

COMPLAINANT v ALLERGAN

Alleged promotion of Botox on digital and social media channels

CASE SUMMARY

This case was in relation to Allergan allegedly using its medical device, Juvéderm (Hyaluronic Acid Filler), to promote its prescription only medicine, Botox.

The Panel ruled no breach of the following Clauses of the 2021 Code because it noted that if a reader followed the original link from the Juvéderm UK website, he/she was taken to the homepage of the global/US corporate website rather than a product page and a number of active clicks were required before Botox promotional information could be viewed. The Panel did not consider that the circumstances were such that Allergan UK had used its medical device to promote Botox across digital and social media channels as alleged including to the public and health professionals in the UK:

No Breach of Clause 2	Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry
No Breach of Clause 8.1	Requirement to certify promotional material
No Breach of Clause 12.1	Requirement to include up to date prescribing information
No Breach of Clause 12.3	Requirement to include the non-proprietary name in promotional material
No Breach of Clause 12.6	Requirement to include a prominent statement as to where the prescribing information can be found on promotional material on the internet
No Breach of Clause 12.9	Requirement to include a prominent adverse event statement on promotional materials
No Breach of Clause 15	Requirements for the high standard, format and suitability of promotional materials
No Breach of Clause 16	Requirements for the distribution of promotional materials
No Breach of Clause 26.1	Requirement not to advertise prescription only medicines to the public
No Breach of Clause 26.2	Requirement that information about prescription only medicines which is made available to the public must be factual, balanced, must not raise unfounded hopes of successful treatment or encourage the public to ask their health professional to prescribe a specific prescription only medicine.

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

FULL CASE REPORT

COMPLAINT

A contactable complainant who described him/herself as a prescribing pharmacist providing consultancy services to the pharmaceutical industry complained about the alleged promotion of Botox (botulinum toxin type A) by Allergan.

The complainant stated that he/she had worked in multiple therapeutic areas, including aesthetic medicine and had provided consultancy services for Allergan in the past. Whilst the complainant understood that aesthetic medicine was still an evolving therapy area, the Code still applied. The complainant noted that given this, he/she was writing to complain about Allergan using its medical device, Juvéderm (Hyaluronic Acid Filler), to promote its prescription only medicine, Botox, across digital and social media channels.

The complainant alleged that Allergan was in breach of Clause 2 – Upholding confidence in the industry, Clause 8 – Certification and examination, Clause 12 – Prescribing Information and other obligatory information, Clause 15 – High standards, format and suitability, Clause 16 – Material and distribution, and Clause 26 – Relations with the public including patients and journalists.

The complainant stated that from landing on Allergan's Juvéderm website readers were two clicks away from Allergan's Global website actively promoting Botox. The complainant provided the website addresses as follows:

Website <https://www.juvederm.co.uk/> (Click One – Allergan Aesthetics Hyperlink)

www.allergan.com/ (Click Two – Allergan Aesthetics)

www.allerganaesthetics.com/

www.allerganaesthetics.com/botox

www.botoxcosmetic.com/

The complainant included further hyperlinks from [botoxcosmetic.com](http://www.botoxcosmetic.com):

www.instagram.com/BotoxCosmetic/

www.facebook.com/BotoxCosmetic

www.youtube.com/channel/UCgll6aLdtF8G83eNjSYkTaw

The complainant stated that he/she had captured screenshots of the pages landed on as the user clicked through from one digital website to the next and alleged that at no point did it advise the user that they were leaving a UK website. Furthermore, it actively led the user to the social

medial platforms for Botox on Instagram and Facebook and to the Botox Cosmetic YouTube Channel.

The complainant had seen from recent cases that Allergan was recently publicly reprimanded for its activity on digital channels and in 2019 was found in breach of the Code for promoting Botox to the public via its corporate Juvéderm Instagram account. The complainant alleged that the company either had no respect for the Code or the business had no compliance processes in place to ensure it operated within the Code.

The complainant trusted that the complaint would be reviewed particularly given the change in legislation around the change in the law to safeguard children from the potential health risks of botulinum toxins and cosmetic fillers.

When writing to Allergan, the Authority asked it to consider the requirements of Clauses 2, 8, 12, 15, 16 and 26 of the Code as cited by the complainant. Following a request for further information from Allergan as to which sub-clauses of those cited by the complainant should be addressed in the response, the case preparation manager noted that as the complainant had identified a number of clauses of the Code, Allergan needed to respond to each of the clauses raised bearing in mind the complainant's view that Allergan was using Juvéderm to promote Botox, a prescription only medicine. This was more directly applicable for some of the clauses than others, eg Clauses 8.1, 12.1, 12.3, 12.6, 12.9, 26.1 and 26.2.

RESPONSE

Allergan stated that it took its responsibility for compliance with all applicable laws and regulations, including the Code, very seriously and continuously endeavored to maintain these high standards in all its activities.

