etisk nævn for lægemiddelindustrien

**ANKENÆVNET**

**AN-2025-4037, vildledende reklame**

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| Ankenævnets sagsnr.: | AN-2025-4037 |
| Afgørelsesdato: | 25. november 2025 |
| Ankenævn: | Strange Beck (formand), Ghita Astrup og Sisse Rye Ostrowski |
| Anke af afgørelse: | Granskningsmandspanelets afgørelse af 23. september 2025 i sag KO-2025-2946 |
| Klageemne: | Vildledende reklame, Reklamekodeks § 4, stk. 2 og § 7, stk. 1 og 3 |
| Anket af: | Janssen-Cilag A/S (Johnson & Johnson), Østbanegade 123, 2100 København Ø ("J&J")<br><br>og<br><br>AbbVie A/S, Titangade 11, 2200 København N ("AbbVie") |

Denne sag vedrører anken af Granskningsmandspanelets afgørelse af 23. september 2025 i sag KO-2025-2946 i relation til spørgsmålet om, hvorvidt illustration og udsagn i J&J´s reklame for lægemidlet Tremfya er vildledende og i strid med Reklamekodeks.

**Sagens omstændigheder**

Den 14. august 2025 modtager Granskningsmandspanelet klage fra AbbVie over en reklame indrykket i Best Practice Nordic Immunology Perspective af J&J vedrørende virksomhedens lægemiddel Tremfya (guselcumab). Reklamen, der blev udsendt til sundhedspersoner den 24. juni 2025, er gengivet nedenfor:


AbbVie opfatter reklamen som vildledende og dermed i strid med Reklamekodeks, da udsagnet om, at Tremfya er "*den eneste selektive IL-23-hæmmer med dobbelte virkninger*" udelukkende baserer sig på laboratoriedata (in vitro) og ikke på klinisk dokumentation. Ifølge AbbVie fremgår det ganske vist af in vitro-forsøg, at Tremfya kan binde til CD64, men der er ikke gennemført kliniske studier, der dokumenterer en tilsvarende effekt hos patienter. Den påståede dobbelte virkning er ikke klinisk dokumenteret, og den reelle effekt på patienter er ukendt. Andre lægemidler som risankizumab, mirikizumab og ustekinumab binder også til Fcy-receptorer. AbbVie mener derfor, at udsagnet om, at Tremfya er "*den eneste selektive IL-23-hæmmer med dobbelte virkninger*", er misvisende, da det overdriver lægemidlets egenskaber. Desuden finder AbbVie, at billedet i reklamen visuelt understøtter den dobbelte virkning og derved bidrager til et fejlagtigt indtryk af klinisk effekt**.**

J&J gør navnlig gældende, at reklamen for Tremfya er i overensstemmelse med godkendt produktresumé (SmPC) og bygger på relevante, peer-reviewed videnskabelige referencer. Desuden anføres, at reklamens centrale udsagn om dobbelte virkninger ledsages af tydelige fodnoter, der klart angiver, at påstanden er baseret på in vitro-studier, og at den kliniske betydning endnu er ukendt. Ifølge J&J skal tekst og billede læses samlet. Kombinationen giver et objektivt, sandfærdigt og ikke-misvisende billede af produktet, hvor billedet symboliserer SmPC'ets beskrivelse af Tremfyas dobbelte virkningsmekanisme. Den videnskabelige dokumentation understøtter, at Tremfya fungerer som en dual-acting IL-23-hæmmer, som binder både IL-23 og CD64 på immunceller, hvilket

adskiller Tremfya fra andre IL-23-hæmmere. Reklamen præsenterer denne information på en måde, der er let læselig og objektiv for sundhedspersoner. Desuden påpeges, at reklamen tidligere er forhåndsgodkendt af ENLI (sag FO-2025-1772).

Granskningsmandspanelet træffer afgørelse i sagen den 23. september 2025. Panelet anfører blandt andet, at de monoklonale antistoffer risankizumab (markedsføringstilladelse i EU den 26. april 2019) og mirikizumab (markedsføringstilladelse i EU den 26. maj 2023) begge udviser dobbelt virkning i form af hæmning af interleukin IL-23 og blokering af receptoren CD64 samt at begge lægemidler har de samme indikationer som Tremfya (Crohns sygdom og colitis ulcerosa). Da begge lægemidler var markedsført før april 2025, er det Granskningsmandspanelets opfattelse, at Tremfya ikke kan anses for at være det eneste lægemiddel med dobbelt virkning. På den baggrund er det Granskningsmandspanelets vurdering, at reklamen ikke er i overensstemmelse med Reklamekodeks § 4, stk. 2, jf. § 7, stk. 1 og stk. 3, idet udsagnet "*eneste*" anses for vildledende, da der er andre lægemidler, der har samme dobbelt virkning. AbbVie gives derfor medhold i denne del af klagen.

