

CHIEF EXECUTIVE/MERZ PHARMA v IPSEN

Alleged breach of undertaking

CASE SUMMARY

This case concerned an allegation by Merz Pharma UK Ltd that Ipsen UK Ltd had breached its undertaking given following Case AUTH/3228/7/19. Merz referred to an email from a named health professional who raised concerns that an Ipsen representative was seeking to challenge a hospital's switch from Ipsen's Dysport (Clostridium botulinum type A toxin-haemagglutinin complex) to Merz's Xeomin (Clostridium botulinum neurotoxin type A) on the basis that Dysport lasted longer and that injection intervals could therefore be increased. Merz alleged that such messaging was sufficiently similar to those previously ruled in breach of the Code and subject of the undertaking.

The outcome under the 2024 Code was:

Breach of Clause 3.3	Failing to comply with an undertaking
Breach of Clause 5.1	Failing to maintain high standards

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

FULL CASE REPORT

A complaint was received about Ipsen UK Limited from Merz Pharma UK Ltd.

COMPLAINT

The complaint wording is reproduced below:

“As you will be aware the Panel is currently assessing a claim for breach of undertaking by Ipsen UK relating to CASE AUTH/3228/7/19. Since the submission of the breach of undertaking Merz has continued to receive very regular feedback from customers that Ipsen continues to execute the long standing wider corporate strategy differentiating Dysport from Xeomin based on unsubstantiated claims of an extended duration of effect when comparing Dysport to Xeomin. This is despite a clear undertaking to the PMCPA following the above referenced case and subsequent informal intercompany dialogue between company medical directors where explicit assurances were given that claims of this regard would not be made.

Given the digital age, and the lack of physical materials in circulation, evidencing such continued activity represents a challenge. As highlighted in the Appeal Board discussions in case AUTH/3228/7/19 whilst health care professionals (HCPs) are often prepared to feedback to pharmaceutical company's unethical activities or messaging implemented by their competitors, it is uncommon for HCPs to agree to go 'on record' with such assertions, and consequently when they do their views hold significant gravity.

In this most recent case, a named contactable Consultant Physician from [named NHS Foundation Trust] has approached Merz with concerns regarding Ipsen's promotional activities, reviewed in detail in the submission to follow, and [they have] agreed for this communication to be open and 'on record' with regards to a PMCPA complaint. As previously stated, seeking to switch established patients from one product to another based on cost savings derived from less frequent treatment, where an extended duration of effect has not been demonstrated, is clearly not in the interest of patients and may lead to suboptimal care, along with unforeseen healthcare utilisation with the presentation of breakthrough symptoms.

Merz is sensitive to the fact that on receiving a complaint the Panel believes has merit, the Panel may either take the complaint as a new case, or where a similar complaint is ongoing combine the cases for expediency and efficiency. Given the close similarities to the ongoing claim (Case 0774/10/25) by Merz against a breach of undertaking by Ipsen, Merz would propose the two cases are consolidated, but accepts that it is a matter for the Panel. In presenting this complaint, given the very close similarities to the ongoing complaint, the arguments to follow are essentially a restatement of previous arguments. Whilst repetitive they are necessary should the current complaint be accepted as a new 'stand-alone' complaint.

RE: Continued breach of undertaking of CASE AUTH/3228/7/19.

Please find to follow, a claim for continued promotion in breach of the code of practice and previous undertakings by Ipsen UK Ltd. (Ipsen). For clarity and consistency, given the changes in clause numbers during the historical and current applications, clauses have been presented current designation first and historical following in brackets where appropriate.

Background to the claim including previous rulings:

In 2018 Merz Pharma UK Ltd (Merz) entered inter-company dialogue with Ipsen regarding activities and materials conflating post hoc analyses of injection intervals with claims of superior/extended duration of effect of Dysport, which Merz believed were incapable of substantiation and were misleading.

The material (Why choose Dysport? leave piece ref DYS-UK-002956) included the headline '*Dysport extends time to retreatment in some patients*' and '*Dysport offers sustained effect of treatment up to 24 weeks in some patients for upper and lower limb spasticity*'. Merz argued that the claims invited readers to consider a comparison of Dysport to Xeomin or Botox explicitly implying that an extended duration of effect in favour of Dysport had been established which was incapable of substantiation and misleading.

