

**CASE AUTH/3645/5/22**

**COMPLAINANT v PROVECA**

**Concerns about the dosing calculator app for Sialanar (glycopyrronium bromide)**

**CASE SUMMARY**

This case was in relation to the Sialanar dosage application, which was accessible from a promotional webpage of the proveca.com website.

The Panel ruled a breach of the following Clauses of the 2021 Code because:

- the non-proprietary name did not appear immediately adjacent to the first appearance of the brand name Sialanar on the landing page of the dosing calculator app
- the dosing calculator app did not include prescribing information or a clear prominent statement as to where it could be found
- although adverse event reporting information was included in the dosing calculator app, the wording, as stipulated in Clause 12.9 of the Code, was not included:

<b>Breach of Clause 12.1</b>	<b>Failing to include up-to-date prescribing information</b>
<b>Breach of Clause 12.3</b>	<b>Failing to include the non-proprietary name of the medicine immediately adjacent to the most prominent display of the brand name</b>
<b>Breach of Clause 12.6</b>	<b>Failing to include a clear, prominent statement as to where prescribing information could be found</b>
<b>Breach of Clause 12.9</b>	<b>Failing to include the prominent adverse event reporting statement</b>

The Panel ruled a breach of the following Clauses of the 2021 Code for:

- referring to Sialanar dosing in children, which might imply that Sialanar was licensed in all children which was not so; it was only licensed from 3 years
- not certifying the dosage application as a standalone item

<b>Breach of Clause 5.1</b>	<b>Failing to maintain high standards</b>
<b>Breach of Clause 8.1</b>	<b>Failing to certify promotional material</b>
<b>Breach of Clause 11.2</b>	<b>Promotion inconsistent with the Summary of Product Characteristics</b>

The Panel ruled no breach of the following Clause of the 2021 Code because:

- in the particular circumstances of this case the Panel considered that the rulings of a breach of the Code above were sufficient and an additional ruling of a breach of Clause 2 was not warranted:

<b>No Breach of Clause 2</b>	<b>Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry</b>
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The Panel ruled no breach of the following Clause of the 2021 Code because:

- it considered the app to be one piece of promotional material/item and that 'Sialanar' on the landing page was the first mention within the material and therefore, the subsequent mentions, including on the dosage calculator page, the 'User Guide' page, and the 'Adverse Events' page, noting that it appeared that it could not be accessed without first accessing the landing page, would not require inclusion of the non-proprietary name

<b>No Breach of Clause 12.3</b>	<b>Requirement to include the non-proprietary name in electronic promotional material immediately adjacent to the brand name at its first appearance</b>
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The Panel ruled no breach of the following Clauses of the 2021 Code because:

- based on the complainant's narrow allegation, it did not consider that the complainant had established that the dosing calculator app was accessible by patients without a separate area for them

<b>No Breach of Clause 2</b>	<b>Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry</b>
<b>No Breach of Clause 5.1</b>	<b>Requirement to maintain high standards</b>
<b>No Breach of Clause 26.1</b>	<b>Requirement not to advertise prescription only medicines to the public</b>
<b>No Breach of Clause 26.2</b>	<b>Requirement that information about prescription only medicines which is made available to the public must not encourage the public to ask their health professional to prescribe a specific prescription only medicine</b>

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

## **FULL CASE REPORT**

A complainant who described themselves as a health professional, who was originally contactable but later became non-contactable, complained about the Sialanar dosage website (<https://sialanar-website.firebaseio.com/>) which they alleged had multiple issues across all pages.

## **COMPLAINT**

The complainant stated that Proveca was not adhering to compliance regulations. The complainant alleged that there was no generic name noted next to the brand name mentioned on the webpage <https://sialanar-website.firebaseio.com/>; in breach of Clause 12.3.

The complainant stated that the following page <https://sialanar-website.firebaseio.com/#/en-calc-home> mentioned reference to dosing in children but did not make it clear that Sialanar was only licensed from 3 years and alleged breaches of Clauses 11.2, 5.1 and 2. The complainant further alleged that no generic name was provided next to first mention of brand name on this webpage; in breach of Clause 12.3.

The complainant alleged that there was no generic name next to the brand name on the webpage <https://sialanar-website.firebaseio.com/#/user-guide>; in breach of Clause 12.3.