J&J har henvist til, at reklamen er forhåndsgodkendt af Granskningsmandspanelet i FO-2025-1772. Panelet har i forbindelse med behandling af anmodningen om forhåndsgodkendelse ikke foretaget nærmere efterprøvelse af udsagnet "*eneste*", da det påhviler virksomheden loyalt at tilvejebringe sådanne oplysninger, jf. § 6, stk. 2 i Sagsbehandlingsregler for ENLI og Ankenævnets udtalelse i AN-2018-2220. Ifølge Sagsbehandlingsregler for ENLI § 6, stk. 4 bortfalder forhåndsgodkendelsen, hvis Granskningsmandspanelet efterfølgende bliver bekendt med information, som indikerer brud på reglerne. På baggrund af de oplysninger, der er fremkommet under klagesagen, finder Granskningsmandspanelet, at udsagnet om, at Tremfya er "*den eneste selektive IL-23-hæmmer med dobbelte virkninger*" er misvisende. Udsagnet er vildledende og i strid med Reklamekodeksets § 4, stk. 2, jf. § 7, stk. 1 og stk. 3.

For så vidt angår illustrationen i reklamen er Granskningsmandspanelet er enig i, at den viser virkningsmekanismen for lægemidlet Tremfya, der fungerer som dobbelt-hæmmer af cytokinet IL-23 (hæmmer inflammation). Det er Granskningsmandspanelets vurdering, at billedet på en sober og saglig måde illustrerer Tremfyas virkningsmekanisme og øger forståelsen af lægemidlets karakter og funktion, uden at give indtryk af, at lægemidlet "*kurerer sygdommen*". Granskningsmandspanelet finder dermed, at billedet er i overensstemmelse med Reklamekodeksets § 4, stk. 2. AbbVie gives ikke medhold i denne del af klagen.

Granskningsmandspanelet pålægger J&J en bøde på 60.000 kr. + moms i henhold til ENLIs Sanktions- og gebyrregulativ § 4, stk. 1, litra e), for overtrædelse af Reklamekodeks § 4, stk. 2, jf. § 7, stk. 1 og stk. 3, Desuden pålægges virksomheden at ophøre med anvendelsen af reklamen i den foreliggende form.

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Den 21. oktober 2025 anker J&J Granskningsmandspanelets afgørelse af 23. september 2025 i relation til spørgsmålet om, hvorvidt udsagnet i reklamen for Tremfya er i strid med Reklamekodeks. Dagen efter, den 22. oktober 2025, anker AbbVie ligeledes Granskningsmandspanelets og henviser i den forbindelse til de oprindelige klagepunkter i virksomhedens breve til ENLI af 14. august 2025 og 10. september 2025.

Ankenævnet har anmodet Granskningsmandspanelet om at fremkomme med eventuelle bemærkninger og supplerende oplysninger i forbindelse med ankesagen. Granskningsmandspanelet har fremsendt sine bemærkninger ved brev af 5. november 2025.

**J&Js anbringender**

J&J gør i anken af 21. oktober 2025 navnlig følgende gældende

- "*The only* dual-acting selective IL-23". "TREMFYA® blocks IL-23, that drives inflammation, and binds to CD64 on immune cells that produce IL-23**1-4. * "only" based on approved selective IL-23 inhibitors for moderate to severe active ulcerative colitis and Crohn's disease as of April 2025* 2-4 ** *Based on in vitro studies in an inflammatory monocyte model. The clinical significance of these findings is unknown1*. "(Annex 1 - Advertisement). We fully stand behind this claim and will demonstrate that the Panel decision is based on an incorrect understanding of the facts and scientific evidence and should be reversed.

- FIRST: Not all IL-23s have the same mechanism of action: guselkumab is the only dual-acting IL-23. Guselkumab *is the only IL-23 with explicit SmPC text on in-vitro dual acting.* Guselkumab's SmPC explicitly reads that "G*uselkumab has demonstrated in vitro blocking of IL-23 and binding to CD64. These results indicate that guselkumab is able to neutralise IL-23 at the cellular source of inflammation*" (under Section Mechanism of Action). (Annex 2 - SmPC) Guselkumab is the only IL-23 inhibitor with such explicit text in its SmPC. None of the other IL-23s (risankizumab and mirikizumab) can claim the same (as was referenced in the advertisement and provided for ENLI's consideration in the voluntary pre-approval process). The in-vitro documentation expressly contained in our SmPC is visibly displayed in the advertisement: on the same page and in the same visual field. Thus, our only dual-acting claim has been properly contextualized upfront with J&J stating unambiguously and truthfully: "*Based on in vitro studies in an inflammatory monocyte model. The clinical significance of these findings is unknown*". We wish to clarify that the Panel refers to CD64 *blocking* in its decision. J&J does not use or refer to "*CD64 blocking*" but "*CD64 binding*", so the first instance decision is erroneous on this point.

