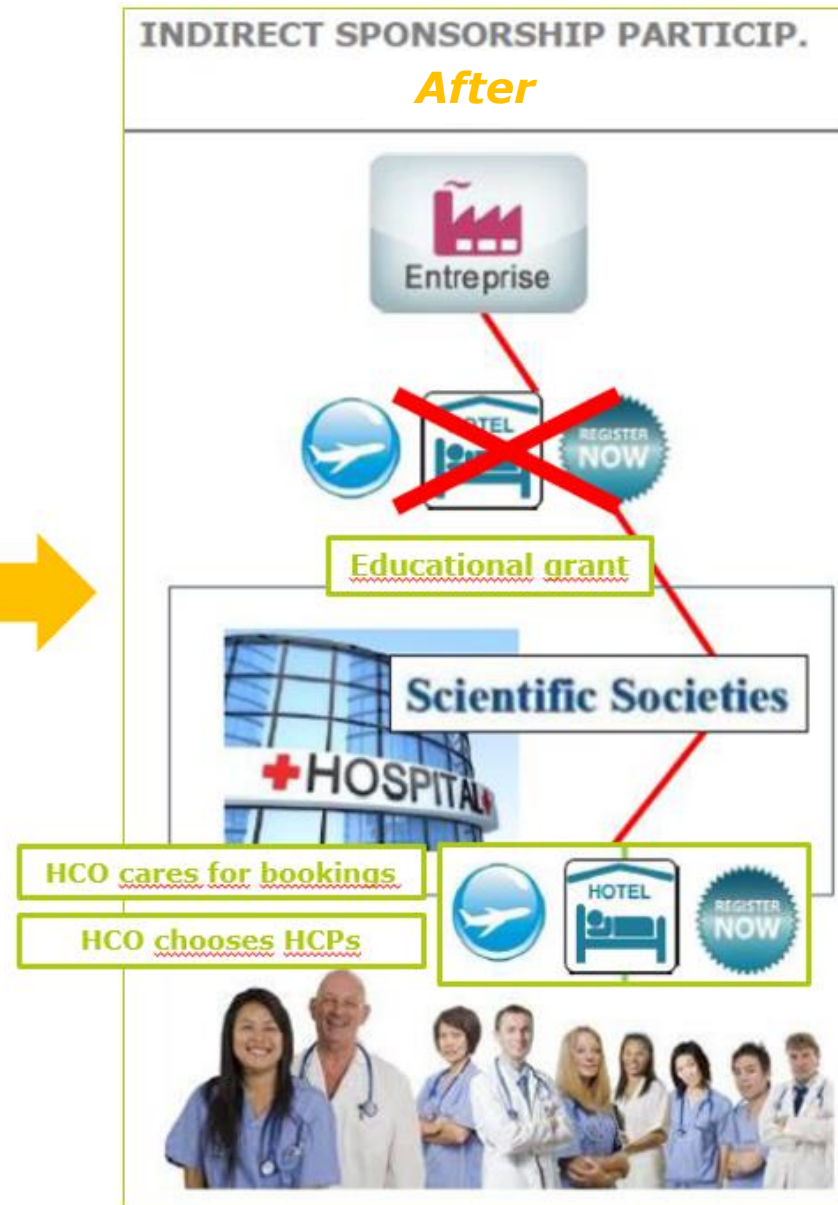
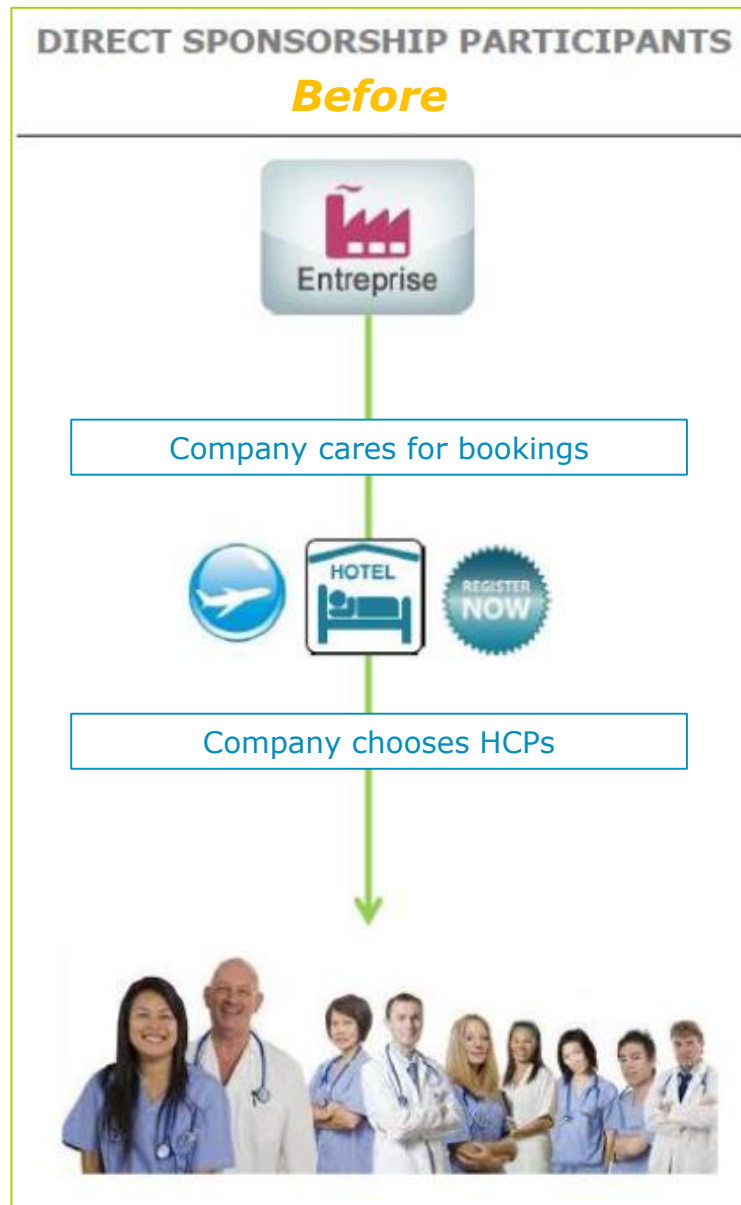


