

CHIEF EXECUTIVE/MERZ PHARMA v IPSEN

Alleged breach of undertaking

CASE SUMMARY

This case was in relation to 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 promotional material for Dysport (Clostridium botulinum type A toxin-haemagglutinin complex) which allegedly included claims 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 Ltd from Merz Pharma UK Ltd.

COMPLAINT

The complaint wording is reproduced below:

“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:

The current material at issue ('Dysport may offer...' promotional item) was passed to Merz by a concerned health care professional in the form of a screen shot. No approval code or date of preparation is available however Ipsen Medical services have confirmed the material was in circulation after the undertaking was entered in to and supplied the references supporting the claims.

Merz believes the claims are sufficiently similar to the original action to be considered a breach of undertaking.

The material contains the headline claim **'Dysport may offer up to 81.5% of your patients with Cervical Dystonia the flexibility to be reinjected at week 16 or later.'** supported by a takeaway question, highlighted in a prominent green box, asking **'Would Dysport's re-injection interval of 16 weeks help your patients and your service?'**

Promotional material is expensive to produce and distribute and has a purpose, and as the Appeal Board highlighted when reviewing the case *'the purpose of many promotional claims was to differentiate one medicine from another'*. The material is clearly designed to invite a comparison of the prescribers current Botulinum toxin to Dysport's extended duration of effect and to consider the benefits to the clinicians' patients the service in switching brands. This approach 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.

The promotional material is supported by three published references, Truong 2005, Truong 2010 & Esquenazi 2020., along with the SPC. Data from Truong 2005 is not directly referenced in the promotional claims, and its inclusion as supporting evidence does not appear to substantiate the claims made. Indeed, **the authors of Truong 2005 note the design of this study does not lend itself to analysis of treatment duration effects**, principally due to 41% (15/37) of the Dysport patients withdrawing at week 4 due to lack of response, rendering the subsequent analysis (which was not conducted on an intention to treat bases) a responder analysis.

The data presented in the material was generated by Truong 2010. The Truong 2010 methodology upon which the claims are based reported that patients were assessed at fixed time points;

Double blind phase

Screening, Week 0 and Weeks 4, 8 and 12 post-treatment.

Open label extension

Week 0 and every 4 weeks following each subsequent treatment cycle (weeks 12, 16 etc).

In this regard the clinical trial structure was similar in design to previous Ipsen studies with 4 weekly treatment opportunities post the 12-week review. i.e. if a patient is not treated at week 12 the next fixed appointment for review would be in 4 weeks' time, this is key to the claims made.

The majority of the claims are drawn not from Truong 2010 directly but from a post hoc analysis of Truong 2010 data not previously reported, presented in a review article published by Esquenazi in 2020.

As stated, Esquenazi 2020 does not present new primary data but a collection of post hoc analyses of reinjection intervals for Dysport in open label extension studies, conflating these data with laboratory potency data to create a rationale for a superior duration of effect. It specifically does not demonstrate superior duration of effect through comparative studies and/or predefined endpoints.

In this regard Merz believes no new evidence has been presented.

Below the promotional claims and their context are reviewed in detail. It is noted that in the Appeal Board ruling Ipsen were found in breach of clauses 6.1 and 14.4 and 5.1. Although potentially outside of the scope of a breach of undertaking claim where claims are clearly incapable of substantiation breach of clause 6.2 will be highlighted for completeness.

1. Sub head claim (*Time to retreatment...*).

At the core of the promotional material is the proposition that Dysport's time to retreatment, an implied surrogate for duration of effect, was a predefined secondary endpoint.

Predefined endpoints in Truong 2005

The primary efficacy endpoint was the change in TWSTRS-Total score at week 4 compared with baseline. Secondary endpoints were the change in the pain VAS and patient assessment of signs and symptoms at week 4 compared with baseline. All other endpoints were considered tertiary.

At no point in Truong 2005 is re-injection interval described as a primary or secondary endpoint.

Predefined endpoints in Truong 2010

The primary efficacy variable was the mean changes in TWSTRS total score from baseline at each double-blind phase assessment at Week 4, 8 and 12. No primary efficacy outcomes were reported beyond week 12.

Secondary efficacy outcomes during the double-blind phase included: change from baseline in TWSTRS total scores at Weeks 8 and 12, change from baseline on the visual analogue scale (VAS) for symptom severity (investigator and patient ratings) at each assessment; change from baseline in Short Form 36 (SF-36) Quality-of-Life questionnaire [15] scores at Week 8; and the percentage of patients considered by the Investigator to be overall treatment successes at Week 12 defined as a global assessment of efficacy ratings of 'better' or 'much better' and a global safety assessment of no worse than moderate.

