CASE/0224/07/24 *NO BREACH OF THE CODE*

COMPLAINANT v ALNYLAM

Alleged promotion on LinkedIn

CASE SUMMARY

This case was in relation to multiple LinkedIn posts. It was alleged that the posts (some of which were made by the Alnylam Pharmaceuticals US-based company LinkedIn account) promoted an unlicensed medicine/indication to the public and that they directed a UK audience to global sites via hashtag links. It was also alleged that UK clinicians were being used to promote an unlicensed medicine/indication.

Some of the matters were ruled out of scope of the Code.

The outcome under the 2021 Code was:

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 3.1 (x3)	**Requirement that a medicine must not be promoted prior to the grant of its marketing authorisation**
No Breach of Clause 3.2 (x6)	**Requirement that prescription only medicines must not be advertised to the public**
No Breach of Clause 3.4 (x6)	**Requirement that companies must comply with all applicable codes, laws and regulations to which they are subject**
No Breach of Clause 3.6	**Requirement that materials and activities must not be disguised promotion**
No Breach of Clause 5.1	**Requirement to maintain high standards at all times**
No Breach of Clause 5.6	**Requirement that material should only be provided or made available to those groups of people whose need for or interest in it can reasonably be assumed**
No Breach of Clause 8.1 (x6)	**Requirement to certify promotional material**
No Breach of Clause 8.3 (x6)	**Requirement to certify certain non-promotional material**
No Breach of Clause 11.2 (x6)	**Requirement not to promote a medicine for an unlicensed indication**
No Breach of Clause 12.4 (x6)	**Requirement to include prescribing information within digital material or via direct, single click link**
No Breach of Clause 12.6 (x6)	**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 12.8 (x6)	**Requirement that promotional material other than advertisements in professional publications must include the date on which the promotional material was created or last revised**

No Breach of Clause 12.9 (x6)	**Requirement that all promotional material must include the prominent adverse event statement**
No Breach of Clause 12.10 (x6)	**Requirement to include the black triangle in promotional material**
No Breach of Clause 16.1	**Requirement that promotional material about prescription only medicines directed to a UK audience which is provided on the internet must comply with all relevant requirements of the Code**
No Breach of Clause 26.1 (x6)	**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

A complaint about Alnylam Pharmaceuticals was received from an anonymous, contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

"Complaint against Alnylam UK

- Use of LinkedIn to promote unlicenced medication to the public and other LinkedIn users.
- Redirection of UK audience to Global sites via #links (#Alnylamproud)
- Multiple posts inter-linked from Global to Local UK Employee by linking local UK employee profiles.
- Multiple usage of UK clinicians to promote unlicenced drug or unlicenced indication.

There are several posts that have linked UK employees to Global Accounts. Please see examples where [named UK senior leader] is posting on LinkedIn about Alnylam [global senior leader] and linking it with #Alnylamproud.

Post A

[Link provided]

#Alnylamproud links to Alnylam global LinkedIn site where unlicensed indications of approved drugs are discussed.

[Screenshot provided showing a LinkedIn post from a named UK senior leader]

Complaint: Off label promotion and promoting unlicenced medication to the public in the UK via #Alnylamproud

Please see post B where the top post is post A from [UK senior leader] and the third post down is from [a named global senior employee] at Alnylam posting a video of [a global senior leader] discussing helios B study of vutrisiran – an investigational #RNAi therapeutic …

"Today marks another extraordinary Alnylam Pharmaceuticals *achievement with our positive HELIOS-B topline results. I couldn't be more proud of the unbelievably brilliant and dedicated Alnylam team and their incredible persistence and resiliency to advance an RNAi therapeutic for patients living with ATTR amyloidosis with cardiomyopathy. The opportunity to potentially help even more patients in need with our hashtag#RNAi medicines is both exciting and humbling. The best is yet to come in Alnylam's journey where hashtag#Science and hashtag#Culture come together to make incredible things happen!* hashtag#AlnylamProud*"* (Post C)

Vutrisiran has a UK licence however promotion of helios B results would be seen to be promoting off label use of an available medication.

The post also tags Alnylam Pharmaceuticals which have UK clinicians promoting off label trial results. Post D

Post B: [Screenshot provided showing the #alnylamproud feed with three posts: the first being 'Post A' and the third being 'Post C' (described by the complainant above)]

Post C: [Screenshot provided showing a LinkedIn post from a named global senior employee]

Post D: [Screenshot provided showing two LinkedIn posts from the Alnylam Pharmaceuticals account, side by side under the heading 'Page posts']

Post E

[A global senior leader] of Alnylam [name] in return has also posted for the UK team tagging [named UK senior leader] (linkedin account). Please see post below. The post also links to Alnylam Pharmaceuticals page. The post has had 311 reactions with multiple UK employees interacting with it, including the [UK senior leader].

The linked Alnylam Pharmaceuticals page is currently hosting the same promotion of trial results for a drug which is available in the UK but is not licenced for the cardiology indications. This is also can be seen as a POM being promoted to the public.

Post E from [a global senior leader] linking [named UK senior leader] to Alnylam Pharmaceuticals Global Page of Alnylam Pharmaceuticals

Post E: [Screenshot provided showing a LinkedIn post from a global senior leader]

Post F: Alnylam LinkedIn Page with UK clinician on top
[Screenshot provided showing a portion of the Alnylam Pharmaceuticals company page on LinkedIn, including the same 'Page posts' section that the complainant described as 'Post D']

Please see interactions from [UK senior leader] and other Senior UK officers from the UK interacting with [global senior leader] post (Interactions to Post E) confirming UK link to Global site.

Post G: No separation of Global v Local
[Screenshot provided showing the 'reactions' and comments section below 'Post E', including three comments]

Post H : #rnaitherapeutics linked with Alnylam Pharmaceuticals
[Screenshot provided showing a LinkedIn post from named global senior leader]

Post I: #rnaitherapeutics: utilizing UK clinicians
[Screenshot provided showing a LinkedIn post from a health professional]

Complaints

Breach of Clauses:

5.1: High Standards not maintained

8.1, 8.3 Certification and Examination: Please check for UK certification or Examination of Global Materials and local materials.

5.6 Failing to provide or make available material only to those groups of people whose need for, or interest in, it could reasonably be assumed and tailoring it to the audience to whom it was directed

3.6: Using LinkedIn for disguised promotion of off label and investigational drugs.

3.2, 3.4, 11.2 + 26.1 Promotion POM to the public: Helios b trial results (currently off-label) which is available for another indication in the UK.

