CASE/0665/07/25 and CASE/0683/08/25

COMPLAINANT v CIPLA
LUPIN HEALTHCARE v CIPLA

Allegations about a promotional email

CASE SUMMARY

This amalgamated case concerned two complaints about an email for a primary care rebate scheme for Bibecfo (beclometasone/formoterol), sent by a third party.

The outcome under the 2024 Code was:

CASE/0665/07/25

Breach of Clause 3.6	**Disguising promotional material**
Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 5.6	**Failing to be sufficiently clear about the company's role and involvement**
Breach of Clause 6.1	**Making a misleading claim**
Breach of Clause 15.5	**Failing to have the recipient's prior consent to receive promotional emails**
Breach of Clause 15.6	**Disguising promotional material**

CASE/0683/08/25

Breach of Clause 3.6	**Disguising promotional material**
Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 5.6	**Failing to be sufficiently clear about the company's role and involvement**
Breach of Clause 6.1(x2)	**Making a misleading claim**
Breach of Clause 6.2	**Making an unsubstantiated claim**
Breach of Clause 8.1	**Failing to certify promotional material**
Breach of Clause 12.1	**Failing to include up-to-date prescribing information**
Breach of Clause 12.4	**Failing to include the non-proprietary name immediately adjacent to the brand name at its first appearance**

Breach of Clause 12.6	**Failing to include a clear, prominent statement as to where the adverse event reporting statement could be found**
Breach of Clause 15.5 (x2)	**Failing to have the recipient's prior consent to receive promotional emails or to include information about how to unsubscribe**
Breach of Clause 15.6	**Disguising promotional material**

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**

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

FULL CASE REPORT

Two complaints were received about Cipla (EU) Limited, one from an anonymous, non-contactable complainant and the second from Lupin Healthcare (UK) Ltd.

Case/0665/07/25 and Case/0683/08/25 were amalgamated in accordance with Paragraph 5.2 of the PMCPA Constitution and Procedure.

COMPLAINTS

Case/0665/07/25

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

> "Dear Sir/Madam
>
> Please see enclosed a copy of an email that I received last week from a [redacted]. I have no idea who this [redacted] is nor how [redacted] was able to find my email address. At first reading, [redacted] appears to be some form of independent prescribing advisor, though, on closer inspection, [redacted] seems to be representing Cipla. This appears a little underhand.
>
> The email concerns a rebate on a brand called Bibecfo. There are no details of the rebate scheme given, though [redacted] does quote apparent savings that could be made by switching to this product. This is very difficult to understand, as there are several equivalent brands on the market, all at different prices, and [redacted] does not point out from which we would need to switch to make the savings.
>
> On speaking to colleagues in other ICBs [Integrated Care Boards], I am aware that they have received similar correspondence.

The whole approach is very unprofessional and misleading. I have not made a complaint in this manner before, and do not wish to go to war with a pharmaceutical company, and so would like to retain my anonymity. I trust that either you or the ABPI can speak to either Cipla or [named third party] and ask them to improve the quality of their communication."

Case/0683/08/25

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

"I am writing to you regarding Lupin Healthcare's concerns about an unsolicited e-mail of which we have recently become aware, sent from [an employee] at a third party agency to an NHS health care professional, and concerning *'a primary care rebate switch to Bibecfo supplied by Cipla Health'.*

Lupin has contacted Cipla Health in an attempt to start intercompany dialogue and resolve the matter, however Cipla has declined to engage in inter-company dialogue as they tell us that the matter is being investigated already by PMCPA. However, Cipla has declined to reassure us that the activity has ceased, and they have given us no information about any complaint which is ongoing. Accordingly, we have no other option than to raise a formal complaint under the ABPI Code of Practice. All relevant communications are attached, redacted where appropriate to maintain the confidentiality of the recipient of the email and of the agency involved.

It is clear that the e-mail is promotional in intention and content, with a named product 'Bibecfo' and a product claim of 'no compromise on clinical efficacy', which clearly relates to the situation of switching from one product to another but with no specific comparator products named and which we consider to be a hanging comparison and in breach of **Clause 6.1** of the ABPI Code of Practice.