To resolve the dispute Ipsen committed to a number of actions including; withdrawal of items with the duration of effect claims including; ***'think beyond 12 weeks', 'Dysport extends time to retreatment in some patients' and 'Dysport offers sustained effect of treatment up to 24 weeks in some patients for upper and lower limb spasticity'*** along with a commitment not to use similar claims in future, regardless of the type of material or setting. Merz was satisfied that the concerns raised had been addressed and drew the inter-company dialogue to a close.

Despite the undertakings healthcare professionals had continued to raise concerns with Merz that Ipsen maintained a strategy of differentiation on a platform of sustained duration of effect and reported that this was pervasive throughout Ipsen's activities. One evidenced example of the activity came from a named senior Clinical Pharmacist. In July 2019 Merz submitted a complaint to the Panel, CASE AUTH/3228/7/19, regarding the promotion of Dysport by Ipsen. The Panel found in favour of Ipsen and Merz appealed the decision.

On appeal it was noted that the Ipsen advertising campaign current at the time of the appeal included the claim ***'Dysport – A toxin with a long-lasting effect'***. The Appeal Board highlighted the purpose of many promotional claims was to differentiate one medicine from another. Whilst the claim (Dysport – A toxin with a long-lasting effect) might be factual, in the context of a main promotional claim, the Appeal Board considered it would be read in relation to other medicines and *'was misleading in relation to the undue emphasis on the duration of effect of Dysport with regard to other neurotoxins'*.

The Appeal Board placed significant weight on the evidence provided from a named senior Clinical Pharmacist that Ipsen continued to make general claims of superior duration of effect. The pharmacist went on record to confirm that;

During the meeting with Ipsen, which was led by a senior Ipsen employee, it was argued that the Trust was disadvantaging the patients in its care by using an inferior product, Xeomin, rather than Dysport which it was further argued had a longer duration of effect. The consequence of this practice meant that patients were missing out on the superior product and the Trust was running unnecessary clinics and consequently wasting resource.

The Appeal Board considered that the email from the senior Clinical Pharmacist provided evidence that Ipsen representatives had, on the balance of probabilities, been misleading with regard to the implied benefit of Dysport in terms of its duration of effect. The Appeal Board consequently ruled a breach of Clause 6.1 (7.2).

The Appeal Board considered that, on the evidence provided, the Ipsen representatives had not encouraged the rational use of Dysport and the implied benefit with regards to its duration of effect could not be substantiated and it therefore ruled a breach of Clause 14.4 (7.10). A breach of clause 5.1 (9.1) was also ruled.

Claimed breach of undertaking:

On 17/1/2026 Merz received an e-mail from [named consultant] at [named NHS Foundation Trust]. The e-mail states clearly that the local Ipsen representative has claimed Dysport lasts longer than Xeomin and therefore injection intervals can be

increased with the use of Dysport. [Named consultant] further notes that this assertion is not borne out in [their] clinical experience and that the available data appear inconclusive.

Considering the specific undertaking given by Ipsen not to repeat or deploy similar duration-of-effect claims in any setting, Merz considers this new information significant. The Appeal Board has previously attached considerable importance to evidence of representatives' statements in the field. Therefore, Merz believes that this correspondence constitutes relevant new evidence indicating that the previous undertakings have been breached.

The promotional approach evidenced here directly mirrors the evidence provided by the named senior Clinical Pharmacist in the original case quoted above. Merz argues that this continued messaging drawing a comparison of available Botulinum toxin products against an implied superior duration of effect of Dysport is sufficiently similar to the claims and associated materials found in breach of Clause 6.1 (7.2), and 14.4 (7.10) in case AUTH/ 3228/7/19 to represent a breach of Clause 3.3.

Since 2018 Ipsen has continued to use claims regarding duration of effect that have previously been found to be misleading and unsubstantiated. Previous claims withdrawn through inter-company dialogue and challenged in case AUTH/3228/7/19 include;

- Think beyond 12 weeks
- Dysport extends time to retreatment in some patients
- Dysport offers sustained effect of treatment up to 24 weeks in some patients for upper and lower limb spasticity
- Dysport – A toxin with a long-lasting effect

Additional, is the complaint submitted by Merz on 13/10/25 which is currently being considered by the code of practice panel (Case 0774/10/25). This complaint includes claims of; ***'Dysport may offer up to 81.5% of your patients with Cervical Dystonia, the flexibility to be reinjected at week 16 or later'*** from the most recent material submitted.

