København, den 17. november 2025

AFGØRELSE

Afgørelse vedr. KO-2025-4040 - reklamemateriale

Granskningsmandspanelet har dags dato truffet følgende afgørelse i klagesagen imellem parterne:

Klager: AbbVie A/S
Titangade 11
2200 København N
Danmark

og

Indklagede: Johnson & Johnson
Østbanegade 123
2100 København Ø
Danmark

Vedrørende: Reklamemateriale udarbejdet af indklagede.

Resumé:
Johnson & Johnson findes at have overtrådt reglerne i Reklamekodekset § 7, stk. 3, jf. § 4, stk. 2.
Johnson & Johnson findes *ikke* at have overtrådt reglerne i Reklamekodekset § 8, stk. 3.

Baggrund:
AbbVie A/S [AbbVie] indsendte den tirsdag den 21. oktober 2025 en klage over reklamemateriale udarbejdet af Johnson & Johnson, med henblik på en vurdering af, hvorvidt reklamen er i strid med Reklamekodekset.

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AbbVies bemærkninger

AbbVie har den 21. oktober 2025 fremsendt følgende bemærkninger til sagen:

> *"AbbVie A/S wishes to bring to your attention a breach of the ENLI code in the promotional roll-up campaign for Tremfya (guselkumab), which was displayed by Johnson&Johnson (J&J) at the recent annual meeting of the Danish Society for Gastroenterology and Hepatology (DSGH) September 12th, 2025, at Comwell Kolding (see attached).*
>
> *According to the ENLI Code, the following applies:*
> *"Section 7.1. Promotion of medicinal products must encourage the rational use of medicinal products by presenting them objectively and without exaggerating their properties. Claims must not imply that a medicinal product or an active ingredient has qualities or properties, unless this can be substantiated. Such documentation must at reasonable requests from healthcare professionals, promptly be provided."*
> *and*
>
> *"7.3. All information referred to in sections 7.1 and 7.2 must be adequate, objective, accurate, relevant, verifiable and sufficiently complete to enable the recipient to form his own personal opinion of the therapeutic value of the medicinal product."*
>
> ***1. "Healing is possible"– a misleading, exaggerating and unsubstantiated claim***
> *The headline "healing is possible" is misleading and exaggerating Tremfya's properties with regards to Crohn's disease (CD). The reason being that this cannot be substantiated with regards to CD, for which claims are included below the headline.*
>
> *The reference used to verify is the Summary of Product Characteristics (SmPC). However, the SmPC provides no support for the claim for CD.*
>
> *The SmPC includes CD data from the pivotal GALAXI 2 and 3 trials, however, GALAXI 2 and 3 trials did not investigate "mucosal healing" as an endpoint. Instead, the trials evaluated endoscopic response, endoscopic remission, clinical remission and endoscopic response, as well as deep remission (clinical remission + endoscopic remission), but not actual "mucosal healing" (further on the difference below).*
>
> *Rather than "Healing", the wording should therefore be aligned with the SmPC or as minimum*

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clearly and equally prominently state in the actual claims it is "endoscopic remission" findings only in CD or specify "Healing is possible" in UC alone.

To conclude "healing is possible" in the context of Crohn's disease cannot be substantiated based on the endpoints studied, and it gives a misleading exaggerating impression of the data to healthcare professional (HCPs), contrary to ENLI requirements for accurate, objective and verifiable claims in the ENLI code section 7.1 and 7.3.

2. Co-primary endpoint ("endoscopic remission at week 48" is "endoscopic response at week 48")

The claim is misleading because of the word "remission", which is stronger than endoscopic "response" which would have been correct.

The study descriptions in the roll-up are misleading, exaggerating and unsubstantiated. J&J claims that the co-primary endpoints in the GALAXI 2 and 3 trials were "clinical response at week 12 and endoscopic remission at week 48" which is incorrect. According to the approved SmPC, the actual co-primary endpoints are "clinical response at week 12 and endoscopic response at week 48 (as opposed to endoscopic remission at week 48).

