



Slides for training

Version 01-11-2018

Mdeon asbl - vzw
Belgicastraat 1 b7 | 1930 Zaventem
T.: 02/609.54.90
secretariat@mdeon.be | www@mdeon.be

Agenda

- ❖ The Platform
- ❖ Legal frame
- ❖ Who is concerned?
- ❖ Visa procedure
 - ✓ Sponsorship of participants (V1)
 - ✓ Sponsorship of organizers (V2)
- ❖ Mdeon Guidelines
 - ✓ Premiums and benefits of negligible value
 - ✓ Sponsoring of scientific events not subject to the visa requirements
 - ✓ Fees for scientific services
- ❖ Responsibility-controls-sanctions
- ❖ Communication

Common Ethical Healthplatform

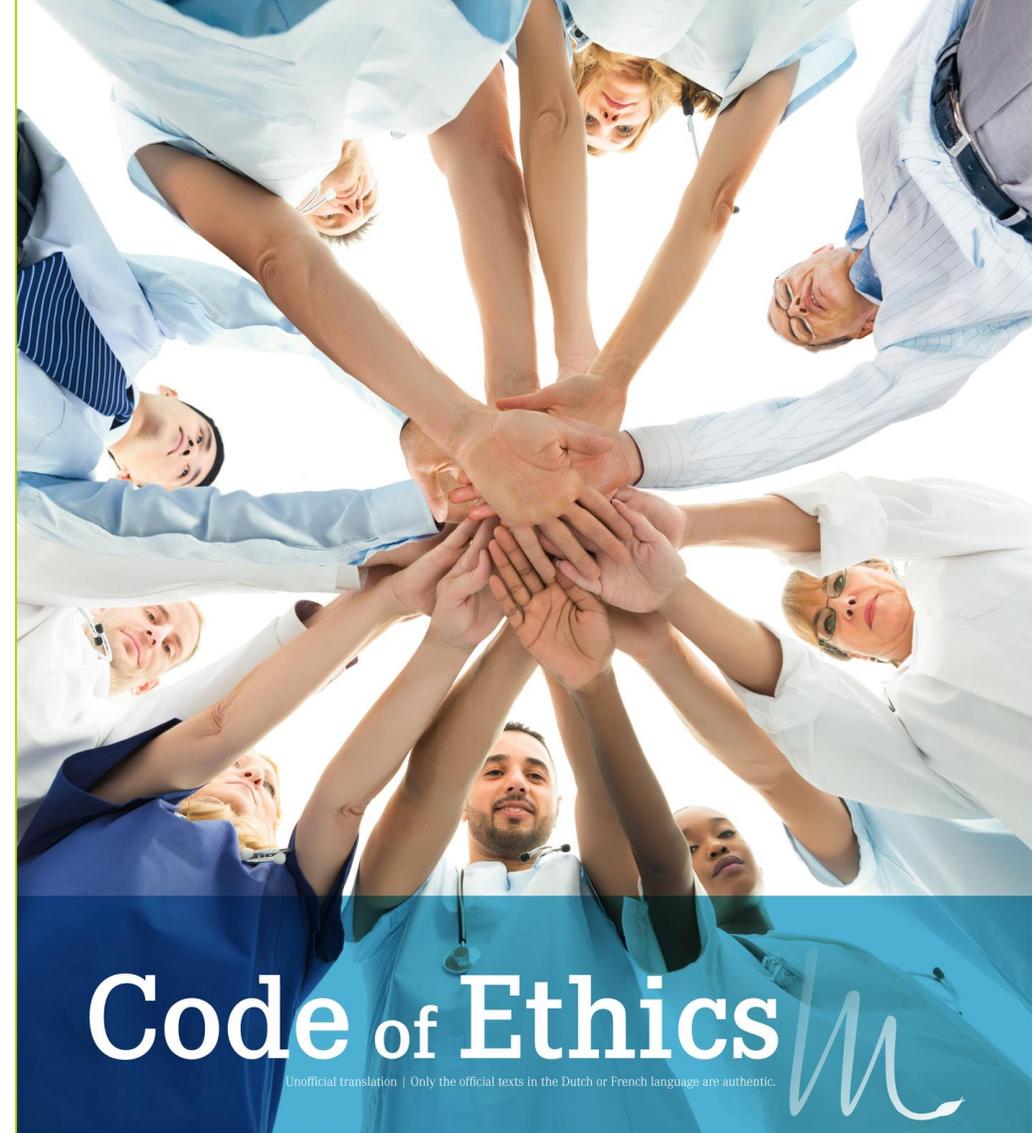
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MEMBERS

Industry	Medical	Pharmacists	
   	     	    	
Veterinary	Paramedical	Hospital technicians	
  	 	 	
Nurses	Wholesalers	Physiotherapists	Dental
 		 	

*M*deon

Objectives

- ▶ To create a frame of quality for the promotion and information about medicinal products and medical devices
- ▶ Auto-regulation
 - ▶ Code of Ethics + Practical Guidelines
- ▶ Co-regulation with authority
 - ▶ Federal Agency for Medicines and Health Products (F.A.M.H.P.)



Ethical Health Platform



The platform: 2 missions

ARTICLE 10

Law Medicinal Products



VISA PROCEDURE

Since 01.01.2007

Agreement via Royal Decree
(d.d. 19.04.2017)

SUNSHINE ACT
Transparency law



BETRANSSPARENT.BE

Since 01.01.2017

Agreement via Royal Decree
(d.d. 31.07.2017)

*M*deon

The platform: 2 missions

Qualitative

Promotion and information

Transparent



thanks a **legal visa** obligation



thanks a **legal transparency** obligation

Legal frame

▶ Article 10 Law on medicinal products

▶ Principe of prohibition

- ▶ the industry **cannot** offer **advantages** to healthcare professionals

▶ Aim legislator?

- ▶ ensure a disinterested prescription/delivering/administration's behaviour
- ▶ conserve the reputation of the industry and healthcare professionals

← **European
Directive 2001/83**



Legal frame

▶ Article 10 Law on medicinal products

▶ Exceptions

1. benefits or **advantages of limited value** related to the exercise of the medical art, dental art, pharmaceutical art or veterinary art
2. compensation of legitimate **scientific services**
3. inviting healthcare professionals to a **scientific meeting** and covering their participation costs, including hospitality, provided that this event meets the cumulative conditions set out in Article 10



↳ For events taking place during several days:
preliminary visa Mdeon



Who is concerned?

Co-responsibility!

▶ The industry

- manufacturers, importers, wholesalers
- medicinal products or medical devices
- Belgian AND foreign companies

Companies: 600

▶ The healthcare professionals

- physicians, pharmacists, nurses, dentists, veterinaries, paramedical, etc.
- institutions where MD/MP are prescribed, dispensed, administered, etc.

Total HCPs: 42.000

82% = medical
specialists

The logo for Mdeon, featuring a stylized 'M' in green followed by 'deon' in blue.

Subject of the visa

- ▶ A sponsorship ...
 - sum money
- ▶ ... offered in the frame of a scientific event
 - scientific event = international or local seminars, investigator's meetings, symposia, scientific congress, training, life surgery, etc.
 - organized by companies or third parties (university, international, national or local scientific association, etc.)