Legal & Compliance Infosession beMedTech

27.03.2017

Consequences of MTE ban of direct sponsorship in Belgium



Decision taken at **European** level

→ without taking all the national specifications into account

=> high consequences at **national level**

Consequences of MTE ban of direct sponsorship in Belgium

Country	National Association	Status	Comments
Austria	Austromed	yes	Yes, but according to option III in the MoU
	OEDGH	No information	
Belgium	BeMedTech	tbc	Positive board decision in 2016, to be confirmed by AGM in May 2017
Czech Republic	CzechMed	To be determined	Discussions have started
	CZEDMA	To be determined	
Denmark	Medicoindustrien	To be determined	No plans yet- discussions will start in 2018
	Dialab	To be determined	
France	Snitem	no	Decision by Board (Feb. 2016)
	SIDIV	To be determined	
Finland	Sai Lab	yes	Preparation work will start in 2017
Germany	BVMed	no	No revision planned
	VDGH	yes	
	Spectaris	yes	
Greece	SIEV	yes	Revision planned
	AMDM	yes	
Hungary	HIVDA	tbc	Vote of the General Assembly: 7/11; decision to partly implement the Code, awaiting clarification
	Irish Medtech Association	yes	
Ireland	IMSTA	yes	Transposition in 2017, Code in full force as of 2018
	Assobiomedica	tbc	
Italy	NEFEMED	yes	Common MT industry Code - 2017: GMH will discuss transposition, possibly in 2018/19
	DIAGNED	yes	
Norway	MedTek Norge	no	Agreement with Health Authorities, no revision planned. Alignment with MTE Code
	LabNorge	No information	
Middle East	MECOMED	yes	Phase out of direct sponsorship as of January 2018
Poland	POLMED	yes	Option III of MOU; Q1/2 2017: Preparation of Polish version of the Code; Q2: Adaption by AGM; 2018 in force
	IPDDL	yes	
Portugal	APORMED	yes	Discussions have started
	APIFARMA	yes	
Spain	FENIN	yes	Board approval on 20.12.2016, Transposition as of 2017
Romania	AFPM	To be determined	Discussions to start end 2016
Russia	IMEDA	yes	Discussions will in 2017. Communication to Member Companies to apply the MTE Code as of 2017
Slovakia	SK-MED	No information	
	SEDMA	No information	
Slovenia	SLO-MED	No information	
	SIEDMA	To be determined	
Sweden	Swedish Medtech	no	Agreement with stakeholders, no transposition planned. Alignment with MTE Code
	Swedish Labtech	no	
Switzerland	FASMED	yes	Preparation work and translation of MTE Code in 2016, Vote on the Code in June 2017
	SVDI	To be determined	
Turkey	Arted	To be determined	
UK	ABHI	yes	Transposition already started, new Code in force as of January 2017
	BIVDA	yes	