26.2 Raising unfounded hopes of a successful treatment (Post I)

Breach of Clause 8.1 Failing to certify promotional material

Breach of Clause 12.4 Failing to include up-to-date prescribing information in digital material

Breach of Clause 12.6 Failing to include a clear, prominent statement as to where prescribing information could be found

Breach of Clause 12.8 Failing to include the date on which the promotional material was created or revised

Breach of Clause 12.9 Failing to include information about how to report adverse events

Breach of Clause 12.10 Failing to include the black triangle when required

Breach of Clause 16.1 Promotional material directed to a UK audience failing to comply with all relevant requirements of the Code

Breach of Clause 2 Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry."

When writing to Alnylam, the PMCPA asked it to consider the requirements of Clauses 2, 3.1, 3.2, 3.4, 3.6, 5.1, 5.6, 8.1, 8.3, 11.2, 12.4, 12.6, 12.8, 12.9, 12.10, 16.1, 26.1 and 26.2 of the 2021 Code.

ALNYLAM'S RESPONSE

The response from Alnylam is reproduced below:

"Thank you for your letter dated 9 July 2024, which Alnylam acknowledged receipt of by email on 10 July 2024.

Your letter detailed a complaint brought under the 2021 ABPI Code of Practice (the **Code**) regarding LinkedIn posts and enclosed a copy of the complaint as submitted by the complainant. We acknowledge the request to consider the requirements of several clauses of the Code in light of the evidence provided by the complainant.

Alnylam and its approach to social media

Alnylam Pharmaceuticals is a global pharmaceutical company, headquartered in the US (**Alnylam US**); Alnylam UK Limited (**Alnylam UK**) is the group's UK affiliate.

Alnylam UK takes compliance with the Code very seriously and is committed to adhering to the Code. As a part of this commitment, Alnylam UK strives to comply with the rules that apply to the use of social media.

As requested in your letter, we enclose a copy of our current policy on employee use of social media that applies to UK employees (the **Policy**). The Policy takes into account the PMCPA's updated guidance for pharmaceutical companies on the use of social media (**PMCPA Social Media Guidance 2023**), published in January 2023. The Policy came into force in February 2024. The social media policy in effect prior to this date is also enclosed.

The Policy provides direction to help Alnylam UK employees using social media to comply with:

- other applicable Alnylam policies;
- Alnylam UK's expectations for conduct when using social media; and
- applicable laws and regulations that govern both company and individual conduct on social media.

The Policy states that, when using social media, employees must take extreme care so that any content posted, liked, shared or commented on is not in breach of local laws and regulations. In the UK, as a rule, the liking or sharing of content with any reference to an Alnylam product, the brand name or INN, or an Alnylam program, is not permitted. This includes sharing links to content which may contain the name of an Alnylam product. The Policy allows employees to like/share/comment on Alnylam posts relating to corporate or individual awards achieved, so long as the post does not mention a brand name or pipeline/investigational products.

In addition to the Policy, Alnylam UK has implemented a social media poster titled 'Social Media Policy for Employees in Europe and Canada - Do's and Don'ts – Think Before You Post'. This poster has been in place since January 2022 and is visible at the Alnylam UK offices.

Alnylam carefully developed the Policy to reflect the Code and the PMCPA's approach to the use of social media guidance as set out in detail in the PMCPA Social Media Guidance and PMCPA cases.

Complaint

The complaint includes screenshots of LinkedIn posts and a short summary of how, in the complainant's view, these posts allegedly breach some of the requirements of the Code.

The complainant sets out the following broad allegations in the complaint:

(1) use of LinkedIn to promote unlicensed medicine to the public and other LinkedIn users;
(2) redirection of a UK audience to global sites via hashtag links (specifically #Alnylamproud);
(3) posts interlinking Global to Local UK employee by linking local UK employee profiles; and
(4) multiple usage of UK clinicians to promote unlicensed medicines or unlicensed indications.

The complaint also contains further allegations in addition to these points. These allegations are interspersed throughout the documentation provided by the complainant. The complaint is brief and does not specify how each post relates to the above allegations or how the allegations correspond to the clauses of the Code cited by the complainant.

Our interpretation of the allegations and our corresponding responses are set out below.

Enclosed with this letter of response are high quality colour copies of the LinkedIn posts relevant to the complaint, as requested.

Alnylam response

We have grouped the first two allegations set out above together as we interpret these points to relate to the same group of posts included in the complaint (Posts A-D). The third and fourth allegations are addressed separately afterwards.

Use of LinkedIn to promote unlicensed medicine to the public and other LinkedIn users through use of #Alnylamproud hashtag and link to Global Alnylam LinkedIn account

Post A

The complainant's allegation appears to relate primarily to Post A as detailed in the complaint.

Post A is a LinkedIn post by [a UK senior leader] dated 12 January 2024. Post A is in itself disseminating corporate news: that [a global senior leader] was named [named award], an award the whole Alnylam team are very proud of.

Further, the PMCPA Social Media Guidance 2023 (page 12) specifically permits posting of corporate information on social media, and so does the Policy as a result. Post A focuses solely on corporate achievements and news and is therefore permissible under each of the Code, PMCPA Social Media Guidance 2023 and Policy. Clause 5.1 of the Code mandates that high standards must be maintained. This post does not mention any specific medicines or clinical outcomes and therefore adheres to ethical corporate communication guidelines.

Alnylam acknowledges that the hashtag #Alnylamproud forms part of Post A. The 2023 PMCPA Social Media Guidance states '*caution must be taken by pharmaceutical companies to ensure that appropriate hashtags which are relevant to the content are chosen*'. #Alnylamproud is a corporate hashtag used by employees to share their pride with the Company. It is formed by the name of the company 'Alnylam' and the word 'proud', so it does not make any reference to a product or therapy area. The hashtag was therefore appropriately used in connection to this corporate post on recognition of the global CEO's achievement. Neither the post nor the hashtag encourages a user to click into the latter to learn about Alnylam's medicines. We believe high standards were maintained.

Your letter requests a copy of the certificate in respect of Post A, but this is not relevant because corporate news do not require certification under Clause 8.3 of the Code or Alnylam's policy on approval of materials.

LinkedIn posts by employees, such as this post, detailing corporate information do not require examination or certification as per the supplementary information detailed in Clause 8.3 of the Code and Alnylam's policy on approval of materials. This is because Post A is not corporate advertising, a press release, market research material, financial information to inform shareholders, the Stock Exchange or the like or written responses from medical information departments or similar to unsolicited enquiries from the public. The PMCPA Social Media Guidance 2023 states that 'content posted/shared/re-shared by pharmaceutical companies that relates to products or diseases should be examined to confirm compliance with the ABPI Code and where applicable certified in advance (e.g. educational material for the public)'. Therefore, consistent with this guidance, this post has not undergone examination or certification and thus the request for a copy of the certificate in respect of Post A is not relevant.

[Alnylam provided details about the UK senior leader's connections and followers on LinkedIn]. We provide further analytics data showing the number of reactions and comments on posts from this account in the period 12 December 2023 to 16 July 2024.