Types of sponsorship

1. Direct sponsorship of participants

V1 submitted by the company

2. Indirect sponsorship of participants

V1 submitted by the company (or *jointly* by the company & organizer)

3. Sponsorship of the organizer

V2 submitted by the organizer



DIRECT SPONSORSHIP PARTICIPANTS

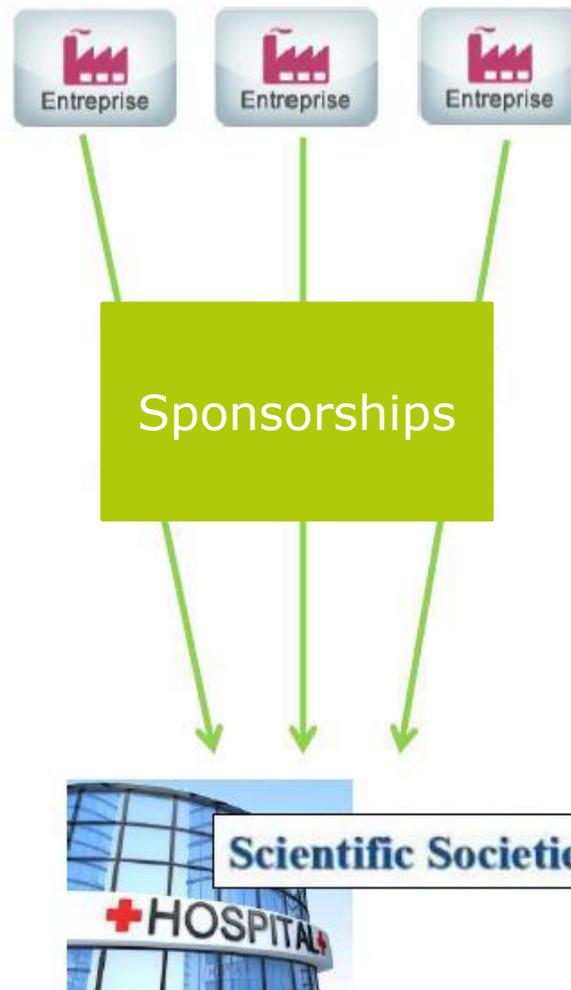
V1



V1 submitted by company

DIRECT SPONSORSHIP ORGANIZERS

V2



V2 submitted by organizer

INDIRECT SPONSORSHIP PARTICIP.

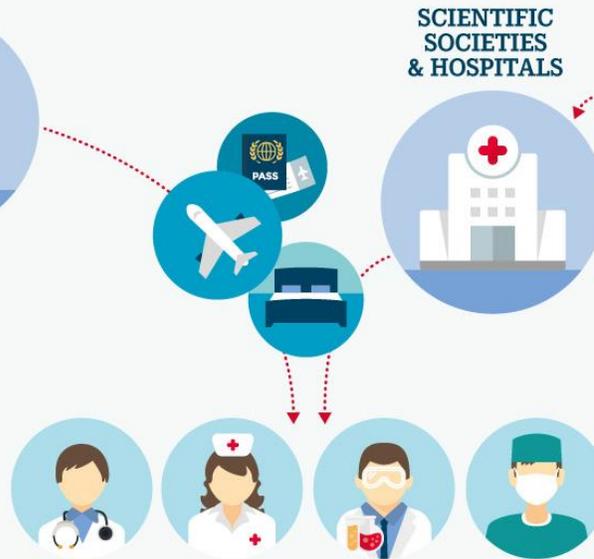
V1



V1 submitted by company

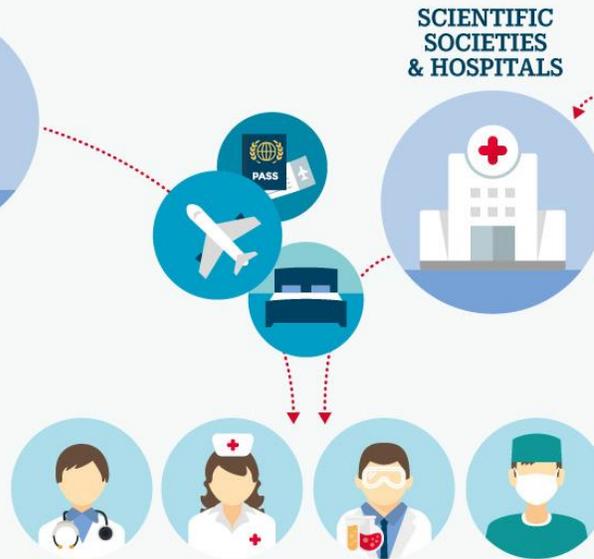
Direct sponsoring

Companies choose individual healthcare professionals and financially support their participation to scientific events organised by healthcare professionals or by companies.



Indirect sponsoring

Companies give a sponsorship (e.g. educational grants) to hospitals, medical societies or other third parties (=intermediaries) to support healthcare professionals participation to scientific events organized by healthcare professionals.



Mdeon visa is legally required for:

hospitality offered **directly** to healthcare professionals

AND hospitality offered **indirectly** through a hospital or a scientific society to take part to a scientific event taking place during several days.

- Use the V1 visa application form for both types of sponsoring www.mdeon.be

Advisory board,
Scientific congress,
Investigator meeting,
Life surgery meeting



Training,
Scientific congress,
Course

Sponsorship of participants

- ▶ = registration, overnight stays, meals and/or transport costs (=V1)
- ▶ Visa obligation if event during several calendar days (*scientific program + eventual overnight stay*)
 - ▶ 3 days program in Barcelona
 - ▶ 2 days program in Belgium, with or without overnight stay
 - ▶ 1 day program in Paris with overnight stay
- ▶ Company introduces visa application
- ▶ Forward visa number to HCP's
= guarantee



Mdeon

Sponsorship of participants

▶ Conditions to respect

▶ the manifestation is exclusively scientific

(Code, art. 4 + Pract. Directives, Section 2)

▶ scientific = whole scope of activities which have a direct link to the professional practice of the participants and which are necessary for a qualitative exercise of this profession *in the interest of the patient*

▶ each day must contain six hours of scientific activity

▶ the offered hospitality is strictly limited to the scientific objective of the manifestation

(Code, art. 5.2 & 5.3 + Pract. Directives, Section 3)

▶ no other activity (sport, visit town, concert, etc.)

Sponsorship of participants

► Conditions to respect

- the offered hospitality is *reasonable*
(Code, art. 5.1 + Pract. Directives, Section 3 + Case law Visa Office on website)
 - overnight stay: max 250 EUR (all in, breakfast, taxes inclusive)
 - dinner: max 80 EUR (drinks and taxes inclusive)
 - lunch: max 40 EUR (drinks and taxes inclusive)

No lunch on day where no scientific program:

Day 1	Day 2
Arrival 11:30	Scientific program
<i>No lunch</i>	<i>Lunch ok</i>
	Scientific program

**! Meal not
always
allowed !**

Day 1	Day 2	Day 3
Arrival 15:00		Scientific program
	<i>Lunch ok</i>	<i>Lunch ok</i>
<i>No meal</i>	Scientific program	

Sponsorship of participants

❖ Transport

- difference in hospitality between 'consultants' & 'participants'
- prove the quality of consultant in the application

Participants = HCPs taking part in a Scientific Event in a *learning situation*

Consultants = HCPs who are *providing scientific acts* within the context of a Scientific Event on behalf of the organizer of the Event or on behalf of a Pharmaceutical or Medical Devices Company.
Examples: Speakers, investigators, etc.

Visa mandatory for hospitality offered to consultants!!



