

COMPLAINANT v OTSUKA EUROPE

Allegations about a congress website

CASE SUMMARY

This case was in relation to a webpage regarding an Otsuka Europe sponsored symposium at a European congress, which appeared in the industry sponsored session programme section of the congress website. The complainant raised numerous concerns about the webpage including that: the sponsorship statement was misleading it omitted information required for promotional material, had not been certified, promoted voclosporin for an unlicensed indication, incorrectly described voclosporin as new, contained claims which were misleading and constituted promotion to the public.

The outcome under the 2024 Code was:

Breach of Clause 3.2	Advertising a prescription only medicine to the public
Breach of Clause 5.1	Failing to maintain high standards
Breach of Clause 5.6	Failing to be sufficiently clear as to the company's role and involvement
Breach of Clause 6.1	Making a misleading claim
Breach of Clause 6.2	Making a claim that was incapable of substantiation
Breach of Clause 6.5	Using the word 'new' to describe a product which has been generally available for more than 12 months in the UK
Breach of Clause 8.1	Failing to certify promotional material
Breach of Clause 11.2	Promoting a medicine for an unlicensed indication
Breach of Clause 12.1	Failing to include prescribing information
Breach of Clause 12.5	Failing to include the date on which the promotional material was created or last revised
Breach of Clause 12.6	Failing to include the prominent adverse event reporting statement

No Breach of Clause 2	Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry
No Breach of Clause 6.1	Requirement that information, claims and comparisons must not be misleading
No Breach of Clause 8.3	Requirement to certify non-promotional material
No Breach of Clause 11.1 (x2)	Requirement that a medicine must not be promoted prior to the grant of its marketing authorisation

No Breach of Clause 11.2	Requirement not to promote a medicine for an unlicensed indication
No Breach of Clause 14.4	Requirement that claims should not imply that a medicine or an active ingredient has some special merit, quality or property unless this can be substantiated

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

FULL CASE REPORT

A complaint was received about Otsuka Pharmaceutical Europe Ltd (Otsuka Europe) from an anonymous, non-contactable complainant who described themselves as an ex-employee.

COMPLAINT

The complaint wording is reproduced below:

“I am writing with concerns about information on the [named healthcare organisation] website about an Otsuka sponsored symposium at the 2025 [named healthcare organisation congress]. The information is still available here [URL provided]. This information can be freely accessed by going to the main congress website [URL provided] and clicking through to the programme, there are no restrictions on access for [named healthcare organisation] members or physicians. Otsuka’s medicine is voclosporin. The information states at the top of the page that This session is sponsored by: Otsuka Pharmaceutical Europe Ltd. However, the image in top right of the page states that this was a promotional symposium organised and funded by Otsuka Pharmaceutical Europe Ltd and intended for healthcare professionals. This means that the main sponsorship statement is misleading.

The description on the page states: The management of systemic lupus erythematosus (SLE) and lupus nephritis (LN) is attractive to the nephrology community as evidenced by high participation rates in prior [named healthcare organisation] E-seminars and full lecture halls during live conferences, but also became more complicated over the past years. The approval of belimumab and voclosporin represents a milestone in the management, and other substances such as obinutuzumab have met the primary endpoint of their approval trial and will likely be marketed soon. As the approval of new substances increase complexity, LN was the first disease entity which received attention by [named kidney disease organisation] and the LN guidelines were updated. In parallel, new SLE recommendations were issued by the [named rheumatology organisation] and new LN recommendations by EULAR are currently drafted. This symposium will summarise “older” therapies and how the newly approved treatment options can be incorporated in the management of LN cases. This will include discussions on belimumab (BLISS-LN), voclosporin (AURORA1 and AURORA2) and obinutuzumab (REGENCY). The symposium should also include an outlook for future therapy options (“CAR-T cells” and others). Besides the importance to preserve nephron mass in the management of LN, this symposium should also focus on the management of extra-renal manifestations and especially the importance of a multi-disciplinary management to overcome the burden of fatigue, reduced quality of life and the impact thereof on

occupancy. Management issues encountered by other specialities such as rheumatologists or dermatologists will be outlined and specific therapies approved for non-renal SLE, such as anifrolumab, will be discussed in this context. Besides treatment of active disease (“remission induction”), long-term prescription of immunosuppression is reality. Our symposium will also discuss the relevance of avoiding disease relapses during follow-up, as renal relapses will lead to nephron loss and subsequently reduction in GFR. As such, “safe” reduction and eventual withdrawal of immunosuppression has become reality only in the context of repeat kidney biopsies. While such an approach is invasive and often disregarded by affected patients, our symposium will outline that this is an essential point moving forward in the individualisation of therapy. In summary, relevant points for nephrologists are tackled from different perspectives in our symposium. These include the implementation of novel therapies in the management of SLE and LN, when referral to other specialities needs to be considered to optimise extra-renal disease manifestations and improve quality of life, and finally discussion around the ideal duration of therapies to prevent disease relapses and thereby worsening of chronic kidney disease.

