CASE AUTH/3552/8/21

ANONYMOUS HEALTH PROFESSIONAL v ROCHE

Roches resources website mobile version

An anonymous complainant, who described him/herself as a health professional complained about the mobile version of the Roche Resources website, https://www.rocheresources.co.uk.

The complainant alleged that the Roche Resources website had not been certified for mobile use and had clear and obvious differences versus the desktop format of the website.

The complainant further alleged that a prominent prescribing information statement was not available on the mobile version of the webpage and both desktop and mobile versions of the webpage did [not] contain a prominent adverse events statement.

The complainant stated that similar issues were present on the medicines page (https://www.rocheresources.co.uk/roche-medicines.html).

The complainant stated that the company showed a lax knowledge and understanding of certification and important requirements in following principles and alleged a breach of Clause 2.

The complainant was concerned that a Polivy webpage, claimed that the medicine was recommended by NICE and SMC which was misleading as NICE and SMC recommended it as an option only if polatuzumab vedotin was provided according to the commercial arrangement. In addition, the claim 'time to appreciate life' was not appropriate as the medicine would require much monitoring, several treatment cycles and had an array of adverse events; it was difficult to understand how a patient could appreciate life with all these factors. The complainant stated that women of childbearing potential should be advised to use effective contraception during treatment with polatuzumab vedotin and for at least 9 months after the last dose. This should have been made clear on the page in view of the image presented which included a young woman.

The detailed response from Roche is given below.

The Panel noted Roche's submission that the Roche Resources website was designed primarily for desktop or laptop computer use and as such was certified on a desktop or laptop computer, with additional checks being performed to ensure all mandatory information, including prescribing information, was prominent on other devices such as an iPad. The Panel further noted Roche's submission that the technology sitting behind the website optimised the statement in question 'Welcome to Roche Resources - access information, news and resources about our medicines and the therapy areas in which they are used' to appear differently on certain mobile devices, however, the context of

the text and nature of the material was the same regardless of the make or model of device, size or orientation on screen.

The Panel noted Roche's submission that on certain mobile devices, the prescribing information link would automatically move to sit in a hamburger menu. The Panel considered that the presentation of a prescribing information link within a hamburger menu did not meet the Code's requirement for a clear prominent statement as to where the prescribing information could be found and a breach of the Code was ruled as acknowledged by Roche in relation to the homepage and medicines page.

Whilst the Panel noted Roche's submission that the website was certified on a computer, with additional checks being performed on other devices such as an iPad, Roche made no submission with regard to checks being performed on any specific smartphones. The Panel noted that the certificates of the job bags for the homepage and medicines webpages (M-GB-00001886 and -GB-00003975) made no mention of the devices that the signatory had reviewed the website on and which devices he/she had performed additional checks to ensure that the requirements of the Code were met; there did not appear to be mention of any device, such as a smartphone or iPad in the metadata. In its response, Roche had only provided a screenshot of how the website was visible on an iPhone 11; the Panel noted that the prescribing information link was not immediately visible and sat within the hamburger menu when viewed in the most likely orientation, portrait. The Panel further noted that, whilst Roche submitted that the website was primarily intended to be viewed from a desktop or laptop computer, there did not appear to be a statement to this effect on the website.

The Panel, on the evidence before it, considered that it appeared that Roche had not adequately reviewed the website on various, commonly used devices to ensure that it met the requirements of the Code when displayed on such devices and considered that if the website was designed primarily for desktop view, that this should have been made clear to readers. The Panel thus ruled a breaches of the Code including that high standards had not been maintained.

The Panel noted Roche's submission that the prescribing information remained available, albeit from a hamburger menu icon. The Panel considered that a robust certification procedure underpinned self-regulation and although noting its comments and ruling above, it did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2, which was a sign of particular censure and was reserved for such use; no breach was ruled.

The Panel noted Roche's submission that a link to adverse event reporting was at the top of all pages when viewed on the majority of devices including desktop computers; the adverse event reporting link, however, was automatically moved into the hamburger menu when viewed on certain mobile devices. Whilst the Panel noted that in its view, a link to adverse event reporting, regardless of its prominence, did not meet the requirements of the Code that all promotional material must include the prominent statement 'Adverse events should be reported. Reporting forms and information can be found at [website address which links directly to the MHRA Yellow Card site]. Adverse events should also be reported to [relevant pharmaceutical company]', it noted Roche's further submission that an adverse event reporting statement was available on all Roche Resources pages and could be viewed regardless of make or model of device, size or

orientation of screen; it was located at the bottom of the page on a banner of darker colour to the background of the rest of the webpage. The Panel noted that the text was in the footer of the webpage, in smaller font size than the text in the main body of the webpage, and, in the Panel's view, was not sufficiently prominent regardless of device and a breach of the Code was ruled in relation to the homepage and medicines page.