We now have new evidence from the e-mail provided that the Ipsen representative has claimed ***'Dysport lasts longer than Xeomin'***

In the original hearing the Appeal Board considered that, on the evidence provided, the Ipsen representatives had not encouraged the rational use of Dysport and the implied benefit with regards to its duration of effect could not be substantiated and it therefore ruled a breach of Clause 14.4 (7.10). In continuing this line of data misrepresentation Ipsen is setting expectations and directly encouraging physicians to extend patient treatment intervals without evidence that efficacy will be maintained, directly putting patient care at risk. Consequently, and in line with the previous finding on the same topic by the Appeal Board, this recent promotional approach by the Ipsen representative does not support the rationale use of a medicine and is in breach of clause 14.4.

In repeatedly failing to adhere to undertakings made to Merz and the PMCPA (breaching clause 3.3) Ipsen have also failed to maintain high standards representing a breach of clause 5.1.

[Screenshot of email from named consultant]"

When writing to Ipsen, the PMCPA asked it to consider the requirements of Clauses 3.3, 5.1 and 14.4 of the 2024 Code. Following further consideration of the procedural basis upon which the complaint had been accepted under Paragraph 5.11 of the Constitution and Procedure, in the absence of intercompany dialogue, the issues for determination were confined to Clauses 3.3 and 5.1.

IPSEN'S RESPONSE

The response from Ipsen is reproduced below:

"Thank you for your letter dated 11th February 2026 concerning a complaint submitted by Merz Pharma UK Ltd ('Merz'), alleging that Ipsen Ltd ('Ipsen') has breached the undertaking given in Case AUTH/3228/7/19.

Ipsen takes its responsibilities under the ABPI Code of Practice with the utmost seriousness and remains fully committed to upholding the highest standards of ethical and compliant conduct.

In this context, we are disappointed that once again Merz has chosen not to initiate inter-company dialogue (ICD) prior to submitting a complaint, particularly given the PMCPA's repeated encouragement of ICD as a constructive and proportionate mechanism for resolving concerns between companies. Merz's continued refusal to do so prevents timely and collaborative resolution.

Merz alleges that an Ipsen representative claimed that '*Dysport lasts longer than Xeomin*', based on an email sent to Merz by a healthcare professional. Merz further asserts that this promotional interaction did not support the rational use of a medicine and is therefore in breach of Clause 14.4 of the Code.

We acknowledge that something must have prompted the healthcare professional to raise their concerns; however, we are unable to speculate on the origin of this perception. Ipsen recognises that, in situations where there is no contemporaneous record of the exact wording used during a verbal interaction, differing recollections may understandably occur. Consistent with the approach taken in previous PMCPA cases, the company has therefore focused its response on related objective, verifiable material, including approved briefing documents and documented correspondence.

Background

The allegations relate to interactions following the hospital's recent switch, from Ipsen's Dysport back to Merz's Xeomin as described in the complaint and believed to be in October 2025. Ipsen has therefore focused its review on materials and documented contacts relevant to this period.

Interactions between [named consultant] and the Ipsen representative

Our thorough investigation of the interaction between [named consultant] and the Ipsen representative concluded that the only contact since 2024, after the hospital made the decision to switch back to Xeomin, occurred in January 2026 during an international conference [name] which [named consultant] was sponsored by Ipsen to attend.

These interactions as per all our healthcare professional interactions were recorded via our internal Customer Relationship Management (CRM) system. Two interactions were recorded between the healthcare professional and the Ipsen representative between the receipt of the complaint (11th Feb 2026) and the recent switch from Dysport back to Xeomin: on the 15th January 2026 and 16th January 2026. Both of these interactions occurred whilst at the congress. The CRM records show that no materials were used during those interactions, as also confirmed by our representative; the CRM records do not allow free text, therefore we do not have records of the conversations.

The Ipsen representative was interviewed regarding the conversations with the healthcare professional. They confirmed that the discussions on 15th and 16th January 2026 related solely to dilution recommendations for Dysport. Prior to these conversations the Ipsen representative had not had any direct interactions with [named consultant] since December 2024.

