

# Update on Belgium for IPCAA



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# Disclaimer



This presentation is a **brief summary** and shall only provide an overview about the framework of valid guidelines/regulations in Belgium.

The contents of the presentation have been compiled to the **best knowledge and ability of the presenter**. However, the contents can be or become inaccurate because recent developments came/come up after compilation. Only the full wording of the relevant provisions in the respective wording are legally binding.

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In no event, the presentation **is meant to give legal advice neither to a topic itself nor to a single case**.

Please approach your Law Department or Legal Advisor for concrete advice.

## pharma.be: the voice of 125+ (bio)pharma companies in Belgium

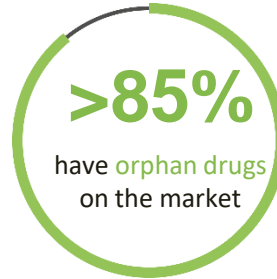
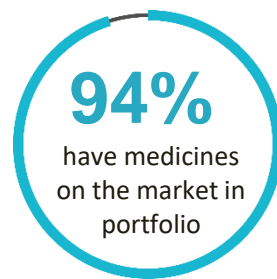


### Start-ups, small, mid-sized and multinational companies

Almost all Belgian companies with R&D activities joined pharma.be – R&D activities as well in preclinical as in clinical stage

pharma.be

**120+**  
members



# Belgian framework for congresses and other scientific meetings

- Legal and deontological framework
- Conditions
- Visa procedure



# Fragmented framework between legal and deontological provisions



Legal  
framework  
applies  
to all  
companies



Laws, Royal Decrees,  
Circular letters



Mdeon Code of Ethics ([link](#))

Deonto-  
logical  
framework  
applies to  
specific  
pharma  
companies



EFPIA & IFMPA Codes



pharma.be Code of  
Deontology ([link](#))

# Belgian framework for scientific events



## - Legal

- Art. 10 of the [Belgian medicines Act](#)
  - [Circular 622](#) of the FAMHP → for stand-alone events
  - [Mdeon Code of conduct](#) → for scientific events that take place over several days

## - Deontological

- pharma.be [code of conduct](#): Chapter 2, section 3

# → Legal framework: Article 10 of the BMA



## General prohibition

- (*when?*) in the context of the supply, prescription, delivery or administration of medicinal products,
- (*how?*) to directly or indirectly gift, offer or promise
- (*what?*) any benefit or advantage - whether in money or in kind –
- (*who?*) to wholesalers, intermediaries, persons qualified to prescribe, supply or administer medicinal products and to institutions where the prescription, delivery or administration of medicinal products takes place

## Excepted for

- Gifts of negligible value
- Reasonable compensation for scientific services
- **Invitations to and financing of participation to a scientific event, hospitality included**

# → Legal framework: Article 10 of the BMA



- Invitations to and financing of participation to a scientific event, hospitality included, are allowed under the following

## 5 cumulative conditions

- i. The meeting must have an **exclusively scientific nature**
  - ii. The **hospitality** must be strictly limited to the scientific purpose
  - iii. The **location, date and duration** of the meeting must leave no doubt as to its scientific character
  - iv. The contribution to participation fees – including hospitality – is limited to the official **duration** of the meeting
  - v. The contribution to participation fees – including hospitality – is not extended to persons or legal entities other than **HCPs**
- Prior to any scientific meeting taking place over several consecutive calendar days, the sponsor must request an **Mdeon visa**



# → Deontological framework



- **pharma.be code** (section 3 of Chapter 2)
  - Framework of quality
  - Deontological codes of the place where event is organised
  - Hospitality is limited to that which HPCs would be prepared to pay themselves
  - The public use of a HCO logo or proprietary material requires written permission
  - Pharma.be members that sponsor the organisation of participation of HCPs in scientific events should clearly acknowledge their involvement

# Two types of scientific events – two different procedures



## Scientific events

That take place over several consecutive calendar days

“Stand-alone” events

**Subject to visa**

**Not subject to visa**

→ 5 conditions in Art. 10 BMA  
→ Mdeon code of conduct

→ 5 conditions in Art. 10 BMA  
→ Circular n°622 of the FAMHP

# Scientific event not subject to visa (“stand-alone meeting”)



No specific procedure but hospitality must be:

- **Reasonable**

- ❖ Lunch – Max. 40 EUR
- ❖ Dinner – Max. 80 EUR
- ❖ All inclusive: drinks, taxes, rent of the room, ... - at market prices

- **Subsidiary**

- ❖ In proportion to the number of hours devoted to scientific activities; max. of 40 + 80 EUR can only be offered if 6 hours of scientific activities (*see next slide*)