Promotional material such as this email should include the product's prescribing information and adverse event reporting details (as detailed in **Clauses 12.1** and **12.6** of the Code), neither of which are included in the e-mail, and nor is the generic name of the product adjacent to the first or most prominent mention of the brand name (as required by **Clause 12.4**). Moreover, the cost data in the email do not include costs for specific comparators for switching to Bibecfo which is misleading (as per **Clause 6.1**), as the recipient is likely to assume that all competitor products with the same ingredients would be included in the comparison and this is not the case. While the e-mail states that there are data to support these claims, no references are provided to provide substantiation (as per **Clause 6.2**), and Cipla has not provided substantiation to us. Furthermore, the time period over which these cost savings would be generated is not stated, which is ambiguous and potentially misleading, and in breach of **Clause 6.1**.

It is not stated in the email that any pharmaceutical company has been involved in this activity. The agency involved has a website which states that they 'have worked with over 20 companies', and whilst the agency has declined to give us any information about the activity (see below) they have acknowledged Cipla's involvement. So while the e-mail is not clear in this regard, it appears highly likely that Cipla is aware of and responsible for this activity due to the specific content; the pharmaceutical company being responsible for the actions of third parties they contract with (as per **Clause 4.8**).

Any involvement of Cipla in sponsoring, approving, reviewing or funding this initiative should be unambiguously disclosed clearly on the email, as required by **Clause 5.6**, so that the recipient is aware of the company's involvement at the outset. In addition, as there is no statement on the e-mail regarding promotional content and the sponsor responsible, this is also misleading and we consider this to be disguised promotion and in breach of **Clauses 6.1**, **15.6** and **3.6**.

All promotional material issued by a pharmaceutical company or on its behalf should be certified (as per **Clause 8.1**) and due to the content of this email it seems unlikely that this has been reviewed by a signatory; there is no evidence of this on the e-mail, such as an item number. E-mail communication itself should only occur after the recipient has consented to receive promotional information (as per **Clause 15.5**) and we do not believe that to be the case in this instance. The email does also not contain any information of how to unsubscribe, which is also in breach of **Clause 15.5**. As stated above the originator of the email content should be clear and promotion must not be disguised; this is then also in breach of **Clause 15.5**).

We have contacted the agency directly to try to clarify this activity and ascertain whether the activity is continuing, but whilst they acknowledge that the work was done for a pharmaceutical company, they have declined to provide any further information to us and have asked that their details are redacted in any correspondence we have with PMCPA.

Due to the seriousness of this matter and the above breaches of the ABPI Code of Practice (Clauses 3.6, 4.8, 5.6, 6.1, 6.2, 8.1, 12.1, 12.4, 12.6 15.5 and 15.6), we believe that this material fails to maintain high standards and is in breach of **Clause 5.1** of the Code. The associated email activity brings discredit upon and reduces confidence in the pharmaceutical industry and is therefore also in breach of **Clause 2** of the ABPI Code of Practice.

Thank you for considering this complaint and the attached documentation,"

When writing to Cipla, the PMCPA asked it to consider the requirements of Clauses **3.6, 4.8, 5.6, 6.1, 6.2, 8.1, 12.1, 12.4, 12.6, 15.5 and 15.6** of the 2024 Code when responding to these amalgamated complaints. The PMCPA subsequently noticed that **Clauses 5.1 and 2** had been inadvertently omitted from the list of Clauses cited in its original letter to Cipla. Both were cited in Lupin's letter of complaint and Cipla had responded in relation to Clause 5.1. Cipla was asked to update its response to also consider the requirements of Clause 2.

CIPLA'S RESPONSE

The response from Cipla is reproduced below:

"Thank you for your follow on letter dated 9th September 2025, and we have added additional information into our original reply specifically regarding Clause 2. We appreciate the opportunity to provide a comprehensive response to the two complaints raised about the e-mail sent via our third-party agency partner [named third party].

