

CASE AUTH/3647/5/22

VOLUNTARY ADMISSION BY LEO

Uncertified promotional material

CASE SUMMARY

This was a voluntary admission by Leo in relation to the 'At a glance' and 'Mode of action' webpages of the Kyntheum (brodalumab) promotional website. The matter had come to Leo's attention following its investigation in relation to Case AUTH/3503/4/21.

The Panel ruled a breach of the following Clause of the 2019 Code, in relation to each webpage, as material published on the 'At a glance' webpage differed to that which was certified, and material approved for the global website had in error been uploaded to the UK website for the 'Mode of action' webpage:

Breach of Clause 14.1	Failing to certify promotional material as required by the Code
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The Panel ruled a breach of the following Clause of the 2019 Code as, in its view, the certification process underpinned self-regulation and the Panel was concerned that Leo did not have adequate control over its promotional materials:

Breach of Clause 9.1	Failing to maintain high standards
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The Panel ruled no breach of the following Clause of the 2019 Code as allegations about the content of the webpages at issue were addressed in the previous case (Case AUTH/3503/4/21), and the Panel considered that the matter in relation to uncertified promotional material in this voluntary admission (Case AUTH/3647/5/22) was adequately covered by its rulings above:

No Breach of Clause 2	Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry
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**This summary is not intended to be read in isolation.
For full details, please see the full case report below.**

FULL CASE REPORT

Leo made a voluntary admission of breaches of Clause 14.1 of the 2019 Code in relation to uncertified promotional material.

COMPLAINT

Background

Leo stated that in May 2021, it received notification from the PMCPA of Case AUTH/3503/4/21 (Kyntheum information page on uk.dermaworld.eu) from an anonymous complainant regarding the content of a promotional website. This case was still under consideration by the Panel at the time of Leo's voluntary admission.

As part of Leo's original response to the complaint in Case AUTH/3503/4/21, dated 18 August 2021, it admitted that two items of material (home tab and 'at a glance' tab) were not the materials that had been certified by the UK organisation owing to errors in the uploading of these materials onto the website by the third-party agency. Leo therefore accepted in its response that there had been breaches of Clause 14.1 of the 2019 Code.

In a follow-up letter, dated 22 March 2022, the Panel requested further information for Case AUTH/3503/4/21 from Leo. In this request, the Panel noted that Clause 14.1 had not been raised by the case preparation manager in relation to either of the items of uncertified material, as these matters had not been alleged by the complainant, and it was not clear as to whether Leo wished to make a voluntary admission in this regard. Leo had further considered this matter and now wished to confirm that a voluntary admission was being made and should be taken up as a separate case.

Leo stated that unfortunately, it needed to include an additional item as part of this voluntary admission. As part of the request for further information in Case AUTH/3503/4/21, the Panel asked for clarification on the approval details of the Kyntheum Mode of Action Tab, which had been provided as part of the original response. Leo had provided 2 pdf versions of a Mode of Action Tab with the job bag code MAT-30814 (version 1 was dated March 2020 and version 2 was dated August 2020). The Mode of Action Tab cited by the complainant had the job code MAT-39266 Nov 2020 and the Panel requested that this was provided.

Upon investigation, Leo found a further error had been made by the third-party agency that managed the websites in that MAT-39266, which was approved for use on the global website, not the UK website, had been uploaded onto the UK website, and therefore Leo had inadvertently used uncertified promotional material. Leo accepted that there was a breach of Clause 14.1 in this regard.

Corrective and preventative actions

Leo stated that it sincerely regretted these errors. In terms of corrective actions, the Dermaworld website was taken down at the time of receiving the initial complaint and a full audit of all Kyntheum materials was undertaken.

Since the complaint, a number of actions had been undertaken to mitigate the risks of similar issues happening again:

- Website content was now predominantly uploaded in release cycles, rather than ad hoc upload, to provide greater control and governance regarding release management of new material.

- An additional 'post live final form' review stage for all online material had been implemented, in which a signatory would check all material uploaded onto the live site immediately after it had been published to ensure it was identical to the signed off and approved material on the 'pre-live' site. This was in addition to the usual final form certification which took place solely on the pre-live loading site just before material was uploaded to the web.
- A new principle procedure and standard operating procedure for creating and managing websites was made effective and rolled out across the organisation for all relevant employees in April 2022.
- In addition, the Dermaworld website was moving to a new site in August 2022 which allowed greater governance and control by Leo rather than a third party. The content would now be uploaded directly by an internal administered freelancer team who would be fully briefed and trained on specific country requirements and would follow an improved automated process for publication of content on the live site.

Voluntary admission

In summary, Leo acknowledged responsibility for the errors outlined, and therefore regrettably voluntarily admitted breaches of Clause 14.1 of the 2019 Code in this matter.

When writing to Leo, the Authority asked it to consider the requirements of Clauses 2, 9.1 and 14.1 of the Code.

