CASE AUTH/3882/2/24

COMPLAINANT v EVOLUS

Allegations about Evolus website

CASE SUMMARY

This case was in relation to numerous allegations made by an unverified health professional about Evolus' company website.

Since this complaint was received and during the consideration of this case, Evolus gave notice that it will no longer accept the jurisdiction of the PMCPA. Following notification of the Panel's rulings, Evolus stated that it did not wish to appeal the Panel's rulings and did not consider it appropriate to provide an undertaking given its withdrawal from jurisdiction. Should Evolus choose to re-join the PMCPA's jurisdiction, it would be required to provide an undertaking and assurance. The complainant, the Medicines and Healthcare products Regulatory Agency (MHRA) and the Code of Practice Appeal Board were informed of the position.

The outcome under the 2021 Code was:

Breach of Clause 4.6	**Failing to include on the home page of their website information as to where details of their clinical trials can be found**
Breach of Clause 5.1 (x4)	**Failing to maintain high standards**
Breach of Clause 8.1	**Failing to meet the requirements for certifying material**
Breach of Clause 12.3	**Failing to include the non-proprietary name of the medicine immediately adjacent to the most prominent display of the brand name**
Breach of Clause 12.4	**Failing to include the relevant prescribing information within the digital material or via a direct, single click link**
Breach of Clause 12.6	**Failing to include a clear, prominent statement as to where the relevant prescribing information could be found**
Breach of Clause 12.10	**Failing to include a black triangle adjacent to the first mention of the product in digital material**

No Breach of Clause 2 (x2)	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1 (x4)	**Requirement to maintain high standards at all times**
No Breach of Clause 6.1 (x3)	**Requirement that claims/information/comparisons must not be misleading**

No Breach of Clause 6.2	**Requirement that claims/information/comparisons must be capable of substantiation**
No Breach of Clause 11.2 (x4)	**Requirement that a medicine must be promoted in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its summary of product characteristics**
No Breach of Clause 12.4	**Requirement to include prescribing information within the digital material or via a clear and prominent direct, single click link**
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 26.4	**Requirement to include a statement on reporting side effects in any material relating to a medicine which is intended for patients taking that medicine**

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

FULL CASE REPORT

A complaint was received from a contactable complainant who described themselves as a healthcare professional by education and profession about Evolus Ltd.

COMPLAINT

"Dear PMCPA,
I would like to make a formal complaint about the evolus website [URL provided].

Now, from what I can see this company only has one product – a botulinum toxin POM. I appreciate it would be therefore trickier having corporate claims as they can only ever be tied to the one product, but that is no excuse on the lack of thought gone on behind this website.

The product is licenced for temporarily improving moderate to severe frown lines when there is an important psychological impact. It is not licenced for 'evolving beauty' or 'beauty' as a whole which is what the messaging implies. It worries me that the company thinks they can push their product for beauty. This is a neurotoxin! which needs to be administered with care and comes with a range of AEs so should in no way be brandished as a beauty product. The serious nature of the POM is disregarded completely and is not what the medicine is licenced for.

In addition, the pages which talk about Nuceiva also include straplines of 'evolve with us'. Now evolving implies a change over time with benefit. Evolution is how the fittest beings in nature survive! From what I can see – there is zero data to suggest that this product is superior to any other on the market. It is just better than placebo. So they haven't really 'evolved' anything. Just added another product on the market. This is misleading.

[Screenshots provided showing how the statements “We’re evolving the future of beauty” and “Evolve with us” appear on the website]

Although sometimes this 'evolving' claim is shown on the public facing corporate section, it's also interwoven throughout the HCP section. Screenshot below shows how the drug is most definitely linked to the evolving claim in the HCP section;

[Screenshot provided showing how the statement “Evolve with us” appears on the Nuceiva webpage]

I was surprised that they didn't try to separate out the public corporate section from the HCP POM section in look and feel - it's hard to notice the difference when you are going from one to the other which again gives the impression that the corporate claims link directly to the drug claims.

Another worrying feature is a video displaying terms such as 'fearless'. Yes I understand this is on the opening screen but again, this company is only linked to one product. The two sections of the website; public and HCP section look the same in colour scheme and feel. So to even hint at ‘we are without fear’ linked to a POM is worrying. The impression is that there is nothing to worry about here. Which is shocking since they obviously do not even know the full extent of the adverse events which is highlighted with the inclusion of the black triangle.

[Screenshot provided showing how the word “Fearless” appears in a video on the website]

The adverse event reporting information looks like any other footnote at the end of the page. Although the tiny banner at the top says AE info below- it still doesn’t catch the eye and looks like footnotes that no one ever reads. It most definitely is NOT prominent as it should be. I would have expected a boxed and BOLD statement, black text on white background - which would not go unnoticed! ESPECIALLY since this is a black triangle drug.

[Screenshots provided showing how the Adverse Event/Reporting Side Effects statements appear on the website]

There is **nowhere** on the company website at all which flags a reader to the clinical trials past and present, which of course is **an industry requirement**. This basic disregard for industry wide mandatory information is worrying and not upholding the high standards I would expect from all UK pharma companies.

[Screenshot provided of footer of website]

They have included these really confusing hyperlinks to the FDA site. Yes, they have a pop up saying the reader is leaving the evolus site but I’m still confused as to what purpose it serves – as drugs licenced in the US have no relevance to the promotional section of a UK website. When I follow the embedded link to the US label for their drug. Firstly, it has a different generic name and secondly even things like the contraindications are different. Evidently this can be confusing and mislead the reader.

I understand they may have wanted to say - look this was licenced in US on XX date but there does not need to be a working hyperlink to the FDA site.

This is what I see on the FDA site; as you can see there are substantial differences in the two labels including brand name and generic name, licenced indication and contraindications;

[Screenshot provided of Jeuveau US prescribing information]

The screen shot below shows how their corporate claims leak into to POM pages - blurring the difference between the two sections (corporate and HCP) AND also the FDA hyperlink;

[Screenshot provided of references section of the webpage]

The healthcare professional promotional section flags that they have courses to help drive the profitability of your business. A POM should never be pushed or encourages to patients with profits in mind! This really makes pharma appear to be that giant with only money on its mind! I am concerned at how their promotional site so brazenly links to profits and business like this. Patient safety in terms of a POM should always be paramount and rational use of medicines is very important - POMs should never be linked to financial gain. The impression here is that they will give ideas on how to grow a business. This toxin should only be used when frown lines have an important psychological impact to **help <u>patients</u>** – **not for profit and to grow a beauty business.**

[Screenshot provided of business course webpage]

[Screenshot provided of 'Reporting of Side Effects' statement on website]

The prescribing information tab was difficult to locate as it sat on the side of the website vertically with no indication of its whereabouts anywhere else on the page.

[Screenshot provided showing location of lprescribing information tab]

I was surprised the prescribing information is not in columns as I'm so used to seeing. The longer lines do interfere with legibility as it's harder to read such long lines on your laptop or phone. In addition, it appears to be just the GB prescribing information here but the website is clearly aimed at a wider UK audience (as shown in the ribbon at the top of the website) – so I would've expected a Northern Ireland Prescribing information too as this is currently missing – and I would've expected the two to be clearly labelled.