This distinction is important, as "endoscopic remission" and "endoscopic response" represent different clinical thresholds and are not interchangeable. Endoscopic response refers to an improvement in the inflammatory state of the intestine, observed by endoscopic examination, while endoscopic remission indicates a complete or near-complete disappearance of active inflammation and its endoscopic signs.
Using "remission" instead of "response" thereby substantially exaggerates the efficacy outcome and may mislead HCPs about the clinical results.

This overstatement of product benefit is expressly prohibited under ENLI codes (e.g., section 7.1: (Claims must not be misleading, and product properties must not be exaggerated).

3. Using secondary endpoints from Head-to-head trials in comparative advertisements

Additionally, it is important to note that all head-to-head endoscopic analyses comparing guselkumab and ustekinumab in CD are based on major secondary endpoints, not primary endpoints. The GALAXI 2/3 studies are explicitly designed to investigate clinical remission and response against placebo as co-primary endpoints whereas head-to-head results are only

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secondary endpoints in the trial hierarchy.

This distinction is not clearly specified in the campaign material which risks misleading HCPs by suggesting head-to-head superiority to ustekinumab as a primary outcome. See ENLI Guidance to 7.3 (documentation): where it is stated that "Claims about one medicine vs. another must be documented.

The distinction matters because primary endpoints are the main outcomes a clinical trial is designed to evaluate. Secondary endpoints, while important, assess additional effects and are usually considered supportive evidence. Presenting secondary endpoint data in a comparative advertisement without clear labelling can be misleading, as it may give the impression that these results represent the primary, most significant findings of the study, thus overstating the strength of the evidence. To ensure ethical and accurate communication, especially in accordance with ENLI requirements, it is essential to be transparent about which endpoints the data refer to, helping HCPs interpret the clinical relevance and strength of the evidence appropriately.

Such misrepresentations may affect the perception of Tremfya's efficacy and influence prescribing behavior based on unsupported or overstated claims (Section 7.1, section 7.2 and section 7.3).

We respectfully request that ENLI reviews this promotional material and instructs Johnson & Johnson to correct the claims, ensuring all campaign information accurately reflects the evidence and endpoints reported in the approved SmPC and pivotal clinical trials."

Johnson & Johnsons bemærkninger

Sagen blev sendt i høring den 22. oktober 2025, jf. ENLI's Sagsbehandlingsregler § 9. I høringssvar af 4. november 2025 havde Johnson & Johnson følgende bemærkninger;

"OUR COMMENTS
As said Janssen is highly surprised by Abbvie's Complaint. Indeed, in the intercompany dialogue that preceded the Complaint Janssen has confirmed to Abbvie – and on numerous occasions – that:

(i) we have indeed ceased and desisted the use of the claims in the Advertisement as early

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as beginning of October soon after these were raised to our attention by Abbvie, initially on 1 October 2025;

(ii) we would no longer be using the Advertisement and/or same claims in the future; and

(iii) our Tremfya promotional / marketing claims are otherwise undergoing a new, internal company review and approval process, which is currently still in progress.

***Annex 3* – Exchange of correspondence between Abbvie and Janssen**

For the sake of completeness, Janssen confirms that no new materials /claims with the same or similar "healing" claims have been put for circulation in Denmark since the start of the dispute.

As such, Abbvie's complaint to ENLI is both surprising and entirely unnecessary and appears to be vindicative. It should be rejected as being without object.

On Claim1:

First, Janssen has immediately removed this claim from circulation and is currently re-evaluating it, making Abbvie's claim without object.

Second, Janssen have otherwise confirmed to Abbvie that if the term "healing" is indeed used again in the future – which is undecided for now - Janssen will ensure to further clarify, contextualize and reference in more detail what is meant by "healing" in compliance with applicable laws and the ENLI Code of Ethics.

In any case, regarding the use of the claim "healing is possible", Janssen emphasizes that it has not claimed that "mucosal healing is possible".

