

as collaborative working. The Panel limited its ruling to the requirements for collaborative working. The matter regarding the incorrect disclosure category was addressed in the section relating to high standards below.

On the limited information before it, the Panel considered it had not been established that the arrangement constituted collaborative working. It followed that there was therefore no requirement for an Executive Summary to be published and the Panel ruled **no breach of Clause 20.3**.

Allegation 9: Pompe physiotherapy service

The complainant alleged the Pompe Physiotherapy Service Executive Summary did not provide key information relevant to the project, including the amount or resources provided by each party, and that it was written to “hide rather than to disclose”. The complainant alleged that the project was the provision of a service rather than collaborative working.

The Panel had been provided with the Executive Summary published on the company’s website, along with the collaborative working agreement and project initiation document. Each defined the arrangement as collaborative working and the project initiation document set out the contributions of each party, including the following from the NHS partner:

- “Access to database of Pompe Disease patients (Only aggregated/anonymised data will be shared)
- Ongoing Project implementation and analysis;
- Metabolic physiotherapy training time.
- Consultant time at monthly project meetings;
- Metabolic physiotherapy time at monthly project meetings
- Refinement of service improvement.”

While the Panel queried whether the Executive Summary was an adequate summary of the collaborative working arrangement, the Panel noted that the case preparation manager had asked Amicus to respond to Clause 20.2. The substance of the complaint, in this regard, was that the project was the provision of a service as opposed to collaborative working.

Clause 20.2 required collaborative working arrangements to demonstrate the pooling of skills, experience and/or resources from all parties involved, with each party making a significant contribution and a shared commitment to delivery.

The Panel noted the complainant had not provided any information that the project constituted service provision rather than collaborative working. It was not for the Panel to make out the complaint. The complainant bore the burden of proof to establish their case on the balance of probabilities and, on the evidence before it, the Panel concluded that the complainant had not established their case in relation to this allegation. The Panel therefore ruled **no breach of Clause 20.2**.

High standards and Clause 2

In addition to the matters addressed above, the complainant alleged systematic failures of the company’s processes, that Amicus was using collaborative working as a tool to provide grants

to the NHS or as an inducement to prescribe, and that Amicus had a poor understanding of the Code, particularly in relation to transparency.

In the Panel's view, transparency in relation to collaborative working and transfers of value was an important means of building and maintaining confidence in the pharmaceutical industry. Companies were expected to have a robust governance framework in place to support Code compliance.

The Panel took account of its breach rulings above, particularly in relation to the collaborative working summaries and inaccurate transfer of value disclosures, that spanned several years, as a result of failures in relation to Amicus's processes. Transparency was a key principle underpinning self-regulation and was important in maintaining public trust. The Panel considered, taken together, the cumulative effect of these matters was such that high standards had not been maintained. The Panel therefore ruled a **breach of Clause 5.1**.

Clause 2 was a sign of particular censure and reserved for such use. The Panel did not consider that the circumstances of this case demonstrated that Amicus had brought discredit upon, and reduced confidence in, the pharmaceutical industry. The complainant had not established that Amicus was using collaborative working as a tool to provide grants to the NHS or as an inducement to prescribe as alleged. The Panel therefore **ruled no breach of Clause 2**.

APPEAL BY AMICUS

Amicus's written basis for appealing is reproduced below.

'The complaint relating to the appeal

1. Amicus' appeal only concerns Complaint 1 brought by the Complainant.
2. Relevant to Complaint 1, the Complainant stated that Amicus' UK "website is very bland" and "seems out of date" (cover letter) and "Website is out of date, misleading or not certified correctly" (Final slide, Summary of Complaints). The Complainant also provided the below reproduced slide [screenshot of About Amicus webpage together with six URLs and bulleted list as follows:
 - o NP-NN-UK-00031021 | April 2022
 - o Multiple web pages not updated or have been certified over 2 years ago.
 - o If recertified, no content updates have been provided for over 2 years
 - o Website contains Collaborative working summaries which have not been updated for over 2 years
 - o Copyright statement mentions 2024 ie website may have been updated without recertification.]
3. Amicus was asked to address Clauses 8.1, 8.3 and 8.5 of the 2021 Code.
4. The above slide lists six webpages included in Complaint 1. Amicus' appeal only concerns the findings of the Panel regarding the Programs webpage. Amicus agrees with the Panel's conclusions regarding the five other webpages (ie no breach of Clauses 8.1, 8.3 or 8.5).
5. The allegations relevant to the Programs webpage are the first three and final bullet

points on the right-hand side of the slide. The allegations in the fourth bullet, regarding collaborative working summaries, are not relevant to Amicus' appeal. The wording reproduced above from the slides and the cover letter are the totality of the evidence provided by the Complainant regarding the Programs webpage. The Complainant did not allege or provide evidence that the content of the Programs webpage was promotional and did not reproduce on the slide, or reference to the PMCPA at all, the language on the Programs webpage.