[Screenshot provided of Nuceiva prescribing information]

There is a video included in the website which shows injection technique. Except the patient is evidently not a patient that fits the licence as even on full frown, she has as much frown lines as a two year old;

[Screenshot of a video frame of a woman frowning]

The lines across the nose bridge are not glabellar lines. Glabellar lines sit vertically upwards like these pictures (these pictures below are not on their website - but would be a better representation of a patient that fits the licence);

[Images of individuals frowning]

The woman in the evolus video has NO glabellar lines let alone 'moderate to severe' as is required by the licence.

The images used throughout the website do not appreciate the special nature of a POM or the audience which is clearly stated in the banner that runs across the top of the page. It gives the impression of a fashion shoot of sporty young adults or a hiphop music video - in which all the people look highly unlikely to fit the licenced patient profile of ‘moderate to severe frown lines’. In the vast majority of people the world over, frown lines are known to appear and get deeper with age and more years of sun exposure. The young group of people here – give the impression of again ‘beauty’ and how to fit into this pushed idea of beauty. This is NOT what the drug is licenced for. The impression given is that the drug is OK to use- even on young adults- to beautify them which is a shocking disregard to the nature of this neurotoxin! It should not be trivialised! A black triangle POM which carries AEs like an immune response, distant spread of a neurotoxin and **DEVELOPMENT or exacerbation** of a neuromuscular disorder is not something to brush under the carpet and it is not what the drug is licenced for.

[Two screenshots of imagery taken from the website each depicting a group of young adults]

The 'glabellar line free' woman receiving injections in the video mentioned earlier reinforces this impression of 'just use it on young people to beautify'. The licenced indication does not come through on any of the images or videos throughout this website.

In conclusion – I was shocked at the total disregard of industry standards here and feel this whole website brings the industry down – as it implies the use of this black triangle POM for beauty purposes and to grow aesthetic businesses. The special nature of a POM or the audience is not appreciated here and we appear to be heading in a direction which trivialises neurotoxins used in aesthetics and treat them in effect different from POMS in other areas.

I would appreciate you looking into this matter. I am a healthcare professional by education and profession but would like my name anonymised.”

Further information from the complainant

“I note that evolus do not take the complaint seriously and have done nothing to rectify the issues even since you have been in contact. I also note that on mobile device their black triangle looks more like an arrow pointing to the next line than a black triangle- as it sits

under their brand name in such a fashion that it doesn't look apparent that it's even a black triangle. In doing the lines this way, the generic name doesn't sit adjacent to the brand name either. So they fall on this requirement too. I have attached a picture for your reference. I am sure when certifying they have not looked at this version. On a patient safety front this does not bode well.

Please raise this further issue with them."

Attachment provided by complainant:

[Screenshot of Nuceiva product page as it appears on a mobile]

When writing to Evolus, the PMCPA asked it to consider the requirements of Clauses 2, 4.6, 5.1, 6.1, 6.2, 11.2, 12.4, 12.6 and 26.4 of the 2021 Code. In relation to further information submitted by the complainant, Evolus was asked to consider the requirements of Clauses 2, 5.1, 8.1, 12.3 and 12.10 of the 2021 Code.

EVOLUS' RESPONSE

The response from Evolus is reproduced below:

"Thank you for the letter of the 28th February in which an anonymous complainant sets out their concerns in relation to the Evolus International corporate and Nuceiva ®▼ (botulinum toxin type A) website.

Upon incorporation in the UK in 2022, Evolus International undertook to submit to the jurisdiction of the PMCPA and takes Compliance with the Code and all applicable regulations extremely seriously.

Accordingly we have undertaken a thorough review of the website to respond in full to this complaint.

The complainant has raised concerns about several aspects of the Evolus International website (URL provided) and we will address these in turn.

The home page is publicly accessible but has a clear statement at the top that it is intended for HCPs and contains a clear link to further content for those who confirm that they are a Healthcare professional by selecting the 'I am a Healthcare Professional' option. Those who are not, can click the 'I am not a healthcare professional' option. Each respective audience is then taken to content that is appropriate for them.

The non-HCP section is non-product promotional and limited in content.

The company has focused on promoting this site to HCPs practicing in Medical Aesthetics. Clicking the HCP option presents a page containing some Nuceiva product promotional information. However for those who are interested in more information, there is the option on this page to select 'Sign up to learn more'. This directs them to a page where they are invited to register, with their professional details, for a password protected account that will give them access to a full range of information and services.

For all the job bags related to the parts of the website referred to by the complainant or by Evolus, please see enclosures (copies provided).

In order to address the complainants' concerns, it is necessary to first provide some background information on the company.

Evolus is a California based company originally incorporated in 2012 that launched an International division ('Evolus International') in 2022 to build on its success and rapid growth in the US.

This success is partly founded on a strong and distinct corporate identity and reputation, well differentiated in the market-place.

The central vision of that identity, from the very outset, is that of a research driven, forward-looking company whose ambition is to bring fresh investment and ideas to a mature, well established market. It has an active R&D function based in the US with an evolving pipeline including medical devices. In GB (although not in Northern Ireland), it markets a prescription medicine, Nuceiva. It also offers business training courses for which it charges attendees.

The companies' founding vision in California was articulated to the world as an invitation to 'Evolve with us' from which the very name of the company presented itself – '**Evol**ve with **us**' (emphases added by Evolus).

When launching an International Division headquartered in the UK in 2022, an overarching commercial priority was to build on the US success by retaining that corporate identity using the same corporate promotional statements.

The central statement is 'Evolve With Us' which is presented in a visual theme of 'wallpaper' to represent a background to a common work-space with the audience. The statement is clearly an invitation to engage and collaborate with the company and the 'Us' is patently a reference to the company and its personnel, not any products.

From the outset, the company has invested in education (including courses for which it charges a fee), in building relationships with clinics, and in articulating a new and distinct vision for all concerned in its therapy area. Crucially, 'Evolve With Us' is an invitation to engage with the company and share in its values which are further articulated in the statements referred to by the complainant. These are clearly personal and company values, not product claims, and would be understood as such by any reasonable audience. We believe these values could have a positive impact on those who take them up and which is the intended benefit implied in the 'Evolve' with us.

It is customary, common place and accepted commercial practice for a company to publicly set out its 'vision' and 'values'.

The statements that the complainant refers to are examples of those values for Evolus, all of which are drawn together in an invitation to 'Evolve with Us' and share those values.

Indeed, the Home page of the website does not contain reference to any product and instead, at the very start sets out a striking and memorable description of the company and its values/vision/aspirations in a rolling visual format with the following narrative :

'*We are Evolus, we are performance beauty. artistry meets science, we're a movement against ordinary, we're open, alive to possibility, we're from California, we embrace the world, we are driven by change and excited by it, we are bold, we are fearless, challenge convention and never stand still. Community, collective, together evolving the future of beauty, Evolus, evolve with us*'.

Furthermore, later in the page, '*we inspire; we are millennial; we are partners; we are agents of change; We are here for you*'

By its very phrasing; its use of '**We**' and '**Us**', this narrative can only be reasonably interpreted as a statement of corporate vision, aspiration, capability and values and as an invitation to share in them, to collaborate and engage with the company (emphases added by Evolus). It cannot be reasonably interpreted as a clinical product claim.

Having set out this corporate narrative at the outset in this way, there is no potential to confuse it for product claims later in Nuceiva pages. In fact the only part of it that recurs is 'Evolve with Us' whose meaning has been so clearly articulated in the Home page as a corporate vision.