*As is widely known in the community of health care professionals experts in Inflammatory Bowel Diseases ("**IBD**"), there are different layers of healing possible in IBD.[1] In other words Abbvie's argument that "healing" can only mean "mucosal healing" should be rejected.*

*As a way of background, endoscopic remission is associated with improved long-term clinical outcomes in CD, and the so-called "SES-CD score" is a widely accepted assessment of endoscopic disease activity in clinical trials. The STRIDE-II guidelines provide evidence and consensus-based recommendations from the International Organization for the Study of IBD (**"IOIBD**") regarding clinically appropriate treat-to-target treatment goals in IBD.[2] In these widely cited recommendations, "endoscopic healing" has been identified as a long-term treatment target, and*

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in CD the recommended measure for this treatment target is an SES-CD of < 3 points or an absence of ulcerations (e.g. SES-CD ulceration subscore = 0). The consensus panel further stated that "It is widely accepted that treating to the target of endoscopic healing… is associated with improved long-term outcomes and may reduce the risk of bowel damage." As part of their recommendations, they also state that assessment of endoscopic healing can be achieved by sigmoidoscopy or colonoscopy.

Both the GALAXI-2 and -3[3] and GRAVITI[4] studies use an "endoscopic remission" definition per one of the two alternatives recommended in the FDA's guidance for industry, an "SES-CD of 0-4 and at least a 2 point reduction from baseline and with no individual subscore greater than 1".

In Tremfya's SmPC approved by the EC Commission, endoscopic remission is defined as SES-CD Score ≤ 2 and at least a 2-point reduction from baseline and no subscore greater than 1 in any individual component.[5]

As evidenced in the SmPC[5] Tremfya meets those thresholds. Janssen's claim "healing is possible" is therefore scientifically supported as it is anchored to endoscopic remission in CD.

Annex 4 - References

1. *Neurath M.F. et al., Different levels of healing in inflammatory bowel diseases: Mucosal, histological, transmural, barrier and complete healing. Gut 2023*
2. *Turner D. et al., International Organization for the Study of IBD. STRIDE-II: An Update on the Selecting Therapeutic Targets in Inflammatory Bowel Disease (STRIDE) Initiative of the International Organization for the Study of IBD (IOIBD): Determining Therapeutic Goals for Treat-to-Target strategies in IBD. Gastroenterology 2021*
3. *Panaccione R, et al., Efficacy and safety of intravenous induction and subcutaneous maintenance therapy with guselkumab for patients with Crohn's disease (GALAXI-2 and GALAXI-3): 48-week results from two phase 3, randomised, placebo and active comparator-controlled, double-blind, triple-dummy trials. The Lancet. 2025*
4. *Hart A. et al. Efficacy and safety of guselkumab subcutaneous induction and maintenance in participants with moderately to severely active Crohn's disease: results from the phase 3 GRAVITI study. Gastroenterology. 2025*
5. *TREMFYA® SmPC (www.ema.europa.eu/en/documents/product-information/tremfya-epar-product-information_en.pdf)*

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On Claim 2:

Here, we have acknowledged from the outset, in our first reply on 6 October, that the use of the word "remission" instead of "response" was the result of an isolated human error, and that the Claim was immediately withdrawn.

In our first reply to Abbvie, Janssen also committed to (i) correct that specific wording and (ii) refer to "endoscopic response" if choosing to mention this endpoint in the future.

On Claim 3:

Janssen disagrees with Abbvie's arguments.

In this respect, Janssen refers to ENLI's guide on information material and documentation paragraph 7.2 (endpoints and study design):

"It is the opinion of the Investigator's Panel that there is the possibility of differentiation of e.g., secondary or tertiary endpoints, however, always taking into account the medicine's therapeutic indication range and the approved SPC for the medicine, as well as the requirements for adequate and objective advertising. This will often mean that a brief statement of the study, its endpoints and the result thereof (a brief study description) is implemented in order for the advertisement to be considered adequate, cf. Art. 4 (2) of the Promotion Code. This means, inter alia, that only clinically recognized endpoints may be used for the area of therapy that confirms or clarifies the SPC. It is considered essential that the listed study description also provide data for the outcome of the other step-higher endpoints (e.g., the primary endpoint of the study if the secondary endpoint is used as the differentiating element) so that a contextual understanding of the presented endpoint is met, cf. R-2024-0465."

