CASE AUTH/3421/11/20

CONTACTABLE COMPLAINANT v NOVARTIS

Promotion of Cosentyx on LinkedIn

A complainant who described him/herself as a concerned UK health professional, complained about the promotion of Cosentyx (secukinumab) by Novartis Pharmaceuticals UK on LinkedIn.

Cosentyx was indicated for certain patients with plaque psoriasis, psoriatic arthritis or axial spondyloarthritis.

The complainant provided a screenshot of a named Novartis employee's LinkedIn profile which stated that he/she had 'liked' a news story that mentioned Novartis. The information on the employee's profile featured the Novartis corporate logo and the statement 'Novartis' Cosentyx reduces synovitis in new psoriatic arthritis study'. The post appeared to be linked to a Pharma Times article, but a copy of the article was not provided by either party.

The complainant noted that information regarding Cosentyx appeared on LinkedIn and had been 'liked' by a member of the medical staff at Novartis.

The complainant noted that this was not the first time that staff at Novartis had undertaken this activity and, in that regard, he/she referred to Case AUTH/3038/4/18.

The complainant stated that there was no evidence that the LinkedIn post had been certified, there was no mention of the generic name and the post promoted to the public. The complainant alleged a breach of undertaking which surely demonstrated both a failure to maintain high standards and brought discredit to the industry (Clause 2).

The detailed response from Novartis is given below.

The Panel noted Novartis' submission that its employee 'liked' the Pharma Times post which mentioned a Novartis medicine and an indication entirely of his/her own volition using his/her own LinkedIn account; the employee's conduct was not associated with any activity supported by Novartis. It appeared from the screenshot provided by the complainant that the statement 'Novartis' Cosentyx reduces synovitis in new psoriatic arthritis study' and link to the Pharma Times article appeared on the employee's LinkedIn profile and was, on the balance of probabilities, highlighted to his/her connections which in the Panel's view would likely include both health professionals and other relevant decision makers and members of the public.

The Panel further noted from Novartis' submission that the post at issue was not limited to the employee's direct connections on LinkedIn.

The Panel considered that the statement 'Novartis' Cosentyx reduces synovitis in new psoriatic arthritis study' which appeared on the Novartis' employee's LinkedIn profile and, on the balance of probabilities, its proactive dissemination to the employee's connections constituted promotion of a prescription only medicine to the public. A breach of the Code was ruled as acknowledged by Novartis.

Furthermore, the Panel considered that the positive statement that Cosentyx reduced synovitis in a new psoriatic arthritis study could have, on the balance of probabilities, encouraged members of the public to ask their health professional to prescribe Cosentyx and therefore a breach of the Code was ruled.

The Panel noted that the Code required a side effect reporting statement to be included on material which related to a medicine and which was intended for patients taking that medicine. The Panel did not consider that the LinkedIn post about Cosentyx was created as material intended for patients taking the medicine and therefore it ruled no breach of the Code.

The Panel considered that the Novartis employee's post which, in the Panel's view, promoted Cosentyx would have, on the balance of probabilities, also been seen by or been proactively disseminated to health professionals and/or other relevant decision makers without the non-proprietary name adjacent to the brand name at its first appearance and a breach of the Code was ruled. With the statement 'Novartis' Cosentyx reduces synovitis in new psoriatic arthritis study' the employee had effectively created his/her own piece of promotional material which should have been certified for such use. A breach of the Code was ruled.

The Panel noted that Novartis had a UK policy document covering the personal use of social media by its employees. That document had been in place since 2018 and stated that employees must not post, re-tweet, 'like' or share any content that referred to a specific medicine either directly or indirectly, including Novartis and non-Novartis products, licensed or not licensed. That included product-specific information emanating from Novartis corporate social media feeds, such as those run by the global organisation. The policy further stated that 'likes' could be viewed as endorsements and reminded readers that a post did not have to contain a product claim to make it promotional. It stated that if the product name and the indication/therapeutic area were mentioned, it could deem it to be promotional and, therefore, not suitable for being shared with the general public. The policy stated that as a general rule, if a medicine was mentioned in a post, not to engage with it. The Panel considered that the instructions to staff not to refer to company products on social media or 'like' posts that made any reference to a specific medicine either directly or indirectly were clear and unambiguous. The employee in question had been trained on the company's social media policy in summer 2020 but had acted in contravention of it in this instance.