The Ipsen internal investigation also shows that there has been an email exchange between the Ipsen representative and the hospital [senior manager] in September and October 2025 when the hospital was considering switching from Ipsen's Dysport back to Merz's Xeomin. The [senior manager] is specifically responsible for neurology services as well as the broader responsibility for general hospital services. In particular, there was a request for information originating from the [senior manager], who stated on 8th October 2025:

'We may end up switching back if I cannot get the consultants to inject at a less frequent rate. Would you be able to send me over guidance which shows that we should be injecting less frequently with Dysport as opposed to Xiomen? (sic) I think the consultants can't understand this as it is the same drug – but ultimately we need to give them guidance to show the change.'

The representative replied the same day:

'I can send this to you, however I would like to discuss it in person or on Teams if possible.'

No written or verbal clarification regarding injection frequency or duration of effect was provided by the Ipsen representative within that email exchange.

A Teams call subsequently took place. Following that call, the representative submitted a request to Ipsen Medical Information (on behalf of the hospital [senior manager]) for Dysport-specific published evidence. Three Dysport publications were then provided via Medical Information.

We have not been able to identify any evidence that the representative made any claims regarding Dysport lasting longer than Xeomin.

Consequently, Ipsen respectfully denies a Breach of the Undertaking given in 2018 (Clause 3.3).

Actions to implement Undertaking

Since providing the undertaking, Ipsen has implemented a number of measures to ensure that a similar breach of the Code does not occur in future. These actions include:

- **UK Specialty Care Briefing (October 2020):**
A comprehensive communication was issued to all UK Specialty Care employees, including all sales teams and head office–based staff. This reminder reinforced the following key principles:
 - Comparisons between medicines must not be made unless supported by robust evidence (e.g., head-to-head clinical studies).
 - Claims must not be misleading in any way.
 - Superiority claims must not be made unless they are capable of substantiation.
 - No statements should be disparaging toward other medicines.
 - High standards of conduct must be maintained at all times.
- **Dysport Sales Team Briefing Call (December 2025):**
Following the recent allegation by Merz of a Breach of Undertaking (Case 0774, currently under consideration by the PMCPA), all members of the Dysport sales team were further briefed via a dedicated call to reiterate and reinforce the above requirements.

Copy of the briefing for UK Specialty Care is provided.

Given these actions and the lack of any evidence that Ipsen has breached the Undertaking, Ipsen respectfully denies a Breach of Clause 5.1.

Irrational promotion

Following a thorough internal review of the complaint and evidence provided, Ipsen respectfully submits that there is no evidence that the Ipsen representative mentioned anything pertaining to duration of action, such as '*Dysport lasts longer*'. However, we acknowledge that the hospital [senior manager] may have held the impression that Dysport would be injected less frequently than Xeomin.

This impression did not come directly from the representative, as the representative did not speak directly with [named consultant].

However, as highlighted above, during our investigation, Ipsen noted that the email from the hospital [senior manager] to our representative did imply that Dysport might be dosed less frequently than Xeomin. While our representative did not make any claims in this regard, the representative failed to immediately correct this statement. This could have left the impression that such evidence existed. This impression could have

been shared by the hospital [senior manager] with [named consultant], although we have no evidence to that effect.

However, because the representative did not immediately correct the hospital [senior manager]'s misleading impression regarding Dysport's dosing frequency, Ipsen regrettably accepts a breach of clause 14.4 for irrational promotion.

For clarity:

- There is no evidence regarding the verbal comments made by the representative in conversations with [named consultant] or the hospital [senior manager]
- There is no evidence that the representative made written statements about the duration of effect with either [named consultant] or any of the pharmacy staff
- We believe the representative failed to correct a statement about duration of effect sent to the representative by the hospital [senior manager] during an email exchange

We do not accept that the representative's inaction amounts to a Breach of Undertaking in case 3228, however we do accept that in failing to correct a misleading impression Ipsen allowed the perception of irrational promotion under Clause 14.4.

Conclusion

In light of the above, Ipsen respectfully submits that:

- No breach of Clause 3.3 has occurred
- No breach of Clause 5.1 has occurred
- We accept the breach of 14.4 through failing to immediately correct a misperception in writing

Ipsen has provided the relevant information identified through its internal review and respectfully leave the panel to determine the outcome based on the evidence submitted."