Nor was there a generic name on the page <https://sialanar-website.firebaseio.com/#/adverse-events> so again a breach of Clause 12.3.

The complainant alleged breaches of Clauses 12.1, 12.6 and 12.9 many times as none of the pages of the website had prescribing information or adverse event reporting.

The complainant alleged that as the website was accessible by patients without a separate area, there were breaches of Clauses 26.1, 26.2, 5.1 and 2.

The complainant alleged that the website had not been approved, although it was a promotional website in breach of Clauses 8.1, 5.1 and 2. The complainant stated that Proveca had no compliance spirit and did not understand self-regulation in the slightest and might need reporting to The Medicines and Healthcare products Regulatory Agency (MHRA) too.

When writing to Proveca, the Authority asked it to consider the requirements of Clauses 2, 5.1, 8.1, 11.2, 12.1, 12.3, 12.6, 12.9, 26.1 and 26.2 of the Code.

## **RESPONSE**

Proveca stated that it had reviewed the original complaint and the screenshots provided by the PMCPA regarding the Sialanar dosing application, which was accessible via Proveca's website. Whilst this case was being investigated, the company took the decision to temporarily suspend access to the dosing application.

### Main observation

Proveca noted that the complaint largely concerned an alleged failure to promote Sialanar within the expectations of the Code. However, the dosage application was not a promotional item and was intended to provide health professionals with factual, accurate reference information on how to dose Proveca's product. The information provided was an exact copy of the information provided within the dosing table (Table 1) in section 4.2 of the summary of product characteristics (SPC). There were no product claims within the application and no other information about Proveca's product was provided.

### Access to website and dosing application

Proveca stated that the dosing application was accessed via the Proveca website; for which most of the content was intended for public viewing. There were dedicated sections for health

professionals, patients and investors, which were separated and clearly indicated. It was noted that direct links to the dosage application were provided to the PMCPA within the complaint. Links to the dosing application were not advertised or provided to health professionals and only the Proveca.com website was advertised. Proveca submitted that as could be seen from the screenshots, there were appropriate checks in place to ensure that only health professionals accessed the application, and these checks were in place regardless of the means of accessing the application.

Health professionals attempting to access the dosing application were notified that they were leaving the Proveca website and being taken to a third-party website when accessing the dosing application, so it was clear that the content was entirely separate from the promotional content they were just viewing.

Given that the Proveca website contained areas dedicated to the public, Proveca believed that the health professional check was appropriate and compliant in this instance.

#### Age range not referenced

Proveca stated that there were links within the application which allowed the health professional to directly access the current SPC and BNFC (British National Formulary for children) for information on using the product, including the indication and age range. Proveca believed that the clear provision of the SPC was sufficient to allow the health professional to access information on the product indication for which they were prescribing. This included the indicated age range of the product being for children aged 3-17. Additionally, when accessing the dosing application via the Proveca.com website, the health professional had passed through the Proveca.com webpages where the indicated age range was clearly visible and available.

#### Approval of webpages

Proveca noted that the complainant alleged that the Proveca webpages were not approved. Website approval was conducted using an internal process; no approval documents would be available to the complainant or any other user of the website or dosing application. Approval of website content was always completed by a signatory to the standards expected by the Code.

As part of this response, Proveca provided evidence of the approval and certification of the relevant webpages by signatories. These included webpages which provided a link to the dosing application. As part of the approval, the signatory had considered the content of the links, including the dosing application when certifying.

Proveca submitted that as the content of the dosing application was non-promotional, a separate medical approval was undertaken with a focus on consistency with the factual information. However, as above, a signatory had certified access to the application.

#### Summary of response

Proveca stated that it had broken down the original complaint into a table of alleged breaches to summarise the Proveca response to the complaint.