Furthermore, the company is intentionally positioning itself to serve the evolving needs of a new generation of patients. These 'millennial patients' (born between 1982 -2000) have grown up in a world where the use of cosmetic interventions such as toxin or filler injections have become established. For context, the millennial patients that are now coming into the clinics have different questions, expectations and demands than the previous generation of patients (Gen X and Baby Boomers). They are much more likely to consider injectable cosmetic procedures and it is this shift (evolution) that also forms a core pillar of the Evolus corporate messaging to 'evolve with us'.

Given the above background, we can address the complainant's concerns:

- Concerns that the '..corporate claims link directly to the drug claims..'; the '..company is only linked to one product.'; that 'Evolve with us' is a product claim; that the company '..didn't try to separate out the public…from the HCP…section in look and feel'; '..displaying terms such as 'fearless'. Clauses 6.1 or 6.2

As explained, the central statement 'Evolve with Us' is an invitation to share in the company values, aspirations and approach to work. All of these values are prefaced by **'We** are..' and, if adopted, we believe they would lead to a positive change which is the intended meaning in the invitation to '**Evolve**…' (emphases added by Evolus).

Also as explained, the market place is 'evolving' with increasing presentation from a new demographic of patient – the 'Millennials', a fact that would be well recognised by HCPs in this field and with whom this would resonate.

Given their positioning at the outset (away from the product page, other than ‘Evolve With Us’), their phrasing (use of ‘We’ and ‘Us’), they can only be reasonably interpreted as corporate vision/values/claims whether the company has one product or many. If a company had set out corporate claims which are phrased as product claims, it is irrelevant whether it has one or many products. The corporate claims would then apply to any or all of its products. In the case of Evolus, unlike many companies, the corporate claims are very distinctly set out as ‘We’ and ‘Us’. Grammatically and semantically, there is no potential for them to be confused with a product claim, even if they appear on product pages and even if the background corporate look and feel of the website is similar throughout all pages.

The complainant asserts that there is video ‘….displaying terms such as 'fearless'…’ but omits to mention that the full statement in the video is ‘We are fearless’ which again is clearly a statement that would be interpreted by any audience as a corporate value. It is clearly and explicitly written as a claim about a corporate capability. Hence the ‘We’. This could not possibly be stated more clearly. There is no semantic link to the product, direct or indirect.

In any case, it is only the statement ‘Evolve with Us’, (the central company vision and source of its very name) that appears as a thread throughout the site and whose meaning is so distinctly explained and apparent in the narrative at the beginning of the home page.

In summary therefore, the corporate promotional narrative and its constituent parts could not reasonably be interpreted as product claims and there is no breach of Clauses 6.1 or 6.2

- Concerns that ‘..should in no way be brandished as a beauty product. The serious nature of the POM is disregarded completely..’ Clause 5.2

Evolus operates in a (private sector only) market-place and therapy area that is known as ‘Medical Aesthetics’, a term that is well established and accepted in the medical/scientific literature of the field and by associated learned societies in the UK. ‘Aesthetics’ is of-course a synonym for ‘beauty’, a colloquial term more likely to be employed by patients presenting in this field and with which health care practitioners in this field are familiar. None of them would consider ‘beauty’ a trivial, non-medical term in the context of this therapy area. They would recognize the clinical (and non-clinical) significance to their patients of this term.

Over the last few years, there has been a trend to categorise medical aesthetics procedures (including toxin injections) as non-surgical cosmetic procedures as evidenced by recent consultations by The Department of Health and Social Care: [URL provided].

The UK government’s own report notes ‘a growing prevalence and normalisation of non-surgical cosmetic procedures.’ This forms part of the ‘shift’ or evolution that Evolus, as a company, is based upon.

Regardless, Evolus fully appreciates the serious nature of prescription medicines and so the pages containing Nuceiva promotional content do not in any case have any

reference to ‘evolving beauty’. The pages are presented in a substantive manner with significant informational content including injection technique and prominent link to Prescribing Information and adverse event reporting statement, all of which in no way disregards the ‘..serious nature of the POM…’ Therefore there is no breach of Clause 5.2.

- Concern that AE statement ….most definitely is NOT prominent as it should be. Clauses 12.9 and 26.4

The Code requires a ‘…prominent statement…’ relating to adverse event (AE) reporting in all promotional material.

The AE statement appears near the bottom in its own space separate to the Prescribing Information and is the same font size as the text of the detailed product claims on the page. There is a clear reference to its location at the top, and it is separated from the footnotes related to company information at the very bottom. The AE statement also appears on the Prescribing Information page. It appears prominently even in the screengrab provided by the complainant.

On the home page and other sections which may be viewed by the general public, the wording of the AE statement is that which is required in Clause 26.4. For HCP sections, the wording is according to Clause 12.9.

Given its prominence, size, clarity and reference to its location, we are puzzled by the complainants’ emphatic belief that it is not prominent. A brief inspection of the website pages will show that it appears prominently and in summary, there is no breach of Clauses 12.9 or 26.4 and therefore no breach of Clause 5.1

- Concern that ‘..The prescribing information tab was difficult to locate as it sat on the side of the website vertically..’; ‘..This basic disregard for industry wide mandatory information’. Clauses 12.4 and 12.6

The complainant implies that prescribing information is ‘difficult to locate’ because the tab for it is ‘sat on the side of the website’. However, the only alternative to the link being to any one side, is for it to always appear in the very centre of every screen. This is not a requirement of the Code. Instead, for digital material, Clause 12.4 requires ‘a clear, and prominent, direct, single click link’ which there manifestly is on the Nuceiva pages and which a cursory inspection would reveal. In fact, the words ‘Prescribing Information’ in the link/tab are of a prominent font size and they appear in white on a black-boxed background. Moreover, this link/tab stays in the **same** position when the Nuceiva pages are scrolled up and down and is the only constant, prominent presence on the screen when scrolling (emphasis added by Evolus). In and of itself, this constantly visible link acts as a prominent statement as to the location of the Prescribing Information as required by Clause 12.6. Its whereabouts are immediately apparent, even with a casual glance. Below, we have included a screengrab of a Nuceiva page showing the tab/link, and in which its prominence, visual reference to its location, legibility and accessibility are immediately appreciated.

[Screenshot highlighting location of link to prescribing information]

Therefore, there is no breach of Clauses 12.4 or 12.6

- '…surprised the prescribing information is not in columns as I'm so used to seeing..' Clauses 12.4 and 12.6

There is no specific requirement in the Code for the Prescribing Information to be displayed in columns as long as it is displayed in a clear and legible manner which assists legibility (Clause 12.1). This requirement has been comfortably met in this case which, again, a cursory examination of the material will confirm. The font used is of a standard type, black on a white background and of a size that is more than adequate for an A4 page that contains nothing but the Prescribing Information. There are fewer than a hundred characters per line, the headings are emboldened and there is adequate separation between lines.

In summary, anyone clicking on the prominent Prescribing Information link will see a page filled with nothing but the Prescribing Information presented in a clear and legible manner. As described previously, there is a clear and prominent link to this Prescribing Information throughout all Nuceiva promotional pages.

Therefore, there is no breach of Clauses 12.4 or 12.6

- Concern that 'I would've expected a Northern Ireland Prescribing information too…' Clauses 12.4 and 12.6

Nuceiva obtained marketing authorization (MA) in the EU through a centralized procedure (CP) and following grandfathering of the CP, Evolus has obtained a MA for UK to cover GB territories only, Northern Ireland (NI) excluded.