RESPONSE

Details of uncertified items

As part of its response to Case AUTH/3503/4/21 (the 'original complaint'), Leo submitted that two items of material (home tab and 'at a glance' tab) had not been certified by the UK organisation. Following further investigation of the matter by Leo, it withdrew its voluntary admission regarding the home tab.

Kyntheum at a glance tab (MAT-21384 May 2019)

Point 58 of the original complaint was with regard to citation of an SPC reference from September 2017 which was out of date. Leo submitted that, unfortunately, in this instance, an error had occurred with the process of uploading the correct document to the live website. Both the reviewed and approved screen shots on PromoMats and the page on the website staging platform showed the correct SPC (last accessed March 2020). However, the live version of the webpage included in error a reference to the SPC of September 2017 as noted by the complainant. The date of the archive was December 2020 which was the last date that snapshots of the website were taken indicating that there were no further updates to the website and so this was what the complainant would have seen.

Kyntheum Mode of Action tab (MAT-39266 Nov 2020)

As part of the request for further information in Case AUTH/3503/4/21, the Panel asked for clarification on the approval details of the Kyntheum Mode of Action Tab, which had been provided as part of the response to the original complaint.

In the response to the original complaint, Leo had provided pdf versions of a Mode of Action Tab with the job code MAT-30814. The Mode of Action Tab cited by the complainant had the job code MAT-39266. Leo submitted that, upon investigation, it found a further error had been made by the third-party agency that managed the websites, in that MAT-39266, which was approved for use on the global website not the UK website, had been uploaded onto the UK website, and therefore Leo had inadvertently used uncertified promotional material.

Third party management

Leo submitted that at the relevant time, and indeed now, contracted third party agencies were fully briefed by the appropriate Leo teams that they were working with, and their outputs closely supervised. With specific regard to third parties managing Leo Pharma UK websites, as stated in the Corrective and Preventative actions listed in its voluntary admission, dated 12 May 2022, the Dermaworld website was moving to a new site in August 2022 which allowed greater governance and control by Leo rather than a third party. The content would now be uploaded directly by an internally administered team who would be fully briefed and trained on specific country requirements and would follow an improved automated process for publication of content on the live site.

Conclusion

Leo accepted that there had been breaches of Clause 14.1 of the 2019 Code with regard to uncertified promotional content on the 'Kyntheum at a Glance' tab and also the 'Kyntheum Mode of Action' tab on the Kyntheum Dermaworld website. Following further investigation, Leo redacted its original voluntary admission regarding uncertified content on the Home page tab on the Kyntheum Dermaworld website.

Leo believed that the two accepted issues, which resulted from human error by a third-party agency, did not demonstrate a failure by Leo to meet high standards, contrary to Clause 9.1 of the 2019 Code. As a consequence, neither did Leo believe there was warrant for a breach of Clause 2, a ruling reserved as a sign of particular censure.

PANEL RULING

The Panel noted that Leo made a voluntary admission in relation to three webpages of a Kyntheum promotional website: home tab (MAT-30813v2 August 2020); at a glance tab (MAT-21384 May 2019) and mode of action tab (MAT-39266 Nov 2020).

Leo subsequently withdrew its voluntary admission in relation to the home tab and therefore the Panel made no ruling in relation to this material.

Clause 14.1 of the 2019 Code stated, amongst other things, that promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by one person on behalf of the company in the manner provided for by this clause, subject to the provisions of the supplementary information to this clause where relevant. This person must be a registered medical practitioner or a pharmacist registered in the UK.

In relation to the at a glance tab (MAT-21384 May 2019), the Panel noted Leo's submission that the material published live on the website differed in content to that which had been certified;

the difference related to reference to an out of date SPC. **A breach of Clause 14.1 of the 2019 Code** was ruled as acknowledged by Leo.

In relation to the mode of action tab (MAT-39266 Nov 2020), the Panel noted Leo's submission that material which was approved for use on the global website, had in error been uploaded onto the UK website and thus Leo had inadvertently used promotional material that had not been certified as required by the Code. **A breach of Clause 14.1 of the 2019 Code** was ruled as acknowledged by Leo.

In the Panel's view, the certification process underpinned self-regulation. It was concerning that Leo did not have adequate control over its promotional materials. High standards had not been maintained in that regard and **a breach of Clause 9.1 of the 2019 Code** was ruled.

The Panel was further concerned that the discrepancies between what had been certified and what was live on the UK Kyntheum promotional website had only come to Leo's attention following a complaint (Case AUTH/3503/4/21) and following the Panel's request for further information in relation to that complaint. However, Clause 2 was a sign of particular censure and was reserved for such use. Given that allegations about the content of the webpages at issue were addressed in the previous case (Case AUTH/3503/4/21), the Panel considered that the matter in relation to uncertified promotional material in this voluntary admission (Case AUTH/3647/5/22) was adequately covered by its rulings of breaches of Clauses 14.1 and 9.1 above, and thus the Panel ruled **no breach of Clause 2**.

Complaint received **13 May 2022**

Case completed **4 May 2023**