

FINAL COMMISSION

SESSION OF 7 May 2026

Dossier 26/001/KL - AbbVie NV vs. Janssen-Cilag NV - Tremfya®

AbbVie NV, with registered office at Avenue Einstein 14, 1300 Wavre, registered in the Business Cross Point Bank under the number (KBO) 0845.096.860,

Member of pharma.be,

hereinafter '**AbbVie**',

Eiseres

AGAINST

Janssen-Cilag NV, with registered office at Antwerpseweg 15-17, 2340 Beerse, registered in the Business Cross Point Bank under the number (KBO) 0415.283.427,

Member of pharma.be,

hereinafter referred to as

'Janssen', defendant

Composition of the seat and representation of the parties

The final committee was composed as follows:

- **Chairman:** Master Pierre Slegers, Xirius
- **Representative of the doctors:** Dr Eric Wyffels, Belgian Association of Physician Syndicates (BVAS)
- **Representative of the pharmaceutical industry:** Mr. Paul Lacante, Medical Director, Bristol-Myers Squibb

The parties were represented by:

AbbVie NV:

- Pollet Sandrine, Medical Director, AbbVie
- Despeghel Aaron, Medical Operations Lead - Responsible Manager for Information and Publicity, AbbVie
- Rousseau Hadrien, Senior Legal Counsel (corporate lawyer) – Belgium, Netherlands and Luxembourg, Abbvie

And their advisors: Peter L'Ecluse and Reem Shehata, lawyers at the desk in Brussels, Glaverbel Building, Terhulpesteenweg 166, 1170 Brussels.

Janssen-Cilag NV:

- Berger Julie, Medical Lead, Janssen-Cilag
- From the time Kaat, Senior Legal Director, Janssen-Cilag
- Van Oevelen Luc, Medical Director, Janssen-Cilag

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and their counselors: Christophe Ronse and Lora Arifagic (apologies For maternity leave), lawyers at the desk in Brussels, Havenlaan 86C/B414, 1000 Brussels.

Prior to the opening of the debates, the counselors of both parties state that they recognize that the DEF Commission is regularly composed.

1. THE PROCEDURE

Having regard to the complaint to the DEF Commission of pharma.be submitted by AbbVie on 11

February 2026; having regard to the statement of reply of Janssen of 9 March 2026;

Attention on de memorial from answer from AbbVie from 23 march 2026;

having regard to the last statement of reply by Janssen-Cilag of 30 March 2026;

Having regard to the amicably agreed timetable of procedures;

Heard the parties by their means at the meeting on 7 May 2026.

2. THE FACTS

2.1. The parties and their products

AbbVie NV and Janssen-Cilag NV are both active in the pharmaceutical sector.

Janssen markets the medicine Tremfya® (active substance: Guselkumab).

Tremfya® has been approved for the treatment of, among others, adult patients with moderately to severely active ulcerative colitis (CU) and adult patients with moderately to severely active Crohn's disease who are insufficiently or no longer responding to either conventional therapy or biological treatment or are intolerant of these treatments.

Tremfya® was approved by the European Commission for these additional indications following research by the European Medicines Agency (EMA) on 23 April 2025.

Tremfya® has also been reimbursed by RIZIV for these indications under Chapter IV of the list of reimbursable pharmaceutical specialities since 1 March 2026. In view of the legal requirements, the nature of these conditions and the required medical expertise, only gastroenterologists as doctors are eligible to prescribe Tremfya®.

2.2. The mechanism of action of Tremfya® as described in the SKP

By binding to IL-23, Tremfya® prevents IL-23 from binding to the IL-23 receptor on cells, thereby inhibiting IL-23 dEpENdENT cell signaling and the release of inflammatory cytokines. In vitro models have shown that Tremfya® inhibits the biological activity of IL-23 by blocking the interaction of IL-23 with the IL-23 receptor on the cell surface, thereby interfering with IL-23 mediated signal transduction, activation and cytokine cascades. Myeloid cells expressing Fc-gamma receptor 1 (CD64) are a source of IL-23 in inflamed tissues. Tremfya® can bind to CD64 on these cells in vitro via its FC region, potentially allowing IL-23 to be neutralized directly at the source of inflammation.

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The SKP of Tremfya® describes this as follows in section 5.1 (Pharmacodynamic properties, section mechanism of action):

"Myeloid cells expressing Fc-gamma receptor 1 (CD64) appear to be a predominant source of IL-23 in inflamed tissue in psoriasis, ulcerative colitis and Crohn's disease. Guselkumab has demonstrated in vitro blocking of IL-23 and binding to CD64. These results indicate that guselkumab is able to neutralize IL-23 at the cellular source of inflammation."