The EU MA is applicable in Northern Ireland (NI) post Brexit and prior to the 'Windsor Framework' coming into effect.

However, Evolus have taken a commercial decision not to market, supply or promote Nuceiva in NI as yet. We do not target or direct promotion specifically at NI audiences and so did not create Prescribing Information to cover NI only.

Although the website was intended only for GB audiences, due to an unintentional oversight, the the statement at the very top declares that 'This website is for HealthCare Professional audiences in the UK' (which includes NI). Therefore, Prescribing Information specific to, or including, NI should have been provided.

Accordingly, we accept a breach of 12.4. We also accept a breach of Clause 12.6 in so far as there is no statement on where prescribing information for Northern Ireland may be found.

We are in the process of updating the website to state 'This website is for HealthCare Professional audiences in GB'

- Concern that '…have included these really confusing hyperlinks to the FDA site' Clause 6.1

The complainant states that there are '…really confusing hyperlinks to the FDA site' and that they are '…confused as to what purpose it serves'.

However, they omit to mention the immediately obvious, which is that this hyperlink is actually one amongst 4 footnote references to marketing authorisations in other countries on the Nuceiva promotional page. These are used to substantiate the following prominent claim:

'**Licensed in 34 countries**[2-5]' (Please note the references 2-5 are those given in the Evolus website where this claim appears).

The references substantiate the claim for 31 EU countries, and 3 others – US, Australia and Canada.

The references contain only what is required for anyone to establish substantiation for the claim themselves, should they wish to do so.

The link itself does **not** lead to the US label as submitted in the screenshot by the complainant (emphasis added by Evolus). Instead, it leads to an FDA search page where those who wish to check substantiation for the claim can do so by checking that the US counts towards the total of 34 countries in the claim.

HCPs are well accustomed to being presented with references to substantiate claims and will certainly not be confused by their presence nor purpose.
Therefore there is no breach of Clause 6.1

- Concern that there is no link to trial results. Clause 4.6 and 5.1

Clause 4.6 of the Code requires that 'Companies must include on the home page of their website information as to where details of their clinical trials can be found'. Due to an unintentional oversight, this information does not appear on the home page, therefore we accept a breach of Clause 4.6. The website will be updated to include the required information.

However, please note that all of the 8 completed Evolus sponsored studies (phase II onwards) that support the marketing authorization and product claims for Nuceiva are published (7 on free, open access journals, and 1 at an international scientific congress pending journal submission). There is currently only one ongoing Evolus sponsored study (details of which are here on URL provided). Therefore, although the home page information required by Clause 4.6 was unintentionally omitted, the more general requirement from the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature to achieve external publication of results have been honoured, and this is a core intent of Clause 4.6. Therefore there is no breach of Clause 5.1.

- Concerns that '..The licenced indication does not come through on any of the images or videos throughout this website'; 'patient is evidently not a patient that fits the licence as even on full frown..'; 'the people look highly unlikely to fit the licenced patient profile of 'moderate to severe frown lines'; '…NOT what the drug is licenced for..' Clauses 6.1, 6.2, 11.2 and 5.2.

The licensed indication for Nuceiva is ‘for the temporary improvement in the appearance of **moderate to severe** vertical lines between the eyebrows seen at **maximum frown** (glabellar lines), when the severity of the above facial lines has an important psychological impact in **adults below 65 years of age**’ (emphases added by Evolus).

The people in the background imagery that the complainant refers to are not at maximum frown.

The indication is stated clearly and prominently on pages that contain Nuceiva promotional statements, including the page in which the video referred to by the complainant is located.

This video appears only in the sections of the website that are visible to those who have clicked ‘I am a Healthcare Professional’ and/or signed in with an account.

Please note that the video was created to demonstrate injection technique to these healthcare professionals and not to illustrate the licensed indication. However, it does include a statement on the licensed indication at the outset and, it is of-course important that the visual of the patient is consistent with, and not inconsistent with, the licensed indication. In clinical practice, the key assessment of the severity of glabellar lines (and the level of their ‘psychological impact) are first assessed by the health care professional.

For the patient in the screenshot provided by the complainant and in the injection video, the ‘Glabellar line scale’ (a commonly used measure of severity) would be calculated as 2 by HCPs with relevant training and experience, indicating at least a moderate severity, consistent with the indication. It is simply not true that the patient has ‘no’ glabellar lines at maximum frown. They can be seen in this screengrab from the video:

[Screenshot from video of a woman frowning provided]

The Glabellar Line Scale (GLS) is a photonumeric grading system designed to evaluate the severity of glabellar lines, which are the vertical lines that appear between the eyebrows as a result of frowning or scowling. *The reliable use of it requires training and clinical experience.*

The GLS serves as a standardized method for both clinicians and patients to assess the severity of glabellar lines. It is used before and after treatments to determine the efficacy of interventions such as Botulinum toxin injections.

The grading criteria for the GLS typically involve both the appearance of glabellar lines at rest and during dynamic movement (maximum frown). The GLS uses a 0 to 3 point system, where:

0: No lines

1: Mild lines

2: Moderate lines

3: Severe lines

The images below are for illustrative purposes, to demonstrate technique for calculating GLS and are not taken from the website.

The scale is used in conjunction with clinical judgment to decide on the appropriate treatment strategy.

[Images showing Glabellar Line Scale]

Glabellar Line Scale—at rest and at maximum frown. The instruction given to subjects to elicit a maximum frown was to 'frown as much as possible, as if concentrating hard.'

Section 4.2 of SPC (Posology and method of administration) states that 'The recommended injection….' includes '…1 injection in the procerus muscle. The surface anatomy demonstrated in the video is intended to illustrate this and other surface anatomy relevant for effective injection technique.

We strongly refute the complainants' assertion that the horizontal wrinkle shown in their screenshot is not part of the glabellar complex. Such a wrinkle originates from the contraction of the procerus muscle , which inserts into the nasal bone at the level of the medial canthus line, well below the wrinkle shown. The procerus muscle, when contracted, can pull the skin cranially, forming the horizontal wrinkles shown in the image on the website. The complainant's assertion is simply incorrect with regard to the functional and dynamic anatomy of the glabellar complex.

The complainant has not provided their own objective assessment of GLS nor stated their expertise/ experience to do so.

Please note that the '…adults…' in the Nuceiva indication statement denotes those who are 18 and above, however likely or not it is that their particular age group is affected by glabellar lines.

Market research conducted by McKinsey and Company indicates market could grow by 12 to 14 percent a year over the next five years including a significantly greater contribution from the millennial age group compared to older generations.

This demographic of patients is represented in the visuals on the Evolus website. Evolus have chosen to represent this population of patients in a positive, life-affirming, aspirational manner and which typify the patient archetypes that we believe reflect the outlook of that generation and Evolus.

In summary, the relevant imagery on the product section of the website is not inconsistent with the licensed indication and is in line with a demographic that is presenting in increasing numbers. Furthermore, the Nuceiva promotional content does not disregard the special nature of medicines as previously explained.

Therefore there is no breach of Clauses 6.1, 6.2, 11.2 or Clause 5.2

- Concern that '..promotional section flags that they have courses to help drive the profitability of your business.'; '..POMs should never be linked to financial gain' Clause 5.1

The business course(s) that the complainant refers to, do not have any content related to Nuceiva.

