**CASE AUTH/3643/5/22**

# COMPLAINANT v NOVARTIS

## Promotion of Kesimpta (ofatumumab)

### CASE SUMMARY

**This case was in relation to a promotional webpage for Kesimpta on a Novartis Pharmaceuticals Limited website and a Kesimpta digital advertisement.**

**Promotional webpage**

**The Panel ruled a breach of the following clauses of the 2021 Code because there was no indication, as part of the use of a Scottish Medicine Consortium (SMC) approval stamp or within its immediate visual field, that approval was restricted and the misleading implication of unrestricted approval by SMC could not be substantiated:**

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| **Breach of Clause 6.1** | **Making a misleading claim** |
| **Breach of Clause 6.2** | **Making an unsubstantiated claim** |
| **Breach of Clause 5.1** | **Failing to maintain high standards** |

**The Panel ruled no breach of the following clauses of the 2021 Code on the basis that:**

- **it did not consider that the health professional audience would be misled by the image to consider that Kesimpta gave MS patients the ability to suddenly perform like a professional gymnast as alleged**
- **the material did not warrant particular censure**

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| **No Breach of Clause 5.2** | **Requirement that all material and activities must recognise the special nature of medicines and respect the professional standing or otherwise of the audience to which they are directed and must not be likely to cause offence** |
| **No Breach of Clause 6.3** | **Requirement that all artwork must conform to the letter and spirit of the Code** |
| **No Breach of Clause 5.1** | **Requirement to maintain high standards** |
| **No Breach of Clause 2** | **Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry** |

**Digital advertisement**

**The Panel ruled a breach of the following clauses of the 2021 Code in relation to the:**

- **omission of 'adult' within the claim 'Now licensed for relapsing forms of multiple sclerosis (RMS) with active disease',**

- **failure to include the Northern Ireland (NI) prescribing information in material aimed at UK health professionals.**

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| **Breach of Clause 11.2** | **Promotion inconsistent with the Summary of Product Characteristics** |
| **Breach of Clause 12.1** | **Failing to include up-to-date prescribing information** |
| **Breach of Clause 5.1** | **Failing to maintain high standards** |

**The Panel ruled no breach of the following clause of the 2021 Code on the basis that in the particular circumstances of this case, the GB prescribing information was included and the only difference between the available GB prescribing information and the omitted NI prescribing information was the MA number and therefore its rulings of a breach of Clause 5.1 in relation to the digital advertisement adequately covered these matters and an additional ruling of a breach of Clause 2 would be disproportionate:**

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| **No Breach of Clause 2** | **Requirement that material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry** |

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

## FULL CASE REPORT

An anonymous contactable complainant who described themselves as a health professional complained about the promotion of Kesimpta (ofatumumab) on a Novartis Pharmaceuticals Limited website and a digital advertisement.

Kesimpta was indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.

## COMPLAINT

The complainant stated that on the homepage for the product (ref 199247, April 2021) (https://www.health.novartis.co.uk/medicines/neuroscience/kesimpta), there was an image of a female gymnast in a central position at the start of the page, with colours around her resembling the brand. The complainant alleged that this implied the product gave individuals with multiple sclerosis (MS) the ability to perform such activities. However, MS was a very serious condition with muscle spasms, weakness and a whole range of muscular problems. To imply one would suddenly be able to perform like a gymnast due to the product was false and misleading. The complainant alleged a breach of Clauses 5.1, 5.2 and 2 for the totally misleading impression given by the image.

The complainant pointed out that to the right-hand side of the picture was a prominent circle claiming SMC (Scottish Medicine Consortium) approval. However, SMC approved this product for restricted usage only. Therefore, the complainant alleged that this statement was misleading without mention of restricted use in breach of Clauses 6.1, 6.2, 5.1 and 2.

With regard to the digital advertisement (ref 120655, May 2021), the complainant alleged that the advertisement had the medicine name, black triangle and a learn more option. The complainant alleged that the advertisement stated it was for UK healthcare professionals but when clicking on the prescribing information, it only landed on the Great Britain (GB) prescribing information and not the Northern Ireland (NI) prescribing information.

The complainant stated that the digital advertisement only had one banner which read 'now licensed for relapsing forms of multiple sclerosis (RMS) with active disease'. The complainant alleged that this was inconsistent with the marketing authorisation which was actually much more specific: indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features. The complainant pointed out that the marketing authorisation used the term adult. Breaches of Clauses 11.2, 12.1, 5.1 and 2 were alleged.

