NO BREACH OF THE CODE

CASE AUTH/3383/9/20

COMPLAINANT v AMGEN

Alleged promotion of Repatha to the public

A complainant who described him/herself as a concerned UK health professional, complained about the online promotion of Repatha (evolocumab) by Amgen Ltd. The material at issue was the repatha.co.uk website (ref UKIE-P-145-1219-080354).

Repatha was a lipid-lowering therapy for use in certain patients with primary hypercholesterolaemia, mixed dyslipidaemia, homozygous familial hypercholesterolaemia or established atherosclerotic cardiovascular disease.

The complainant stated that there was no 'pop-up' or separate page to ensure that the site could only be seen by health professionals. As such, the complainant alleged that the website promoted Repatha to the public.

The complainant referred to a page of the website with the following text: 'Repatha is the first PCSK9i with a licensed indication for the treatment of adults with established CVD1' in the context of the indications for Repatha as stated in the summary of product characteristics (SPC). The complainant alleged that the description given by Amgen was far too broad and vague and alleged that the company was promoting Repatha off-licence since physicians would not know that there were several caveats to its use.

The detailed response from Amgen is given below.

The Panel noted that the landing page of the Repatha.co.uk website accessed from the link provided by the complainant asked readers to confirm whether they were a UK health professional, a Repatha patient in the UK or a member of the UK public and above the health professional link the statement read: 'This site is for use in the United Kingdom only. By clicking to enter this site you are confirming that you are a UK Healthcare Professional'. The Panel noted Amgen's submission that when clicked, each of the three separate navigation options linked to a separate website designed specifically for that target audience. The Panel noted Amgen's submission that once the user had entered the health professional site, all pages within that site carried a banner at the bottom of the page which stated: 'This website is developed and funded by Amgen Limited and intended for UK healthcare professionals only'.

The Panel noted Amgen's explanation that when users arrived at the website for the first time, accepted cookies and navigated to the health professional site, and then subsequently, within the same browsing session, googled 'Repatha UK' the search would default back to the health professional site without going via the landing page. The Panel, however, noted Amgen's submission that irrespective of previous choices

made when arriving at the landing page, when a new browsing session was started, a Google search of 'Repatha UK' would always bring users back to the landing page; it would not be possible to navigate directly to any of the health professional, patient or general public websites without first being presented with this landing page and the navigation options.

The Panel noted the arrangements for the landing page as described by Amgen and that when the case preparation manager had accessed the link from the complainant's email, the case preparation manager had been taken to the landing page as described by Amgen. The Panel further noted Amgen's submission that the landing page linked to further material for each target audience. The Panel did not consider that the Repatha.co.uk website promoted prescription only medicines to the public as alleged and no breach of the Code was ruled.

The Panel noted that the claim at issue 'Repatha is the first PCSK9i with a licensed indication for the treatment of adults with established CVD' appeared on the 'Repatha in practice' page if the user clicked on '2018' within the timeline bar towards the bottom of the page beneath the heading 'Amgen as a forerunner in PCSK9 innovation'.

The Panel noted Amgen's submission that when health professionals landed on the 'Repatha in practice' page, the timeline presented at the bottom of the page automatically defaulted to the 2003 timeline quotation (Role of PCSK9 in LDL Metabolism emerges); the different points on the timeline presented top line key milestones and achievements reached by Amgen in the development of PCSK9 and the information was not intended to present substantive information on the use of Repatha. The 2018 quotation related to when the additional marketing authorization was granted. The Panel further noted Amgen's submission that before the 2018 quotation, and within the same webpage, it stated 'Repatha is given together with a statin or other cholesterol-lowering therapy, or without statins if they are not tolerated or contraindicated'.

The Panel did not consider that the claim 'Repatha is the first PCSK9i with a licensed indication for the treatment of adults with established CVD', within the context of the key milestones timeline and the other information on the webpage at issue, was inconsistent with the Repatha SPC. The Panel therefore ruled no breach of the Code.

Given its rulings of no breaches of the Code, the Panel did not consider that Amgen had failed to maintain high standards and therefore ruled no breach of the Code.