Complaint	Alleged Code Breach	Summary of Proveca response
<p><a href="https://sialanar-website.firebaseio.com/">https://sialanar-website.firebaseio.com/</a>.</p> <p>There was no generic name noted next to brand mention on this page.</p>	12.3	The dosing application was non-promotional and therefore was not subject to the clauses within section 12 of the Code.
<p><a href="https://sialanar-website.firebaseio.com/#/en-calc-home">https://sialanar-website.firebaseio.com/#/en-calc-home</a>. The following page mentioned reference to dosing in children but did not make it clear that Sialanar was only licensed from 3 years.</p>	11.2, 5.1 and 2	The indication for the product, including the age range, could be found in the SPC and the BNFC which was clearly accessible on the dosing application, including on the page where the dosing calculator link was located.
<p><a href="https://sialanar-website.firebaseio.com/#/en-calc-home">https://sialanar-website.firebaseio.com/#/en-calc-home</a>. No generic name was provided next to first mention of brand name.</p>	12.3	The dosing application was non-promotional and therefore was not subject to the clauses within section 12 of the Code.
<p><a href="https://sialanar-website.firebaseio.com/#/user-guide">https://sialanar-website.firebaseio.com/#/user-guide</a>. No generic name next to brand name.</p>	12.3	The dosing application was non-promotional and therefore was not subject to the clauses within section 12 of the Code.
<p><a href="https://sialanarwebsite.firebaseio.com/#/adverse-events">https://sialanarwebsite.firebaseio.com/#/adverse-events</a>. No generic name on this page either.</p>	12.3	The dosing application was non-promotional and therefore was not subject to the clauses within section 12 of the Code.
<p>None of the pages of the website had prescribing information or adverse event reporting.</p>	12.1, 12.6, 12.9 many times	<p>The dosing application was non-promotional and therefore was not subject to the clauses within section 12 of the Code.</p> <p>On the promotional section of the website, the Prescribing Information was linked and always 1-click away. Adverse event reporting instructions were present on the prescribing information too.</p> <p>Tools and instructions on adverse event reporting were clearly available on the dosing application. The application assisted the health professional by taking them directly to the</p>

		MHRA website or sending an email to the appropriate Proveca department.
Website was accessible by patients without a separate area.	26.1, 26.2, 5.1 and 2	The dosing application was only available to health professionals, which was entirely separate to other areas of the Proveca website, where there was labelled content for patients.
Website had not been approved although it was a promotional website.	8.1, 5.1 and 2	The Proveca website had a formal approval process and promotional webpages had been approved by a signatory.  The dosing application, although non-promotional, was also approved by a medical signatory as it contained medical information. The non-promotional dosing application was provided by a 3 <sup>rd</sup> party website, entirely separate to promotional website. This was made clear when the health professional entered the application.

Supporting evidence was provided. Proveca had created videos which demonstrated the concerned webpages and how someone would navigate the Proveca website and the dosing application.

## PANEL RULING

The Panel noted that whilst the complainant referred to Proveca's Sialanar dosage website, based on the evidence provided by Proveca, it appeared that the links included in the complaint were to the dosing calculator app for Sialanar which was accessible from a promotional webpage of the Proveca.com website. The Panel, therefore, made its rulings in relation to the pages of the dosing calculator app as highlighted by the complainant.

The Panel noted Proveca's submission that the dosing application was accessed via the Proveca website and links to the dosing application were not advertised or provided to health professionals and only the Proveca.com website was advertised. The Panel noted from the videos provided by Proveca that it appeared that if a reader selected the Products tab at the top of the Proveca.com website, they were presented with a pop-up which stated 'Access Restricted to Healthcare Professionals. You are attempting to access information restricted to healthcare professionals. Click OK to confirm you are a healthcare professional or Cancel to be directed to our home page'. Upon selecting 'OK', readers were directed to a webpage titled 'Paediatric Medicine for HCPs' followed by 'Proveca medicines for children' and then 'This section is only for Healthcare Professionals and relates to paediatric medicine developed and licensed by Proveca. Proveca also invests in the provision of educational items which are listed on the side menu, these can be given to carers and patients by Healthcare Professionals'.

The first product listed on the webpage was Sialanar, which included the generic name directly below followed by links to separate prescribing information for the UK and Ireland and an image of two bottles of the medicine. This was followed by 'Sialanar received a Paediatric Use Marketing Authorisation (PUMA) in September 2016 for the symptomatic treatment of severe

sialorrhoea (chronic pathological drooling) in children aged 3 years and older with chronic neurological disorders'. To the side there was the option to select the following options: 'How to get Sialanar/Prescribing information'; 'Sialanar Dose Calculator'; 'Information about Drooling'; 'Drug Utilisation Study'; 'App dosing calculator (UK)'; and 'App dosing calculator (Ireland)'.