The Panel noted its comments and rulings above and considered that high standards had not been maintained. A breach of the Code was ruled.

Nonetheless, the Panel did not consider that this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such use. Novartis had the requisite policies in place but had been badly let down by one of its relatively junior

employees not following the company guidelines upon which he/she had been trained. No breach of the Code was ruled.

With regard to the alleged breach of undertaking, the Panel noted that Case AUTH/3038/4/18 involved, among other things, a press release about Cosentyx data, initiated by Novartis' Swiss based headquarters, which was 'liked' by an employee. In Case AUTH/3038/4/18, the complainant had considered it inappropriate for employees to use LinkedIn to promote information, including studies, about their companies' products. The Panel considered that the activity now in question in Case AUTH/3421/11/20 was similar to the previous case ie an employee had 'liked' material about a Cosentyx study on LinkedIn. The Panel considered in that regard that the undertaking given in Case AUTH/3038/4/18 had been breached. A breach of the Code was ruled. This ruling was appealed by Novartis.

The Panel noted the importance of complying with undertakings; the supplementary information to Clause 2 listed inadequate action leading to a breach of undertaking as an example of an activity likely to lead to a breach of Clause 2. The Panel considered that failure to comply with its undertaking brought discredit upon and reduced confidence in the industry. A breach of the Code was ruled. This ruling was appealed by Novartis.

The Appeal Board agreed that the reference to 'all possible steps' as set out in Paragraph 7.1 of the Constitution and Procedure and included on the form of undertaking to be signed by respondent pharmaceutical companies following a Code of Practice Panel ruling of a breach of the Code should, in general, be interpreted to mean all reasonable, proportionate and lawful steps.

The Appeal Board noted Novartis' submission that its employee had 'liked' the Pharma Times post which mentioned a Novartis medicine and an indication entirely of his/her own volition using his/her own LinkedIn account in a momentary lapse in judgement; the employee's conduct was not associated with any activity supported by Novartis.

The Appeal Board noted from Novartis that its employees completed mandatory interactive online social media training and were sent regular email reminders on the appropriate personal use of social media. Training records were provided. Employees who did not complete the training were followed up. The Appeal Board considered that Novartis had social media policies in place but it had been badly let down by one of its relatively junior employees not following the company guidelines upon which he/she had been trained. The Appeal Board noted that Novartis had accepted the Panel's rulings in relation to advertising a prescription only medicine on LinkedIn.

The Appeal Board queried whether there were sufficient checks in place including validation to ensure that the social media training was fully understood and embedded and considered that it would in addition be prudent to clearly state the consequences of breaching the social media policy when communicating with employees about it rather than the general reference to the employee handbook. It would be more helpful if Novartis used more consistent language in its policies, training and emails. Whilst the Appeal Board noted these general concerns and the similarities between the activities at issue in Case AUTH/3421/11/20 and Case AUTH/3038/4/18, it considered that, on balance, in the particular circumstances of this case, it had not been established that Novartis had

failed to comply with its undertaking given in Case AUTH/3038/4/18. No breaches of the Code were ruled including Clause 2. The appeal on both points was successful.

A complainant who described him/herself as a concerned UK health professional, complained about the promotion of Cosentyx (secukinumab) by Novartis Pharmaceuticals UK on LinkedIn.

Cosentyx was indicated for certain patients with plaque psoriasis, psoriatic arthritis or axial spondyloarthritis.

The complainant provided a screenshot of a named Novartis employee's LinkedIn profile which stated that he/she had 'liked' a news story that mentioned Novartis. The information on the employee's profile featured the Novartis corporate logo and the statement 'Novartis' Cosentyx reduces synovitis in new psoriatic arthritis study'. The post appeared to be linked to a Pharma Times article, but a copy of the article was not provided by either party.