Allergan noted that the complainant alleged that there was a website link on the Juvéderm UK website (www.juvederm.co.uk) which would connect a user to a different global/US website and that if a user took additional actions that connected the user to other global/US websites, the user could access information about Botox. It was further alleged that information contained within those other global/US websites (not the Juvéderm UK website) would constitute promotion of a prescription only medicine to the public in the UK as well as breaches of several other clauses of the Code.

Scope of Code:

In the complaint letter, the case preparation manager raised the issue that it was not entirely clear whether all the matters that were the subject of the complaint were covered by the Code. Allergan stated that having investigated the complaint in detail, the matters raised therein, namely Botox material on global/US websites, fell outside the scope of the Code. Allergan made a number of points in this regard as follows:

- As Juvéderm was registered as a medical device, any information and material related to Juvéderm fell outside the scope of the Code because the promotion of medical devices to the public was not prohibited in the UK, including on the above mentioned Juvéderm UK website (www.juvederm.co.uk). Allergan acknowledged that should information or material on a UK website make reference directly or indirectly to

a prescription only medicine (POM), such as Botox, which was not the case here, then such information or material might be within the scope of the Code.

- The complaint did not fall within the scope of the Code as the requirements detailed in Clause 1.2 had not been satisfied: (i) none of the Botox material presented in the complaint was placed on the internet within the UK nor with the authority or direction of the UK Allergan Aesthetics business, but rather it originated from, and was placed in the US on US-owned websites, and (ii) nor did any of the Botox material on the global/US websites contain any specific reference to the availability or use of Botox in the UK.
- Allergan was aware that material which would be deemed to be outside the scope of the Code as defined in Clause 1.2 could come within scope if it was directed to a UK audience (Clause 16.1). Here, however, the Botox material in question was not directed to a UK audience. Instead, the Botox information could only be accessed after taking several steps directing the user to other non-UK websites that were clearly marked as US websites.
- Further, the link of the Juvéderm UK website that directed users to global/US websites, was not apparent. The link was included in a company logo, which unless a user scrolled over the logo the user would not be aware that the logo was a link to a global/US website.
- Even if a user did click on the logo and arrive on the global/US website, that website was a corporate website that did not include information related to Botox. At that point, the user must click on a link to another global/US website for Allergan Aesthetics. Now twice removed from the original UK website, the user could access Botox information on the global/US website. As for the information contained on social media channels, the user would have to click on those links to access the US social media accounts, which would be three websites removed from the original UK website.
- More importantly, in the event that a user did click on the logo, based on the information provided by the complainant, they would then have to click again to access any mention of Botox (in the form of some factual indication/safety information) and at least once more to access any promotional material. For example, it would have taken five clicks to get from the logo on the Juvéderm UK website to the Instagram social media account mentioned in the complaint.
- Allergan concluded that it was common practice for UK pharmaceutical company websites to link to the home page of its global organization and listed three other named pharmaceutical companies, providing links to their websites as examples amongst others.
- As Juvéderm was a medical device, the Juvéderm UK website did not require certification. Accordingly, there were no certificates to provide for review.

Allergan stated that, given the above rationale, the matters presented in the complaint were not within the scope of the Code.

Allergan provided screenshots to describe the number of steps it would take a member of the public to access Botox information after leaving the Juvéderm website:

From www.juvederm.co.uk clicking on the link took users to:

Click 1 – www.allergan.com – The target audience was highlighted as Global/US. No specific Botox information contained on this page.

Click 2 – www.allerganaesthetics.com – this could be accessed by clicking on the picture with 'Allergan Aesthetics is Now an AbbVie Company'. The homepage of this website contained statutory non promotional Botox product information and was labelled as a US website as was indicated on the screenshot provided.

Click 3 – www.allerganaesthetics.com/botox – accessed by clicking on 'Our Brands' and Botox Cosmetic' from Allergan Aesthetics.com as shown on screenshots provided.

Click 4 – www.botoxcosmetic.com – accessed by clicking a link on the page www.allerganaesthetics.com/botox. This page gave access to the Instagram/Facebook and YouTube channels referenced by the complainant, which, by being placed on a US website, were intended for US audiences only.

Allergan assured the PMCPA that there had never been any intention to direct users to non-UK-approved content, directly or indirectly, through any of its UK websites. Based on the above rationale that a user would only be able to access US websites/platforms which were not for UK audiences, through multiple website clicks, it was Allergan's position that, on the balance of probabilities, any UK user of its Juvéderm UK website would not have direct or indirect access to information related to Botox.

The target audiences of the websites listed on the complainant's email were as follows:

- www.allergan.com – global/US corporate site
- www.allerganaesthetics.com – US corporate site
- www.allerganaesthetics.com/Botox - US Residents
- www.botoxcosmetic.com – US Residents
- BotoxCosmetic Instagram account – US Residents
- BotoxCosmetic Facebook account – US Residents
- YouTube channel – US Residents.

Government Legislation

Allergan noted that the complainant referred to the Botulinum Toxin and Cosmetic Fillers (Children) Act 2021 (the Act). Allergan asked that these comments were disregarded in relation to this case as they not only fell outside the scope of the Code but, as Allergan had communicated to the PMCPA before, Allergan had been wholly supportive of the Act as the company saw it to be a positive step towards raising patient awareness and safety by tightening regulation surrounding the accessibility of aesthetic interventions to people under the age of 18.