Exploratory efficacy endpoints during double-blind treatment included: change from baseline to Weeks 4, 8, and 12 in VAS pain scores, TWSTRS severity, disability, and pain subscale scores, VAS pain scores (subgroup of patients with baseline scores >40 mm), and proportion of responders (30% decrease in TWSTRS total score from baseline). During the open-label extension phase, additional secondary efficacy outcomes included change from baseline in the TWSTRS severity, disability, and pain subscale scores at Week 4 after the start of each treatment cycle.

At no point in Truong 2010 is re-injection interval described as a primary, secondary or exploratory endpoint.

Predefined endpoints in Esquenazi 2020

Esquenazi 2020 was a review article including post hoc analyses across a number of studies. Consequently, there were no predefined endpoints in Esquenazi 2020.

As such the claim ***“time to retreatment with Dysport was a secondary endpoint reported in clinical trials...”*** referenced to Truong 2005, Truong 2010 and Esquenazi 2020 immediately below the headline *‘Dysport may offer up to 81.5% of your patients the flexibility to be reinjected at week 16 or later’* is not accurate, directly misleads the reader and consequently in breach of clause 6.1 of the code. The claim is also incapable of substantiation and in breach of clause 6.2 of the Code. This misleading sub-headline is clearly designed to add credibility to the overall promotional item so all of the claims within the material, most particularly the headline claim, should be reviewed with this in mind.

2. Headline is misleading and incapable of substantiation on multiple counts

The promotional item has the headline *‘Dysport may offer up to 81.5% of your patients with cervical dystonia, the flexibility to be reinjected at week 16 or later’* referenced to Esquenazi 2020.

As stated, the Esquenazi review paper included a post hoc analysis of previously unseen data from the Truong 2010 study regarding the proportion of patients with cervical dystonia **not** requiring retreatment at different timepoints during each cycle in the open-label extension phase. These data should be presented with caution as it was not a predefined endpoint and are consequently open to selection bias. The promotional material does not include appropriate disclaimers or context to prevent misinterpretation, which is required for compliance with the Code.

[Visual of graph reproduced from Esquenazi 2020 showing the percentage of cervical dystonia patients not requiring retreatment at weeks 12, 16, 20 and ≥24 weeks]

From the data reported in the Esquenazi review paper it can be claimed that in the open label extension 72.6% of patients in cycle 1, 77% of patients in cycle 2 and 81.5% of patients in cycle 3 **were judged not to require re-treatment at week 12** by the investigators, subsequently going on to be re-treated at the next treatment opportunity (week 16).

The claim by Ipsen that ***‘Dysport may offer up to 81.5% of your patients with Cervical Dystonia, the flexibility to be reinjected at week 16 or later’*** is problematic on two counts.

Firstly, the statement leaves the reader with the impression that patients were assessed to not need reinjection until week 16. It is an assumption that patients not treated at week 12 would not benefit from retreatment before week 16, so the statement is incapable of substantiation and is misleading by implication, consequently representing a breach of clauses 6.1 and 6.2.

Secondly only presenting the highest figure of 81.5% of patients not requiring re-injection at week 12 in cycle 3 in isolation is clearly cherry picking the highest number, despite the more robust double-blind section reporting 14.4 weeks as the mean time to re-injection and cycle 1 and 2 reporting 72.6% and 77.0% of patients not requiring retreatment respectively at week 12 represents a breach of clause 6.1 of the code.

It should be no surprise that the last reported treatment cycle provided the most impressive results. At the end of the double-blind phase 18% Dysport treated patients discontinued, half of these for insufficient response. At the end of the first open label treatment cycle 7% discontinued with 42% of these withdrawals due to insufficient response and a further 4% discontinued at the end of the open label treatment cycle 2, half of which were due to insufficient response. Cycle 3 would have benefited from the successive withdrawal of non-responding patients due to insufficient response, so could in effect be considered a responder analysis rather than a normal clinical population.

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

Added to this is the current 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 under review.

All of these claims leave the reader with the impression that Dysport has a demonstrably extended duration of effect when compared to the alternatively available botulinum toxins and that this a credible point of differentiation. In seeking to provide substantiation for these claims, Ipsen have relied on post hoc analyses of open label extension studies across dystonia and spasticity (Gracies & Esquenazi) which were not designed to support insights into Dysport's duration of effect, with even the authors of the source data commenting in that regard (Truong 2005). Reinjection intervals are directly constrained by study protocols; they are not a measure of duration of effect. In this most recent material reinjection intervals were even, wrongly, described as a study secondary endpoint to build credibility in data where they should have been urging caution in interpretation.