COMPLAINT

The complainant noted that information regarding Cosentyx appeared on LinkedIn and had been 'liked' by a member of the medical staff at Novartis.

The complainant noted that this was not the first time that staff at Novartis had undertaken this activity and in that regard he/she referred to Case AUTH/3038/4/18.

The complainant stated that there was no evidence that the LinkedIn post had been certified (Clauses 14.1, 14.5 and 14.6), there was no mention of the generic name and the post promoted to the public (Clauses 26.1, 26.2 and 26.3). Overall, the complainant alleged a breach of undertaking (Clause 29) which surely demonstrated both a failure to maintain high standards (Clause 9.1) and brought discredit to the industry (Clause 2).

When writing to Novartis, the Authority asked it to consider the requirements of Clauses 2, 4.3, 9.1, 14.1, 26.1, 26.2, 26.3 and 29 of the Code. Novartis did not have to respond to Clauses 14.5 or 14.6 which had been cited by the complainant in relation to the alleged failure to certify, as it had been agreed with the complainant that such clauses were not relevant to that allegation.

RESPONSE

Novartis stated that it was very concerned to have received the complaint, particularly given its previous complaint involving LinkedIn (Case AUTH/3038/4/18) and as such had taken the matter very seriously. Novartis noted that it was committed to operating in accordance with the required standards and met the relevant requirements and expectations.

Novartis noted that the complaint centred on a Novartis employee 'liking' a post on LinkedIn, originating from www.pharmatimes.com, about Cosentyx which, as the complainant suggested, brought the matter into the scope of the Code. Novartis had reviewed this incident in depth and although it accepted a breach of Clause 26.1 it did not believe it had breached the other clauses.

Certification and promotion

Novartis noted that the post which had been 'liked' by one of its employees was an article that had been independently authored and shared by Pharma Times on LinkedIn; Novartis did not have any input into the drafting or dissemination of the article. There was no intent or instruction from Novartis to share or 'like' the post. The Pharma Times post was 'liked' by a Novartis employee entirely of his/her own volition and was not associated with any activity supported by Novartis. Novartis stated that it recognised however, that that act brought the Code into scope and consideration for the complaint. Novartis neither shared nor 'liked' the post; furthermore, it was corporate policy not to post, share, 'like' or re-tweet any social media posts that mentioned medicines including Novartis and non-Novartis products on any corporate-owned UK social media channels including, but not limited to Twitter, LinkedIn, Facebook and Instagram. Any social media activities that Novartis did engage with were approved and certified in accordance with the requirements of the Code.

As the post was independently authored and shared with no input from Novartis, and as Novartis had no plan to share or 'like' this post, there was no requirement for certification, and hence Novartis believed that it did not breach Clause 14.1. Similarly, Novartis did not believe that it had breached Clause 4.3 as this was not material created or intended for use by Novartis.

As the material was neither conceived nor produced by Novartis, but an independent entity sharing its own material, and there was no plan, intent or instruction to proactively 'like' or share the post on Novartis' behalf, the requirement for balanced presentation of information and requisite statements specified in the Code related to Clauses 26.2 and 26.3 did not apply. Hence Novartis believed that it had not breached Clauses 26.2 and 26.3.

Novartis noted that it was important to distinguish Case AUTH/3038/4/18 where it was found to have breached the Code in respect of (amongst others) Clauses 26.1 and 14.1 pertaining to the 'liking' of a hyperlink (as specified in Case AUTH/3038/4/18). The material within the hyperlink originated from Novartis Pharma AG, the global headquarters of the Novartis Group, in the form of a press release. In the matter now in question, there was complete independence of the article, hence Novartis did not believe that it should be expected to certify and/or examine the article as it was independently produced by another organisation, with no input from Novartis.