- No claim is made on clinical significance, let alone clinical or therapeutic benefit. J&J briefly reiterates that our dual-acting statement does not include any claims as to the possible clinical significance, let alone clinical benefit, of CD64 binding, which is itself evident from the advertisement. Indeed, our advertisement focuses on Tremfya's unique mechanism of action and contains a clear disclaimer "*Based on in vitro studies in an inflammatory monocyte model. The clinical significance of these findings is unknown."*

- There is solid scientific substantiation behind guselkumab being the only in vitro dual acting IL-23 inhibitor. There is contemporaneous and solid scientific evidence in the form of a peer-reviewed publication demonstrating that not all IL-23s have the same mechanism of action and guselkumab is the only demonstrated dual-acting IL-23 inhibitor in vitro (see Annex 3 - KL Sachen et all, Frontiers in Immunology, Volume 16, "*Guselkumab binding to CD64 IL-23-producing myeloid cells enhances potency for neutralizing IL-23 signaling*") Indeed, as we will explain in more detail,

guselkumab is *structurally* and *functionally* different from other IL-23 inhibitors approved for ulcerative colitis and Crohn's disease available on the market. It is the only IL-23 inhibitor in ulcerative colitis and Crohn's disease that has the native Fc domain and the only product demonstrated to selectively bind IL-23 with high affinity, blocking IL-23 activity, and to bind to CD64, leading to enhanced functional potency in *in vitro* assays. Such results have been considered sufficiently robust and solid for inclusion in guselkumab's SmPC, which provides the factual basis for the claim. Abbvie has not submitted at any stage of the procedure to either J&J or ENLI any documentary evidence to demonstrate that other approved IL-23 inhibitors, including its own Risankizumab (Skyrizi®), are dual-acting in the sense of simultaneously blocking IL-23s and binding to CD64. On the contrary, it appears from the publication by Zhou L, et al., a preclinical comparison conducted by Abbvie researchers, that risankizumab does not bind to CD64 with high affinity. For deeper scientific discussion, please see Annex 4 - Scientific substantiation on Tremfya being the only in-vitro dual acting IL-23.

SECOND: ENLI has previously pre-approved the text that guselkumab is the only in vitro dual acting IL-23 inhibitor and there has been no change of circumstances thereafter justifying a different outcome. The advertisement was pre-approved by ENLI (with the caveat that the materials were then submitted to ENLI in English and the advertisement itself is in Danish) (Annex 5 - ENLI pre-approval) The Danish version is a faithful and accurate translation of the English version that was pre-approved. Contrary to Abbvie's argument and the Panel's belief, there was no change of materials, information, market circumstances or scientific context between J&J for pre-approval submission and the Panel's decision that objectively justifies that ENLI should reach a different outcome. It is therefore surprising and undermines the ENLI's pre-approval process made available to its member companies that the Panel comes to opposite conclusions in the pre-approval decision and in the proceedings especially as Abbvie has not brought any new evidence. The Panel now volunteers a recommendation that the in-vitro documentation should be more clearly informed, a comment not offered during the pre-approval process (whilst context and basis for approval remain the same). Whilst J&J can make this observation more prominent, this does not impact the fact described that J&J's guselkumab is and remains the only IL-23 inhibitor with demonstrated in-vitro blocking of IL-23 and binding to CD64 to date for the indications cited.

- CONCLUSION: Guselkumab remains the only dual-acting IL-23 inhibitor, approved for moderate to severe active ulcerative colitis and Crohn's disease, that blocks IL-23 and binds to CD64 on immune cells that produce IL-23. This has been documented in vitro, scientifically demonstrated, and explicitly included in the SmPC. There is no objective justification for ENLI to depart from the pre-approval decision in which ENLI had concluded that the advertisement was compliant with ENLI's Advertising Code.

**AbbVies anbringender**

AbbVie henviser i anken af 22. oktober 2025 til virksomhedens klage til ENLI af 14. august 2025 og supplerende bemærkninger af 10. september 2025 vedrørende J&Js reklame for Tremfya. De væsentligste punkter i disse breve gengives nedenfor:

- The complaint is based on the discrepancy between the text used in the advertisement and the actual content of the references cited, as well as a misleading image in the advertisement. According to the advertising recognition, reference must be made loyally, and references must be included to the extent necessary to illuminate the overall knowledge in the field. References must be clearly stated. None of these may refer to outdated information or otherwise be misleading.
In the advertisement, Tremfya is highlighted with large and visible text, as "*Den eneste selektive IL23-hæmmer med dobbelt virkning*". This is misleading and erroneous in that Tremfya is an IL-23 inhibitor that binds to CD64 in vitro. As an IgG1 monoclonal antibody, Tremfya binds to Fcγreceptors, including CD64, which is an expected property and not unique to Tremfya. Although binding has been observed in vitro, this observation does not mean that it contributes to any effect. Evidence for binding, efficacy and clinical efficacy in vivo is still lacking. Other drugs, such as risankizumab, mirikizumab, and ustekinumab also bind to Fcγ-receptors, although risankizumab and mirikizumab have reduced binding due to mutations in the FC region. Thus, the claim of "*only selective IL-23 inhibitor*" is misleading and erroneous, as this is not unique to Guselkumab. There is a disclaimer at the bottom of the advertisement regarding double effect, which is written with smaller text types than the main message of the advertisement, and thus much less clear to the recipient.