Polivy webpage

The Panel noted Roche's submission that the claim 'time to appreciate life' implied that patients prescribed polatuzumab vedotin had the potential to see a longer progression free period, complete response and/or higher chance of overall survival and therefore more time to appreciate life. The Panel noted Roche's submission that the pivotal randomised data that supported the grant of a conditional marketing authorisation demonstrated a significant improvement in overall survival, progression free survival and complete response in those patients administered polatuzumab vedotin, rituximab and bendamustine vs those administered rituximab plus bendamustine. Beneath the Efficacy rectangular tab below the image and claim in question the material stated 'Find out how POLIVY + R-Benda could offer patients more time to appreciate life vs R-Benda alone'.

The Panel did not consider based on the evidence provided that the claim 'time to appreciate life', implied that the patient's life would be free of monitoring, treatment cycles, or risk of adverse events as alleged and based on the narrow allegation ruled no breaches of the Code including no breach of Clause 2.

With regard to allegation that the image was not of a high standard, as it included a woman of childbearing potential and it should have been made clear on the page that such women be advised to use effective contraception during treatment with polatuzumab vedotin and for at least 9 months after the last dose, the Panel noted Roche's submission that the image depicted a scene of a woman (approximately 60 to 70 years of age) appearing to be calmly reflecting and appreciating life whilst an active family were enjoying themselves in the background. The Panel nonetheless considered that DLBLC could occur at any age and therefore the presence of other individuals within the image, including the young adult woman, was not irrelevant.

The Panel noted that Polivy was not contraindicated in women of childbearing potential. However, the SPC included that women of childbearing potential should be advised to use effective contraception during treatment with Polivy and for at least 9 months after the last dose and that male patients with female partners of childbearing potential should be advised to use effective contraception during treatment with Polivy and for at least 6 months after the last dose.

Section 4.4 of the Polivy SPC (special warnings and precautions for use) included a number of warnings and precautions, which covered a number of different clinical issues across a wide demographic.

The Panel considered that whether a special warning or precaution needed to be highlighted within a particular section of promotional material, in addition to its requirement to be included within the prescribing information depended on all of the

circumstances including the nature of the warning/precaution and the content, layout, audience and intended use of the material.

The Panel noted that Polivy was a specialist product only to be administered under the supervision of a healthcare professional experienced in the diagnosis and treatment of cancer patients. The Panel considered that such health professionals would take particular care when prescribing oncology medicines to women of childbearing potential. Nonetheless, the Panel considered that material must not be misleading in this regard.

The Panel, on balance, did not consider that the image misleadingly implied that Polivy could be used in women of childbearing potential without any concerns or considerations. The Panel did not consider that the complainant had established that high standards had not been maintained nor that the special nature of medicines or the professional nature of the audience had not been respected or that it had caused offence and based on the very narrow allegation no breaches of the Code were ruled.

In relation to the allegation that the claim 'Recommended by NICE and SMC' on the Polivy webpage was a false endorsement, the Panel noted that the claim was immediately above the statement 'POLIVY + R-Benda [rituximab and bendamustine] is indicated for the treatment of adult patients with relapsed/refractory diffuse large B-cell lymphoma who are not candidates for haematopoietic stem cell transplant'.

The Panel noted that the NICE recommendation stated 'Polatuzumab vedotin with rituximab and bendamustine is recommended, within its marketing authorisation, as an option for treating relapsed or refractory diffuse large B-cell lymphoma in adults who cannot have a haematopoietic stem cell transplant. It is recommended only if the company provides polatuzumab vedotin according to the commercial arrangement'.

Similarly, the SMC stated that this advice applied only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that was equivalent or lower. The Panel noted Roche's submission that both recommendations for Polivy by NICE and the SMC were provided on the basis of a simple discount patient access scheme between Roche and the NHS and that the commercial arrangements for Polivy were automatically in place whenever the product was supplied to the NHS.

