

BRITANNIA PHARMACEUTICALS v EVER PHARMA**Allegations about Promotional Activities and Representative Activities and Alleged Breach of an intercompany agreement****CASE SUMMARY**

This case was in relation to concerns raised by Britannia Pharmaceuticals Limited, about an email sent by an EVER Pharma UK Ltd employee regarding their nurse service. Britannia alleged that the email was unsolicited and promoted EVER Pharma's nurse service as an incentive to prescribe their product. Britannia further alleged that as a result, this communication breached an intercompany agreement previously provided by EVER Pharma to Britannia.

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 5.1(x2)	Requirement to maintain high standards at all times
No Breach of Clause 15.6	Requirement that promotional materials and activities must not be disguised

**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 from Britannia Pharmaceuticals Ltd about EVER Pharma UK Ltd.

COMPLAINT

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

[Details about intercompany dialogue in 2024 were provided]

"Britannia wishes to formally escalate unresolved matters from the unsuccessful inter-company dialogue and register a complaint in relation to EVER Pharma's unsolicited emails sent to NHS customers promoting their nurse service (which we consider to be non-promotional) as an incentive to prescribe their POM and for breach of a previous inter-company dialogue undertaking. Britannia is deeply concerned and considers that

numerous clauses of the Association of the British Pharmaceutical Industry (ABPI) Code of Practice (here-after referred to as “The Code”) have been breached.

Background:

EVER Pharma is the Marketing Authorisation Holder for Dacepton® (apomorphine hydrochloride) in the UK. D-mine® pen and pump are the only devices that are compatible for the administration of Dacepton®. EVER Pharma provides a nurse service under the registered trademark D-mine® care.

Details of the matter unresolved at the inter-company dialogue at senior level is given below:

Promotional email – communication about EVER Pharma’s nurse service being registered with the CQC:

An HCP decided to share an email with Britannia in the context of drawing attention to the fact that EVER Pharma was deploying questionable behaviour in using their nurse service to promote their Dacepton® via unsolicited emails. EVER Pharma’s Commercial Team have been proactively emailing customers informing them about their nurse service being registered with the CQC and that the Trusts should thus consider EVER Pharma’s Dacepton® in any formulary choices made within their organisation. Please find enclosed the original email and the redacted copy of the email (Enclosure 1 and 2 respectively) copies provided. This has been shared previously with EVER Pharma on 22nd February 2024. Should the PMCPA wish to share it again then Britannia requests that only the redacted copy of the email should be shared, as the details of the HCP should not be disclosed. This is because the email was shared by the HCP in confidence; thus, we do not have consent from them to disclose their details to EVER Pharma. The email appears to be unsolicited, which in Britannia’s opinion renders the email promotional both in content and intent.

Britannia would also highlight that during a previous inter-company dialogue between Britannia and EVER Pharma in 2021 on the same issue, EVER Pharma had given a written undertaking that they would raise a CAPA [Corrective and Preventative Action Plan] and ensure such occurrences of sending unsolicited mailings would not occur in the future thus preventing any disguised and unsolicited promotion. An undertaking on the same issue is a confirmation of the fact that EVER Pharma agreed that the action was not in compliance with the ABPI Code.

EVER Pharma have breached the undertaking given in the letter sent to Britannia on 12th October 2021. EVER Pharma have also failed to provide a copy of this CAPA and its implementation when requested by Britannia during the current intercompany dialogue.

Britannia had also repeatedly requested information on how many unsolicited emails promoting the nurse service have been sent to HCPs. To date, EVER Pharma have failed to provide a response to this query. Britannia would request the assistance of the PMCPA in this matter.

Britannia is deeply concerned that the previous undertaking has not been honoured by EVER Pharma, and they continued to send promotional emails, proactively drawing attention to their nurse service as an incentive to prescribe and use their POM product.

The fact that the HCP felt compelled to alert Britannia of this email leads us to believe that such activity and behaviour has brought discredit upon, and reduced confidence in the pharmaceutical industry. Britannia thus considers the following clauses of the ABPI Code have been breached:

Clause 5.1 - High standards must be maintained at all times

Clause 15.6 - Promotional material and activities must not be disguised

Clause 2 - Activities or materials must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry

The Further Guidance section of the Inter-company Dialogue Guidance of PMCPA available at <https://www.pmcpa.org.uk/complaint-procedure/inter-company-dialogue/> (accessed on 31.07/2024) states; 'Should a company fail to honour its commitment to withdraw or amend material or practices, further inter-company dialogue is encouraged although a complaint to the PMCPA could be submitted on the basis that inter-company dialogue was unsuccessful'.

