CASE AUTH/3676/7/22

COMPLAINANT v ROCHE

Allegations about content on a patient organisation website

CASE SUMMARY

This case was in relation to the provision of a grant by Roche to support the development of a patient organisation website. The complainant alleged that the declaration of support was not clear from the outset, and that the grant agreement was not robust enough to make it clear to the patient organisation that the declaration of support should be visible from the start of the webpages. The complainant further alleged that two articles on the website in question promoted Hemlibra, a prescription only medicine, to the public.

Roche appealed four of the Panel's rulings of breaches of the Code in relation to the allegations about declaration of support on the patient organisation website and the content of the grant agreement; the outcome under the 2021 Code was:

No Breach of Clause 5.1(x2) [Panel's breach rulings overturned at appeal]	**Requirement to maintain high standards at all times**
Breach of Clause 23.2 [Panel's breach ruling upheld at appeal]	**Failing to include, in the written agreement for a donation or grant, a statement that all parties are fully aware that the donation or grant must be clearly acknowledged and apparent from the start**
Breach of Clause 25.3 [Panel's breach ruling upheld at appeal]	**Failing to ensure that all sponsorship is clearly acknowledged from the outset and that the wording of the declaration of sponsorship is unambiguous and accurately reflects the extent of the company's involvement and influence over the material.**

In relation to the allegations about the declaration of support on the patient organisation website and the content of the grant agreement, the Panel ruled no breach of the following Clause of the 2021 Code:

No Breach of Clause 2(x2)	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**

In relation to the allegations that two articles on the website promoted Hemlibra to the public, the Panel ruled no breaches of the following Clauses of the 2021 Code:

No Breach of Clause 2(x2)	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No breach of Clause 5.1(x2)	**Requirement to maintain high standards at all times**
No breach of Clause 6.5 (Only for one article – see full case report)	**Requirement that the word 'new' must not be used to describe any product which has been generally available for more than 12 months in the UK**
No breach of Clause 12.1(x2)	**Requirement to include prescribing information in promotional material**
No breach of Clause 26.1(x2)	**Requirement to not advertise prescription only medicines to the public**
No breach of Clause 26.2(x2)	**Requirement that information about prescription only medicines which is made available to the public must not raise unfounded hopes of successful treatment and must not encourage the public to ask their health professional to prescribe a specific prescription only medicine.**

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

FULL CASE REPORT

COMPLAINT

The complainant submitted whistleblowing concerns over Roche's internal compliance procedures. The complainant alleged that Roche did not consider compliance seriously and the senior employee responsible needed to urgently address the problems with the lack of knowledge and competency of the medical affairs team. According to the complainant, a named patient organisation website was supported by a grant by Roche. However, this was not clear from the outset on any pages of the website. A link to the website was provided. The pharmaceutical involvement statement was hidden away at the bottom of webpages. On most pages there was just a logo and not the actual involvement listed. A link to a second webpage was provided. The complainant alleged a breach of Clauses 27.9, 5.1 and 2 of the Code. It was of paramount importance that patients and members of the public knew Roche had contributed to this website. The grant agreement was not robust enough to make it clear to the patient organisation that the declaration should be visible from the start of the webpages. The complainant alleged a breach of Clauses 23.2, 5.1 and 2 of the Code. It was concerning that the wording of the declaration also made it clear that this arrangement with Roche was more than a grant. The wording was 'The update of this website was supported by a restricted grant from Chugai Pharma UK Ltd and Roche Products Limited. Chugai Pharma UK Ltd and Roche Products Limited has had no control or influence over the information/content included on this website unless where stated'. The complainant alleged that Roche should not have influenced

the content on this website anywhere or had information solely about its products as this was not acceptable as a grant. Roche had used the website as a promotional hub.

1 Announcement from NHSE [NHS England]

The complainant alleged that the above article was a high level product information page on Hemlibra, which Roche marketed. As this website was accessible by members of the public, the complainant alleged a breach of Clauses 26.1, 26.2, 5.1 and 2 of the Code. As health professionals saw this information, the complainant alleged a breach of Clause 12.1 of the Code as no prescribing information had been given. Within the article, a named senior leader of the patient organisation, stated: 'This news means people with haemophilia A who have inhibitors will now have access on the NHS to a new treatment that could improve their quality of life'. The word 'new' was inappropriate as the product had been on the market for more than 12 months. The complainant alleged a breach of Clause 6.5.