The Panel considered that whilst it would have been helpful to include the information that Polivy was only recommended if provided according to the commercial arrangement, on the evidence before it, the Panel did not consider that the claim 'Recommended by NICE and SMC' was misleading, incapable of substantiation or did not encourage the rationale use of the medicine as alleged and no breaches of the Code were ruled.

An anonymous complainant, who described him/herself as a health professional and was not contactable on the details provided, complained about the mobile version of the Roche Resources website, https://www.rocheresources.co.uk.

COMPLAINT

The complainant alleged that the Roche Resources website had not been certified for mobile use and had clear and obvious differences versus the desktop format of the website.

The complainant stated that the mobile version of the home page had the text at the top of the page which read 'Roche is transforming, if you are not sure who you should be contacting for your query, please ask us by clicking the link below.' This text had a blue background around it on the mobile phone version but the same homepage on the desktop version did not have any background colour.

The complainant further alleged that a prominent prescribing information statement was not available on the mobile version of the webpage but was available on the desktop version.

Despite the differences of the presentation of the same page between mobile vs desktop, the code appeared to be the same for both mobile and desktop - M-GB-00001886, Date of preparation: October 2020. The complainant alleged a breach of Clause 8.1 of the Code as the format was different between devices with specific colour changes, Clause 12.6 as there was no clear prescribing information statement provided on the mobile version, Clause 5.1 and Clause 2. The complainant alleged that both desktop and mobile versions of this page did [not] contain a prominent adverse events statement in breach of Clause 12.9.

The complainant stated that similar issues were present on the medicines page. On the mobile phone version, the text at the top which read 'welcome to Roche resources - access information, news and resources about our medicines and the therapy areas in which they are used' was presented within a dark blue background on the mobile phone version but the same text was presented in a light blue background on the desktop version. A prominent prescribing information statement was not available on the mobile version of the webpage but was available on desktop version. Despite the differences of the presentation of the same page between mobile vs desktop, the Code appeared to be the same, M-GB-00003975 Date of preparation: June 2021. This seemed a breach of Clause 8.1 as the format was different between devices with specific colour changes, Clause 12.6 as there was no clear prescribing information statement provided on the mobile version and a breach of Clause 5.1 and Clause 2. The complainant alleged that both desktop and mobile versions of this page did [not] contain a prominent adverse events statement in breach of Clause 12.9.

The complainant alleged that none of the mobile phone version pages of any of the website had prominent prescribing information or adverse event reporting resulting in multiple breaches of Clauses 12.6 and 12.9. The complainant queried how the entire website had been allowed for mobile phone release without being uncertified [sic]. The complainant stated that such a well-known company not applying the guidance in the Code showed a lax knowledge and understanding of certification and important requirements in following principles and alleged a breach of Clause 2.

The complainant was concerned that on the Polivy webpage, it was claimed that this medicine was recommended by NICE and SMC directly below the image at the top of the page. The complainant alleged that it was misleading as NICE and SMC recommended it as an option only if polatuzumab vedotin was provided according to the commercial arrangement; this was a clearly false endorsement in breach of Clauses 6.1, 6.2, 5.1 and 14.4. In addition, 'time to appreciate life' was not appropriate as the medicine would require much monitoring, several treatment cycles and had an array of adverse events. The complainant stated that it was difficult to understand how a patient could appreciate life with all these factors in breach of

Clauses 6.1, 6.2, 5.1 and Clause 2. The complainant alleged that the image used for this page was not of a high standard, as there was a dog, a woman seated, a young woman with a water gun and a boy. The complainant stated that women of childbearing potential should be advised to use effective contraception during treatment with polatuzumab vedotin and for at least 9 months after the last dose. This should have been made clear on the page in view of the image presented. The complainant alleged a breach of Clauses 5.1 and 5.2.

When writing to Roche, the Authority asked it to consider the requirements of Clauses 2, 5.1, 5.2, 6.1, 6.2, 8.1, 12.6, 12.9 and 14.4 of the 2021 Code as cited by the complainant.

RESPONSE

Roche reassured the Authority 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.

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

Blue background on mobile device & website/mobile certification

Roche noted that the complainant alleged that the Roche Resources website had not been certified for mobile use as the section of text on the Roche Resources home page (M-GB-00001886), 'Roche is transforming, if you are not sure who you should be contacting for your query, please ask us by clicking the link below' on the mobile version appeared on a blue background yet appeared without the blue background when viewed on a desktop. Similarly on the Roche Medicines page (M-GB-00003975), the text at the top which read 'Welcome to Roche Resources - access information, news and resources about our medicines and the therapy areas in which they are used' was presented within a dark blue background on the mobile phone version but the same text was presented in a light blue background on the desktop version.