There are multiple issues with this: • A link to the SmPC is provided but the full PI requirements are not met • There is no AE reporting statement • There is no date of preparation • There is no job code • The wording refers to the treatment of SLE and LN but voclosporin is only licensed for LN • Voclosporin is referred to as a newly approved treatment yet was launched over 1 year ago • Voclosporin is referred to a milestone in the management but it is not clear why it is milestone. This is misleading, ambiguous and not capable of substantiation • It positions obinutuzumab as a treatment for LN and that it will likely be marketed soon but this is misleading as at the time of the symposium obinutuzumab did not have a marketing authorisation for the treatment of LN but was available and licensed for chronic lymphocytic leukaemia and follicular lymphoma • All the above suggest that this was not certified • As this information was available to the public it also constitutes promotion to the public
Some of these issues are very serious in their own right but collectively this number of issues is embarrassing the pharmaceutical industry.”

When writing to Otsuka, the PMCPA asked it to consider the requirements of 3.2, 5.6, 6.1, 6.2, 6.5, 8.1, 8.3, 11.1, 11.2, 12.1, 12.6, 14.4, 5.1 and 2 of the 2024 Code. The case preparation manager later wrote to Otsuka following receipt of its response to request that it also consider the requirements of Clause 12.5.

OTSUKA EUROPE’S RESPONSE

The response from Otsuka Europe is reproduced below:

“Background

Otsuka Pharmaceutical Europe Ltd (Otsuka) was a sponsor of the [named healthcare organisation congress], which was held in [location] on [date] June, 2025. As part of Otsuka’s sponsorship package Otsuka had space for a stand in the exhibition area and two industry sponsored symposia slots. One of the industry sponsored symposia was titled ‘Multi-target treatments and a multidisciplinary approach: How they can improve care for patients with lupus nephritis’ which took place on [date and time]. This symposium promoted Otsuka’s medicine Lupkynis (voclosporin). At the time of the

symposium, Lupkynis was indicated in combination with mycophenolate mofetil for the treatment of adult patients with active class III, IV or V (including mixed class III/IV and IV/V) lupus nephritis (LN)

Investigation

For clarity, this response refers to Otsuka's activity as an *industry sponsored symposium*, the [named healthcare organisation] online listing as the *Industry Sponsored Sessions Programme*, and the individual listing for Otsuka's symposium as the *symposium page*.

As the employees that worked on Otsuka's activities at the [named healthcare organisation congress] 2025 have now left Otsuka, our investigation has focussed on a review of relevant email records, discussions with the agency that supported Otsuka in relation to the symposium, and engagement with [named congress organisers], the professional congress organiser appointed by [named healthcare organisation] for this congress.

To apply for an industry sponsored symposium slot at the [named healthcare organisation congress] 2025, [named healthcare organisation] required that companies registered for a symposium slot by 8 November 2024 and submitted an abstract for the symposium by 22 November 2024. We were unable to ascertain the actual date that Otsuka applied for an industry sponsored symposium slot but Otsuka received email confirmation of our application on 8 November 2024 and on the same date an email reminder was received requesting that we submit the online abstract submission form by the 22 November 2024. The purpose of this abstract submission was to provide information to allow the [named healthcare organisation] committee to decide on whether to grant a symposium slot. [Named congress organisers] confirmed that this submission was for the scientific committee's review and not for publication when asked as part of our investigation.

We were unable to ascertain the exact date when Otsuka submitted the abstract for this symposium but Otsuka received confirmation by email that our symposium slot had been granted on 18 December 2024. This email also confirmed that the final programme needed to be uploaded by 4 March 2025. An email between Otsuka and our agency on 8 January 2025 shared the abstract that had been submitted.

When the person responsible for this symposium at Otsuka was preparing to submit the final programme for the symposium using the online portal, it appears that they were unsure which elements of the form would be published in the Industry Sponsored Sessions Programme. They emailed [named congress organisers] on 3 March 2025 asking if the abstract and learning objectives will be published too, as some of this information was prepopulated in the form. [Named congress organisers] responded by email on the same day confirming that the learning objectives would not be published but unfortunately the person responsible for this symposium did not pursue clarity on whether the abstract would be published. As this person has left Otsuka we cannot ask the person as to why this question was not clarified. Otsuka subsequently submitted the final programme with the abstract text as previously submitted. When questioned during our investigation, [Named congress organisers] stated that the abstract field should have

been titled “description” and this has now been changed on their system as of February 2026.

On 2 April 2025 [named congress organisers] emailed Otsuka requesting that Otsuka check the details of our two industry sponsored symposia and that the layout would mirror that in the scientific planner. These did not contain the description text that the complainant has referenced, and Otsuka confirmed that the details were correct by email.

Despite the abstract text not being present when Otsuka checked the details of the two symposia as described above, text entered in the “abstract” field of the programme submission form was subsequently displayed in the description field on the page for the symposium on the Industry Sponsored Sessions Programme, which was accessible on the [named healthcare organisation congress] 2025 website. [Named congress organisers] was unable to confirm when this description text was published. When Otsuka’s agency became aware that the page for Otsuka’s industry sponsored symposium had been published in the online programme they emailed [named congress organisers] on 30 April 2025 asking for the page to be taken down, as one of the speakers listed had not signed a written agreement and therefore was not confirmed to speak. Otsuka’s agency does not recall seeing the abstract published on the symposium page at this time.

