CASE AUTH/3464/1/21

COMPLAINANT v NOVARTIS

Beovu video

A named contactable complainant, who described him/herself as a healthcare practitioner and wished to remain anonymous, complained about the promotion of Beovu (brolucizumab) by Novartis Pharmaceuticals UK Limited. The material at issue was a video of a health professional discussing his early experiences with Beovu; the video titled 'First experience in [country]: Patient cases and implementation' was available on a promotional Beovu website.

Beovu was presented as a pre-filled syringe for intravitreal injection, for use in adults for the treatment of neovascular (wet) age-related macular degeneration (nAMD).

The complainant explained that in July 2020, he/she had remotely attended a Novartis meeting about Beovu. One of the presenters discussed his/her experience with the medicine which included stressing the need for caution after the reports from the US of retinal vasculitis and occlusions post Beovu use which had emerged in February 2020.

The complainant stated that in the December/January 2021 issue of Eye News, Novartis had an advertisement with a QR code linking to a Novartis website which included a link to the presentation.

The complainant submitted that if the material was viewed, one would see all the positive aspects of the presentation but then at the end it just faded out; the complainant alleged that Novartis had purposefully cut out the 'negative' parts. The wider UK ophthalmology audience accessing the site, having not seen the original full presentation, would be misled by this blatant editing designed to alter the presenter's view; all balance had been lost and the complainant regarded it as blatant misrepresentation.

The detailed response from Novartis is given below.

The Panel noted that the original live webinar in July 2020 was entitled 'Experience sharing with Beovu (brolucizumab). An innovation in the treatment of Wet AMD Webinar'. The webinar lasted just over an hour and included three presentations and a Q&A session at the end; the presentation 'Beovu: patient cases and implementation in [country]', lasted about 22 minutes during which the presenter shared his/her experience of treating patients with Beovu and discussed a series of case studies.

The Panel noted that the presenter made a number of positive comments about his/her clinical experience with Beovu including describing the very positive effects seen in a patient 2 weeks after an injection. The Panel noted that at the end of the presentation, within a section titled 'What are we doing now? July 2020', the presenter referred to what was being done based on the discussions of intraocular inflammation and that clinicians needed to be aware of the relevant data that was available. In that regard, he/she

cautioned that he/she would not treat eyes which previously had uveitis or 'better seeing eye conditions' and explained that in his/her country controls were put in place at two weeks after an injection to rule out any signs of inflammation/endophthalmitis which would be treated accordingly. At that point another presenter took over the webinar. At the end of the webinar, in a Q&A session, the presenter was asked whether in the 47 patients he/she had treated, had there been an increase in intraocular inflammation; the presenter stated that he/she had not noticed an increase but that intraocular inflammation needed to be taken seriously and that clinicians particularly needed to look for signs of it.

The Panel noted that according to the Beovu SPC (date of revision of the text 14 October 2020), Section 4.2 stated that the recommended dose was 6mg brolucizumab (0.05ml solution) administered by intravitreal injection every 4 weeks (monthly) for the first 3 doses. Thereafter, the physician might individualise treatment intervals based on disease activity as assessed by visual acuity and/or anatomical parameters. The Panel further noted that Section 4.4 Special warnings and precautions for use stated 'Intravitreal injections, including those with Beovu, have been associated with endophthalmitis, intraocular inflammation, traumatic cataract and retinal detachment (see section 4.8). Proper aseptic injection techniques must always be used when administering Beovu. Retinal vasculitis and/or retinal vascular occlusion, typically in the presence of intraocular inflammation, have been reported with the use of Beovu (see sections 4.3 and 4.8). In patients developing these events, treatment with Beovu should be discontinued and the events should be promptly managed. Patients should be instructed to report any symptoms suggestive of the above-mentioned events without delay'. The Panel noted Novartis' submission that when the webinar took place (July 2020) this safety signal had not been incorporated into the SPC but had been included by the time the website containing the video was created (November 2020).

The Panel noted Novartis' submission that the live webinar initially seen by the complainant and the video available on the website were two different activities. Novartis explained that it did not provide any on-demand access to the webinar but that it had produced an excerpt of the webinar, resulting in the video, which formed part of the promotional Beovu website it had created separately. The Panel noted Novartis' submission that that website was the relevant standalone promotional material against which compliance with the Code should be assessed and that the edited video (certified in November 2020) was not intended to be viewed in isolation or as a standalone item and could only be viewed as part of the broader website in its entirety which included directions to the prescribing and safety information.