Following a robust review of this dynamic content, it had been identified that the different coloured backgrounds only occurred when viewing the page on certain mobile devices.

Roche acknowledged that digital channels were typically designed to be used on a preferred device eg a website for viewing on a desktop/laptop, an app for a Smartphone or tablet. Roche Resources was built on a platform that adjusted the content to dynamically respond to the device the user had chosen to view it on. Roche certified content for the device it was primarily intended for and stipulated as standard practice to ensure that the mandatory information including prescribing information was still prominent on other devices where possible. Roche believed this approach was consistent with Clause 8.1 Supplementary Information regarding certifying dynamic content since the layout could change on different devices, but the context would remain the same.

As a website, Roche Resources had been designed primarily for desktop or laptop computer use and as such was certified on a desktop or laptop computer, with additional checks being performed to ensure all mandatory information, including prescribing information, was prominent on other devices such as an iPad. It had become apparent that the technology sitting behind

the website optimised the aforementioned statement to appear differently on certain mobile devices, the context of the text and nature of the material however, remained the same regardless of the make or model of device, size or orientation on screen. As such Roche denied any breach of Clause 8.1 in that regard.

Furthermore, Roche took its responsibility seriously and was fully committed to operating in an ethical and compliant manner, with full commitment to maintaining high standards. Roche refuted the allegation that this was a circumstance of particular censure and therefore strongly denied a breach of Clause 2.

Prominence of the Prescribing Information statement on certain mobile devices

Roche submitted that it regularly considered, shared, and embedded learnings from recently completed cases. The recently completed and published Case AUTH/3446/12/20 being one example of this which was discussed internally with a group convened to consider implications for any Roche online resources. It was therefore a shame to receive a complaint whilst internally addressing and implementing any learnings from case precedent on a similar matter.

The complainant alleged there was no clear prescribing information statement provided on the mobile version of the Roche Resources website and was therefore a breach of Clause 12.6.

All pages of the Roche Resources website had access to prescribing information both in the navigation menu and in the footer of the page. The claimant had brought to Roche's' attention that on certain mobile devices, the navigation menu where the prescribing information link would ordinarily remain in display on other devices was not always displayed. On these devices, the prescribing information link was automatically moved to sit in a hamburger menu, as such the prescribing information remained available but was regrettably not as prominent as on the primary device for which the website was built. As such Roche did consider this to be a breach of Clause 12.6.

In line with Roche's commitment to patient safety, Roche had taken the decision to take the Roche Resources website offline at this stage to enable a thorough investigation and for any corrective actions to be implemented.

Roche stated that it took its responsibility seriously and was fully committed to operating in an ethical and compliant manner, with full commitment to maintaining high standards and whilst regrettably the navigation menu moves on certain mobile devices, the relevant information was available in a number of places on the site and accessible regardless of make or model of device or size or orientation of screen. In that regard Roche denied a breach of Clauses 5.1 and 2.

Prominence of the AE statement

Roche submitted that an adverse event statement was available on all Roche Resources pages and could be viewed regardless of make or model of device, size or orientation of screen. This was located at the bottom of the page on a banner of darker colour to the background of the rest of the website page and included the necessary mandatory information. As part of Roche's commitment to patient safety, Roche included a link to adverse event reporting at the top of all pages which was visible when viewed on the majority of devices including desktop computers - the primary device for which the website was intended to be used. Regrettably this adverse

event reporting link was automatically moved into the hamburger menu when viewed on certain mobile devices, however, the necessary adverse event reporting information remained in place in the page footer.

Although the prominence of the adverse event statement in the footer could be argued, Roche did accept the perception of the complainant with regards to breaching Clause 12.9 and had taken the decision to amend Roche's website in order to make the adverse event statement more prominent.

Roche stated that it took its responsibility seriously and was fully committed to operating in an ethical and compliant manner, with full commitment to maintaining high standards and whilst regrettably the navigation menu moved on certain devices in certain orientations, the adverse event reporting wording was readily available and clearly legible on all pages regardless of make or model of device or size or orientation of screen. In that regard Roche denied a breach of 5.1 and 2.