Based on the above it is clear that EVER Pharma has breached a commitment made previously as part of a previous inter-company dialogue from October 2021. This was communicated to EVER Pharma as part of the recent inter-company dialogue together with a copy of the redacted email on 22nd February 2024. EVER Pharma failed to provide an explanation for this breach of the commitment, nor did they address this matter and so Britannia is now compelled to escalate this matter as a complaint to the PMCPA as per Paragraph 5.3 of the Constitution and Procedure.

As clearly outlined in our initial letter to EVER Pharma dated 31st January 2024, Britannia's intention has been to resolve all concerns raised to a mutually satisfactory outcome. We understand that the concerns raised by Britannia were serious breaches of the Code and thus, we expected EVER Pharma to provide us with a comprehensive response and robust Corrective and Preventive actions to avoid such occurrences in the future. The concerns raised by Britannia were limited due to time constraints available to review all materials and in the interest of speedy resolution and patient safety it was decided to alert EVER Pharma to the breaches as soon as possible; with the intent that EVER Pharma would go beyond what was flagged by Britannia when addressing the issues. However, EVER Pharma could not provide any satisfactory assurance or confirmation of a complete horizon scanning of their activities on social media and so Britannia continues to remain concerned.

Britannia acknowledges that EVER Pharma have tried to resolve some of the matters. However, the very fact that Britannia had to bring the above obvious issues to EVER Pharma's attention leads us to conclude that EVER Pharma lacks appropriate knowledge of the Code and its application thus putting patients at risk and misleading HCPs.

Britannia acknowledges that this letter of complaint, which covers 3 serious breaches, brings with it a vast number of issues and concerns. We look forward to hearing from the Panel once they have had time to give this due consideration."

When writing to EVER Pharma, the PMCPA asked it to consider the requirements of Clauses 5.1, 15.6, and 2 of the 2021 Code.

EVER PHARMA'S RESPONSE

The response from EVER Pharma is reproduced below:

"Thank you for confirming that Britannia is not able to share an unredacted copy of the email under investigation. As previously stated, the author of the email left the company several months ago and without further information, we regret that we have been unable to identify the original email. During the extensive inter-company dialogue, we requested more details regarding the email to adequately respond to their concerns. We also have some concerns that searching for the original email could lead to the identification of the health care professional (HCP) who asked Britannia not to disclose his/her identity. We would not want to act in a manner that contradicted the HCP's wish to remain anonymous. Therefore, we are only able to respond to the redacted fragment of the email correspondence provided.

Allegations

Britannia alleges that the email:

- was unsolicited;
- constitutes disguised promotion; and
- breaches a previous written undertaking.

Britannia alleges breaches of Clause 15.6, Clause 5.1 and Clause 2 of the Code.

1. Allegation that email was unsolicited

We do not believe it is possible to determine, from the limited information provided, that this email was unsolicited. The first line of the email states that this email formed part of an "email chain". As set out above, we have not been provided with the rest of the email chain. Britannia has provided a single email from this wider email chain in redacted form. If Britannia is willing to disclose a single excerpt of the wider email chain in redacted form, we do not understand why it refuses to disclose a redacted version of the full chain.

The statement in the email that "it looks like over two years have passed since we last spoke" is not evidence that this email was unsolicited. This statement does not preclude this email being sent in response to a discussion with a representative or that there had been additional email dialogue preceding this message. Without further evidence to show the full details and context we are not in a position to respond. We also note that, based on the evidence, the recipient of the email appears to have consented to be contacted as there is an unsubscribe link at the bottom of the message.

The evidence provided to us does not establish that this email was unsolicited.

2. Allegation that the email is disguised promotion

As reflected in the email signature, the author of the email was acting in [their] capacity as a [commercial role]. It was [their] role to engage with key decision makers in the Trust to discuss formulary decisions for example.

Although the nurse service per se is indeed non-promotional, it is part of the package of care offered to support patients on apomorphine and is an appropriate topic of conversation for key decision makers. Package deals are commercial in nature and therefore we believe that it was an appropriate exchange between a [commercial role] and a key decision maker in the Trust. The information provided regarding the EVER Pharma nurse service provision is entirely factual, and the package of care provided by each company is an important element for consideration in the Formulary decision making process. We believe that similar emails were sent to key decision makers at a number of NHS Trusts.