In fact they are **paid-for** courses relating to business practice rather than free medical-educational meetings and are only accessible to HCPs registered with an account on the website (emphasis added by Evolus). Many of these HCPs are likely to be operating in small private clinics (often sole-traders) who may have little expertise in setting up and running a successful commercial enterprise. The courses are designed to help them consider general business needs of their clinics without which they are more likely to fail and forego the opportunity to help their patients. Our offerings to address the unmet needs of these HCPs for this kind of training is another illustration of the intended meaning of the corporate statement 'Evolve With us'.

The cost of the courses is not trivial (even for HCPs) and their paid-for nature is stated very clearly as illustrated below:

[Screenshot of advert for business course]

The intended audience is concerned with both clinical and commercial matters since they have no recourse to public-sector health care funds and they rely entirely on payment by their patients. This audience will therefore immediately recognize the distinction between courses designed for these different learning needs. Evolus has been careful to maintain this distinction in the description of the courses on the website as well as in the nature of the content itself. These courses do not contain any content on Nuceiva, whether promotional or non-promotional and therefore it is only the very in-depth business training that these contain which is intended to 'drive profitability' and would be perceived as such by the audience. The content could be applicable to any other industry. Therefore, there is no breach of Clause 5.1

In summary, Evolus takes compliance with the Code and all applicable regulations extremely seriously and from its incorporation in the UK in 2022 has invested significantly in people and processes to help in its compliance.

This is the first complaint we have received from the PMCPA and we have considered it in the very fullest in order to submit as thorough a response as possible.

Accordingly, we have addressed in detail the complainants' concerns and set out the reasons for why we believe these to be without merit, wherever this was the case.

Conversely, we accepted breaches of the Code as set out above in relation to Northern Ireland Prescribing Information and the lack of information on clinical trial results on the home page.

In the case of Northern Ireland, the accepted breach is mitigated by the fact that we have never supplied Nuceiva there and nor have we directly and specifically targeted

that market for promotion. In the case of clinical trial results, the mitigation follows from the fact that all completed Evolus sponsored Nuceiva studies (phase II onwards) have been published (7 in free, open access journal sites, 1 at an international congress, pending journal submission) in keeping with the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature to achieve external publication and which is a core intent of Clause 4.6

With these mitigations, we do not believe that there has been a breach of Clause 5.1 (high standards), and therefore cumulatively no breach of Clause 2."

Further response from Evolus

Further information was received from Evolus in response to the additional information provided by the complainant. The response from Evolus is reproduced below:

"Please find below our response to each in turn in the following 3 main bullet points:

- That Evolus "...have done nothing to rectify the issues even since you have been in contact"

We can confirm that, as set out in our letter of 19th March 2024, we responded in detail to each of the complainant's concerns. Specifically in relation to two matters, we accepted a breach and subsequently amended the website accordingly on June 26th. Please see updated home page here – URL provided

These amendments were:

- To update the statement in the header to read "For GB HCPs only" since we had not provided prescribing information for Northern Ireland;
- To include a link to clinical trial results on the home page

- That the "...black triangle looks more like an arrow pointing to the next line than a black triangle..." and "...the generic name doesn't sit adjacent to the brand name..."

As you will see from the complainant's screenshot, the triangle is black, inverted, equilateral, is adjacent to the product name and of a size that cannot be overlooked. This is in keeping with the requirements of Clause 12.10

Also apparent in the screenshot is the fact that the brand name and generic name are the most prominent pieces of information that appear and are sufficiently juxtaposed that there could be no confusion with regard to the product name(s) for even a casual reader. This is in keeping with the requirements of Clause 12.3

- That "..when certifying they have not looked at this version.."

The website (and specific page at issue) was intended for a healthcare professional audience in the UK who were either themselves searching for this content or had been directed to it by links from promotional material or by sales representatives

As well as being constructed for viewing on traditional desktop devices, the site was also made responsive for viewing on mobile and tablet devices. This fact was captured in the metadata for the 'job bag' in which the site was approved

When viewed on a mobile device (iPhone or Android), the black triangle and generic name positioning are as they appear in the certified desktop version. It requires the user to undertake an extreme zoom for the position of the black triangle to change, and is not the intended presentation of the content.

Please find enclosed a copy of the certificate approving the website in question and qualifications of the signatory. This meets the requirement for Certification and Clause 8.1

As stated, the item complies with the specific requirements for black triangle and generic name and so recognizes the special nature of medicines and respects the professional standing of the intended audience. Therefore, the requirements of Clause 5.2 have been met.

Given our response above and our actions to address the initial concerns raised by the complainant, we do not believe there has been a breach of Clause 5.1 nor of Clause 2"

PANEL RULING

This case related to numerous allegations made by an unverified health professional about Evolus' company website.

The homepage started with an embedded video on the company, beneath which was the prominent statement "*We're evolving the future of BEAUTY*" and three buttons: *"I'm a healthcare professional"*, "*I'm not a healthcare professional*" and "*Contact Us*". Below this was a branding pattern with the phrase "*EVOLVE WITH US*" repeated, and a section headed "*We are performance beauty*" with the statements:

- "*we inspire*
- *we are millennial*
- *we are partners*
- *we are agents of change*
- *We are here for you*"

At the top of the page in very small font, was the statement "*This website is for HealthCare Professional audiences in the U.K. Adverse event information can be found at the bottom of this page"*. The adverse event information comprised the following statement "*Reporting of Side Effects. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at yellowcard.mhra.gov.uk/. By reporting side effects, you can help provide more information on the safety of this medicine"*. Given the intended target audience of the website, the Panel considered that the website fell within the scope of the Code.

The Panel noted Evolus' submission that the website was intended for health professionals in medical aesthetics. While the homepage was publicly accessible, Evolus submitted that it was intended for health professionals and provided separate routes for health professionals and non-health professionals. The non-health professional section was described as limited in

content and non-promotional, whereas the health professional section contained promotional information on Nuceiva, which was Evolus' only product. Nuceiva was indicated for the temporary improvement in the appearance of moderate to severe vertical lines between the eyebrows seen at maximum frown (glabellar lines), when the severity of the above facial lines has an important psychological impact in adults below 65 years of age.

While Evolus submitted that the homepage was intended for health professionals, the Panel noted the homepage was publicly accessible by default and users would likely go to the webpage intended for members of the public via the homepage. The Panel therefore queried how the homepage could reasonably be considered to be for health professionals only. In this regard, the Panel noted Evolus' contradiction that it had included the side effect reporting statement in line with Clause 26.4, on the homepage, as it may have been viewed by the general public.

The Panel considered that, given its public accessibility and the presence of separate, clearly signposted routes to a section for members of the public and to a promotional section for health professionals, the homepage was a corporate webpage directed at both health professionals and users classed as members of the public.

Distinction between public corporate and health professional sections

The Panel noted the complainant's allegation was that Evolus had not attempted to separate the public corporate section from the promotional section in terms of look and feel. The complainant submitted that it was difficult to distinguish between the two areas when navigating from one to the other, which, in their view, gave the impression that the corporate claims were directly linked to the product.

The Panel considered where websites included non-promotional followed by promotional sections for health professionals, it was important these were clearly separated, and users were aware that they were accessing promotional information. In this regard, the Panel noted that when accessing the health professional page(s), users were required to self-certify the following "*By selecting the healthcare professional option, you confirm you are a health professional and acknowledge that you will be exposed to promotional information relating to prescription only medicines*."