Polivy Page - reference to NICE and SMC

Roche noted that on the Polivy (polatuzumab vedotin) Roche Resources page was the statement 'Recommended by NICE and SMC' 'POLIVY + R-Benda is indicated for the treatment of adult patients with relapsed/refractory diffuse large B-cell lymphoma who are not candidates for haematopoietic stem cell transplant'. Both statements were clearly referenced. The statement 'Recommended by NICE and SMC' was referenced to the NICE Final Appraisal Document and the SMC Advice for polatuzumab vedotin which clearly demonstrated the recommendation status of the two bodies. As such this statement was capable of substantiation (provided via a link at the bottom in the material itself) and therefore not in breach of Clause 6.2.

Both recommendations for polatuzumab vedotin by NICE and SMC were indeed provided on the basis of a simple discount patient access scheme between Roche and the NHS. As such the commercial arrangements for polatuzumab vedotin were automatically in place whenever the product was supplied to the NHS. Therefore, the decision to prescribe polatuzumab vedotin in line with the recommendation from NICE and SMC automatically resulted in polatuzumab vedotin being supplied at the price agreed in the commercial arrangement. There was no relevance of the commercial agreement to the clinical decision making required when considering polatuzumab vedotin for a patient in line with NICE/SMC recommendations. Roche considered the statement accurate, not to be misleading and as such, not a false endorsement as claimed by the claimant and therefore not in breach of Clause 6.1. Furthermore, Roche believed that the statement did not include any exaggeration or special merit that could not be substantiated and therefore denied any breach of Clause 14.4. In light of the above, Roche had maintained high standards and therefore also denied a breach of Clause 5.1.

Claim 'Time to appreciate life'

Towards the top of the Roche Resources page for Polivy, alongside the main image was the text 'Time to Appreciate life'. Polatuzumab vedotin was licensed for use in combination with bendamustine and rituximab for the treatment of adult patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) who were not candidates for haematopoietic stem cell transplant. The pivotal randomised data that supported the grant of a conditional marketing authorisation demonstrated a significant improvement in overall survival, progression free survival and complete response in those patients administered polatuzumab vedotin, rituximab

and bendamustine vs those administered rituximab plus bendamustine. This data was shown in the efficacy section of the Polivy Roche Resources page. Follow up of the randomised cohort and an additional extension cohort for this data were also provided which further support these findings. In addition to the efficacy data, the Roche Resources Polivy page included, *inter alia*, safety data and dosing information.

The statement 'Time to appreciate life' implied that patients prescribed polatuzumab vedotin had the potential to see a longer progression free period, complete response and/or higher chance of overall survival and therefore more time to appreciate life, something that could be done through inward reflection at any point. This statement did not imply that their life would be free of monitoring, treatment cycles, or risk of adverse events.

In light of the above, Roche believed that the claim 'Time to appreciate life' was capable of substantiation and was based on robust published data, so therefore denied breaches of Clause 6.1 and 6.2 respectively. Roche also believed it had done so and continued to maintain high standards and that the claim was in no way impacting the importance of patient safety or bringing the industry into disrepute and so denied a breach of Clause 5.1 or Clause 2.
Of note, upon obtaining the marketing authorisation, Polivy materials were to be vetted by the MHRA until the MHRA deemed it suitable that vetting was no longer required. The claim 'Time to appreciate life' was included in the material that was vetted by the MHRA. The MHRA ceased the need to vet materials as of January 2020.

Roche resources page - Polivy image

With regard to the image used on the Roche Resources Polivy page, the image, placed along the top of the page consisted of a woman in her later stages of life, sitting in a chair in a garden on a sunny day wearing a sun hat whilst holding a cup and saucer, smiling in the approximate direction of the camera. Next to the woman was a small barbeque. In the background was a younger woman kneeling on the grass, looking away from the camera actively interacting with a dog, a younger gentleman facing away from the camera exercising on the grass and an older gentleman kneeling on the grass undertaking some light gardening. The image depicted a scene of the woman appearing to be calmly reflecting and appreciating life whilst an active family were enjoying themselves in the background.