First, the presented secondary endpoints are fully supported by the GALAXI Study, which results have been published in an independent high-impact peer reviewed journal. In fact, the scientific publication refers to these as "major secondary endpoints" in several instances.

Second, Janssen submits that these secondary endpoints have been adequately presented aligned with the guidance above: they were mentioned informatively in a way that does not imply that they are primary endpoints. The primary endpoints as well as the study description and data for the outcome of the other higher endpoints (primary endpoints for both ulcerative colitis and Crohn's disease) were included in the Advertisement footnote. Thus, the presentation of these major secondary endpoints was duly put in context, as per ENLI Guidance.

Annex 4 Exhibit 3 *– The GALAXI 2 and 3 study by Panaccione et al., Lancet. 2025 July (referenced*

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above)

- *1 October 2025: Abbvie asked Janssen to immediately cease and desist the use of the Advertisement ("this misleading material") asking for Janssen reply before EOB 6 October 2025 (Annex 3).*

Janssen replied in several communications that it had ceased to use the said Advertisement, the first time being on 6 October 2025.

- *6 October: Janssen confirms for the first time that we have decided to withdraw the material to take the opportunity to further review and update to the extent needed.*

- *6 October: Abbvie wrote again on 6 October asking Janssen to cease using the problematic claims "in any form", and to confirm by 7 October 2025. Failing that confirmation, Abbvie threatened to file a complaint with ENLI.*

- *7 October: Janssen confirmed for the second time that we had decided to cease the use of the Advertisement ("the specific material that you raised to our attention") highlighting that we were otherwise conducting an overall review of our Tremfya materials. The materials had already been removed from circulation.*

- *7 October: Abbvie wrote again: "(...) you will cease the use of the specific advertisement and review your materials, whereas you do not want to confirm, that you will cease the use of the problematic claims in scope of our complaint requesting another confirmation from Janssen." It seems that Janssen's prior replies and clarifications did not satisfy Abbvie, which is surprising given Janssen had already committed to remove the claims challenged and the full Advertisement rightly reserving itself the right to review and adapt the materials in its discretion.*

- *8 October: Janssen, despite earlier confirmations provided, responded in detail to the concerns set out in Abbvie's initial letter. We confirmed for the third time that we had indeed ceased and desisted the use of the Tremfya material in question and that they were no longer in use. We specified with regard to correction of future claims and/or materials, that this was under review. We also asked for Abbvie's confirmation that we had addressed their concerns suggesting a dialogue between the companies if this had not been the case.*

- *21 October: Despite having duly received the assurances requested, Abbvie informed Janssen*

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in the afternoon, almost two full weeks after our last reply to their ultimate request, that they would proceed to seize ENLI. Abbvie also hinted that they had seen examples where clarifications had been made, but these were "not prominent or balanced". This is inaccurate and wrong – the materials have been removed and new materials are still under consideration. It is therefore unclear what Abbvie alludes to here, which does not provide Janssen with a fair opportunity to respond.

CONCLUSION
In light of the above, we respectfully request that Abbvie's complaint is considered without object, or as a minimum unfounded.

It is true that the Advertisement did include an unfortunate isolated human error with regard to the use of one specific term, which explains why Janssen took the decision to immediately withdraw the materials from the market. This was also done in an attempt to achieve a mutually agreeable resolution between the companies in a manner considered both cost and effort-effective for all parties involved, including ENLI, whilst Janssen reviewed the materials.

This being said, and as described above, Janssen otherwise disagrees with Abbvie's Claims 1 and 3 and therefore respectfully asks ENLI to dismiss the complaint in its entirety"

Granskningsmandspanelet tog herefter sagen op til afgørelse.