What is the issue in Belgium?

✓ Belgian Law provides

- a visa obligation
- applicable to both direct and indirect sponsorship
- visa application has to be submitted by the companies
- penal co-responsibility between companies and beneficiary of the sponsorship

✓ Works perfect with direct sponsorship

Company organizes travel => has the necessary elements to fill in the visa application form (costs, program, flight ticket, ...)

➤ *How to work with educational grant??*

- *Company doesn't organize the travel anymore*
- *HCO has the necessary elements to fill in the visa application form*
- *But Law doesn't provide that HCO may submit visa applications*

Mdeon



New form V1bis

- HCO submits visa application
- "Mandate theory"
- HCO mentions several sponsors in the same file

Consequences of MTE ban of direct sponsorship in Belgium



COMMENTS COMING FROM COMPANIES:

Problem with V1 visa application form.
Companies ask for a new form adapted to ban of direct sponsorship

Companies ask whether visa is necessary or not in case of indirect sponsorship

Decides it is **important to give an adapted form** to the companies

Decides it is **important to inform the companies** about the visa obligation in case of indirect sponsorship

Decides however to wait until the official vote of MedTech Europe

FORUM/DEBATE:

"The end of direct sponsorship".

Speaker: Serge Bernasconi (CEO MedTech Europe)

Objective: to **prepare the HCPs** to the ban of direct sponsorship

ETHIQUE | SPONSORING

POURQUOI CHOISIR ?

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

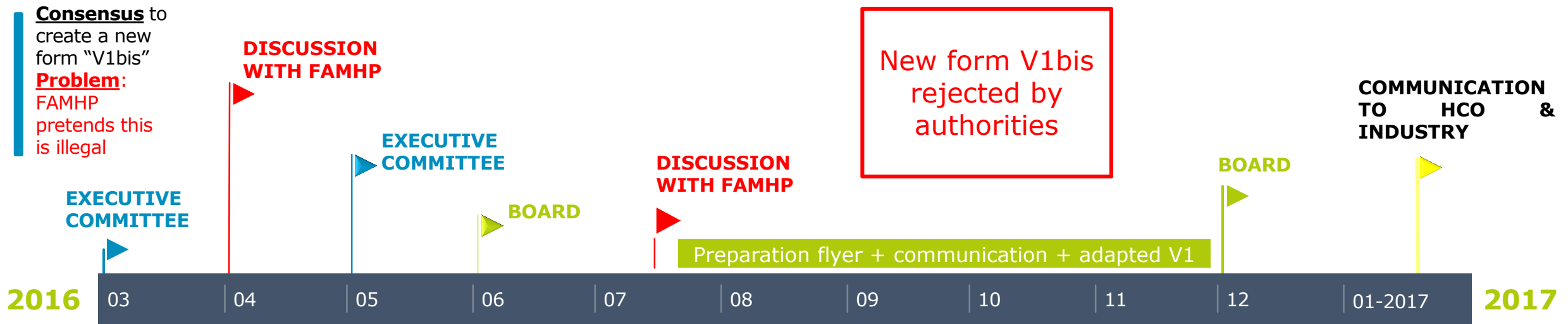


mdeon

www.mdeon.be
Plateforme Déontologique Santé

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

Consequences of MTE ban of direct sponsorship in Belgium



Mdeon communicates external **legal advice** confirming that the "V1bis" is perfect legal