2 Article on non-factor replacement therapies

The complainant submitted that this was a second detailed article on a Roche product, Hemlibra. As this website was accessible by members of the public, the complainant alleged a breach of Clauses 26.1, 26.2, 5.1 and 2. As health professionals saw this information, the complainant alleged a breach of Clause 12.1 of the Code as no prescribing information had been given. As Roche had given a grant, dedicated webpages on its product was wholly inappropriate. The compliance importance needed to be coached and the senior employee responsible needed to take accountability to ensure this happened.

When writing to Roche, the Authority asked it to consider the requirements of Clauses 2, 5.1, 6.5, 12.1, 23.2, 26.1, 26.2 and [27.9] of the 2021 Code as cited by the complainant.

RESPONSE

Roche submitted that it prided itself on having the highest ethical standards and strove for a culture where all employees acted as guardians for high standards of compliance, ethics and safety. As a result, Roche was incredibly disappointed to receive a complaint of this nature.

Background

Roche submitted that within the area of haemophilia, it marketed Hemlibra▼(emicizumab), a monoclonal antibody indicated for the prophylaxis of bleeding episodes in people with haemophilia A and inhibitors to factor VIII or those with severe haemophilia A. This molecule was part of a co-promote arrangement between Roche and Chugai Pharmaceuticals and the two companies co-operated with regard to their work within haemophilia.

Roche acknowledged that the complaint was made solely against Roche on this occasion, although, in this instance, the specific grant agreement was signed on behalf of Chugai Pharmaceuticals as the payment was made by Chugai. The grant agreement was certified through the joint companies approval process.

In their complaint the complainant alleged that Roche had breached Clauses 2, 5.1, 6.5, 12.1, 23.2, 26.1 and 26.2. The complainant also alleged a breach of Clause 27.9, although, as no such clause existed in the 2021 Code of Practice, Roche assumed that the complainant was

referring here to the 2019 Code of Practice. With that in mind, Roche had considered the allegations against the representative clause in the 2021 Code of Practice, ie Clause 25.3.

Declaration of Roche's involvement

Roche submitted that the complainant specifically referred to two webpages and alleged that Roche's involvement in the website was not clear from the outset, breaching Clauses 27.9, 5.1 and 2. Also that the grant agreement was not robust enough to make it clear to the named patient organisation that the declaration should be visible from the start of the page, breaching Clauses 23.2, 5.1 and 2.

Response

Roche submitted that the complaint concerned a grant provided to the patient organisation in November 2020. The grant provided support to develop the website which replaced the patient organisation's previous website as part of a wider rebranding exercise undertaken by the patient organisation.

Within the signed grant agreement, it was explicit that the support was provided without any expectation of influence or endorsement for the companies' products and that the companies did not endorse the promotion of prescription only medicines to the public, the raising of unfounded hopes or the provision of misleading information. The grant agreement did not require any information provided by either Roche or Chugai in relation to the company(ies) products to be included on the website. The agreement also requested that the patient organisation included the statement on its website 'Supported by a restricted grant from Chugai Pharma UK Ltd and Roche Products Limited'.

Clause 23.2 of the Code of Practice required that, when providing grants, the company's involvement 'should be made clear … to the extent possible'. This had been achieved through the clear statement with a bold heading and prominent inclusion of the company logos, found at the bottom of the patient organisation homepage (image provided).

Furthermore, the support of Roche, Chugai and a third supporter, [named pharmaceutical company], was acknowledged by an abbreviated statement 'Website update supported by: [company logos]' at the footer of each page across the whole website.

On the basis of the above, Roche believed the nature of support and level of involvement was made suitably clear and denied any breach of Clause 23.2 and the associated alleged breach of Clauses 2 and 5.1. With regard to Clause 27.9 (now Clause 25.3 in the 2021 Code), since the support was the provision of funding via a grant, Roche believed that this clause was specific to sponsorship and did not apply. However, in the spirit of being transparent and in line with Clause 23.2, Roche considered that the statement on the website did make it clear that Roche had provided a restricted grant for updating the website but had no influence over the content of the website and it refuted any breach of Clauses 25.3, 5.1 and 2.