The Panel acknowledged that the visual style, branding, and thematic elements were consistent across both the homepage and the subsequent health professional promotional section. While the Panel considered there was little distinction between the non-promotional and promotional content and that it would have been helpful for the company to use distinct corporate and product branding to aid differentiation, it noted that access to the health professional section required self-certification, with a clear statement that users would be exposed to promotional information about a prescription-only medicine. The Panel considered that it was sufficiently clear to users when they were entering promotional content, and it did not consider that the promotional nature of that material had been disguised. The Panel therefore ruled **no breach of Clause 5.1** in this regard.

Claims

The next matter for the Panel to consider was whether the claims in question would be regarded as corporate claims, as submitted by Evolus, or whether they would be interpreted as being linked to the promotion of the company's product, as alleged by the complainant.

In the Panel's view, the fact that health professionals were required to self-certify to access promotional content did not necessarily mean that claims on any preceding pages, such as the homepage, were entirely separate or would not be interpreted as linked to a product, particularly in the context that Evolus only had a single product.

The claim "*We're evolving the future of BEAUTY*" appeared within a banner on the homepage, beneath a corporate manifesto video, which was stated in white text on a red background. The corporate manifesto video started with "*We are Evolus*" and then featured several 'We are…' statements, including "*We are performance beauty*", "*We are 'FEARLESS*" and "*Community, collective, together evolving the future of beauty, Evolus, evolve with us*." The complainant alleged that the messaging implied the product was licensed for 'evolving beauty' or 'beauty' which is not what Nuceiva was licensed for and completely disregarded the serious nature of the prescription-only medicine. The complainant also raised concerns with use of the term 'fearless'.

The Panel noted that the repeated use of 'We are…' in the claims at issue positioned the statements as referring to the company itself rather than to any product. In the Panel's view, the claims were more likely to be interpreted as aspirational or brand values associated with the company's identity within the aesthetics sector, rather than as promotional claims for Nuceiva. The claims did not reference any clinical outcomes, indications, or the product itself, directly or indirectly.

Accordingly, the Panel, on balance, did not consider that the claims promoted Nuceiva or implied that it was licensed for the improvement of "beauty" or that the messaging was inconsistent with the terms of its marketing authorisation. The Panel therefore ruled **no breach of Clause 11.2**.

The Panel noted its view that the references to 'beauty' on the homepage were not, in themselves, product claims for Nuceiva. Nonetheless, the Panel was concerned about the overall emphasis placed on the term 'beauty', on the corporate homepage of a pharmaceutical company, particularly as the homepage was publicly accessible. In this regard, the Panel considered that the significant focus on 'beauty' on the homepage, which was not suitably qualified by any reference to medical aesthetics, was likely to create confusion about the nature of the company's business. This impression was compounded by the lack of any clear or immediate indication on the homepage that Evolus was a pharmaceutical company; the only indications were the single reference to 'this medicine' in the statement regarding reporting of side effects at the foot of the page and the generic references to adverse event reporting in the header and footer.

The Panel considered, 'beauty' was a very broad term and was generally associated with cosmetic products. Medicines, in contrast to cosmetic products, are considered to be of a special nature, due to their rigorous regulatory obligations, and the contraindications, warnings and adverse events they carry. In the Panel's view, the repeated messaging and emphasis on 'beauty' on the Evolus homepage blurred the distinction between cosmetic and medicinal products. This did not reflect the special responsibilities borne by pharmaceutical companies when issuing information to the public, nor did it recognise the distinct nature of medicines and

medical conditions. The Panel considered Evolus had failed to maintain high standards in this regard and ruled a **breach of Clause 5.1.**

With regard to the claim "*We are fearless*", the Panel noted that the statement appeared within the corporate manifesto video and formed part of a broader series of 'We are…' affirmations, which, in the Panel's view, were likely to be interpreted as corporate positioning statements rather than product claims. The complainant was concerned that the claim gave the impression there was nothing to worry about with Evolus' product, despite its black triangle status and associated risks. The Panel did not consider use of the term 'we are fearless' would likely be interpreted by a viewer as claims for the product including that Evolus' product Nuceiva was without risk as alleged. The Panel ruled **no breach of Clause 6.1** in this regard.

The Panel noted one of the claims in question, "*EVOLVE WITH US*", appeared on a large, ripped paper effect banner with the words continuously repeated over five lines. Certain iterations had the words 'EVOLVE' and 'US' in red, whereas others had 'EVOLVE WITH US' all in black text. Based on the evidence provided to the Panel, this banner appeared on the bottom half of every page of the website including the homepage and the promotional product page. The complainant alleged that the claim was misleading as it implied a change over time with benefit but that there was zero data to suggest that this product was superior to any other on the market except placebo.

In the Panel's view the claim "*EVOLVE WITH US*" did not reference any clinical outcomes, indications, or the product itself, directly or indirectly and the Panel did not consider that the phrase would be interpreted by a reasonable reader as implying product superiority or that there was data supporting a clinical advantage over other available treatments on the market. The Panel therefore ruled **no breach of Clause 6.1 and Clause 6.2.**

<u>AE wording</u>

The Panel noted that the complainant had submitted two screenshots: one appeared to show the adverse event reporting information from the promotional Nuceiva page, and the other from the corporate homepage. The complainant alleged that the adverse event reporting statement resembled a typical footnote at the end of the page and was not as prominent as it should have been. The complainant stated, particularly given the black triangle status of the medicine, the statement should have appeared in a more visible format, such as bold black text on a white background within a boxed layout.

The Panel noted that across the website, a small banner at the top of the page stated, "*This website is for HealthCare Professional audiences in the U.K. Adverse event information can be found at the bottom of this page*".

On the promotional Nuceiva page, the Panel noted that the adverse event reporting statement, aligned to the wording in Clause 12.9, was located towards the bottom of the page, positioned between the reference list and the footer.

The Panel disagreed with Evolus' submission that the reference to the location of the adverse event reporting information at the top of the page was clear and that the statement itself was presented prominently. The Panel noted that the font size of the banner at the top of the page was very small, and the colour of the background in which it appeared blended with the browser window, making it easy to overlook. The Panel further noted that the adverse event reporting

information at the bottom of the page appeared in the same font style, colour, and background as the references. Although the header *"ADVERSE EVENTS SHOULD BE REPORTED"* was capitalised and emboldened, the Panel did not consider this sufficient to distinguish it from the surrounding reference material or to ensure prominence.

Noting the context of Nuceiva being a black triangle medicine, the Panel considered that the placement and presentation of the adverse event reporting statement on the promotional webpage for Nuceiva did not meet the requirements of Clause 12.9. As Clause 12.9 had not been raised by the Case Preparation Manager, the Panel considered the matter under Clause 5.1. The Panel considered that the lack of a clearly visible and prominent adverse event reporting statement on a promotional webpage for a black triangle medicine that was subject to additional monitoring, meant that high standards had not been maintained. A **breach of Clause 5.1** was ruled.

With regard to the corporate homepage, the Panel noted that the side effect reporting statement appeared in a similar position and size above the footer and contained wording consistent with Clause 26.4 for material intended for patients taking that medicine.

While Evolus submitted that this wording was used because the homepage might be viewed by members of the public, the Panel noted there was no reference to or information about Nuceiva on this page for patients. As such, the Panel did not consider the homepage was material intended for patients taking Nuceiva and ruled **no breach of Clause 26.4**.

Clinical trial disclosure

The complainant alleged that the Evolus website failed to include any reference to clinical trials. In this regard, the Panel noted that Clause 4.6 of the Code required companies to disclose details of clinical trials in accordance with the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature; companies must also include on the home page of their website information as to where details of their clinical trials can be found.