The Panel noted that the Code did not prohibit extracts of recorded promotional presentations being included in other promotional material, such as on a website, provided that it complied with the Code.

The Panel noted that an email from Novartis to the presenter in October 2020 stated 'Following your talk at the UK Beovu webinar in July we have had a number of clinicians ask us if they could watch the Beovu webinar as they could not make the live event. As you know we recorded the webinar for the purpose of sharing with clinicians. Please could we kindly request your permission to share the recording both by email and on our Beovu UK website, this is a closed website only available to HCPs. We have reviewed the videos and edited in line with the code'. It appeared to the Panel that, contrary to

Novartis' email to the presenter, the website did not provide on-demand access to the July 2020 webinar *per se*, rather it featured edited extracts from that webinar in the form of individual videos from each of the speakers which formed part of the broader promotional website. There was no video of the Q&A section from the webinar. Nonetheless, the presenter was sent a link to the video for review to which he replied, 'OK from my side'.

The Panel noted that readers were directed to the promotional website via a QR code in a Beovu journal advertisement. On the landing page of the website within a section titled 'Beovu (brolucizumab): on-demand webinars', was the video in question described as: '…[full name and place of practice] provides valuable insights into how Beovu is being used in clinics in [country] and early treatment outcomes in patients'. The video was an edited version of the original presentation delivered at the July 2020 webinar. The Panel noted that a statement at the bottom of the opening slide of the video read, 'This promotional meeting was organised and funded by Novartis UK'. It was thus apparent that the recording had come from a presentation at a Novartis promotional meeting. The presenter's positive comments about Beovu including in relation to patient case studies presented at the July 2020 webinar were retained in the edited video on the promotional website, including the case study where he/she referred to the positive effects on a patient after 2 weeks. There was, however, contrary to the description of the video and reference to 'implementation' in the title, not all of the information as to how Beovu was being used in clinical practice for example, that the presenter put controls/checks in two weeks after Beovu injections to look for any signs of intraocular inflammation had been omitted from the video.

The Panel noted Novartis' submission that during the production of the webinar in July 2020, Novartis acknowledged the need to proactively communicate safety information and it was included in the Q&A section. Novartis submitted, however, that technically it could not know at that time what information would be included in the SPC and discussions based on the personal opinions of health professionals prior to the definitive inclusion of the safety information in the SPC were edited out to reduce the risk of any potential information being shared that was inconsistent with the final wording within the SPC. In that regard, the Panel further noted Novartis' submission that the safety signal had been incorporated into the SPC by the time the website was created and was in Novartis' view appropriately incorporated into the website.

The Panel queried whether all of the information that had been edited from the July 2020 presentation needed to be removed when creating the video to comply with the Code. In the Panel's view, information related to the presenter's clinical practice of managing the risk of intraocular inflammation gave a balanced view of his/her early experience of using Beovu and put his/her presented case reports into context.

The Panel noted its comments above and considered that focusing on the presenter's experience of the positive effects of Beovu without including his caution in relation to intraocular inflammation within a video about his/her first experiences and implementation of Beovu was thus misleading. Novartis had failed to maintain high standards and breaches of the Code were ruled.

In the Panel's view, the video at issue was not a quotation as such and thus it ruled no breach of the Code in this regard.

A named contactable complainant, who described him/herself as a healthcare practitioner and wished to remain anonymous, complained about the promotion of Beovu (brolucizumab) by Novartis Pharmaceuticals UK Limited. The material at issue was a video of a health professional discussing his early experiences with Beovu; the video titled 'First experience in [country]: Patient cases and implementation' was available on a promotional Beovu website.

Beovu was presented as a pre-filled syringe for intravitreal injection, for use in adults for the treatment of neovascular (wet) age-related macular degeneration (nAMD).

COMPLAINT

The complainant explained that in July 2020, he/she had remotely attended a Novartis meeting about Beovu. One of the presenters, discussed his/her early experience with the medicine. The complainant remembered that presentation quite clearly as the presenter was very well balanced. The presenter was very impressed by the medicine's performance but what really stuck in the complainant's mind was that he/she was very keen to stress the abundance of caution with which he/she was proceeding when using Beovu after the reports from the US of retinal vasculitis and occlusions post Beovu use which had emerged in February 2020.

The complainant stated that in the December/January 2021 issue of Eye News, Novartis had a full-page advertisement with a QR code linking to a page (link provided) on a Novartis website which included a link to the presentation given in July 2020.