[UK senior leader] has never posted content directly referring to a medicinal product on [their] LinkedIn account.

Posts B, C, D

The complainant alleges that:

- the use of the hashtag '#Alnylamproud' in Post A redirects a UK audience to the LinkedIn feed page for that hashtag (for clarity, Post B is not a social media post or account, but a feed page containing various posts that incorporate the hashtag '#Alnylamproud');

- that a LinkedIn post from a US employee (Post C) included on the above-mentioned feed page falls within the scope of the Code due to use of the same hashtag. As a result of which, the complainant alleges that Post C is promoting an unlicensed medicine; and

- Post A also reshares a post from the Alnylam Pharmaceuticals global LinkedIn account (the **Global Account**). This account allegedly includes UK clinicians promoting off-label trial results (Post D).

Alnylam strongly refutes that either the use of the hashtag #Alnylamproud or the link to the Global Account in Post A brings Post C or Post D within the scope of the Code. Post C and Post D fall outside the jurisdiction of the PMCPA for the following reasons.

Firstly, Post A was made on 12 January 2024 whereas Post C and Post D were both made on 24 June 2024. Therefore, Post C and Post D were posted to LinkedIn more than 4 months after Post A was made by [UK senior leader], this being a very significant period of time on social media and demonstrating a lack of direct linkage and clear temporal separation between the posts.

We sought input from a digital marketing expert for life sciences companies, [named], for the purposes of corroborating that 4 months between posts is a very significant time on social media. In [their] expert report, [they give] details as regards the impact that this temporal separation between the posts will have on the information disseminated to a UK audience. As [they state], '[o]*nce a post is older than seven days, it is most likely that it can only be found via a user's personal profile*.' Therefore Post A would not be accessible via people's feed at the time Posts C and D were posted for the latter to be accessed via Post A.

There is no evidence that any product-related post appeared on the #Alnylamproud hashtag feed or on the Global Account at the time Post A was made, making any relationship between Post A and Posts C and D so tenuous and retroactive that it is highly unlikely that Post A would have led any LinkedIn follower to Post C and Post D. As further stated in the statement from the digital marketing expert, '*[a]fter 12th February 2024 (the date at which post A would be hidden from default view on the [UK senior*

leader's] profile), the primary ways in which somebody would find the post is by actively searching through [UK senior leader's] profile or searching through the #AlnylamProud hashtag feed.' Given the lack of evidence, the complainant has not satisfied the burden of proof and based on the balance of probabilities, it is Alnylam's position that Posts C and D are not within the scope of the Code.

In addition, the PMCPA Social Media Q&A published on 1 June 2023, states in relation to hashtags that '[e]ach case is considered on its own merits taking into account all of the circumstances including amongst other things the content of the hashtag feed and the chronology of the hashtag link.' (Q&A number 32, page 9).

Supplementary information to clause 26.2 of the Code states that 'companies should take particular care if they use social media' and the 2023 PMCPA Social Media Guidance permits the use of tagging (page 10), with the caveat that 'companies should be cautious about the effect of tagging others and thus directing readers to the associated social media account. If a pharmaceutical company/company employee linked to a health professional's social media account that contained promotional content for the company's medicine this would likely be in breach of Clause 26.1 of the Code if there was evidence to show that the promotional content appeared on the linked account at the point the linkage was made' (our emphasis). This is not the case with Post A.

Secondly, clause 1.2 of the Code states that 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.

Neither Post C nor Post D satisfies the above conditions. Post C and Post D originate from Alnylam US and do not specifically mention the availability or use of a medicine in the UK. Furthermore, they are not directly linked by Post A, so they should not be regarded as part of the same post.

Although Post C shares the same #Alnylamproud hashtag as Post A, this in itself would not cause Post C to automatically 'disseminate' or appear in the feed of a UK-based employee or their respective connections. Such dissemination would only occur if Post C was liked by a UK-based employee, which is not the case. Accordingly, none of the scenarios set-out in the PMCPA Social Media Guidance in relation to 'When do posts placed on social media platforms outside the UK fall within the scope of the ABPI Code?' apply in this case (page 7). The same principle applies to Post D.

In summary, Alnylam UK considers that:

- Post A is a mere corporate news post that does not relate to the promotion of medicines and is permissible under the Code as a corporate news post; and
- Post B, C, D should not be considered to fall within the scope of the Code despite their alleged relationship with Post A through linking or the use of a common hashtag. The primarily reason being the chronology and time separation of more than 4-months between Post A and Posts C and D.

In respect of allegations (1) and (2), we therefore refute a breach of the following clauses of the Code:

- **Clause 2 –** Alnylam has maintained high standards of corporate communication in line with the Code and associated guidance on the use of social media. Post A does not promote specific medicines or make any therapeutic claims, focusing instead on corporate achievements and news.
- **Clause 3.1 –** Post A does not promote any unlicensed medicines. Post A is purely corporate in nature and does not reference any medicinal products or their indications. At the time of posting, Post A did not link and/or direct a UK audience to the posts alleged by the complainant to be unlicensed promotion (Posts C, D).
- **Clause 3.2 –** Post A does not promote POMs to the public. The post focuses on corporate achievements and does not include any information about specific medicines or their uses, ensuring compliance with Clause 3.2. At the time of posting, Post A did not link and/or direct a UK audience to the posts alleged by the complainant to be promotional.
- **Clause 3.4 –** Post A does not promote medicines for unlicensed indications. The content is corporate communications and does not discuss clinical research or unapproved uses of any medicinal products. At the time of posting, Post A did not link and/or direct a UK audience to the posts alleged by the complainant to be promotion of medicines for unlicensed indications.
- **Clause 3.6 –** Post A is clearly corporate communications, celebrating the achievements of the company and its employees, without any disguised promotion of medicines. The use the hashtag #Alnylamproud is intended to share corporate pride and does not reference specific therapies or clinical outcomes.
- **Clause 5.1 –** Alnylam has upheld high standards in all communications. The corporate nature of Post A and the use of the hashtag #Alnylamproud adheres to ethical guidelines and does not mislead or provide false information. This ensures compliance with Clause 5.1.
- **Clause 5.6 –** Post A is tailored to an audience interested in corporate news and achievements, not to healthcare professionals or patients seeking medical information. The content does not target or mislead any specific group regarding medicinal products.
- **Clause 8.1 –** Post A is a corporate post that does not constitute promotional material as defined by the Code. Therefore, it does not require certification under Clause 8.1. The content is purely corporate, focusing on awards and company news.
- **Clause 8.3 –** Post A falls outside the scope of promotional and non-promotional materials requiring certification or examination.
- **Clause 11.2 –** Post A is not directed at healthcare professionals and does not promote specific medicines. It focusses on corporate news and achievements, ensuring compliance with Clause 11.2.
- **Clause 12.4 –** Post A does not promote specific medicines, there is no requirement to include prescribing information. The content is purely corporate, aligning with Clause 12.4.