- The image in the advertisement of the root with the text "*IL-23*" at the root and "*CD64+*" in the root net in relation to the claims in the advertisement further contributes to the impression of a unique treatment that acts on the disease at the root by binding "*CD64*", although the advertisement also states that the clinical significance of "CD64" binding is unknown. The claim that "GUS" by binding to "*CD64*" acts on the disease and, moreover, is based only on the fact that GUS binds to CD64. A CD64 binding has not been proven to contribute to efficacy in vitro, and no evidence exists that this will also have clinical significance and efficacy.

- The claims in the advertisement are based solely on limited, preliminary in vitro models that have not been confirmed by clinical studies or patient outcomes. This approach is misleading healthcare professionals (HCPs) to overestimate Tremfya's clinical benefits, in direct contradiction to regulatory requirements for objectivity, accuracy, and verifiability.

- Specifically, the advertisement (ad) is in breach of the following sections of the ENLI code:
1. § 4 (2) The ad is not objective, it is misleading and it exaggerates the properties of Tremfya and is not in compliance with the SmPC
2. §7 (1) The ad does not encourage the rational use by presenting Tremfya objectively without exaggerating its properties and the claims (words and pictures) imply qualities and properties that are unsubstantiated
3. § 7 (3) The information referred to in § 7 (1) is not objective or accurate and it is unverifiable (see below reg. § 7 (5))
4. § 7 (4) The artwork included in the add is misleading
5. § 7 (5) There is no "scientifically substantiated research" supporting the claims. The referenced journal does not provide clinically relevant scientific evidence. Relying on in vitro findings alone (whether mentioned in footnotes or not) cannot substantiate clinical or therapeutic benefit.
6. § 8 (3) There is indirectly a comparison to other IL-23 ("The only") in the claim. This is misleading as Tremfya cannot make these claims as described below and thereby disparage competition.

- There has been pre-approval by ENLI, but it is also stated by J&J that the advertisement has been changed since the approval. AbbVie is not familiar to what extend changes have been made nor what was pre-approved.

- It is noted, that aside from being an infringement of the ENLI code, it would also be a breach of the EU directive related to advertisement of Pharmaceutical products as well as Danish regulation implementing this directive if such advertisements were allowed. It goes against the whole principle and purpose of the law to ensure that only claims that are based on solid scientific evidence (clinical trials) is allowed in advertisement of pharmaceutical products, thereby ensuring rationale use of medicine to safeguard patients and public health.

- The claims lack clinical efficacy –
the clinical significance of preliminary "in vitro" findings is unknown.The advertisement for Tremfya claims that Tremfya has a 'dual effect' ("*Den eneste selektive IL-23-hæmmer med dobbelt virkning. Tremfya blokerer både IL-23, der driver inflammation og binder til CD64, på immunceller, der producerer IL-23"*) and (*"Hvad hvis du kunne ramme IL-23-induceret inflammation ved dens rod*?"). The artwork reinforces and even underlines the same message and is a claim in itself.

- References for substantiation - About § 7.5. The claims lack substantiation from human clinical data (clinical trials), as is required by § 7 (5). Laboratory "in vitro" findings (Sachen KL et al 2025 as cited in the ad) cannot be used to verify clinical efficacy nor claims in advertisements. This is for good reasons. J&J even confirms themselves that conclusions cannot be made based on in vitro (see footnote in add), but nevertheless it is clearly the message they are trying to convey to the HCPs. In vitro is Latin for "*in glass*". It describes medical procedures, tests, and experiments that researchers perform outside of a living organism. An in vitro study occurs in a controlled environment, such as a test tube or petri dish and are not a substitute for clinical trials. Therefore, no conclusions regarding clinical benefit can be drawn from such data.The fact that "*in vitro*" models cannot be used to substantiate claims, is also supported by the SmPC, Section 5 "*Pharmacological Properties*" which mentions that "*in vitro models*" "*indicate*" (as opposed to substantiating), that Tremfya might be able to neutralise IL23 at the cellular source of inflammation, but it does not conclude, because this is not possible based on in vitro models. There is also no support for the claim regarding *"double effect*" etc. in the SmPC. Rather the SmPC, defines Tremfya's clinical efficacy and mechanism of action solely as selective IL-23 inhibition.

