NO BREACH OF THE CODE

CASE AUTH/3628/4/22

COMPLAINANT v NOVARTIS

Concerns about Novartis press releases

CASE SUMMARY

This case was in relation to six press releases available in the news section of Novartis' UK website.

Based on the complainant's narrow allegation, the Panel ruled no breach of the following Clauses of the 2021 Code because:

- **it did not consider that the four preleases for licensed medicines hosted on the webpage in question were directed to, nor limited to, an audience of health professionals and other relevant decision makers and thus was not advertising to that audience as alleged and the allegations relating to the promotion to health professionals and associated requirements were not relevant**
- **it did not consider that the four press releases for licensed medicines hosted on the webpage in question were directed to the general public and thus was not advertising to that audience as alleged**
- **the complainant had not established that the two press releases related to pre-licensed medicines constituted promotion of medicines to health professionals prior to the grant of their marketing authorisation**

No Breach of Clause 2	**Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1	**Requirement to maintain high standards**
No Breach of Clause 11.1	**Requirement that a medicine must not be promoted prior to the grant of its marketing authorisation**
No Breach of Clause 12.1	**Requirement to include up to date prescribing information**
No Breach of Clause 12.6	**Requirement to include a prominent statement as to where the prescribing information can be found on promotional material on the internet**
No Breach of Clause 12.9	**Requirement that all promotional material must include the prominent adverse event statement**
No Breach of Clause 26.1	**Requirement not to advertise prescription only medicines to the public**
No Breach of Clause 26.2	**Requirement that information about prescription only medicines which is made available to the public must be factual, balanced, must not raise unfounded hopes of successful treatment or encourage the public to ask**

	their health professional to prescribe a specific prescription only medicine.

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 Novartis press releases.

COMPLAINT

The complainant alleged that Novartis UK was proactively disseminating promotional and pre-licence product content on its website through the form of press releases. The complainant stated that press releases should only be released by a journalist as opposed to proactive distribution and availability via the Novartis UK website, which was accessible to both health professionals and members of the public. There were a number of these press releases which were available and exposed product information to health professionals and members of the public as listed below:

1 www.novartis.co.uk/news/media-releases/novartis-uk-response-nice-appraisal-consultation-document-acd-piqray-alpelisib

The complainant stated that this press release was for Piqray (alpelisib) which was a licensed product; it related to an extra indication applied for which was rejected by NICE and included information on mechanism of action and indication for the product. The complainant stated that as the press release was available to health professionals, it required prescribing information and adverse event reporting which were not available and alleged breaches of Clauses 12.1, 12.6, 12.9, 5.1 and 2. The complainant further alleged that as members of the public could access this proactive dissemination, members of public were promoted to in breach of Clauses 26.1, 26.2, 5.1 and 2.

2 www.novartis.co.uk/news/media-releases/new-analysis-shows-kesimptav-ofatumumab-treated-adults-relapsing-remitting March 2022 | 197975

The complainant stated that this press release was about Kesimpta▼ (ofatumumab), a licensed product. The complainant stated that as the press release was available to health professionals, it required prescribing information and adverse event reporting which were not available and he/she alleged breaches of Clauses 12.1, 12.6, 12.9, 5.1, and 2. The complainant further alleged that as members of the public could access this proactive dissemination, members of public were promoted to in breach of Clauses 26.1, 26.2, 5.1 and 2.

3 www.novartis.co.uk/news/media-releases/people-chronic-myeloid-leukaemia-granted-early-access-novartis%27-investigational UK | January 2022 | 183607

The complainant stated that this press release was related to the pipeline product asciminib and stated that Novartis UK had announced that the UK's Medicines and Healthcare products Regulatory Agency (MHRA) had given a positive scientific opinion for the investigational

treatment asciminib to be made available to appropriate patients under the UK Early Access to Medicines Scheme (EAMS). The decision meant that adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) without T315I mutation, who had previously been treated with two or more tyrosine kinase inhibitors (TKIs), might now potentially gain access to asciminib while the relevant regulatory bodies continued to review the marketing authorisation application. The complainant alleged that this was clear pre-licence promotion using proactive dissemination on Novartis' own website in breach of Clauses 11.1, 5.1 and 2.