If the reader selected the 'App dosing calculator (UK)', they were presented with a pop-up which stated 'You are leaving our site You are about to leave the Proveca website, please be aware that we are not responsible for any third party content. Do you wish to continue?' and readers could select 'YES' or 'NO'. If 'YES' was selected, a further pop-up titled 'Confirmation' stated 'This application is only intended for use by healthcare professionals. Are you a healthcare professional?' and asked readers to confirm 'YES' or 'NO'. Upon selecting 'YES', a page (sialanar-website.firebaseio.com) was presented which appeared to be the same as the screenshot taken by the case preparation manager of the link provided by the complainant.

The Panel noted Proveca's reference to checks being in place to ensure that only health professionals accessed the application, and stated these checks were in place, regardless of the means of accessing the application.

The Panel noted the wording in the pop-up, which appeared when clicking the App dosing calculator (UK) link from the products page of the Proveca website, stated, among other things, 'Please be aware that we are not responsible for any third party content' and Proveca's submission that the dosing application, although non-promotional, had been approved by a Proveca medical signatory as it contained medical information. The Panel further noted that the User Guide page of the dosing calculator app stated that the Sialanar dosing app was a product of Proveca Ltd and that the app and all of its content was the copyright of Proveca Ltd. In the Panel's view, the application was wholly owned by Proveca, the fact that it was hosted on a third party website did not mean Proveca was not responsible for the content.

The Panel noted Proveca's submission that the dosage application was not a promotional item and was intended to provide health professionals with factual, accurate reference information on how to dose Sialanar, which was an exact copy of the information provided within the dosing table (Table 1) in section 4.2 of the SPC for Sialanar.

In the Panel's view, as the link to the dosing calculator app was accessed directly through the promotional area of Proveca's website aimed at health professionals, the application, which was product-related, was promotional and it was on this basis that the Panel made its rulings.

1 <https://sialanar-website.firebaseio.com/>

The link in question provided by the complainant opened the Sialanar dosing calculator app, the landing page of which was titled 'Sialanar dosage calculator' and featured a menu listing the following pages of the app: 'Dosage Calculator', 'User Guide', 'Product Information', 'Guidance for HCPs and Carers', 'Adverse reporting and Feedback' and 'Privacy Policy'.

The Panel noted the complainant's allegation that there was no generic name next to the first brand mention on this page. It appeared to the Panel that each of the pages listed in the menu above could not be accessed without first accessing the landing page; the app could therefore be considered as one piece of promotional material/item and it was on this basis that the Panel made its rulings.

The Panel noted its comments above, that in its view, the dosing calculator app was promotional, and that the non-proprietary name did not appear immediately adjacent to the first appearance of the brand name Sialanar on the landing page of the dosing calculator app as alleged, and as required by Clause 12.3 for electronic advertisements. A **breach of Clause 12.3** was therefore ruled.

2 <https://sialanar-website.firebaseio.com/#/en-calc-home>

The Panel noted that when 'Dosage Calculator' was selected from the menu described above, a page titled 'Sialanar dosage calculator' appeared. Below the title was a link to 'DOSAGE CALCULATOR' in a blue box. This was followed by the statement 'Sialanar dosing, for children with normal renal function, can be calculated by clicking the button above. The Sialanar SmPC shows dosing for children with mild to moderate renal impairment'. Below was a link to the SPC, followed by the statement 'A comparison of the dosing differences between Sialanar and 1mg/5ml glycopyrronium bromide can be found in the BNFC through this link: BNFC Website. When using this calculator, evaluation of the individual patient's condition should be taken into consideration. Please link to the Sialanar SPC for further advice if needed'.

The Panel noted the complainant's allegation that the page made reference to dosing in children but did not make it clear that Sialanar was only licensed from 3 years. The Panel noted Proveca's submission that there were links within the application which allowed health professionals to access the current SPC and BNFC, which included the indication and age range. The Panel noted Proveca's submission that when accessing the dosing application via the Proveca website, the health professional had passed through the Proveca.com webpages where the indicated age range was visible and available.