Form of Transport	Healthcare Professionals as <u>Participant</u>	Healthcare professionals as <u>Consultant</u>
Train	Economy Class or Business Class	Economy Class or Business Class
Plane	Economy Class* , for whatever the destination and duration of flight	Economy Class* . For flights longer than 6 hours, Business Class is Authorized. First class is not allowed.
	Non-flexible tickets, save for (cumulative conditions):	
	<ul style="list-style-type: none"> - justified motivations (e.g. luggage, cancel option, to leave earlier in case the congress ends sooner than expected, etc.), - statement that the flex character will not be used to prolong the stay (leave earlier or come back later). 	
	The Healthcare Professional may travel in Business or First Class if he or she pays the difference in cost of an (standard) Economy Class ticket.	
Use of personal vehicle	Maximum rate of 0.35€ per kilometer. For long distances by car (> 500 km), sponsorship is limited to the cost of an airline ticket in economy class if this is a reasonable and cheaper alternative.	
Transport to/from airport/railway station within Belgium	Transportation costs from home to the airport/railway station for departure abroad are to be paid by the Healthcare Professional.	Reasonable transfer costs may be funded.
Transfer costs whilst abroad	Reasonable transfer costs abroad may be refundable. If several healthcare professionals are travelling together, taxis should be shared or a larger transport must be used (e.g. minibus or shuttle).	
Parking costs	Parking costs at the scientific event or at the airport or railway station are borne by the Healthcare Professional	Reasonable parking costs may be funded.

Sponsorship of participants

▶ Conditions to respect

- ▶ the hospitality is limited to the official duration of the event
 - ▶ arrival and departure of participants coincide with begin and end of manifestation
 - ▶ lengthening of stay? Yes, but impact on the sponsorship *(Code, art. 8 + Pract. Directives, Section 6, b)*
- ▶ the hospitality cannot be extended tot other persons *(Code, art. 7 + Pract. Directives, Section 5)*
- ▶ the place, date and duration of the manifestation do not create confusion about its scientific character *(Code, art. 6 + Pract. Directives, Section 4)*

Sponsorship of participants

► Justificatives

❖ Flight

- justificatif of the cost and the class of the chosen flight ticket
- prinstscreen from the internet / sworn statement travel agency

❖ Registration fee

- justificatif of what is included in the registration's fee (lunch, dinner, social activity, etc.) and of its amount
- prinstscreen from the internet / sworn statement organizer

No email, invoice, ticket !

Justificative flight

LUFTHANSA Totaalprijs **169.82 €**

normaal tarief 64.00 + 105.82 Tax

Heenvlucht Vertrek naar

LH1011	Ma 27.11.2017	13:05	BRU Brussel	→	14:05	FRA Frankfurt	0 Party	> 9	Economy Standard	1:00	319	
							Total per person					
LH1019	Ma 27.11.2017	19:05	BRU Brussel	→	20:05	FRA Frankfurt	0 Party	2	Economy Standard	1:00	320	
							Total per person					

Terugvlucht

LH1010	Wo 29.11.2017	11:25	FRA Frankfurt	→	12:25	BRU Brussel	0 Party	> 9	Economy Standard	1:00	320	
							Total per person					

JUSTIFICATIF OF THE COST AND THE CLASS OF THE CHOSEN FLIGHT TICKET
(to be attached to the V1 visa application in accordance with art. 18.2 of the Code of Ethics of Mdeon)

PS: This document has been developed for the companies that book flight tickets through a travel agency. The other companies can still prove the price and the class of the flight ticket via a printscreen of the webpage of the chosen airline company.

Undersigned,	Last name, first name:	
Valid acting on behalf of the travel agency,	Name travel agency:	
	Address:	
	Legal form:	
	Enterprise number:	

MAKES THE SWORN STATEMENT THAT THE DATA MENTIONED BELOW ARE CORRECT AT THE DATE OF SIGNATURE:

Mandator:	Name and address of the company:		
Tickets to be booked:	Outbound flight:	Place of departure, date and time:	
		Destination and time of arrival:	
		Class:	<input type="checkbox"/> Economy <input type="checkbox"/> Business
		Flex:	<input type="checkbox"/> no <input type="checkbox"/> yes → reason:
	Return flight:	Place of departure, date and time:	
		Destination and time of arrival:	
		Class:	<input type="checkbox"/> Economy <input type="checkbox"/> Business
		Flex:	<input type="checkbox"/> no <input type="checkbox"/> yes → reason:
Duration flight:			
Total price in euro:			

Remarks:	
Place:	
Date:	
Signature:	
Stamp of the travel agency:	

→ Completed and signed by travel agency (not by company) + stamp

Justificative registration

Registration fees:

International Participants 150,00 Euro
National delegates 100,00 Euro
Students (BA, MA/MSc, PhD) 50,00 Euro
Symposium participation fee 25,00 Euro.



The Congress fee includes:

- Admission to all scientific sessions
- Admission to exhibition
- Congress materials (bag, programme, book of abstracts and full texts CD version)
- Coffee breaks at the Conference Centre
- Cocktail for the opening of the Congress
- Farewell dinner
- Gala Concert for the 75th anniversary of the NSA

Fees, meals, gift, social activities are not mentioned
=> use sworn statement

The Fee Includes:

- UEMS accreditation
- Access to all Scientific Sessions
- Access to the Exhibition area
- Congress Kit and attendance badge

Justificative registration

JUSTIFICATIF OF WHAT IS INCLUDED IN THE REGISTRATION FEE OR IN CASE OF NO REGISTRATION FEE OF WHAT IS OFFERED BY THE ORGANISER

(to be attached to the V1 visa application in accordance with art. 18.2 of the Mdeon Code of Ethics)

This justificatif is mandatory when a scientific event organized by healthcare professionals is sponsored, regardless of whether or not there is a registration fee and regardless the registration fee is sponsored or not.