The focal point of the image was the inactive woman in the chair, who was in a central position in the image with a clear view of her face. The woman was approximately 60 to 70 years of age and not of childbearing potential. This focal point clearly depicted a representative picture of a typical DLBCL patient, and as such the need to include details of the specific advice for atypical patients including those for women of childbearing age would not be appropriate. Key safety information was provided within the material, the prescribing information and the referenced material, including the SPC. Roche was committed to maintaining high standards and considered the special nature of the products it promoted a privilege and responsibility to maintain. As such Roche strongly denied any breach of Clause 5.1 and 5.2.

Roche stated that it considered that high standards had been maintained and denied any breach of Clause 5.1 and noting that Clause 2 should be reserved for matters of particular censure, would not consider these such circumstances, and so denied a breach of Clause 2.

Of note, Roche also undertook message testing on the above claims and imagery prior to release to understand how the material would be perceived by the target audience. Included in

the findings from that testing were clear indications that the image of the woman depicted a typical DLBCL patient. Furthermore, the claim 'Time to appreciate life' resonated most with the target audience given the data and potential impact on a patient's life following polatuzumab vedotin treatment.

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

PANEL RULING

The Panel noted that whilst the complainant alleged a breach of Clauses 12.6 and 12.9 in relation to every webpage of the website when viewed from a mobile phone, he/she only referred specifically to the homepage and medicines page and so the Panel made its rulings in relation to each of those webpages.

The Panel noted Roche's submission that the Roche Resources website, when viewed on certain mobile devices, appeared on a different coloured background compared to when viewed on a desktop. The Panel further noted Roche's submission that it certified content for the device it was primarily intended for and stipulated as standard practice to ensure that the mandatory information including prescribing information was still prominent on other devices where possible. The Panel noted Roche's submission that the Roche Resources website was designed primarily for desktop or laptop computer use and as such was certified on a desktop or laptop computer, with additional checks being performed to ensure all mandatory information, including prescribing information, was prominent on other devices such as an iPad. The Panel further noted Roche's submission that the technology sitting behind the website optimised the statement in question 'Welcome to Roche Resources - access information, news and resources about our medicines and the therapy areas in which they are used' to appear differently on certain mobile devices, however, the context of the text and nature of the material was the same regardless of the make or model of device, size or orientation on screen.

The Panel noted Roche's submission that on certain mobile devices, the prescribing information link would automatically move to sit in a hamburger menu. Clause 12.6 stated that promotional material provided on the internet must include a clear prominent statement as to where the prescribing information could be found. The Panel considered that the presentation of a prescribing information link within a hamburger menu did not meet the Code's requirement for a clear prominent statement and a breach of Clause 12.6 was ruled as acknowledged by Roche in relation to the homepage and medicines page.

In the Panel's view, the Code did not necessarily require a website to be certified multiple times for each different device it might be viewed upon, however, it considered that the appearance of the material on different devices should be taken into consideration prior to certification to ensure that the content met the requirements of the Code when viewed on each different commonly used type of electronic device, eg desktop, laptop, tablet, smartphone etc.

Whilst the Panel noted Roche's submission that the website was certified on a computer, with additional checks being performed on other devices such as an iPad, Roche made no submission with regard to checks being performed on any specific smartphones. The Panel noted that the certificates of the job bags for the homepage and medicines webpages (M-GB-00001886 and -GB-00003975) made no mention of the devices that the signatory had reviewed

the website on and which devices he/she had performed additional checks to ensure that the requirements of the Code were met; there did not appear to be mention of any device, such as a smartphone or iPad in the metadata. In its response, Roche had only provided a screenshot of how the website was visible on an iPhone 11; the Panel noted that the prescribing information link was not immediately visible and sat within the hamburger menu when viewed in the most likely orientation, portrait. The Panel further noted that, whilst Roche submitted that the website was primarily intended to be viewed from a desktop or laptop computer, there did not appear to be a statement to this effect on the website.

The Panel, on the evidence before it, considered that it appeared that Roche had not adequately reviewed the website on various, commonly used devices to ensure that it met the requirements of the Code when displayed on such devices and considered that if the website was designed primarily for desktop view, that this should have been made clear to readers. The Panel thus ruled a breach of Clause 8.1. The Panel considered that high standards had not been maintained in that regard and a breach of Clause 5.1 was ruled.

The Panel noted Roche's submission that the prescribing information remained available, albeit from a hamburger menu icon. The Panel considered that a robust certification procedure underpinned self-regulation and although noting its comments and ruling above, it did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2, which was a sign of particular censure and was reserved for such use; no breach was ruled.