The complainant stated that the misleading promotion would be shared with other health professionals in the locality to ensure patient safety, whilst the claims were investigated by the PMCPA. In the complainant's view, there were major challenges with Novartis' credibility in terms of this promotion of Kesimpta.

When writing to Novartis, the Authority asked it to consider the requirements of Clauses 2, 5.1, 5.2, 6.1, 6.2, 6.3, 11.2 and 12.1 of the Code.

**RESPONSE**

Novartis stated that Kesimpta was indicated for the treatment of adult patients with RMS with active disease defined by clinical or imaging features and received its UK marketing authorisation for this indication on 6 April 2021.

Novartis dealt with the complainant's allegations as follows.

**1 Imagery**

Novartis stated that it strongly refuted the claims made in relation to the pictorial content and submitted that the imagery was representative of the brand and not of any purported MS patient. References were provided to support the claims on the image, these being, superior, sustained efficacy, targeted, precise regimen and confidence and flexibility, all of which Novartis submitted were capable of substantiation. Novartis submitted that such claims were in keeping with the depiction of a gymnast's ability, precision, confidence and flexibility. The image was accompanied with a statement 'Not representative of an actual patient – this image is intended to depict the brand'.

With regard to the complainant's suggestion that the depiction of a gymnast inferred typical MS patients might [citing complaint] 'suddenly be able to perform like a gymnast due to the product was false and misleading', Novartis submitted that whilst MS was indeed a debilitating disease, it could be effectively controlled and, if so, permitted MS patients to lead a full life. There were numerous examples of athletes with MS competing at the highest levels, examples of which were provided. However, the purpose of the image was not to imply that Kesimpta necessarily gave individuals with MS the ability to perform such activities, but the ability to live with, and control, the disease with confidence, in the same manner as a gymnast moved. The image merely supported the branding – the existence of the disclaimer above further served to

illustrate this point. In any event, the image and associated wording (including the tagline 'control with confidence') were approved by The Medicines and Healthcare products Regulatory Agency (MHRA) during the pre-vetting stage.

Novartis submitted that the material was appropriately presented and was, in any event, indicative of the brand, rather than any subliminal messaging pertaining to any purported ability of an MS patient to undertake certain activities; if there was any doubt, the disclaimer under the image effectively removed such doubt. As a final point, the material was solely aimed at health professionals (and other decision makers) with a link re-directing members of the public; respect for the audience was always present. Accordingly, Novartis refuted any breaches of Clauses 5.1 and/or 5.2 of the Code.

**2 SMC approval information**

Novartis stated that the SMC approval stamp accompanying the image was only present in order to highlight that Kesimpta was recommended for use in Scotland by the SMC; this was indeed correct. Novartis provided notice on the specific SMC guidance by providing a prominent box on the same page – below the image and fully cited including detailing the restricted use. The use of the stamp did not indicate that reimbursement in Scotland was beyond that stated in the SMC recommendation.

Novartis submitted the page itself provided the complete, unambiguous information to health professionals and did not distort, exaggerate, or mislead the information presented therein. In addition, the page itself provided the complete information regarding SMC approval and did not suggest anything different, either expressly or by implication. Accordingly, Novartis refuted any breaches of Clauses 6.1 and/or 6.2 of the Code.

**3 Alleged inconsistency with the summary of product characteristics (SPC)**

Novartis submitted that the advertisement was a static banner advertisement with a clear single-click link to Kesimpta prescribing information and a prominent 'Learn More' link to the Novartis healthcare professional portal for further information, including the full indication. In accordance with the Code, the advertisement should be considered in its entirety, hence the banner advertisement and the referenced links were one and the same advertisement. Therefore, the omission of 'adults ... defined by clinical or imaging features' was simply not relevant as the link provided the full information.

Accordingly, Novartis submitted the advertisement was not inconsistent with the Kesimpta SPC and was, and remained, in accordance with the terms of the marketing authorisation.

**4 Prescribing information**

Novartis stated that it noted the PMCPA's comments regarding access to the first link of the complaint and lack of substantiation of the same.

