CASE AUTH/3541/7/21

ANONYMOUS HEALTH PROFESSIONAL v ROCHE

Alleged errors and omissions on Roche Resources website

An anonymous complainant, who described him/herself as a health professional complained about errors and omissions on the Roche Products Ltd Resources website.

The complainant provided a link to a particular page and alleged that the generic name for Gazyvaro was not legible.

The complainant further referred to text directly above all of the product logos that:

> **'Our aim is to develop new and improved therapies that offer benefits over existing treatment options Roche has a portfolio of therapies for the treatment of cancer as well as diseases including haemophilia, central nervous system disorders, lung disorders and inflammatory diseases.'**

The complainant alleged that not all the products displayed on this page were new as many had been on the market for more than 12 months.

The complainant stated that the marketing authorisations for these products were very specific and by only referring to cancer, haemophilia etc, this was promoting outside of the licence as one could easily assume all the products were for any form of cancer etc. It was not clear from the product logos underneath the claim which products were licensed for which indications precisely and for a health professional this was misleading and off-label promotion which would have a risk to patient safety. By claiming benefits over existing therapies, this was misleading as the actual benefits had not been qualified or stated anywhere on the page.

The complainant provided a link to a second page which promoted Phesgo and noted the claim 'PHESGO is a new combined fixed-dose subcutaneous (SC) formulation of pertuzumab and trastuzumab that requires just 20–38 minutes for administration and monitoring[1]'. The complainant alleged that the 20-38 minutes was misleading as the 20 minutes only related to the maintenance dose of the product, 38 minutes was always the time taken for a loading dose administration. The complainant alleged that it was a patient safety risk to claim lower time of administration without segregation of the different time intervals for the different types of treatments.

The complainant provided a link to a third page which included the claim 'With the sustained protection of HEMLIBRA, life can be beautifully spontaneous'. The complainant alleged that this was a false and misleading claim as one could interpret this as life would be beautiful after taking hemlibra.

The complainant provided a fourth link to a webpage on which the dosing section for Ocrevus claimed 'OCREVUS is dosed every 6 months'. The complainant alleged that this was false as the summary of product characteristics (SPC) stated to provide the initial dose of 600mg in 2 infusions (first infusion and the second infusion 2 weeks later). Important safety information that patients should be monitored during the infusion and for at least one hour after the completion of the infusion was missing as part of this claim. This would have a grave patient safety impact. The SPC also said:

> **'The following two premedications must be administered prior to each Ocrevus infusion to reduce the frequency and severity of IRRs (see infusion-related reactions in section 4.4 for additional steps to reduce IRRs):**
>
> - **100 mg intravenous methylprednisolone (or an equivalent) approximately 30 minutes prior to each Ocrevus infusion;**
> - **antihistamine approximately 30-60 minutes prior to each Ocrevus infusion;.'**

The complainant stated that this information had been missed on the dosing claim as it only mentioned dosing at 6 months and no further information was provided.

The website and the different sections mentioned within this complaint had allegedly breached Clause 2 repeatedly by not adhering to patient safety values.

The detailed response from Roche is given below.

1 Medicines Webpage

The Panel noted that for electronic advertisements, the Code required the non-proprietary name of the medicine to appear immediately adjacent to the brand name at its first appearance in a size such that the information was easily readable. From the material provided by Roche, the non-proprietary name for Gazyvaro, obinutuzumab, appeared to be small and blurry, and was thus not easily readable. The Panel therefore ruled a breach of the Code.

The Panel considered that the statement 'Our aim is to develop new and improved therapies that offer benefits over existing treatment options' did not appear to refer to any particular product as being new, including any of the fourteen medicines listed on the page that were referred to as products currently supported on the website and were therefore already developed. The Panel therefore ruled no breach of the Code.

The Panel also did not consider that the complainant had established that referring to Roche's aim to develop 'improved therapies that offer benefits over existing treatment options' without qualification of the actual benefits constituted a misleading comparison as alleged and no breach of the Code was ruled.

With regard to the statement 'Roche has a portfolio of therapies for the treatment of cancer as well as diseases including haemophilia, central nervous system disorders, lung disorders and inflammatory diseases', the Panel considered that the statement was referring to Roche's portfolio and the therapy areas in which the products in its portfolio fell and was not referring to the indications of the products listed. The Panel noted

Roche's submission that the website provided further information via a direct link for the products listed. The Panel did not consider that the complainant had established that the statement constituted off license promotion of any of the fourteen medicines listed as alleged. The Panel ruled no breaches of the Code in relation to each medicine.