- Misleading, exaggerating, inaccurate and jeopardizing rationale use of medicine (§ 4.2, § 7.1 and § 7.4). The use of terms like *'dual effect'* and the related picture creates the misleading impression of two distinct clinically relevant actions and exaggerates Tremfya's properties, which is not objective or accurate, but rather misleading HCPs to believe in unverified qualities (§ 4 (2) and § 7 (4)). Allowing the advertisement of potential indicative findings based on in vitro models only, without any clinical evidence in living organisms would be highly dangerous – and it is both misleading and exaggerating Tremfya's properties, implying unsubstantiated benefits and most importantly it jeopardizes the rational use of a medicine § 7 (1) which may potentially harm patient outcomes.
The same would apply even if "*in vitro*" was highlighted in the main text of the advertisement and not in a small footnote (as is the case in J&J's ad). Even J&J themselves conclude in the footnote, that "*the clinical importance of these findings are unknown*". The footnote is also very small, so

even if it was assumed that in vitro studies could be used as substantiation, then hiding such an important fact in a footnote is misleading in itself and unbalanced.

- Additionally, the claim "only" ("*Eneste selective IL-23-hæmmer med dobbelt virkning*") is both misleading and disparaging to other IL-23 products, because the claim is inaccurate and unsubstantiated (see above) and thereby disparage competition in an undue manner (§ 8 (3)).

- In summary the clinical significance of CD64 binding remains unknown. The approved Tremfya SmPC indicates that guselkumab shows in vitro activity in blocking IL-23 and binding to CD64+ cells, but these findings are limited to laboratory studies (in vitro) and are not supported by clinical evidence of patient benefits (in vivo). In vitro results are preliminary and do not confirm efficacy in clinical practice without further in vivo validation. The SmPC describes only selective IL-23 inhibition and does not support any dual mechanism of action, nor does it recognize CD64 binding as an established therapeutic benefit. Therefore, the promotional claims are inaccurate, highly misleading and exaggerate the properties of Tremfya in a way that disparage competition - and most importantly jeopardize the rational use of medicines to the risk of patients.

**Granskningsmandspanelets anbringender**

Granskningsmandspanelet gør i høringssvar af 5. november 2025 navnlig følgende gældende:

- Granskningsmandspanelet fastholder sin vurdering i afgørelse af 23. september 2025. J&J har anført, at guselkumab er den eneste IL-23-hæmmer, der ifølge det godkendte produktresumé (SPC) eksplicit har dokumenteret dobbeltvirkning in vitro, idet lægemidlet både blokerer IL-23 og binder til CD64. J&J fremhæver, at ingen andre IL-23-hæmmere, herunder risankizumab og mirikizumab, kan påberåbe sig samme dobbelte virkning, og at disse forskelle tydeligt fremgår af både reklamen og den videnskabelige litteratur.

Granskningsmandspanelet finder imidlertid, at det ikke udgør et tilstrækkeligt tungtvejende argument for at ændre den trufne afgørelse, at guselkumab er den eneste IL-23-hæmmer, hvor den dobbelte virkning eksplicit fremgår af det godkendte produktresumé (SPC). Dette forhold tillægges ikke afgørende betydning, idet udarbejdelsen af SPC-udkastet påhviler den enkelte lægemiddelvirksomhed, hvorefter den endelige godkendelse foretages af enten Lægemiddelstyrelsen eller EMA. Indholdet af SPC'et kan derfor i væsentligt omfang afspejle virksomhedens egne prioriteringer og vurderinger af, hvilke oplysninger der bør indgå, snarere end en objektiv forskel mellem de pågældende lægemidler. Det forhold, at guselkumabs SPC indeholder mere detaljerede beskrivelser af visse mekanismer, afspejler således ikke nødvendigvis en objektiv forskel i de respektive produkters farmakodynamiske egenskaber.

Nedenfor gengives relevante uddrag fra de godkendte produktresuméer for de tre IL-23-hæmmere, herunder virkningsmekanismer (afsnit 5.1, farmakodynamiske egenskaber), hvoraf det fremgår, at samtlige præparater beskriver en virkningsmekanisme, der omfatter både blokering og binding – den såkaldte dobbelte funktion – om end med varierende detaljeringsgrad.