One specific tactic by Ipsen of misrepresenting duration of effect, specifically reporting patients not treated at week 12 as having a successful duration of effect until their next scheduled review at week 16, despite having no evidence to support the claim, was outlined in detail in the 2019 Appeal Board submission by Merz and is a matter of record in that regard. It is concerning to observe the recurrence of such claims despite previous undertakings.

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 exactly the same topic by the Appeal Board, this new promotional material 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.”

When writing to Ipsen, the PMCPA initially 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 24 October 2025 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 in relation to material DYS-UK-006852.

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. Following a thorough internal review, Ipsen respectfully submits that the material in question does not constitute a breach of the undertaking under Clause 3.3 of the Code. We therefore consider this to be a new complaint, which should be subject to the intercompany dialogue requirement. Accordingly, Ipsen does not believe that a breach of Clause 14.4 or 5.1 has occurred, as no attempt has yet been made to resolve the matter directly between Merz and Ipsen, in line with the Complaints Procedure.

Alleged Breach of Undertaking – Clause 3.3

Ipsen is committed to complying with undertakings. The steps taken to ensure that a similar breach of the Code would not occur can be found in [copy provided]. Ipsen rejects any breach of Undertaking. Our explanation is set out below.

The claim in Case AUTH/3228/7/19 was:

- “Dysport – A toxin with a long-lasting effect”

The claim alleged to be similar in this new Case AUTH/0774/10/25 is:

- “Dysport may offer up to 81.5% of your patients with cervical dystonia the flexibility to be re-injected at week 16 or later”

Ipsen respectfully submits this claim is not sufficiently similar in content or implication to the claims previously ruled in breach in Case AUTH/3228/7/19.

Clause 3.3 requires a company to comply with any undertaking given following a ruling under the code. In practice, this means that any material which relates to the subject of a previous undertaking should be carefully assessed to ensure that it does not conflict with or repeat the content of the earlier material.

The current claim is factual, descriptive, and aligned with the Dysport Summary of Product Characteristics (SmPC) for cervical dystonia, which states in section 4.2 that “injections may be repeated approximately every 16 weeks or as required to maintain a response, but not more frequently than every 12 weeks.”

This claim does not compare Dysport with other products, nor does it imply superiority. It reflects the proportion of patients who, in a published clinical study, did not require retreatment before 16 weeks. The statement is entirely consistent with the licensed dosing interval.

Furthermore, the claim is supported by Esquenazi et al. (2020), which presents post-hoc analysis of the open-label extension study in cervical dystonia. This publication post-dates the material assessed in Case AUTH/3228/7/19 and therefore constitutes new evidence not previously available to the Panel or Appeal Board.

The study reports:

“In Dysport treated patients with cervical dystonia, 72.6–81.5% did not require retreatment before 16 weeks.” (Front Neurol 2020; 11:576117)

Previously, the Appeal Board noted that the claim “Dysport – A toxin with a long-lasting effect” lacked clarity regarding the meaning of “long-lasting effect.” In contrast, the current material presents factually accurate and referenced figures. The full observed range (72.6–81.5%) and the mean time to retreatment are displayed alongside the headline claim. The 81.5% figure is not presented in isolation but is clearly qualified by the phrase “may offer up to.”

This approach provides appropriate context and enables healthcare professionals to make informed judgments. It cannot reasonably be characterised as “cherry-picking,” as alleged by Merz.

In the previous case, the Appeal Board concluded that Ipsen had not encouraged rational use and that the implied benefit regarding duration of effect was unsubstantiated. Ipsen strongly refutes any suggestion that the current claim promotes irrational use. The statement is substantiated, consistent with the licensed posology, and supports rational prescribing consistent with the SmPC which allows for treatment intervals of approximately 16 weeks, subject to prescriber discretion.

Furthermore, the use of qualifiers such as “may offer” and “up to” introduces appropriate caution and reflects variability, in line with previous PMCPA precedent (Case AUTH/0248/07/24), which recognises such phrasing as adding necessary nuance.

Additionally, the material in question was last used in April 2024. Ipsen is concerned that this issue has been raised after more than 15 months and without any prior attempt at intercompany dialogue resolution, which appears contrary to the spirit of section 5.11 of the Complaints Procedure.

Conclusion

In light of the above, Ipsen respectfully submits that:

- Material DYS-UK-006852 does not repeat, nor is it sufficiently similar in tone, content, or implication to, materials previously ruled in breach in Case AUTH/3228/7/19
- The claim is factual, evidence-based, and consistent with the SmPC
- Esquenazi 2020 represents new evidence from that considered in 2019

Accordingly, Ipsen does not consider that a breach of Clause 3.3 has occurred. Therefore, Ipsen does not consider that a breach of Clause 14.4 or 5.1 has occurred until an attempt at resolving any new matter has been made between Merz and Ipsen via intercompany dialogue.

