

Johnson & Johnson  
Bregnerødvej 133, 2.  
3460 Birkerød

Att: [REDACTED]

Sendt pr. e-mail til: [REDACTED]

København, den 12. februar 2025

AFGØRELSE

**Vedr.: Ad-2025-0047-C, ELCC 2025**

### **Baggrund:**

Granskningsmandspanelet udtog ovenstående sponsorat, anmeldt af Johnson & Johnson den 9. januar 2025, til kontrol.

Granskningsmandspanelet vurderede på det foreliggende grundlag, at ovenstående sponsorat umiddelbart stred mod ENLI's regelgrundlag, jf. Lægemiddelindustriens kodeks vedrørende reklame mv. for lægemidler rettet mod sundhedspersoner (Reklamekodekset). Sagen blev derfor sendt i høring den 20. januar 2025.

Johnson & Johnson har den 30. januar 2025 svaret i sagen.

### **Granskningsmandspanelets vurdering:**

Efter gennemført høring, har Granskningsmandspanelet genvurderet sagen og fundet, at følgende regel er overtrådt:

- Reklamekodeksets § 13, stk. 8

## Begrundelse:

- Forplejning, jf. Reklamekodeksets § 13, stk. 8

Granskningsmandspanelet skal bemærke, at vurderingen af ovenstående forhold ikke er ensbetydende med en vurdering af alle individuelle forhold i den fremsendte aktivitet.

## Regelgrundlag

Det fremgår af Reklamekodeksets § 13, stk. 8, at:

*”Virksomhederne må ikke give eller tilbyde måltider (mad og drikkevarer) til sundhedspersoner, undtagen i de tilfælde, hvor værdien af sådanne måltider ikke overstiger et af følgende beløbslofter: 450 kr. for frokost, 850 kr. for middag eller 1.400 kr. for bispisning ved heldagsmøder/konferencer mv. De nævnte beløbslofter gælder for måltider i Danmark. Ved måltider i andre europæiske lande gælder de beløbslofter, der er fastsat herfor af lægemiddelbrancheorganisationerne i disse lande.”*

Af Vejledningen til Reklamekodeksets § 13, stk. 8, fremgår, at:

*”Med vedtagelsen af EFPIA’s Disclosure Code den 24. juni 2013 om lægemiddelindustriens offentliggørelse af betalinger til sundhedspersoner er der endvidere besluttet, **at hvert land i egne nationale kodeks skal fastlægge et beløbsloft (maksimal pris) for bispisning, inkl. drikkevarer til sundhedspersoner. Reglen er implementeret i EFPIA’s Code of Practice Sec. 10.05 og i Reklamekodekset i denne bestemmelse.** De oplyste priser afspejler markedsprisen for måltiderne, dvs. ikke priser opnået med eksempelvis mængderabatter, men derimod den pris, som sundhedspersonen selv skulle betale, hvis de købte tilsvarende måltider.*

*Lif har med vedtagelsen tilkendegivet, at:*

- *Beløbsloftet er entydigt. Dvs. priser over dette niveau tillades ikke, mens priser under dette niveau altid tillades (under forudsætning af, at kravet om et arrangement med minimum 2 timers fagligt indhold i øvrigt er overholdt).*
- *Beløbslofterne er inklusive drikkevarer, moms og evt. drikkepenge.*

*Tilbud om bispisning uden for Danmark skal for så vidt angår andre europæiske lande følge de beløbslofter, der gælder i disse lande – se listen over beløbsgrænser/EFPIA bispisningskort på [www.enli.dk](http://www.enli.dk). For bispisning i lande, der ikke er med i EFPIA, vurderer ENLI, at prisniveauet skal*

tage udgangspunkt i det danske beløbsloft, og kun hvor der kan dokumenteres væsentlige prisforskelle i forhold til det danske prisniveau, vil beløbsloftet skulle justeres op eller ned i overensstemmelse hermed. Det vil derfor som udgangspunkt være det danske beløbsloft, der er gældende.

