CASE AUTH/3743/2/23

COMPLAINANT v BIOMARIN

Promotion of therapies via social media (LinkedIn)

CASE SUMMARY

This case was in relation to the alleged promotion of two therapies in a LinkedIn post made by a senior leader based in the United Arab Emirates.

The outcome under the 2021 Code was:

Breach of Clause 5.1(x2)	**- Failing to maintain high standards**
Breach of Clause 26.1	**- Advertising a prescription only medicine to the public**

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

FULL CASE REPORT

A complaint was received about BioMarin, from an anonymous, contactable complainant who had now become non-contactable.

COMPLAINT

The complaint wording is reproduced below:

> 'Promotion of Therapies via Social Media (LinkedIn). On 15 February a senior executive at Biomarin posted referencing the "recent approvals by FDA for Biomarin;s [sic] first therapy for Achondroplasia as well as EMA approval for First ever gene therapy for Severe adult hemophilia A". Given Biomarins products are the only [sic] in these spaces this is a clear references [sic] to Biomarins products voxzogo and roctavian. The post was liked by multiple Biomarin personnel many of who are based in Europe - including the U.K. [named senior leader] and also senior global executives [named global executives], additionally various directors in [named departments] based in U.K. and Ireland liked or commented on the post. All of these individuals have broad connections across LinkedIn including HCPs, Patients and Patient Organisations broadening the reach of the post and ensuring it was visible on multiple LinkedIn users timelines in clear breach of advertising laws and ABPI Code.'

When writing to BioMarin, the Authority asked it to consider the requirements of Clauses 5.1 and 26.1 of the Code.

RESPONSE

The response from BioMarin is reproduced below:

'Thank you for your letter of 23rd February, by email, the contents of which are noted. Please see our response to the complaint below.

Factual Summary

On 23rd February the PMCPA received a complaint relating to a LinkedIn post ("the post") by an employee of BioMarin MENA FZ-LLC, in which they referenced the following:

"…this visit happened in parallel with recent approvals by FDA for Biomarin;s [sic] first therapy for Achondroplasia as well as EMA approval for First ever gene therapy for Severe adult hemophilia A"

While the post did not identify any product names, BioMarin Pharmaceutical Inc ("BPI") and its subsidiaries (collectively "BioMarin") manufacture and sell VOXZOGO® (Vosoritide), the first therapeutic treatment for children with Achondroplasia, and ROCTAVIAN™ (Valoctocogene Roxaparvovec), the first gene therapy for adults with severe Haemophilia A. VOXZOGO® received a marketing authorisation from the European Commission on 26 August 2021, and from the FDA on 19th November 2021. ROCTAVIAN™ received a marketing authorisation from the European Commission on 24th August 2022. Neither VOXZOGO® or ROCTAVIAN™ are approved for use in the UK.

The complaint was provided to BioMarin (UK) Limited on February 23rd, the same day it was received by the PMCPA and a screenshot of the post provided by the PMCPA shows the post was made "5 days ago," indicating that the post was made on or about the 18th of February. The matter was escalated internally to the US where BioMarin (UK) Limited's and BioMarin MENA FZ-LLC's parent company, BPI, is based. BioMarin immediately took the precautionary measure of requesting that the post be removed from LinkedIn and it was taken down the same day.

At the time BioMarin was advised of the complaint, the post had received over 130 'likes' or similar interactions on LinkedIn from users, the vast majority (100+) of whom were not employees of, nor associated with, BioMarin. Of those that were from BioMarin, only one was an employee of BioMarin UK Ltd; the rest were BioMarin employees based outside of the UK.

The complainant is an anonymous contactable Healthcare Professional (HCP). It is unclear to BioMarin how the post was received by that individual.

BioMarin's Response

The Post Is Out of Scope of the PMCPA

The post in question was a factual and nonpromotional attempt to celebrate recent BioMarin community activities, and it originated from a LinkedIn account operated by a BioMarin MENA FZ-LLC employee based in the United Arab Emirates. The post was thus drafted and uploaded with no involvement by BioMarin (UK) Limited. In addition, the post did not target UK users of LinkedIn, and it did not directly or indirectly reference the UK or any products available therein.