Regelgrundlag:
Af Reklamekodeksets § 4, stk. 2, fremgår det, at:

"Reklame for et lægemiddel skal være fyldestgørende og saglig, og den må ikke være vildledende eller overdrive lægemidlets egenskaber. Oplysninger i reklamen skal være i overensstemmelse med lægemidlets godkendte produktresumé."

Af Reklamekodeksets § 7, stk. 1, fremgår det, at:

"Lægemiddelreklamer skal tilskynde rationel brug af lægemidler ved at præsentere lægemidler objektivt og uden overdrivelse af deres egenskaber. Påstande må ikke antyde, at et lægemiddel eller en aktiv bestanddel har særlige fordele, kvaliteter eller egenskaber, medmindre dette kan dokumenteres. En sådan dokumentation skal ved rimelige forespørgsler fra sundhedspersonale kunne tilvejebringes hurtigt."

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Det følger af Reklamekodeksets § 7, stk. 3, at:

> *"Alle oplysninger, jf. stk. 1 og 2, skal være fyldestgørende, saglige, nøjagtige, aktuelle, kontrollerbare og tilstrækkeligt udførlige til, at modtageren kan danne sig en personlig mening om lægemidlets behandlingsmæssige værdi."*

Af Reklamekodeksets § 8, stk. 3, fremgår følgende:

> "*Sammenligninger mellem forskellige lægemidler må ikke være vildledende eller nedsættende."*

Granskningsmandspanelets vurdering og afgørelse:
I forhold til de tre klagepunkter, har Granskningsmandspanelet lavet følgende vurdering:

Ad punkt 1, udsagn om *"healing is possible"*:
Klager påpeger overordnet, at udsagnet er misvisende, overdrivende og udokumenteret, idet lægemidlets produktresumé, som udsagnet underbygges med, ikke indeholder data for Crohns sygdom (CD) svarende til endepunktet *mucosal healing*.

Indklagede anfører, at reklamen er trukket tilbage fra markedet efter forudgående dialog mellem virksomhederne. Indklagede gør desuden gældende, at udsagnet ikke er misvisende, idet lægemidlets produktresumé, anvender endepunktet *endoscopic remission*, der ifølge indklagede opfylder kriterierne for STRIDE-II definition af *'endoscopic healing'.*

Granskningsmandspanelet anerkender klagers argumentation om, at udsagnet *"healing is possible"* mest nærliggende kan tolkes som en henvisning til en række anerkendte og hyppigt anvendte *healing*-endepunkter, såsom *endoscopic healing*, *mucosal healing* og/eller *transmural healing*, som følge af det beslægtede ordvalg. Det står således klart, at begrebet *healing* kan dække over flere forskellige definitioner. Det fremgår imidlertid ikke af materialet, hvad udsagnet konkret henviser til, ud over den generelle reference til produktresuméet, ligesom sådanne endepunkter og ordvalg ikke fremgår af produktresuméet vedr. CD.

Studierne GALAXI 2/3 , som fremgår af lægemidlets produktresumé for CD-indikationen, anvender co-primære endepunkter, der omfatter *clinical response week 12 + clinical remission week 48* samt *clinical response week 12 + endoscopic response week 48*. *Endoscopic response* defineres her som ≥ 50 % forbedring fra baseline i SES-CD-score eller SES-CD-score ≤ 2. Blandt de sekundære endepunkter anvendes

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endoscopic remission, som i studierne defineres som SES-CD-score ≤ 4, ≥ 2-point reduktion fra baseline, og ingen SES-CD delscore > 1 i nogen komponent. I produktresuméet er *endoscopic remission* imidlertid defineret som SES-CD-score ≤ 2 i gennemgangen af selvsamme studier, hvorfor diskrepansen herimellem kan undre.

Indklagede henviser i høringssvaret endvidere til STRIDE-II-konsensusguidelines, hvor *endoscopic healing* er defineret som SES-CD < 3 point eller fravær af ulcerationer (dvs. SES-CD ulceration subscores = 0), og anfører på den baggrund, at udsagnet er *"...scientifically supported as it is anchored to endoscopic remission"* med henvisning til definitionen i produktresuméet under gennemgangen af GALAXI 2/3, som dog afviger fra definitionen anvendt selve publikationen svarende til *endoscopic remission*. Granskningsmandspanelet bemærker, at reklamematerialet ikke indeholder reference til STRIDE-II.