2 Phesgo Webpage

The Panel noted that the claim 'PHESGO is a new combined fixed-dose subcutaneous formulation of pertuzumab and trastuzumab that requires just 20–38 minutes for administration and monitoring' was referenced to the SPC. Table 1 titled 'Phesgo recommended dosing and administration' in Section 4.2 of the Phesgo SPC provided timings for the loading dose and maintenance dose with the approximate duration of subcutaneous injection for the loading dose and maintenance dose was 8 minutes and 5 minutes, respectively; the observation time was 30 minutes and 15 minutes, respectively. The Panel noted Roche's submission that the 20-38 minutes was calculated by combining the 'Approximate duration of subcutaneous injection' and 'Observation time' columns for the Phesgo loading and maintenance doses. The Panel further noted Roche's submission that on the same webpage was a box titled 'Dosing and administration' where the administration and observation times for the loading and maintenance doses were explained. The Panel considered that whilst a health professional would likely read the dosing and administration section on the webpage in question or refer to the SPC for more detailed dosing information, each webpage must not be misleading when read in isolation. Nonetheless, the Panel did not consider that the complainant had established that the claim in question, by referring to a time range of 20-38 minutes for administration and monitoring without segregation of the different time intervals for loading and maintenance doses was misleading as alleged. The complainant had not established that the claim in question was incapable of substantiation. No breaches of the Code were ruled.

3 Hemlibra Webpage

The Panel noted that Hemlibra was indicated for use in certain patients for routine prophylaxis of bleeding episodes in haemophilia A. Whilst the Panel considered that it was unclear what was meant by 'life can be beautifully spontaneous' and noted Roche's lack of submission in this regard, it considered that the complainant had not established that the claim 'With the sustained protection of HEMLIBRA, life can be beautifully spontaneous' implied that life would be beautiful after taking Hemlibra as alleged. Based on the very narrow allegation, the Panel ruled no breaches of the Code.

4 Ocrevus Webpage

The Panel noted that the Ocrevus SPC stated that the initial 600mg dose was to be administered as two separate 300mg intravenous infusions, 2 weeks apart, and that subsequent doses would be administered as a single 600mg infusion every 6 months. The first subsequent dose of 600mg should be administered six months after the first infusion of the initial dose. Whilst the Panel noted Roche's submission that the claim 'OCREVUS is dosed every 6 months' was only in relation to dose cadence, the Panel considered that this would not be immediately apparent to readers. The Panel considered that the statement within the section titled 'Dosing' lacked the important information that the initial dose required two separate infusions two weeks apart and that

the first subsequent dose of 600mg should be administered six months after the first infusion of the initial dose. The Panel considered that the claim was misleading in that regard and incapable of substantiation and therefore ruled breaches of the Code. The Panel noted that it appeared that there was further information on dosing, albeit that needed to be expanded with an additional click, beneath the claim and thus did not consider that in the particular circumstances of this case Roche had failed to maintain high standards. No breach of the Code was ruled.

The Panel noted that the Ocrevus SPC stated Ocrevus treatment should be initiated and supervised by specialised physicians experienced in the diagnosis and treatment of neurological conditions and who have access to appropriate medical support to manage severe reactions such as serious infusion-related reactions. The Panel noted Roche's submission that Ocrevus was administered intravenously which, without exception, occurred in a controlled and monitored hospital environment. The Panel further noted that within the section on the webpage at issue titled 'Dosing' below the claim 'Ocrevus is dosed every 6 months' it stated 'Find out how to: Dose Ocrevus; Store Ocrevus; Prepare Ocrevus; and Administer Ocrevus' and appeared to provide the option for readers to click on each for further information. Whilst the Panel did not have the information within each subsection before it, it noted Roche's submission that additional relevant information was provided in the links directly below the posology statement. The Panel considered that readers would likely access the required information in relation to each of the labelled topics. The Panel noted that each webpage must not be misleading when read in isolation. Nonetheless, the Panel did not consider that the complainant had established that referring to the dosing of Ocrevus every six months without referring to the requirements for premedication and monitoring was misleading as alleged; readers were directed to information on how to administer Ocrevus and no breaches of the Code were ruled.