Clause 1.2 of the ABPI Code of Practice 2021 ("the Code") states:

> "*Information about medicine which is placed on the internet outside the UK will be regarded as coming within the scope of the Code, if it was placed there by a UK company/with a UK company's authority, or an affiliate of a UK company, or with the authority of such a company, and it makes specific reference to the availability or use of the medicine in the UK*"

Furthermore, Section 12 of the *PMCPA Digital Guidelines 2016* effectively confirms that UK companies should not be held responsible for information placed on the Internet outside the UK by an employee of a parent company unless:

> (i) such activities were on the instigation or authority of the UK company; and
> (ii) the information referred to the availability of a product in the UK.

Accordingly, the post is not attributable to BioMarin UK Ltd and would fall outside the scope of the Code because:

> (i) The source of the post was an employee of BioMarin MENA FZ-LLC, without involvement of BioMarin (UK) Ltd, and therefore the published content was clearly under the authority of a BioMarin employee without nexus to BioMarin UK Ltd.
> (ii) The owner of the source account had a global audience, predominantly based in the Middle East.
> (iii) The LinkedIn post was addressed to an internal BioMarin community and not specifically to UK users.
> (iv) The post was liked by only one employee of BioMarin UK Ltd; the rest were BioMarin employees based outside of the UK with limited if any professional dealings with UK-based Health Care Professionals.

In addition, the very recently published *PMCPA Social Media Guidance 2023* reiterates the requirement for a UK nexus. This would necessitate establishing that (1) the activity was carried out by the UK company or with its authority or an affiliate of a UK company or with its authority and (2) that it makes specific reference to the availability or use of the medicine in the UK. As set forth above, no such nexus to the UK can be established under the facts at issue.

On the basis that the post lacks a UK nexus and specific reference to UK availability or use of the medicine in the UK, we submit that that the activity does not fall within the scope of the Code and request the complaint be dismissed.

The Post Was Non-Promotional In Purpose, Content, and Tone

Notwithstanding BioMarin's position that the post falls outside the scope of the Code, it is clear that the post in question was factual, nonpromotional, and directed at an internal BioMarin audience. Such communications are permitted under the Code.

The post did not stimulate patient or Healthcare Professional interest in a specific product, as no product claims were made and no product name was referenced. Additionally, as no Marketing Authorisation has been submitted to the MHRA, no product will be available for the foreseeable future and therefore there is no available product to promote.

Furthermore, given the highly specialised nature of both VOXZOGO® and ROCTAVIAN™ and their suitability for tiny patient populations within the UK, as a practical matter the post cannot, even inadvertently have a promotional effect. The small number of patients with the relevant diseases and the limited number of clinicians operating in the relevant fields within the UK would already likely be aware of BioMarin's products and pipeline. The post simply celebrated an ex-UK milestone with the BioMarin community. Any patient or Healthcare Professional who saw the post and whose awareness was increased would not be in a position to prescribe, recommend, use, request or administer treatment with any BioMarin product.

Accordingly, we see no grounds to support the alleged breach and request the complaint be dismissed.

BioMarin Has a Robust Social Media Policy and Process with a Comprehensive Training Program

BioMarin has in place a robust global social media policy ("Global Social Media Policy") for all employees and a supplementary Europe Middle East and Africa (EUMEA) regional social media policy ("EUMEA Social Media Policy") for all EUMEA based employees, of which UK employees are a subset.

BioMarin Policy strictly prohibits EUMEA based employees from generating and posting BioMarin related content unless as an authorised representative and then only when such content is reviewed and approved by the appropriate external communications review body. Additionally, EUMEA based employees are prohibited from sharing, liking or otherwise interacting with social media posts that reference or link to any BioMarin product or pipeline related information.