- **Clause 12.6 –** Post A does not discuss specific medicines or their indications, so there is no need for a statement about where to find prescribing information, so there is no breach of Clause 12.6.
- **Clause 12.8 –** The corporate nature of Post A means it is not considered promotional material. Therefore, there is no requirement to include the date of creation or revision under Clause 12.8.
- **Clause 12.9 –** Post A does not promote specific medicines or discuss their use, so there is no need to include information on reporting adverse events, in line with Clause 12.9.
- **Clause 12.10 –** Post A does not reference any specific medicines requiring a black triangle symbol. It is a corporate communication.
- **Clause 16.1 –** The content of Post A adheres to the requirements of the Code and is directed at a global audience with a corporate focus. No specific medicinal products are promoted to the UK audience, ensuring compliance with Clause 16.1.
- **Clause 26.1 –** Post A does not promote POMs or any specific treatments to the public. It focusses on corporate achievements and news, ensuring compliance with Clause 26.1.
- **Clause 26.2 –** Post A does not raise unfounded hopes of successful treatment or imply any therapeutic benefits of specific medicines. It celebrates company achievements without discussing clinical outcomes, ensuring compliance with Clause 26.2

Posts interlinking Global to Local UK employee by linking local UK employee profiles

We interpret this allegation as relating to Post E, Post F and Post G.

The complaint cites a LinkedIn post by Alnylam Pharmaceuticals [a global senior leader] (Post E) from 6 June 2024. This post includes a link to the Global Account and tags [a UK senior leader]. Similarly to Post A, Post E relates to corporate news, specifically a recent visit to the Alnylam UK team by [global senior leader]. Post E does not in any way relate to any medicines or disease areas and is clearly not promotional of medicinal product.

Alnylam Pharmaceuticals [global senior leader] has [almost 2000] connections, [less than 300] of whom are based in the UK.

Post E has been liked and commented on by some Alnylam UK personnel, but this is permissible under the Code and the 2023 PMCPA Social Media Guidance because Post E's contents are appropriate for the public: it simply relates to the visit of [a global senior leader] to the UK. It is not promotional nor related to any medicines or disease areas. Further, liking and commenting on a corporate news post such as Post E by Alnylam UK employees is permitted by the Policy.

Post E links the Global Account. About this, the complainant alleges that 'The linked Alnylam Pharmaceuticals page is currently hosting the same promotion of trial results for a drug which is available in the UK but is not licensed for the cardiology indications. This also can be seen as a POM being promoted to the public.'

We strongly disagree that the inclusion of a link to the Global Account in Post E constitutes a breach of the Code for the following two reasons.

Post E was made on 6 June 2024, approximately one-month before the subsequent posts on the Global Account relating to the clinical trial results mentioned by the complainant (as shown in Post C, Post D, Post F). As set out in the previous section, the chronology of linked content on social media is a crucial consideration, and we refer to the same allegations made above about this. Alnylam strongly refutes any breach of the Code (including but not limited to Clauses 3.2 and 26.2), given there is no evidence to show that any product-related content appeared on the Global Account at the point the linkage was made. The social media expert states, '[o]*nce a post is older than seven days, it is most likely that it can only be found via a user's personal profile*.' Therefore Post E would not be accessible via people's feed at the time Post F was posted.

In addition to the chronology, consideration of the proximity between Post E and Post F is important. As acknowledged above, Post E falls within the scope of the Code on the basis that Alnylam UK employees interacted with it. However, the only content disseminated to followers of those Alnylam UK personnel that interacted with Post E was Post E itself, a corporate, non-promotional post that is compliant with the Code. The content behind the link to the Alnylam Global Account is only accessible if a user chooses to click on the link. Other than the corporate news content in Post E, no content on the Alnylam Global Account (such as Posts C and D) was directly or automatically disseminated to a UK audience through UK employees interacting with Post E. Given the lack of evidence the complainant has not satisfied the burden of proving the complaint on the balance of probabilities in relation to Post F, so it should not be within the scope of the Code.

In summary, Alnylam considers that:

- Post E is subject to the Code and it complies with the Code as a corporate news post; and
- Post F should not be considered in scope of the Code through linking, primarily given the one month separation in time from Post E and Post F.

We refute breaches of the following clauses of the Code in respect of allegation (3):

- **Clause 2 –** Alnylam has maintained high standards of corporate communication in line with the Code and associated guidance on the use of social media. Post E does not promote specific medicines or make any therapeutic claims, focusing instead on corporate achievements and news.
- **Clause 3.1 –** Post E does not promote any unlicensed medicines. Post E is purely corporate in nature and does not reference any medicinal products or their indications. At the time of posting, Posts E did not link and/or direct a UK audience to the post alleged by the complainant to be unlicensed promotion (Post F).
- **Clause 3.2 –** Post E does not promote POMs to the public. The post focuses on corporate achievements and does not include any information about specific medicines or their uses, ensuring compliance with Clause 3.2. At the time of posting, Post E did not link and/or direct a UK audience to the posts alleged by the complainant to be promotional.

- **Clause 3.4 –** Post E does not promote medicines for unlicensed indications. The content is corporate and does not discuss clinical research or unapproved uses of any medicinal products. At the time of posting, Post E did not link and/or direct a UK audience to the posts alleged by the complainant to be promotion of medicines for unlicensed indications.
- **Clause 3.6 –** Post E is clearly corporate communications, celebrating the achievements of the company and its employees, without any disguised promotion of medicines.
- **Clause 5.1 –** Alnylam has upheld high standards in all communications. The corporate nature of Post E adheres to ethical guidelines and does not mislead or provide false information in compliance with Clause 5.1.
- **Clause 5.6 –** Post E is tailored to an audience interested in corporate news and achievements, not to healthcare professionals or patients seeking medical information. The content does not target or mislead any specific group regarding medicinal products.
- **Clause 8.1 –** Post E is a corporate post that does not constitute promotional material as defined by the Code. Therefore, it does not require certification under Clause 8.1. The content is purely corporate, focusing on awards and company news.
- **Clause 8.3 –** As Post E falls outside the scope of materials requiring certification or examination.
- **Clause 11.2 –** Post E is not directed at healthcare professionals and does not promote specific medicines. It focusses on corporate news and achievements, in compliance with Clause 11.2.
- **Clause 12.4 –** Post E does not promote specific medicines, there is no requirement to include prescribing information. The content is purely corporate, aligning with Clause 12.4.
- **Clause 12.6 –** Post E does not discuss specific medicines or their indications, so there is no need for a statement about where to find prescribing information.
- **Clause 12.8 –** The corporate nature of Post E means it is not considered promotional material. Therefore, there is no requirement to include the date of creation or revision under Clause 12.8.
- **Clause 12.9 –** Post E does not promote specific medicines or discuss their use, so there is no need to include information on reporting adverse events, aligning with Clause 12.9.
- **Clause 12.10 –** Post E does not reference any specific medicines requiring a black triangle symbol. It is a corporate communication.
- **Clause 16.1 –** The content of Post E adheres to the Code and is directed at a global audience with a corporate focus. No specific medicinal products are promoted to the UK audience, ensuring compliance with Clause 16.1.
- **Clause 26.1 –** Post E does not promote POMs or any specific treatments to the public. It focusses on corporate achievements and news, ensuring compliance with Clause 26.1.
- **Clause 26.2 –** Post E does not raise unfounded hopes of successful treatment or imply any therapeutic benefits of specific medicines. It celebrates company achievements without discussing clinical outcomes, ensuring compliance with Clause 26.2

Multiple usage of UK clinicians to promote unlicensed medicines or unlicensed indications

We interpret this allegation as relating to Post F and Post I.