Roche's influence over content on the website

Roche submitted that the complainant alleged that Roche had influence over the content of the website and that having dedicated pages about a Roche product was inappropriate, given that Roche had provided a grant. The complainant also alleged that Roche used the website as a

promotional hub, making reference specifically to two web pages, promoting both to the public and health professionals without including the prescribing information. Breaches of Clauses 26.1, 26.2, 12.1, 5.2 and 5.1 were alleged for each of the webpages.

Response

Roche submitted that at the heart of the complainant's allegations appeared to be the suggestion that the involvement of Roche, Chugai and a third entirely independent company, [named pharmaceutical company], in supporting this website, was more than simply providing financial support for website development and might have influenced the content in some way. This was entirely inaccurate.

Regarding the announcement from NHSE, this article referred to Hemlibra being made available to people with haemophilia who had inhibitors to FVIII in the UK. Neither Roche nor Chugai had any involvement in the content or creation of this page of the website and there was no evidence to suggest Roche's or Chugai's involvement. This information was posted in July 2018, which was more than two years before the provision of the grant. On this basis, Roche denied any breach of Clauses 26.1, 26.2, 12.1 and the associated alleged breach of Clauses 5.1 and 2.

Regarding the article on non-factor replacement therapies, this information was provided to the patient organisation reactively, in response to a request for information, in anticipation of emicizumab being routinely commissioned for patients with severe haemophilia A without inhibitors in 2019. Roche did not have any subsequent involvement in, or visibility of, how the patient organisation used the information provided. This information was posted by the patient organisation in July 2019, long before the provision of the grant. It was thus apparent that this content was in no way linked to the provision of the grant. Therefore, Roche refuted any of the Code breaches alleged by the complainant, specifically Clauses 12.1, 26.1, 26.2, 5.1 and 2.

Use of the word new

Roche submitted that the complainant referred to the announcement from NHSE article, and alleged a breach of Clause 6.5, for the use of the word 'new' for more than 12 months after a product had been made available. This word related to a quote from a senior leader from the patient organisation at the time of Hemlibra first being made available for patients in the UK in 2018.

Response

Roche submitted that neither Roche nor Chugai had any involvement in the content or creation of this page and there was no evidence to suggest its involvement. Furthermore, it would be inappropriate to influence the content that the patient organisation posted on their website. Roche refuted the allegation of breaching Clause 6.5.

Taken as a whole, Roche denied all of the allegations made by the complainant. Roche was proud to support patient advocacy groups to enhance their efforts in supporting patients. Roche had clear and robust procedures in place to ensure that support of patient groups was done in a way that complied with all of the requirements of the Code of Practice. Roche believed that this applied to all of the questions raised in this case.

Roche's response for additional information

In response to a request for further information by the Panel, Roche submitted that as the patient organisation website was independent, Roche did not have, and was therefore unable to provide, roadmaps of how a reader would historically navigate around various pages of the patient organisation website. Given the complaint related to website content and structure from over 12 months ago, the current navigation and content would have evolved since then.

Roche confirmed that it had not approved any part of the patient organisation website content.

In addition, Roche provided a redacted version of the written agreement for the grant provided to the patient organisation in November 2020.

PANEL RULING

The Panel noted that the complainant raised concerns about a named patient organisation website which was supported by a grant from Roche. Four links to the webpages at issue were provided by the complainant and the Panel made its rulings based on these. The Panel noted that the first link led to what appeared to be the homepage of the patient organisation website. The homepage began with the patient organisation logo and contact information, followed by information on help and support, news and events, members stories and further information on bleeding disorders. Near the bottom of the webpage was a bold statement in large font 'Thank you to our sponsors' followed by the statement in smaller font 'We are thankful to the companies below who have supported the update of our website in 2021: [named pharmaceutical company] has provided sponsorship to the patient organisation to support with the costs of updating this website. [Named pharmaceutical company] has had no control or influence over the information/content included on this website unless where stated. The update of this website was supported by a restricted grant from Chugai Pharma UK Ltd and Roche Products Limited. Chugai Pharma UK Ltd and Roche Products Limited has had no control or influence over the information/content included on this website unless where stated'. This was followed by logos for Chugai, [named pharmaceutical company] and Roche.