4 www.novartis.co.uk/news/media-releases/mhra-approves-licence-extension-novartis%27-targeted-therapy-advanced-breast December 2021 | 162255

The complainant explained that this press release stated, 'today Novartis announced that the Medicines and Healthcare products Regulatory Agency (MHRA) has approved the marketing authorisation to extend the licence in Great Britain for Piqray▼ (alpelisib) for use in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor positive(HR+), human epidermal growth factor receptor 2 negative(HER2-), locally advanced or metastatic breast cancer with a PIK3CA mutation after disease progression following endocrine-based therapy'. The complainant stated that as the press release was available to health professionals, it required prescribing information and adverse event reporting which were not available and he/she alleged breaches of Clauses 12.1, 12.6, 12.9, 5.1 and 2. The complainant further alleged that as members of the public could access this proactive dissemination, members of public were promoted to in breach of Clauses 26.1, 26.2, 5.1 and 2.

5 www.novartis.co.uk/news/media-releases/novartis-pharmaceuticals-uk-awarded-innovation-passport-investigational-oral October 2021 | 135437

The complainant stated that this press release was about a pre-licence product. The press release stated, 'About iptacopan (LNP023) Iptacopan is an investigational, first-in-class, orally administered factor B inhibitor of the alternative pathway of the complement system.3,4,5. It has the potential to become the first targeted therapy to delay progression to dialysis in C3G and was discovered at the Novartis Institutes for BioMedical Research. While Novartis has a 35-year history in kidney transplantation treatments, iptacopan is the first treatment in the nephrology pipeline addressing CDRDs. Our aim is to transform treatment by targeting one of the key drivers of these rare and often progressive diseases and, in doing so, potentially extend dialysis-free life for people with CDRDs'. The complainant alleged that this was clear pre-licence promotion using proactive dissemination on Novartis' own website in breach of Clauses 11.1, 5.1 and 2.

6 www.novartis.co.uk/news/media-releases/first-treatment-sickle-cell-disease-over-20-years-novartis%27-adakveov October 2021 | 143180

The complainant stated that this press release stated, 'London, UK, October 5, 2021 Novartis is pleased to announce that eligible patients in England and Wales will soon have routine access to Adakveo▼ (crizanlizumab) under a Managed Access Agreement (MAA). The news comes as the National Institute for Health and Care Excellence (NICE), published the Final Appraisal Determination (FAD) recommending crizanlizumab as an option for preventing recurrent sickle cell crises (two or more vaso-occlusive crises, VOCs, in a year, managed at home or in hospital) in people aged 16 or older with sickle cell disease (SCD)'. The complainant stated that as the press release was available to health professionals, it required prescribing information and

adverse event reporting which were not available and he/she alleged breaches of Clauses 12.1, 12.6, 12.9, 5.1 and 2. The complainant further alleged that as members of the public could access this proactive dissemination, members of public were promoted to in breach of Clauses 26.1, 26.2, 5.1 and 2.

The complainant stated that for each press release referenced above, a snippet of the text from the press release was provided but he/she noted that the entire content of all [6] press releases hosted and freely available on the website were promotional in effect. The complainant was shocked to see Novartis had such a compliance culture whereby it thought it was suitable to provide product information directly on its own website. The complainant stated that this showed a lack of ethics and transparency and was a clear breach of Clause 2.

When writing to Novartis, it was asked to consider the requirements of Clauses 2, 5.1, 11.1, 12.1, 12.6, 12.9, 26.1 and 26.2 of the Code in relation to the six press releases above.

RESPONSE

Novartis stated that the complaint had caused the company great concern and it had taken its contents very seriously.

Novartis noted that the complaint alleged that Novartis Pharmaceuticals UK Limited (Novartis) had committed a number of breaches of the 2021 Code in the context of press releases on the Novartis UK corporate website concerning: (i) licensed; and (ii) pre-license medicines (together the 'Press Releases'). Novartis addressed Clauses 5.1 and 2 together as these were alleged to apply to both the licensed and pre-license medicine press releases.

Before addressing each category of press release, Novartis disagreed with the complainant that press releases should only be released by a journalist as opposed to proactive distribution and availability on the Novartis website. Novartis stated that there was no requirement under the Code or applicable laws in the United Kingdom for press releases to be released by a journalist. The Code made multiple references to press releases and the requirements that pharmaceutical companies must comply with to ensure that the relevant material did not fall foul of the Code. Novartis noted that this was highlighted in the guidance of the PMCPA on this particular question raised by the complainant, which Novartis provided. Additionally, the target audience was clearly specified on the webpage where Novartis' press releases were hosted, so the company firmly disagreed that Novartis proactively disseminated the press releases to the audiences which the complainant alleged and addressed this in detail below.