Novartis sought to clarify the position with regard to the prescribing information. In May 2021, Novartis updated the prescribing information with GB information – primarily the marketing authorisation number. Although the NI prescribing information (same information, different MA number) was also available, as there was no stock available in Northern Ireland until August 2021, only the GB prescribing information was uploaded to this banner advertisement which

Novartis submitted, in the circumstances, was appropriate. However, from August 2021 (when NI stock became available) until May 2022, the complainant was indeed correct regarding the prescribing information for this banner advertisement – the GB prescribing information was the only version accessible. Notwithstanding the content of the GB and NI prescribing information was identical, save for marketing authorisation number, and therefore at all times the prescribing information and, in particular, the safety information, was accurate and consistent with the SPC; at no point was patient safety compromised. It was important to note that:

a) the NI omission only pertained to this banner advertisement, which occurred in error;
b) all other marketing material included the combined GB/NI prescribing information; and
c) to date (25 May 2022), there had been no Kesimpta prescriptions for Northern Ireland and therefore the omission of the NI prescribing information had not made any discernible difference.

Novartis acknowledged that the situation regarding the prescribing information in this case was not adequate. Novartis had since undertaken an audit of all marketing material including the banner advertisement, the subject of the complaint, and confirmed that all the prescribing information was currently correct, including the combined GB/NI prescribing information. Details were provided.

With regard to the complaint, Novartis refuted any breach of Clauses 11.2 and/or 12.1. The prescribing information was available at all times, and notwithstanding the NI omission, the prescribing information was clear, legible and not inconsistent with the SPC.

**5 Other considerations**

Novartis had also been asked to give specific regard to Clause 6.3 of the Code. Novartis submitted that the imagery provided in the material was clearly referenced, in addition to being within both the letter and spirit of the Code. With regard to the use of the female gymnast, as outlined above, it was made expressly clear that the image pertained to the brand; there was no implication, either overtly or surreptitiously, to suggest anything different. Similarly, the use of the SMC stamp was not misleading as Kesimpta was indeed approved; details regarding the SMC recommendation were clearly evident on the same page.

Regarding a potential breach of Clause 2, Novartis saw no evidence that its materials could bring discredit upon, or reduce confidence in, the pharmaceutical industry. Accordingly, Novartis did not accept a breach of Clause 2.

In summary, the complaint had raised a number of issues related to the advertising and promotion of Kesimpta. Novartis submitted that there was a legitimate defence to the alleged breaches of Clauses 2, 5.1, 5.2, 6.1, 6.2, 6.3, 11.2 and 12.1.

In response to a request for further information, Novartis provided a copy of the digital advertisement at issue and, upon further request, the accompanying certificate to the Panel.

**PANEL RULING**

The Panel noted the complainant's allegation that the image of a female gymnast in a central position in a banner at the start of the webpage in question, with colours around her resembling the brand, implied the product gave individuals with MS the ability to suddenly perform such

activities and was misleading. The Panel noted that the image in question depicted a gymnast in the air, mid-jump with a leg extended to the front and behind. The Panel noted the product's licensed indication and, whilst mindful of Novartis' submission about athletes with MS competing at the highest level, considered that for the average patient the condition was associated, amongst other things, with some physical deterioration over time. In such circumstances, it was important to be cautious about images of physical prowess in case such images constituted a claim. The Panel noted that the banner at issue included a statement 'Not representative of an actual patient – this image is intended to depict the brand' as submitted by Novartis and queried whether its meaning was sufficiently clear to busy health professionals as opposed to those more familiar with marketing terminology, some health professionals might associate the word 'brand' with the name of the product. The Panel had concerns about the image but noted the very narrow nature of the allegation. The Panel did not consider that the health professional audience would be misled by the image to consider that Kesimpta gave MS patients the ability to suddenly perform like a professional gymnast as alleged and, on this narrow ground, ruled **no breach of Clauses 2, 5.1, 5.2 and 6.3**.

The complainant alleged that the use of the SMC approval stamp was misleading without mention of the restricted use. The Panel noted that the SMC approval stamp was an integral part of the banner featuring the gymnast referred to above and appeared immediately below a similarly unqualified The National Institute for Health and Care Excellence (NICE) approval stamp. The Panel noted that the banner at issue appeared towards the top of a continuously scrolling webpage. The Panel noted that whilst information about SMC approval was given further down the webpage, given the continuously scrolling nature of the webpage, the SMC information did not appear either within the immediate field of vision of the SMC approval stamp or on the relevant part of the scrolling webpage such that it would be read in conjunction with the advertisement. In addition, it appeared on the information before the Panel, that the qualifying information about the SMC restriction was part of expanded text accessible by clicking on the sub-heading 'NICE and SMC recommendations'. It was unclear whether the complainant had seen the expanded text.