We have treated this matter with utmost seriousness. Cipla has worked in good faith throughout this initiative with no intention to mislead, promote inappropriately, or bring

the industry into disrepute. We are committed to acting transparently, compliantly, and with the interests of NHS partners and patients in mind.

The email in question was sent as part of the Bibecfo rebate programme managed by [named third party]. This was a primary care rebate scheme - a contractual arrangement offering financial rebates on GP prescribing expenditure for a branded medicine. Such schemes aim to provide the NHS with lower acquisition costs for medicines. Details of the scheme are provided in the attached document 'Background and Process for Introduction of the Bibecfo Rebate to Primary Care'. This document contains details of the rebate rates applied and is therefore company confidential material which is provided solely to the PMCPA for the purposes of handling this complaint and must not be shared with any other parties.

Cipla understands that rebate schemes are a commercial activity, related to prices, margins and discounts. A flat rate rebate could be regarded as a discount, constituting terms of trade and therefore not included under the Code definition of promotion (Clause 1.17). However, depending on its nature, communication about a rebate scheme could be considered to be promotional. This distinction is relevant in this case.

1. **Explanation of the relationship and contracting, if any, between Cipla and the third-party agency:**
Cipla engaged [named third party] under a business-to-business arrangement to support the implementation of the Bibecfo primary care rebate scheme. [Named third party] has 10 years' experience working with NHS organisations and pharmaceutical partners in this capacity. [Named third party]'s responsibilities included communication of rebate propositions directly to relevant integrated care bodies (ICBs) and NHS stakeholders. [Named third party] have third party compliance advisors to ensure their approach is aligned with the ABPI Code and is not promotional in nature. The services started on 1st April 2025. Cipla instructed [named third party] to stop new approaches in relation to the rebate scheme on the day the complaint was received (17th July 2025). These services will only be resumed once Cipla has completed its review of all related communications and ensured that they are in line with Code requirements.'

2. An original or good quality colour copy of the email at issue:
This is attached.

3. Details of how the activity was initiated and how the email content was developed:
The activity was initiated as a commercial rebate proposition, communicating cost efficiencies to NHS ICB stakeholders. [Named third party] have an existing customer base at ICB level that manage commercial access schemes rebates across multiple therapy areas. [Named third party] renew consent for communication with these customers on an annual basis to ensure they are communicating with the appropriate person.

[Named third party] use standard email templates. However, on this occasion the [named third party] [employee] included a non-approved clinical claim within the email ('no compromise to clinical efficacy') which therefore rendered the message promotional. [Named third party] have advised that all their staff have undergone ABPI and GDPR training and are briefed regularly to avoid inclusion of clinical or promotional

claims in rebate communications. [Named third party] attribute this oversight to human error and have subsequently put in place additional training and external support in reviewing their processes and templates.

4. Details of how the email at issue was used:
The email was sent to a Head of Medicines Management at an ICB in line with [named third party] procedures. The individual had consented to the receipt of communications regarding rebate schemes from [named third party].

5. A copy of the certificate approving the email and qualifications of signatories:
Cipla did not certify the email as it considered that the rebate scheme was a financial arrangement which fell outside the Code. At the time it was believed that the communications from [named third party] were not promotional and hence did not require certification.

6. Copies of any additional intercompany dialogue with Lupin Healthcare:
We attach correspondence between Cipla and Lupin, as well as [named third party] and Lupin. The correspondence with Lupin concluded once Case/0665/07/25 was received as it covered the same matters. In addition, Cipla was concerned that that Lupin had obtained a copy of the [named third party] email without the consent of either Cipla or [named third party] and had then attempted to solicit commercially sensitive information directly from both.

7. Copies of any references cited:
No additional references were included in the original email.

8. A copy of the relevant Summary of Product Characteristics (SPC):
SPCs for Bibecfo 100/6 and 200/6 are attached.

Our response to the specific clauses cited is as follows:

Clauses 3.6 and 15.6 relate to disguised promotion. Whilst we acknowledge that the email was promotional, we do not consider that it represents disguised promotion. There was no intent to disguise the commercial nature of the communication; it was clearly a business message about Bibecfo. We therefore deny breaches of these clauses.