The email is clearly promotional as indicated by the prescribing information link at the bottom of the email. The email was not certified as it is a routine conversation between a [commercial role] and an HCP. We do not have any briefing materials on this matter to share.

In summary, although we are unable to properly investigate, because of the HCP's confidentiality request, the email concerned is clearly promotional, as demonstrated by the prescribing information link at the bottom of the email. Therefore, we do not accept the allegation that the email constitutes disguised promotion and corresponding alleged breach of Clause 15.6.

3. Alleged breach of prior undertaking

Britannia also allege that the email referred to above is in breach of a prior undertaking given by EVER Pharma in 2021.

The undertaking followed an email to HCPs regarding the "in-life" use of Dacepton®, which was intended to be non-promotional. After intercompany dialogue it was accepted by EVER Pharma that some of the content could be perceived to be promotional and therefore in breach of clauses including 5.5, 5.6, 8.1, 15.5 and 15.6. A CAPA was undertaken to address these issues. We provided an ICD response letter and CAPA to Britannia ([name and role]) on 22nd November 2021.

As stated above, we are unable to investigate the current email, because we do not have access to the full email chain and its context. However, we do not accept that the email currently under discussion is relevant to this prior undertaking, since it is clearly promotional, and sent to a key decision maker within the Trust regarding Formulary access. As mentioned above, based on the evidence the recipient of the email appears to have consented to be contacted as there is an unsubscribe link at the bottom of the message. Therefore, we do not believe that we have breached the prior written undertaking.

4. Alleged failure to maintain high standards/bring the industry into disrepute

Britannia also allege a breach of Clause 2 (upholding confidence in the industry) and Clause 5.1 (high standards must be always maintained). We consider that EVER Pharma

has maintained high standards at all times. Further, we do not consider that this matter could bring discredit on the pharmaceutical industry.

Documents requested by the PMCPA

Below we set out a list of the documents requested by the PMCPA and our comments in relation to each:

- An original copy of the email at issue - we are unable to provide this as set out above;
- Briefing documents to staff about communications in relation to the nurse service (contemporaneous to the email in question being sent) – we confirm that no such briefing documents exist;
- A copy of the certificate approving the material in question and associated briefing documents – we confirm that this email was not certified, the final signatory is medically qualified [qualifications];
- A copy of the relevant summary of product characteristics (SPC). – these can be accessed via: [link provided]
- Provide details of [commercial employee] role and their representative examination status at the time of sending the email in question – please find attached;
- Please provide details of the actions taken following your letter to Britannia of 12 October 2021 in relation to Clause 15.6 wherein state, “We have launched an internal CAPA to investigate and revise our internal processes to ensure this type of error does not occur in future” – We provided an ICD response letter and CAPA to Britannia (employee name and role) on 22nd November 2021 – please find attached.

We appreciate the opportunity to address these concerns and reiterate our commitment to compliance with the Code.”

PANEL RULING

This complaint relates to concerns raised by Britannia Pharmaceuticals Limited (“Britannia”) about an email sent by an EVER Pharma employee regarding their nurse service. Britannia alleges that as a result, this communication breached an intercompany undertaking previously provided by EVER Pharma to Britannia.

The email was sent by a [commercial employee] at EVER Pharma to a healthcare professional. The healthcare professional who received the email, shared it with Britannia, who submitted that the email was unsolicited and promoted EVER Pharma’s nurse service as an incentive to prescribe their product, Dacepton.

Email

The Panel considered the content of the email which included the following statements:

“Looking at this email trail it looks like over two years have passed since we last spoke...”

“I hoped to raise the following with you and ask if I could meet with you to discuss the topic...”

“..it is our understanding that this [a defined regulated activity] should only be undertaken by an organisation registered with the Care Quality Commission (CQC). EPUK funds [named third party], a CQC registered provider, to undertake and provide the D-mine® nurse service and such regulated activities in patients’ homes within your ICB...”

“We believe the D-mine nurse service is the only CQC registered nurse service in the UK that specifically supports Parkinson’s patients on Apomorphine therapy (Dacepton and D-mine devices), and we believe should be fully considered in any formulary choices made within your ICB, as well as how patients receive ongoing compliant care in the community.”

Britannia alleges that as the email appears to be unsolicited this renders the email promotional in both content and intent. EVER Pharma accept that the email was promotional given the commercial role of the employee who sent it. EVER Pharma also drew the Panel’s attention to the prescribing information and link contained in the footer of the email, further indicating that it was a promotional email. The Panel noted that promotional material did not need to be labelled as such, however, it must not be disguised and should otherwise comply with the Code.