In this context, in the interest of clarity and certainty, Allergan encouraged the PMCPA to confirm to the complainant (and to potential future complainants should they refer to this legislation) that matters related to the Act were outside the scope of the Code and the PMCPA's

jurisdiction. As quite rightly pointed out by the PMCPA in a letter of 30 March 2022, 'The PMCPA will only make rulings in relation to the requirements of the Code'.

To conclude, Allergan submitted that the material referenced in the complaint fell outside the scope of the Code and the requirements of Clauses 2, 8, 12.1, 12.6, 15, 16, 26.1 and 26.2 of the Code did not apply. Allergan took its responsibility for compliance with the Code very seriously and Allergan continuously endeavored to maintain these high standards in all its activities.

PANEL RULING

The Panel noted Allergan's submission that, in its view, the material referenced in the complaint fell outside the scope of the Code because Juvéderm was a medical device and promotion of medical devices to the public including on the Juvéderm UK website was not prohibited in the UK, and further, the requirements detailed in Clause 1.2 had not been satisfied as none of the Botox material presented in the complaint was placed on the internet within the UK nor with the authority or direction of the UK Allergan Aesthetics business, but rather it originated from, and was placed in, the US on US-owned websites, and nor did any of the Botox material on the global/US websites contain any specific reference to the availability or use of Botox in the UK.

The Panel noted, however, that Allergan acknowledged that material deemed to be outside the scope of the Code, as defined in Clause 1.2, could come within scope if it was directed to a UK audience (Clause 16.1).

The Panel noted Allergan's submission that Botox information could only be accessed after taking several steps directing the user to other non-UK websites that were clearly marked as such. The Panel noted Allergan's submission that the link on the Juvéderm UK website that directed users to a global/US website was not apparent; it was included in a company logo which unless a user scrolled over the logo, they would not be aware that it was a link to a global/US website. The Panel noted Allergan's submission that clicking on this link took readers to the www.allergan.com homepage which highlighted the target audience as Global/US and contained no specific Botox information. In this regard, the Panel noted that the website stated GLOBAL/US in the top left-hand corner in small font beside what looked like an image of the world. The Panel noted Allergan's submission that by clicking the picture stating 'Allergan Aesthetics is Now an Abbvie Company' on www.allergan.com, www.allerganaesthetics.com could be accessed, the homepage of which contained statutory non promotional Botox product information and was labelled as a US website. In this regard, the Panel noted that the website stated US in the top right-hand corner in small font beside what looked like an image of the world. The homepage contained information regarding Botox including its indication. The Panel further noted Allergan's submission that www.allerganaesthetics.com/botox could be accessed from allerganaesthetics.com by clicking on 'Our Brands' and selecting 'Botox Cosmetic' from the drop-down list. Further, botoxcosmetic.com, which gave access to the Instagram/Facebook and YouTube channels referenced by the complainant could be accessed from a direct link on www.allerganaesthetics.com/botox and by being placed on a US website, were intended for US audiences only. The Panel noted that it stated 'For US Residents' in small font at the top of botoxcosmetic.com.

Whether a matter fell within the scope of the Code depended on the facts of each individual case. The Panel noted all of its comments above, noting that the original link to the US site was not apparent which was compounded by the fact that it was not immediately clear to the user by way of a pop-up box or prominent text or some other mechanism that he/she had entered a site

for a US audience. In such circumstances the Panel considered that it was reasonably foreseeable that some readers of the Juvéderm website might follow the various links and find the information referred to by the complainant. In the Panel's view given the speed at which a reader might click through links on a website it was important that the intended audience was made unambiguously clear. In the Panel's view, the matter, therefore, fell within the scope of the Code.

Whilst the Panel considered that it could have been clearer when clicking the link on the Juvéderm UK website that the reader was leaving a UK website, it noted that the intended audience was stated at the top of www.allergan.com and subsequent websites albeit in small font and if a reader followed the original link from the Juvéderm UK website, he/she was taken to the homepage of the global/US corporate website rather than a product page and a number of active clicks were required before Botox promotional information could be viewed.

The Panel did not consider, noting its comments above, that the circumstances were such that Allergan UK had used its medical device to promote Botox across digital and social media channels as alleged including to the public and health professionals in the UK. The Panel, therefore, based on the complainant's allegation, ruled no breach of Clauses 26.1, 26.2, 12.1, 12.3, 12.6, 12.9 and 8.1.

The Panel noted that the complainant had raised Clause 15, High standards, format and suitability and Clause 16, Material and distribution, in general, but had not provided reasons as to why he/she considered Allergan had breached any of the particular sub-clauses. The Panel considered that the complainant had not made out his/her allegation in this regard. It was not for the Panel to infer reasons to support a complainant's allegations. The Panel, therefore, ruled no breach of Clauses 15 and 16.

The Panel noted its comments and rulings above and consequently ruled no breach of Clause 2.

Complaint received **20 March 2022**

Case completed **12 April 2023**