The Panel noted its comments and rulings above and, overall, did not consider that a breach of Clause 2, which was a sign of particular censure, was warranted and no breach was ruled.

An anonymous complainant, who described him/herself as a health professional and was not contactable on the details provided, complained about errors and omissions on the Roche Products Ltd Resources website.

COMPLAINT

The complainant alleged that there were a number of compliance errors and omissions on the Roche Resources website, which were not in line with the ABPI Code. This was concerning to the complainant considering Roche was a big organisation which promoted multiple products for multiple therapy areas on this website.

The complainant provided a link to a particular page (https://www.rocheresources.co.uk/roche-medicines.html M-GB-00003975. Date of preparation: June 2021) on which he/she alleged that the generic name for Gazyvaro was not legible in breach of Clause 12.3.

The complainant further stated that text directly above all of the product logos was written as:

> ‘Our aim is to develop new and improved therapies that offer benefits over existing treatment options Roche has a portfolio of therapies for the treatment of cancer as well as diseases including haemophilia, central nervous system disorders, lung disorders and inflammatory diseases.’

The complainant alleged that not all the products displayed on this page were new as many had been on the market for more than 12 months in breach of Clause 6.5.

The complainant stated that the marketing authorisations for these products were very specific and by only referring to cancer, haemophilia etc, this was promoting outside of the licence as one could easily assume all the products were for any form of cancer etc. It was not clear from the product logos underneath the claim which products were licensed for which indications precisely and for a health professional this was misleading and off-label promotion in breach of Clauses 11.2 and 5.1 (in relation to each of the 14 products as the indications were not clear for the 14 products and one would assume the products were licensed for all therapy areas mentioned above, eg cancer) in the headline claim which would have a risk to patient safety. By claiming benefits over existing therapies, this was misleading as the actual benefits had not been qualified or stated anywhere on the page; a breach of Clause 14.1 was alleged.

The complainant provided a link to a second page (https://www.rocheresources.co.uk/roche-medicines/oncology/Phesgo.html M-GB-00002654. Date of preparation: February 2021) which promoted Phesgo and noted the large claim ‘PHESGO is a new combined fixed-dose subcutaneous (SC) formulation of pertuzumab and trastuzumab that requires just 20–38 minutes for administration and monitoring[1]’. The complainant alleged that the 20-38 minutes was misleading as the 20 minutes ONLY (emphasis added by complainant) related to the maintenance dose of the product, 38 minutes was ALWAYS (emphasis added by complainant) the time taken for a loading dose administration. The complainant alleged that it was a patient safety risk to claim lower time of administration without segregation of the different time intervals for the different types of treatments; in breach of Clauses 5.1, 6.1 and 6.2.

The complainant provided a link to a third page (https://www.rocheresources.co.uk/roche-medicines/Rare-Diseases/HEMLIBRA21.html M-GB-00002757. Date of preparation: March 2021) which included the claim ‘With the sustained protection of HEMLIBRA, life can be beautifully spontaneous’. The complainant alleged that this was a false and misleading claim as one could interpret this as life would be beautiful after taking hemlibra; in breach of Clauses 5.1, 6.1 and 6.2.

The complainant provided a fourth link to a webpage (https://www.rocheresources.co.uk/roche-medicines/Neuroscience/Ocrevus.html M-GB-00003114. Date of preparation: March 2021) on which the dosing section for Ocrevus claimed ‘OCREVUS is dosed every 6 months’. The complainant alleged that this was false as the summary of product characteristics (SPC) had guidance to provide initial dose of 600mg in 2 infusions (first infusion and then 2nd infusion 2 weeks later). Important safety information that patients should be monitored during the infusion and for at least one hour after the completion of the infusion was missing as part of this claim. This would have a grave patient safety impact. The SPC also said:

> ‘The following two premedications must be administered prior to each Ocrevus infusion to reduce the frequency and severity of IRRs (see Infusion-related reactions in section 4.4 for additional steps to reduce IRRs):

- 100 mg intravenous methylprednisolone (or an equivalent) approximately 30 minutes prior to each Ocrevus infusion;
- antihistamine approximately 30-60 minutes prior to each Ocrevus infusion;.'

The complainant stated that this information had been missed on the dosing claim as it only mentioned dosing at 6 months and no further information was provided; in breach of Clauses 5.1, 6.1 and 6.2.