The SKP describes two mechanisms – blocking IL-23 and binding to CD64 – in fact, in the section on the mechanism of action, without attaching the marketing qualification "dual action".

2.3. The Disputed Promotional Materials

Following the approval of Tremfya® for the above mentioned indications, Janssen has distributed or used various promotional materials from May 15, 2025:

- On **15 May 2025**: Digital materials via 'Veeva Approved E-mail' (UAE) to announce EMA approval for the indications Crohn's disease and CU in Belgium;
- On **25 July 2025**: a mailing concerning the mechanism of action of Tremfya®;
- On **4 August 2025**: A promotional brochure (leave-behind) accompanied by a steel application form, distributed in Flanders;
- On **5 September 2025**: a roll-up banner during the Intestinal US (IBUS) course organized by BIRD in Zaventem;
- On **22 November 2025**: A stand at the VVGE-Herfst Symposium in Flanders, Leuven.

The Promotional Materials contain the following publicity slogans:

1. **'The only dual-acting IL-23 inhibitor' / 'the only double-acting IL-23 inhibitor'; and**
2. **"dual-acting IL-23 inhibitor" / "double-acting IL-23 inhibitor".**

2.4. The structure and content of the Promotional Materials

Each advertising message distributed by Janssen consists of a coherent set of elements:

- (i) a visual representation of a soil with a plant and roots, with explanatory text of "IL-23" above the surface and "CD64+" below the ground, making a visual distinction between these two elements;
- (ii) A statement that describes Tremfya® as *"TREMFYA® is the only double-acting IL-23 inhibitor that works by BLOCKING IL-23, a cytokine that is responsible for inflammation, and BINDS to CD64, a receptor on cells that produce IL-23"*;
- (iii) A reference to the SKPs of IL-23 inhibitors available in Belgium (Tremfya®, Skyrizi® and Omvoh®): *"Based only on approved selective IL-23 inhibitors for moderately to severely active UC and CD from April 2025"*;
- (iv) Contextual clarification in footnote: *"Based on in vitro studies in an inflammatory monocyte model. The clinical significance of these findings is unknown"*; and
- (v) Additional references to peer-reviewed scientific publications and the SKP of Tremfya® and the other IL-23 inhibitors available for the Belgian patient.

2.5. History of the dispute

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Janssen used the relevant promotional materials as of May 2025.

On 9 October 2025, the medical director of AbbVie contacted the medical director of Janssen to raise objections.

Janssen replied by letter dated 22 October 2025.

On 12 November 2025 AbbVie, through its counselors, founded a formal letter of formal notice to Janssen, who rejected it by letter of 24 November 2025.

AbbVie subsequently lodged a formal complaint with the DEF Committee on 11 February 2026 pursuant to article 66 from de Code.

3. THE CLAIMS OF THE PARTIES

3.1. The claims of AbbVie (plaintiff)

AbbVie asks the DEF Commission to:

- declare its complaint admissible and well-founded;
- Establish that the use of the slogans (i) '*dual-acting IL-23 inhibitor*' / '*double-acting IL-23 inhibitor*' and (ii) '*the only dual-acting IL-23 inhibitor*' / '*the only double-acting IL-23 inhibitor*' infringes the Code for Deontology, the Medicines Act and the Royal Dutch Medicines Advertisement Manual;
- To order , in accordance with Article 81(A) Code, the immediate cessation of the use of the above slogans in advertising material in any form whatsoever;
- In accordance with Article 81(C) Code, order direct communication by letter of the decision to all healthcare professionals who have received or come into contact with the slogans;
- Impose a financial safeguard measure in accordance with Article 81(E) Code;
- In accordance with Article 81(F) Code, to order the nominative publication in Acta Gastro- Enterologica Belgica, Journal du médecin and Artsenkrant;
- To charge Janssen with the costs of the proceedings and a legal settlement fee of EUR 4,500.

3.2. Janssen's claims (defendant)

Janssen rejects the complaint in its entirety as unfounded and asks the Commission to declare the complaint admissible but unfounded and to charge AbbVie with the costs of the proceedings.

4. THE LEGAL FRAMEWORK

4.1. Applicable legal and deontological provisions

Article 9(1) of the Law of 25 March 1964 on Medicines (the "Medicines Act"):

"All aspects of the advertising of a medicinal product [...] shall be in accordance with the data to be included in the summary of product characteristics."

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Article 10(2) of the Royal Decree of 7 April 1995 on the information and advertising of medicinal products for human use (the "**Royal Decree on Medicines Advertising**"):

"All the information contained in [advertising to professionals] must be precise, up-to-date, verifiable and sufficiently complete to enable the recipient to form a personal picture of the therapeutic value of the medicinal product."