The complainant makes the following statement about Post F: 'LinkedIn Page with UK clinician on top'. It is unclear what the complainant is trying to allege. However, the post details a quote from a UK professor who is the lead investigator on the clinical study that is being cited in the post.

This post was created outside of the UK on the Global Alnylam Pharmaceuticals LinkedIn account. There is no evidence to suggest that any UK Alnylam employees have interacted with Post F.

Alnylam does not consider Post F to fall within the scope of the Code on the basis of clause 1.2 of the Code. This clause states that 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.

Post F was placed on the US Alnylam Global Account by Alnylam US without the authority of Alnylam UK. Post F does not make specific reference to the availability or use of a medicine in the UK. Post F does not tag or contain a link to the profile of the UK HCP, so this post would not be disseminated or appear on the feed of any followers of this HCP. Finally, there is no evidence that Post F was liked by any Alnylam UK employees.

The complaint also cites a LinkedIn post by a UK HCP, [named] from March 2024 on [their] personal account (Post I) in which [they share] a post from the Global Alnylam Pharmaceuticals LinkedIn account, both comment on results (including a reference to a product name) from a clinical trial (KARDIA-1) for which [they were] an investigator.

Based on the very little information provided by the complainant in relation to Post I, it is difficult to establish what parts of the Code the complainant is alleging to have been breached. The complainant states that Post I is 'utilizing UK clinicians' and cites the hashtag #rnaitherapeutics. The complainant cites Clause 26.2 as relevant to Post I.

Alnylam's position is that Post I is not within the scope of the Code. [Named health professional] is a UK HCP with no affiliation with Alnylam UK. [Named health professional's] post was made independently from Alnylam UK, without its involvement, and no Alnylam UK employees have interacted with this post, so it does not fall within the jurisdiction of the Code or the PMCPA. Alnylam US was not involved with Post I.

Alnylam UK acknowledges that [named health professional] is an investigator on an Alnylam US-sponsored study, but was not engaged by Alnylam US or Alnylam UK to fill this role as the contractual arrangements are with the clinical trial site where [named health professional] acts as investigator.

In summary, Alnylam considers that:

- Post F and Post I fall outside the Code as it does not meet the criteria set out in clause 1.2 of the Code; and
- Alnylam UK is not responsible for Post F or Post I and nobody in the UK organization liked or commented, or otherwise interacted with, the posts.

Therefore Alnylam refutes all alleged breaches of the Code in relation to allegation (4) on the basis that the posts relevant to this allegation are not subject to the Code.

Use of hashtag #RNAiTherapeutics

This allegation is not mentioned in the first page of the complaint but introduced in relation to Post H.

The complaint cites a second LinkedIn post by Alnylam Pharmaceuticals [global senior leader] (Post H) from April 2024 that shares a post from the Global Alnylam Pharmaceuticals LinkedIn account and uses the hashtag #RNAiTherapeutics. Post H discusses results from a clinical trial and mentions the INN [(international non-proprietary name)] of the trial, zilebesiran, and the disease area, hypertension. This product is not approved in the UK and is in development for the treatment of hypertension.

Post H was created outside of the UK on the Global Alnylam Pharmaceuticals LinkedIn account. There is no evidence provided by the complainant that any UK Alnylam employees have interacted with Post H and therefore it falls outside the scope of the Code and we therefore refute any allegation of a breach of the Code.

Therefore Alnylam refutes all alleged breaches of the Code in relation to the allegation related to the use of the hashtag #RNAitherapeutics on the basis that the post relevant to this allegation is not subject to the ABPI Code.

Final remarks

In addition to the clauses of the Code set out in the sections above, the complainant alleged a breach of Clause 2 (upholding confidence in the industry) and Clause 5.1 (high standards must be maintained at all times). Alnylam considers that it has maintained high standards at all times. Further, Alnylam does not consider that this matter could bring discredit on the pharmaceutical industry.

We hope that the detail included in this response and our efforts in interpreting the complaint demonstrate to the PMCPA the culture of transparency and compliance that we aim to foster at Alnylam. To reiterate, Alnylam takes compliance with the Code very seriously and strives to ensure that its employees act with due caution when using social media platforms such as LinkedIn.

If your interpretation of the allegations is different to ours, please could you let us know and provide an opportunity to respond.

Once again, we appreciate the opportunity to address these concerns and reiterate our commitment to compliance with the ABPI Code of Practice."

PANEL RULING

This complaint related to multiple LinkedIn posts.

The complainant made four general allegations at the beginning of their complaint:

- "Use of LinkedIn to promote unlicensed medication to the public and other LinkedIn users"
- "Redirection of UK audience to Global sites via #links (#Alnylamproud)"
- "Multiple posts inter-linked from Global to Local UK Employee by linking local UK employee profiles"
- "Multiple usage of UK clinicians to promote unlicenced drug or unlicenced indication."

The complainant provided nine screenshots from LinkedIn and cited numerous clauses of the Code that they alleged had been breached in a list at the end of their complaint.

The Panel noted that exactly how the allegations related to each screenshot was not always clear. The PMCPA was not an investigatory body and it was not for the Panel to make out the complaint.

The Panel considered each screenshot provided by the complainant and the associated allegations in turn.

'Post A'

'Post A' was posted by a UK senior leader. It was a repost of a post from the Alnylam Pharmaceuticals global company account.

The original post from Alnylam Pharmaceuticals read:

> "Deeply #AlnylamProud to share that our [global senior leader] [tagged account of global senior leader] has been named [named award] by [tagged account of the awarding body]! This award honors a leader who has made extraordinary contributions to healthcare and the advancement of women in the workplace. [hashtag relating to the award]"

The commentary added by the UK senior leader when reposting read:

> "Sending my congratulations to [tagged account of global senior leader] our inspiring [job title] who has been named [named award] by [tagged account of the awarding body]. This well-deserved recognition is not only a testament to [name]'s contributions as an industry leader, but also [their] unwavering commitment to serving patients, advancing health equity and shaping the brilliant culture of inclusivity, respect and empowerment that we strive for at Alnylam. #AlnylamProud"

The Panel accepted Alynlam's submission that 'Post A' was posted on 12 January 2024.