The Panel noted Roche's submission that it had not approved any part of the patient organisation website content.

The Panel noted that further links to webpages provided by the complainant, including the webpage about haemophilia A and B, displayed the statement in small font 'Website supported by:' followed by company logos for Chugai, [named pharmaceutical company] and Roche at the footer of each webpage.

The Panel noted Roche's submission that the grant provided support to develop the website which replaced the patient organisation's previous website as part of a wider rebranding exercise undertaken by it.

The Panel noted the complainant's allegation that Roche's involvement in the website was not clear from the outset.

The Panel noted that the complainant had alleged a breach of clauses from the 2021 Code, albeit the 2019 Code applied at the time of the grant agreement dated November 2020. The

Panel noted that the website in question was live when the complaint was received and the 2021 Code was applicable and therefore the Panel made its rulings against the 2021 Code.

The Panel noted that the complainant had alleged a breach of Clause 27.9, however, no such clause existed in the 2021 Code but was listed in the 2019 Code; the Panel therefore made its ruling against the closely similar clause, Clause 25.3 in the 2021 Code. Given that Clause 25.3 of the 2021 Code reflected the established interpretation of Clause 27.9 in the 2019 Code, the Panel did not consider that either party would be disadvantaged in this regard.

The Panel noted that Clause 25 concerned relationships with health professionals, other relevant decision makers, healthcare organisations and patient organisations.

Clause 25.3 stated, among other things, that companies must ensure that all sponsorship is clearly acknowledged from the outset and the wording of the declaration of sponsorship must accurately reflect the extent of the company's involvement and influence over the material.

The Panel noted that the allegation was in relation to the provision of a grant and that Roche had submitted that as this clause was specific to sponsorship it did not apply in this instance. However, the Panel noted that the 2019 and the 2021 Codes defined sponsorship as a contribution, financial or otherwise, in whole or in part, provided by, or on behalf of, a company towards an activity (including an event/meeting or material) performed, organised, created etc by a healthcare organisation, patient organisation or other independent organisation.

Furthermore, the Panel considered that it was well established that transparency was key and, regardless of how it was provided, sponsorship must be declared, and accordingly Clause 25.3 was relevant.

In any event, the Panel considered the immediate and overall impression to a reader. In the Panel's view, the length of the continuously scrolling homepage was such that the statement of involvement by Roche would not appear until the reader had scrolled down to the bottom of the webpage. The Panel further noted that the continuously scrolling webpage on haemophilia A and B displayed the statement 'Website supported by:' followed by company logos for Chugai, [named pharmaceutical company] and Roche at the very bottom of the page in a small white font against a maroon background, beneath several quick links which formed part of the small print at the bottom of the page. The Panel noted that some readers might not scroll to the bottom of the page and might thereby be left with the impression that there was no industry involvement. The Panel considered that, on balance, Roche had failed to ensure that it was sufficiently clear at the outset that the update to the patient organisation website was supported by a grant from Roche. The Panel therefore ruled **a breach of Clause 25.3** in this regard.

The Panel noted the requirement of the Code that when providing a grant to a patient organisation, the company must ensure, among other things, that the involvement of the company is made clear and that all of the arrangements comply with the Code. This includes the need to declare the provision, and the wording of the declaration must accurately reflect the nature of the company's involvement. The Panel, based on its comments and rulings above, considered that high standards had thus not been maintained and ruled **a breach of Clause 5.1** in this regard.

The Panel noted its comments and rulings above and did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2; whilst the declaration did

not satisfy the relevant requirements of the Code it was, nonetheless, part of the relevant webpages and on this basis **no breach of Clause 2** was ruled.

The Panel noted the complainant's allegation that the grant agreement was not robust enough to make clear to the patient organisation that the declaration should be visible from the start of the webpages.

The Panel noted that the co-promote written agreement between Chugai/Roche and the patient organisation outlined the terms of the agreement between the parties. The Panel noted that following a request for support from the patient organisation, Chugai/Roche agreed to provide a restricted grant for the purpose of supporting the patient organisation with the renewal of its website. The purpose of the support stated, among other things, that the patient organisation will include the logos of the supporting companies on the updated website, to acknowledge the support. The Panel noted that the Declarations of Involvement clause stated that the patient organisation must agree, per the clause, to acknowledge Chugai by including the following statement when it writes or speaks in public about a matter that is the subject of the Agreement or any other issue in relation to Chugai: 'Supported by a restricted grant from Chugai Pharma UK Ltd and Roche Products Limited'. The Panel noted that the Agreement was entered into by Chugai on behalf of Roche and that it was signed by Chugai alone.