Article 2(A) of the pharma.be Code for Deontology:

"Advertising should be supported and this evidence should be able to be provided quickly in response to reasonable requests from healthcare professionals. [...]."

However, no substantiation shall be provided, as regards the validity of elements authorized in the marketing authorization."

Article 4 of the Code of Deontology states that advertising shall be presented objectively and in accordance with good practice, avoiding the use of misleading images or exaggerated descriptions.

Article 2(C) of the Code for Deontology requires that where reference is made to published studies, clear references are provided.

4.2. The fundamental distinction between advertising to the public and advertising to professionals: Ratio legis and impact on evaluation

The DEF Commission points out that the (European and Belgian) legislator has deliberately introduced different rules for advertising according to the target group. Separate rules for advertising to professionals are motivated by the fact that these professionals have received specific training, play a specific role in the choice of medicine and can and must treat the information differently from patients.

The doctors' specialists concerned are obliged, inter alia, in accordance with Article 8 of the Law of 22 August 2002 on patients' rights, to inform the patient in advance so that he cannot rely solely on the visual promotion of a medicinal product to make his therapeutic choices. As is also apparent from Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, the Law of 25 March 1964 on medicinal products for human use and the Royal Decree of 7 April 1995, advertising aimed at professionals should contribute to the information of these persons. In this respect, this legislation also requires that professionals have access to the detailed scientific information relating to the product

When assessing the possible deception of a professional, these peculiarities, in particular the fact that the information is not limited to the visual aspect of the message, will be taken into account.

5. THE TERMS AND CONSIDERATIONS OF THE PARTIES

The DEF Commission distinguishes **three** separate points of contention:

- (I) whether the *dual-acting* qualification is scientifically sound and not misleading;

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- (II) whether Tremfya® can rightly be designated as *the only* double acting IL-23 inhibitor;
- (III) whether the advertising in question, assessed as a whole and in the context of the reference target public, gives a misleading overall impression.

POINT I — the claim 'dual-acting' / 'double-acting'

5.1. Position of AbbVie

The claimed "double action" refers to the combination of IL-23 inhibition with binding to CD64 receptors (Fcγ receptors). Although it is scientifically correct that Tremfya®, as IgG1 monoclonal antibody, binds to Fcγ receptors, this determination is based solely on in vitro data, without any supporting evidence demonstrating clinical relevance or therapeutic significance in vivo. Mere demonstration of a molecular interaction under laboratory conditions is not sufficient to determine that this interaction contributes to a clinically relevant therapeutic effect in patients.

In pharmaceutical advertising addressed to healthcare professionals, the qualification of a medicinal product as having a certain "effect" clearly implies that this effect is therapeutically relevant and effectively contributes to the clinical efficacy of the medicinal product. By proposing binding to CD64 as a constituent element of the alleged "double action", it is suggested that this binding mechanism plays a crucial role in the therapeutic effect, while there is no evidence of binding efficacy or clinical efficacy in vivo.

AbbVie states at the hearing that the SKP does not at any time speak of a "double action" or "dual action". This terminology is a mere marketing creation by Janssen itself and does not find a basis in the product information approved by the EMA. AbbVie therefore argues that Article 2(A) in fine of the Code – which provides for an exception to the requirement to provide support for elements authorized in the marketing authorization – does not apply, now that the term 'dual-acting' itself has never been approved by the EMA or the European Commission.

5.2. Janssen's position

The contested expressions are not a commercial "slogan" but a factual finding that is fully in line with the SKP for Tremfya® and the relevant scientific literature. The dual action of guselkumab – blocking IL-23 and binding to CD64 – is explicitly included in section 5.1 of the EMA-approved SKP of Tremfya®, under the heading "Mechanism of action". Consequently, Article 2(A) of the Code exempts Janssen from the obligation to provide additional evidence for this element.

The above expressions are always accompanied by relevant contextual information: '*Based on in vitro studies in an inflammatory monocyte model*' and '*the clinical significance of these findings is unknown*'. The statement of AbbVie is essentially based on the false and unproven assumption that the reference to "dual action" will be understood by the healthcare professionals concerned as a reference to the therapeutic effect of the medicinal product, while the context of the message clearly relates to the mechanism of action has.

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POINT II — The claim 'the only' / 'the only'

6.3. *Position of AbbVie*

Even if the qualification "dual-acting" would be acceptable, the claim that Tremfya® "the only" such product is factually incorrect. Other IL-23 inhibitors, such as risankizumab and mirikizumab, also have the potential to bind to Fcγ receptors and thus exhibit a similar combination of IL-23 inhibition and Fcγ receptor interaction. AbbVie also refers to the decisions of the Danish Ethics Committee, where the Appellate Body found that the content of product information is to a large extent the result of editorial choices made by the company itself rather than objective findings on therapeutic differentiation.