**Husk at beløbsgrænserne for bespisning skal kunne kontrolleres af ENLI.** Det skal understreges, at i forhold til den samlede heldagsmødepris på 1.400 kr., skal maksimalprisen på 450 kr. for frokost og 850 kr. for middag fortsat overholdes. Således skal mødepakker udspecificeres, så det er muligt for ENLI at se, hvad prisen for morgenmad, frokost og middag er, samt øvrig forplejning i løbet af dagen.” [min fremhævning]

### Johnson & Johnsons bemærkninger

Johnson & Johnson har den 30. januar 2025 indsendt følgende bemærkninger til sagen:

#### **“J&J comments on the assessment made in the Hearing by ENLI’s Review Panel**

*“According to ENLI’s Advertising Code § 13, subsection 8, pharmaceutical companies must not give or offer meals to HCPs, except in cases where the value of such meals does not exceed the limits set by the pharmaceutical industry organizations in those countries. It is therefore the maximum limits set by the pharmaceutical industry organisation in the hosting country that apply.*

*We would like to refer ENLI to the recent decision of the “Comité Ethique et Déontologique des Entreprises du Médicament” (“CODEEM”, the Ethics and Deontology Committee of Pharmaceutical Companies in France) taken on 27 March 2024 which increased the maximum meal limit that can be paid to HCPs in events taking place in the French territory by 10 (ten) euros to a maximum limit of 70 (seventy) euros.*

*As a way of background, CODEEM is an independent body in France created by “Les Entreprises du Médicament” (“LEEM” or the Professional Trade Association for pharmaceutical companies in France). CODEEM’s mission is to promote and enforce ethical and deontological rules within pharmaceutical companies and as such, they play a crucial role in regulating and providing forward-thinking reflections on ethical and deontological practices in the pharmaceutical sector for the French territory. Their missions include: (i) providing opinions and recommendations on ethical issues related to the activities of pharmaceutical companies and (ii) monitoring and ensuring compliance with Professional Deontological Provisions (“DDP”) thereby facilitating transparency in interactions between pharmaceutical companies and HCPs. As such, CODEEM plays a role very comparable to that of ENLI whereas LEEM is the French equivalent to the Danish LIF as the local association of the pharmaceutical industry in France.*

On 10 April 2024, CODEEM posted on the website of LEEM and thus made accessible to all LEEM members its decision of 27 March 2024 increasing the maximum meal hospitality limit to 70 (seventy) EUR (see **Annexes 1 and 2**). Such decision is directly applicable and has since then been reflected in the local practice as/when applying meal hospitality limits paid in France.

**See Annex 1 – « Recommendations du CODEEM – Conditions d’hospitalité octroyées aux professionnels de santé », Decision of 27 March 2024 (CODEEEM recommendations – Hospitality conditions for HCPs).**

**See Annex 2 - « Recommendations du CODEEM – Conditions d’hospitalité octroyées aux professionnels de santé », communication to LEEM members, 10 April 2024 (CODEEEM recommendations – Hospitality conditions for healthcare professionals)**

CODEEM’s decision of 27 March 2024 sets out the following recommendations:

*“The Codeem, the Ethics and Deontology Committee of Pharmaceutical Companies, guardian of the respect for the "Professional Deontological Provisions" (the DDP) and the ethics of the profession, contributes, through its opinions and actions, to promoting the ethics of the pharmaceutical sector.*

*The Codeem is currently working on updating the DDP (version in force since December 2020), which will be finalized by the end of 2024.*

*Given the economic context and the new guidelines from the CNOM, particularly regarding hospitality amounts, the Codeem wishes to share its recommendations with pharmaceutical companies and remind them of the need to comply with the DDP.*

*The notion of hospitality may include the following elements:*

- *meals (including breakfast, lunch, dinner, etc.)/snacks,*
- *overnight stays,*
- *transportation,*
- *registration fees for a professional and scientific event.*

*The Codeem wishes to inform its members of the following recommendations:”*

#### *Meals*

*Article 4.1.5 of the DDP stipulates that the maximum amount for meals that can be granted by a pharmaceutical company to a healthcare professional, among others, cannot exceed €60 including tax.*

*In the current economic context, which has led to the evolution of the doctrine of various professional orders applicable within the framework of the legal "regulation of benefits" system, the Codeem wishes to propose an increase in this amount.*

*Therefore, the Codeem recommends that pharmaceutical companies do not exceed the amount of €70 including tax per meal (including drinks) per person, within French territory. It will be proposed to the Board of Directors of Leem that this recommendation be integrated into the DDP soon.*

*For meals granted to French healthcare professionals in countries other than France, the reference value for meals is the monetary threshold authorized by the local self-regulation code, as per the "Scorecard Meals and Drinks" document of the EFPIA (hereinafter "Host Country Rule").*

*In this case, it will be necessary to align this maximum threshold from the local self-regulation code with the French "regulation of benefits" system."*

*(free translation into English)*

*LEEM's communication to its members dated 10 April 2024 (Analysis n° 24-026) refers to the text of the CODEEM's decision of 27 March 2024 adding that LEEM wishes to inform its members of CODEEM's most recent recommendations.*