The Lupkynis European Summary of Product Characteristics (‘SmPC’) were uploaded to the congress platform at a later date to be available for those watching the symposium online. Otsuka included the legal classification and the cost within the content of the presentation at the symposium. The investigation was unable to establish evidence that the SmPC was deliberately provided for publication on the symposium page in the programme, as opposed to being intended for restricted use during the live or on-demand symposium.

Based on the information above, whilst it appears that Otsuka did not intend for the abstract to be published in the online Industry Sponsored Sessions Programme, Otsuka is ultimately responsible for this and that the page for this symposium in the programme promoted Lupkynis.

Complaint

The complainant appears to have raised 12 allegations relating to the page into the online Industry Sponsored Sessions Programme for Otsuka’s promotional symposium. We have responded to each of these allegations below.

Allegation 1 ‘The information states at the top of the page that This session is sponsored by: Otsuka Pharmaceutical Europe Ltd. However, the image in top right of the page states that this was a promotional symposium organised and funded by Otsuka Pharmaceutical Europe Ltd and intended for healthcare professionals. This means that the main sponsorship statement is misleading.’

As stated by the complainant, the page for this symposium in the online Industry Sponsored Sessions Programme contained the statement ‘This session is sponsored by: Otsuka Pharmaceutical Europe Ltd’ at the top of the page. There was a thumbnail image

in the top right of the page, which if clicked on opened an advert for this symposium. That advert contained a more detailed statement, it stated 'Otsuka Pharmaceutical Europe Ltd. are a sponsor of [named healthcare organisation congress]. A promotional symposium organised and funded by Otsuka Pharmaceutical Europe Ltd, intended for Healthcare Professionals only'.

All industry sponsored symposia pages detailed in the online programme contain the statement 'This session is sponsored by...' Otsuka attempted to provide a more detailed statement so that readers were immediately able to understand the extent of the company's involvement and influence; however, this statement was not sufficiently prominent as it required clicking on the thumbnail image to access the advert where this more detailed statement was contained. Therefore, Otsuka accepts a breach of Clause 5.6.

Allegation 2 'A link to the SmPC is provided but the full PI requirements are not met'

Clause 12.1 requires that the prescribing information listed in Clause 12.2 must be provided in a clear and legible manner in all promotional material. Clause 12.2 allows the summary of product characteristics to be provided for certain elements of the prescribing information. A direct, single click link to the Lupkynis European SmPC was provided. However, the material did not include, either by inclusion as text, or by way of a clear and prominent, direct, single click link, the legal classification and the cost. Furthermore, Otsuka was unable to ascertain if the SmPC was available at the same time the promotional information was uploaded to the online Industry Sponsored Sessions Programme. As the page for this symposium in the programme was promotional for Lupkynis, Otsuka accepts a breach of Clause 12.1.

Allegation 3 'There is no AE reporting statement'

Otsuka confirms that the page in the online Industry Sponsored Sessions Programme for Otsuka's sponsored symposium did not include the adverse event reporting statement as required by Clause 12.6. Otsuka therefore accepts a breach of Clause 12.6.

Allegation 4 'There is no date of preparation'

The page into the online Industry Sponsored Sessions Programme did not include the date on which the promotional material was created or last revised, as required by Clause 12.5. However, Otsuka have not been asked to respond in relation to the requirements of this clause.

Allegation 5 'There is no job code'

The Guidelines on Company Procedures Relating to the 2024 ABPI Code of Practice for the Pharmaceutical Industry states that *'For materials/activities that are required to be certified under the Code, each certificate should bear a reference number with the same reference number appearing on the material, item, etc. in question or some other means so that there can be no doubt as to what has been certified and the certificate can be matched to the material.'* However, the Guidelines also state that they 'are regarded as good practice'. The ruling in Case AUTH/3640/5/22 indicated that this requirement is

good practice rather than a requirement of the Code. Therefore, Otsuka denies a breach of the Code on this point.

Allegation 6 ‘The wording refers to the treatment of SLE and LN but voclosporin is only licensed for LN’

The wording in the symposium description is not clear what Lupkynis is indicated for and may give some readers the impression that it is indicated for both the treatment of systemic lupus erythematosus (SLE) and LN. Otsuka accepts a breach of Clause 6.1 and a breach of Clause 11.2. Clause 11.1 requires that a medicine must not be promoted prior to the grant of the marketing authorisation. As Lupkynis had a marketing authorisation, Otsuka does not consider that this clause is relevant in this case and therefore denies a breach of Clause 11.1.