På baggrund af sagens omstændigheder er det Granskningsmandspanelets vurdering, at der bør udvises særlig opmærksomhed og agtpågivenhed vedr. den præcise afgrænsning af definitioner, således at der ikke opstår tvivl om betydning og fortolkning af udsagn i forhold til de bagvedliggende endepunkter.

Granskningspanelet vurderer, at materialet på dette punkt ikke besidder en tilstrækkelig grad af nøjagtighed og udførlighed til at skabe klarhed over betydningen af udsagnet *"healing is possible"*. Det bemærkes, at e*ndoscopic healing* ikke fremgår af lægemidlets produktresumé, selvom det anerkendes, at STRIDE-II-definitionen kan siges at overlappe med definitionen af *endoscopic remission*, som den er angivet i produktresuméet. Dette understreger vigtigheden af præcis, tilstrækkeligt og udførligt informationsniveau i det konkrete materiale, da udsagnet her giver anledning til tvivl om den egentlige betydning og afgrænsning - særligt når der foreligger forskel i den definitoriske afgrænsning af endepunktet mellem SmPC og de bagvedliggende pivotale studier.

Udsagnet vurderes i strid med Reklamekodeksets § 7, stk. 3, hvoraf fremgår, at alle oplysninger skal være fyldestgørende, saglige, nøjagtige, aktuelle, kontrollerbare og tilstrækkeligt udførlige til, at modtageren kan danne sig en personlig mening om lægemidlets behandlingsmæssige værdi.

Klager gives på denne baggrund medhold i klagepunktet.

<u>Ad punkt 2, vedr. vildledende og fejlagtig angivelse af co-primært endepunkt i studiebeskrivelse:</u>
Klager har gjort gældende, at studiebeskrivelsen i det anvendte reklamemateriale er vildledende, overdrivende og udokumenteret, idet beskrivelsen af et co-primært endepunkt fra GALAXI 2/3-studiet fejlagtigt gengiver *endoscopic remission* som delelement. Klager anfører, at dette er urigtigt, idet det korrekte endepunkt i studiet er *endoscopic response*.

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Indklagede har anført, at virksomheden allerede i forbindelse med tidligere dialog har erkendt den fejlagtige angivelse og foretaget de nødvendige korrektioner i det materiale, hvori fejlen måtte have forekommet.

Det er Granskningsmandspanelets vurdering, at studiebeskrivelser i markedsføringsmateriale skal være fyldestgørende, korrekte og nøjagtige. Der påhviler virksomheden et særligt ansvar for at sikre, at gengivelsen af videnskabelige data ikke ved brug af fejlagtige endepunktsdefinitioner kan medføre en urigtig eller misvisende fremstilling af studiets resultater.

I nærværende sag vurderer Granskningsmandspanelet, at forskellen mellem definitionerne af *endoscopic remission* (SES-CD score ≤4, ≥2-point reduktion fra baseline samt ingen SES-CD sub-score >1 i nogen komponent) og *endoscopic response* (≥50 % forbedring fra baseline i SES-CD score eller SES-CD score ≤2) udgør en væsentlig forskel, som har betydning for fortolkningen af de opstillede kliniske tærskelværdier.

Granskningsmandspanelet vurderer derfor, at udsagnet er i strid med Reklamekodeks § 7, stk. 3, hvorefter alle oplysninger skal være fyldestgørende, saglige, nøjagtige, aktuelle, kontrollerbare og tilstrækkeligt udførlige til, at modtageren kan danne sig et selvstændigt og velunderbygget indtryk af lægemidlets behandlingsmæssige værdi.

Klager gives på denne baggrund medhold i klagepunktet.