The Panel interpreted the complainant's primary allegation relating to the post to be that the use of the hashtag "#AlnylamProud" linked Post A (the UK senior leader's post) to the Alnylam global (headquartered in the US) corporate LinkedIn account, where unlicensed indications for Alnylam medicines were discussed.

The first matter for the Panel to consider was whether 'Post A' was within the scope of the Code.

In the Panel's view, the UK senior leader had proactively disseminated the material to their connections on LinkedIn and had thus brought the post within the scope of the UK Code.

The Panel then considered whether the content of the post itself was promotional. The Panel noted the broad definition of promotion in Clause 1.17 of the Code, which referred to "any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines." The Panel noted it was an accepted principle under the Code that it was possible, given the broad definition of promotion, for material to be promotional without mentioning products by name.

The Panel considered that 'Post A' itself did not mention any specific medicines (directly or indirectly). The Panel determined that the content of 'Post A' itself was not promotional for an Alnylam medicine.

The Panel considered that any material associated with a post, for example, a link, would normally be interpreted as being part of that post. Regarding the complainant's allegation relating to the promotion of off-label use of vutrisiran, the Panel observed that 'Post A' included the hashtag #AlnylamProud and, as a repost, also linked through to the Alnylam Pharmaceuticals global corporate account page.

The Panel noted that clicking on a hashtag would take readers to the hashtag's feed where they could view all posts which mentioned that hashtag. The complainant had provided a screenshot of the hashtag feed for #AlnylamProud ('Post B') and had highlighted a post ('Post C') which discussed results from the HELIOS-B Phase 3 study of vutrisiran in patients with ATTR amyloidosis with cardiomyopathy.

The Panel noted that at the time Post A was made (12 January 2024), vutrisiran was indicated for the treatment of hereditary transthyretin amyloidosis in adult patients with stage 1 or stage 2 polyneuropathy (hATTR-PN). It was not indicated for patients with ATTR amyloidosis with cardiomyopathy.

The Panel accepted Alnylam's submission that 'Post C' was posted on 24 June 2024. While the Panel noted that 'Post C' referred positively to the use of vutrisiran for patients with ATTR amyloidosis with cardiomyopathy (which remained an unlicensed indication in the UK at the time), the Panel considered that chronology was important. The Panel noted with reference to the screenshot of the hashtag feed (described by the complainant as 'Post B') that 'Post A' had been published *before* the other posts visible in the screenshot, including several months before 'Post C'. The Appeal Board has previously ruled (in Case AUTH/3431/11/20) that chronology of the linkage is an important consideration in cases of this type. In the Panel's view, there had to be evidence that the content at issue appeared on the 'linked' hashtag feed *at the time* the link was made i.e. the time Post A was made. The Panel noted that the complainant bore the burden of proof. On the evidence before it, the Panel considered that it had not been established that clicking on the hashtag in 'Post A' at the time the post was made on 12 January 2024 would take the reader to content that promoted vutrisiran.

The complainant provided screenshots ('Post D' and 'Post F') from the Alnylam Pharmaceuticals company LinkedIn page, which was linked to 'Post A' via the original post that the UK senior leader had reposted. Whether a linked account came within the scope of the Code had to be

decided on a case-by-case basis, taking into account all of the circumstances including, among other things, the content of the linked account and the chronology of the link.

The Panel noted that one of the two posts visible on the Alnylam Pharmaceuticals company page screenshot provided by the complainant was the original post that was reposted as part of 'Post C'. The other post also mentioned the HELIOS-B study of vutrisiran. The Panel observed that both posts were made in June 2024 – five months after 'Post A'. On the evidence before it, the Panel considered that it had not been established that clicking on the link to the global corporate account page in 'Post A' would take the reader to content that promoted vutrisiran at the time Post A was made.

The Panel concluded that 'Post A' was not promotional for vutrisiran. The Panel therefore made the following rulings in relation to 'Post A':

- Vutrisiran was licensed in the UK at the time of the post and the post did not promote vutrisiran – the Panel therefore ruled **no breach of Clause 3.1**.
- The post did not promote vutrisiran for an unlicensed indication – the Panel therefore ruled **no breach of Clause 11.2**.
- The post did not promote a prescription only medicine to the public – the Panel therefore ruled **no breaches of Clauses 3.2, 26.1 and 3.4**.
- The obligatory information for promotion to health professionals detailed in Clause 12 was not required – the Panel therefore ruled **no breaches of Clauses 12.4, 12.6, 12.8, 12.9 and 12.10**.
- It had not been established why certification or examination was required – the Panel ruled **no breaches of Clauses 8.1 and 8.3**.

'Post B'

The screenshot described by the complainant as 'Post B' showed the #alnylamproud feed page. The Panel considered that the complainant had not made any specific allegations in relation to this screenshot that were not covered elsewhere in the complaint. The Panel therefore made no rulings on 'Post B' itself.

'Post C'

As the complainant had provided a separate screenshot of 'Post C', in addition to it being visible in the hashtag feed ('Post B') and considered as part of the allegations about 'Post A', the Panel considered whether this post fell within the scope of the Code in its own right.

'Post C' was posted by a global senior employee. Alnylam submitted that the employee was based in the US. 'Post C' was a repost of a post from the global Alnylam Pharmaceuticals company account (headquartered in the US).

The original post from Alnylam Pharmaceuticals read:

> "Our [global senior leader] [tagged account of global senior leader] shares [their] thoughts on the positive Phase 3 topline results from our HELIOS-B study of vutrisiran, an investigational #RNAi therapeutic in development for the treatment of #ATTR #amyloidosis w/ cardiomyopathy. Read the press release: [link to press release] #RNAitherapeutics #siRNA"

Under this text there was a video titled "[Named employee] Discusses HELIOS-B Topline Results".

The commentary added in 'Post C' by the US-based employee when reposting the above read:

> "Today marks another extraordinary Alnylam Pharmaceuticals achievement with our positive HELIOS-B topline results. I couldn't be more proud of the unbelievably brilliant and dedicated Alnylam team and their incredible persistence and resiliency to advance an RNAi therapeutic for patients living with ATTR amyloidosis with cardiomyopathy. The opportunity to potentially help even more patients in need with our #RNAi medicines is both exciting and humbling. The best is yet to come in Alnylam's journey where #Science and #Culture come together to make incredible things happen! #AlnylamProud"

Clause 1.2 of the Code 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 noted Alnylam's submission that Post C originated from Alnylam US and did not specifically mention the availability or use of a medicine in the UK, and that although the post included #AlnylamProud, this did not mean that the post would be proactively disseminated to a UK audience.