The Panel noted the company's acceptance that, due to an unintentional oversight, this information did not appear on the homepage at the time of the complaint and ruled **a breach of Clause 4.6**, as acknowledged by Evolus.

The Panel considered that transparency was a key principle underpinning self-regulation and was important in maintaining public trust in the pharmaceutical industry. While the Panel considered the requirement to publish details on the homepage of the website was not met, the Panel noted Evolus' submission that the broader requirement of Clause 4.6, which was disclosure of clinical trial data, had been met, given that all completed sponsored trials were published and that ongoing trials were listed on clinicaltrials.gov. In this regard, the Panel considered, on balance, that the circumstances did not amount to a failure to maintain high standards and ruled **no breach of Clause 5.1.**

Reference to FDA label for Jeuveau

The complainant was concerned that the inclusion of hyperlinks to the US Food and Drug Administration (FDA) website on the Nuceiva promotional webpage was confusing and potentially misleading. A screenshot was submitted displaying that the hyperlink directed

readers to the US label for Jeuveau (prabotulinumtoxinA-xvfs) which had a different brand name and generic name, licensed indication and contraindications to Nuceiva, according to the complainant.

The Panel noted that the hyperlink to the US FDA site appeared as a reference on the Nuceiva promotional webpage and was one of four that was used to support a claim that Nuceiva was licensed in 34 countries. The Panel noted the reference was cited as "FDA. Jeuveau Drugs@FDA: FDA Approved Drugs Products" and appeared to hyperlink to a search page. Evolus submitted the reference was for those who wished to check substantiation for the claim and the other three references substantiated the claim for 31 EU countries, Canada and Australia.

According to evidence provided by Evolus, when a viewer clicked the hyperlink, a pop-up message appeared stating: "*You are now leaving the Evolus Service Platform. Evolus is not responsible for the content after you leave*," which the user was required to acknowledge to proceed. The Panel noted that the link appeared to direct users to the FDA Approved Drugs search page, not directly to the US product label, and that a viewer would need to conduct a search to access product specific information.

In the Panel's view, it was clear that the reference and hyperlink to the FDA search page were provided to substantiate the claim that the product was licensed in 34 countries. The Panel did not consider that the inclusion of the hyperlink, which was clearly identified as linking to the FDA and led to a pop-up message informing users that they were leaving the company website, blurred the distinction between the Evolus website and external FDA website, as alleged by the complainant.

The Panel concluded that the inclusion of the reference and link to the FDA search page, to support the claim at issue, was not misleading nor did it amount to Nuceiva being promoted outside the terms of its licence. The Panel therefore ruled **no breach of Clauses 6.1 and 11.2.**

Business Courses

The complainant alleged that the healthcare professional section of the website included business courses with a focus on driving profitability but that prescription-only medicines should never be linked with financial gain in mind and that Nuceiva was being used to grow a beauty business.

The complainant provided a screenshot of what appeared to be part of a video thumbnail. The image had the heading "*Growth courses now available*" beneath which was a video screen with "*Learn with us*" accompanied by the wording: "*You want to drive **growth** and **profitability** in your clinic? Worried about **building your business** and **managing your time**? Evolus will bring **new courses** to inspire growth every quarter. Due to regulations governing the behaviour of pharmaceutical companies, Evolus is required to charge for these courses. **Take a look at what's available today***" (emphasis present in screenshot).

From the evidence before it, the Panel noted that the business courses appeared to be housed within a restricted section of the website, accessible only to registered health professionals. The courses did not appear to be advertised on the promotional Nuceiva page. Evolus provided one example course titled 'Faster Growth, more time with [named individual]', which was priced at £199 and focused on general business skills such as goal setting, time management, and

growth mindset. The Panel noted that not all supporting materials from the course were provided, but the available content contained no references—either direct or indirect—to Nuceiva or any other medicine.

The Panel considered, given the nature of aesthetics and that a large proportion of these treatments take place in the private sector, that the target health professionals were also likely to be business owners. It was not necessarily unacceptable to provide educational courses, including those related to business aspects, to health professionals provided these were not an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

Only one example of a business course had been provided by Evolus and the Panel considered the course was not offered free of charge, nor was it associated with any promotional content related to Nuceiva. The complainant had the burden of proving their complaint on the balance of probabilities and the Panel considered it had not been established that the course, or the way it was presented, linked Nuceiva to financial gain as alleged. The Panel therefore ruled **no breach of Clause 5.1** in this regard.

Prescribing Information

The complainant alleged that the prescribing information was difficult to locate as it appeared as a vertical tab on the side of the webpage, with no further indication of its whereabouts elsewhere on the page.

From the evidence before it, the Panel noted that the prescribing information, in PDF format, was accessible by clicking a vertical tab labelled "*Prescribing Information*" which appeared in white text on a black rectangular background. According to Evolus, the tab remained visible in a fixed position as users scrolled through the Nuceiva promotional page and was the only constant visual element on the screen while scrolling.

The Panel noted that Clause 12.4 required that digital promotional material included a clear and prominent direct single-click link to the prescribing information. Clause 12.6 required that promotional material provided on the internet must include a clear prominent statement as to where the prescribing information can be found.

In the Panel's view, based on the screenshots before it, although the tab was positioned vertically, it appeared within the first visual section of the page and subsequently followed the reader down the page as they scrolled. The Panel considered the tab was sufficiently prominent and acted as a signpost to where prescribing information could be found. The Panel, therefore, ruled **no breach of Clauses 12.4 and 12.6**.

In relation to the complainant's concerns about legibility, the Panel noted the complainant alleged the prescribing information was not presented in columns and included long lines of text which interfered with readability.

The Panel noted that the Code did not mandate the use of columns but required that prescribing information be provided in a clear and legible manner. The prescribing information appeared in a standard font, black text on a white background, presented on an A4 page. There was adequate line spacing, bolded headings, and fewer than 100 characters per line. The Panel noted that Clause 12.1 had not been raised by the Case Preparation Manager and therefore considered the allegation under Clause 5.1. Failure to provide legible prescribing information

would constitute a failure to maintain high standards. In the Panel's view, the prescribing information was provided in a clear legible manner, and **no breach of Clause 5.1** was ruled.

The complainant also alleged that there appeared to only be prescribing information for Great Britain on the website, but the website was intended for a wider UK audience and should have also included Northern Ireland prescribing information. Evolus acknowledged that due to an unintentional oversight, the statement at the top of the website declared that "*This website is for HealthCare Professional audiences in the U.K…*" when it should have specified for GB audiences only as Evolus did not market, supply or promote Nuceiva in Northern Ireland.

As the website was indicated for a UK audience, the Panel considered that the website should have provided clearly labelled prescribing information for Northern Ireland and **ruled a breach of 12.4 and 12.6**, as acknowledged by Evolus.

Use of imagery and videos

The complainant was concerned that the individual shown in an injection technique video was "*not a patient that fits the licence as even on full frown, she has as much frown lines as a two year old*".

Nuceiva was indicated for the temporary improvement in the appearance of moderate to severe vertical lines between the eyebrows (glabellar lines) seen at maximum frown, when the severity of those lines has an important psychological impact in adults under 65 years of age.

The Panel noted that the video in question appeared under the heading "*Injecting Nuceiva*" within the health professional section of the website. The opening screen of the video clearly displayed the licensed indication for Nuceiva before proceeding to demonstrate the injection technique for Nuceiva.