A complainant who described him/herself as a concerned UK health professional, complained about the online promotion of Repatha (evolocumab) by Amgen Ltd. The material at issue was the repatha.co.uk website (ref UKIE-P-145-1219-080354).

Repatha was a lipid-lowering therapy for use in certain patients with primary hypercholesterolaemia, mixed dyslipidaemia, homozygous familial hypercholesterolaemia or established atherosclerotic cardiovascular disease.

COMPLAINT

The complainant stated that there was no 'pop-up' or separate page to ensure that the site could only be seen by health professionals. As such, the complainant alleged that the website promoted Repatha to the public.

The complainant referred to a page of the website (Practical information to help you make your prescribing decisions; link provided) and noted that the following text was displayed: 'Repatha is the first PCSK9i with a licensed indication for the treatment of adults with established CVD[1]'.

The complainant noted that as stated in the summary of product characteristics (SPC) the indications for Repatha were:

> *Hypercholesterolaemia and mixed dyslipidaemia*
>
> Repatha is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:
> • in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin or,
> • alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.
>
> *Homozygous familial hypercholesterolaemia*
>
> Repatha is indicated in adults and adolescents aged 12 years and over with homozygous familial hypercholesterolaemia in combination with other lipid-lowering therapies.
>
> *Established atherosclerotic cardiovascular disease*
>
> Repatha is indicated in adults with established atherosclerotic cardiovascular disease (myocardial infarction, stroke or peripheral arterial disease) to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors:
>
> • in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or,
> • alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin was contraindicated.

The complainant alleged that the description given by Amgen was far too broad and vague and alleged that the company was promoting Repatha off-licence since physicians would not know that there were several caveats to its use.

When writing to Amgen, the Authority asked it to consider the requirements of Clauses 3.2, 9.1 and 26.1 of the Code.

RESPONSE

Amgen had examined the issues raised by the complainant and submitted that Amgen's website (https://www.repatha.co.uk) was entirely consistent with the ABPI Code.

With regard to access, Amgen noted that upon landing on the Repatha.co.uk website, the user was presented with three clear separate navigation options according to whether they were a health professional, a Repatha patient or a member of the UK general public (screenshot provided).

When clicked, each of these separate navigation options linked to a separate website designed specifically for that target audience, in compliance with the Code. Amgen noted that at the start of each new browsing session, it was not possible to navigate directly to any of the health professional, patient or general public websites without first being presented with this landing page and the navigation options. To assist the user in selecting the correct website there were explanatory statements above the health professional and Repatha patient links. Above the health professional link the statement read: 'This site is for use in the United Kingdom only. By clicking to enter this site you are confirming that you are a UK Health Professional'. Above the patient link the statement read: 'This site is intended for UK Repatha patients. By clicking to enter this website you are confirming that you are a Repatha patient in the UK who has been prescribed Repatha.' Amgen submitted that the guidance displayed on this landing page was undoubtedly clear and unambiguous. Furthermore, there was no product branding or promotion of Repatha on the landing page.

Amgen explained that once the user had entered the health professional site, all pages within that site carried a banner at the bottom of the page which stated: 'This website is developed and funded by Amgen Limited and intended for UK healthcare professionals only' (a screenshot was provided).

Once users clicked on the navigation link to enter the site designed for Repatha patients, that website contained pages on the following topics all of which were entirely appropriate for those who had been prescribed Repatha: Understanding cholesterol, About Repatha (evolocumab), How to use Repatha Sureclick, Side effects, Homecare, FAQs and Patient information leaflet. By clicking on any of those options patients were not taken into the any of the pages within the health professional website.

If users clicked on the navigation link to enter the site designed for members of the UK public, the pages within that site would not take them to any of the health professional or Repatha patient pages. The UK public site provided users with information about Amgen as a company; it did not contain any promotional information regarding Repatha.

Amgen stated that, based on the above, the website build and landing page were therefore consistent with the requirements set out in the supplementary information of Clause 28.1 which stated:

> 'Unless access to promotional material about prescription only medicines is limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This is to avoid the public needing to access material for health professionals unless they choose to. The MHRA Blue Guide states that the public should not be encouraged to access material which is not intended for them.'