- **Limited to the official duration of the event**

- ❖ Only meals immediately before or after the scientific activities

→ Mdeon/FAMHP [guidelines](#) on sponsoring of scientific events not subject to visa requirements

# Scientific event not subject to visa (“stand-alone meeting”)



- **Subsidiary** → FAMHP: **20 EUR/h rule**
- Circular n° 622 ([NL](#) – [FR](#))

De aangeboden gastvrijheid is redelijk en strikt beperkt tot het wetenschappelijke doel van de manifestatie. In totaal, wordt **maximaal 20 euro gastvrijheid per persoon per volledig uur wetenschappelijke manifestatie** toegestaan, met een maximum van 40 euro per lunch en 80 euro per diner (alles inbegrepen : o.a. maaltijd, alle dranken, BTW, huur van de zaal, etc.).

L’hospitalité offerte est raisonnable et strictement limitée à l’objectif scientifique de la manifestation. **Un maximum de 20 euros d’hospitalité par personne et par heure complète de manifestation scientifique** est autorisé au total, avec cependant un maximum de 40 euros pour un lunch et de 80 euros pour un souper (tout compris : e.a. repas, toutes les boissons, TVA, location de la salle, etc.).

# Scientific event subject to visa from Mdeon



## What is Mdeon?

- **Common ethical platform** composed of 29 associations of physicians, pharmacists, veterinarians, dentists, nurses, paramedicals, physiotherapists, hospital technicians, wholesalers-distributors and of the pharmaceutical and medical devices industry
- Entitled by law to **issue Visa for scientific events** that take place over several days
- Visa = **guarantee** that the project to organise or take part in a scientific event is **consistent with the relevant legislation and ethical rules**



# Scientific event subject to visa from Mdeon - Conditions



- Hospitality must:
  - ❖ remain **subordinate** to the scientific aims of the event
  - ❖ **never bring into disrepute** the medical industry or HCPs (in any case no sponsoring of sports or leisure activities)
  - ❖ always be restricted to the organization of **travel arrangements, meals, overnight stays and course registration**
  - ❖ **not be extended to a period** longer than the official duration of the event

# Scientific event subject to visa from Mdeon - Conditions



❖ Must remain reasonable: **thresholds** are defined in FAQ

Mdeon:

- max. 40 EUR for lunch & 80 EUR for dinner (drinks incl.)
- max. 250 EUR for an overnight stay (breakfast incl.)
- Belgian HCP → Belgian thresholds, even abroad

<b>Healthcare Professionals as <u>Participant</u></b>	<b>Healthcare professionals as <u>Consultant</u></b>
<b>Economy Class*, for whatever the destination and duration of flight</b>	<b>Economy Class*. For flights longer than 6 hours, Business Class is Authorized.</b> <b>First class is not allowed.</b>

# Scientific event subject to visa from Mdeon - Conditions



Mdeon provides practical directives concerning scientific events in its:

- Code of Ethics:

<https://www.mdeon.be/nl/wettelijk-kader-en-code-voor-deontologie/>



- Frequently Asked Questions:

<https://www.mdeon.be/nl/frequently-asked-questions/>

FAQ 1. Healthcare Professionals Concerned

FAQ 2. Companies Concerned

FAQ 3. The Concept of 'event of several days'

FAQ 4. Scientific Programmes

FAQ 5. Types of Scientific Events

FAQ 6. Sponsoring of Organisers

FAQ 7. Arrival and Departure – Days and Times

FAQ 8. Midday and Evening Meals and Overnight Stays

FAQ 9. Registration Fees

FAQ 10. Transport Costs

FAQ 11. The Concept of Hospitality

FAQ 12. Extending of a Stay

FAQ 13. The Procedure

FAQ 14. Overseeing of Visa Requirements

FAQ 15. Technical Tips



# Visa procedure



- Article 10: **Prior** to any scientific meeting taking place over several consecutive calendar days, the **sponsor must request a VISA with Mdeon**
- **The visa number provided by Mdeon** is a guarantee that the proposed sponsorship to organise or take part in a scientific event is consistent with the relevant legislation and ethics.



# Visa procedure: 2 types of sponsorship



## Sponsorship of participants in a scientific event (V1)

This can be done in a DIRECT or INDIRECT way:

- if the company pays the costs directly, it is the **company** that applies for the visa for the participants it sponsors.
- if the company sponsors the participants through a healthcare organisation (hospital, scientific association, etc.), the visa application must be submitted either **by the company** or **jointly by the company and the healthcare organisation**.