6.4. *Janssen's position*

Tremfya® is the only approved (selective) IL-23 inhibitor for moderate to severe CU and Crohn's disease for which the competent authority has accepted a description of double action in the SKP. None of the other IL-23 inhibitors available on the Belgian market included a similar entry of CD64 binding as part of the mechanism of action in its SKP. In addition, the LALA and FALA mutations present in risankizumab and mirikizumab greatly reduce the ability to bind to CD64.

POINT III OF CONTEST — The overall impression and perception by the reference target audience

6.5. *Position of AbbVie*

The prominent head claims about an alleged "double action" fully determine what remains with the average viewer, while the essential nuanced information is downgraded to barely legible small print. The alleged relative reservation is contained in a densely packed text in small print, at the very bottom of the displays, visually disconnected from the slogan and displayed in a font size that is apparently unreadable from any normal viewing distance. AbbVie asks the DEF Committee to assess the slogans from the overall impression that an average gastroenterologist receives in congress context.

6.6. *Janssen's position*

The advertisements are addressed to specialized gastroenterologists who, in the relevant "congress or stock market context", with interaction with Janssen representatives and the possibility of taking note of the available documents, will also take note of what AbbVie does as "small print". AbbVie is asking the Commission for DEF to assess the slogans as if it were a mention on a "billboard" on public roads, which is fundamentally incorrect. AbbVie cannot even present a beginning of evidence that the target audience would ignore the contextual information provided by Janssen.

7. ASSESSMENT BY THE COMMISSION DEFINITION

7.1. Methodological framework: The overall impression and the reference target audience

When assessing the admissibility of advertising, consideration should be given to the overall impression that advertising gives to those whom it reaches or is intended for (Court of Appeal Brussels, 5 June 2018, *JB.Markt*. 2018, Lead 1, 351; ECJ, judgment of 8 February 2017, C-562/15, paragraph 21.

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The risk of misleading should be assessed from the point of view of the reference consumer, which is defined as the normally informed, reasonably attentive and cautious consumer with an average discernment in the target group addressed (CJEU, judgment of 18 November 2010, Lidl, C-159/09, EU:C:2010:696, paragraphs 47 and 48); Court of Appeal of Ghent, 28 September 2018, JBM 2015, 75). The target group targeted is a crucial element in this.

In this case, the reference audience is specialized gastroenterologists. These are not just "average" health professionals: They are doctors specialists with a thorough knowledge of the pharmacology of IL-23 inhibitors, of the advantages and disadvantages of the available biological treatments and of the current state of scientific literature. The DEF Committee takes account of this increased level of specialization when assessing the possible deception.

The Commission would point out that professionals could in principle be misled, but that the deception must be assessed with regard to the target public and the regulatory context surrounding advertising of medicinal products. The professional is and is informed and does not limit his consideration to a single element.

7.2. Concerning Dispute Point I: The 'dual-acting' / 'double-acting' claim

A. No dispute over the actual basis

The DEF Committee first notes that there is no dispute between the parties as to the actual basis for the CD64 binding of guselkumab as such. Both parties acknowledge that it is scientifically correct that Tremfya®, as IgG1 monoclonal antibody, binds in vitro to Fcγ receptors, including CD64. The contest concerns only the manner in which this fact is presented in the Promotional Materials.

B. The absence of the term "dual-acting" in the SKP: Not decisive

The DEF Committee takes note of the argument put forward by AbbVie's Counsellor, reiterated with particular emphasis at the hearing, that the SKP does not formally use the term "double acting" or "dual acting" anywhere. This is correct: The SKP of Tremfya® describes in section 5.1 the two mechanisms – IL-23 blocking and CD64 binding – in fact, in the section "mechanism of action", but does not use the term "double action" as such.

However, the DEF Committee considers that this argument is not decisive. Indeed, both mechanisms are included in the EMA-approved SKP, in the section specifically dedicated to the mechanism of action of guselkumab. The term "double-acting" or "dual-acting" is a communicative synthesis of these two validated mechanisms – a synthesis that does not literally appear in the SKP – but does not constitute a substantive addition that goes beyond what the SKP describes. It summarizes the essence of a description contained in the SKP as part of the mechanism of action.

C. The context of the message: A mechanistic, not a therapeutic claim

The DEF Committee also takes note of the argument put forward by Janssen's Counsellor at the meeting that the context of the message is essential: the message aims to draw the attention of the gastroenterologists to the mechanism of action of Tremfya®, not to an alleged clinical superiority. The Commission considers this argument to be valid.