Allegation 7 ‘Voclosporin is referred to as a newly approved treatment yet was launched over 1 year ago’

Lupkynis received EMA approval in September 2022. Therefore, at the time of symposium in June 2025 it had been approved for over 1 year. Clause 6.5 states that the *‘word ‘new’ must not be used to describe any product or presentation which has been generally available, or any therapeutic indication which has been promoted, for more than twelve months in the UK.’* As the material described Lupkynis as ‘newly approved’ rather than ‘new’, Otsuka does not consider that Clause 6.5 is relevant and denies a breach of this clause. However, Otsuka accepts that by describing Lupkynis as ‘newly approved’ this may have misled some readers into understanding that approval was later than it was, and Otsuka accepts a breach of Clause 6.1

Allegation 8 ‘Voclosporin is referred to a milestone is the management but it is not clear why it is milestone. This is misleading, ambiguous and not capable of substantiation’

The description field of the online Industry Sponsored Sessions Programme stated that *‘The approval of belimumab and voclosporin represents a milestone in the management.’* The description of these medicines as a milestone was because Benlysta (belimumab) was the first medicine approved for LN by the FDA and EMA, and Lupkynis was the first oral medicine approved for LN by the FDA and EMA. However, as it was not clear why voclosporin was referred to as a milestone on the symposium page, Otsuka accept a breach of Clause 6.1 and a breach of Clause 6.2. Otsuka does not consider this to be a breach of Clause 14.4 as we consider that these medicines are milestones in the treatment of LN.

Allegation 9 ‘It positions obinutuzumab as a treatment for LN and that it will likely be marketed soon but this is misleading as at the time of the symposium obinutuzumab did not have a marketing authorisation for the treatment of LN but was available and licensed for chronic lymphocytic leukaemia and follicular lymphoma’

Roche is the Marketing Authorisation Holder for Gazyvaro (obinutuzumab). It was initially approved by the EMA in 2014 for Chronic Lymphocytic Leukaemia (CLL). At the time of Otsuka’s symposium it was approved for both CLL and follicular lymphoma. Full details

of these indications can be found in the current Gazyvaro summary of product characteristics.

Clause 1.11 defines 'promotion' as '*any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines*' (emphasis added). Clause 11.1 prohibits the promotion of a medicine prior to the grant of the marketing authorisation and Clause 11.2 prohibits the promotion of a medicine outwith the terms of its marketing authorisation. As Gazyvaro is not Otsuka's medicine Clause 11.1 and 11.2 do not apply. This is supported by the rulings in Case AUTH/2842/4/16 and Case AUTH/3524/6/21.

The statement in the symposium description '...other substances such as obinutuzumab have met the primary endpoint of their approval trial and will likely be marketed soon' may be interpreted by some readers that Gazyvaro was already approved for LN but was not yet promoted for LN. However, Gazyvaro did not receive EMA approval for a LN in indication until December 2025. Therefore, Otsuka accepts a breach of Clause 6.1.

Allegation 10 'All the above suggest that this was not certified'

As the page for this symposium in the online Industry Sponsored Sessions Programme was promotional it required certification as per Clause 8.1. The description text on the page which included reference to voclosporin cited by the complaint was not certified, as there was no intention or understanding by Otsuka that this description would be published, and Otsuka accepts a breach of Clause 8.1. The thumbnail in the top right-hand corner of the page opened an advert for the symposium and this advert was certified. As the meeting was held in [named country], the certificate was signed by a signatory from [named country] as well as an ABPI Code signatory. The qualifications of the Otsuka ABPI Code signatory for this material is enclosed. This advert was intended to be displayed on a digital signage board at the [named healthcare organisation congress], rather than in the online Industry Sponsored Sessions Programme. A separate advert for the symposium was certified and sent to [named congress organisers] for inclusion in the programme, however [named congress organisers] did not use this advert.

Clause 8.3 requires the certification of certain non-promotional material, which does not apply to the entry page into the online Industry Sponsored Sessions Programme subject to the complaint. Consequently, Otsuka denies a breach of Clause 8.3.

Allegation 11 'As this information was available to the public it also constitutes promotion to the public'

Otsuka does not have a breakdown of attendee types for the [named healthcare organisation congress], however, like many medical congresses it is attended by healthcare professionals (HCPs) and those that are not HCPs such as researchers, students and patient organisations. Therefore, the online Industry Sponsored Sessions Programme is likely to be viewed by those people attending the [named healthcare organisation congress] that are not HCPs. As the page in the programme promoted Lupkynis, Otsuka accepts that this also promoted Lupkynis to the public. Therefore, Otsuka accepts a breach of Clause 3.2.

Allegation 12 ‘Some of these issues are very serious in their own right but collectively this number of issues is embarrassing the pharmaceutical industry’

Given the breaches of the Code acknowledged above, Otsuka accepts that this amounts to a failure to maintain high standards in breach of Clause 5.1. However, Otsuka does not consider that it has brought discredit upon the pharmaceutical industry and denies a breach of Clause 2.

Upon receipt of this complaint, as the online Industry Sponsored Sessions Programme was still accessible, Otsuka promptly requested that this page for our symposium was removed. [Named congress organisers] confirmed that the symposium page could not be accessed via the programme on 3 February 2026 and that they could not be accessed using the direct URL on 3 March 2026.”