The Panel's finding

6. The Panel found that:

- The "Contact", "About Us", "Beliefs" and "Careers" webpages consisted of general corporate information.
- The "Transparency" webpage contained descriptions of Amicus' engagement with patient organisations, healthcare professionals, healthcare organisations and the NHS.
- While the Beliefs and Careers webpages included aspirational statements and references to Amicus' commitment to rare and orphan diseases, the webpages did not contain promotional claims. The webpages did not refer to specific medicines or otherwise sought to encourage the use of Amicus' products.
- None of the five webpages amounted to promotional material.
- No breach of Clauses 8.1, 8.3 and 8.5 ruled.

7. With regard to the Programs webpage, the Panel acknowledged that it did not refer to specific medicines but considered the statements it made were very positive about Amicus' medicines:

- Taking account of the terms "cutting-edge", "first- or best-in-class" and "healing beyond disease", the overall impression created, on balance, went beyond corporate messaging and in the Panel's view this webpage required certification under Clause 8.1. A breach of Clause 8.1 was ruled.
- The Programs webpage available at the time of the complaint had not been recertified within the two years required by Clause 8.5. A breach of Clause 8.5 was ruled.
- The Programs webpage did not fall under the list of materials requiring certification as specified in Clause 8.3 and therefore no breach of Clause 8.3 was ruled.

Amicus' appeal

8. Clause 8.1 of the 2021 Code stated:

“Promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by one person on behalf of the company in the manner provided for by this clause”.

9. Clause 8.5 stated:

“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”.

10. Thus, Clause 8.1 can only apply to “promotional material” and recertification under Clause 8.5 can only be relevant if the material was required to be certified initially (under Clause 8.1 or otherwise). Amicus appeals the breaches of Clause 8.1 and 8.5 for the Programs webpage on the following bases:

- A. The content of the Programs webpage is not, and was never intended to be, promotional;
- B. Certifying the Programs webpage as “promotional material” would have been a misapplication of the Code; and
- C. The Complainant did not substantiate an allegation of promotion or provide evidence that the Programs webpage was promotional.

11. Amicus agrees with the Panel that the Programs webpage does not fall under the list of materials requiring certification as specified in Clause 8.3.

A The content of the Programs webpage is not, as was never intended to be, promotional

The content does not refer directly or indirectly to specific medicines

12. Clause 1.1 clarifies the scope of the Code:

“This Code applies to the promotion of medicines to members of the United Kingdom (UK) health professions and to other relevant decision makers.”

13. The definition of promotion in Clause 1.17 of the Code is:

“Promotion” means any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines”

[....]

It does not include:

[....]

information relating to human health or diseases provided there is no direct or indirect reference to **specific** medicines.” (emphasis added).

14. It is a well-established principle, confirmed by the Appeal Board that promotion relates to specific medicines. CASE AUTH/3308/2/20 Anonymous/Director v GlaxoSmithKline the

Appeal Board found ‘triple therapy’ and ‘ICS/LABA’ did not identify any specific medicine and as such was not promotional; CASE AUTH/2681/11/13 Hospital Doctor v GlaxoSmithKline the Appeal Board noted the corporate mission statement was not making any claims for any products on the material as no specific medicines were mentioned. In addition, in AUTH/3817/9/23 Complainant v AstraZeneca the Panel concluded that a positive statement about a class of medicines is not promotion unless it encourages prescription of a specific medicine; and in AUTH/3868/12/23 Complainant v Rosemont Pharmaceuticals the Panel concluded that positive statements regarding the concept of liquid medicines were made on LinkedIn but the statements did not mention specific medicines and therefore were not promotional.