However, the Novartis employee 'liked' the Pharma Times post on LinkedIn via channels that were not affiliated with Novartis; in doing so Novartis accepted that there had unfortunately unwittingly been a breach of Clause 26.1 as a result of the individual's actions – an employee 'liking' a post which mentioned a medicine and an indication, and thereby highlighting that to his/her network, had therefore resulted in inadvertent promotion to the public. Novartis regretted that the employee had failed to comply with the Novartis Social Media Policy on this occasion; however, Novartis had ensured a consistent approach to social media use throughout the organisation by providing regular training and reminders as described below.

Undertaking

Novartis noted that as part of the outcome to Case AUTH/3038/4/18, it gave an undertaking to ensure such a matter should not come before the Panel again. Specifically, it undertook to 'take all possible steps to avoid similar breaches of the Code occurring in the future'.

Whilst Novartis accepted there had unwittingly been promotion to the public, it did not consider that that necessarily led to a breach of the undertaking. Novartis reasonably believed that it had

indeed taken all possible steps to mitigate a potential breach as outlined in Case AUTH/3038/4/18:

- Novartis had created and maintained a UK Social Media Policy (copy provided) and an accompanying decision tree (copy provided) for use by all Novartis associates.
- All associates were required to undertake training in 2018 and all new Novartis associates were required to undertake training as part of their on-boarding process.
- Novartis had created lunch and learn sessions, for example in May and June 2020 (presentation slides provided) and regularly reminded all Novartis associates to undertake refresher training in regular internal email communications (including links to training/updates/personal use and decision tree), for example in July, October and November 2020 (copies provided).

Accordingly, Novartis considered that it was evident that it had taken its responsibilities seriously as a result of Case AUTH/3038/4/18. Although the breach in the present case had similarities to Case AUTH/3038/4/18, it was also distinguishable from that case for the reasons outlined above. However, a single act by a single employee had resulted in promotion to the public; Novartis was steadfast in its view there was no breach of the undertaking and therefore no breach of Clause 29.

Novartis employee individual response

With particular regard to the employee responsible for 'liking' the article, he/she:

- was informed on 27 November 2020 of the complaint
- removed the 'like' from his/her LinkedIn profile on 28 November and re-took the UK Social Media Policy training
- had completed an updated UK Social Media Policy training in July 2020
- had downloaded a pdf of the Personal Use of Digital Engagement Platforms, Novartis Global Guideline dated 15 July, 2020 (copy provided) and saved it for reference.

Novartis noted that the employee had around 140 connections on LinkedIn of which approximately 90% were Novartis employees. The employee who 'liked' the post had demonstrated sincere contrition since learning of his/her momentary lapse in judgement and had taken prompt action to remove the 'like' from his/her LinkedIn profile, undertaken fresh training on social media use and amended privacy settings such that his/her profile activity was only visible to direct connections.

As stated above, this was a momentary lapse of judgement and the employee was fully aware of Novartis' policies on social media use. The employee had since amended his/her LinkedIn profile accordingly to mitigate any recurrence.

Standards and confidence

Novartis refuted any breaches of Clauses 2 and 9.1. With regard to the latter, Novartis set high standards for its employees, and although there was an individual error which resulted in promotion to the public, Novartis believed it had maintained significant engagement on social media use to minimise such an occurrence, as evidenced by the company's Social Media Policy, decision tree and regular communications and/or reminders.

In considering the entirety of the matter, with particular regard to the supporting evidence and of the employee's action, Novartis submitted that this was a single lapse of judgement and that there was subsequent mitigation to the complaint. Novartis denied a breach of Clause 2.

In summary, the complaint had raised a number of issues about social media use. Novartis believed that there was a legitimate defence to the alleged breaches of Clauses 2, 9.1, 14.1, 26.2, 26.3 and 29, but conceded promotion to the public (Clause 26.1) occurred as a result of individual actions.