Negotiations however fail

Association of medical specialists + FAMHP **deplore the move to indirect sponsorship**

beMedTech stresses the importance to remain flexible, to adapt to new developments

=> Negotiations to be followed

FAMHP stays saying that the HCOs cannot submit the visa applications. Visa applications has to be submitted by the company

FAMHP finally:

- 1) accepts to **modify** the existing **V1-form** to mention the identity of the HCO
- 2) allows the **HCOs to prepare** the visa application
- 3) at the explicit condition that the **company** would still finally **submit** it to Mdeon

Mdeon proposed to make an **evaluation after 1 year**


Approves flyer + communication

Urgent to send it to HCO and industry

Objectives:

- Announce that the adapted V1-form is finally ready
- Bring attention on the correct scope of the visa obligation
- Help HCOs to submit visa applications in the place of the companies

Communication to HCOs (January 18, 2017)




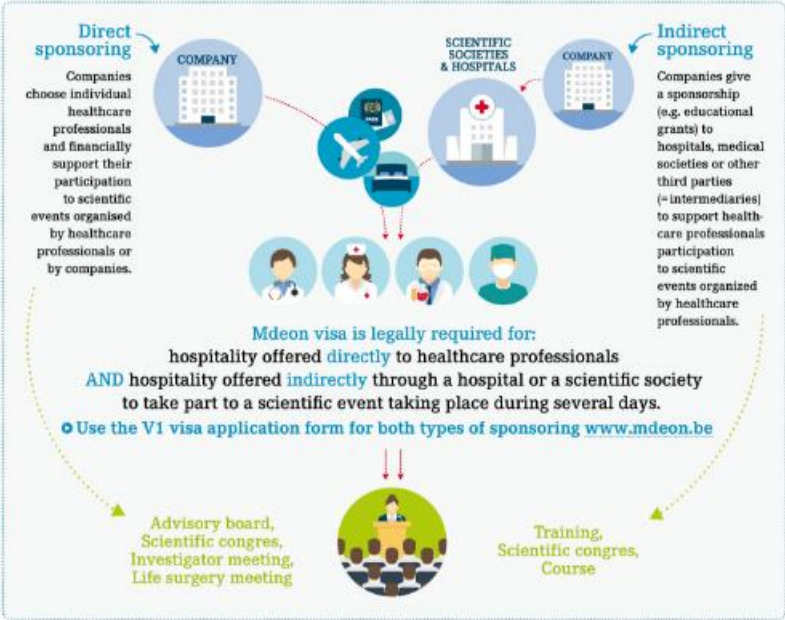
Sponsoring of continuous medical education

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!





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


MDEON VISA THE GUARANTEE OF AN ETHICAL SPONSORSHIP!

Mdeon is a **common ethical platform** constituted of 24 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.

MDEON ASBL | Rue Belgica 1 b7 | 1930 Zaventem | +32 2 609 54 90 | secretariat@mdeon.be | www.mdeon.be

FLYER + GUIDELINES

- Explain the difference between direct and indirect sponsorship
- Explain how to work with indirect sponsorship
- Answer the question of the companies: "Is visa necessary for indirect sponsorship?"
- Explain how to submit a visa application jointly



Indirect sponsoring of the participation to scientific meetings

JOINT INTRODUCTION OF A VISA APPLICATION

A. INTRODUCTION

More and more pharmaceutical or medical devices companies (hereinafter referred to as "companies") are sponsoring the participation of healthcare professionals in scientific events not **directly**, but through healthcare organisations (hospitals, scientific associations). This is commonly referred to as "**indirect sponsorship**" of scientific events (or sometimes "educational grant").

This new form of sponsorship is a **choice** made by the companies concerned and is by no means a legal obligation. Many companies continue to sponsor healthcare professionals **directly**, without going through an intermediary (organization of the healthcare sector).

The objective of this communication is to remind that the visa requirement under Article 10 of the Law of 25 March 1964 on medicinal products applies in an undifferentiated way to direct sponsorship and indirect sponsorship of the participation of healthcare professionals to scientific events (taking place over several consecutive calendar days, including hospitality) (see point B below). If the company sponsors through an intermediary, the introduction of the visa application will nevertheless need to be adapted (see point C below).