1 Press Releases – Licensed Medicines (Clause(s) 12.1, 12.6, 12.9, 26.1 and 26.2)

Novartis stated that the complaint referred to the following press releases concerning licensed medicines:

i) Novartis UK response to NICE Appraisal Consultation Document (ACD) for Piqray (alpelisib) for advanced breast cancer patients (published March 31, 2022) (Piqray Press Release 1);

ii) New analysis showed that Kesimpta▼ (ofatumumab)-treated adults with relapsing remitting multiple sclerosis (RRMS) were not at increased risk of severe COVID-19 infections (published March 24, 2022) (Kesimpta Press Release);

iii) MHRA approved licence extension for Novartis' targeted therapy for advanced breast cancer patients in Great Britain (published December 23, 2021) ('Piqray Press Release 2'); and

iv) The first treatment for sickle cell disease in over 20 years, Novartis' Adakveo▼ (crizanlizumab) received NICE recommendation for preventing recurrent vaso-occlusive crises (published October 5, 2021),

together referred to as the "Licensed Medicine Press Releases".

Copies of the Licensed Medicine Press Releases and the summaries of product characteristics (SmPC) applicable to the medicines were provided.

The complainant alleged that because the Licensed Medicine Press Releases:

i) were available to healthcare professionals, prescribing information and adverse event reporting information were required; and
ii) were accessible by the public, and therefore the public were promoted to.

Novartis disagreed with the complainant and addressed each point below.

Clauses 12.1, 12.6 and 12.9 of the Code, which required prescribing information and adverse event reporting information to be present, were only engaged when the material was promotional to health professionals. The Licensed Medicine Press Releases were reviewed and certified as non-promotional materials. A copy of the certificates approving the Licensed Medicine Press Releases were provided. Novartis' signatory of the Press Releases was a non-medical AQP.

Novartis submitted that the Licensed Medicine Press Releases were, objectively, non-promotional, newsworthy, factual and balanced.

As an example, Novartis released Piqray Press Release 1 to provide information on its intention to continue to find ways to work with NICE to secure approval of Piqray, and to demonstrate its commitment to treatment options for advanced breast cancer patients with PIK3CA mutation. Novartis felt this particularly newsworthy in the surrounding context, as Piqray demonstrated a significant development in this therapy area, and the approval pathway had not been straightforward, as highlighted by Piqray Press Release 2. The EMA license that had been granted for Piqray in other jurisdictions was too restrictive (with many entities no longer proceeding with approval) and this release was published to support with any questions related to the approval of Piqray in the United Kingdom.

As an additional example, the Kesimpta Press Release was released at a time where Novartis assessed and deemed the information newsworthy and important in the context. The pandemic created many challenges for people living with multiple sclerosis (MS), who were advised to shield due to the nature of their disease and the risk exposure to Covid-19 posed. Added to this challenge was the fact that many MS treatments could interfere with the Covid-19 vaccine, which created uncertainty for health professionals and patients. In light of this, Novartis believed that the data from the ALITHIOS trial, which revealed that patients who were on treatment were not at an increased risk of severe Covid-19 infections, was newsworthy.

Novartis submitted that the Licensed Medicine Press Releases were hosted on Novartis' UK corporate website (novartis.co.uk) and were accessible by navigating to 'News' on the menu bar at the top of the page and then selecting 'UK News Archive' from the drop-down options. The UK News Archive webpage (the webpage) was indexed, and was therefore also accessible by a search engine, provided that the search parameters were specific enough. In any event, the webpage was accessed, the webpage clearly and prominently specified at the beginning of the page that the intended audience was journalists, by stipulating 'The UK News Archive contains resources intended for journalists only'. Novartis noted that in Case AUTH/3414/11/20 the Panel acknowledged that a webpage which was not directed to, nor limited to, an audience of health professionals was not advertising to that audience, and therefore considered that the allegations relating to promotion to health professionals were not relevant.