Both Global and EUMEA employees are required to read and certify as read and understood the global and EUMEA policy. Further, all EUMEA based employees are required to receive in person training on the EUMEA Social Media Policy, and we confirm that all Europe Middle East and Africa (EUMEA) employees identified in this complaint did in fact receive that in person training. Additionally, BioMarin Compliance regularly send out reminders and follow up communications in relation to the topic of Social Media.

Compliance with Social Media policy is monitored and where instances of non-compliance are identified Notice of Violations are sent. Overall, we observe high rates of compliance with Global and Regional Social Media policies. Accordingly, we submit that BioMarin has at all times maintained high standards.

Action Taken to Date

BioMarin's Social Media policies are currently under review to consider whether any changes are needed, and additional training is planned in relation to the process for the approval of material that is posted on social media. Individual follow up with the employees identified in this complaint will be undertaken.'

PANEL RULING

The Panel noted the original LinkedIn post made on or about 18 February 2023 originated from a LinkedIn account operated by a BioMarin MENA FZ-LLC employee based in the United Arab Emirates. The content of the post was in regard to the BioMarin Dubai office having received a senior management visit which reflected the importance and significance of the Middle East and Africa 'MEA' region to BioMarin. Further information was provided regarding the visit which was followed by the wording at issue: 'Nevertheless this visit happened in parallel with recent approvals by FDA for BioMarin;s [sic] first therapy for Achondroplasia as well as EMA approval for First ever gene therapy for Severe adult haemophilia A'. This was followed by two further paragraphs about the development of BioMarin in the MEA region and thanking those who came for the visit.

The Panel noted that LinkedIn was a social media platform which was a business and employment-orientated network; its application was not limited to the pharmaceutical industry or to healthcare. 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 often 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 which included '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.

The Panel noted that UK employees were likely to follow the social media accounts of overseas affiliates which might have codes, laws and regulations that differed to the UK. BioMarin had submitted the Global and European Social Media policies that provided guidance on what was, and what was not, acceptable.

The Panel noted that BioMarin had submitted that, in their view, the post and the UK employee 'liking' the post was not in scope of the Code and in this regard evidenced Clause 1.2 of the Code which stated:

> Information or promotional material about medicines which is placed on the internet outside the UK will be regarded as coming within the scope of the Code, if it was placed there by:
>
> - a UK company/with a UK company's authority, or
> - an affiliate of a UK company, or with the authority of such a company, and it makes specific reference to the availability or use of the medicine in the UK.

The Panel considered the wording in the post at issue, if it was placed there by a UK company, or included engagement by any UK company employee.

The Panel noted BioMarin's submission that at the time BioMarin was advised of the complaint, the post had received over 130 'likes' or similar interactions on LinkedIn from users, the vast majority (100+) of whom were not employees of, nor associated with, BioMarin. Of those that were from BioMarin, only one was an employee of BioMarin UK Ltd; the rest were BioMarin employees based outside of the UK.

The Panel noted that the individual UK employee who 'liked' the LinkedIn post would, on the balance of probabilities, have members of the public, health professionals and other relevant decision makers among others, as connections with their account on LinkedIn and as such the message would have been disseminated to these individuals in the UK. On the evidence before it, the Panel considered the Code did not apply to the original post, as it had been placed by a BioMarin MENA FZ-LLC employee based in the United Arab Emirates, and made no reference to the availability or use of the medicines in the UK. However, the interaction with the post by a UK-based employee had brought it within the scope of the Code, and it was well-established that 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 BioMarin's submission that the post in question was non-promotional in purpose, content and tone. The Panel noted the broad definition of promotion and considered that the post in question promoted Roctavian and Voxzogo; with the mention of BioMarin's 'unique portfolio of breakthrough medication to serve more patients worldwide' and the indications of both medicines, the Panel considered that the post could not be seen as anything other than promotional material.