The Panel noted that it was well-established that images could constitute a claim and that companies had to carefully consider whether all images used in promotional materials were appropriate and ensure that they were not inconsistent with the summary of product characteristics or likely to create a misleading impression.

The Panel noted Evolus' submission that the patient shown in the video would be classed as having Glabellar Line Scale 2 (moderate) at maximum frown and that determining severity on such scales required clinical judgement and training.

The Panel noted the individual in the video was clearly an adult under 65 years but beyond this, it was not for the Panel to make any clinical assessment or infer a diagnosis. The Panel considered the complainant, who had the burden of proving their complaint on the balance of probabilities, had not established that the use of the individual within the injection technique video meant that Nuceiva had been promoted in a manner inconsistent with its summary of product characteristics. The Panel ruled **no breach of Clause 11.2**.

The complainant was further concerned that the use of imagery on the company's website gave the impression that Nuceiva, a black triangle prescription-only medicine, was suitable for cosmetic use in young adults, contrary to its licensed indication.

The Panel examined two black and white images provided by the complainant. The first image showed seven young adults posing styled in urban or athletic fashion, wearing Evolus branded clothing. The second image depicted four young adults in similar clothing that were posing against a red background with the text "*evolve with us*" above them, and accompanied information aimed at health professionals about ordering Nuceiva from a pharmacy of their choice.

Evolus submitted that the background imagery on the website represented the demographic of millennials, as they were likely to play an increasing contribution to the aesthetics market over the next five years and were presenting in increasing numbers.

It was not clear to the Panel exactly where these images appeared on the Evolus website. The Panel considered the second image which included reference to Nuceiva was likely to have formed part of the health professional section of the website. While the individuals in the imagery were younger adults, the Panel noted that they were not depicted at maximum frown. The Panel did not consider young adults were precluded from the Nuceiva license which was indicated for the temporary improvement in the appearance of moderate to severe vertical lines between the eyebrows (glabellar lines) seen at maximum frown, where the severity of these lines has an important psychological impact in adults under 65.

In any instance, the Panel considered it was not for it to make any clinical assessment or infer a diagnosis. The Panel considered the complainant, who had the burden of proving their complaint on the balance of probabilities, had not established that the images of young adults used throughout the website promoted Nuceiva in a manner inconsistent with its summary of product characteristics. The Panel ruled **no breach of Clause 11.2**.

The Panel noted the complainant's concern that the promotional imagery failed to reflect the special nature of a black triangle POM and gave the impression of cosmetic lifestyle branding aimed at a younger demographic, thereby trivialising the seriousness of treatment with a neurotoxin.

While the Panel considered the imagery did not appear to be inconsistent with the license at the face of it, the Panel considered, in the context of a black triangle prescription-only medicine indicated only for glabellar lines with psychological impact, the choice of imagery should be carefully judged. In this regard, the Panel was concerned the imagery resembled a contemporary fashion shoot or music video and, on the balance of probabilities, gave the impression that Nuceiva was being promoted for cosmetic or "fashionable" purposes. In the Panel's view, the use of this imagery did not recognise the special nature of medicines, particularly one requiring additional monitoring. The Panel considered Evolus had failed to maintain high standards in this regard and ruled a **breach of Clause 5.1**.

Overall

The Panel noted that Clause 2 was a sign of particular censure and reserved for such use. The Panel considered that the matters raised by the complainant were adequately covered by its rulings of the Code above and did not consider that a breach of Clause 2 was warranted. The Panel therefore ruled **no breach of Clause 2**.

Follow-up Complaint: Mobile version of website

In a follow-up complaint, the complainant highlighted concerns with what appeared to be the Nuceiva webpage when viewed on a mobile device and alleged the version had not been certified. The complainant alleged that the black triangle appeared more like an arrow and sat under the brand name, such that it was not apparent, and that the generic name did not appear alongside the brand name.

The Panel noted the screenshot provided by the complainant included "*Discover Nuceiva*" and that the brand name Nuceiva was separated from its generic name, Botulinum Toxin Type A, by what appeared to be an isosceles black triangle. Evolus provided no alternative version as to how the website appeared on a mobile device and the complaint was judged on the evidence provided by the complainant.

The Panel considered that whilst the triangle was black and inverted, its positioning on the line below the brand name meant that it was not immediately apparent that this was a black triangle and could reasonably be misinterpreted as a downwards facing arrow. Additionally, the triangle did not appear to be equilateral to the Panel. Taking the above into account, the Panel ruled a **breach of Clause 12.10**.

The Panel further considered Clause 12.3 of the 2021 Code stated that in electronic advertisements, the non-proprietary name of the medicine must appear immediately adjacent to brand name at its first appearance. The Panel considered the non-proprietary name appeared two lines below the brand name and was not immediately adjacent as required, in the mobile version. The Panel therefore ruled a **breach of Clause 12.3.**

In relation to certification, Evolus submitted that the website was made responsive for reviewing on mobile and tablet devices which had been captured in the metadata when the website was approved. While Evolus stated that the black triangle and generic name positioning on a mobile device were as they appear in the certified desktop version, and that only zooming in would change this, the Panel noted Evolus provided no evidence in this regard; all complaints were judged on the evidence provided by the parties.

In the Panel's view, the Code did not necessarily require a website to be certified multiple times for each different device it might be viewed upon, however, it considered that the appearance of the material on different devices should be taken into consideration prior to certification to ensure that the content met the requirements of the Code when viewed on each different commonly used type of electronic device, e.g. desktop, laptop, tablet, smartphone etc.

The Panel considered that the black triangle and non-proprietary name appeared in different positions on the mobile version compared to the desktop version, such that the requirements of Clauses 12.3 and 12.10 had not been met. The Panel considered that the final form of the versions of the webpage before it differed substantively in this regard, and each should have been certified separately which had not occurred. The Panel therefore ruled a **breach of Clause 8.1**.

Nuceiva was a black triangle medicine requiring additional monitoring in relation to adverse events. It appeared to the Panel, based on the evidence provided, that the mobile version of the Evolus website, including the Nuceiva promotional page, had not been checked to ensure it appeared the same as the certified desktop version. This had resulted in the failure to show an equilateral black triangle in accordance with Clause 12.10. Taking note of this, the Panel considered that Evolus had failed to maintain high standards and ruled **a breach of Clause 5.1**.

The Panel noted that Clause 2 was a sign of particular censure and reserved for such use. The Panel considered that the matters raised by the complainant were adequately covered by its rulings of the Code above, that patient safety had not been prejudiced and did not consider that a breach of Clause 2 was warranted. The Panel therefore ruled **no breach of Clause 2.**

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Since this complaint was received and during the consideration of this case, Evolus gave notice that it will no longer accept the jurisdiction of the PMCPA. Following notification of the Panel's rulings, Evolus stated that it did not wish to appeal the Panel's rulings and did not consider it appropriate to provide an undertaking given its withdrawal from jurisdiction. Should Evolus choose to re-join the PMCPA's jurisdiction, it would be required to provide an undertaking and assurance. The complainant, the Medicines and Healthcare products Regulatory Agency (MHRA) and the Code of Practice Appeal Board were informed of the position.

Complaint received	**24 February 2024**
Evolus withdrew its agreement to comply with the Code and accept the jurisdiction of the PMCPA	**18 March 2025**
Case completed	**30 May 2025**