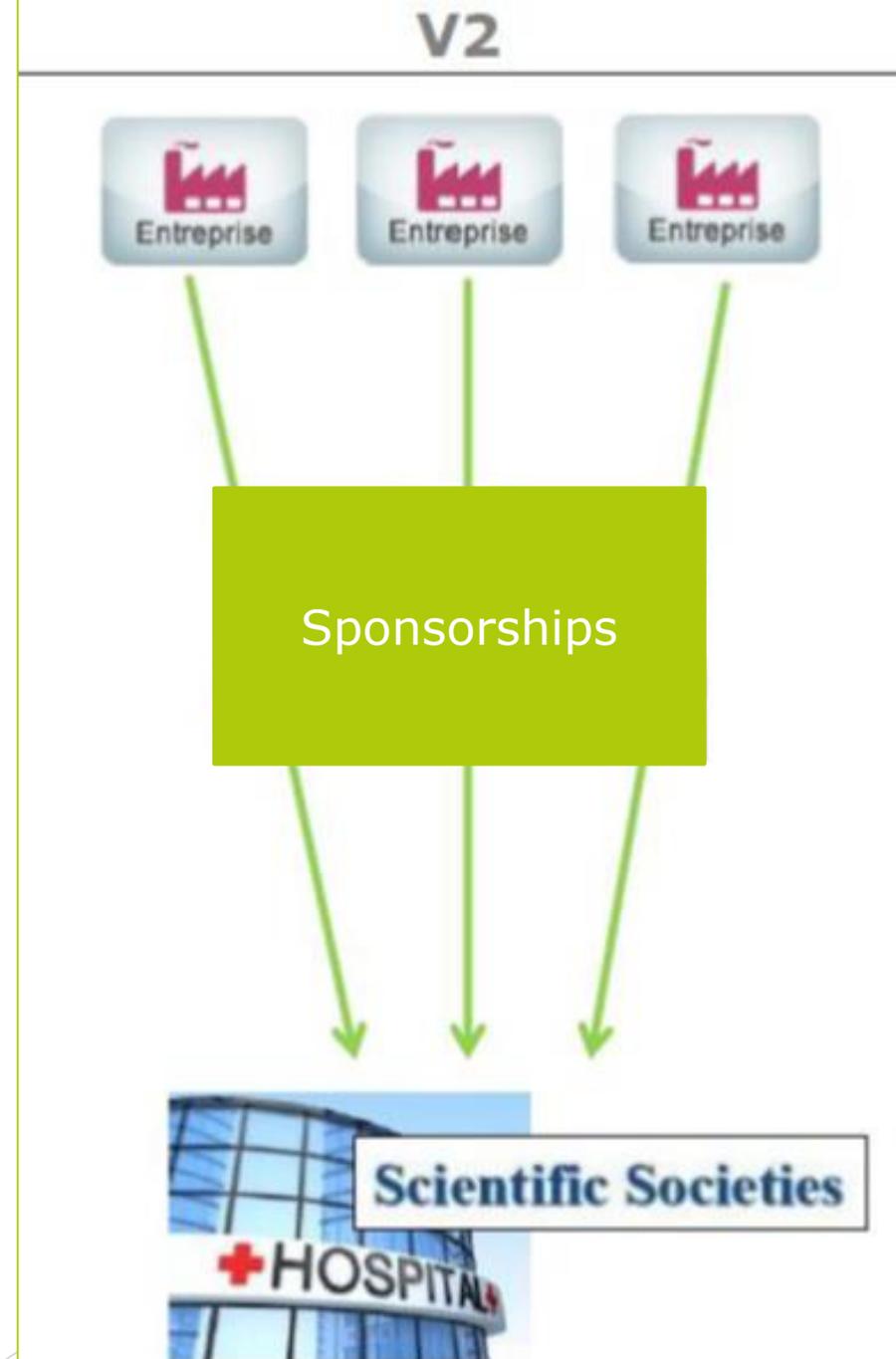
PS: this document has been developed for scientific events whose official website does not detail what is included in the registration fee. If it is detailed, companies can still prove the content of the registration through a printscreen of the website.

Undersigned,	Last name, first name:	
Valid acting on behalf of the organising organisation,	Name and address of the organising organisation:	
Of the following scientific event,	Name scientific event:	
	Start of scientific event:	
	End of scientific event:	
	Place of scientific event:	
<input type="checkbox"/> MAKES THE SWORN STATEMENT THAT THE FOLLOWING IS INCLUDED IN THE REGISTRATION FEE:		<input type="checkbox"/> MAKES THE SWORN STATEMENT THAT THERE IS NO REGISTRATION FEE AND THAT THE FOLLOWING WILL BE OFFERED:
Lunch	<input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> date(s): <input type="checkbox"/> remark:	
Dinner	<input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> date(s): <input type="checkbox"/> remark:	
Social activity	<input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> market value in €: <input type="checkbox"/> description: <input type="checkbox"/> date(s):	
Overnight stay	<input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> date(s): <input type="checkbox"/> remark:	
Gift or advantage with no direct link with the scientific manifestation (e.g. subscription to a journal, access to another event, membership, online access to database, etc.)	<input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> description: <input type="checkbox"/> market value: <input type="checkbox"/> free for everyone, also for non-participating persons <input type="checkbox"/> _____ EURO: in that case: <input type="checkbox"/> this advantage will be offered to the Belgian participants; or <input type="checkbox"/> the organisation solemnly swears not to offer this to Belgian participants.	
Remarks:		
Place:		
Date:		
Stamp of organisation: (in the absence of a stamp: to be printed at stationery of the organisation)	→ Completed and signed by congress organizer (not by company) + stamp	
Signature:		

<input type="checkbox"/> MAKES THE SWORN STATEMENT THAT THE FOLLOWING IS INCLUDED IN THE REGISTRATION FEE:		<input type="checkbox"/> MAKES THE SWORN STATEMENT THAT THERE IS NO REGISTRATION FEE AND THAT THE FOLLOWING WILL BE OFFERED:	
Lunch	<input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> date(s): <input type="checkbox"/> remark:		
Dinner	<input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> date(s): <input type="checkbox"/> remark:		
Social activity	<input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> market value <input type="checkbox"/> description: <input type="checkbox"/> date(s):	→ If social activity included => HCP has to pay a part of registration	
Overnight stay	<input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> date(s): <input type="checkbox"/> remark:		
Gift or advantage with no direct link with the scientific manifestation (e.g. subscription to a journal, access to another event, membership, online access to database, etc.)	<input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> description: <input type="checkbox"/> market value: <input type="checkbox"/> free for everyone, also for non-participating persons <input type="checkbox"/> _____ EURO: in that case: <input type="checkbox"/> this advantage will be offered to the Belgian participants; or <input type="checkbox"/> the organisation solemnly swears not to offer this to Belgian participants.	If gift included => sworn statement that won't be offered to the Belgian sponsored HCPs	

Sponsorship of the organizer (1/2)

- ▶ = booth, badges, leaflets, speakers, etc.
 - ▶ Visa obligation if event
 - is during several calendar days (scientific program + eventual social program)
 - and 1) organized by an association managed by a majority of HCPs working in Belgium and/or 2) attract a majority of healthcare professionals practising in Belgium.
- ⇒ no visa necessary for booth at international congress with international delegates, even if in Belgium !
- ⇒ visa always necessary when event organized by Belgian association of HCPs