In light of this, it was Novartis' submission that the Licensed Medicine Press Releases were not promoting to health professionals on the basis that: (i) the Licensed Medicine Press Releases were non-promotional, newsworthy, factual and balanced; and (ii) the intended audience was clearly specified as journalists and was not directed to health professionals. It should be noted that Novartis had a separate website which was directed to health professionals and other relevant decision makers ('**ORDMs**'), entitled '"Novartis" HCP Portal' (health.novartis.co.uk) which contained promotional material. This was accessible directly, through a search engine, or from Novartis' UK corporate website by selecting 'Our Work' from the menu bar and then navigating to 'For UK Healthcare Professionals'. In any case, that an individual accessed this website, a pop-up gateway was displayed specifying that the website was intended for health professionals and ORDMs only, and a disclaimer of the same was present on this website. Novartis therefore believed that the company had not acted in breach of Clauses 12.1, 12.6 and 12.9 of the Code, and consequently there was no requirement to include prescribing information or adverse event reporting information on the Licensed Medicine Press Releases.

Novartis disagreed with the complainant that the Licensed Medicine Press Releases were proactively disseminated to the public, and therefore the public were promoted to. As stated above, Novartis believed the Licensed Medicine Press Releases to be non-promotional in nature and furthermore, Novartis did not consider the Licensed Medicine Press Releases to raise unfounded hopes of successful treatment or be misleading with respect to the safety of the products to which the press release related. Novartis noted that the supplementary information to Clause 26.2 did not preclude a company making information available (directly or indirectly) to the public via press announcements, and this included information made available on a company's website. Furthermore, the Code made express reference to 'press releases' under proactive information. The supplementary information to Clause 26.2 concerning 'Website Access' provided that a pharmaceutical company providing information for the public on its website must have sections for each target audience clearly separated and intended audience specified. As noted above, Novartis had clearly and prominently specified that the intended audience of the Licensed Medicine Press Releases on the Webpage was journalists. Novartis believed that the Licensed Medicine Press Releases, their placement and target audience, was consistent with the requirements of the Code, and Novartis therefore believe that it had not acted in breach of Clause(s) 26.1 and 26.2.

2 Press Releases - Pre-License Medicines (Clause 11.1)

Novartis stated that the complainant referred to the following press releases concerning pre-license medicines:

i) People with chronic myeloid leukaemia granted early access to Novartis' investigational treatment (published January 24, 2022); and
ii) Novartis Pharmaceuticals UK awarded an Innovation Passport for investigational oral therapy iptacopan (LNP023) (published October 28, 2021),

together referred to as the 'Pre-License Medicine Press Releases'.

A copy of the Pre-License Medicine press releases and the summaries of product characteristics applicable to the medicines were provided. Novartis noted that the SPC for iptacopan was not yet available.

Novartis stated that the complainant alleged that the Pre-License Medicine Press Releases were pre-license promotion by Novartis through proactive dissemination on Novartis' website. Novartis disagreed with the complainant.

In Case AUTH/3414/11/20 the Panel noted that it was not unacceptable for a company to refer to pipeline products on its corporate website, however, language, context, location, layout and overall impression would be important factors when deciding whether such references were acceptable, and such references should not otherwise constitute promotion of an unlicensed medicine. Novartis addressed each factor below in the context of the Pre-License Medicine Press Releases.

With regard to language and context, the Pre-License Medicine Press Releases were reviewed and certified as non-promotional materials; as they were newsworthy, factual and balanced. The Pre-License Medicine Press Releases contained minimum detail and did not contain any detail regarding either the efficacy or safety of the products in question. The Pre-License Medicine Press Releases were intended to be solely for information purposes and to demonstrate Novartis' commitment to these therapy areas.

Addressing location and layout, as discussed above, the Press Releases were hosted on the webpage, where a reader would have to navigate through three links (Homepage > News > UK News Archive) to reach the webpage or use specific search parameters on a search engine to find the webpage or press release in question. The Pre-License Medicine Press Releases were not intended for access by health professionals, ORDMs or the general public, and, as Novartis noted above, the webpage clearly and prominently specified up front that the intended audience was journalists. The layout of the webpage was simple and did not include links on the sidebar to divert readers to other information on the Novartis website. A reader would have to actively seek out the menu bar to navigate the site and access further non-promotional information (eg Novartis' external funding, partnerships and disease areas) or Novartis' dedicated website containing promotional information, which was intended solely for health professionals and ORDMs, as discussed above.

In light of these factors, it was Novartis' submission that the overall impression of the Pre-License Medicine Press Releases on the webpage was that they were non-promotional in nature and intended solely for an audience of journalists. Novartis had not acted in breach of Clause 11.1 of the Code.