PANEL RULING

The Panel noted that LinkedIn was different to some other social media platforms in that it was a business and employment-orientated network and was primarily, although not exclusively, associated with an individual's professional heritage and current employment and interests; its application was not limited to the pharmaceutical industry or to health care. In the Panel's view, it was of course not unacceptable for company employees to use personal LinkedIn accounts; the Code would not automatically apply to all activity on a personal account. The Panel noted that compliance challenges arose when the personal use of social media by pharmaceutical company employees overlapped with their professional responsibilities or the interests of the company. The Panel noted that material could be disseminated or highlighted by an individual on LinkedIn in a number of ways, by posting, sharing, commenting or liking. The Panel understood that if an individual 'liked' a post it increased the likelihood that the post would appear in his/her connections' LinkedIn feeds, appearing as '[name] likes this'. In the Panel's view, activity conducted on social media that could potentially alert one's connections to the activity might be considered proactive dissemination of material. In addition, an individual's activity and associated content might appear in the individual's list of activities on his/her LinkedIn profile page which was visible to his/her connections; an individual's profile page was also potentially visible to others outside his/her network depending on the individual's security settings. Company employees should assume that such activity would therefore, potentially, be visible to both those who were health professionals or other relevant decision makers and those who were members of the public. In that regard, it was imperative that they acted with extreme caution when using all social media platforms, including LinkedIn, to discuss or highlight issues which impinged on their professional role or the commercial/research interests of their company. Whether the Code applied would be determined on a case-by-case basis, taking into account all of the circumstances including, among other things, content and distribution of the material. If an employee's personal use of social media was found to be in scope of the Code, the company would be held responsible. The Panel considered that companies should assume that the Code would apply to all work-related, personal LinkedIn posts/activity by their employees unless, for very clear reasons, it could be shown otherwise. Any material associated with a social media post, for example a link within a post, would be regarded as being part of that post. Companies must have comprehensive and up to date social media policies that provide clear and unequivocal guidance on what was, and what was not, acceptable and it was extremely important that employees were trained upon them and followed them.

The Panel noted Novartis' submission that the post which had been 'liked' by one of its employees was an article that had been independently authored and shared by Pharma Times on LinkedIn.

The Panel noted Novartis' submission that its employee 'liked' the Pharma Times post which mentioned a Novartis medicine and an indication entirely of his/her own volition using his/her

own LinkedIn account; the employee's conduct was not associated with any activity supported by Novartis. It appeared to the Panel from the screenshot provided by the complainant that the result was that the activity and thus the statement 'Novartis' Cosentyx reduces synovitis in new psoriatic arthritis study' and link to the Pharma Times article appeared on the employee's LinkedIn profile and was, on the balance of probabilities, highlighted to his/her connections which in the Panel's view would likely include both health professionals and other relevant decision makers and members of the public.

The Panel further noted Novartis' submission that since learning of the complaint the employee had amended the privacy settings such that his/her profile activity was only visible to direct connections. It appeared therefore that the post at issue was not limited to his/her direct connections on LinkedIn.

The Panel considered that the statement 'Novartis' Cosentyx reduces synovitis in new psoriatic arthritis study' which appeared on the Novartis' employee's LinkedIn profile and, on the balance of probabilities, its proactive dissemination to the employee's connections constituted promotion of a prescription only medicine to the public. A breach of Clause 26.1 was ruled as acknowledged by Novartis.

Furthermore, the Panel considered that the positive statement that Cosentyx reduced synovitis in a new psoriatic arthritis study could have, on the balance of probabilities, encouraged members of the public to ask their health professional to prescribe Cosentyx and therefore a breach of Clause 26.2 was ruled.

The Panel noted that Clause 26.3 required a side effect reporting statement to be included on material which related to a medicine and which was intended for patients taking that medicine. The Panel did not consider that the LinkedIn post about Cosentyx was created as material intended for patients taking the medicine and therefore it ruled no breach of Clause 26.3.