Sponsorship of the organizer

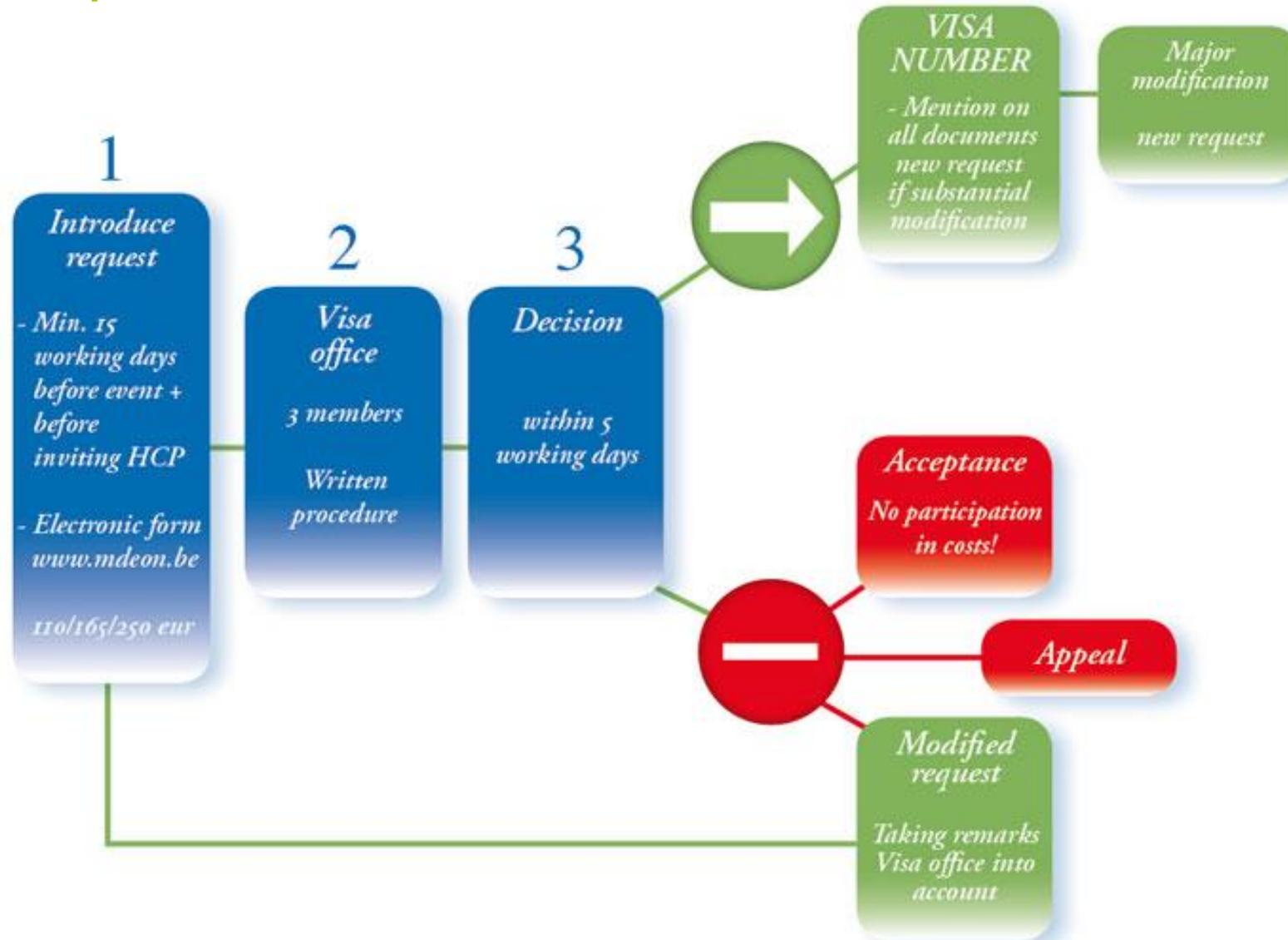
- ▶ Grouped visa application introduced by organizer

(final responsibility also -> company)

- ▶ Forward visa number to sponsors
= **guarantee**

(ask official decision with name companies covered by visa number)

Visa procedure



Figures 2017*

- ✓ 6.636 visa applications
- ✓ 680 companies
- ✓ 150 associations of healthcare professionals
- ✓ 26 visa requests each working day
- ✓ 5-6 meetings Office of visa / week
- ✓ 80% applications => visa
 - ✓ 96,6% after resubmission

**See Annual Activity reports on Mdeon website*



Agenda

- ❖ The Platform
 - ❖ Legal frame
 - ❖ Who is concerned?
 - ❖ Visa procedure
 - ✓ Sponsorship of participants (V1)
 - ✓ Sponsorship of organizers (V2)
-
- ❖ Mdeon Guidelines
 - ✓ Premiums and benefits of negligible value
 - ✓ Sponsoring of scientific events not subject to the visa requirements
 - ✓ Fees for scientific services
 - ❖ Responsibility-controls-sanctions
 - ❖ Communication

The following guidelines have been designed to guide Healthcare Sector professionals and companies to apply and interpret the dispositions of the Law on medicinal products and of the Mdeon Code of Ethics in relation to premiums and benefits of negligible value.

The Mdeon Guidelines

Approved by Authorities

LEGAL FRAMEWORK?

It is permissible for companies from the pharmaceutical or medical devices sector to offer premiums and benefits to Healthcare professionals, to the extent that these gifts are of negligible value and related to the practice of the profession (article 10, §2, 1° of the Law of 25 March 1964 concerning medicinal products*).

A QUESTION?

Companies or Healthcare professionals who so wish can ask the Mdeon Visa Office *written advice* about the question if a proposed gift is in accordance with the Mdeon Code of Ethics.



PRINCIPLE?

Companies from the pharmaceutical or medical devices sector may sponsor scientific events which take place only one day and which do not require a visa.

Rules applicable are identical to the events requiring a visa (article 10, of the law of 25 March 1964 concerning medicines*).

TYPES OF SPONSORING?

The principles of these guidelines equally to the sponsoring of *participative* and to the sponsoring of *organizational* scientific events.

QUESTIONS?

Healthcare professionals or companies who so wish can ask the Mdeon Visa Office *written advice* about the question if a proposed gift is in conformity with the Mdeon Code of Ethics.

* It must not be forgotten that §1 of this article forbids in general the offering of all premiums and benefits by companies to Healthcare professionals as well as requests of the same by the said professionals.

ACCEPT
Diaries, calendars, scientific or pharmaceutical nature stationery items, clinical nail brushes, tongue-depressors, etc.) computer professional use, etc.

SPONSORING OF SCIENTIFIC EVENTS NOT SUBJECT TO VISA REQUIREMENTS: GUIDELINES (D.D. 25.09.2012)

The following guidelines have been designed to guide Healthcare Sector professionals and companies to apply and interpret the dispositions of the Law on medicinal products and of the Mdeon Code of Ethics in relation to events which do not require a preliminary visa.



FEES FOR SCIENTIFIC SERVICES: GUIDELINES (D.D. 18.06.2013)

The following guidelines have been designed to guide Healthcare Sector professionals and companies to apply and interpret the dispositions of the Law on medicinal products and of the Mdeon Code of Ethics in relation to fees for scientific services.

PRINCIPLE ?

Healthcare professionals may be remunerated by the pharmaceutical or medical devices companies as payment for legitimate scientific acts on behalf of those companies (article 10, §2, 3° of the Law of 25 March 1964 on medicinal products*).

WRITTEN AGREEMENT ?

A written agreement has to be established in advance of the commencement of the services which clearly specifies in detail the nature and the content of the services to be provided, as well as the basis for payment of those services.

TRANSPARENCY ?

In the interests of transparency, it is recommended to include in the agreement a provision regarding the obligation of the consultant to declare that he/she is a consultant to the company whenever he/she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company. This is a declaration of interests.

SCIENTIFIC SERVICES ?

By scientific services is meant the involvement of Healthcare professionals in clinical trials, the giving of scientific papers during teaching lectures, seminars, symposiums or congresses, the participation at advisory board meetings or experts meetings.

The following services are not scientific and may consequently not be remunerated: commercial survey, 'registries', etc.

LEGITIMATE SERVICES ?

- A service is *legitimate* if
- ❖ it corresponds to a real need of the company
 - ❖ it is provided for the purpose of supporting healthcare or research
 - ❖ it is not an inducement to influence the prescription-, supply-, administration-, recommendation-, or using's behavior of the consultant
 - ❖ it is performed by a qualified consultant who has the required expertise
 - ❖ and it is effectively performed.

REASONABLE FEES ?

The compensation for the services has to be *reasonable* and reflects the *fair market value* of the services provided. The market of reference is the *Belgian* market.

The compensation is calculated on the basis of multiple criteria as the duration of the services, their degree of complexity, the required level of experience and expertise, the degree of urgency of the services, etc. The past or future volume of prescription of the consultant is not a relevant criteria.

The compensation is *proportional* to the performed services. It is important to be able to explain how this was determined.

The compensation should be *consistent*. To identical services and situations, identical compensation.

HOSPITALITY ?