FURTHER INFORMATION FROM OTSUKA EUROPE

Further information was provided by Otsuka Europe following a request from the case preparation manager to consider the requirements of Clause 12.5 of the 2024 Code. The response from Otsuka Europe is reproduced below:

“We are surprised to be asked to respond to an additional clause in relation to this complaint. In our response submitted on 13 March 2026 we acknowledged that the complainant had alleged that the date of preparation was missing and that we had not been asked to respond in relation to Clause 12.5 of the Code (extract below):

‘Allegation 4 ‘There is no date of preparation’

The page into the online Industry Sponsored Sessions Programme did not include the date on which the promotional material was created or last revised, as required by Clause 12.5. However, Otsuka have not been asked to respond in relation to the requirements of this clause.’

In your email of 14 May 2026, you stated that you had considered our response and referred our case to the Panel but did not request that we additionally consider Clause 12.5. Even though we were not asked to respond to Clause 12.5, our response sets out our position in relation to the material in question complying with Clause 12.5. Therefore, we have nothing further to add to our original response in relation to this.”

PANEL RULING

This case was in relation to a webpage regarding an Otsuka Europe sponsored symposium at the 2025 [named healthcare organisation congress], which appeared in the industry sponsored session programme section of the congress website. The symposium was titled *“Multi-target treatments and a multidisciplinary approach: How they can improve care for patients with lupus nephritis”*.

The complainant raised concerns about the webpage including that:

1. the sponsorship statement at the top of the webpage was misleading regarding Otsuka Europe’s involvement,

2. the webpage omitted information required for promotional material, including the full prescribing information, adverse event reporting statement, date of preparation and job code,
3. the webpage referred to the treatment of systemic lupus erythematosus (SLE) and lupus nephritis (LN) when voclosporin was only licensed for LN,
4. voclosporin was referred to as a “newly approved treatment” despite being launched over a year earlier,
5. the claim that the approval of voclosporin represented a milestone in management was misleading, ambiguous and not capable of substantiation,
6. the webpage positioned obinutuzumab as a treatment for LN which was likely to be marketed soon, when, at the time, obinutuzumab was not licensed for the treatment of LN but was licensed for chronic lymphocytic leukaemia and follicular lymphoma,
7. the webpage had not been certified,
8. it constituted promotion to the public as the webpage was available to members of the public.

The symposium webpage

The complainant provided a link to the webpage which appeared in the industry sponsored session programme section of the congress website. The webpage related to an Otsuka Europe sponsored symposium at [named healthcare organisation congress] 2025. At the top of the webpage was “*This session is sponsored by Otsuka Pharmaceuticals Europe Ltd*”, to the right of which was a small thumbnail image that displayed an advert for the symposium when expanded.

Beneath the sponsorship declaration statement was the title of the symposium (“*Multi-target treatments and a multidisciplinary approach: How they can improve care for patients with lupus nephritis*”) along with logistical details for the symposium, a description of the symposium, a link to the EU summary of product characteristics (SPC) for Lupkynis (voclosporin), details of the chair and a session outline.

The description field contained the following information:

“The management of systemic lupus erythematosus (SLE) and lupus nephritis (LN) is attractive to the nephrology community as evidenced by high participation rates in prior Europe Renal Association (ERA) E-seminars (Frangou E, as IWG contribution) and full lecture halls during live conferences, but also became more complicated over the past years. The approval of belimumab and voclosporin represents a milestone in the management, and other substances such as obinutuzumab have met the primary endpoint of their approval trial and will likely be marketed soon. As the approval of new substances increase complexity, LN was the first disease entity which received attention by [named kidney disease organisation] and the LN guidelines were updated. In parallel, new SLE recommendations were issued by the [named rheumatology organisation] and new LN recommendations by EULAR are currently drafted.

This symposium will summarise “older” therapies and how the newly approved treatment options can be incorporated in the management of LN cases. This will include discussions on belimumab (BLISS-LN), voclosporin (AURORA1 and AURORA2) and obinutuzumab (REGENCY). The symposium should also include an outlook for future therapy options (“CAR-T cells” and others). Besides the importance to preserve nephron

mass in the management of LN, this symposium should also focus on the management of extra-renal manifestations and especially the importance of a multi-disciplinary management to overcome the burden of fatigue, reduced quality of life and the impact thereof on occupancy. Management issues encountered by other specialities such as rheumatologists or dermatologists will be outlined and specific therapies approved for non-renal SLE, such as anifrolumab, will be discussed in this context.

Besides treatment of active disease (“remission induction”), long-term prescription of immunosuppression is reality. Our symposium will also discuss the relevance of avoiding disease relapses during follow-up, as renal relapses will lead to nephron loss and subsequent reduction in GFR. As such, “safe” reduction and eventual withdrawal of immunosuppression has become reality only in the context of repeat kidney biopsies. While such an approach is invasive and often disregarded by affected patients, our symposium will outline that this is an essential point moving forward in the individualisation of therapy.