The Panel noted that there was no allegation that 'Post C' was linked to the UK in any other way than that dealt with for 'Post A', above. The Panel determined that 'Post C' did not, itself, fall within the scope of the Code because:

- It was posted by a US-based employee
- There was no allegation or evidence that 'Post C' had been disseminated to a UK audience by an interaction from a UK employee
- The post did not make specific reference to the availability or use of vutrisiran in the UK.

The Panel therefore ruled **no breaches of Clauses 3.2, 3.4, 8.1, 8.3, 11.2, 12.4, 12.6, 12.8, 12.9, 12.10 and 26.1** because 'Post C' was not within the scope of the Code.

'Post D' and 'Post F'

The screenshot described by the complainant as 'Post D' showed two posts from the global Alnylam Pharmaceuticals company LinkedIn account.

The post on the right of the screenshot was that which was reposted in 'Post C' (above). The Panel considered that the complainant had not made any specific allegations in relation to this post that were not covered elsewhere in the complaint. The Panel therefore made no rulings in this regard.

The post on the left of the screenshot read:

> "Dr. [surname], an investigator on the HELIOS-B Phase 3 study of vutrisiran, an investigational #RNAi therapeutic in development for the treatment of #ATTR #amyloidosis

with cardiomyopathy, shares [their] thoughts on the positive topline results. Full results will be presented at an upcoming medical meeting. #RNAiTherapeutics"

Beneath this was an image of a person that the Panel assumed to be the named health professional, with a quote, "I am incredibly excited about the potential of these data to be transformational for patients who live with ATTR amyloidosis with cardiomyopathy, both those who have not yet been diagnosed as well as those who continue to experience progression of their disease.", attributed to the named health professional and stating their place of work in the UK.

The Panel accepted Alnylam's submission that this post was published on 24 June 2024.

The screenshot described by the complainant as 'Post F' showed a portion of the Alnylam Pharmaceuticals company LinkedIn page, including the two posts in 'Post D'. The Panel considered that the complainant had made no allegations against any of the other information shown in 'Post F' and therefore the Panel made no separate rulings in relation to 'Post F'.

The Panel interpreted the complainant's primary allegation relating to 'Post D' and 'Post F' to be "usage of UK clinicians to promote unlicenced drug or unlicenced indications".

The first matter for the Panel to consider was whether the post on the left of the screenshot was within the scope of the Code.

Clause 1.2 of the Code 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 observed that the post mentioned the health professional was based in the UK. However, the Panel determined that the post did not fall within the scope of the Code because:

- It was posted by the US-based global company LinkedIn account.
- There was no allegation or evidence that the post had been disseminated to a UK audience.
- The Panel did not consider that a reference to the health professional's work address in the UK in a post that mentioned vutrisiran constituted a "specific reference to the availability or use of the medicine in the UK" (Panel's emphasis) for the purpose of Clause 1.2.

The Panel therefore ruled **no breaches of Clauses 3.1, 3.2, 3.4, 8.1, 8.3, 11.2, 12.4, 12.6, 12.8, 12.9, 12.10 and 26.1** because the post on the left side of the 'Post D' and 'Post F' screenshots was not within the scope of the Code.

'Post E' and 'Post G'

'Post E' was posted by a global senior leader based in the US. The post included a photograph of a group of employees and read:

> “I spent an energizing afternoon in our UK office this week, connecting with our amazingly talented and diverse team. I loved hearing what inspires them about their work for patients and discussing the exciting future ahead of us at [tagged Alnylam Pharmaceuticals company account].
>
> The UK has long been a leader in the life sciences and has contributed to so many breakthroughs that continue to drive biopharmaceutical innovation. It’s always special for me to return to the country where I spent so much of my life and my career.
>
> Thank you to [tagged account of UK senior leader] and the whole Alnylam team for your warm welcome! I can’t wait to come back.
>
> #RNAiRevolution #RNAiRevolutionary #RNAiTherapeutics”

The screenshot described by the complainant as ‘Post G’ showed interactions with ‘Post E’, including three comments. Alnylam acknowledged that some of these interactions and comments were from UK-based employees.

In the Panel’s view, the interactions by UK-based employees in ‘Post G’, showing them engaging with ‘Post E’ would have proactively disseminated Post E to their LinkedIn connections in the UK. The Panel determined that this brought ‘Post E’ within the scope of the UK Code. 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. Given that ‘Post E’ contained the substantive content complained about, the Panel based its ruling on that post rather than ‘Post G’.

The Panel interpreted the complainant’s primary allegation relating to ‘Post E’ to be that a prescription medicine had been promoted to the public, and for an unlicensed indication, because ‘Post E’ linked through to the Alnylam Pharmaceuticals company LinkedIn page, which had “promotion of trial results for a drug which is available in the UK but is not licenced for the cardiology indications”.

The Panel first considered whether the content of the post itself was promotional. The Panel noted the broad definition of promotion in Clause 1.17 and that it was possible, given this broad definition, for material to be promotional without mentioning products by name. The Panel considered that the post itself did not identify any medicine (directly or indirectly). The Panel determined that the content of ‘Post E’ itself was therefore not promotional for any Alnylam medicine.

The Panel considered that any material associated with a post, for example, a link, would normally be regarded as being part of that post. The Panel observed that, as alleged by the complainant, the post linked through to the Alnylam Pharmaceuticals company LinkedIn page. The complainant had provided a screenshot of this page (labelled as ‘Post F’). As described above, this screenshot showed two posts that mentioned the HELIOS-B Phase 3 study of vutrisiran in patients with ATTR amyloidosis with cardiomyopathy.

The Panel noted that, at the time of the posts, vutrisiran was not indicated for patients with ATTR amyloidosis with cardiomyopathy.

The Panel accepted Alnylam's submission that 'Post E' was published on 6 June 2024 and that the posts on the company LinkedIn page ('Post F') were published on 24 June 2024. The Panel had not been provided with the dates on which all the interactions with 'Post E' by UK employees took place.

The Panel noted that the complainant bore the burden of proof. On the evidence before it, the Panel considered that the complainant had not established that the linked global company LinkedIn page would have contained information that was promotional for vutrisiran at the time of the engagement with 'Post E' by UK employees.

The Panel concluded that the complainant had not established that 'Post E' was promotional for vutrisiran. The Panel therefore made the following rulings in relation to 'Post E' and the interactions shown in 'Post G':

- The post did not promote vutrisiran to the public – **no breaches of Clauses 3.2, 26.1 and 3.4**.
- The post did not promote vutrisiran for an unlicensed indication – **no breach of Clause 11.2**.
- The obligatory information for promotion to health professionals detailed in Clause 12 was not required – **no breaches of Clauses 12.4, 12.6, 12.8, 12.9 and 12.10**.
- It had not been established why certification or examination was required – **no breaches of Clauses 8.1 and 8.3**.