If hospitality is offered to the consultant in addition to the fees (meals, overnight stays or transport), this has to be *reasonable*. Such hospitality will have to be subject to a *preliminary visa delivered by Mdeon* if it is offered in the framework of a scientific event taking place over several consecutive calendar days.

A QUESTION ?

Companies or Healthcare professionals who so wish may ask the Mdeon Visa Office for *written advice* concerning whether or not a proposed fee is in accordance with the Mdeon Code of Ethics.

* It must not be forgotten that §1 of this article forbids in general the offering of all premiums and benefits by companies to Healthcare professionals as well as requests of the same by the said professionals.

The following guidelines have been designed to guide Healthcare Sector professionals and companies to apply and interpret the dispositions of the Law on medicinal products and of the Mdeon Code of Ethics in relation to premiums and benefits of negligible value.

LEGAL FRAMEWORK?

It is permissible for companies from the pharmaceutical or medical devices sector to offer premiums and benefits to Healthcare professionals, to the extent that these gifts are of negligible value and related to the practice of the profession (article 10, §2, 1° of the Law of 25 March 1964 concerning medicinal products*).

A QUESTION?

Companies or Healthcare professionals who so wish can ask the Mdeon Visa Office *written advice* about the question if a proposed gift is in accordance with the Mdeon Code of Ethics.

NEGLIGIBLE VALUE?

- ❖ Of a nature which will have no influence on medical decisions
- ❖ Maximum 50 EUR per gift (market value, VAT included)
- ❖ Maximum 125 EUR per annum, per Healthcare professional and per company (VAT included)
- ❖ The limited value is determined on the basis of the gift as a whole entity and not on the value of its constituent parts

LINK WITH PROFESSIONAL ACTIVITY?

- ❖ The gift has a function in the *normal and current* exercise of the Healthcare professional's profession
- ❖ The gift has a link with the practice of medicine, pharmacy, dentistry, veterinary medicine, etc. of the Healthcare professional or with the administrative activity relating to his or her work
- ❖ The gift is not intended for purely personal use
- ❖ The giving of the gift is not associated with a private or personal event (birth, birthday, wedding, etc.)

TYPE OF GIFT?

- ❖ Only in kind / no cash or its equivalent
- ❖ Small / discreet
- ❖ Principles also applicable to gifts distributed on exhibition stands / to immaterial gifts



A C C E P T A B L E U N A C C E P T A B L E

Diaries, calendars, scientific books of a medical or pharmaceutical nature, scientific CD Roms stationery items, clinical items (reading charts, nail brushes, tongue-depressor, surgical gloves, wipes, etc.) computer accessories for professional use, etc.



Decorative objects, digital photo frame, iPod, champagne cooler, coffee machine, mp4, gift voucher, reduction voucher, camera, bottles of wine, tickets for the theatre or other cultural, sporting or recreational events, mobile phone, scanner, radio, suitcase, sport/travel bag, alarm clock, cups, watch, etc..

SPONSORING OF SCIENTIFIC EVENTS NOT SUBJECT TO VISA REQUIREMENTS: GUIDELINES (D.D. 17.12.2015)

The following guidelines have been designed to guide Healthcare Sector professionals and companies to apply and interpret the dispositions of the Law on medicinal products and of the Mdeon Code of Ethics in relation to the sponsoring of scientific events which do not require a preliminary visa.

PRINCIPLE?

Companies from the pharmaceutical or medical devices sector may sponsor scientific events which take place over only one day and which do not therefore require a visa.

Rules applicable are identical to those for events requiring a visa (article 10, §2, 2° of the law of 25 March 1964 concerning medicines*).

TYPES OF SPONSORING?

The principles of these guidelines apply equally to the sponsoring of *participants* and to the sponsoring of *organisers* of scientific events**.

QUESTIONS?

Healthcare professionals or companies who so wish can ask the Mdeon Visa Office *written advice* about the question if a scientific event not subject to visa requirements is in conformity with the Mdeon Code of Ethics.

WHICH PROGRAMME?

The event is of an *exclusively scientific* nature – as is the programme: scientific symposium, investigators meeting, advisory board meeting, working party operating within the framework of a scientific consultancy contract, etc.

Events which do not have a scientific programme may *not be sponsored*. i.e.: asbl Board Meetings, Emeritus celebrations with no scientific programme, Open Days with no scientific programme, business lunches, meetings of a purely promotional nature, etc.

LEVEL OF HOSPITALITY?

- ❖ *Reasonable*: maximum 40 EUR per lunch and 80 EUR per evening meal, all inclusive (drinks, taxes, hire of room, ...), at market prices
- ❖ *Subsidiary*: the offered hospitality is in proportion to the number of hours devoted to scientific activities, with the understanding that the maximum of 40 EUR + 80 EUR may only be attributed when the programme includes a minimum of six hours of effective scientific activities
- ❖ *Limited to the official duration of the event*: meals taken immediately before or after the scientific activities

SOCIAL ACTIVITIES?

Healthcare professionals may *organise* social activities to take place after a *complete* day's proceedings which were of a scientific nature, with the proviso that such activities do not last any longer than one hour, that such activities are financed by the participants themselves and that the nature of the activities is compatible with the scientific nature of the daytime events.

Companies do not organise social activities – even if such activities were to be financed by the Healthcare professionals themselves.

Social activities must *never be sponsored*. Eg.: sports days for hospital staff, festivities linked to Saint-Nicolas feast day, golf afternoons, wine-tasting sessions, town visits or museum visits, etc.

ACCOMPANYING PEOPLE?

Companies do not invite persons to accompany participants. In any case, companies do not support the costs of eventual accompanying persons.

VENUE?

The chosen venue suites to the scientific nature of the event and does not lead to any confusion in this area.

* It must not be forgotten that §1 of this article forbids in general the offering of all premiums and benefits by companies to Healthcare professionals as well as requests of the same by the said professionals.

** The Guidelines are however not applicable to the sponsoring of foreign organisers, as defined in article 16.2 of the Code of Ethics.

Personne de contact : Ethel Mertens
Tél : 02 528 40 00
Fax: 02 528 40 01
e-mail : Ethel.Mertens@fagg-afmps.be

Circulaire n° 622
À l'attention des professionnels du secteur de
la santé humaine et vétérinaire

Votre lettre du	Vos références	Nos références	Annexe(s)	Date
		854791		01 DEC. 2015

Objet : Rappel de la législation relative :

- aux relations entre l'industrie des médicaments et des dispositifs médicaux et les professionnels du secteur de la santé humaine et vétérinaire
- au sponsoring de manifestations scientifiques : conditions et visa

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.).

FEES FOR SCIENTIFIC SERVICES: GUIDELINES (D.D. 01.03.2017)

The following guidelines have been designed to guide Healthcare Sector professionals and companies to apply and interpret the dispositions of the Law on medicinal products and of the Mdeon Code of Ethics in relation to fees for scientific services.

PRINCIPE ?

Healthcare professionals may be remunerated by the pharmaceutical or medical devices companies as payment for legitimate scientific acts on behalf of those companies (article 10, §2, 3° of the Law of 25 March 1964 on medicinal products*).

WRITTEN AGREEMENT ?

A written agreement has to be established in advance of the commencement of the services which clearly specifies in detail the nature and the content of the services to be provided, as well as the basis for payment of those services.

TRANSPARENCY ?

In the interests of transparency, it is recommended to include in the agreement a provision regarding the obligation of the consultant to declare that he/she is a consultant to the company whenever he/she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company. This is a declaration of interests.