Guselkumab (Tremfya) – ATC L04AC16 (markedsført 10.11.2017)
Indikationer: Plaque-psoriasis, psoriasisartrit, colitis ulcerosa
Virkningsmekanisme: *"Guselkumab er et humant monoklonalt IgG1λ-antistof (mAb), som binder selektivt til proteinet IL-23 (interleukin 23) med høj specificitet og affinitet via antigenbindingsstedet. IL-23 er et cytokin, der er involveret i inflammatorisk respons og immunrespons. Ved at blokere IL-23 og forhindre binding til IL-23 receptorerne hæmmer guselkumab IL-23-afhængig cellesignalering og frigivelse af proinflammatoriske cytokiner. Patienter med plaque-psoriasis har forhøjede IL-23-niveauer i huden. Hos patienter med colitis ulcerosa eller Crohns sygdom er niveauet af IL-23 forhøjet i kolonvæv. I in vitro-modeller blev det påvist, at guselkumab hæmmer bioaktiviteten af IL-23 ved at blokere dets interaktion med IL-23- receptorer på celleoverfladen, hvilket forstyrrer IL-23-medieret signal-, aktiverings- og cytokinkaskader. Guselkumabs kliniske virkning på plaque-psoriasis, psoriasisartrit, colitis ulcerosa og Crohns sygdom sker gennem blokade af IL-23-cytokinet. Myeloidceller, der udtrykker Fc-gammareceptor 1 (CD64), er påvist at være en dominerende kilde til IL-23 i inflammeret væv ved psoriasis, colitis ulcerosa og Crohns sygdom. Det er påvist in vitro, at guselkumab blokerer IL-23 og binder til CD64. Disse resultater viser, at guselkumab er i stand til at neutralisere IL-23 ved den cellulære kilde til inflammation*." [Granskningsmandspanelets fremhævelse]

Risankizumab (Skyrizi) – ATC L04AC18 (markedsført 26.04.2019)
Indikationer: Plaque-psoriasis, psoriasisartritis
Virkningsmekanisme: *"Risankizumab er et monoklonalt humaniseret immunglobulin G1 (IgG1)-antistof, der binder selektivt og med høj affinitet til p19-underenheden af humant interleukin 23 (IL-23)-cytokin, uden at binde til IL-12 og hæmmer dets interaktion med IL-23-receptor-komplekset. IL-23 er et cytokin, der er involveret i inflammatorisk respons og immunrespons. Ved at blokere IL-23 og forhindre binding til IL-23 receptorerne hæmmer risankizumab IL-23-afhængig cellesignalering og frigivelse af proinflammatoriske cytokiner*." [Granskningsmandspanelets fremhævelse]

Mirikizumab (Omvoh) – ATC L04AC24 (markedsført 26.05.2023)
Indikationer: Colitis ulcerosa, Crohns sygdom
Virkningsmekanisme: *"Mirikizumab er et humaniseret IgG4 monoklonalt anti-interleukin-23 (anti-IL-23)-antistof, som selektivt binder sig til p19-underenheden af humant IL-23-cytokin og hæmmer dets interaktion med IL-23-receptoren. IL-23 er et regulatorisk cytokin, der påvirker differentiering, ekspansion og overlevelse af T-celleundergrupper (f.eks. Th17-celler og Tc17-celler) og innate immuncelleundergrupper, som repræsenterer kilder til effektorcytokiner, herunder IL-17A, IL-17F og IL-22, som driver inflammatorisk sygdom. Hos mennesker viste selektiv blokering af IL-23 sig at normalisere produktionen af disse cytokiner."* [Granskningsmandspanelets fremhævelse]

J&J anfører endvidere, at reklamen tidligere er blevet forhåndsgodkendt af Granskningsmandspanelet, og at der ikke er fremkommet nye omstændigheder, som kan begrunde en ændring af denne godkendelse. Granskningsmandspanelet skal hertil bemærke, at der i forbindelse med forhåndsgodkendelsen ikke blev foretaget en nærmere prøvelse af udsagnet "eneste", idet det efter Sagsbehandlingsregler for ENLI § 6, stk. 2, "*er virksomhedens ansvar at tilvejebringe den nødvendige og retvisende information om aktiviteten i forbindelse med anmodningen, således at Granskningsmandspanelet kan træffe afgørelse om forhåndsgodkendelse på et oplyst grundlag*." På tidspunktet for forhåndsgodkendelsen havde Granskningsmandspanelet således alene de oplysninger

Johnson & Johnson fremlagde til vurdering, og lagde på den baggrund til grund, at udsagnet om "*eneste*" var korrekt. På baggrund af de i klagesagen fremkomne oplysninger, blev udsagnet om, at Tremfya er "*den eneste selektive IL-23-hæmmer med dobbelte virkninger*" vurderet til at være misvisende, og Granskningsmandspanelet vurderede dermed, at udsagnet var vildledende og i strid med Reklamekodeksets § 4, stk. 2, jf. § 7, stk. 1 og stk. 3.