The website and the different sections mentioned within this complaint had allegedly breached Clause 2 repeatedly by not adhering to patient safety values.

When writing to Roche, the Authority asked it to consider the requirements of Clauses 2, 5.1, 6.1, 6.2, 6.5, 11.2, 12.3 and 14.1 of the 2021 Code as cited by the complainant.

RESPONSE

Roche submitted that in light of the allegations made, it would like to reassure the PMCPA that it had very high standards for materials and robust processes in place to ensure that all materials were accurate and met the requirements of the Code.

Roche noted that the complaint referred to pages included in Roche's Resources website, an online resource provided for health professionals to be able to access news, information and resources about Roche medicines. Roche's response below dealt with each of the complaint areas in turn.

Allegations relating to M-GB-00003975

Roche submitted that this page was navigated to by selecting the 'Roche Medicines' tab and was intended to visually represent to health professionals the Roche medicines that were currently supported on the Roche Resources website. It showed an initial statement 'Roche's aim is to develop new and improved therapies' followed by the following paragraph 'Roche has a portfolio of therapies for the treatment of cancer as well as diseases including haemophilia, central nervous system disorders, lung disorders and inflammatory diseases'. There were subsequently images of the product logos of Roche products that were currently supported on the Roche Resources website enabling health professionals to be able to quickly navigate to areas of interest.

Roche noted that the complainant made two allegations concerning the initial statement at the top of the page, 'Roche's aim is to develop new and improved therapies'. Firstly, the complainant alleged a breach of Clause 6.5 by way of the use of the term 'new' in the statement, specifically with regard to the images of the products shown further down the page, some of which might have been on the market for longer than 12 months. This sentence was a visionary, forward looking statement and as written, was not claiming that Roche's products supported on the Roche Resources website were all new, but rather that it was **aiming** *(emphasis added)* to produce new therapies. As such, Roche did not consider this to be a breach of Clause 6.5.

Secondly, the complainant alleged that Roche was claiming benefits over 'improved existing therapies' without stating or qualifying product benefits and, as such, was a breach of Clause 14.1. Again, the statement was visionary and was highlighting Roche's ambition to **develop**

(emphasis added) improved therapies, therefore it did not consider this to be misleading and therefore not in breach of Clause 14.1.

The complainant referenced the size of the generic name of Gazyvaro, specifically that he/she felt it was not legible. Roche submitted that the Code did not make any recommendations in terms of size for digital content other than ensuring legibility. Roche's view was that the generic name of Gazyvaro was an appropriate size and clearly legible when viewed on computer or mobile screens and therefore not in breach of Clause 12.3. Given, however, the feedback from the complainant and the relative size of the generic name of Gazyvaro in comparison to others on the page, Roche had increased the size of the generic name of Gazyvaro for consistency.

The final allegation on this page related to the following statement: 'Roche has a portfolio of therapies for the treatment of cancer as well as diseases including haemophilia, central nervous system disorders, lung disorders and inflammatory diseases' which featured, indirectly, above the list of products currently supported on the Roche Resources website. The complainant alleged that this was misleading and constituted off-label promotion as not all products listed were indicated in these therapy areas and, as such, breached Clauses 11.2 and 5.1 (on 14 occasions).

For context, Roche had a number of medicines that covered a variety of indications. The reference to 'portfolio' in this statement indicated that products might cover some, but not all, disease areas in the text.

Following the statement there was a clear demarcation line with the text (in more prominent font) directly above the list of products which stated, 'Our products currently supported on rocheresources.co.uk' and provided the context for following content ie a list of products where Roche Resources provided further information, which also provided a direct link to the appropriate page for more information. Given this, Roche did not consider this misleading nor that it constituted off-label promotion and, as such, refuted the allegation of 14 breaches of Clauses 11.2 and 5.1.

Allegations relating to M-GB-00002654

Roche noted that the complainant stated that the sentence 'PHESGO is a combined fixed-dose subcutaneous formulation of pertuzumab and trastuzumab that requires just 20–38 minutes for administration and observation[1]' was misleading and had a patient safety risk.

The claim quoted by the complainant was based on factual information provided in 'Table 1: Phesgo recommended dosing and administration' of the SPC for Phesgo.