A QUESTION ?

Companies or Healthcare professionals who so wish may ask the Mdeon Visa Office for *written advice* concerning whether or not a proposed fee is in accordance with the Mdeon Code of Ethics.

SCIENTIFIC SERVICES ?

By scientific services is meant the involvement of Healthcare professionals in clinical trials, the giving of scientific papers during teaching lectures, seminars, symposiums or congresses, the participation at advisory board meetings or experts meetings.

The following services are not scientific and may consequently not be remunerated: commercial survey, 'registries', etc.

LEGITIMATE SERVICES ?

A service is *legitimate* if

- ❖ it corresponds to a real need of the company
- ❖ it is provided for the purpose of supporting healthcare or research
- ❖ it is not an inducement to influence the prescription-, supply-, administration-, recommendation-, or using's behavior of the consultant
- ❖ it is performed by a qualified consultant who has the required expertise
- ❖ and it is effectively performed.

REASONABLE FEES ?

The compensation for the services has to be *reasonable* and reflects the *fair market value* of the services provided. The market of reference is the *Belgian* market.

The compensation is calculated on the basis of multiple criteria as the duration of the services, their degree of complexity, the required level of experience and expertise, the degree of urgency of the services, etc. The past or future volume of prescription of the consultant is not a relevant criteria.

The compensation is *proportional* to the performed services. It is important to be able to explain how this was determined.

The compensation should be *consistent*. To identical services and situations, identical compensation.

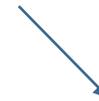
HOSPITALITY ?

If hospitality is offered to the consultant in addition to the fees (meals, overnight stays or transport), this has to be *reasonable*.

Such hospitality will have to be subject to a *preliminary visa delivered by Mdeon* if it is offered in the framework of a scientific event taking place over several consecutive calendar days.

Responsibility

- ▶ Penal co-responsibility companies and healthcare professionals
- ▶ Federal Agency for Medicines and Health Products (FAMHP) in charge of controls
- ▶ Penal fines up to 100.000 EUR
- ▶ Complaint Contact-Point



Communication

*M*deon

Hoe een visumaanvraag indienen?

Inleiding

Heb ik een visum nodig?

Zich inschrijven op de website

Zich inloggen

Een visumaanvraagformulier openen

Aandachtspunten bij het invullen van een aanvraag

Quid na verzending van een aanvraag?



2011

Mdeon



Mdeon

MDEON, DO THE RIGHT THING

2012

MDEON,
VOOR EEN
ETHISCHE
SPONSORING,
IN HET
BELANG
VAN ONZE
PATIËNTEN!



mdeon

www.mdeon.be
Deontologisch Gezondheidsplatform

**BEL MDEON OP OM UW
INFORMATIE TE CHECKEN!
0800/64.001**

2013

ETHIQUE | SPONSORING

POURQUOI CHOISIR ?

MDEON, POUR UNE **HOSPITALITÉ ÉTHIQUE**,
DANS UN **CONTEXTE SCIENTIFIQUE**!



Mdeon

www.mdeon.be
Plateforme Déontologique Santé

UNE QUESTION ?
APPELEZ-NOUS AU 0800/64.001
NOUS VOUS AIDERONS AVEC PLAISIR!

2014

Communication

Mdeon opens
free phone
especially for HCPs



Call us
0800/64.001

Mdeon : « Appelez-nous, vous serez positivement surpris ! »



BRUXELLES 08/05 - Fin janvier, Mdeon a ouvert une ligne téléphonique spéciale pour les professionnels de la santé afin de leur permettre de vérifier leurs informations. Si la ligne n'est pas saturée d'appels, il est cependant étonnant de constater à quel point les professionnels de la santé qui contactent ce 0800 sont surpris (positivement) de la réponse apportée à leur question.



2015

Mdeon

Mdeon: bel ons, u zal aangenaam verrast zijn !



BRUSSEL 08/05 - Eind januari heeft Mdeon een telefoonlijn geopend speciaal voor gezondheidszorgbeoefenaars opdat deze zouden kunnen nagaan of hun informatie wel correct is. Hoewel deze lijn nog niet rood staat, is het nu reeds verrassend vast te stellen op welk vlak de gezondheidszorgbeoefenaars die het 0800-nummer bellen (positief) verrast zijn van het verschaft antwoord op hun vraag.

Communication

Indirect sponsorship
=> visa still necessary

2016



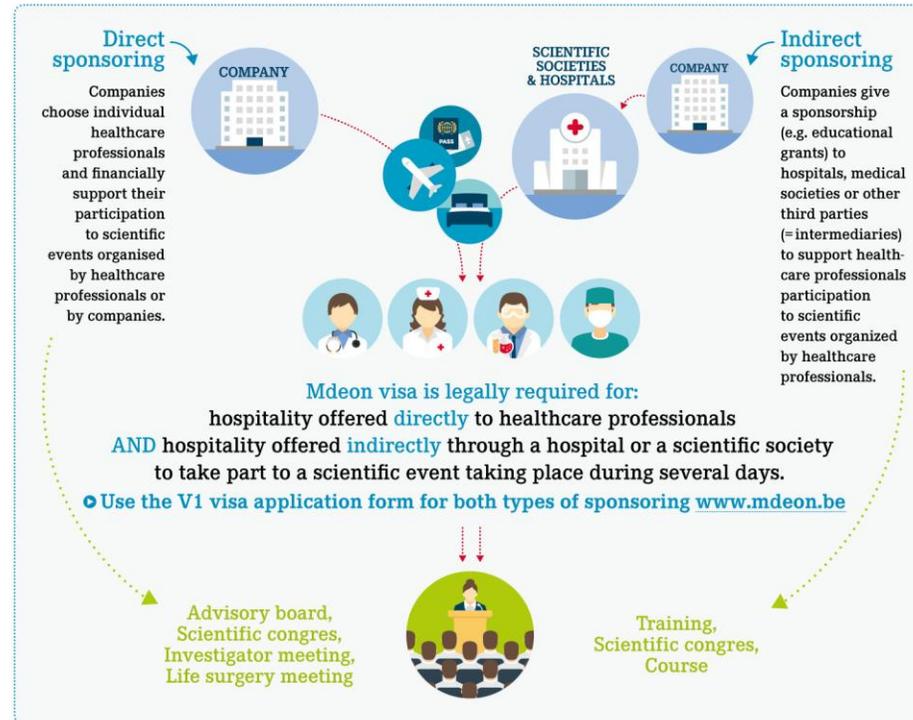
Sponsoring of continuous medical education

Preliminary visa required by law

You take part to a **scientific event**?

You receive **hospitality** from a pharmaceutical/medical devices **company** or an intermediary?

DON'T FORGET THE MDEON VISA!



MDEON VISA THE GUARANTEE OF AN ETHICAL SPONSORSHIP!

Mdeon is a **common ethical platform** constituted of 26 associations of the healthcare sector. Healthcare professionals and the medicinal products and medical devices industry have joined forces as **continuing training partners**. They are involved in organising scientific events where healthcare professionals have the opportunity to keep abreast of trends in their profession. The industry extends **hospitality** to some healthcare professionals anxious to take part in these events.

As the funding for some of these events is subject to a PRELIMINARY VISA by law, industry and healthcare professionals have joined forces to create the common ethical platform **Mdeon**, the primary aim of which is to guarantee the visa procedure through self-regulation and in a transparent manner. The visa number provided is a **guarantee** that the project sponsorship to organise or take part in a scientific event is consistent with the relevant legislation and ethics.