3 Clause(s) 5.1 and 2

Novartis disagreed with the complainant that Novartis had breached Clause 5.1 of the Code by failing to maintain high standards. Novartis submitted that as an organisation, it set and expected extremely high standards to comply with the Code, and the company did not believe that the press releases amounted to a failure by Novartis to maintain high standards in light of the points that Novartis set out below.

Novartis press releases underwent a rigorous, multi-stage, review process to ensure that by certification, the Press Releases were assessed to be non-promotional, newsworthy, factual, balanced and met the requirements of the Code as well as Novartis' own policies and standards for the audience they were intended for.

In Case AUTH/3414/11/20 Novartis provided an undertaking to the PMCPA to take all possible steps to avoid similar breaches of the Code occurring in the future on the Novartis UK corporate website. While the facts are considerably different to the present case, the Webpage was hosted on the Novartis UK corporate website, and Novartis had, since providing the previous undertaking, implemented further internal steps for press releases to ensure that the company met the high standards expected by the Code. In particular, Novartis no longer permitted pipeline product information to be included on its public facing website, with the exception of press releases, which were specifically intended for a journalist audience. Novartis had a process in place to review press releases regularly and, in any event, removed them from the webpage after twelve months to ensure that the content was relevant and up-to-date for the intended audience.

Novartis understood that Clause 2 was a sign of particular censure and was reserved for such use. Novartis was particularly concerned to receive this complaint, in light of the fact that hosting press releases on a corporate website regarding both licensed and pre-license medicines to an audience of journalists, was common practice across the industry. Change in this area would mark a significant departure from current practice and would impact many other organisations. As an organisation, Novartis had taken proactive steps to ensure that sections of the Novartis UK website had their audience clearly identified, and content was up-to-date and relevant for the target audience. Novartis strongly believed that the Press Releases did not bring discredit upon, or reduce confidence in, the pharmaceutical industry and Novartis were committed to maintaining high standards in this area, and as such, Novartis submitted that it had not acted in breach of Clauses 5.1 and 2 of the Code.

PANEL RULING

In the Panel's view, it was not necessarily unacceptable for a company to have press releases within a clearly labelled section of a corporate website which made the intended audience (journalists/ the media) clear. Such information should not otherwise constitute promotion or promotion of an unlicensed medicine.

The Panel noted Novartis' submission that the press releases were hosted on Novartis UK's corporate website and were accessible by navigating to 'News' on the menu bar at the top of the page and then selecting 'UK News Archive' from the drop-down options. The Panel further noted Novartis' submission that the UK News Archive webpage was indexed, and was therefore also accessible by a search engine, provided that the search parameters were specific enough. It was, however, unclear to the Panel what search terms would be required for this to occur.

The Panel noted that the press releases appeared to be hosted on the webpage, where a reader would have to navigate through three links (Homepage > News > UK News Archive) to reach the webpage or use specific search parameters on a search engine to find the webpage or press release in question.

The Panel further noted Novartis' submission that when accessed, the webpage clearly and prominently specified at the beginning of the page that the intended audience was journalists, by stipulating 'The UK News Archive contains resources intended for journalists only'.

The Panel noted its comments above and considered that the press releases hosted on the webpage in question were neither directed to, nor limited to, an audience of health professionals and other relevant decision makers and thus was not advertising to that audience as alleged. The Panel therefore considered that the allegations relating to the promotion to health professionals and associated requirements were not relevant. The Panel thus, based on the complainant's narrow allegation, ruled no breach of Clauses 12.1, 12.6 and 12.9 in relation to each of the four press releases for licensed medicines. Nor did the Panel consider that the complainant had established that the two press releases related to pre-licensed medicines constituted promotion of medicines to health professionals prior to the grant of their marketing authorisation and based on the complainant's narrow allegation, no breach of Clause 11.1 was ruled in relation to each.

The Panel noted its comments above and considered that the press releases hosted on the webpage in question were not directed to the general public and thus was not advertising to that audience as alleged. The Panel thus ruled no breach of Clauses 26.1 and 26.2 in relation to each of the four press releases for licensed medicines based on the complainant's narrow allegation.

The Panel noted its rulings above and consequently ruled no breach of Clauses 5.1 and 2 in relation to each of the press releases as alleged.

Complaint received **3 April 2022**

Case completed **14 March 2023**