In summary, relevant points for nephrologists are tackled from different perspectives in our symposium. These include the implementation of novel therapies in the management of SLE and LN, when referral to other specialities needs to be considered to optimise extra-renal disease manifestations and improve quality of life, and finally discussion around the ideal duration of therapies to prevent disease relapses and thereby worsening of chronic kidney disease.”

Otsuka Europe submitted that the information which appeared in the description had originally been submitted as a symposium abstract which formed part of an application for an industry sponsored symposium slot at the [named healthcare organisation congress] 2025. The purpose of the abstract was to provide information to allow the [named healthcare organisation] committee to decide on whether to grant a symposium slot.

During submission of the final programme for the symposium, the Otsuka Europe employee responsible sought clarification as to whether the abstract and learning objectives would be published as some of this information was pre-populated in the online form. It was confirmed that the learning objectives would not be published but further clarity was not obtained as to whether the abstract would be published. Otsuka Europe stated it submitted the final programme with the abstract text as previously submitted.

Otsuka Europe submitted that, when it was requested to check the symposium details, the description text was not displayed. However, text entered in the abstract field of the programme submission form was subsequently displayed in the description field on the page for the symposium in the programme accessible on the [named healthcare organisation congress] 2025 website.

Otsuka Europe accepted that while it did not intend for the abstract to be published in the online programme, it was ultimately responsible for this page.

The Panel considered each allegation in turn.

Misleading sponsorship statement (Clause 5.6)

The complainant stated that whilst the top of the webpage stated that the session was sponsored by Otsuka Pharmaceuticals Europe Ltd, the image in the top right of the page stated that the session was a promotional symposium organised and funded by Otsuka Pharmaceutical Europe Ltd. The complainant alleged that this meant the main sponsorship statement was misleading.

Otsuka Europe submitted that all industry sponsored symposia pages detailed in the online programme contained the statement “*This session is sponsored by...*” and that it had attempted to provide a more detailed statement so that readers were immediately able to understand the extent of the company’s involvement and influence. However, it acknowledged that this statement was not sufficiently prominent as it required clicking on the thumbnail image to access the advert where a more detailed statement was contained.

Clause 5.6 of the Code included, amongst other things:

“Material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company or in which a pharmaceutical company has any other involvement, must clearly indicate the role of that pharmaceutical company.”

The supplementary information to Clause 5.6 included, amongst other things:

“The wording of the declaration of involvement must be unambiguous so that readers are immediately able to understand the extent of the company’s involvement and influence...The declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material are aware of it at the outset.”

The Panel noted that once the thumbnail image was expanded, an advert for Otsuka Europe’s symposium was displayed, which stated towards the top of the page that “*Otsuka Pharmaceuticals Europe Ltd. are a sponsor of [named healthcare organisation congress] 2025*” and that this session was “*a promotional symposium organised and funded by Otsuka Pharmaceuticals Europe Ltd, intended for Healthcare Professionals only*”.

In the Panel’s view, the generic sponsorship statement at the top of the webpage did not make sufficiently clear the extent of Otsuka Europe’s involvement, including that it had organised and funded the symposium. This was only apparent if the small thumbnail image was clicked which the Panel considered not all viewers would necessarily do. The Panel therefore considered that readers would not immediately be able to understand the extent of Otsuka Europe’s involvement and influence. The Panel ruled a **breach of Clause 5.6**, as acknowledged by Otsuka Europe.

Information omitted from the webpage (Clauses 12.1, 12.5 and 12.6)

The complainant alleged that although the webpage included a link to the Lupkynis SPC, the full prescribing information requirements were not met. The complainant also alleged that the webpage contained no adverse event reporting statement, date of preparation or job code.

Otsuka Europe accepted that the symposium webpage in the programme was promotional for Lupkynis and whilst a link to the SPC was provided, it did not include the legal classification and cost as listed in Clause 12.2. Otsuka Europe also acknowledged that the webpage did not

include an adverse event reporting statement or a date on which the material was created or last revised as required by Clause 12.5 and 12.6, but that the inclusion of a reference number was regarded as good practice rather than a requirement of the Code.

The first matter for the Panel to consider was whether the description section of the webpage was promotional. The Panel noted the section clearly referred to voclosporin, the non-proprietary name of Lupkynis as a treatment for lupus nephritis and that its approval represented a milestone. The Panel therefore considered the content could not be considered anything other than promotional for Lupkynis and that the requirements of Clause 12, amongst other things, applied.

The Panel considered that although the webpage provided a link to the SPC, this did not alone satisfy the requirements of Clause 12.2 of the Code. The webpage also did not include the required adverse event reporting statement or the date on which the material was created or revised. The Panel ruled **breaches of Clauses 12.1, 12.5 and 12.6**, as acknowledged by Otsuka Europe.

The Panel noted that the Code did not refer to “job codes” or reference numbers, but they were referred to in the Guidelines on Company Procedures Relating to the Code of Practice in relation to ‘Certification and Examination’. They were considered good practice as a way of ensuring that a certificate was linked to a specific piece of material. No clause had been raised in relation to this matter and so the Panel made **no ruling**.