The complainant submitted that if the material was viewed, one would see all the positive aspects of the presentation but then at the end it just faded out; the complainant alleged that Novartis had purposefully cut out the 'negative' parts. The complainant considered that the wider UK ophthalmology audience accessing the site, having not seen the original full presentation, would be misled by this blatant editing designed to alter the view the presenter had given; all balance had been lost and the complainant regarded it as blatant misrepresentation.

When writing to Novartis, the Authority asked it to consider the requirements of Clauses 7.2, 9.1 and 10.2 of the Code.

RESPONSE

Novartis stated that it was very concerned to have received the complaint, and it took the complainant's allegations very seriously; the company was committed to operating in accordance with the required standards and meeting the relevant requirements and expectations.

Novartis noted that the complainant had attended a live Novartis webinar in July 2020 which involved, in part, a presentation from a health professional, discussing his/her early experiences with Beovu. The complainant asserted that the webinar was not shown in full in the video which formed part of a Novartis promotional Beovu website and that, therefore, important and relevant information was deliberately omitted by Novartis.

Novartis submitted, however, that the webinar initially seen by the complainant and the video were two different activities. Novartis did not provide any on-demand access to the webinar. Novartis had produced an excerpt of the webinar, resulting in the video, which formed part of

the website. Therefore, the website was the relevant standalone promotional piece/site against which compliance with the Code should be assessed.

Novartis explained that the webinar with the presenter named by the complainant, along with presentations from other health professionals, was held in July 2020 and that it had separately created the promotional Beovu website which included:

- information on how Beovu worked, including a clear link to the prescribing information
- visual acuity and anatomical outcomes
- treatment intervals and clinical trial information
- safety information and
- a series of videos on Beovu which included the presentation from the webinar by the presenter named by the complainant, modified to ensure compliance with the Code.

The video (a link to the video together with a transcript was provided) was available to view on the website. It had never been intended to be viewed in isolation or as a standalone item and had been certified accordingly; the video could only be viewed as part of the broader website in its entirety.

Novartis refuted any breach of Clause 7.2 as the information provided in the video was accurate, balanced and objective because:

i) the video was hosted within the website, and could not be used as a standalone item
ii) the QR code did not direct to the video directly; it directed users to the website landing page which provided all necessary information as listed above
iii) the video was an appropriate representation of the information presented in the webinar.

Novartis submitted that the website should be viewed in its entirety – as one would similarly view a leavepiece – and every effort had been taken to ensure that the website was fair, balanced and sufficiently complete. The information available on the website, as identified above, included and signposted clearly to the prescribing and safety information. In addition, any promotional advertisement took users to the website landing page and not directly to the video. The video was never intended to be used standalone; it was part of the website, which in its entirety, should be viewed as a standalone item.

Novartis stated that the review and certification of the video (copy provided) demonstrated the proposed use of the video. The webinar was not appropriate to sit as an on-demand piece, hence the editing to produce the video, and the website taken in its entirety provided appropriate context for the video with which users might draw their own informed conclusions based on scientifically accurate information.

Novartis noted that the complainant had incorrectly asserted that the QR code led directly to the section of the website with the embedded videos. The QR code led to the landing page of the website and users then had to confirm that they were health professionals before accessing the site (the advertisement in Eye News, where the QR code had been cited, was provided). At that stage, users had access to the full content of the website, including relevant prescribing and safety information (a screenshot of the website landing page was provided). It was not possible

to access the video directly from any links provided on advertising (including copying the link and pasting it into a new browser). In addition, the on-demand webinars were clearly visible and accessible from the website landing page.

Novartis noted that the webinar (a link to the original webinar, together with the transcript for the same, was provided), recorded in July 2020, contained, as the complainant stated, more information than was presented in the video. However, during the editing of the video, sections including personal opinions were removed to ensure the website (and its content) complied with the Code. Novartis disagreed with the allegation that the safety discussion present in the webinar was removed deliberately to mislead because:

- The presenter did not have any patient cases with adverse events and therefore a substantive discussion on safety did not occur during his presentation
- the webinar contained a Q&A section, where a wider safety discussion ensued, based on other published reports. None of the speakers, including the presenter named by the complainant, had any cases to highlight as they had not experienced a safety event themselves. Therefore, this was not included on the website due to challenges with substantiating and/or referencing some of the physicians' discussion.