In relation to the adverse event reporting statement, the Panel noted that Clause 12.9 stated that all promotional material must include the prominent statement 'Adverse events should be reported. Reporting forms and information can be found at [website address which links directly to the MHRA Yellow Card site]. Adverse events should also be reported to [relevant pharmaceutical company]'.

The Panel noted Roche's submission that a link to adverse event reporting was at the top of all pages when viewed on the majority of devices including desktop computers; the adverse event reporting link, however, was automatically moved into the hamburger menu when viewed on certain mobile devices. Whilst the Panel noted that in its view, a link to adverse event reporting, regardless of its prominence, did not meet the requirements of Clause 12.9, it noted Roche's further submission that an adverse event reporting statement was available on all Roche Resources pages and could be viewed regardless of make or model of device, size or orientation of screen; it was located at the bottom of the page on a banner of darker colour to the background of the rest of the webpage. The Panel noted that the text was in the footer of the webpage, in smaller font size than the text in the main body of the webpage, and, in the Panel's view, was not sufficiently prominent regardless of device and a breach of Clause 12.9 was ruled in relation to the homepage and medicines page.

Polivy webpage

The Panel noted that the Polivy webpage included an image of a woman, aged 60 to 70 years according to Roche, at the forefront sitting in a garden chair holding a drink, behind whom was a gentleman of similar age undertaking some gardening. The image also showed a dog, a young adult female shooting a water pistol and the back of a male doing a cartwheel. To the right of the image was the headline claim 'Time to appreciate life' followed by the Polivy logo and non-proprietary name. Beneath the image was the claim 'Recommended by NICE and SMC' followed by POLIVY + R-Benda is indicated for the treatment of adult patients with

relapsed/refractory diffuse large B-cell lymphomas who are not candidates for haematopoietic stem cell transplant.' Below this were a number of rectangular tabs, namely Efficacy, Safety, Dosing, Patient flow, MOA, and Expert discussions; it appeared to the Panel that each could be clicked on to obtain further information on each topic, however, the Panel did not have before it the information accessible from all of these tabs.

Whilst the Panel noted Roche's submission that that the claim 'time to appreciate life' was included in the material that was vetted by the MHRA, pre-vetting by the MHRA did not preclude consideration of a complaint under the Code nor did it preclude rulings of breaches of the Code. The Panel noted Roche's submission that the claim implied that patients prescribed polatuzumab vedotin had the potential to see a longer progression free period, complete response and/or higher chance of overall survival and therefore more time to appreciate life, something that could be done through inward reflection at any point. The Panel noted Roche's submission that the pivotal randomised data that supported the grant of a conditional marketing authorisation demonstrated a significant improvement in overall survival, progression free survival and complete response in those patients administered polatuzumab vedotin, rituximab and bendamustine vs those administered rituximab plus bendamustine. The Panel noted that the study in question (Sehn *et al* 2019) was an open-label, multicentre, randomised Phase II study. The study authors stated that in the randomly assigned cohort (n = 80; 40 per arm), polatuzumab vedotin with rituximab and bendamustine patients had a significantly higher independent review committee [IRC]-assessed complete response rate (40.0% v 17.5%; P = 0.026) and longer IRC-assessed progression-free survival (median, 9.5 v 3.7 months; hazard ratio [HR], 0.36, 95% CI, 0.21 to 0.63; P <0.001) and overall survival (median, 12.4 v 4.7 months; HR, 0.42; 95% CI, 0.24 to 0.75; P = 0.002; median follow up, 22.3 months) versus rituximab and bendamustine patients. The authors further stated that the polatuzumab vedotin with rituximab and bendamustine group had higher rates of grade 3-4 neutropenia (46.2% v 33.3%), anemia (28.2% v 17.9%), and thrombocytopenia (41% v 23.1%), but similar grade 3-4 infections (23.1% v 20.5%), versus the rituximab and bendamustine group. Peripheral neuropathy associated with polatuzumab vedotin (43.6% of patients) was grade 1-2 and resolved in most patients.

The Panel further noted that beneath the Efficacy rectangular tab below the image and claim in question it stated 'Find out how POLIVY + R-Benda could offer patients more time to appreciate life vs R-Benda alone'.

The Panel did not consider based on the evidence provided that the claim 'time to appreciate life', implied that the patient's life would be free of monitoring, treatment cycles, or risk of adverse events as alleged and based on the narrow allegation ruled no breach of Clauses 6.1, 6.2, 5.1 and 2 in that regard.