Off-label promotion (Clause 11.1, 11.2 & 6.1)

The complainant alleged that the wording in the description referred to the treatment of SLE and LN but that voclosporin was only licensed for LN.

Otsuka Europe submitted that the wording in the symposium description did not make it clear what Lupkynis was indicated for and may have given some readers the impression that it was indicated for both the treatment of SLE and LN. Otsuka denied a breach of Clause 11.1 on the basis that Lupkynis had a marketing authorisation at the relevant time.

Clause 11.2 of the Code stated:

“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....”

Section 4.1, Therapeutic indications, of the SPC for Lupkynis stated it was *“indicated in combination with mycophenolate mofetil for the treatment of adult patients with active class III, IV or V (including mixed class III/V and IV/V) lupus nephritis (LN).”*

The Panel noted that the first paragraph of the symposium description stated that *“the management of systemic lupus erythematosus (SLE) and lupus nephritis (LN) is attractive..”* and that the *“approval of belimumab and voclosporin represents a milestone in the management...”* The description later referred to *“the implementation of novel therapies in the management of SLE and LN.”* The Panel considered that, taken together, these statements gave the impression that voclosporin was approved for both SLE and LN, which was not so. The Panel therefore

concluded that the webpage promoted Lupkynis outside the terms of its marketing authorisation and ruled a **breach of Clause 11.2**, as acknowledged by Otsuka Europe.

The Panel noted that Clause 11.1 prohibited the promotion of a medicine prior to the grant of its marketing authorisation. Lupkynis had a marketing authorisation at the time of complaint, and the Panel therefore ruled **no breach of Clause 11.1**.

Whilst the Panel noted that Otsuka Europe had also accepted a breach of Clause 6.1 in relation to this allegation, it did not consider that the complainant had made an allegation in relation to this specific clause and so made no ruling.

Reference to “newly approved treatment” (Clause 6.5)

The complainant raised concerns that the symposium description referred to voclosporin as a newly approved treatment when it had been launched over a year earlier.

Otsuka Europe submitted that Lupkynis received EMA approval in September 2022 and had therefore been approved at the time of the symposium (June 2025) for over one year. Otsuka Europe accepted that describing Lupkynis as “newly approved” may have misled some readers into understanding that the approval of Lupkynis was later than it was. However, as the material did not describe Lupkynis as “new”, Otsuka Europe submitted that Clause 6.5 was not relevant.

Clause 6.5 of the Code stated:

“The word ‘new’ must not be used to describe any product or presentation which has been generally available, or any therapeutic indication which has been promoted, for more than twelve months in the UK.”

The Panel noted that the description stated that the symposium “*will summarise “older” therapies and how the newly approved treatment options can be incorporated in the management of LN cases. This will include discussions on belimumab (BLISS-LN), voclosporin (AURORA1 and AURORA2) and obinutuzumab (REGENCY)*”.

The Panel noted Otsuka Europe had provided the date of the European marketing authorisation but had not provided the date of authorisation in the UK. The Panel took into account Otsuka Europe’s acceptance that reference to Lupkynis as “newly approved” could be misleading and considered it did not dispute the complainant’s assertion that Lupkynis had been approved for more than twelve months.

The Panel considered that reference to “newly approved treatment options”, in the context in which it appeared and immediately followed by reference to voclosporin, meant a reader would, on the balance of probabilities, conclude that “newly approved” was synonymous with “new”. The Panel therefore did not accept Otsuka Europe’s submission that use of “newly approved” rather than “new” meant that Clause 6.5 did not apply. Noting that Lupkynis appeared to have been approved for several years by the time of the symposium, the Panel ruled a **breach of Clause 6.5**.

Whilst the Panel noted that Otsuka Europe had accepted a breach of Clause 6.1 in relation to this allegation, it did not consider that the complainant had made an allegation in relation to this specific clause and so made no ruling.

“Milestone” claim (Clauses 6.1, 6.2, 14.4)

The complainant stated that, in the symposium description, voclosporin was referred to as a “milestone”, but that it was not clear why it was a milestone. The complainant alleged that this was misleading, unambiguous and not capable of substantiation.

Otsuka Europe submitted that the approval of voclosporin represented a milestone because it was the first oral medicine approved for the treatment of LN by the FDA and EMA. It acknowledged, however, that the webpage was not clear why voclosporin was referred to as a milestone.

The Panel noted the symposium description stated, “*The approval of belimumab and voclosporin represents a milestone in the management...*” and that this was followed by reference to treating LN and SLE.

The Panel considered that, in the absence of further information, the statement was unqualified and ambiguous as to the basis on which the approval of voclosporin was considered a milestone. In the context of references to both SLE and LN, the Panel considered it might imply that voclosporin was considered a milestone in the management of both SLE and LN, when voclosporin was only licensed for the treatment of LN. The Panel therefore considered the statement to be ambiguous and misleading and ruled a **breach of Clause 6.1**, as acknowledged by Otsuka Europe. The Panel considered the misleading impression was not capable of substantiation and ruled a **breach of Clause 6.2** accordingly, as acknowledged by Otsuka Europe.