The Panel considered that the Novartis employee's post which, in the Panel's view, promoted Cosentyx would have, on the balance of probabilities, also been seen by or been proactively disseminated to health professionals and/or other relevant decision makers without the non-proprietary name adjacent to the brand name at its first appearance and a breach of Clause 4.3 was ruled. With the statement 'Novartis' Cosentyx reduces synovitis in new psoriatic arthritis study' the employee had effectively created his/her own piece of promotional material which should have been certified for such use. A breach of Clause 14.1 was ruled.

The Panel noted that Novartis had a UK policy document covering the personal use of social media by its employees. That document had been in place since 2018 and stated that employees must not post, re-tweet, 'like' or share any content that referred to a specific medicine either directly or indirectly, including Novartis and non-Novartis products, licensed or not licensed. That included product-specific information emanating from Novartis corporate social media feeds, such as those run by the global organisation. The policy further stated that 'likes' could be viewed as endorsements and reminded readers that a post did not have to contain a product claim to make it promotional. It stated that if the product name and the indication/therapeutic area were mentioned, it could deem it to be promotional and, therefore, not suitable for being shared with the general public. The policy stated that as a general rule, if a medicine was mentioned in a post, not to engage with it. The Panel considered that the instructions to staff not to refer to company products on social media or 'like' posts that made any reference to a specific medicine either directly or indirectly were clear and unambiguous.

The employee in question had been trained on the company's social media policy in summer2020 but had acted in contravention of it in this instance.

The Panel noted its comments and rulings above and considered that high standards had not been maintained. A breach of Clause 9.1 was ruled.

Nonetheless, the Panel did not consider that this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such use. Novartis had the requisite policies in place but had been badly let down by one of its relatively junior employees not following the company guidelines upon which he/she had been trained. No breach of Clause 2 was ruled.

With regard to the alleged breach of undertaking, the Panel noted that Case AUTH/3038/4/18 involved, among other things, a press release about Cosentyx data, initiated by Novartis' Swiss based headquarters, which was 'liked' by an employee. In Case AUTH/3038/4/18, the complainant had considered it inappropriate for employees to use LinkedIn to promote information, including studies, about their companies' products. The Panel considered that the activity now in question in Case AUTH/3421/11/20 was similar to the previous case ie an employee had 'liked' material about a Cosentyx study on LinkedIn. The Panel considered in that regard that the undertaking given in Case AUTH/3038/4/18 had been breached. A breach of Clause 29 was ruled.

The Panel noted the importance of complying with undertakings; Clause 29 underpinned self-regulation. The Panel noted that the supplementary information to Clause 2 listed inadequate action leading to a breach of undertaking as an example of an activity likely to lead to a breach of Clause 2. The Panel considered that failure to comply with its undertaking brought discredit upon and reduced confidence in the industry. A breach of Clause 2 was ruled.

APPEAL FROM NOVARTIS

Novartis accepted the Panel's rulings of breaches of Clauses 4.3, 9.1, 14.1, 26.1 and 26.2. Novartis appealed the Panel's rulings of a breach of Clause 29 and Clause 2 which flowed from this breach. Novartis identified two key questions of relevance for the appeal:

i) In relation to the ruling of a breach of Clause 29 of the Code, did Novartis take 'all possible steps' to ensure compliance with the undertaking given in Case AUTH/3038/4/18? and
ii) If a breach of Clause 29 was upheld on appeal, did Novartis' actions amount to 'inadequate action leading to a breach of an undertaking' sufficient to be a breach of Clause 2?

1 Compliance with undertaking (breach of Clause 29)

On 5 December 2018, Novartis gave an undertaking to the PMCPA following the Panel's ruling in Case AUTH/3038/4/18, which related to a similar scenario regarding the promotion of medicinal products on the LinkedIn platform. The particular details of the case were not relevant for the purposes of this appeal; notwithstanding, the form of undertaking given by Novartis following that case was as follows:

> 'We hereby give an assurance that we will take all possible steps to avoid similar breaches of the Code occurring in the future' (the '**2018 Undertaking'**).

In the present case, the Panel considered that the 2018 Undertaking had been breached, and as such, a breach of Clause 29 was ruled.