## Sponsorship of the organiser of a scientific event (V2)

- In that case it is up to the **scientific organiser of the event** to submit the visa application, featuring all the event sponsors

# Justificatives for V1



## 1. Detailed scientific programme

- Detailed timetable per units of 30 minutes if needed
- Detailed content (title of each scientific topic)

## 2. Justificative of the cost, the class and the date and hours of the chosen flight

## 3. Justificative of what is included in the registration fee

Example of what is included in the registration's fee:

*Registration fee includes:*

- *Access to the scientific sessions*
- *Congress material*
- *Lunches on day xyz*
- *Diner on day xyz*
- *Social activity (cost/pp is ... EUR)*
- *Welcome reception*
- *Etc.*

# Justificatives for V2



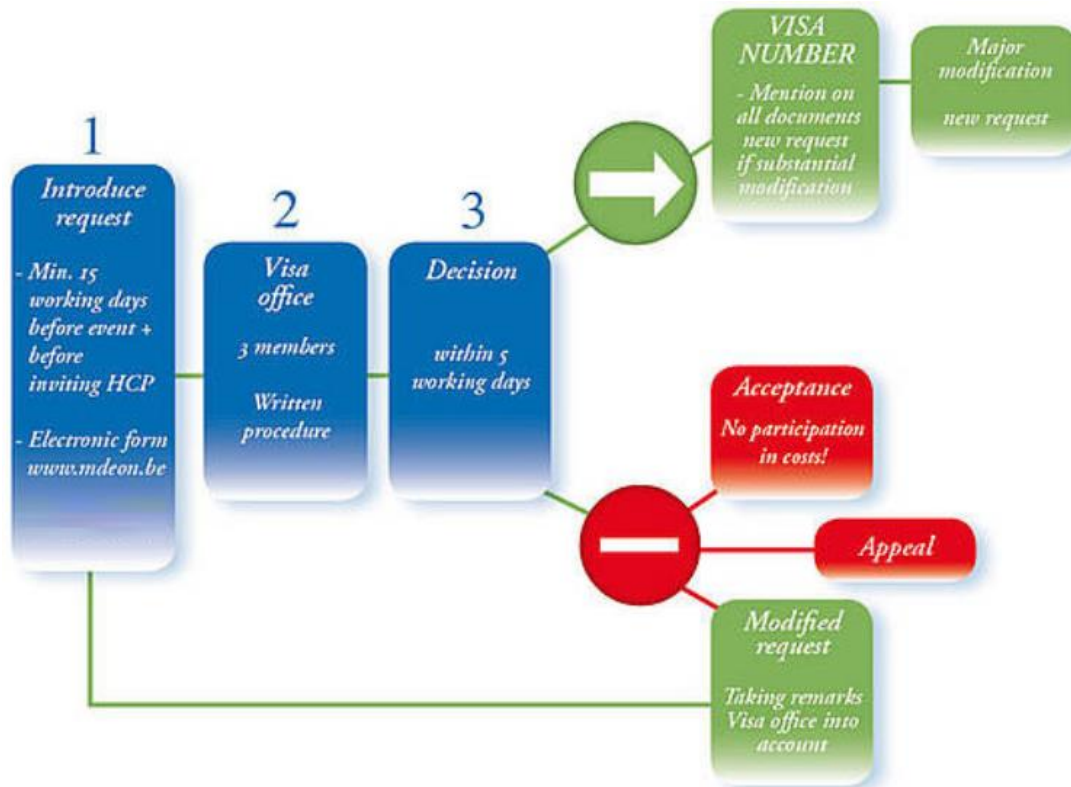
- 1) Detailed **scientific program** of the event
- 2) Detailed **budget** of the event with an enumeration of the different costs and incomes and their amounts
- 3) If submitted by the logistic organizer of the congress: the **declaration of the scientific organizer** concerning the allocation of the funds:

*"- I declare that the sponsored amounts will only be allocated to finance the actual scientific activities or forms of hospitality which are permissible under Article 5.2 of the Mdeon Code of Ethics.*

*- I declare furthermore that any advantage realised will be assigned in accordance with Article 10 of the law of 25 March 1964 on medicinal products.*

*- I undertake to send to the Mdeon Secretariat by e-mail within the three months following the scientific event, the amount and the allotment of the closed account's result."*

# Visa procedure: flowchart



- [Flow chart](#) of the procedure
- [Indirect Sponsorship information brochure](#)
- **NEW**: [urgent procedure](#) for submitting a visa application
- [Checklist V1](#)
- [Checklist V2](#)