FURTHER INFORMATION PROVIDED BY IPSEN

Following a request by the Panel for a copy of the full email exchange between the Ipsen representative and the [hospital senior manager] in September 2025 and October 2025, Ipsen provided copies on 03 July 2026.

On 31 July 2026, Ipsen provided a further response which is reproduced below:

"In the spirit of transparency and self-regulation and to ensure that the Panel has access to all relevant information, we wish to bring to the Panel's attention an additional email connected to this matter and to revisit the position in our original response dated 5th March 2026 (the **Response**), accordingly.

Further to Ipsen's initial investigation into this matter, an additional relevant correspondence has been identified and as Ipsen was not aware of this correspondence

at the time of its initial investigation, it was not considered, nor included, as part of the Response. Rather, Ipsen prepared the Response to the PMCPA based on the information and materials provided at the time, and considered its investigation to have been sufficiently methodical and detailed.

Upon receipt of this Response, the PMCPA requested copies of the relevant email exchanges as referenced therein to the PMCPA. As a result of this request, and as a matter of good practice, Ipsen then made additional enquiries with the representative, including conducting a further review of the available correspondence. During this process, the representative identified and provided one additional email which had not been disclosed to Ipsen at the time of the initial investigation. This appears to have been a genuine oversight on the part of the representative who did not immediately identify the email as being relevant. Ipsen had no reason to doubt that the review carried out by the representative during the initial investigation was not exhaustive. Appropriate actions have been put in place regarding the sales representative actions, as per company policy. Ipsen considers these measures appropriate and proportionate to ensure that similar issues do not arise in the future.

Upon being provided with this additional email, Ipsen immediately reviewed its contents, reassessed the conclusions reached during the initial investigation, and undertook an even broader review of associated communications to determine whether (i) these were related in any way to the matter under review; and (ii) any further action or notification to the PMCPA was required. In addition, Ipsen's Investigations team conducted an interview with the representative, who was fully cooperative throughout the process.

Based on this review of the wider communication history and the interview findings, no evidence of malicious intent was identified, and the matter was assessed as an isolated case rather than a wider issue. We also confirm that the only additional communication which was identified during this review is the single email correspondence which is discussed below.

Nature of the additional email correspondence

The email in question relates to a correspondence with the [named NHS Foundation Trust] sent by the representative to the hospital [senior manager] dated 15th October 2025 in the context of an earlier request from the [senior manager] seeking information that might support less frequent injection intervals with Dysport.

The email indicates that the representative shared two Veeva Approved Email (VAE) fragments with the [senior manager]. These VAE fragments contained videos featuring consultant neurologists. The VAEs and videos have since been withdrawn (November 2025). The content of both videos discussed clinical evidence supporting retreatment intervals of approximately 16 weeks with Dysport in patients with cervical dystonia. In addition, the videos included discussion of the potential operational benefits associated with extended retreatment intervals, including potentially reduced frequency of hospital visits and increased clinic capacity through fewer treatment appointments.

Taking into consideration this newly identified email, Ipsen accepts that the representative's actions could reasonably be interpreted as reinforcing the perception that Dysport offered longer treatment intervals than competing botulinum toxin products.

Ipsen acknowledges that such messaging could be interpreted as being associated with the subject matter of the undertaking provided following Case AUTH/3228/7/19, namely claims or implications regarding superior duration of effect or extended injection intervals.

Accordingly, considering this new piece of information, Ipsen no longer maintains the position set out in the Response that there was no evidence of duration-related messaging associated with these discussions.

Having reviewed all the available evidence, Ipsen accepts that the representative's conduct was inconsistent with the undertaking given following Case AUTH/3228/7/19. Ipsen therefore accepts that a breach of **Clause 3.3** has occurred.

Ipsen recognises that compliance with both the letter and spirit of undertakings given to the PMCPA is fundamental to maintaining high standards under the Code.

In light of the circumstances described above, Ipsen accepts that high standards were not maintained and therefore accepts a breach of **Clause 5.1**.

Ipsen regrets that this information was not identified during its initial investigation and apologises for the omission. Ipsen considers it important that the Panel is provided with the fullest and most accurate account of the circumstances and has therefore submitted this additional information at the earliest opportunity following its discovery."