The Panel noted Clause 14.4 required promotion to encourage the rational use of a medicine by presenting it objectively, without exaggerating its properties and that claims should not imply that a medicine had some special merit, quality or property unless this could be substantiated. The Panel considered that the complainant had not raised a specific allegation in relation to this clause and that its concerns regarding the milestone claim had been adequately addressed by its rulings above. The Panel therefore ruled **no breach of Clause 14.4**.

Information regarding obinutuzumab (Clauses 6.1, 11.1, 11.2)

The complainant stated that the symposium description positioned obinutuzumab as a treatment for LN, due to be marketed soon, when, at the time of the symposium, it was licensed for chronic lymphocytic leukaemia and follicular lymphoma. The complainant alleged this was misleading.

Otsuka Europe submitted that Gazyvaro (obinutuzumab) was not one of its medicines and that Clauses 11.1 and 11.2 did not apply. However, it acknowledged a breach of Clause 6.1 on the basis that the statement in the description may have been interpreted by some readers to mean that obinutuzumab was already approved for LN, when it did not receive EMA approval for LN until December 2025.

The relevant excerpt of the symposium description included “...and other substances such as obinutuzumab have met the primary endpoint of their approval trial and will likely be marketed soon.”

The Panel noted that Clause 1.17 of the Code defined promotion as any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of **its medicines** (emphasis added by the Panel). The Panel noted that Gazyvaro was marketed by Roche and in that regard, it was an established principle that a pharmaceutical company could not promote another company's medicine. Consequently, the Panel ruled **no breaches of Clauses 11.1 and 11.2**.

Clause 6.1 of the Code referred to information, claims and comparisons and the Panel considered it was not limited to the promotion of a company's own medicines. In the Panel's view, the statement that obinutuzumab "will likely be marketed soon" made clear that it was not yet licensed for LN. Therefore, the Panel did not consider this statement to be misleading in this regard and ruled **no breach of Clause 6.1**.

Certification (Clauses 8.1, 8.3)

The complainant alleged that issues identified suggested that the webpage had not been certified.

Otsuka Europe submitted that the description text on the webpage, which included reference to voclosporin, was not certified as there had been no intention or understanding by Otsuka that this description would be published.

Clause 8.1 of the Code required that promotional material must not be issued unless its final form had been certified. Noting its determination above, that the webpage was promotional for voclosporin, the Panel ruled a **breach of Clause 8.1**, as acknowledged by Otsuka Europe.

Clause 8.3 of the Code required certain non-promotional materials to also be certified in advance in a manner similar to Clause 8.1. Noting its determination above that the webpage was promotional for voclosporin, the Panel ruled **no breach of Clause 8.3**.

Promotion to the public (Clause 3.2)

With regard to the allegation that the symposium webpage was available to the public, Otsuka Europe submitted that the [named healthcare organisation congress] was attended by those that were not classed as health professionals such as researchers, students and patient organisations, and consequently the industry sponsored session programme was likely viewed by those attending the conference that were not health professionals.

The Panel noted that the webpage appeared to be accessible without any requirement for a viewer to confirm that they were a health professional, and that the webpage did not state the intended audience. Noting its determination above that the webpage was promotional for voclosporin, and Otsuka Europe's submission that non-health professional attendees of the [named healthcare organisation congress] would likely have accessed the industry sponsored session programme containing the webpage in question, the Panel considered that, on the balance of probabilities, the webpage promoted a prescription only medicine to the public and ruled a **breach of Clause 3.2**, as acknowledged by Otsuka Europe.

Overall (Clauses 5.1, 2)

The complainant alleged that some of the issues with the symposium page were “very serious in their own right” and that collectively the number of issues was “embarrassing” to the pharmaceutical industry.

The Panel noted Otsuka Europe’s submission that the publication of the symposium description in the online industry sponsored session programme was unintentional but that it was ultimately responsible for the content published on the page. The Panel further took into account that although clarification had been sought as to whether information would be published, sufficient clarification had not been obtained in relation to the abstract before the final programme was submitted.

The Panel took into account its determinations above including that the webpage, which was accessible to the public, promoted voclosporin outside the terms of its marketing authorisation and omitted important obligatory information such as the prescribing information and adverse event reporting statement. In this regard, the Panel considered that Otsuka Europe had failed to maintain high standards and ruled a **breach of Clause 5.1**, as acknowledged by Otsuka.

Clause 2 was a sign of particular censure and reserved for such use. The Panel noted Otsuka Europe’s submission that when it had been asked to check the symposium details, the description was not displayed and considered that it appeared to have been let down in this regard. The Panel considered that the matters raised by the complainant were adequately covered by its rulings above, including its ruling of a breach of Clause 5.1, and did not consider that it had been established that a breach of Clause 2 was warranted. The Panel therefore ruled **no breach of Clause 2**.

Complaint received 28 January 2026

Case completed 29 September 2026