Novartis also noted that when the webinar took place the safety signal had not been incorporated into the summary of product characteristics (SPC) but had been included by the time the website was created. During the production of the webinar, Novartis acknowledged the need to proactively communicate safety information; therefore this was included in the Q&A section. However, technically, Novartis could not know at that time what information would be included in the label. However, once the information was included in the SPC, it was appropriately incorporated into the website. Discussions based on opinions of health professionals prior to the definitive inclusion of the safety information in the SPC were edited out to reduce the risk of any potential information being shared that was inconsistent with the final wording within the SPC.

Accordingly, Novartis submitted that there was no breach of Clause 7.2 as the video complied with the Code in the information presented and the claims made. This was further supported by the reasons put forward below.

Novartis refuted the complainant's allegation that it had misrepresented the presenter's participation in the webinar and noted that the presenter confirmed his/her acceptance to the video in its current form.

On engaging the presenter to record his section of the webinar, the contract (redacted copy provided) permitted Novartis to use the content. Novartis, however, recognised the potential issue in editing the webinar as stated above, particularly as about 6 months had passed since the webinar was delivered, and therefore sought the consent and confirmation of the presenter prior to using the video (copy provided). Novartis noted the date of that confirmation, 27 November 2020, which also coincided with the publication date of the website; Novartis sought confirmation from the presenter that the views in the video were indeed attributable and contemporaneous to him/her as of November 2020. Novartis thus rejected any breach of Clause 10.2.

Novartis also refuted any breach of Clause 9.1; it sought to operate at the highest standards and in making available the webinar 'on demand', in this case as the video, it had sought to

comply with the Code at every juncture. Such compliance included verifying the contemporaneous views of the health professional before publication and providing substantiated information in conjunction with the appropriate prescribing information.

Notwithstanding the above, Novartis recognised that there were areas that could benefit from further clarification. Novartis acknowledged that the complainant had recognised a disparity in what was seen in the webinar and what it subsequently made available on the website. Therefore to make that clear on the landing page of the website, Novartis would:

i) display a clarifying statement that such material might be derived from larger webinars, and that such material was consistent with, and a fair representation of comments made when the initial webinar(s) was made, published and/or broadcast
ii) highlight that efficacy and safety information was available on the website and ensure that appropriate links were in place.

In summary, the complainant alleged misrepresentation on the part of Novartis in the promotion of the website and in relation to the contents thereof. However, Novartis believed that there was a valid case to refute the alleged breaches of Clauses 7.2, 9.1 and 10.2.

In response to a request for further information, Novartis provided an accurate copy of the webinar transcript detailing those parts of the webinar presentation that were included within the video in question.

PANEL RULING

The Panel noted that the original live webinar in July 2020 was entitled 'Experience sharing with Beovu (brolucizumab). An innovation in the treatment of Wet AMD Webinar'. The webinar lasted just over an hour and included three presentations and a Q&A session at the end; the presentation delivered by the health professional named by the complainant, the subject of which was described on the agenda as 'Beovu: patient cases and implementation in [country]', lasted about 22 minutes during which the presenter shared his experience of treating patients with Beovu and discussed a series of case studies.

The Panel noted that during the live webinar presentation, the presenter made a number of positive comments about his/her clinical experience with Beovu including describing the very positive effects seen in a patient 2 weeks after an injection. The Panel noted that at the end of his webinar presentation, within a section titled 'What are we doing now? July 2020', the presenter referred to what was being done based on the discussions of intraocular inflammation and that clinicians needed to be aware of the relevant data that was available. In that regard, he/she cautioned that he would not treat eyes which previously had uveitis or 'better seeing eye conditions' and explained that controls were put in place in his/her country at two weeks after an injection to rule out any signs of inflammation/endophthalmitis which would be treated accordingly. At that point the presenter handed over to another speaker to talk about experience in another country. At the end of the webinar, in a Q&A session, the presenter was asked whether in the 47 patients he/she had treated, he/she had noticed an increase in intraocular inflammation. The reply was that he/she had not but that intraocular inflammation needed to be taken seriously and that clinicians particularly needed to look for signs of it.