The Panel noted Roche's submission that within the signed grant agreement, it was explicit that the support was provided without any expectation of influence or endorsement for the companies' products and that the companies did not endorse the promotion of prescription only medicines to the public, the raising of unfounded hopes or the provision of misleading information. The grant agreement did not require any information provided by either Roche or Chugai in relation to the companies' products to be included on the website. The agreement also requested that the patient organisation included the statement on its website 'Supported by a restricted grant from Chugai Pharma UK Ltd and Roche Products Limited'.

Clause 23.2 stated, among other things, that there must be a written agreement in place for each donation or grant. It also stated that the arrangements for written agreements with patient organisations were set out in Clause 27.2 which required that the written agreement must, among other things, include a statement that all parties are fully aware that the donation or grant must be clearly acknowledged and apparent from the start. The Panel noted that Roche had referred to the requirement in Clause 23.2 that 'Company involvement should be made clear for donations and grants to the extent possible' and, in this regard, considered that Roche had failed to note the specific requirements for patient organisations in Clause 23.2 and its supplementary information which referred to Clause 27.2.

In the Panel's view, it would have been more helpful if the written agreement had specifically stated that readers of the website must be made aware of the companies' involvement from the outset or similar. Given the importance of transparency, the Panel considered that written agreements should be unequivocal about the requirements regarding declarations of involvement by companies. The Panel noted that a written agreement between the parties, which referred to the need to acknowledge the companies' involvement, was in place. However, in the Panel's view, it was not clear within the agreement that not only must the provision of support by the companies be clearly acknowledged, but that it must also be apparent from the start and, on balance, **a breach of Clause 23.2** was ruled.

The Panel noted its comments and rulings above and considered that high standards had not been maintained. **A breach of Clause 5.1** was ruled.

The Panel noted its comments and rulings and considered that its concerns were adequately covered by the breach rulings above. The Panel did not consider that the particular circumstances of this case warranted a breach of Clause 2 which was reserved to indicate particular censure; **no breach of Clause 2** was ruled in this regard.

The Panel noted that the complainant had provided links to two separate articles containing information about Roche's product, Hemlibra (emicizumab). The Panel had requested roadmaps of how a reader would navigate from the patient organisation website homepage to the two articles at issue to inform the Panel in its rulings. The Panel was concerned to note Roche's submission that as the site was independent of Roche, it did not have, and was therefore unable to provide, roadmaps of how a reader would historically navigate around various pages of the website. Noting that Roche and Chugai had a written co-promote support agreement with the patient organisation in which one of the purposes of the grant was analysis of the current user journey and new navigation, the Panel was concerned that Roche did not appear to have sought the roadmaps from the patient organisation.

The Panel noted that it was acceptable for companies to provide grants to patient organisations. A company would be liable under the Code if it had been able to influence the content of the material or activity in a manner favourable to its own interests. It was possible for a company to provide support for activities or materials which mentioned its own products and not be liable under the Code for its contents, but only if it had been a strictly arm's-length arrangement with no input by the company and no use by the company of the material for promotional purposes. In this regard, the Panel noted that Clause 23.1 stated that in relation to donations and grants there must be no consequent obligation on the recipient organisation to provide goods or services to the benefit of the pharmaceutical company in return.

In the Panel's view, companies should undertake due diligence at the outset in relation to compliance with the Code when deciding whether to provide a grant to any organisation including wholly arm's-length arrangements. This was especially important when the restricted use grant was for an upgrade to a website that contained favourable information about Roche's product which was the only available treatment of its kind and an area in which the company had a commercial interest. The Panel noted Roche's submission that the grant agreement was signed on behalf of Chugai Pharmaceuticals as the payment was made by Chugai and the grant agreement was certified through the companies' joint approval process. The Panel, however, did not have information on the due diligence undertaken by Chugai prior to the agreement, nor any comment from it in relation to this complaint.