The Panel considered that while it was not necessary to include the restriction wording in full at the first mention of SMC approval, there was no indication, as part of the approval stamp or within its immediate visual field, that approval was restricted. The Panel considered that the misleading impression to a busy heath professional was that the SMC approval was unrestricted and that was not so. A **breach of Clause 6.1** was ruled. The misleading implication of unrestricted approval by SMC could not be substantiated, therefore the Panel ruled a **breach of Clause 6.2**.

The Panel noted that while the qualifying information had been provided on the webpage as expanded text, the user had to decide to expand the heading 'NICE and SMC recommendations' to access the full SMC information. The heading did not indicate that SMC approval was restricted which, in the Panel's view, contributed to the misleading impression that SMC approval was unrestricted. The Panel also noted the location of the expanded text on the continuously scrolling webpage as referred to above. Novartis had failed to maintain high standards and the Panel ruled a **breach of Clause 5.1** accordingly.

The Panel considered that the matter was adequately addressed in the ruling of Clause 5.1 and the circumstances of the case did not warrant the particular censure denoted by Clause 2. **No breach of Clause 2** was ruled.

In relation to the digital advertisement and the claim 'Now licensed for relapsing forms of multiple sclerosis (RMS) with active disease', the complainant alleged that this statement was inconsistent with the Kesimpta SPC as it omitted 'adults ... defined by clinical or imaging features'. The complainant was particularly concerned about the omission of the word 'adult'. The Panel noted the submission from Novartis that it was a static banner advertisement and that it contained a prominent link to 'learn more' and a link to the prescribing information and adverse event reporting. Novartis submitted that the advertisement should be considered in its entirety, hence the banner advertisement and the referenced links were one and the same advertisement. Therefore, the omission of 'adults ... defined by clinical or imaging features' was simply not relevant as the link provided the full information. The Panel rejected this submission as the Code required material to be capable of standing alone with regard to the requirements of the Code and to be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of a medicine. Therefore, while links and the like could provide additional information about a claim, any information required to ensure Code compliance should form part of the material itself.

The Panel considered that Kesimpta was a black triangle product and the SPC stated that treatment should be initiated by a physician experienced in the management of neurological disorders who would be familiar with the diagnosis and treatment of MS. However, the Panel noted that the digital advertisement had been certified by Novartis for use with a target audience that included physicians, pharmacists, nurses and other healthcare stakeholders. It could be reasonably assumed that not all viewers within this target audience would have an understanding of MS or be familiar with the particulars of the Kesimpta licence. In this regard, the Panel considered that the omission of the word 'adult' was, in these particular circumstances, inconsistent with the licensed indication and ruled a **breach of Clause 11.2** in this regard.

The complainant provided a direct link to prescribing information which, he/she alleged, was that linked from the advertisement in question and complained it was only for GB, not both GB and NI. In its response, Novartis submitted that only the GB prescribing information was uploaded to this banner advertisement in May 2021 as stock was not available in Northern Ireland at that time. Novartis submitted further to this, that from August 2021 (when NI stock became available) until May 2022, only the GB prescribing information was accessible from this banner advertisement in error. Novartis acknowledged that was not adequate and had since undertaken an audit of all marketing material – including the banner advertisement which was the subject of the complaint, and confirmed that all prescribing information was correct at the time of the response, including the combined GB/NI prescribing information.

The Panel considered that the banner advertisement stated 'For UK healthcare professionals only' and that the targeting of promotion towards a UK audience required the provision of prescribing information for all territories, regardless of stock availability. The Panel noted the admission from Novartis that NI prescribing information had not been available from August 2021 to May 2022. The Panel considered that complete prescribing information had not been provided for the audience from May 2021 and **ruled a breach of Clause 12.1**.

The Panel considered that Novartis had failed to maintain high standards both for the omission of 'adult' and the poor decision to not include the NI prescribing information on the banner advertisement. Therefore, the Panel **ruled a breach of Clause 5.1**.

The Panel considered that the matters ruled upon in relation to the omission of the word 'adult' and missing NI prescribing information in the banner advertisement, were sufficiently covered by its ruling of a breach of Clause 5.1. The Panel considered that in matters involving prescribing information, patient safety was paramount. In the particular circumstances of this case, the Panel noted that the only difference between the available GB prescribing information and the omitted NI prescribing information was the MA number. The Panel considered that an additional ruling of a breach of Clause 2 would be disproportionate in the particular circumstances of this case and, therefore, **ruled no breach of Clause 2**.

**Complaint received** **8 May 2022**

**Case completed** **24 May 2023**