Konklusion: Granskningsmandspanelet fastholder sin afgørelse af 23. september 2025. Granskningsmandspanelet anerkender, at guselkumabs produktresumé indeholder en mere detaljeret beskrivelse af et in vitro-forsøg, hvor guselkumab hæmmer CD64-receptoren, som er en dominerende kilde til IL-23 på myeloidceller. Denne dokumentation er dog ikke understøttet af humane forsøg, og der foreligger derfor ikke evidens for, at mekanismen medfører en klinisk relevant fordel ved anvendelse af guselkumab i forhold til de øvrige monoklonale antistoffer (de øvrige IL-23-hæmmere). På baggrund af de foreliggende oplysninger, herunder produktresuméerne, finder Granskningsmandspanelet ikke grundlag for at fravige vurderingen i afgørelsen af 23. september 2025. Udsagnet om, at guselkumab er den *"eneste*" IL-23-hæmmer med dobbelt virkning, må derfor anses for vildledende, idet forskellene i produktbeskrivelserne ikke dokumenterer en objektiv eller klinisk betydende forskel mellem lægemidlerne. Granskningsmandspanelet fastholder således sin afgørelse i sin helhed.

**J&J´s bemærkninger til Granskningsmandspanelets høringssvar og AbbVies efterfølgende kommentarer hertil**

I e-mail af 17. november 2025 kommenterer J&J Granskningsmandspanelets høringssvar af 5. november 2025. J&J anfører i denne forbindelse følgende:

> **"**Clarifying "Dual-Acting" — Beyond Semantic Debate
>
> The Panel's interpretation appears overly semantic and misaligned with the scientific context intended in our communication:
> - We define "dual-acting" as the unique combination of:
>   1. IL-23 neutralization, and
>   2. CD64 binding on IL-23–producing myeloid cells.
> - The Panel cited general SmPC phrasing used by guselkumab, risankizumab, and mirikizumab — emphasizing only the IL-23 blocking aspect— but omitted mention of CD64 binding, which is the critical differentiator in our messaging.
>
> Thus, the Panel's critique overlooks the scientific nuance that distinguishes our product's mode of action from others.
>
> Misaligned Use of SmPC—Contradiction Between Principles and Practice
>
> The Panel claims that the SmPC is not definitive yet simultaneously uses selectively curated quotes from rival products' SmPCs to reject our "dual-acting" claim. This contradictory stance raises two key issues:

- Inconsistency: If SmPC content is considered irrelevant, its selective excerpting to counter our assertion is illogical.
- Selective Emphasis: By spotlighting IL-23 blocking language while ignoring explicit mentions of CD64 binding, the Panel distorts the evidence base underlying our claim.

Per ENLI guidelines and practice, SmPCs remain the primary reference in evaluating claims—yet this principle appears to be inconsistently applied here.

Scientific Evidence on CD64 Binding — Fact-Based Distinction

Our characterization is grounded in published scientific research demonstrating guselkumab's CD64 binding:

- A 2025 Frontiers in Immunology study shows guselkumab binds CD64 + myeloid cells, enhancing neutralisation of IL-23 signaling—supporting our mechanistic differentiation.
- An ECCO 2023 press release confirms guselkumab's capacity to dose-dependently bind CD64 + IL-23–producing cells, a feature not shared by competitors like risankizumab or mirikizumab.

These data reinforce that our "dual-acting" designation reflects established science—not marketing spin.

Panel's Failure to Raise Questions Pre-Approval

The Investigator Panel asserts that relevant information was unavailable during the pre-approval review. However:

- The risankizumab and mirikizumab SmPCs were in full circulation at that time, placing the Panel in knowledge of competitor mode sof action— yet no issue was raised regarding our terminology during their prior review and approval process.
- The omission suggests that, had the Panel genuinely viewed our claim as misleading or scientifically inaccurate – which we disagree with - they would have queried it at an earlier phase.

This retrospective objection seems inconsistent and procedurally untimely.

Conclusion

- Our use of "dual-acting" is scientifically accurate, and distinct from IL-23 blocking claims.
- The SmPC remains the rightful benchmark to assess claims—yet the Panel selectively misapplies it.
- Substantial peer-reviewed evidence supports our claim.
- When reviewing our claim during the pre-approval phase the Panel had full knowledge of the evidence supporting our claim; their change of opinion raises doubts on the value of the pre-approval process."

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Den 21. november 2025 kommenterer AbbVie bemærkningerne af 17. november 2025 fra J&J:

"AbbVie A/S hereby confirms that AbbVie A/S maintains the position and points previously submitted in our original complaint communicated by letter of 14 Aug 2025 and our supplementary comments of 10 Sep 2025. After reviewing Johnson & Johnson's recent response in the appealcase number AN2025-4037 (KO-2025-2946), we have the following comments. First of all, AbbVie A/S wishes to support and reinforce the Review Panel's previous decision, and would like to highlight the following key points:

1. In Vitro data
While Johnson & Johnson emphasizes guselkumab's CD64-binding as a differentiator, it is crucial to note, that this is based solely on in vitro data with no supporting evidence for clinical relevance, which is not clearly stated in the main message of the advertisement. There is, to date, no documentation demonstrating that this mechanism translates into a meaningful, objective, or clinically significant benefit for patients compared to other IL-23 inhibitors.