Ad punkt 3, vedr. Anvendelse af komparative sekundære endepunkter:
Klager påpeger, at et af reklamens iøjnefaldende udsagn *"ved sammenligning med Ustekinumab[#] var Tremfya superior på tværs af endoskopi-drevne resultater ved uge 48[x2]"* fremstilles som en primær intention med studiet, selvom det studie-metodologisk udgør et sekundært endepunkt, hvorfor udsagnet dermed ikke besidder tilstrækkelig transparens i kommunikationen.

Indklagede påpeger, at det præsenterede major secondary end-point er præsenteret informativt, ligesom der i materialets fodnote fremgår en studiebeskrivelse hvor data og resultater af højere ordens endepunkter for hhv. CD og CU-studier er præsenteret, hvorfor påstanden anfægtes.

Granskningsmandspanelet bemærker, at studiedesignet anføres som: *"...phase 3, randomised, double-blind, triple-dummy, registrational trials with head-to-head comparisons with an active comparator (ustekinumab) and a placebo in the treat-through design".* Det bemærkes endvidere, at *"The head-to-head comparisons of guselkumab with ustekinumab at week 48 were first assessed in the pooled GALAXI-2 and GALAXI-3 dataset and then in each study individually. These long-term major secondary endpoints were*

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endoscopic response at week 48, endoscopic remission at week 48, the composite of clinical remission at week 48 and endoscopic response at week 48, deep remission at week 48 (the composite of clinical remission at week 48 and endoscopic remission at week 48), and clinical remission at week 48".

Det fremgår af studiernes resultat-sektion, at *"Prespecified, multiplicity-controlled analyses of the pooled GALAXI-2 and GALAXI-3 dataset showed that both guselkumab regimens were statistically superior (p<0·05) to ustekinumab at week 48 for endoscopic response; endoscopic remission; the composite of clinical remission and endoscopic response; and deep remission, which is the composite of clinical remission and endoscopic remission"*

Det er Granskningsmandspanelets vurdering, at materialets formulering er i overensstemmelse med studiets konklusioner, og at materialet tillige indeholder en studiebeskrivelse, hvori studiets kombinerede placebo- og aktivkontrollerede design fremhæves. Endvidere fremgår studiernes co-primære endepunkter med tilhørende resultater.

I den foreliggende sag vurderes dette som tilstrækkeligt til, at modtageren (implicit) orienteres om, at studiets aktiv-komparative design-del mod ustekinumab indebærer en hierarkisk lavere prioritering af de pågældende endepunkter i forhold til de fremhævede co-primære endepunkter, som er placebo-kontrollerede.

På denne baggrund gives indklagede medhold i, at materialet må anses for tilstrækkeligt fyldestgørende og oplyst i forhold til klagepunktet og vurderes dermed ikke at være i strid med Reklamekodeksets § 8, stk. 3, desangående.

Klager gives således ikke medhold i klagepunkt 3.

Afgørelse:
Johnson & Johnson findes således at have overtrådt Reklamekodeksets § 7, stk. 3, jf. § 4, stk. 2, og pålægges som følge heraf følgende sanktioner:

Sanktion:

- Johnson & Johnson pålægges at ophøre med at anvende reklamen i dens foreliggende form. Granskningsmandspanelet har noteret, at Johnson & Johnson anfører, at nærværende reklamemateriale er trukket tilbage pr. 1. oktober 2025 og ikke anvendt siden.

- Johnson & Johnson pålægges endvidere en bøde på kr. 70.000 kr. + moms i henhold til ENLI's

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Sanktions- og gebyrregulativ § 4, stk. 1, litra e), for overtrædelse af Reklamekodekset § 7, stk. 3, jf. § 4, stk. 2.

Granskningsmandspanelet bemærker, at selvom reklamen ikke fortsat benyttes af Johnson & Johnson, og selvom der har været en forudgående dialog mellem parterne, afskærer det ikke en part at klage til enten ENLI eller Lægemiddelstyrelsen.

Kopi af nærværende skrivelse sendes til klager hhv. indklagede og til Lægemiddelstyrelsen til orientering, når sagen er endelig.

Med venlig hilsen

Kasper Andersen
Lægefaglig granskningsmand

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