The promotional material explicitly describes *how* the molecule works (IL-23 blocking and binding to CD64), not *that* this mechanism is clinically superior to other available treatments.

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The message is further nuanced by the statement in footnote that CD64 binding is based on in vitro studies and the clinical significance of these findings is unknown. The DEF Committee finds that the data underlying the dual-acting claim are factually accurate. Guselkumab has been shown in in vitro models to be able to simultaneously block IL-23 and bind to CD64. These are two distinct molecular actions, justifying the term "double acting" or "dual acting" in a strictly molecular-mechanistic sense.

D. The recording in the SKP as an indication of the informational importance to the prescriber

The DEF Committee also attaches particular importance to the system of the SKP itself and to the conclusions that may be drawn from it for the assessment of the admissibility of the promotional material.

The Royal Decree of 7 April 1995 requires advertising to professionals to *be precise, up-to-date, verifiable and sufficiently complete to enable the recipient to form a personal picture of the therapeutic value of the medicinal product.* The legislator thus requires the professional to have at his disposal relevant and complete information in order to make his therapeutic choices. This implies that information relevant for the therapeutic evaluation of a medicinal product must be communicated effectively to the prescriber.

In this respect, the DEF Commission notes that the mechanism of action of guselkumab, and in particular its dual action – the IL-23 blocking and CD64 binding – has been assessed as sufficiently relevant by EMA and the European Commission to be included in the SKP, more specifically in section 5.1 (pharmacodynamic properties). In accordance with Article 11 of Directive 2001/83/EC, the SKP should contain the information necessary for the rational use of the medicinal product.

The inclusion of a pharmacodynamic characteristic in the 'mechanism of action' section of the SKP is therefore not a purely administrative record: It reflects the assessment of the competent regulatory authority that this information is informative and relevant to the prescriber. Therefore, the inclusion of the double molecular activity of guselkumab in section 5.1 of the SKP implies that the regulatory authority has assessed this information as useful for the prescriber's medical decision-making.

This will result in an important consequence for the evaluation of the Promotional Materials. If the Regulatory Competent Body – EMA, whose assessment is being followed by the European Commission – considers that the double molecular activity of guselkumab is sufficiently relevant to be included in the SKP as part of the mechanism of action, this implies that this information is also considered to be relevant and meaningful information for the prescriber. A pharmaceutical company that communicates this information – which the competent authority considers relevant enough to formally include in the product information for the prescriber – in its promotional communication to those same prescribers, not only acts in accordance with the law, but it also contributes to the quality of information for professionals, which is precisely the finality of the regulation on the advertising of medicinal products for professionals.

The Code for Deontology expressly confirms this in Article 2(A) *in fine*: no substantiation should be provided for the validity of elements approved in the marketing authorization, precisely because the competent authority has already validated these elements as relevant and scientifically-based information.

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The Committee therefore concludes that the claim "dual-acting" / "double-acting", read in the integral context of the Promotional Materials, does not infringe Article 2(A) of the Code of Deontology, neither Article 10(2) of the Royal Decree for Medicines Advertising nor Article 9(1) of the Medicines Act.

7.3. Concerning Dispute Point II, the 'the only' / 'the only' claim

The DEF Committee considers that the claim "the only" / "the only" may be assessed in conjunction with the context given to it by Janssen, namely, Tremfya® is the only approved IL-23 inhibitor for moderate to severe CU and Crohn's disease for which the SKP – the product information approved by the EMA – describes the double action (IL-23 blocking and CD64 binding) as part of the mechanism of action.

The DEF Committee notes that this is factually correct. None of the other IL-23 inhibitors available on the Belgian market – especially risankizumab (Skyrizi®) and mirikizumab (Omvoh®) – has included a similar mention of CD64 binding as part of the mechanism of action in its SKP. This distinction in the SKPs is objectively verifiable.

The argument put forward by AbbVie that risankizumab and mirikizumab may also potentially bind to Fcγ receptors does not alter this, as this potential – contrary to guselkumab – is not included in their respective SKPs as part of the mechanism of action, and is also significantly reduced by the presence of LALA and FALA mutations.

The DEF Committee further recalls that the mere inclusion of the mechanism of action in the SKP testifies that the regulatory body considers this mechanism to be informally relevant to the prescriber. Now only the SKP of Tremfya® – and not that of the other available IL-23 inhibitors – describes the double molecular activity as part of the mechanism of action, does this constitute an objective and verifiable distinction that justifies the claim "the only" / "the only" in the context of the SKPs of the products available on the Belgian market.