Table 1: Phesgo recommended dosing and administration

	Dose (irrespective of body weight)	Approximate duration of subcutaneous injection	Observation time [ab]
Loading dose	1200 mg pertuzumab/ 600 mg trastuzumab	8 minutes	30 minutes
Maintenance dose (every 3 weeks)	600 mg pertuzumab/ 600 mg trastuzumab	5 minutes	15 minutes

The number of minutes was calculated by combining the 'Approximate duration of subcutaneous injection' and 'Observation time' columns for the Phesgo loading and maintenance doses respectively. This information on the Roche Resources page was clearly referenced to the SPC immediately at the end of the sentence where this factual information could be found.

Furthermore, on the same page, underneath this statement, there was a clearly obvious click-through box entitled 'Dosing and administration'. Here the administration and observation times were clearly explained for Phesgo with particular reference to the time distinction between the loading and maintenance doses. This information was readily available for health professionals that were using the Phesgo pages on the Roche resources website and clearly visible on the Phesgo landing page. Screenshots for the relevant pages were provided.

In summary, Roche considered the claim relating to the timing of dosage and administration of Phesgo was accurate, fair, objective and unambiguous. Furthermore, Roche believed that the Roche resources pages relating to Phesgo were sufficiently complete to enable recipients to make appropriate prescribing, administration and monitoring decisions for their patients. Accordingly, Roche believed the pages met the requirements of Clause 6.1.

Furthermore, as noted above, given the information was factual and contained within the SPC (and referenced as such), Roche also believed that this met the requirements of Clause 6.2.

Finally, Roche believed that high standards continued to be maintained as per Clause 5.1 and that the complainant's view of a patient safety risk was unfounded.

Allegations relating to M-GB-00002757

Roche noted that the complainant stated that the claim 'With the sustained protection of Hemlibra life can be beautifully spontaneous' could be interpreted that life would be beautiful after taking Hemlibra. Roche believed that the complaint mis-represented its claim in two important respects. Firstly, by re-stating 'can be' as 'would be' and secondly, by taking 'beautiful' in isolation from 'spontaneous'. When taken as a whole, and as written, Roche believed that this claim was fair, reasonable and capable of substantiation.

Roche believed that there was no evidence of a breach of Clauses 5.1, 6.1 or 6.2.

Allegations relating to M-GB-00003114

1 Ocrevus dosing claim

Roche submitted that when considering this allegation, a nuanced, but important distinction, needed to be made between '**infusion**' and '**dose**' cadence. Roche had not made any claims in relation to infusion cadence but instead had focused on dosing cadence in accordance and in alignment with the SPC text.

The initial dose of 600mg was the only dose that was split into two separate infusions given two weeks apart; each of these infusions being a 300mg infusion. It was both infusions that together made up the initial dose of 600mg. This was clearly explained in the SPC: '*The initial 600 mg dose is administered as two separate intravenous infusions; first as a 300 mg infusion,*

followed 2 weeks later by a second 300 mg infusion'. The Roche claim was only in relation to dose cadence.

The SPC went on to state that following the **initial dose** (administered as two infusions), '…*subsequent doses of Ocrevus thereafter are administered as a single 600 mg intravenous infusion* ***every 6 months****. The first subsequent dose of 600 mg should be administered* ***six months*** *after the first infusion of the* ***initial dose***'.

Roche did not consider the claim to be misleading or inaccurate but rather a statement of fact in accordance with the SPC.

More detailed information about the different aspects of the dosing and administration of Ocrevus could be found on the relevant pages as indicated on the landing page which stated 'Find out how to: Dose Ocrevus, Store Ocrevus, Prepare Ocrevus, Administer Ocrevus'.

2 Important safety information regarding monitoring, pre-medications and patient safety

Roche submitted that Ocrevus was administered intravenously which, without exception, occurred in a controlled and monitored hospital environment. It was part of routine hospital care that patients were monitored during Ocrevus infusions within this hospital setting. Additional information about how to store, prepare and administer Ocrevus, as well as any relevant precautions and pre-medications, were provided in the links directly below the posology statement. Additionally, there was a direct link to the SPC on the webpage. The information claimed to be missing, was available via links directly below the posology statement and via the link to the SPC.

Roche submitted that there was no evidence of a Clause 5.1 breach as high standards had been maintained. The special nature of the medicine had been respected with the material exclusively targeted at the appropriate audience via the landing page and the health professional self-selection function as well as the statement at the top of the health professional content page stating that '*This website is intended for healthcare professionals (HCPs) only*'. Additionally, the indication statement indicated the intended use of the medicine and additional features, such as the black triangle to alert the reader to the fact that the medicine was subject to additional monitoring.