PANEL RULING

This complaint concerned an allegation by Merz Pharma UK Ltd that Ipsen UK Ltd had breached its undertaking given following Case AUTH/3228/7/19. Merz referred to an email from a named health professional who raised concerns that an Ipsen representative was seeking to challenge a hospital's switch from Ipsen's Dysport (Clostridium botulinum type A toxin-haemagglutinin complex) to Merz's Xeomin (Clostridium botulinum neurotoxin type A) on the basis that Dysport lasted longer and that injection intervals could therefore be increased. Merz alleged that such messaging was sufficiently similar to those previously ruled in breach of the Code and subject of the undertaking. Merz raised a further allegation of a breach of undertaking of Case AUTH/3228/7/19 which was considered separately by the Panel in Case/0774/10/25.

The Panel noted that an undertaking was an important document. It included an assurance that all possible steps would be taken to avoid similar breaches of the Code in future. It was very important for the reputation of the industry that companies complied with undertakings. The Panel considered that given the Authority's responsibility in ensuring compliance with undertakings, intercompany dialogue as set out in Paragraph 5.11 of the Constitution and Procedure was not required in this regard before a complaint could be accepted.

The Panel noted that whilst Merz had also cited Clause 14.4 in its complaint, intercompany dialogue had not been conducted in relation to that allegation. The matters before the Panel were whether Ipsen had failed to comply with its undertaking and, if so, whether it had failed to maintain high standards. The Panel therefore limited its consideration to Clauses 3.3 and 5.1 and made no ruling in relation to Clause 14.4 referred to by Merz in its complaint.

The previous case, AUTH/3228/7/19, arose following intercompany dialogue between Merz and Ipsen in 2018 regarding activities and materials which Merz alleged conflated injection intervals with claims of superior or extended duration of effect of Dysport. During intercompany dialogue, Ipsen committed to withdraw materials with duration of effect claims, or similar claims, regardless of the type of material or the setting. Ipsen committed to withdraw items containing the claims “think beyond 12 weeks”, “Dysport extends time to retreatment in some patients” and “Dysport offers sustained effect of treatment up to 24 weeks in some patients for upper and lower limb spasticity”. The intercompany dialogue was subsequently considered successful and drawn to a close.

In July 2019, Merz submitted a complaint to the Authority regarding a claim “Dysport – A toxin with a long-lasting effect” together with statements made by Ipsen representatives, implied that Dysport had a longer duration of effect than other botulinum toxins. The Panel ruled no breach and Merz appealed that ruling.

In relation to the claim, the Appeal Board stated,

“The purpose of many promotional claims was to differentiate one medicine from another. Whilst the claim might be factual, in the context of a main promotional claim, the Appeal Board considered it would be read in relation to other medicines and was misleading in relation to the undue emphasis on the duration of effect of Dysport with regard to other neurotoxins. The Appeal Board noted that there had been no head to head studies to show a difference in the duration of effect of any neurotoxins.”

The Appeal Board also took account of an email exchange between Merz and a pharmacist which it considered provided evidence that Ipsen representatives had “on the balance of probabilities, been misleading with regard to the implied benefit of Dysport in terms of its duration of effect”. The Appeal Board further considered that the representatives had not encouraged the rational use of Dysport and that the implied benefit with regards to its duration of effect could not be substantiated.

The Appeal Board consequently overturned the Panel’s no breach rulings of Clauses 7.2, 7.10 and 9.1 of the 2019 Code.

An undertaking accepting the decision of the Appeal Board was provided by Ipsen with the assurance that all possible steps would be taken to avoid similar breaches of the Code in future.

Email correspondence and associated materials

The Panel considered the email from the named health professional which led to the present complaint. The email, received by Merz in January 2026, stated,

“Based on cost our trust has moved our toxin of choice over the years. Pharmacy makes the decision. We are currently back on Xeomin.

However, the local Ipsen Rep is pushing back quite hard over our recent switch back to Xeomin. [They] insists that Dysport lasts longer than Xeomin and so [they suggest] we can

increase the injection intervals. In practice I am not really seeing this and the data I've looked at seems inconclusive.

Is the Rep correct on insisting to me and our pharmacy team that Dysport lasts longer than Xeomin?"

Merz submitted that the email provided evidence indicating the previous undertaking had been breached and alleged that "this continued messaging drawing a comparison of available Botulinum toxin products against an implied superior duration of effect of Dysport is sufficiently similar to the claims and associated materials found in breach" in Case AUTH/3228/7/19.