The Panel noted the complainant's allegation that Roche should not have influenced the content on this website anywhere or had information solely about its products as this was not acceptable as a grant, and that Roche had used the website as a promotional hub.

The Panel noted that the patient organisation website contained articles, published almost 2 years prior to the provision of the grant, which referred favourably to Roche's product. It was unclear to the Panel how readers navigated to those pages that were the subject of complaint.

The Panel noted Roche's submission that neither Roche nor Chugai had any involvement in the content or creation of the patient organisation website and there was no evidence to suggest

Roche's or Chugai's involvement; additionally, Roche had not approved any part of the patient organisation website content.

The Panel noted that the complainant bore the burden of proof to establish that Roche was responsible for the content of the website. There was no information before the Panel about the due diligence undertaken by Chugai when deciding whether to provide the grant. The Panel noted its comments above about the content of the website and Roche's commercial interests.

The Panel noted that the first article at issue was in the 'News' section of the patient organisation website, titled 'Announcement from NHSE on Inhibitor Treatment' and dated 7 July 2018. The article referred to an announcement by NHSE [NHS England] stating that Hemlibra could be provided to Haemophilia A patients with current inhibitors under the Framework Agreement for the supply of products for the treatment of bleeding disorders. The Panel noted Roche's submission that this information was posted in July 2018, which was more than two years before the provision of the grant. The Panel noted its comments above about whether it had been established that Roche was responsible for the content of the website. The Panel noted that there was no information before it on whether Roche or Chugai had provided any specific information for the article in question.

Clause 26.1 stated that prescription only medicines must not be advertised to the public and Clause 26.2 stated, among other things, that statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine.

Clause 12.1 required, among other things, that prescribing information must be provided in a clear and legible manner in all promotional material for a medicine.

Clause 6.5 stated, among other things, that the word 'new' must not be used to describe any product or presentation which has been generally available for more than twelve months in the UK.

Clause 5.1 required that high standards must be maintained at all times, and Clause 2 stated that activities or materials must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry.

Nothing its comments above, overall and on balance, the Panel decided that the complainant had not established that Roche was responsible for the content of the article. On this narrow basis, the Panel ruled **no breach of Clauses 6.5, 26.1, 26.2, 12.1, 5.1 and 2** of the Code.

The Panel noted that the second article at issue was titled 'Non-factor replacement therapies', which sat under the Bleeding Disorders, Treatment Types section of the patient organisation website. Beneath the title was a statement 'Information correct as of July 2019'. The first part of the article gave a brief background of different treatments for haemophilia, including regular prophylaxis of factor replacement, treatments that are not clotting factors and treatments made from protein or small molecules which look to replace the activity of the missing clotting factor, or to re-balance clotting capacity.

The Panel noted that the article stated 'Emicizumab (which is also called Hemlibra▼) is the only non-factor replacement therapy currently available by prescription in the UK. It is approved for people of all ages who have congenital haemophilia A with FVIII inhibitors, or severe congenital

haemophilia A (FVIII <1%) without FVIII inhibitors'. The Panel noted that the remainder of the article then discussed Hemlibra, its indication, method of administration, mode of action and some information about serious side-effects. This was followed by a reporting of side-effects statement.

The Panel noted Roche's submission that this information had been provided to the patient organisation reactively, in response to a request for information, in anticipation of emicizumab being routinely commissioned for patients with severe haemophilia A without inhibitors in 2019. It subsequently transpired that the patient organisation had posted the information on its website in July 2019, long before the provision of the grant. The Panel noted that the circumstances differed from the first article as Roche had provided requested information. The Panel did not have sight of the original information provided by Roche but noted that if material was published by a patient organisation based on information that it had requested from a pharmaceutical company, the Panel would consider the acceptability of the material provided by the company. The Panel noted that Roche did not have any involvement in, or visibility of, how the information provided was subsequently used and, in any event, the provision of information by Roche was not a matter raised by the complainant. Overall, and on balance, the Panel decided that the complainant had not established that Roche was responsible for the content of the article. On this narrow basis, the Panel ruled **no breach of Clauses 26.1, 26.2, 12.1, 5.1 and 2** of the Code.

APPEAL BY ROCHE

Roche appealed the Panel's rulings of breaches of Clauses 25.3, 23.2 and two breaches of 5.1.