Clause 4.8 states that companies are responsible for information about their products which is issued by their agencies. We have never sought to absolve ourselves of this responsibility and believe that our response to this complaint demonstrates clearly that we accept it. We therefore deny a breach of this clause.

Clause 5.6 states that material relating to medicines and their uses which is sponsored by a pharmaceutical company, must clearly indicate the role of the company. Although the email text states that Bibecfo is supplied by Cipla, we acknowledge that this is not prominent, and it does not make Cipla's support for the scheme clear at the outset. We accept that the email is in breach of this clause.

Clause 6.1 states that claims must not be misleading, and clause 6.2 that they must be capable of substantiation. In common with the other non-originator brands of

beclometasone/formoterol inhalers on the UK market, Bibecfo was approved for use by the MHRA on the basis that it had been shown to be therapeutically equivalent to the reference medicine (Fostair), with benefits and potential side effects taken as being the same (Bibecfo PAR). The statement 'no compromise on clinical efficacy' describes the effect of switching current prescribing of beclometasone/formoterol inhalers to Bibecfo, a product with a therapeutically equivalent effect. It represents the legal basis on which the product was licensed, and is therefore accurate, not misleading and substantiated, and hence not a breach of this clause.

We have attached the Bibecfo PAR [Public Assessment Report].

Clause 8.1 states that promotional material must not be issued unless it has been certified. We acknowledge a breach of this clause.

Clauses 12.1, 12.4, and 12.6 relate to the obligatory information required on promotional material. The email in question was promotional but did not contain prescribing information, the non-proprietary name of the medicine or adverse event reporting details, and we therefore acknowledge breaches of these clauses.

Clause 15.5 requires that emails must not be used for promotional purposes, except with the prior permission of the recipient. [Named third party] gains email consent from relevant stakeholders before communicating with them. The consent statement they use is attached - however it does not cover third party promotional content. Given that the email sent by [named third party] was promotional, we acknowledge a breach of this clause.

In view of the Code breaches acknowledged above Cipla accepts that its oversight of this activity has fallen short of the high standards required by the Code and is in breach of clause 5.1. However, we do not consider that the failure to recognize the promotional nature of this email, which was part of a business to business activity relating to financial arrangements, is a matter which would bring discredit on, or reduce confidence in, the pharmaceutical industry and we therefore deny a breach of clause 2.

Conclusion: Cipla takes full responsibility for the conduct of our third-party agencies and we acknowledge the importance of appropriate oversight and processes. We accept that the email in question was promotional and that it breached the Code on many points, as acknowledged above.
We would also like to point out that as a result of this complaint we have reviewed the nature of the communications and materials used for a rebate scheme. In light of the broad definition of promotion in the Code we will be working to ensure that, moving forward, any materials about a Cipla rebate scheme which are promotional are certified through our usual processes."

PANEL RULING

This amalgamated case concerned two complaints about an email for a primary care rebate scheme for Bibecfo, sent by a third party. The first complainant, who was non-contactable, had received the email while the second complaint was received from Lupin Healthcare after its approach to Cipla to engage in intercompany dialogue was declined on the grounds that the

matter had already been raised with PMCPA. In accordance with Paragraph 5.2 of the PMCPA Constitution and Procedure the Case Preparation Manager amalgamated the two complaints.

The Panel noted both complaints related to an email sent by the third party on 8 July 2025 and that no allegations had been raised about the acceptability of the Bibecfo primary care rebate scheme *per se*.

The first matter for the Panel to consider was whether Cipla was responsible for the email. In its view it was well established that pharmaceutical companies were responsible for information about their products which was issued by their third parties and this was reflected in both Clauses 1.24 and 4.8 of the Code. Cipla's response indicated that it had engaged the third party to support the implementation of the primary care rebate scheme including the communication of rebate propositions directly to integrated care boards (ICBs) and NHS stakeholders. Cipla did not dispute that it was responsible for the third party's actions in this regard. The Panel noted that Clause 4.8 had been raised and while finding that Cipla was responsible for the email it considered that Clause 4.8 was a statement of fact that was not capable of being breached and therefore did not make a ruling on this point.