B. WORKING OF INDIRECT SPONSORING

Companies that have decided from now on to sponsor participation in scientific events through indirect sponsorship, generally work as follows:

1. The healthcare organisation prepares the educational project:
 - it determines which scientific event(s) will be sponsored
 - it documents the expenses that will be covered by the sponsoring: registration's fee for the scientific event, transport costs, overnight stays
 - it chooses how many and which healthcare professionals will benefit from sponsorship
2. The healthcare organisation proposes the educational project to the pharmaceutical or medical devices company. The two parties sign a contract describing the educational project and the costs that the sponsorship is intended to cover.
3. if the sponsorship concerns a scientific event that takes place over several consecutive calendar days (including hospitality), Mdeon's prior visa is legally mandatory. The visa application is then introduced jointly by the healthcare organisation and the company: the healthcare organisation completes the visa application and appends the necessary annexes and then sends the application to the company who checks it, pays it and introduces it (see Guidelines below)
4. once Mdeon's prior approval has been obtained, the company can pay the funds to the healthcare organisation, which can then make the various reservations.

January 1st, 2017

Joint introduction of a visa application

- ✓ HCO creates an account at the name of the **company** on Mdeon website
- ✓ HCO gives to the company the status of “**manager**”
- ✓ **HCO prepares** the visa application (fill the form, add scientific program, add justificatives flight, etc.)
- ✓ HCO sends draft application to the “manager”
- ✓ **Manager** can chose:
 - to **submit** the visa application/send it to Mdeon
 - to **send** the draft form **back** to the HCO, asking to modify some points
 - to delete the draft visa application
- ✓ Mdeon sends visa to HCO + company
- ✓ Company then pays the educational grant



Negative point, due to absence of V1bis:
HCO will have to submit 1 visa application per company and per meeting...

How to disclose Educational Grants?



- ✓ To be determined by Royal Decree (in preparation)
- ✓ Two possibilities
 - disclosure at the name of the HCO receiving the educational grant
 - disclosure at the name of the HCP benefitting from the hospitality
 - Perfectly compatible with ban of direct sponsorship: HCO is choosing the HCPs benefitting from the grant
 - MedTech Europe has prepared a Q&A confirming that companies may *a posteriori* receive the names of the HCPs in some cases:

QXX: Is it appropriate for a Member Company that has provided an Educational Grant to support Healthcare Professional attendance at a Third Party Organised Educational Event to receive the names of the Healthcare Professionals benefitting from the Educational Grant?

AXX: Generally, Member Company should not proactively seek to receive the names of the Healthcare Professionals benefitting from their Educational Grant. In some cases, and in particular for legal disclosure and/or audit reasons, it may be acceptable for Member Companies to receive the names of the Healthcare Professionals participating in the Event. However, such names should never be received before the independent selection of Healthcare Professionals is closed and the Educational Grant agreement has been signed.

- betransparent.be could highlight in the Transparency Register which ToV are offered indirectly and explain that companies haven't chosen who would benefit from the grant

Conference Vetting System vs. Visa Mdeon

				
Name:	"VISA PROCEDURE"		"CONFERENCE VETTING SYSTEM" (CVS)	
Basis:	Legal obligation -> Art. 10 Law Medicinal Products		Ethical obligation -> Code of Ethics MTE	
Mandatory for:	All the companies in the world active in Belgium		The <u>companies</u> member of MTE	
Type of sponsorship concerned?	Sponsorship of participants Direct & indirect (V1)	Sponsorship of organizer (V2)	Sponsorship of participants Only indirect	Sponsorship of organizer
Which scientific meetings are concerned?	- national or international - during more than one day	- national - international if organized by Belgian HCPs - during more the one day	- international - independently of the duration	
Who submits the application?	- Direct: the companies - Indirect: companies + organizer jointly	The scientific meeting organizers	The scientific meeting organizers or the companies <i>Check first if meeting already vetted:</i> http://www.ethicalmedtech.eu/conference-vetting-system/objective	
File?	1 file per company & per meeting	1 file per meeting	1 unique file per meeting	
Delay of answer?	5 working days		45 days	
Sanctions?	Penal fines		Ethical sanctions	

**Thank you
for your
attention!**



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Mdeon
Ethical Health Platform