Acknowledgement of sponsorship - Appeal of breaches ruled of Clause 25.3 and 5.1

With particular reference to the ruling of a breach of Clause 25.3, Roche submitted that its sponsorship of the patient organisation website was clearly acknowledged and visible from the outset on the 'Landing Page' of the website. Overall Roche recognised the importance of transparency of company involvement in initiatives such as this. In no way had Roche tried to hide or misrepresent its involvement to users of this website or to the patient organisation.

Clause 25.3 stated, among other things, that companies must ensure that all sponsorship was clearly acknowledged from the outset and the wording of the declaration of sponsorship must accurately reflect the extent of the company's involvement and influence over the material.

Roche provided the initial letter of request from the patient organisation. Roche appreciated the request letter wasn't referenced in its initial response to the PMCPA nor requested by it in its request for additional information. It was not apparent until the ruling that this would appear relevant. This request letter outlined several key points:

1) It was clear that the grant request was associated with updating the website to improve the user navigation and overall user experience. This was not a grant provision to support particular information sections of the website/content where specific declarations might be warranted
2) It was clear from the request letter that there was an additional pharmaceutical supporter of the website, i.e. Roche/Chugai would not be the sole supporter
3) The request towards Roche/Chugai was for [specified amount in GBP] which was part support for a project with a larger overall cost

4) The initial letter of request made it clear that the declaration of support would appear in the footer of the website. Roche submitted that for a grant request of this nature (based around the navigation of a website) that a clear declaration of its involvement in the footer was unambiguously clear from the outset.

   NB the patient organisation sent the proposed wording of the declaration to Roche for agreement prior to website publication, which included that language in the contract and additional text to highlight that Roche had no involvement in the content.

Roche submitted an image of the declaration of involvement within the 'Landing Page'.

Roche submitted that the bold statement in large font towards the bottom of the page (not footnoted in small text) clearly signposted the companies involved in providing financial support as well as the arm's length arrangement of the provision.

In addition, the logos for all companies involved in supporting the website update featured in the footer of all subsequent pages of the patient organisation website.

Roche submitted that as the 'Landing Page' was the first point of interface between the user and the patient organisation, Roche's sponsorship was noted at the outset of the users' experience, and as such complied with the requirements of Clause 25.3.

Roche submitted that whilst acknowledging the point from the Panel that users would need to scroll to the bottom of the page to see the statement, given the nature of the request for support and the important balance between ensuring appropriate declarations of support and the independence of a patient organisation, on the balance of reasonableness, Roche submitted that the bold large statement in the footer was sufficient to ensure full transparency.

In summary, Roche considered that it had met the requirements of the Code in terms of making the involvement of the company clear, with an accurate reflection of its involvement, which was in a position that was clear at the outset for the user. As such, Roche appealed the ruling of Clause 25.3 and the further suggestion that high standards had not been maintained with an associated breach of 5.1.

Clarity of transparency requirements in Contract - Appeal of breaches ruled of Clause 23.2 and 5.1

Roche also appealed the Panel's ruling in relation to a breach of Clause 23.2 and consequent breach of Clause 5.1.

Clause 23.2 stated, among other things, that there must be a written agreement in place for each donation or grant. It also stated that the arrangements for written agreements with patient organisations were set out in Clause 27.2.

Clause 27.2 required that the written agreement must, among other things, include a statement that all parties were fully aware that the donation or grant must be clearly acknowledged and apparent from the start.

The Panel acknowledged that a written agreement between the parties, which referred to the need to acknowledge the companies' involvement, was in place. This included a Declarations of

Involvement clause stating that the patient organisation must agree, per the clause, to acknowledge support by including the following statement whenever it writes or speaks in public about a matter that was the subject of the Agreement or any other issue in relation to Chugai: 'Supported by a restricted grant from Chugai Pharma UK Ltd and Roche Products Limited'.

Roche submitted that the contract and hence this clause became effective upon the date of the last signature. This clause was therefore intended to ensure any activities from that date onwards were within scope of the terms of the agreement and the declaration of involvement. Furthermore, as noted above, the patient organisation included in their initial letter of request the undertaking that acknowledgement of support from all companies would be included in the footer of the website. Roche submitted that this would also make it clear to the user from the start, the level of company involvement.