'Post H'

The complaint relating to Post H was that the use of "#rnaitherapeutics" linked to the Alnylam Pharmaceuticals corporate LinkedIn page.

'Post H' was posted by a global senior US-based leader. It was a repost of a post from the Alnylam Pharmaceuticals company LinkedIn account. The repost read:

> "I'm very excited about the results from our KARDIA-2 Phase 2 study of zilebesiran, our investigational RNAi therapeutic in development for hypertension, which we shared this weekend at the [tagged account of a US medical association] Scientific Session. The unmet need in #hypertension is enormous – it's the number one preventable cause of cardiovascular morbidity and death worldwide.
>
> Approximately one in every three adults worldwide – at least 200 million people in just the U.S. and other major markets – is living with hypertension, and for up to 80% of these people, their blood pressure remains uncontrolled, despite the availability of numerous treatments.
>
> As the leader in #RNAi therapeutics, Alnylam Pharmaceuticals has the potential to reinvent the treatment of cardiovascular disease and – in the case of hypertension – address one of the biggest healthcare challenges.
>
> #[hashtag related to the medical association] #RNAiTherapeutics #siRNA #cardiology"

The original post from the Alnylam Pharmaceuticals company LinkedIn account read:

> "Today, we presented full results of our KARDIA-2 Phase 2 study as a late- breaking clinical trial at the [tagged account of a US medical association] Annual Scientific Session. The study evaluated zilebesiran, an investigational #RNAi therapeutic for the treatment of #hypertension, when added to standard of care antihypertensives. Learn more: [link to a press release] #siRNA #[hashtag related to the medical association]"

In the Panel's view, the complainant did not make out any clear allegations relating to this post. The complainant had merely stated "#rnaitherapeutics linked with Alnylam Pharmaceuticals". It was not for the Panel to make out the complaint. The Panel first considered whether 'Post H' fell within the scope of the UK Code.

Clause 1.2 of the Code 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 determined that 'Post H' did not fall within the scope of the Code because:

- It was posted by a US-based employee.
- There was no allegation or evidence that 'Post H' had been disseminated to a UK audience.
- The post did not make specific reference to the availability or use of the medicine in the UK.

The Panel therefore ruled **no breaches of Clauses 3.2, 3.4, 8.1, 8.3, 11.2, 12.4, 12.6, 12.8, 12.9, 12.10 and 26.1** because 'Post H' was not within the scope of the Code.

Post I

'Post I' was posted by a health professional based in the UK. It was a repost of a post from the Alnylam Pharmaceuticals company LinkedIn account.

The Panel noted that the screenshot provided by Alnylam in relation to this post did not match that provided by the complainant. The Panel made its ruling based on the screenshot provided by the complainant.

The original post from Alnylam Pharmaceuticals read:

> "We are proud to announce that the Journal of the American Medical Association (JAMA) has published results from the Phase 2 KARDIA-1 study of our investigational #RNAi therapeutic targeting hepatic synthesis of" [the complainant's screenshot showed only the truncated version of the message with a link to "…see more" and a link to "Read the manuscript"].

The commentary added by the UK health professional when reposting read:

> "Delighted with the results of Kardia-1 HTN study…a great step forward in developing Zilebesiran as a potential treatment option for HTN. Novelty of six monthly SC injections

makes it unique and attractive treatment option" [the complainant's screenshot showed only the truncated version of the message with a link to "…see more"]

The Panel accepted Alnylam's submission that 'Post I' was posted in March 2024.

The Panel interpreted the complainant's primary allegations relating to the post to be:

1. "usage of UK clinicians to promote unlicenced drug or unlicenced indications",
2. that the use of the #rnaitherapeutics linked the post to the global Alnylam Pharmaceuticals company account, and
3. that the post raised unfounded hopes of a successful treatment.

The Panel noted that, as a repost, 'Post I' linked to the global Alnylam Pharmaceuticals company LinkedIn page, regardless of the hashtag used. The Panel did not consider that the complainant had made out their allegation in relation to the use of #rnaitherapeutics.

The Panel considered the first question to be addressed was whether the health professional's post was within scope of the Code.

Alnylam submitted that the health professional was an investigator on an Alnylam US-sponsored study, but was not engaged by Alnylam US or Alnylam UK to fulfil this role as the contractual arrangements were with the clinical site where the health professional acted as investigator.

In determining whether the post fell within the scope of the Code, the Panel took into account the following:

- The contract with the health professional's employer was with Alnylam US.
- The post was made without the authority of either Alnylam UK or Alnylam US.

The Panel bore in mind the Appeal Board's ruling in Case AUTH/3894/4/24 and determined that Alnylam UK did not bear responsibility for the actions of the personnel of a third-party to an overseas affiliate who had acted without authority from the company or its affiliate. The Panel therefore ruled **no breaches of Clauses 3.1, 3.2, 3.4, 8.1, 8.3, 11.2, 12.4, 12.6, 12.8, 12.9, 12.10, 26.1 and 26.2** because 'Post I' was not within the scope of the Code.

Overall

The Panel noted that the complainant had cited Clause 5.6 "Failing to provide or make available material only to those groups of people whose need for, or interest in, it could reasonably be assumed and tailoring it to the audience to whom it was directed". In the Panel's view, the complainant had not made out a specific allegation in this regard. It was not for the Panel to make out the complaint. The Panel therefore ruled **no breach of Clause 5.6**.

Likewise, the Panel noted that the complainant had cited Clause 3.6 "Using LinkedIn for disguised promotion of off label and investigational drugs" but had not made out an allegation about how they considered that any promotional activity had been disguised. The Panel therefore ruled **no breach of Clause 3.6**.

Clause 16.1, cited by the complainant, required that promotional material about prescription only medicines directed to a UK audience which is provided on the internet must comply with all

relevant requirements of the Code. Noting its rulings of no breaches of the Code in relation to this complaint, the Panel ruled **no breach of Clause 16.1**.

The Panel queried whether Alnylam's UK staff should conduct any activity on LinkedIn that could link to the global corporate LinkedIn account owned by its US affiliate, or use hashtags that were commonly used by their US colleagues. The Panel considered that Alnylam UK should exercise caution in this area, given the Code requirements in the UK were different to the requirements in the US.

However, based on the totality of information before it, the chronology of events and the no breach rulings discussed above, the Panel did not consider the complainant had established that Alnylam had failed to maintain high standards or had brought discredit upon, or reduced confidence in, the pharmaceutical industry. The Panel therefore ruled **no breach of Clause 5.1** and **no breach of Clause 2**.

Complaint received **2 July 2024**

Case completed **6 October 2025**