In its initial response, Ipsen submitted that its investigation identified that the only contact between its representative and the named health professional, since the hospital had switched from Dysport to Xeomin, was at a conference in January 2026 and related solely to dilution recommendations for Dysport.

Ipsen also identified and provided email exchanges between its representative and the hospital [senior manager] in September and October 2025, when the hospital was considering a switch from Dysport to Xeomin. In September, the representative sought a meeting with the hospital [senior manager] to discuss concerns regarding Dysport and "revisit the solutions" presented during earlier discussions. In October, the hospital [senior manager] asked for guidance which showed that Dysport could be injected less frequently compared to Xeomin.

Following a meeting with the representative, the hospital [senior manager] emailed to say they had asked the named health professional to consider whether they can move patient appointments back to increase capacity and asked the representative for information that might assist. Later that day, the [senior manager] stated that the health professional felt "the dysport team may be pushing [them] to do something [they are] not clinically comfortable with".

The representative replied they did not want to push the health professional and stated "...we're just trying to ensure that you get the best clinical effectiveness whilst also improving the capacity issues facing the service." The representative later suggested a meeting with an Ipsen medical employee to "clarify the clinical aspects of Dysport separate from the capacity challenged and the commercial side of things".

Ipsen initially asserted that no written or verbal clarification regarding injection frequency or duration of effect was provided by the Ipsen representative within that email exchange. Ipsen stated that the representative submitted a request to medical information, on behalf of the hospital [senior manager], for Dysport-specific published evidence and that three Dysport publications were provided via medical information. Ipsen submitted it had not identified any evidence that the representative made any claims regarding Dysport lasting longer than Xeomin, although it acknowledged that the representative had failed to immediately correct the [senior manager]'s impression regarding Dysport's dosing frequency.

In a subsequent response by Ipsen to the PMCPA, it stated that it had identified an additional email sent by the representative to the [senior manager] which Ipsen was not aware of during its initial investigation. The email referred to the provision of information concerning a Phase III

cervical dystonia trial and two videos featuring consultant neurologists. The representative stated:

“Both videos demonstrate that 16 weeks is a viable treatment period for most patients, and the one from the consultant from [location] [redacted] also discusses the positive impact this can have on capacity.

As mentioned in my previous email, my medical colleague [redacted name and role] is very happy to have a scientific, medical-focussed discussion with [redacted name], and the other consultants, which we hope will reinforce the clinical benefits and put [their] mind at ease with what is being proposed.”

Ipsen submitted that “both videos discussed clinical evidence supporting retreatment intervals of approximately 16 weeks with Dysport in patients with cervical dystonia and the potential operational benefits associated with extended retreatment intervals, including fewer hospital visits and increased clinic capacity.”

The first video was provided through a Veeva Approved Email (VAE) fragment titled ‘Flexibility with Dysport in Clinical Practice’. The fragment described the video as presenting the named consultant’s experience of using Dysport to manage cervical dystonia and “how a time to treatment interval of approximately 16 weeks reduced the frequency of injections”.

The video was 5 minutes 41 seconds and featured the named consultant presenting a case study of a “typical patient”. The consultant stated “Dysport is my toxin of choice” because it allowed for “a flexible time to retreatment of approximately 16 weeks”. The consultant described 16 weeks as a typical time for retreatment interval for most of their patients, aligned with Dysport’s clinical trial, and that such an interval might reduce the frequency of hospital visits, improve capacity and reduce waiting lists. The video concluded with a slide asking “Would Dysport’s reinjection interval of approximately 16 weeks help your patients and your clinic?”

The second video was provided through a VAE fragment titled ‘Tackling the capacity challenges in your clinics with Dysport’. The description of the video stated “[Named consultant 2] discusses Dysport time to retreatment in clinical trials and how moving to Dysport may allow adult patients with cervical dystonia to avoid unnecessary appointments and contribute to increasing clinic capacity”.