The DEF Commission takes note of the Danish decisions as a comparative legal source. It was also cited at the hearing that a Swiss decision is of a different opinion, where a Norwegian decision would also indicate that the claim "the only" / "the only" is not assessed unambiguously. Therefore, on the basis of its own considerations and findings, the DEF Commission considers that the CD64 binding of guselkumab by the European Commission is expressly approved as part of the mechanism of action in the SKP, whereas this is not the case for the other IL-23 inhibitors available on the Belgian market, which the Commission considers to be decisive.

The DEF Committee therefore considers that the claim 'the only' / 'the only', in the context

within which it is used, is factually accurate and verifiable, and therefore does not infringe the applicable provisions.

7.4. On Dispute Point III: The overall impression and perception by the specialized gastroenterologist

A. The specialization of the target group as an inherent feature of advertising to professionals

The DEF Commission recalls that the legislator (European and Belgian) has deliberately introduced different rules for advertising to professionals, precisely because these professionals have received specific training and can and must treat the information differently from patients. This distinction is inherent in the system of

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Pharmaceutical regulation and forms the basis for the special assessment standard applicable to advertising to professionals (Directive 2001/83/EC; Law of 25 March 1964; Royal Decree of 7 April 1995).

The specialized gastroenterologists who are the reference target group of the Promotional Materials have a thorough and specialized knowledge of the pharmacology of IL-23 inhibitors. The specialization of the target group implies that it is invited to take note of all the elements of the advertising message. A specialist gastroenterologist who receives a message about the mechanism of action of a new medicinal product in his field of expertise will critically read and assess the content of the advertising message, including the footnotes and contextual clarifications. This is inherent in its professional role and in the system of advertising medicines to professionals. AbbVie does not in any way suggest that the professional limits his consideration to a single element.

A specialized gastroenterologist aware of the claim "the only dual-acting IL-23 inhibitor" accompanied by the footnote that "the clinical significance of these findings is unknown" is considered to understand by itself that it is a mechanistic description that has been demonstrated in vitro, and not for an alleged clinical superiority. The target population should be self-identified and will effectively determine, taking into account the nuance of the message by the clear footnote, that the mechanism demonstrated is in vitro data for which the clinical relevance has not yet been established. This is exactly the kind of nuance that a specialist physician specialist is expected to process when he becomes acquainted with promotional materials that concern his field of expertise.

B. The full assessment of the Promotional Materials

In addition to the disputed slogans, the Promotional Materials contain the following contextual elements that are an integral part of the overall impression:

- A visual representation that explicitly reflects the distinction between IL-23 blocking ("above ground") and CD64 binding ("below ground") and which is undeniably mechanistic — does not convey a therapeutic message;
- An explicit statement that the statements '*are based on in vitro studies in an inflammatory monocyte model*';
- An explicit statement that '*the clinical significance of these findings is unknown*';
- A reference to the SKPs of all IL-23 inhibitors available in Belgium; and
- References to peer-reviewed scientific publications.

The DEF Committee considers that the Promotional Materials thus, taken as a whole, contain a nuanced and contextually embedded message that enables the specialized gastroenterologist to correctly understand the scope of the dual-acting claim. The footnotes are not contradictory, but an essential part of the message, which defines and nuances its scope.

C. The validation by the European Commission and the informative interest for the prescriber

In this context, the DEF Commission attaches particular importance to the fact that the dual activity of guselkumab – the fact that it simultaneously blocks IL-23 and binds to CD64 – is included in the SKP assessed by the EEA and approved by the European Commission. The acquisition of a market authorization and the content of the SKP are not simply approved at the 'simple request' of the market authorization holder. It is the result of a lengthy, rigorous and intensive assessment process where every statement in the SKP should be supported by robust scientific evidence.

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By including this information in the SKP, the European Commission – as the competent authority – has validated the scientific basis of the two mechanisms described. Information accepted by the competent authority and included in the approved product information can therefore be lawfully communicated to health professionals.

More fundamentally, the mere inclusion of the mechanism of action in the SKP testifies that the regulatory organ considers this mechanism to be informally relevant to the prescriber. Indeed, the SKP is not just a technical-scientific document for internal use; it is primarily intended to enable the prescriber – the doctor – to make an informed therapeutic choice. In accordance with Article 11 of Directive 2001/83/EC, the SKP should contain the information necessary for the rational use of the medicinal product. Therefore, the inclusion of the double molecular activity of guselkumab in section 5.1 of the SKP implies that the regulatory authority has assessed this information as useful for the prescriber's medical decision-making. A pharmaceutical company which, in its advertising to prescribers, includes information that the competent authorities have already considered relevant to the same prescribers and formally included in the product information, not only complies with the law, but also contributes to the qualitative information of the professionals, this is precisely the finality of the regulation on the advertising of medicinal products to professionals.