Novartis disagreed with the Panel's decision. Assessing compliance with the 2018 undertaking required an assessment of whether Novartis had taken 'all possible steps to avoid similar breaches'.

Novartis' position on this was comprised of three principles:

i) the 2018 undertaking might not properly be construed as requiring an absolute guarantee by Novartis as to the conduct of employees acting in a personal capacity and using personal social media accounts and Novartis did not understand this to be the scope of the undertaking when it was given;
ii) that Novartis had taken 'all possible' steps (ie those that were lawful, reasonable and proportionate to take in the circumstances) and
iii) consistent with (ii), to absolutely ensure that no breach of the 2018 undertaking would occur was impossible in practice, even if unreasonable (and very likely unlawful) employment conditions infringing the personal privacy of individuals were imposed.

Novartis submitted that since providing the 2018 undertaking, it had provided extensive online training and disseminated numerous internal communications on the appropriate personal use of social media. Details of Novartis' internal communications were provided. In addition, there were several standard operating procedures (SOPs) and policies which had been put in place to address social media use (copies provided). Finally, Novartis had delivered extensive face to face and live online training sessions on this topic to the business (details provided).

Novartis submitted internal training records, confirmed a 96% completion rate of the social media training module amongst UK employees (copies provided). A redacted list of Novartis employees together with completion dates was also provided to further highlight the scope and outreach of this internal training programme.

Novartis submitted that the Panel made no criticism of Novartis' procedures and training in relation to personal use of social media and its decision positively noted that:

- 'The Panel considered that the instructions to staff not to refer to company products on social media or 'like' posts that made any reference to a specific medicine either directly or indirectly were clear and unambiguous' and

- 'Novartis had the requisite policies in place but had been badly let down by one of its relatively junior employees not following the company guidelines upon which he/she had been trained.

Novartis' position was that it was patently impossible for the company to provide an absolute guarantee of employees' conduct when acting in a personal capacity on their personal social media accounts. In circumstances where Novartis took very seriously any undertaking provided to the PMCPA, it would not have given an undertaking in respect of activity over which it could not exercise control.

Novartis submitted that while there were always further ways to communicate its policies or repeat its training even more frequently, there would be a point of diminishing returns. Novartis maintained that the actions it took constituted 'all possible steps' in the circumstances. However, and importantly, the Panel did not suggest what further steps Novartis could reasonably have taken in this regard that would have definitely stopped (or even incrementally reduced the likelihood of) a single employee choosing to act against the instructions and guidance contained in the trainings and messages circulated by Novartis.

While Novartis (i) could update its SOPs and policies to permit Novartis a greater level of scrutiny of its employees' use of social media channels; and/or (ii) update its SOPs and policies to prohibit in absolute terms any use of social media channels by its employees, such steps would lead to difficult questions of employment law and implications for the personal privacy of individual employees of the company. Further, taking such steps would impose a significantly higher burden on Novartis employees than that of employees of other companies in its industry; this could not have been the intention of the 2018 undertaking.

For these reasons, Novartis' position was that Novartis did not breach the 2018 undertaking and the Panel's finding of a breach of Clause 29 of the Code should be overturned.

Novartis submitted that should the Appeal Board not be persuaded of Novartis' position, Novartis and the wider industry would be looking to the Appeal Board's ruling in this case for firm and specific guidance as to what steps a pharmaceutical company must take with its employees to ensure compliance with the Code when it came to using personal social media accounts and the steps they should now take to limit employees' activities on social media outside of their working time.

2 Discredit to, and Reduction of Confidence in, the Industry (breach of Clause 2)

Novartis submitted that the ruling of a breach of Clause 2 in this case flowed directly from the finding that the 2018 undertaking had been breached. Having determined that there was a breach of the 2018 undertaking, the Panel noted that the supplementary information to Clause 2 listed 'inadequate action leading to a breach of undertaking as an example of an activity likely to lead to a breach of Clause 2'.