The Panel reviewed the email at issue and noted the following:

- the subject line "Bibecfo Rebate Opportunity – Savings for NHS …ICB." suggested its purpose was to create awareness of the availability of the primary care rebate scheme and encourage recipients to find out more
- the body of the email included
    - the statement "I'm reaching out to highlight a potential opportunity to reduce prescribing costs within [named] ICB through a primary care rebate switch to Bibecfo (beclometasone/formoterol inhaler), supplied by Cipla Health"
    - an illustrative example of potential savings for the recipient's ICB based on a 100% switch to Bibecfo and a [percentage] rebate and stated that this represented a "significant financial saving with no compromise on clinical efficacy....".
    - an offer to share the full data breakdown and offer any implementation support that may be helpful for the recipient's team or local practices.

Disclosure of company involvement

Having determined that Cipla was responsible for the email communication the Panel considered Clause 5.6 which required, among other things, that materials relating to medicines and their uses, whether promotional or not, in which a pharmaceutical company has any involvement must clearly indicate the role of that pharmaceutical company and that this should be clear from the outset.

In this regard, the Panel noted the first complainant (Case/0665/07/25) alleged that at first reading the email appeared to have been sent by some sort of independent prescribing advisor, though on closer inspection, it appeared the sender was representing Cipla. The Panel further noted that the second complainant (Case/0683/08/25) stated that it is not stated in the email that any pharmaceutical company has been involved in this activity and any involvement of Cipla in sponsoring, approving, reviewing or funding this initiative should be unambiguously disclosed clearly on the email so that the recipient is aware of the company's involvement at the outset.

The Panel noted Cipla was named in the email as the suppliers of Bibecfo, albeit in the second paragraph as the final phrase of a sentence, but neither its relationship with the third party sending the email nor its involvement in the rebate scheme were made explicit in the communication. The Panel also bore in mind that the recipient ought to be aware of the company's involvement at the outset. The Panel considered that the email did not make Cipla's role in the scheme clear and it ruled a **breach of Clause 5.6** in relation to each complaint.

Disguised promotion

The first complainant stated that at first reading, "[redacted] appears to be some form of independent prescribing advisor, though, on closer inspection, [redacted] seems to be representing Cipla and that this appears a little underhand". The second complainant considered the email to be disguised promotion as there is no statement on the e-mail regarding promotional content and the sponsor responsible.

The Panel therefore had to consider whether the email amounted to disguised promotion; it noted the supplementary information to Clause 15.6 and particularly that the identity of the responsible pharmaceutical company must be obvious, and sponsorship must be declared in accordance with Clause 5.6.

The Panel firstly had to decide whether the email was promotional. It considered the overall impression created by the email, noting that at first sight it might appear to be a business communication about a commercial opportunity. The sender's email address was that of the third party.

The Panel noted that the broad definition of promotion in Clause 1.17 of the Code included any activity by a pharmaceutical company which, among other things, promotes the prescription, purchase or use of its medicines. The Panel considered the email and noted it claimed a 100% switch to Cipla's product Bibecfo would obtain significant financial savings with no compromise on clinical efficacy which would align well with formulary and value-for-money objectives and offered support to implement such a switch. Having considered the content including the clinical claim within the context of encouraging a 100% switch to Bibecfo and the offer of support to implement a switch the Panel determined that the email was promotional.

It further noted the subject line did not indicate that the email included promotional information from a pharmaceutical company such that recipients could decide whether to engage with the content before opening it. The product name alone was insufficient in this regard given the sender's email address was not that of the pharmaceutical company. The Panel further noted its ruling of a breach of Clause 5.6 above as, within the body of the email, the name of the pharmaceutical company was not obvious.

For the above reasons the Panel concluded that the promotional nature of the email was disguised and ruled **breaches of Clauses 3.6 and 15.6** in relation to each complaint.