15. The Programs webpage, as it was at the time of the complaint, was contained in [document] and provided to the Panel with Amicus’ response (dated 29 August 2024). The large heading “Programs” is followed by a smaller sub-heading “Our Science and Technology”. It features a photo of a gloved hand holding a vial that is being filled by a syringe. The text on the page reads:

[*Science that's powered by passion*

We are leveraging our innovative technology platforms to develop treatments for human genetic diseases. The scientists researching these methods are dedicated to finding enhanced treatments for patients suffering from these rare diseases.

Their passion fuels progress as we work to deliver meaningful benefits. We are proud to take this bold approach towards these developments, in the hope of offering healing beyond disease.

With extraordinary patient focus, Amicus Therapeutics is committed to advancing and expanding a robust pipeline of cutting-edge, first- or best-in-class medicines for metabolic diseases.]

16. The above language on the Programs webpage makes no reference, directly or indirectly, to specific medicines. Indeed, the Panel acknowledged that “No specific medicines were referred to on the Programs webpage”. However, the Panel concluded that the Programs webpage was “positive about Amicus’s medicines”. This conclusion is difficult to understand when, as the Panel stated, there are no references directly or indirectly to medicines on the page. The webpage is only “positive” about the company’s aspirations and goals.
17. The Panel concluded that the Beliefs and Careers webpages were not promotional as they did not refer to specific medicines or otherwise sought to encourage the use of Amicus’ products. This is the correct approach which should have also been applied to the Programs webpage. There is no content on the Programs webpage that can be interpreted as encouraging use of Amicus’ products – no products, indications nor specific diseases are referred to. It is not possible to promote a hypothetical treatment that a company aspires one day to produce to treat an unspecified disease; only specific medicines can be promoted.

The content is general corporate information

18. It is clear from the heading, photo, and language used in the main body of text that the Programs webpage concerns scientific discovery and research programs. Amicus is a

biotechnology company researching advanced therapies to treat a range of devastating rare diseases and the language used, “to develop”, “researching”, “dedicated to finding”, “fuels progress”, “work to deliver”, “in the hope of offering” “committed to advancing”, is clearly aspirational wording regarding the company’s aims for the future.

19. The Panel selected the terms “cutting-edge”, “first- or best-in-class” and “healing beyond disease” as giving an overall impression that “went beyond corporate messaging” and concluded, as a result, that the Programs webpage required certification under Clause 8.1. However, Clause 8.1 only applies to “promotional material” and, as explained above (paragraphs 12-14), “promotion” under the Code is concerned with promotion of specific medicines. The three terms selected by the Panel are not applied on the Programs webpage to specific medicines. Rather, the terms are used as general aspirational corporate statements about the company’s dedication and focus on improving the lives of patients with metabolic diseases, directed at the public and, in particular, investors and potential employees. The branding and content of the page was developed as Amicus’ corporate messaging and is, not product- specific. The content and the context of the webpage is not promotion of medicines, and does not give an overall impression of promotion of medicines as no specific medicines are referred to. Clause 8.1 does not require certification of material that only promotes a company.
20. In considering the Panel’s ruling, Amicus has reviewed some UK webpages of other pharmaceutical companies and believes its website is in compliance with the Code and in line with industry standards. Aspirational language of the type used by Amicus is prevalent as companies look to convey company expertise, integrity, innovation and credibility to potential investors, new hires and the general public. Amicus has observed that, in particular, the terms “cutting-edge” and “first or best-in-class” are frequently used in corporate messaging on the UK websites of other pharmaceutical companies. Companies are able to promote the company itself, and the company beliefs, in compliance with the Code, without promoting specific medicines. If the Appeal Board upholds this ruling it risks UK-based companies being put at a disadvantage when trying to attract investment and new talent if they are unable to use aspirational language to talk about their ambitions on their corporate website, the shopfront of the company. As the Appeal Board is aware, the UK positions itself as a global leader in life sciences. A ruling that categorises aspirational language as promotional material risks creating unintended barriers to innovation and growth in the sector.

B Certifying the Programs webpage as “promotional material” would have been a misapplication of the Code

21. As unlicensed medicines may not be promoted and prescription-only medicines may not be promoted to the public, promotional materials requiring certification under Clause 8.1 may only concern licensed medicines and be directed to healthcare professionals and other relevant decision makers.
22. The Programs webpage is directed at the public (most likely investors or job applicants) and the statements at issue are corporate aspirational statements, without reference to specific medicines. As such, it would have shown a lack of understanding of the Code if Amicus had concluded that the Programs webpage required certifying as promotional material. It does not make sense to be found in breach of the Code for not doing something that if Amicus had done would have been an incorrect application of the

Code.