The Panel noted the post stated 'this visit happened in parallel with recent approvals by FDA for Biomarin;s [sic] first therapy for Achondroplasia as well as EMA approval for First ever gene therapy for Severe adult haemophilia A'. BioMarin had submitted that BioMarin Pharmaceutical Inc and its subsidiaries (collectively 'BioMarin') manufactured and sold VOXZOGO' (Vosoritide), the first therapeutic treatment for children with Achondroplasia, and ROCTAVIAN (Valoctocogene Roxaparvovec), the first gene therapy for adults with severe Haemophilia A. VOXZOGO received a marketing authorisation from the European Commission on 26 August 2021. ROCTAVIAN received a marketing authorisation from the European Commission on 24 August 2022. BioMarin also submitted that neither VOXZOGO nor ROCTAVIAN were approved for use in the UK.

The Panel noted that Northern Ireland was part of the UK and within which a prescription only medicine with an EMA licence could be made available. At the time the post was made, in February 2023, Roctavian and Voxzogo both had an EMA licence.

The Panel considered that Roctavian and Voxzogo were prescription only medicines in Northern Ireland but were unlicensed medicines in Great Britain on the day the post in question was 'liked' by the UK based employee. For the purposes of the Code which covered the UK (Great Britain and Northern Ireland), Clauses 3.1, 11.1 and 26.1 were relevant.

The Panel noted that Clauses 3.1 and 11.1 prohibited the promotion of a medicine prior to the grant of its marketing authorisation. Once the marketing authorisation had been granted, Clause 26.1 prohibited the promotion of a prescription only medicine to the public. The Panel noted that BioMarin had not been asked to respond to Clauses 3.1 and 11.1, and therefore the Panel considered that element of the complaint under Clause 5.1.

The Panel considered that in 'liking' the LinkedIn post at issue, the UK based employee had, on the balance of probabilities, proactively disseminated the information to their LinkedIn connections and promoted Roctavian and Voxzogo prior to the grant of the marketing authorisation in Great Britain, which was a serious matter. In the Panel's view BioMarin had failed to maintain high standards in this regard, and ruled **a breach of Clause 5.1**.

The Panel had no information before it about how many connections on LinkedIn the employee in question had and what their professional status was; BioMarin made no submission in that regard. On the balance of probabilities, not all of the employee's connections on LinkedIn would meet the Code's definition of a health professional or other relevant decision maker and therefore the information had likely been made available to members of the public.

The Panel noted BioMarin had submitted their EUMEA Social Media Policy which stated, among other things, that 'Any direct-to-consumer promotion or advertisement of prescription medicinal products is strictly prohibited in EUMEA. Any publicly facing Social Media channels such as Facebook, Instagram, Twitter, LinkedIn and YouTube, accessible to the General Public may not be used to promote BioMarin products in EUMEA. BioMarin Employees and/or Authorised Representatives may not "like", share, post, comment on, or link any BioMarin product or pipeline related information (pre-approval communication) via their personal Social Media accounts.' The policy further stated that 'BioMarin employees MAY NOT: Re-post, "like", share, comment on, or give the impression of approval to content that relates to approved products or unapproved investigational products, or any content/information regarding the development status of investigational products even if originally posted by BioMarin, itself'.

The Panel considered that BioMarin had been badly let down by the UK employee who had 'liked' the post despite BioMarin training its employees with the social media policy. The Panel noted that prompt action was taken by BioMarin in instructing that the post be removed from LinkedIn as a precaution on the receipt of the complaint.

The Panel considered that the UK employee's 'like' and, on the balance of probabilities, proactive dissemination of information about Roctavian and Voxzogo on LinkedIn, including the claims 'first therapy for Achondroplasia' and 'first ever gene therapy for severe adult haemophilia A' meant that Roctavian and Voxzogo, which were prescription only medicines in Northern Ireland, had been promoted to the public and **a breach of Clause 26.1** was ruled.

The Panel, noting its ruling of a breach of Clause 26.1 above, considered that BioMarin had failed to maintain high standards, and a breach of **Clause 5.1 was ruled**.

Complaint received **23 February 2023**

Case completed **2 May 2024**