There was no evidence of a Clause 6.1 or 6.2 breach as the complainant had not provided any evidence of a claim that had been inaccurate or misleading. The claim mentioned with regard to dosing cadence was a statement of fact referencing the text from the SPC. The allegation that important safety information was missing was unfounded as all the relevant information was provided in contextually relevant links and via the direct SPC and prescribing information links.

There was no evidence to support any of the material in question prejudicing patient safety and thus no evidence of a Clause 2 breach.

In summary, Roche reiterated its commitment to the maintenance of high standards and the assurance of robust processes in place to ensure that all materials were accurate and met the requirements of the Code.

PANEL RULING

The Panel noted Roche's submission that the Roche Resources website was an online resource provided for health professionals to be able to access news, information and resources about its medicines.

1 Medicines Webpage

The Panel noted that the Roche Medicines webpage stated, 'Our aim is to develop new and improved therapies that offer benefits over existing treatment options. Roche has a portfolio of therapies for the treatment of cancer as well as diseases including haemophilia, central nervous system disorders, lung disorders and inflammatory diseases'. This was followed by the statement 'Our products currently supported on rocheresources.co.uk' beneath which were fourteen brand logos containing both brand and non-proprietary names.

The Panel noted that for electronic advertisements, the Code required the non-proprietary name of the medicine to appear immediately adjacent to the brand name at its first appearance in a size such that the information was easily readable. In the Panel's view, from the material provided by Roche, the non-proprietary name for Gazyvaro, obinutuzumab, appeared to be small and blurry, and was thus not easily readable. The Panel therefore ruled a breach of Clause 12.3.

The Panel noted that the statement 'Our aim is to develop new and improved therapies that offer benefits over existing treatment options' appeared to be describing Roche's ongoing aim to develop new products; it did not appear to refer to any particular product as being new including any of the fourteen medicines listed on the page that were referred to as products currently supported on the website and were therefore already developed. The Panel therefore ruled no breach of Clause 6.5.

The Panel also did not consider that the complainant had established that referring to Roche's aim to develop 'improved therapies that offer benefits over existing treatment options' without qualification of the actual benefits constituted a misleading comparison as alleged and no breach of Clause 14.1 was ruled.

With regard to the statement 'Roche has a portfolio of therapies for the treatment of cancer as well as diseases including haemophilia, central nervous system disorders, lung disorders and inflammatory diseases', the Panel noted the complainant's allegation that the marketing authorisations for each product were very specific and that only referring to therapy areas constituted off-licence promotion. The Panel considered that the statement was referring to Roche's portfolio and the therapy areas in which the products in its portfolio fell and was not referring to the indications of the products listed. The Panel noted Roche's submission that the Resources website provided further information via a direct link for the products listed. The Panel did not consider that the complainant had established that the statement 'Roche has a portfolio of therapies for the treatment of cancer as well as diseases including haemophilia, central nervous system disorders, lung disorders and inflammatory diseases' constituted off license promotion of any of the fourteen medicines listed as alleged. The Panel ruled no breach of Clauses 11.2 and 5.1 in relation to each medicine.

2 Phesgo Webpage

The Panel noted that the claim 'PHESGO is a new combined fixed-dose subcutaneous formulation of pertuzumab and trastuzumab that requires just 20–38 minutes for administration

and monitoring' was referenced to the SPC. The Panel, however, noted that Table 1 titled 'Phesgo recommended dosing and administration' in Section 4.2 of the Phesgo SPC dated 9 March 2022 accessed by the PMCPA on 12 May 2022 provided timings for Phesgo's loading dose and maintenance dose as submitted by Roche. The approximate duration of subcutaneous injection for the loading dose and maintenance dose was 8 minutes and 5 minutes, respectively; the observation time was 30 minutes and 15 minutes, respectively. The Panel noted Roche's submission that the 20-38 minutes was calculated by combining the 'Approximate duration of subcutaneous injection' and 'Observation time' columns for the Phesgo loading and maintenance doses. The Panel further noted Roche's submission that on the same webpage was a box titled 'Dosing and administration' where the administration and observation times for the loading and maintenance doses were explained. The Panel considered that whilst a health professional would likely read the dosing and administration section on the webpage in question or refer to the SPC for more detailed dosing information, each webpage must not be misleading when read in isolation. Nonetheless, the Panel did not consider that the complainant had established that the claim in question, by referring to a time range of 20-38 minutes for administration and monitoring without segregation of the different time intervals for loading and maintenance doses was misleading as alleged. No breach of Clause 6.1 was ruled. The complainant had not established that the claim in question was incapable of substantiation and no breach of Clause 6.2 was ruled. The Panel consequently ruled no breach of Clause 5.1.