*In France, the decision of CODEEM increasing the maximum hospitality meal limit to 70 euros has already been reflected in the pharmaceutical industry's local hospitality limits grid applicable for French HCPs. As a way of background, in France, and in conformity with the French anti-kickback law, meals exceeding 50 (fifty) euros per person must be submitted to the prior authorization of the relevant external professional board. As far as French HCPs are concerned, the relevant Board is the "Conseil National de l'Ordre des Médecins" ("CNOM"). We are aware that the CNOM has already authorised a number of events with French HCPs involving meals with a maximum limit of 70 euros per person per meal. When it comes to the present event (ELCC/ESMO), the French J&J affiliate has already submitted for CNOM's prior authorization their proposed sponsorship of French HCPs reflecting this updated hospitality meals limit of 70 euros per HCP and per meal. This is pending as per their review timeline.*

*For the sake of full transparency and comprehensiveness, we also provide a document issued by LEEM that provides the CNOM's most recently applicable framework presented during a meeting on 21 February 2024 that took place between CNOM, LEEM, the SNITEM (which is the equivalent of LEEM but for the MedTech Professional Organisation) as well as the SIDIV (the invitro diagnostics professional association).*

**See Annex 3 – Framework for advantages, New guidelines from the CNOM**

*CNOM applicable guidelines set out a maximum limit for meals provided to French HCPs of 90 (ninety) euros for Paris & Paris area, 85 (eighty-five) euros outside Paris area and 100 (hundred) euros outside France which are said to be applicable as of the start of 2024.*

*“To facilitate the processing of files submitted under the authorization regime, the National Council of the Order of Physicians (CNOM) has developed guidelines for physicians and the companies with which they conduct operations. The CNOM has recently updated these guidelines to take into account the general economic context and to enhance the attractiveness of French research.*

*These new guidelines are summarized in the table below. The amounts indicated represent the maximum acceptable amounts for the CNOM, which retains the discretion to assess, adjust, and control on a case-by-case basis. They have been applicable since the beginning of 2024. The new CNOM guidelines were presented during the CNOM/Leem/Snitem/Sidiv steering committee on February 21, 2024, and then publicly during an ethics and compliance seminar organized by Snitem on April 2.*

*This document has been validated by the CNOM and aims solely to inform Leem members of the evolution of its doctrine.*

*These new guidelines are not intended to replace the rules set out by the Professional Deontological Provisions (DDPs) of Leem, as illustrated by the Codeem Q&A Events that came into force on January 1, 2024.*

*Given the evolution of the professional orders' doctrine and the economic context, Codeem published today, April 10, 2024, its recommendations on the conditions of hospitality granted to healthcare professionals (see the Codeem document attached to the news). Hospitality offered during events of an exclusively professional or scientific nature, or during promotional events for products or services.*

*The registration fees for the aforementioned events are inclusive of all taxes (TTC). For meals:*

- *Île-de-France and major cities: €90 maximum*
- *Provinces: €85 maximum*
- *Abroad: up to €100 for countries where hospitality is high (see above) (footnote 2)*

*Footnote 2: These amounts must be aligned with the deontological provisions applicable to pharmaceutical companies.*

*Finally, we also provide in support of our reply an email communication received by the Legal and Compliance Director of LEEM which confirms that the maximum meal limit of 70 euros is already effective and applicable and can be implemented. Importantly, the Legal and Compliance*

Director of LEEM emphasizes that this is not a deviation to the EFPIA guidance as the local hosting country limits determined by the relevant local professional organization (in this case LEEM) apply.

**See Annex 4 – Email from the Legal and Compliance Director of the Pharmaceutical Trade Association in France (LEEM) dated 28 January 2025 (personal data redacted)**

Please find below a full translation of the email (personal data redacted) in which the Legal and Compliance Director of LEEM also attaches the CODEEM's decision published and communication to the members of LEEM on 10 April 2024 (bold highlighting added):

"Dear [redacted],

The current Leem DDPs state that the maximum amount for meals that can be covered by companies is 60 euros. However, the Codeem has recently issued a recommendation to raise the meal threshold to 70 euros including tax, in order to:

- Take into account the evolution of the guidelines from the authority in charge of controlling the benefits for doctors (National Council of the Order of Physicians) under French regulations ("regulation of benefits" system). According to these new guidelines, if the amount is below this 70- euro threshold, the file can be submitted under a prior declaration regime. If the meal exceeds this threshold, the file must be submitted under a declaration regime.
- Consider the context of inflation (see attached document).

**This recommendation allows Leem member companies to already apply this new threshold, pending the update of the DDPs. For your information, this update is being finalized and will soon be validated by the Leem Board of Directors and communicated to the EFPIA, which can then update its "Scorecard Meals and Drinks" document.**

Contrary to what I mentioned over the phone, **there is no need for an EFPIA deviation as the applicable rule is set by the host country's deontological body.** We will soon liaise with the EFPIA to see how they can mention this context, pending a formal change to their document (which can only occur once the new Leem DDPs are formally adopted).