The second video was 7 minutes 16 seconds and opened with: “I’m going to be speaking to you today about an issue that is faced by many, if not all, botulinum toxin services; the challenge of managing capacity within our clinics. In so doing, I’ll be sharing with you the evidence for the use of Dysport, for the treatment of cervical dystonia”. The consultant notably stated that “the use of Dysport allows us to extend the treatment interval for the majority of patients”, “the advantages of using or switching to Dysport are seen at many levels of clinical provision” and “I’ve shared with you trial data, which challenges some of the conventional concept of retreatment intervals when using botulinum toxin. An important proportion of patients treated with Dysport experience symptom relief for 16 weeks or longer. By recognising this, we create the opportunity to plan and organise our services differently, maximising efficiency and allowing us to deliver the very best for our patients”.

In light of the additional email, and videos sent, Ipsen stated it no longer maintained the position set out in its initial response that there was no evidence of duration-related messaging. Ipsen

accepted that the representative's actions could reasonably be interpreted as reinforcing the perception that Dysport offered longer treatment intervals than competing botulinum toxin products.

Breach of undertaking

Clause 3.3 of the Code stated that when an undertaking had been given in relation to a ruling under the Code, the company concerned must ensure that it complies with that undertaking. Respondent companies must provide a written undertaking that the activity or use of the material, if not already discontinued or no longer in use, will cease forthwith and that all possible steps will be taken to avoid a similar breach of the Code in the future.

Whether a case was in breach of an undertaking depended on a consideration of all the circumstances and each case should be looked at on its individual merits. The nature of the materials or activities in question and the steps taken to avoid similar breaches in the future would be relevant. It was not possible to determine whether there was a breach of undertaking merely based on breaches of the same clause.

The Panel observed that in Case AUTH/3228/7/19, the Appeal Board had concluded that Ipsen representatives had, on the balance of probabilities, been misleading with regard to the implied benefit of Dysport in terms of its duration of effect and that such benefit could not be substantiated. The Appeal Board also considered that “the purpose of many promotional claims was to differentiate one medicine from another” and that, whilst the claim “Dysport – A toxin with a long-lasting effect” might be factual, it “would be read in relation to other medicines” and was misleading in relation to “the undue emphasis on the duration of effect of Dysport with regard to other neurotoxins”.

Ipsen had provided details of steps it had taken to comply with the undertaking by way of an internal memo issued to its employees which set out the outcome of Case AUTH/3228/7/19, the assurances it had provided the PMCPA by way of an undertaking and key learnings.

The Panel noted that the circumstances in the present case were different. There was no documented statement before the Panel that Dysport lasted longer than Xeomin or that it was a “toxin with a long-lasting effect”. The matter before the Panel in this case was whether the representative had conveyed a message sufficiently similar to that previously ruled in breach.

The Panel noted that the hospital [senior manager] had expressly asked for guidance which showed that Dysport could be injected less frequently than Xeomin and that the representative failed to correct this impression, as acknowledged by Ipsen. The Panel considered that the representative subsequently conveyed messaging and provided material emphasising extended 16-week retreatment intervals with Dysport and its associated benefits including fewer hospital visits and increased clinic capacity. One video referred to the retreatment interval as a reason for Dysport being the consultant’s “toxin of choice”; the other included that the advantages of “using or switching to Dysport” were seen at many levels of clinical provision and that patients treated with Dysport experienced symptom relief for 16 weeks or longer.

The Panel acknowledged that reinjection interval and duration of clinical effect were not entirely synonymous. The Panel considered, however, the emphasis on 16-week retreatment intervals, symptom relief and associated capacity benefits in the context of a request for evidence

supporting less frequent administration of Dysport compared with Xeomin. The Panel considered that the materials implicitly conveyed a message regarding the duration of Dysport's clinical effect and invited comparison compared with existing treatment.

Taking all the circumstances into account, the Panel considered that the overall messaging conveyed by the correspondence and attached materials was sufficiently similar to that previously ruled in breach. The Panel therefore considered that Ipsen had breached the undertaking given following Case AUTH/3228/7/19 and ruled a **breach of Clause 3.3**, as acknowledged by Ipsen.

The Panel considered the allegation of a failure to maintain high standards solely in relation to the alleged breach of undertaking. The Panel took into account the importance of undertakings, which were fundamental to the integrity of self-regulation and considered that Ipsen's failure to comply with the undertaking and assurance previously given in Case AUTH/3228/7/19 meant that it had failed to maintain high standards. The Panel ruled a **breach of Clause 5.1**, as acknowledged by Ipsen.

Complaint received 6 February 2026

Case completed 5 September 2026