Communication

Sunshine Act:

- Flyer beneficiaries
- Website
- FAQ
- Info sessions

2017



BETRANSSPARENT.BE: la transparence des collaborations entre les entreprises pharmaceutiques et de dispositifs médicaux et les organisations de patients, les professionnels et organisations du secteur de la santé

Le progrès médical et les meilleurs soins et traitements possibles pour le patient sont les pierres angulaires de notre système de soins de santé. Une collaboration efficace entre l'industrie pharmaceutique et l'industrie des dispositifs médicaux d'une part et les organisations de patients, les professionnels et organisations du secteur de la santé d'autre part, joue un rôle essentiel à cet égard.

L'industrie pharmaceutique et des dispositifs médicaux attache une grande importance à la transparence. Ses relations avec les acteurs du secteur de la santé sont déjà strictement réglementées par la législation et des codes de déontologie. Pour aller vers une plus grande transparence, la Ministre des Affaires Sociales et de la Santé Publique, Maggie De Block, a donné une base légale à l'obligation de transparence dans le *Sunshine Act* belge¹.

OBLIGATION DE TRANSPARENCE

L'obligation de transparence légale impose aux entreprises pharmaceutiques et de dispositifs médicaux, tant belges qu'étrangères, de documenter et rendre annuellement publiques sur la plateforme betransparent.be les primes et avantages qu'elles octroient à partir du 1er janvier 2017 directement ou indirectement aux professionnels du secteur de la santé, organisations du secteur de la santé ou organisations de patients.



PUBLICATION DES PRIMES ET AVANTAGES

Qu'est-ce qui est rendu public *nominativement* sur betransparent.be?

- Les honoraires, paiements et remboursements de frais octroyés pour **services et consultance** à des professionnels du secteur de la santé, organisations du secteur de la santé ou organisations de patients.
- Les contributions aux frais relatifs à l'organisation ou la participation à des **manifestations scientifiques** (coûts d'inscription, frais de voyage et de séjour, conventions de sponsoring) octroyées à des professionnels du secteur de la santé, organisations du secteur de la santé ou organisations de patients.
- Les **donations et subventions** qui soutiennent les soins de santé, octroyées à des organisations du secteur de la santé.
- Les **soutiens financiers ou autres** octroyés à des organisations de patients.

S'agissant d'une obligation légale, il n'est pas nécessaire d'obtenir le consentement des professionnels du secteur de la santé concernés pour rendre leurs données publiques. Les entreprises ont par contre l'obligation de préalablement les **informer** du traitement de leurs données.

Qu'est-ce qui est rendu public de manière *agrégée* sur betransparent.be?

Les primes et avantages octroyés dans le cadre de la **recherche scientifique** sont rendus publics de manière agrégée, donc sans mention de l'identité des professionnels ou organisations du secteur de la santé concernés. Il s'agit entre autres des primes et avantages octroyés dans le cadre d'essais cliniques.

Quand et pour combien de temps?

Les primes et avantages sont rendus publics à la fin du mois de juin qui suit l'année calendrier dans laquelle ils ont été octroyés.

Le *Sunshine Act* est d'application pour la première fois aux primes et avantages octroyés dans l'année calendrier 2017 et à rendre publics fin juin 2018 sur betransparent.be*. Les données publiées restent publiquement consultables pendant trois ans dans le Registre transparence. Elles en sont ensuite supprimées.

*A titre d'exception, un délai additionnel a été octroyé pour les primes et avantages liés aux médicaments à usage vétérinaire. Ceux-ci ne seront soumis au *Sunshine Act* qu'à partir du 1er janvier 2018, avec une première publication en juin 2019.

Home About the transparency register About us **F.A.Q.**

F.A.Q.

Frequently Asked Questions

[Click here for a printable version.](#)

- + FAQ 1. What exactly is the obligation of transparency ?
- + FAQ 2. Some definitions in the context of the transparency obligation
- + FAQ 3. What exactly is made public ?
- + FAQ 4. What is not made public ?
- + FAQ 5. On whose behalf the premiums and benefits are made public ?
- + FAQ 6. How can I consult the Transparency Register ?
- + FAQ 7. I do not find some data in the Transparency Register. How can this be explained ?
- + FAQ 8. I am a healthcare professional and do not agree with my published data. What can I do ?
- + FAQ 9. Sanctions



Mdeon

be
transparent
● be building transparency
in healthcare relationships

RAISE THE BAR

**CHECK YOUR SPONSORS'
MDEON VISA NUMBER**

JOIN TRANSPARENCY

CONTACT MDEON ETHICAL HEALTH PLATFORM: 0800/64.001 - SECRETARIAT@MDEON.BE

2018

**Thank you
for your
attention!**



*M*deon

For more information:

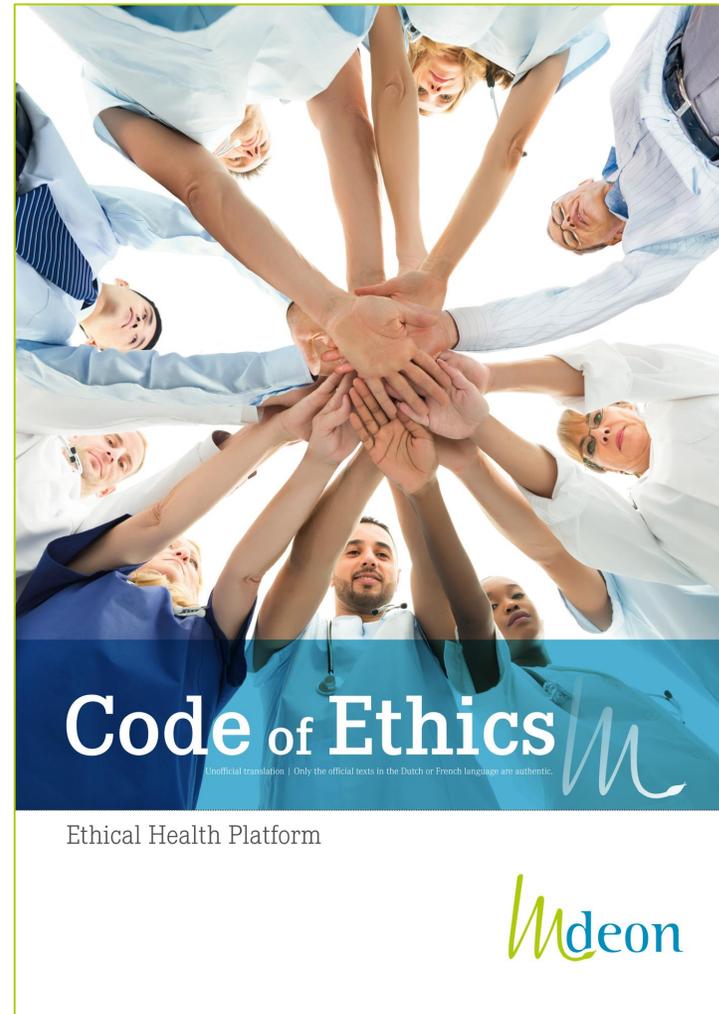
Mdeon asbl - vzw
Belgicastraat 1 b7 | 1930 Zaventem

Visa obligation

- www.mdeon.be
- [02/609.54.90](tel:026095490)
- secretariat@mdeon.be

betransparent.be

- www.betransparent.be
- [02/609.54.95](tel:026095495)
- management@betransparent.be



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