The Panel noted that the 'Products' webpage from which the dosing calculator app was accessed stated 'Sialanar received a Paediatric Use Marketing Authorisation (PUMA) in September 2016 for the symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children aged 3 years and older with chronic neurological disorders'. The Panel, however, noted Proveca's reference to checks being in place to ensure that only health professionals accessed the application, and stated these checks were in place regardless of the means of accessing the application. It was thus unclear if the app could be accessed in another way; nonetheless, it was an established principle that each piece of material must be capable of standing alone with regard to the requirements of the Code. In this regard, the Panel noted Proveca's submission that the app content was entirely separate from the promotional content that health professionals were viewing on the Proveca website.

Clause 11.2 states that 'The promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its summary of product characteristics'. In the Panel's view, in referring to Sialanar dosing for children on the dosage calculator app page at issue, it might imply that Sialanar was licensed in all children, which was not so. It was only licensed in children aged 3 years and over. The Panel noted that companies could not rely on information in linked material for such clarification and it therefore ruled a **breach of Clause 11.2** as alleged.

The Panel considered that high standards had not been maintained in this regard and a **breach of Clause 5.1** was ruled.

Clause 2 of the Code was a sign of particular censure and was reserved for such use. Whilst the Panel was concerned with regard to the omission of the age of children for which Sialanar



was licensed on the page in question, it noted that the information was available in the SPC which readers were signposted to directly below the statement at issue. In the particular circumstances of this case, the Panel considered that the rulings above were sufficient and an additional ruling of a Clause 2 was not warranted and **no breach of Clause 2** was ruled.

The Panel noted its comments, as set out in Point 1 above, that it considered the app to be one piece of promotional material/item and that Sialanar on the landing page was the first mention within the material. Therefore, the subsequent mentions, including on the dosage calculator page, noting that it appeared that it could not be accessed without first accessing the landing page, would not require inclusion of the non-proprietary name, thus **no breach of Clause 12.3** was ruled in relation to the dosage calculator page.

3 <https://sialanar-website.firebaseio.com/#/user-guide>

The Panel noted its comments, as set out in Point 1 above, that it considered the app to be one piece of promotional material/item and that Sialanar on the landing page was the first mention within the material. Therefore, the subsequent mentions, including on the 'User Guide' page, noting that it appeared that it could not be accessed without first accessing the landing page, would not require inclusion of the non-proprietary name, thus **no breach of Clause 12.3** was ruled in relation to the 'User Guide' page.

4 <https://sialanar-website.firebaseio.com/#/adverse-events>

The Panel noted its comments, as set out in Point 1 above, that it considered the app to be one piece of promotional material/item and that Sialanar on the landing page was the first mention within the material. Therefore, the subsequent mentions, including on the 'Adverse Events' page, noting that it appeared that it could not be accessed without first accessing the landing page, would not require inclusion of the non-proprietary name, thus **no breach of Clause 12.3** was ruled in relation to the 'Adverse Events' page.

5 Lack of Prescribing Information and Adverse Event Reporting

The Panel noted that the complainant alleged breaches of Clauses 12.1, 12.6 and 12.9 many times as none of the pages of the 'website' had prescribing information or adverse event reporting. The Panel noted that, in this regard, the complainant had only provided links to the landing page, 'Dosage Calculator' page, 'User Guide' page and 'Adverse Events' page of the dosing calculator app which they referred to as a website and thus the Panel made its rulings solely in relation to these pages.

Whilst the Panel noted that the Sialanar product page on the Proveca website, prior to accessing the dosing calculator app, included separate links to the UK and Ireland Prescribing Information, as noted above, it was the dosing calculator app which was the subject of this complaint which was, in the Panel's view, promotional and had to stand alone with regard to the requirements of the Code. In this regard, the Panel noted Proveca's submission that the app content was entirely separate from the promotional content that health professionals were viewing on the Proveca website.

The Panel noted that upon accessing the dosing calculator app, the landing page contained a list of areas which could be navigated to which included: 'Dosage Calculator', 'User Guide', 'Product Information', 'Guidance for HCPs and Carers' and 'Adverse reporting and Feedback'. The Panel noted Proveca's submission that the dosing application was non-promotional and

therefore was not subject to the clauses within section 12 of the Code. In the Panel's view, however, as the link to the dosing calculator app was accessed directly through the promotional area of Proveca's website aimed at health professionals, the application, which was product-related, was promotional and it was on this basis that the Panel made its rulings.