I hope this clarifies things for you."

For completeness, it is indeed correct that the local French Professional Deontological Provisions ("DDP") have not yet been formally revised to incorporate and reflect this immediately applicable decision from the LEEM. In this respect, for your awareness, the initial plan was to update the DDP before the end of calendar year 2024. However, such formalization has been postponed on several occasions and is now not expected to take place before May 2025 at the earliest. Indeed, the process to update the local Code or DDP takes time as it is subject to a formal process including the review and adoption by the Board of LEEM. Besides, any update will seek

*to incorporate several amendments at the same time in the interest of efficacy and simplification. We are aware that there are other additional changes of critical importance that need to be incorporated in the next version of the DDP and which are still pending (also reflecting the situation in France where the health budget has not yet been secured or voted creating some uncertainty for the healthcare sector).*

**Conclusion: J&J is of the view that the maximum hospitality meal limit of 70 EUR notified to ENLI in the Sponsorship is in compliance with the local hosting country limits (namely France) as communicated and confirmed by CODEEM and LEEM**

*As a result of the above clarifications, J&J is of the view that the maximum hospitality meal limits notified for ELCC / ESMO 2025 are in compliance with the locally prescribed limits in France.*

*We have otherwise been in touch with LEEM to thank them for their input in this case and will certainly ask them to bring such developments to the attention of EFPIA to avoid any future misunderstanding on the hospitality limits applying in France, particularly given the high number of international events taking place in France where both French and foreign healthcare professionals may be invited.“*

Johnson & Johnson har med deres høringsvar bl.a. fremsendt anbefalinger fra CODEEM [Codeem's recommendations], CNOM guidelines, ["Supervision of benefits" scheme New CNOM guidelines] samt deres korrespondance med LEEM.

#### Granskningsmandspanelets bemærkninger

Af Reklamekodeksets § 12 følger et forbud mod økonomiske fordele og gaver til sundhedspersoner. Det er ikke tilladt at udlevere, tilbyde eller love sundhedspersoner gaver eller økonomiske fordele.

Dette er hovedreglen. Undtagelser kræver særlig hjemmel og fortolkes restriktivt i overensstemmelse med det overordnede princip om, at lægemiddelvirksomheder til enhver tid skal opretholde høje etiske standarder, ligesom salgsfremmende foranstaltninger aldrig må være af en sådan art, at de bringer lægemiddelindustrien i miskredit eller mindsker tilliden til den, jf. Reklamekodeks § 1, stk. 2.

Princippet om restriktiv fortolkning gælder således også og i høj grad bestemmelsen i Reklamekodeksets § 13 om lægemiddelvirksomheders mulighed for betaling af udgifter i forbindelse med sundhedspersoners deltagelse i fagligt relevante kurser, konferencer mv. I § 13, stk. 7 præciseres det således, at alle former for repræsentation, der ydes til sundhedspersoner, skal holdes på et rimeligt niveau og være nøje begrænset til hovedformålet med den reklamemæssige eller faglige aktivitet.



Det fremgår af Reklamekodeksets § 13, stk. 8, at lægemiddelvirksomheder ikke må give eller tilbyde måltider til sundhedspersoner, undtagen i de tilfælde, hvor værdien af sådanne måltider ikke overstiger et af følgende beløbslofter: 450 kr. for frokost, 850 kr. for middag eller 1.400 kr. for bespisning ved heldagsmøder/konferencer mv. De nævnte beløbslofter gælder for måltider i Danmark. Ved måltider i andre europæiske lande gælder de beløbslofter, der er fastsat herfor af lægemiddelbrancheorganisationerne i disse lande. Beløbsloftet er entydigt. Dvs. priser over dette niveau tillades ikke.

Af vejledningen til Reklamekodeksets § 13, stk. 8, fremgår det, at det med vedtagelsen af EFPIA's Disclosure Code den 24. juni 2013, om lægemiddelindustriens offentliggørelse af betalinger til sundhedspersoner er besluttet, at hvert land i egne nationale kodeks skal fastlægge et beløbsloft (maksimal pris) for bespisning, inkl. drikkevarer til sundhedspersoner.

På [www.enli.dk](http://www.enli.dk) fremgår beløbslofterne for samtlige EFPIA-lande. For så vidt angår Frankrig, fremgår det, at Frankrigs beløbsloft er på 60 euro for et måltid, beløbet er pr. måltid inkl. skatter og afgifter. Den franske lægemiddelindustriforening, LEEM, er medlem af EFPIA.