3 Hemlibra Webpage

The Panel noted that the webpage for Hemlibra (emicizumab) had the claim 'With the sustained protection of HEMLIBRA, life can be beautifully spontaneous'. The Panel noted that according to the SPC dated 1 January 2021, accessed by the PMCPA on 12 May 2022, Hemlibra was indicated for routine prophylaxis of bleeding episodes in patients with haemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors / severe haemophilia A (congenital factor VIII deficiency, FVIII < 1%) without factor VIII inhibitors. The Panel noted the complainant's allegation that the claim was false and misleading as it could have been interpreted that life would be beautiful after taking Hemlibra. Whilst the Panel considered that it was unclear what was meant by 'life can be beautifully spontaneous' and noted Roche's lack of submission in this regard, it considered that the complainant had not established that the claim implied that life would be beautiful after taking Hemlibra as alleged. Based on the very narrow allegation, the Panel ruled no breach of Clauses 6.1, 6.2 and 5.1.

4 Ocrevus Webpage

The Panel noted that Section 4.2 of the Ocrevus SPC dated 28 July 2021 accessed by the PMCPA on 12 May 2022 stated that the initial 600mg dose was to be administered as two separate 300mg intravenous infusions, 2 weeks apart, and that subsequent doses would be administered as a single 600mg infusion every 6 months. The first subsequent dose of 600mg should be administered six months after the first infusion of the initial dose. Whilst the Panel noted Roche's submission that the claim 'OCREVUS is dosed every 6 months' was only in relation to dose cadence, the Panel considered that this would not be immediately apparent to readers. The Panel considered that the statement within the section titled 'Dosing' lacked the important information that the initial dose required two separate infusions two weeks apart and that the first subsequent dose of 600mg should be administered six months after the first infusion of the initial dose. The Panel considered that the claim was misleading in that regard. The Panel therefore ruled a breach of Clause 6.1. The misleading impression given by the claim was incapable of substantiation and a breach of Clause 6.2 was ruled. The Panel noted

that it appeared that there was further information on dosing, albeit that needed to be expanded with an additional click, beneath the claim and thus did not consider that in the particular circumstances of this case Roche had failed to maintain high standards. No breach of Clause 5.1 was ruled.

The Panel noted that Section 4.2 of the Ocrevus SPC stated Ocrevus treatment should be initiated and supervised by specialised physicians experienced in the diagnosis and treatment of neurological conditions and who have access to appropriate medical support to manage severe reactions such as serious infusion-related reactions. The Panel noted Roche's submission that Ocrevus was administered intravenously which, without exception, occurred in a controlled and monitored hospital environment; it was part of routine hospital care that patients were monitored during Ocrevus infusions within this hospital setting. The Panel further noted that within the section titled 'Dosing' below the claim 'Ocrevus is dosed every 6 months' it stated 'Find out how to: Dose Ocrevus; Store Ocrevus; Prepare Ocrevus; and Administer Ocrevus' and appeared to provide the option for readers to click on each for further information. Whilst the Panel did not have the information within each subsection before it, it noted Roche's submission that additional information about how to store, prepare and administer Ocrevus, as well as any relevant precautions and pre-medications, were provided in the links directly below the posology statement. The Panel considered that readers would likely access the required information in relation to each of the labelled topics. The Panel noted that each webpage must not be misleading when read in isolation. Nonetheless, the Panel did not consider that the complainant had established that referring to the dosing of Ocrevus every six months without referring to the requirements for premedication and monitoring was misleading as alleged; readers were directed to information on how to administer Ocrevus and no breach of Clause 6.1 was ruled. The Panel subsequently ruled no breach of Clause 5.1.

The Panel noted its comments and rulings above and, overall, did not consider that a breach of Clause 2, which was a sign of particular censure, was warranted and no breach was ruled.

Complaint received **15 July 2021**

Case completed **27 May 2022**