Novartis submitted that its primary position was that there had not been a breach of undertaking at all, for the reasons set out above. If this accepted, then it appeared to follow that the breach of Clause 2 could not be upheld.

However, if a breach of Clause 29 was upheld, Novartis' alternative position was that such a breach had not been due to Novartis' 'inadequate action' to ensure ongoing compliance with the 2018 undertaking.

Novartis submitted that there were obviously limits to the control any company could exert over the actions of its employees, particularly in relation to social media, some of which Novartis had touched on in the earlier sections. Novartis submitted that any reasonable person would assess that the very thorough and diligent efforts taken by Novartis (as set out extensively above and in the supporting appendices) to ensure immediate and ongoing compliance by its employees with the 2018 undertaking clearly satisfy the requirements of 'adequate action'. This view was also

supported by the conclusions of the Panel, quoted above, recognising that Novartis' instructions to staff were 'clear and unambiguous' and Novartis 'had the requisite policies in place'.

Novartis submitted that if an employee's actions in the face of such steps was held to be in breach of the 2018 undertaking, it did not automatically follow that this necessarily meant that the actions of Novartis were inadequate. Rather, it just demonstrated the limits of what could actually be controlled, something the Panel apparently acknowledged when it noted 'Novartis had the requisite policies in place but had been badly let down by one of its relatively junior employees not following the company guidelines upon which he/she had been trained'.

From the above, Novartis submitted that the Panel's finding of a breach of Clause 2 of the Code should be overturned.

Novartis submitted that it considered the information provided in the appendices to be confidential and proprietary in nature. Any references to individuals were also subject to data protection laws and were also subject to conditions of confidence.

COMMENTS FROM THE COMPLAINANT

The complainant had no fresh evidence to submit.

APPEAL BOARD RULING

The Appeal Board agreed that the reference to 'all possible steps' as set out in Paragraph 7.1 of the Constitution and Procedure and included on the form of undertaking to be signed by respondent pharmaceutical companies following a Code of Practice Panel ruling of a breach of the Code should, in general, be interpreted to mean all reasonable, proportionate and lawful steps.

The Appeal Board noted Novartis' submission that its employee had 'liked' the Pharma Times post which mentioned a Novartis medicine and an indication entirely of his/her own volition using his/her own LinkedIn account in a momentary lapse in judgement; the employee's conduct was not associated with any activity supported by Novartis.

The Appeal Board noted from Novartis that its employees completed mandatory interactive online social media training and were sent regular email reminders on the appropriate personal use of social media. Training records were provided. Employees who did not complete the training were followed up. The 2018 UK policy document covering the personal use of social media by its employees stated that employees must not post, re-tweet, 'like' or share any content that referred to a specific medicine either directly or indirectly, including Novartis and non-Novartis products, licensed or not licensed. The Appeal Board considered that Novartis had social media policies in place but it had been badly let down by one of its relatively junior employees not following the company guidelines upon which he/she had been trained. The Appeal Board noted that Novartis had accepted the Panel's rulings of breaches of Clauses 4.3, 9.1, 14.1, 26.1 and 26.2 of the Code.

The Appeal Board queried whether there were sufficient checks in place including validation to ensure that the social media training was fully understood and embedded and considered that it would in addition be prudent to clearly state the consequences of breaching the social media policy when communicating with employees about it rather than the general reference to the

employee handbook. It would be more helpful if Novartis used more consistent language in its policies, training and emails. Whilst the Appeal Board noted these general concerns and the similarities between the activities at issue in Case AUTH/3421/11/20 and Case AUTH/3038/4/18, it considered that on balance, in the particular circumstances of this case, it had not been established that Novartis had failed to comply with its undertaking given in Case AUTH/3038/4/18. It followed that no breach of Clause 29 was ruled. The appeal on this point was successful.

The Appeal Board considered that consequently a breach of Clause 2 was not warranted and no breach was ruled. The appeal on this point was successful.

Complaint received **12 November 2020**

Case completed **22 July 2021**