Amgen denied a breach of Clause 26.1 which prohibited advertising of prescription only medicines to the public.

Amgen noted that the claim cited by the complainant, 'Repatha is the first PCSK9i with a licensed indication for the treatment of adults with established CVD1', appeared on the 'Repatha in practice' page if the user clicked on '2018' within the timeline bar towards the bottom of the page beneath the heading 'Amgen as a forerunner in PCSK9 innovation' (screenshot provided). Amgen noted the complainant's allegation that the claim (the 2018 quotation) was too broad and vague and that Amgen had promoted off-label since physicians would not know there were several caveats to the use of Repatha. Amgen did not accept there was any merit to the complainant's allegations because:

a) When health professionals landed on the 'Repatha in practice' page, the timeline presented at the bottom of the page automatically defaulted to the 2003 timeline quotation (Role of PCSK9 in LDL [Metabolism] emerges). If health professionals clicked through the different time points listed it was clear that each of these time points merely presented top line key milestones and achievements reached by Amgen in the development of PCSK9, and that the information in the timeline was not intended to present substantive information on the use of Repatha. The 2018 quotation related to when the additional marketing authorization was granted. This was also consistent with Clause 7.5 of the Code (the validity of indications approved in the marketing authorization could be substantiated by provision of the summary of product characteristics).

b) The 2018 quotation was followed by a footnote reference which stated 'Repatha (evolocumab) summary of product characteristics'. The indication stated that Repatha was indicated in adults with established atherosclerotic cardiovascular disease **with or without** other lipid-lowering therapies or; alone or in combination with other lipid-lowering therapies. Therefore this quotation was entirely consistent with the Repatha SPC.

c) Situated further up on the same page as the 2018 quotation, the page clearly stated 'Repatha is given together with a statin or other cholesterol-lowering therapy, or without statins if they are not tolerated or contraindicated'. This clearly indicated (before someone read the 2018 quotation) that there were caveats to the use of Repatha (screenshot provided).

d) Furthermore, prescribing physicians commonly looked at the prescribing information on a product, links to the full prescribing information were easily accessible on all pages of the health professional site; with a link visible under the heading 'Legal' in the banner at the bottom of every page (screenshot provided) and a second prescribing information link at the top of every page (depending upon the view this was either located across the top of the page or within the burger menu at the top right hand corner of every page) (screenshots of both views of the link at the top of the pages were provided).

Amgen submitted that when the information which was presented on and accessible from the 'Repatha in practice' page was considered as a whole, it was evident that health professionals were provided with precise and accurate information about the medicine. It was clear that the 2018 quotation was not intended to be read in isolation and Amgen would not expect health professionals to make treatment decisions based on this timeline. Amgen therefore submitted that all information presented on the health professional site, including the 2018 quotation, was in accordance with Clause 3.2.

In relation to both of the complainant's allegations, Amgen considered that it had met Clause 9.1 of the Code and had applied high standards throughout the process of developing all elements of each of the websites aimed at health professionals, patients and members of the public.

Amgen explained that in order to locate the website, users would specifically need to google 'Repatha UK'; a Google search for just 'Repatha' would not lead to the site. Users would not be able to find the Repatha.co.uk website by searching under the term 'cholesterol'.

With regard to cookies, Amgen noted that when users arrived at the website for the first time, they were presented with a cookies notification. Should the cookies be accepted and users then navigated to the health professional site, and they subsequently, within the same browsing session, googled 'Repatha UK' the Google search would default back to the health professional site without going via the landing page. However, when the same users started a new browsing session by Googling 'Repatha UK' they would be directed back to the landing page. The same was not, however, true for users who arrived at the website for the first time and selected either the Repatha patient site or the public site. Should those users, within the same browsing session, google 'Repatha UK', the Google search would always default back to the landing page.

Irrespective of previous choices made when arriving at the landing page, when a new browsing session was started, a Google search of 'Repatha UK' would always bring users back to the landing page.