# Most frequent refusal motives



- Bureau is **incompetent** (not for an event taking place on several days, foreign HCPs (V1), event not organised in Belgium (V2))
- **Late** request
- **Incomplete** request:
  - In general: no programme or timetable
  - Sponsoring of participants (V1): amount of sponsoring is not detailed, no detailed travel plan, lack of supporting documents for the plane ticket and registration fee (what does the registration fee entail?)
  - Sponsoring of organisers (V2): no detailed budget (e.g. show expenditure but not income or budgets that do not show expenditure in sufficient detail), no declaration from organiser that the amount received will only be used to finance scientific activities that are in line with legal framework
- **Unfounded** claim: event is not exclusively scientific (e.g. topics are not scientific, free time), unreasonable hospitality)

→ See Mdeon annual report (useful information re grounds for refusal of visas): [FR](#) - [NL](#)

# e4Ethics for pharma.be members in Belgium





- **EFPIA: e4ethics became binding since 1<sup>st</sup> January**
  - Only for EFPIA **direct** members (not in pharma.be code)
  - Events concerned:
    - 3d party events
    - Organised in the EU
    - Min. 500 HCPs present representing min. 5 different countries
  - **Event organizer** must introduce a demand for assessment of the event
  - EFPIA members cannot provide sponsor to an event which is found to be non-compliant

- FAQ e4Ethics: <https://www.ethicalmedtech.eu/e4ethics/faq/>





- **The event organizer introduces the demand for assessment (free of charge)**
  - Every supporting **pharmaceutical company** needs to **verify** whether a positive e4ethics assessment is available before supporting an event in scope.
  - If no assessment is available, **other stakeholders** may submit an event for review (i.e. the supporting pharmaceutical company, an EFPIA national association or an HCO)
- **Consequences of non-compliance:**
  - The event assessed as not compliant cannot receive any form of support by the EFPIA member companies

# e4Ethics: online calendar



➤ All events submitted for assessment are posted [in the online calendar](#)

■ Compliant 
 ■ Correction notice 
 ■ Non compliant 
 ■ Provisionally compliant 
 ■ To be reviewed 
 ■ Not assessed

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Feb 1 – 7, 2021

CHOOSE MONTH

MONTH

WEEK

Mon 2/1	Tue 2/2	Wed 2/3	Thu 2/4	Fri 2/5	Sat 2/6	Sun 2/7
ADVANCED ONLINE COURSE: INTRATHECAL DRUG DELIVERY						
Clinical Cases in Acute Kidney Injury: Applications for Clinical Practice						
Radiofrequency Ablation and Pulsed Radiofrequency Seminar Series						
Intensive Course in Laparoscopic General Surgery					1 Internationales Fachtagung	2nd International Masterclas
DASCAM - Module 8 - Guideline implementation and future trends in arrhythmia mana			13. Deutsche Kardiagnostik-Tage 2021		SCTS Virtual Annual Meeting	
European Training Course in Neurosurgery- Head Injury/ Functional			23rd Düsseldorf international Symposium			
8th ESO-ESMINT-ESNR Stroke Winter School						
21st International Symposium on HIV and Emerging Infectious Diseases				12. MKG-Update-Seminar		
ISHEID			Abdominal Wall Reconstruction Europe 2021			
International ECMO Network Meeting and Virtual Scientific Series						
15th Portuguese Stroke Conference						
SIO2021						
XL COURSE: WHAT IS NEW IN SURGERY INNOVATION AND MINIMALLY INVASIVE SURGE						
Artificial Intelligence in Cardiovascular Disease				13th Cancer Surgery Conference		
Congres Aquitain de Medecine d'Urgence				32. Workshop Kniegelenk		
ECOS-TCS International Congress				6. Essener Kardiologie Update		
EANM Focus 4 Molecular Imaging and Therapy in Haematological Tumours						
HaemCon-2021, 23rd Pakistan Society of Haematology Annual Meeting 2021 - Virtual						
26th Saudi Otorhinolaryngology Society Annual Conferen						
3rd Gulf Intervention Society Conference - Post COVID19						
Curso Diagnostico Prenatal Genetico						
Curso Diagonóstico Prenatal Genético						
Fokus Kinderurologie Linz 2020						

# e4Ethics: what about Mdeon?



- **The e4ethics platform is complementary to the Mdeon procedure**
- **Scope of application for a Mdeon visa:**
  - several days events
  - whether company organised or 3rd party organised
  - for pharmaceutical companies that are inviting Belgian HCPs, or sponsoring a scientific event taking place in Belgium.
  - As where e4ethics addresses the event, Mdeon addresses the event and the hospitality, as a whole.
- **Who is eligible to make submissions?**
  - Mdeon visa requests can be introduced by the event organiser (V2) as well as by the pharmaceutical company (V1).



## **pharma.be vzw | asbl**

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