On this basis, Roche submitted that compliance with Clause 23.2 was achieved and the condition of the Clause had been satisfied in the associated contract documentation. As such, it appealed the Panel's ruling of a breach of Clause 23.2 and associated breach of Clause 5.1.

FINAL COMMENTS FROM COMPLAINANT

No comments were received.

APPEAL BOARD RULING

The Appeal Board observed that the complaint concerned a named patient organisation website, which was supported by a grant from Roche. Near the bottom of the homepage, in bold large font, it stated 'Thank you to our sponsors' followed by the statement in smaller font:

> 'We are thankful to the companies below who have supported the update of our website in 2021: [named pharmaceutical company] has provided sponsorship to [named patient organisation] to support with the costs of updating this website. [Named pharmaceutical company] has had no control or influence over the information/content included on this website unless where stated. The update of this website was supported by a restricted grant from Chugai Pharma UK Ltd and Roche Products Limited. Chugai Pharma UK Ltd and Roche Products Limited has had no control or influence over the information/content included on this website unless where stated'.

This was followed by logos for Chugai, [named pharmaceutical company] and Roche. Further webpages, including those about haemophilia A and B, displayed the statement in small font 'Website supported by:' followed by company logos for Chugai, [named pharmaceutical company] and Roche at the footer of each webpage.

The Appeal Board took into account Roche's submission that it had not approved any part of the patient organisation website content; the grant it provided was for support to develop the website, which replaced the patient organisation's previous website as part of a rebranding exercise undertaken by it.

The Appeal Board reminded itself of the broad definition of sponsorship in Clause 1.22 as a contribution, financial or otherwise, in whole or in part provided by or on behalf of a company, towards an activity (including an event/meeting or material) performed, organised, created etc by a healthcare organisation, patient organisation or other independent organisation.

The Appeal Board observed that the website at issue was intended for patients and, noting the established principle of transparency, considered that it was important that patients be aware of any company involvement and the nature of the support at the outset.

The Appeal Board considered that the length of the continuously scrolling landing page was such that the statement of involvement by Roche would not appear until the reader had scrolled down four screens worth of content to the bottom of the webpage. The Appeal Board considered, given the length of the landing page and the number of links to other content near the beginning of the landing page, it was entirely possible that a patient could use the website and never see the declaration of Roche's involvement. The Appeal Board considered that Roche had failed to ensure that it was sufficiently clear at the outset that the update to the patient organisation website was supported by a grant from Roche and it upheld the Panel's ruling of **a breach of Clause 25.3.** The Appeal on this point was not successful.

The Appeal Board considered that whilst the declaration of Roche's involvement was not apparent at the outset as required by Clause 25.3, it was included on the landing page; if a patient had scrolled to the bottom of the landing page they would see company logos under the heading 'Thank you to our sponsors' with accompanying text. In the particular circumstances of this case, the Appeal Board did not consider that Roche had failed to maintain high standards and ruled **no breach of Clause 5.1**. The appeal on this point was successful.

The Appeal Board reminded itself of the requirements of Clause 23.2 and its supplementary information, which further refers to Clause 27.2 and the arrangements for written agreements with patient organisations, including that the written agreement should include a statement that all parties are fully aware that the donation or grant must be clearly acknowledged and apparent from the start. The Appeal Board observed Roche's submission that the written agreement was made using a Chugai template, which was different to the Roche template, and did not include the required statement.

The Appeal Board considered that written agreements should be unequivocal about the requirements regarding declarations of involvement by companies. Whilst in this case there was a written agreement between the parties, which referred to the need to acknowledge the companies' involvement, it did not state that it must also be apparent from the start. The Appeal Board therefore upheld the Panel's ruling of **a breach of Clause 23.2**. The Appeal on this point was not successful.

The Appeal Board was concerned that those involved in the activity did not notice that the written agreement template used did not meet the above requirement of the Code. Nonetheless, there was a reference in the written agreement to the requirement for a declaration of involvement statement; in that regard, the Appeal Board did not consider that Roche had failed to maintain high standards and **no breach of Clause 5.1** was ruled. The appeal on this point was successful.

Complaint received **7 July 2022**

Case completed **28 February 2024**