Consent to receive promotional emails

The first complainant stated I have no idea who this [redacted] is nor how [redacted] was able to find my email address. The second complainant stated that the e-mail communication itself should only occur after the recipient has consented to receive promotional information which

they did not believe to be the case and further the email did not contain any information of how to unsubscribe.

Clause 15.5 of the Code states that emails must not be used for promotional purposes except with the prior permission of the recipient. The Panel noted therefore that such permission should be obtained in advance of the communication. Further the supplementary information required that where such permission has been given each email should inform the recipient how to unsubscribe.

In its response Cipla submitted an email with the subject, 'introduction and contact confirmation for rebate database' which it submitted was used to obtain consent for communications. This email had been sent, on 8 May 2025, to an unidentified individual in the integrated care board who had confirmed that they were "the appropriate point of contact for handling matters relating to information about quarterly primary care rebates claims and other associated information".

The Panel could not determine whether the first complainant and the recipient of the consent email were the same person but concluded that this was immaterial in this instance given that the 'consent' email did not explicitly mention that the information circulated could include promotional material from a pharmaceutical company and therefore did not seek consent for this.

The Panel therefore concluded that the consent provided on 8 May did not extend to the receipt of pharmaceutical company promotional communications and it ruled a **breach of Clause 15.5** in relation to each complaint.

Lupin Healthcare further alleged that the email did not include an unsubscribe option as required by the supplementary information to Clause 15.5. There was no unsubscribe option included in the body of the email, however the Panel noted that the copies of the email provided by the parties did not include a footer. Cipla's response was silent on this point. The Panel considered that while it was possible that an unsubscribe option may have been included within a footer, on the evidence before it, it was likely that the recipient of the email was not provided with a mechanism to unsubscribe from promotional content and it therefore ruled a **breach of Clause 15.5** in relation to Case/0683/08/25 only.

Obligatory information for promotional materials

The Panel noted that as the email was promotional material a number of other Code requirements were triggered including the requirement for prescribing information and an adverse event reporting statement as alleged by Lupin Healthcare. Neither were provided in the email and thus the Panel ruled **breaches of Clauses 12.1 and 12.6,** in relation to Case/0683/08/25 only as accepted by Cipla.

In addition, Clause 12.4 of the Code required digital promotional materials to include the non-proprietary name immediately adjacent to the brand name at its first appearance. In this case the non-proprietary name (beclometasone/formoterol inhaler) was included adjacent to the brand name (which appeared in bold font), in the body of the email, however the first iteration of Bibecfo was in the subject line of the email and therefore the provisions of Clause 12.4 had not been met and on this narrow ground the Panel ruled a **breach of Clause 12.4** in relation to Case/0683/08/25 only as accepted by Cipla.

Certification

Clause 8.1 of the Code requires promotional material to be certified prior to use. Cipla acknowledged that the material had not been certified as it had understood that the third party's communications about the rebate scheme were non promotional and as such did not require certification. On the basis that the email at issue was promotional and had not been certified the Panel ruled a **breach of Clause 8.1** in relation to Case/0683/08/25 only.

Misleading and substantiation

The first complainant stated in relation to the stated cost savings that it was very difficult to understand, as there are several equivalent brands on the market, all at different prices, and [redacted] does not point out from which we would need to switch to make the savings. The second complainant stated that the cost data in the email did not include costs for specific comparators for switching to Bibecfo which is misleading as the recipient is likely to assume that all competitor products with the same ingredients would be included in the comparison and this was not the case. Furthermore, the time period over which these cost savings would be generated is not stated.

The Panel considered the allegations that the email was misleading principally related to the email containing insufficient information about the assumptions made, how the savings had been calculated and what the comparable efficacy claim had been based on. The Panel noted Clause 6.1 required material to be sufficiently complete to enable recipients to form their own opinion on the matters covered; in this case to evaluate the cost savings promised or the comparable clinical efficacy. In the Panel's view the absence of any information detailing the basis of the calculation of savings including comparator products, cost assumptions and time period meant that the email created a misleading impression and contained insufficient detail to enable the recipient to form their own opinion on the material. Accordingly, the Panel ruled a **breach of Clause 6.1** in respect of each complaint in relation to the cost savings.