The Commission concludes that the inclusion of the double molecular activity of guselkumab as part of the mechanism of action in the SKP approved by the European Commission implies that this element has been assessed by the competent authority as being relevant to the prescriber, and that Janssen's promotional communication can therefore make a legitimate claim.

The DEF Committee therefore considers that the Janssen Promotional Materials, assessed as a whole and addressed to the specialized gastroenterologists as a reference target audience, do not give a misleading overall impression.

7.5. On the argument concerning AbbVie's own beHAViour: Not relevant for the assessment

Janssen has repeatedly referred to AbbVie's own promotional beHAViour in her response and in session as an argument in favor of the admissibility of its Promotional Materials. In particular, Janssen pointed out that AbbVie herself uses footnotes and disclaimers in similar ways in her promotional materials, including her stand at the UEGW congress in 2023 (part 11.a by Janssen) and her stand at the UEGW congress in 2025 (part 11.b by Janssen). Janssen also refers to a risankizumab slide by AbbVie presented at the ECCO congress 2025 in Berlin and to an AbbVie slide presented during a theoretical presentation outside the European Union.

The final committee shall adopt the following.

The argument put forward by Janssen concerning AbbVie's own beHAViour is not relevant for the assessment of the present complaint.

The DEF Committee is only called to assess the admissibility of the Promotional Materials of Janssen in the light of the applicable legal and deontological provisions. The question whether AbbVie has applied similar techniques in its own promotional practices – such as the use of footnotes or disclaimers – has no influence whatsoever

to that assessment. The standards of ethics apply to all the members of pharma.be, and any failure by the plaintiff to comply with them in another context does not indemnify the defendant in any way from its own obligations or vice versa.

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This principle stems from the very nature of the complaint procedure before the DEF Commission. In accordance with the Code of Deontology, the decisions of the DEF Committee *"relate only to the facts submitted to them and concern only the parties concerned in dispute."* The DEF Committee has not taken note of, nor assessed, the promotional materials of AbbVie to which Janssen refers. It cannot and must not implicitly approve such materials, nor use them as a benchmark for the assessment of the Promotional Materials of Janssen.

Therefore, Janssen's argument – that AbbVie's own promotional practices would confirm or substantiate the admissibility of Janssen's Promotional Materials – is not considered relevant by the DEF Committee for the assessment of the present complaint and is discarded.

For the sake of completeness, the DEF Committee states that its decision in the present case does not rule on the admissibility of AbbVie's promotional practices cited by Janssen. Should these practices give rise to a complaint, this should be assessed in the context of a separate procedure initiated for that purpose.

8. DECISION

FOR THESE REASONS

THE COMMISSION, acting unanimously, SHALL DECIDE AS FOLLOWS:

- Declares AbbVie's complaint admissible but unfounded.
- Notes that the use of the slogans *"the only dual-acting IL-23 inhibitor"* / *"the only double-acting IL-23 inhibitor"* and *"dual-acting IL-23 inhibitor"* / *"double-acting IL-23 inhibitor"* does not infringe Article 2(A) of the Code for Deontology of pharma.be, Article 10(2) of the Royal Decree of Medicines Advertising and Article 9, §1 of the Medicines Act.
- In accordance with Article 84(C) of the Code for Deontology, charges AbbVie NV for the costs of the procedure.
- Declares this decision enforceable in stock.

Done at Brussels on 13 May 2026

Master Pierre Slegers
Chairman of the final committee



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Text in Dutch

**Commission for Deontology and Ethics in the Pharmaceutical Industry* (DEF Committee),
pharma.be**

Session of 7 May 2026

On dossier 26/001/KL – AbbVie NV / Janssen-Cilag NV - Tremfya®

Summary of decision of 13 May 2026

The DEF Committee, compiled by Mr. Pierre Slegers (Chairman, Xirius), Dr. Eric Wyffels (doctor's representative, BVAS) and Mr. Paul Lacante (representative of the pharmaceutical industry, Medical Director Bristol-Myers Squibb), a complaint from AbbVie NV against Janssen-Cilag NV concerning the use of the slogans *"the only dual-acting IL-23 inhibitor"* / *"the only double-acting IL-23 inhibitor"* and *"dual-acting IL-23 inhibitor"* / *"double-acting IL-23 inhibitor"* in promotional materials for the medicinal product Tremfya® (guselkumab) directed to specialized gastroenterologists.