The Panel noted that according to the Beovu SPC (date of revision of the text 14 October 2020), Section 4.2 stated that the recommended dose was 6mg brolucizumab (0.05ml solution) administered by intravitreal injection every 4 weeks (monthly) for the first 3 doses. Thereafter, the physician might individualise treatment intervals based on disease activity as assessed by visual acuity and/or anatomical parameters. The Panel further noted that Section 4.4 Special warnings and precautions for use stated 'Intravitreal injections, including those with Beovu, have been associated with endophthalmitis, intraocular inflammation, traumatic cataract and retinal detachment (see section 4.8). Proper aseptic injection techniques must always be used when administering Beovu. Retinal vasculitis and/or retinal vascular occlusion, typically in the presence of intraocular inflammation, have been reported with the use of Beovu (see sections 4.3 and 4.8). In patients developing these events, treatment with Beovu should be discontinued and the events should be promptly managed. Patients should be instructed to report any symptoms suggestive of the above-mentioned events without delay'. The Panel noted Novartis' submission that when the webinar took place (July 2020) this safety signal had not been incorporated into the SPC but had been included by the time the website was created (November 2020).

The Panel noted Novartis' submission that the live webinar initially seen by the complainant and the video available on the website were two different activities. Novartis explained that on engaging the presenter to record his/her section of the July 2020 webinar, the contract permitted Novartis to use the content. Novartis explained that it did not provide any on-demand access to the webinar but that it had produced an excerpt of the webinar, resulting in the video, which formed part of the promotional Beovu website it had created separately. The Panel noted Novartis' submission that that website was the relevant standalone promotional material against which compliance with the Code should be assessed and that the edited video (certified in November 2020) was not intended to be viewed in isolation or as a standalone item and could only be viewed as part of the broader website in its entirety which included directions to the prescribing and safety information.

The Panel noted that the Code did not prohibit extracts of recorded promotional presentations being included in other promotional material, such as on a website, provided that it complied with the Code.

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The Panel noted that readers were directed to the promotional website via a QR code in a Beovu journal advertisement. On the landing page of the website within a section titled 'Beovu (brolucizumab): on-demand webinars', was the video in question described as: '[full name and place of practice] provides valuable insights into how Beovu is being used in clinics in [named

country] and early treatment outcomes in patients'. The video was an edited version of the original presentation at the July 2020 webinar and lasted just 8 minutes. The video was entitled 'First experience in [named country]: Patient cases and implementation' although the second slide of the video carried the title 'First treatments using brolucizumab "Is it all the same?"'. The Panel noted that a statement at the bottom of the opening slide of the video read, 'This promotional meeting was organised and funded by Novartis UK'. It was thus apparent that the recording had come from a presentation at a Novartis promotional meeting. The presenter's positive comments about Beovu including in relation to patient case studies presented at the July 2020 webinar were retained in the edited video on the promotional website, including the case study where he referred to the positive effects on a patient after 2 weeks. There was, however, contrary to the description of the video and reference to 'implementation' in the title, not all of the information as to how Beovu was being used in clinical practice; for example, that the presenter put controls/checks in two weeks after Beovu injections to look for any signs of intraocular inflammation had been omitted from the video.

The Panel noted Novartis' submission that during the production of the webinar in July 2020, Novartis acknowledged the need to proactively communicate safety information and it was included in the Q&A section. Novartis submitted, however, that technically it could not know at that time what information would be included in the SPC and discussions based on the personal opinions of health professionals prior to the definitive inclusion of the safety information in the SPC were edited out to reduce the risk of any potential information being shared that was inconsistent with the final wording within the SPC. In that regard, the Panel further noted Novartis' submission that the safety signal had been incorporated into the SPC by the time the website was created and was in Novartis' view appropriately incorporated into the website.

The Panel queried whether all of the information that had been edited from the July 2020 presentation needed to be removed when creating the video to comply with the Code. In the Panel's view, information related to the presenter's clinical practice of managing the risk of intraocular inflammation gave a balanced view of his/her early experience of using Beovu and put the presented case reports into context.

The Panel noted its comments above and considered that focusing on the presenter's experience of the positive effects of Beovu without including his/her caution in relation to intraocular inflammation within a video about his/her first experiences and implementation of Beovu was thus misleading and a breach of Clause 7.2 was ruled.

The Panel noted that Clause 10.2 required that the use of quotations from medical and scientific literature or from personal communications be faithfully reproduced, must accurately reflect the meaning of the author and that the precise source of the quotation must be identified. In the Panel's view, the video at issue was not a quotation as such and thus Clause 10.2 was not relevant and therefore no breach was ruled.

The Panel noted its comments and rulings above and considered that Novartis had failed to maintain high standards and a breach of Clause 9.1 was ruled.

Complaint received **26 January 2021**

Case completed **5 August 2021**