The second complainant stated that 'while the e-mail states that there are data to support these claims, no references are provided to provide substantiation (as per **Clause 6.2**), and Cipla has not provided substantiation to us'. In this regard the Panel noted that the email, when introducing the cost savings, stated that they were based on 'a review of prescribing data.' The Panel was concerned that Cipla had not responded to a request for substantiation but queried whether the Code required references to be cited within the email.

Cipla's response indicated that the savings had been calculated using the third party's budget impact model which could demonstrate the savings that could be achieved with the rebate compared to the current list price and list prices for other products in the same category, in conjunction with the integrated care board's ePACT data from publicly available data from the NHS Business Services Authority. The Panel noted that, if this information had been provided it could have been the basis for substantiating the claim however the savings claim as it appeared in the email was presented without any additional information. The Panel considered that in the context of the email the savings could not be substantiated, and it ruled a **breach of Clause 6.2** in relation to Case/0683/08/25 only.

In relation to the clinical claim 'no compromise on clinical efficacy' the second complainant stated that it clearly relates to the situation of switching from one product to another with no

specific comparator products named and which they considered to be a hanging comparison and in breach of Clause 6.1.

Cipla submitted that Bibecfo had been licensed on the basis of therapeutic equivalence to Fostair, the reference medicine for beclometasone/formoterol inhalers. The Panel had no information regarding other comparator products or the basis for their licences. The Panel considered that the comparable clinical efficacy claim may have been acceptable in relation to named comparators if supported by the data but in the absence of any named comparator the email was ambiguous and misleading on this point. The Panel ruled a **breach of Clause 6.1** in relation to Case/0683/08/25 only.

High standards

The Panel was concerned that aspects of Cipla's response indicated a poor understanding of Code requirements and governance issues that went beyond the complaint. In particular, the Panel was concerned that Cipla appeared to have handed over compliance for the rebate scheme to the third party and was unaware that its responsibilities in this regard could not be delegated or that non-promotional material was also required to comply with the Code.

The Panel noted that the email could be interpreted as promoting a 100% switch to Bibecfo which suggested the parties may not be entirely clear about the distinction between a rebate scheme as potentially covered by the exclusion to the definition of promotion in Clause 1.17, "*measures or trade practices relating to prices, margins or discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993"* and a switch service which falls outside of the exemption. Clauses 19.1 and 23.1 prohibit switch services paid for or facilitated by a pharmaceutical company whereby a patient's medicine is simply changed to another without any clinical assessment.

The third party's standard operating procedure set out the processes to be followed by its staff. This document included template emails for an initial introduction to a rebate scheme for a specific product but no further details, and a follow up email providing additional information including a list of comparator products, discount rate and illustration of projected savings. The Panel noted that the email at issue did not match either of the two templates but appeared to be a mixture of elements from both together with the promotional claim "… with no compromise on clinical efficacy…". Cipla submitted that on becoming aware of the issue it had immediately instructed the third party to stop any new approaches until such time as Cipla had completed a review of all related communications and ensured that they were in line with Code requirements.

The Panel acknowledged that Cipla had been let down by its third party's failure to follow its own internal processes, and that it had taken prompt action to cease the activity on being made aware of the error. Nonetheless, the Panel noted that Cipla was responsible for the material and the actions of the third party and concluded that the governance failures identified demonstrated Cipla's poor understanding of the requirements of the Code. In this respect high standards had not been maintained and the Panel ruled a **breach of Clause 5.1** in relation to each complaint and as accepted by Cipla.

Clause 2

Whilst the Panel was concerned about the material it considered that the rulings of breaches adequately covered the matters raised and that an additional ruling of a breach of Clause 2

would be disproportionate in the specific circumstances of this case. A ruling of a breach of Clause 2 was used as a sign of particular censure and reserved for such use. The Panel, on balance, ruled **no breach of Clause 2** in relation to Case/0683/08/25 only.

Complaint received

Case/0665/07/25	**15 July 2025**
Case/0683/08/25	**6 August 2025**
Case completed	**24 February 2026**