23. The Panel stated “Amicus submitted that the webpages had initially been certified in its electronic approval system with the job code included. It was later decided that certification was not required and changes to the webpages would be approved via “offline examination””. This is not an accurate reflection of Amicus’ submission. Amicus did not say in its response to PMCPA that it “later decided that certification was not required” (implying a change in position). Amicus was aware at all times that the Programs webpage did not require certification (under Clause 8.1 or 8.3). In 2022, although Amicus knew that the Programs webpage only required examination, the company took a decision to certify the webpage as non-promotional material – please find the certification attached. Certifying materials that only require examination is acceptable and common practice. Two years later, when the time came to recertify, because the material did not require certification and the process for examination was more in use, rather than re-certify Amicus decided to move the webpages to its offline examination process. Amicus’ response said “It was later decided that as the Webpages did not require certification pursuant to the ABPI Code, examination and approval of changes would be performed ‘offline’”.
24. On reflection, Amicus’ submission may have given the Panel the impression that Amicus originally certified the Programs webpage as promotional material under Clause 8.1. This was not the case and we apologise for not being clearer in this regard. However, as there was no allegation from the Complainant that the Programs webpage contained promotional material, it did not occur to us to make submissions to the Panel that the content was non-promotional or clarify that the original certification was non-promotional.

C The Complainant did not substantiate an allegation of promotion or provide evidence that the Programs webpage was promotional

25. As the Appeal Board is aware, the Complainant has the burden of proving their complaint on the balance of probabilities. In order to do this, a complainant must articulate why there may be a breach of the Code and provide evidence. Where such evidence is not present, the PMCPA’s remit is not as an investigatory body.
26. As noted in paragraphs 2 – 5 above, the Complainant did not refer to the content of the Programs webpage at all and, aside from noting the webpage contained a job code, did not make any comments about the basis on which the webpage was originally certified, be that pursuant to Clause 8.1, Clause 8.3 or voluntarily. Further, the Complainant did not substantiate a case, or provide any evidence to suggest, that the webpage was promotional to warrant investigation by PMCPA. In fact, the Complainant referred to Amicus’ website as “very bland”. As a result Amicus viewed the fact of certification as an administrative matter to explain to the Panel rather than an allegation of promotion to which Amicus was required to respond. Despite the lack of explanation or evidence, or responsive submission from Amicus, the Panel investigated the wording of the webpage and concluded the wording required certification as promotional material and ruled a breach of Clause 8.1. Amicus does not consider this is a correct application of the process set out in the PMCPA constitution and procedure.

Conclusion

27. In summary, there is no basis for a finding that the Programs webpage should have been certified pursuant to Clause 8.1. Clause 8.1 concerns certification of promotional materials. However, the Programs webpage:

- i. does not meet the definition of promotion, as it does not refer directly or indirectly to specific medicines;
- ii. and contains only aspirational general corporate language directed at the public.

28. As such, certifying the Programs webpage under Clause 8.1 would have reflected a misapplication of the Code.

29. The Complainant did not substantiate an allegation, or provide any evidence to support, that the Programs webpage was promotional. As the webpage did not require certification, it logically follows that there can be no finding that it required recertification under Clause 8.5.

30. We respectfully request that the Appeal Board reconsider this ruling in light of the above, and we remain available to provide any further information that may assist in reaching a fair and balanced outcome.'

RESPONSE FROM THE COMPLAINANT

The complainant provided no response to the appeal.

APPEAL BOARD RULING

The Appeal Board observed that although terms such as "cutting-edge", "first- or best-in-class", and "healing beyond disease" appeared on the Programs webpage, no specific medicines were referred to. The Appeal Board considered the definition of promotion in Clause 1.17 and concluded that, although the language was strongly aspirational, the overall impression created was general corporate messaging about pipeline products that did not promote a specific medicine or medicines. In the Appeal Board's view, this webpage did not require certification under Clause 8.1 and consequently, there could be no requirement to re-certify it under Clause 8.5. The Appeal Board ruled **no breaches of Clauses 8.1 and 8.5** in relation to the Programs webpage. The appeal on this point was successful.

Complaint received **18 June 2024**

Case completed **12 November 2025**