The Panel noted that, from the evidence before it, it did not appear that the dosing calculator app included prescribing information or a clear prominent statement as to where it could be found. The Panel therefore ruled **breaches of Clauses 12.1 and 12.6** in relation to each.

Clause 12.9 stated that 'All promotional material must include the prominent statement "Adverse events should be reported. Reporting forms and information can be found at [website address which links directly to the MHRA Yellow Card site]. Adverse events should also be reported to [relevant pharmaceutical company]"'.

Although adverse event reporting information was included in the dosing calculator app, the wording, as stipulated in Clause 12.9 of the Code, was not included and **a breach of Clause 12.9** was therefore ruled.

#### 6 Website accessible by patients without a separate area

The Panel noted the supplementary information to Clause 26.2, Website Access, which referred to websites providing information for the public as well as promotion to health professionals and the need to have the sections for each target audience clearly separated and the intended audience identified. This was to avoid the public needing to access material for health professionals unless they chose to. The MHRA Blue Guide advised that the public should not be encouraged to access material which was not intended for them.

The Panel noted that to access the dosage application in question, users could click on the 'App Dosing Calculator (UK)' link on the Sialanar section of the 'Products' page of the Proveca website. The Panel noted that to access the 'Products' page on the Proveca website, readers had to confirm that they were a health professional and, if not, it appeared that they were directed back to the website's homepage.

The Panel noted Proveca's submission that the dosing application was accessed via the Proveca website for which most of the content was intended for public viewing. The Panel noted that, according to the video provided by Proveca showing navigation to the app, if the reader selected the 'App dosing calculator (UK)' they were presented with a pop-up which stated 'You are leaving our site. You are about to leave the Proveca website, please be aware that we are not responsible for any third party content. Do you wish to continue?' and readers could select 'YES' or 'NO'. If 'YES' was selected, a further pop-up titled 'Confirmation' stated 'This application is only intended for use by healthcare professionals. Are you a healthcare professional?' and asked readers to confirm 'YES' or 'NO'. Upon selecting 'YES', the dosing calculator app was accessed. Whilst it was not clear where readers who selected 'NO' were directed to, the Panel noted that the app was accessed from a page aimed at health professionals and which readers had to confirm that they were health professionals prior to accessing or if not were directed to the Proveca website homepage.

The Panel, noting the above, did not consider that the complainant had established that the dosing calculator app was accessible by patients without a separate area for them, as alleged, and based on the complainant's narrow allegation, **no breaches of Clauses 26.1 and 26.2** were ruled and consequently **no breach of Clauses 5.1 and 2**.

## 7 Website had not been approved

Clause 8.1 stated that, among other things, 'Promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified...'

The Panel noted the complainant's allegation that the 'website' had not been approved, although it was a promotional website. The Panel noted that the subject of the complaint was the dosing calculator app. The Panel noted that Proveca provided evidence of the approval and certification of the relevant webpages of the Proveca website which included webpages which provided a link to the dosing application. According to Proveca, as part of the approval, the signatory had considered the content of the links including the dosing application when certifying and a signatory had certified access to the application.

Whilst the Panel noted Proveca's submission that a separate medical approval was undertaken with a focus on consistency with the factual information, it did not appear that the dosing calculator app had been certified.

The Panel, noting Proveca's submission that the app content was entirely separate from the promotional content that health professionals were viewing on the Proveca website, and noting that, in the Panel's view, the app was promotional, considered that the dosing calculator app should have been certified as a standalone item, which it had not been. The Panel ruled a **breach of Clauses 8.1 and 5.1** accordingly.

The Panel, noting that a signatory had certified access to the dosing calculator application, its content was considered when certifying the website and a separate medical approval was undertaken with a focus on consistency with the factual information, did not consider that, in the particular circumstances of this case, a breach of Clause 2 was warranted and **no breach of Clause 2** was ruled.

**Complaint received**      **12 May 2022**

**Case completed**        **29 June 2023**