The Panel acknowledged EVER Pharma’s submission that although the nurse service itself was non-promotional it forms part of a package deal which is commercial in nature and therefore communications around the nurse service are likely to be promotional. The Panel considered that the email was clearly promotional. It was a request by an employee in a commercial role seeking to speak with a healthcare professional about the offering of their nurse service. It appeared to be written with promoting the product in mind and was a request to discuss the nurse service and product in more detail. The email heading included the name of the product, a link to prescribing information was provided and the Panel considered the language used was persuasive. The Panel did not consider that promotion was disguised in any way. Further the complainant had not provided any substantive reasons to support their position. The complainant bore the burden of proof and in the absence of any evidence to support the allegation, the Panel ruled **no breach of Clause 15.6**.

The Panel considered the allegation that the email was unsolicited and promoted EVER Pharma’s nurse service as an incentive to prescribe their product. Clause 1.17 of the Code and the supplementary information sets out the definition of promotion and excludes replies made in response to unsolicited individual enquiries from members of the health profession or other relevant decision makers.

The email provided by Britannia had been redacted to ensure the healthcare professional’s anonymity however in doing so, EVER Pharma and the Panel were provided with a single email rather than the whole chain of emails. EVER Pharma submitted that without the full chain of emails, they could not determine whether it was solicited or not. EVER Pharma asserted that it was unable to properly investigate, because of the HCP’s confidentiality request. The Panel considered carefully the wording of the email and whether there was any indication that the

author was responding to a question from the healthcare professional. The Panel accepted that phrases “looks like 2 years have passed...” and “I hoped to raise the following with you and ask if I could meet with you to discuss the topic...” might be viewed as an unsolicited request to EVER Pharma’s nurse service offerings. The Panel considered that the act of sending an unsolicited email about a package deal was not in itself necessarily a breach of the Code, but that context and the circumstances including consent to receive promotional communications were important. The wording of the email suggested that this particular hospital did not have a contract in place for a package deal with EVER Pharma. The Panel considered whether it was appropriate to promote a package deal that a Trust had not already signed up to as a benefit to encourage the use of its medicine. Communications around package deals are likely to be deemed promotional given their commercial nature, however, the Panel concluded that communications encouraging a Trust to sign up to a package deal should be limited to those responsible for budget and formulary decisions in a healthcare organisation (HCO) and not individual prescribers. In protecting the healthcare professional’s anonymity, the Panel were unclear as to the healthcare professional’s role within the hospital. The Panel acknowledged that the complainant bore the burden of proof and on the limited evidence provided, the Panel ruled **no breach of Clause 5.1**.

Intercompany agreement

In sending the email, Britannia alleged that this was a breach of an undertaking previously provided by EVER Pharma in 2021. The Panel considered that the reference to an undertaking was to an inter-company agreement which related to an email sent by EVER Pharma that was intended to be non-promotional but EVER Pharma accepted, in relation to a statement about stability of Dacepton, could be perceived as promotional. A letter from EVER Pharma dated 12 October set out the matters in the email that it acknowledged were in breach of the Code and referred to an internal CAPA to investigate and revise its internal processes ‘to ensure this type of error does not occur in future’.

The Panel considered that this previous email and the one under consideration were fundamentally different in terms of content and following its findings above, concluded that the inter-company agreement had not been breached. The Panel therefore considered EVER Pharma had not established that high standards had not been maintained in this regard. **No breach of Clause 5.1** was ruled.

Clause 2

Given the Panel’s findings above, it follows that the Panel ruled **no breach of Clause 2**.

* * * * *

During the consideration of this case, the Panel queried whether it was appropriate to promote or communicate the package deal to a healthcare professional in a Trust that did not appear to have agreed to its use. The status of the health professional would be relevant and the Panel had no additional information in this regard.

In the Panel’s view, detailed discussion about the potential for a package deal should not be with individual prescribers as they are not in a position to decide on whether to purchase the medicine or agree to the package deal. Such discussions should only be with those responsible for budget and formulary decisions in a healthcare organisation (HCO). Bearing in mind the

definition of promotion, such discussions would likely be considered promotional and thus would need to comply with all the relevant requirements of the Code in this regard. In promotional calls with individual prescribers, representatives may refer to the existence of a package deal should it have been taken up by that HCO.

Complaint received **18 July 2024**

Case completed **12 May 2025**