With regard to site navigation, Amgen stated that once users had clicked into the health professional website, from the home page the users were presented with seven tabs across the top of the page with links to the following pages: Repatha in Practice, Safety Profile, Expert Opinion, Patient Profiles, Guidelines & Funding, Knowledge Centre and Prescribing Information.

A copy of the certificate approving the website and details of the signatories were provided.

In summary, Amgen refuted that this website breached Clauses 3.2 or 26.1 of the Code and submitted that it continued to meet the requirements of Clause 9.1 of the Code.

PANEL RULING

With regard to the complainant's allegation that the website promoted Repatha to the public, the Panel noted that the landing page of the Repatha.co.uk website accessed from the link provided by the complainant asked readers to confirm whether they were a UK health professional, a Repatha patient in the UK or a member of the UK public and above the health professional link the statement read: 'This site is for use in the United Kingdom only. By clicking to enter this site you are confirming that you are a UK Healthcare Professional'. The Panel noted Amgen's submission that when clicked, each of the three separate navigation options linked to a separate website designed specifically for that target audience. The Panel noted Amgen's submission that once the user had entered the health professional site, all pages within that site carried a banner at the bottom of the page which stated: 'This website is developed and funded by Amgen Limited and intended for UK healthcare professionals only'.

The Panel noted Amgen's explanation that in order to locate the Repatha.co.uk website, users would specifically need to google 'Repatha UK'; a Google search for just 'Repatha' or the term

'cholesterol' would not lead to the site. The Panel noted Amgen's explanation that when users arrived at the website for the first time, accepted cookies and navigated to the health professional site, and then subsequently, within the same browsing session, googled 'Repatha UK' the search would default back to the health professional site without going via the landing page. The Panel, however, noted Amgen's submission that irrespective of previous choices made when arriving at the landing page, when a new browsing session was started, a Google search of 'Repatha UK' would always bring users back to the landing page; it would not be possible to navigate directly to any of the health professional, patient or general public websites without first being presented with this landing page and the navigation options.

The Panel noted the arrangements for the landing page as described by Amgen and that when the case preparation manager had accessed the link from the complainant's email, the case preparation manager had been taken to the landing page as described by Amgen. The Panel further noted Amgen's submission that the landing page linked to further material for each target audience. The Panel did not consider that the Repatha.co.uk website promoted prescription only medicines to the public as alleged and no breach of Clause 26.1 was ruled.

The Panel noted that Clause 3.2 stated that the promotion of a medicine must be in accordance with the terms of its marketing authorization and must not be inconsistent with the particulars listed in its summary of product characteristics.

The Panel noted that the claim at issue 'Repatha is the first PCSK9i with a licensed indication for the treatment of adults with established CVD' appeared on the 'Repatha in practice' page if the user clicked on '2018' within the timeline bar towards the bottom of the page beneath the heading 'Amgen as a forerunner in PCSK9 innovation'.

The Panel noted Amgen's submission that when health professionals landed on the 'Repatha in practice' page, the timeline presented at the bottom of the page automatically defaulted to the 2003 timeline quotation (Role of PCSK9 in LDL Metabolism emerges); the different points on the timeline presented top line key milestones and achievements reached by Amgen in the development of PCSK9 and the information was not intended to present substantive information on the use of Repatha. The 2018 quotation related to when the additional marketing authorization was granted. The Panel further noted Amgen's submission that before the 2018 quotation, and within the same webpage, it stated 'Repatha is given together with a statin or other cholesterol-lowering therapy, or without statins if they are not tolerated or contraindicated'.

The Panel did not consider that the claim 'Repatha is the first PCSK9i with a licensed indication for the treatment of adults with established CVD', within the context of the key milestones timeline and the other information on the webpage at issue, was inconsistent with the Repatha SPC. The Panel therefore ruled no breach of Clause 3.2.

Given its rulings of no breaches of the Code, the Panel did not consider that Amgen had failed to maintain high standards and therefore ruled no breach of Clause 9.1.

Complaint received **10 September 2020**

Case completed **29 January 2021**