2. Objectivity and Non-Misleading Claims
Regulations and the ENLI Advertising Code require that promotional claims be based on objective, verifiable differences relevant to clinical patient outcomes. The assertion that Tremfya is the "only" dual acting IL-23 inhibitor is misleading, as it implies a clinically meaningful advantage not supported by current scientific evidence or regulatory approved SmPC.

3. The image
The image in the advertisement in relation to the claims contributes to the impression of a unique treatment that acts on the disease at the root by binding "CD64", although the advertisement also states, that the clinical significance of "CD64" binding is unknown. A CD64 binding by guselkumab has not been proven to contribute to clinical efficacy. AbbVie A/S continues to find the image misleading as it exaggerates the properties of Tremfya and does not align with the SmPC.

4. Consistency and Precedent on "only" - No New Material Evidence
AbbVie A/S agrees with the conclusion of the ENLI Review Panels thorough review of all the relevant SmPC's, scientific descriptions finding no substantiated difference justifying Johnson & Johnson's use of the term "only" in reference to dual acting. AbbVie A/S agrees with the Panel's deliberations, which correctly distinguish mechanistic findings and clinical evidence, and apply the objective standards set by ENLI. AbbVie A/S wishes to emphasize that Johnson & Johnson's submission does not present new clinical data or substantial scientific evidence that would merit a change in assessment. The argument continues to rely on mechanistic or semantic grounds, rather than patient-clinically relevant outcomes."

**Ankenævnets bemærkninger og konklusion**

Udsagnet i J&J´s reklame, "*Den eneste selektive IL-23-hæmmer med dobbelt virkning. Tremfya blokerer både IL-23, der driver inflammation og binder til CD64, på immunceller, der producerer IL-23"*), baseres på laboratoriedata (in vitro). Lægemidlets virkningsmekanisme er nærmere

beskrevet i produktresuméet. Andre IL-23-hæmmere, herunder risankizumab og mirikizumab, påberåber sig ikke en tilsvarende dobbelt virkning, uanset produktresuméerne for disse lægemidler også beskriver en virkningsmekanisme med både blokering og binding (dobbelt virkning).

Produktresuméer udformes efter udkast fra den enkelte lægemiddelvirksomhed (med efterfølgende godkendelse af Lægemiddelstyrelsen eller EMA). Indholdet af produktresumèerne afspejler derfor i et ikke uvæsentligt omfang virksomhedernes egne prioriteringer og vurderinger af, hvilke oplysninger der bør indgå. I lyset heraf, og da udsagnet i J&J´s reklame alene er baseret på laboratoriedata og ikke er understøttet af humane forsøg, kan Ankenævnet tilslutte sig, at forskellene i produktbeskrivelserne ikke i tilstrækkeligt omfang dokumenterer en relevant forskel mellem lægemidlerne. Reklameudsagnet er dermed vildledende og i strid med Reklamekodeks § 4, stk. 2, jf. § 7, stk. 1 og stk. 3.

Ankenævnet kan ligeledes tilslutte sig, at illustrationen i reklamen af en træstub med rødder og teksten "*IL-23*" ved jordoverfladen og "*CD64+*" under jorden belyser Tremfyas virkningsmekanisme uden at skabe indtryk af, at lægemidlet helbreder sygdommen. Illustrationen er i overensstemmelse med Reklamekodeks § 4, stk. 2.

Forhåndsgodkendelsen af J&J´s reklame var baseret på J&J´s oplysning om, at udsagnet "*den eneste selektive IL-23-hæmmer med dobbelte virkninger*" var korrekt. Som det fremgår af § 6, stk. 2 i Sagsbehandlingsregler for ENL er det virksomhedens ansvar at tilvejebringe nødvendig og retvisende information i forbindelse med godkendelsen. Da der efterfølgende fremkom oplysninger, der ville have været relevante og væsentlige for behandlingen af forhåndsgodkendelsen, bortfaldt denne, og Granskningsmandspanelet kunne vurdere sagen på ny.

**Ankenævnets afgørelse**

Granskningsmandspanelets afgørelse af 23. september 2025 stadfæstes.

J&J pålægges en bøde på 60.000 kr. + moms, jf. Sanktions- og gebyrregulativ for ENLI § 4, stk. 1, litra e), for overtrædelse af Reklamekodeks § 4, stk. 2, jf. § 7, stk. 1 og stk. 3. Desuden pålægges virksomheden at ophøre med anvendelsen af reklamen i den foreliggende form.

J&J og AbbVie pålægges hver et gebyr på 6.000 kr. + moms for anke af Granskningsmandspanelets afgørelse, jf. Sanktions- og gebyrregulativ for ENLI, § 7, stk. 8.