The Panel noted the complainant's allegation that the image was not of a high standard, as it included a woman of childbearing potential and it should have been made clear on the page that such women be advised to use effective contraception during treatment with polatuzumab vedotin and for at least 9 months after the last dose. The Panel noted Roche's submission that the image depicted a scene of a woman (approximately 60 to 70 years of age) appearing to be calmly reflecting and appreciating life whilst an active family were enjoying themselves in the background. Whilst the Panel noted Roche's submission that its message testing found that the woman aged approximately 60 to 70 years, who was according to Roche the focal point of the image, depicted a typical DLBCL patient, the Panel nonetheless considered that DLBLC

could occur at any age and therefore the presence of other individuals within the image, including the young adult woman, was not irrelevant.

The Panel noted that Polivy was not contraindicated in women of childbearing potential. However, the Panel noted that section 4.4 (Special warnings and precautions for use) of the Polivy SPC dated 24 May 2021 and accessed by the Panel on emc on 19 May 2022 stated, *inter alia*, that women of childbearing potential should be advised to use effective contraception during treatment with Polivy and for at least 9 months after the last dose and that male patients with female partners of childbearing potential should be advised to use effective contraception during treatment with Polivy and for at least 6 months after the last dose.

The Panel noted that Section 4.4 of the Polivy SPC (special warnings and precautions for use) included a number of warnings and precautions, which covered a number of different clinical issues across a wide demographic.

The Panel considered that whether a special warning or precaution needed to be highlighted within a particular section of promotional material, in addition to its requirement to be included within the prescribing information that was required on all promotional material, depended on a consideration of all of the circumstances including the nature of the warning/precaution and the content, layout, audience and intended use of the material.

Whilst the Panel noted that there was a navigation bar with a link to the prescribing information, it did not have a copy of the prescribing information before it and Roche made no submission in that regard.

The Panel noted that Polivy was a specialist product and its SPC stated that it must only be administered under the supervision of a healthcare professional experienced in the diagnosis and treatment of cancer patients; the Panel considered that such health professionals would take particular care when prescribing oncology medicines to women of childbearing potential. Nonetheless, the Panel considered that material must not be misleading in this regard.

The Panel noted its description of the image above. The Panel, on balance, did not consider that the image misleadingly implied that Polivy could be used in women of childbearing potential without any concerns or considerations. The Panel did not consider that the complainant had established that high standards had not been maintained nor that the special nature of medicines or the professional nature of the audience had not been respected or that it had caused offence and based on the very narrow allegation no breach of Clauses 5.1 and 5.2 were ruled.

In relation to the allegation that the claim ‘Recommended by NICE and SMC’ on the Polivy webpage was a false endorsement, the Panel noted that the claim was immediately above the statement ‘POLIVY + R-Benda [rituximab and bendamustine] is indicated for the treatment of adult patients with relapsed/refractory diffuse large B-cell lymphoma who are not candidates for haematopoietic stem cell transplant’.

The Panel noted that the NICE recommendation stated ‘Polatuzumab vedotin with rituximab and bendamustine is recommended, within its marketing authorisation, as an option for treating relapsed or refractory diffuse large B-cell lymphoma in adults who cannot have a haematopoietic stem cell transplant. It is recommended only if the company provides polatuzumab vedotin according to the commercial arrangement’.

Similarly, the SMC stated that this advice applied only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower. The Panel noted Roche's submission that both recommendations for Polivy by NICE and the SMC were provided on the basis of a simple discount patient access scheme between Roche and the NHS and that the commercial arrangements for Polivy were automatically in place whenever the product was supplied to the NHS. The Panel further noted Roche's submission that the decision to prescribe polatuzumab vedotin in line with the recommendation from NICE and SMC automatically resulted in polatuzumab vedotin being supplied at the price agreed in the commercial arrangement.

The Panel considered that whilst it would have been helpful to include the information that Polivy was only recommended if provided according to the commercial arrangement, on the evidence before it, the Panel did not consider that the claim 'Recommended by NICE and SMC' was misleading, incapable of substantiation or did not encourage the rationale use of the medicine as alleged and no breach of Clauses 6.1, 6.2 and 14.4 was ruled. The Panel consequently ruled no breach of Clause 5.1.

Complaint received **5 August 2021**

Case completed **27 May 2022**