The DEF Committee has declared the complaint **admissible but unfounded**. It notes that the mechanisms described – IL-23 blocking and CD64 binding – are in fact exact and included as part of the mechanism of action of guselkumab in the Tremfya® SKP assessed by the EMA and approved by the European Commission. The inclusion of these mechanisms in the SKP implies that the regulatory authority has assessed this information as relevant and informative to the prescriber, so that the promotional communication can claim it justifiably. The term "dual-acting" provides a correct synthesis of these two validated molecular actions. The message is nuanced by explicit footnotes that explicitly mention the in vitro character and the unknown clinical significance of CD64 binding. The specialized gastroenterologists as a reference audience are able to read the message as a mechanistic description by their education and professional knowledge and conclude for themselves that it is a purely in vitro demonstrated mechanism. The claim "the only" is verifiable now that none of the other IL-23 inhibitors available on the Belgian market have similarly described the double action in their SKP. The plaintiff's own conduct, if any, is not relevant for the assessment of Janssen's Promotional Materials. The costs of the proceedings shall be charged to AbbVie.

* The DEF Committee and the Board of Appeal are bodies established by pharma.be to ensure proper compliance with the rules of its Code of Deontology. These committees consist of members who are not affiliated with the pharmaceutical industry (lawyer and person from the medical or pharmaceutical corps or from the scientific or academic world) as well as a representative of the pharmaceutical industry. All these members act in complete independence in implementation of the Code.

Decisions of the final committee and of the Board of Appeal shall be taken by a simple majority of the members present, shall relate only to the facts submitted to them and shall concern only the parties to the dispute.

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Text in French

**Commission de déontologie et d'éthique dans l'industrie pharmaceutique* (Commission DEP)
DE pharma.be**

Séance du 7 mai 2026

Concernant le dossier 26/001/KL – AbbVie SA / Janssen-Cilag SA - Tremfya®

Résumé de la décision du 13 mai 2026

La Commission DEP, composée de Me Pierre Slegers (président, Xirius), du Dr Eric Wyffels (représentant des médecins, BVAS) et de M. Paul Lacante (représentant de l'industrie, directeur médical pharmaceu chez Bristol-Myers Squibb), a été saisie d'une plainte déposée par AbbVie SA contre Janssen-Cilag SA concernant l'utilisation des slogans « *the only dual-acting IL-23 inhibitor* » / « *le seul inhibiteur de l'IL-23 à double action* » et « *dual-acting IL-23 inhibitor* » / « *inhibiteur de l'IL-23 à double action* » dans des supports promotionnels pour le médicament Tremfya® (guselkumab), destinés aux gastro-entérologues spécialisés.

La Commission DEP a déclaré la plainte **recevable mais non fondée**. Elle constate que les mécanismes décrits – blocage de l'IL-23 et liaison au CD64 – sont factuellement exacts et qu'ils sont inclus, en tant que partie intégrante du mécanisme d'action du guselkumab, dans le résumé des caractéristiques du produit (RCP) de Tremfya® évalué par l'EMA et approuvé par la Commission européenne. L'inclusion de ces mécanismes dans le RCP implique que l'autorité réglementaire a jugé ces informations pertinentes et utiles pour le prescripteur, de sorte que la communication promotionnelle peut légitimement s'en prévaloir. Le terme « double action » constitue une synthèse correcte de ces deux modes d'action moléculaires validés. Le message est nuancé par des notes de bas de page explicites qui mentionnent clairement le caractère in vitro et la signification clinique inconnue de la liaison au CD64. Les gastro-entérologues spécialisés, en tant que public cible de référence, sont, de par leur formation et leurs connaissances professionnelles, en mesure de lire le message comme une description mécanistique et de conclure par eux-mêmes qu'il s'agit d'un mécanisme démontré uniquement in vitro. L'allégation « the only » est vérifiable, car aucun des autres inhibiteurs de l'IL-23 disponibles sur le marché belge n'a décrit cette double action de manière comparable dans son RCP. Le comportement éventuellement contestable de la partie requérante n'est pas pertinent pour l'évaluation des supports promotionnels de Janssen. Les frais de procédure sont mis à la charge d'AbbVie.

* La Commission DEP et la Chambre de recours sont des organes créés par pharma.be afin de garantir le respect des règles de son Code de déontologie. Ces commissions se composent à la fois de membres non liés à l'industrie pharmaceutique (juriste et personne issue du corps médical ou pharmaceutique ou du monde scientifique ou universitaire) et d'un représentant de l'industrie pharmaceutique. Tous ces membres agissent en toute indépendance dans l'application du Code.

Les décisions de la Commission DEP et de la Chambre de recours sont prises à la majorité simple des membres présents, ne portent que sur les faits qui leur sont soumis et ne concernent que les parties au litige.

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