Johnson & Johnson har i forbindelse med anmeldelsen anført, at der tilbydes aftensmad for 70 euro på dag 1 og 2. Johnson & Johnson har i deres høringsvar af 30. januar 2025 gjort gældende, at det reelle bespisningsloft i henhold til CODEEMs anbefalinger og LEEMs udtalelse, udgør 70 euro.

Granskningsmandspanelet bemærker, at når en lægemiddelvirksomhed opererer inden for en af undtagelserne fra den klare hovedregel om forbud mod økonomiske fordele, jf. Reklamekodeksets §§ 13-15, påhviler det lægemiddelvirksomheden nøje at påse, at betingelserne for at fravige hovedreglen til enhver tid er opfyldt.

Granskningsmandspanelet henleder Johnson og Johnsons opmærksomhed på, at de tilsluttede virksomheder er forpligtet til at overholde de nationale kodekser, ligesom det af hensyn til Granskningsmandspanelet's muligheder for at håndhæve reglerne i Reklamekodeks er afgørende nødvendigt, at Panelets vurdering kan tage udgangspunkt i de anmeldte forhold samt bespisningslofterne fastsat i et lands eget nationale kodeks, som for EFPIA-landene vedkommende, indberettes til EFPIA.

Dette er et grundlæggende element i ENLIs selvjustitssystem jf. Vejledningen til Reklamekodeksets § 13, stk. 8, hvoraf fremgår, at beløbsgrænser for bespisning fremgår af EFPIAs bespisningskort på [www.enli.dk](http://www.enli.dk), ligesom det fremgår, at beløbsgrænserne for bespisning skal kunne kontrolleres af ENLI.

Granskningsmandspanelet bemærker i den forbindelse, at CODEEMs anbefalinger endnu ikke er vedtaget af LEEMs bestyrelse og dermed ikke er indarbejdet i det gældende nationale kodeks for Frankrig, ligesom Granskningsmandspanelet noterer sig, at dette tidligst vil finde sted i maj 2025. Den angivne grænse på 70 euro er således ikke officielt gældende i det franske LEEM-kodeks, efter ENLI's henvendelse til EFPIA kan det konstateres, at LEEM ej heller har indberettet et gældende bespisningsloft på mere end 60 euro til EFPIA.

Granskningsmandspanelet medgiver dog, at udmeldingen fra franske LEEM kan så berettiget tvivl om gældende bespisningsloft i Frankrig, hvorfor det er Granskningsmandspanelet vurdering, at dette skal føre til en lempeligere vurdering i forhold til sanktionen for overtrædelse af Reklamekodeksets § 13, stk. 8.

Granskningsmandspanelet finder på den baggrund, at Johnson og Johnsons tilbud om aftensmad til 70 euro pr. person, er i strid med Reklamekodeksets § 13, stk. 8, da beløbet overstiger det tilladte beløbsloft i Frankrig med 10 euro, som i henhold til gældende nationale kodeks og EFPIA, er 60 euro.

#### **Afgørelse:**

Johnson & Johnson findes således at have overtrådt Reklamekodeksets § 13, stk. 8 og pålægges som følge heraf sanktioner.

#### **Sanktion:**

- Pålæg om at aflyse/ændre arrangementet, så det er i overensstemmelse med reglerne på området, jf. Sanktions- og gebyrregulativ for ENLI § 1, stk. 1.
- Påtale for overtrædelse af Reklamekodeksets § 13, stk. 8, jf. § 5 litra a), jf. § 1, stk. 3, i Sanktions- og gebyrregulativ for ENLI

#### **Ankevejledning:**

Afgørelsen kan ankes til Ankenævnet, jf. Sagsbehandlingsregler for ENLI § 11, stk. 1.

Anke skal ske senest 21 arbejdsdage og sker online på anmeldersitet via [www.enli.dk](http://www.enli.dk). Fristen regnes fra den dag, afgørelse træffes, og den pågældende dag tæller som 1. dag. Weekend- og helligdage medregnes ikke.

Anken skal indeholde en redegørelse for de synspunkter og oplysninger, som anken støttes på.

Der pålægges et gebyr på 6.000 kr., for at anke en afgørelse truffet af Granskningsmandspanelet, jf. Sanktions- og gebyrregulativets § 7, stk. 8.

En anke har som udgangspunkt ikke opsættende virkning.

Kopi af den endelige afgørelse vil blive fremsendt til Lægemiddelstyrelsen til orientering.

Med venlig hilsen

Nuzaht Yasmin Ahmad

Juridisk granskningsmand