Ipsen remains fully committed to ensuring that all its materials reflect both scientific accuracy and the spirit of the Code. We remain open to further dialogue and to resolving any concerns transparently and constructively."

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 promotional material for Dysport (Clostridium botulinum type A toxin-haemagglutinin complex) which allegedly included claims 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/0872/02/26.

The Panel noted the material at issue was headed in bold text "Dysport may offer up to 81.5% of your patients with cervical dystonia, the flexibility to be reinjected at Week 16 or later". Immediately beneath this stated that "time to retreatment with Dysport was a secondary endpoint reported in clinical trials, with results showing that most patients with cervical dystonia did not require retreatment before week 16 or later". Accompanying this statement was a graphical illustration of the mean time to retreatment being between 15 and 17 weeks, along with an illustration representing the proportion of patients reinjected at week 16 or later across three treatment cycles. A prominent green panel, which appeared towards the bottom, prior to footnotes and references, asked, "Would Dysport's reinjection interval of ~16 weeks help your patients and your service?"

Merz's principal concern appeared to relate to the headline claim, "Dysport may offer up to 81.5% of your patients with Cervical Dystonia, the flexibility to be reinjected at week 16 or later" and Merz also referred to the supporting claim "Would Dysport's reinjection interval of ~16 weeks help your patients and your service?". Merz alleged that the material encouraged the consideration of switching from other botulinum toxins and invited comparison to Dysport's implied superior duration of effect in this regard. Merz submitted that this messaging, regarding

implied duration of effect, was sufficiently similar to the claim ruled in breach in Case AUTH/3228/7/19.

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 Clauses 6.1, 6.2 and 14.4 in its complaint, intercompany dialogue had not been conducted in relation to those allegations. 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 the other clauses referred to by Merz in its complaint.

Case AUTH/3228/7/19

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 including those 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". It was alleged that the claim, 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.

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.

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.

Ipsen submitted that the claim "Dysport may offer up to 81.5% of your patients with cervical dystonia, the flexibility to be re-injected at week 16 or later" was not sufficiently similar in content or implication to the claim previously ruled upon in Case AUTH/3228/7/19 and that the claim was factual, descriptive and aligned with the Dysport Summary of Product Characteristics (SPC) for cervical dystonia. In this regard, Section 4.2 of the SPC stated, "injections may be repeated approximately every 16 weeks or as required to maintain a response, but not more frequently than every 12 weeks."

Ipsen submitted that the claim did not compare Dysport with other products, nor imply superiority, but reflected the proportion of patients who did not require retreatment before 16 weeks in a published post-hoc analysis that post-dated Case AUTH/3228/7/19. Ipsen further submitted that the wording "may offer" and "up to" appropriately reflected variability and provided suitable qualification.

The Panel noted that Ipsen made no specific submissions in relation to the accompanying claim "Would Dysport's reinjection interval of ~16 weeks help your patients and your service?".

The Panel noted that there were differences between the claims at issue in the present material and that previously considered in Case AUTH/3228/7/19. In particular, the present material did not refer to Dysport as a "toxin with a long-lasting effect", nor did it expressly refer to the duration of effect of Dysport or expressly compare Dysport with another botulinum toxin. The Panel also took account of Ipsen's submission that the material reflected the licensed reinjection interval within the Dysport SPC and relied upon published evidence that post-dated the previous case.

The Panel observed that in Case AUTH/3228/7/19, the Appeal Board had 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.

The claims at issue in the present material were “Dysport may offer up to 81.5% of your patients with cervical dystonia, the flexibility to be re-injected at week 16 or later” and “Would Dysport’s reinjection interval of ~16 weeks help your patients and your service?”.

The Panel considered that whether the claims accurately reflected the supporting evidence, gave an appropriate impression of the data or otherwise complied with the requirements of the Code were separate matters not under consideration by the Panel. The matter before the Panel in this case was whether the present material conveyed a message sufficiently similar to that previously ruled in breach.

The Panel acknowledged that the reinjection interval and duration of clinical effect were not entirely synonymous. However, it considered the context of the overall material which emphasised, and solely related to, reinjection at approximately 16 weeks and invited readers to consider whether the reinjection interval would help “your patients and your service”. On balance, the Panel considered that the material implicitly conveyed a message regarding the duration of Dysport’s clinical effect and invited comparison with existing treatment. In the Panel’s view, the headline claim, together with the prominent takeaway question asking whether Dysport’s reinjection interval would help their patients and service, encouraged health professionals to regard that characteristic as a point of differentiation compared to existing treatments.

Taking all the circumstances into account, the Panel considered, on balance, that the overall message conveyed by the material and claims 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**.

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**.

Complaint received **13 October 2025**

Case completed **5 September 2026**