


Cross Border Interaction

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Date: 26 May 2018
Sector: MD
Countries: Belgium

General

 Whenever you see this symbol, or limits/ text highlighted in orange, please note that there are additional details you should consult, clicking the arrow or the orange number/text will take you to the corresponding Laws & Regulations section. **It is a good practice to always consult the Laws & Regulations section.**

Locations

The list of locations shows cities that are considered generally **appropriate** or **inappropriate** to hold meetings with HCPs. Some locations may have **conditions that apply** and depending on those may be appropriate or inappropriate. Please note that locations that are generally appropriate may at some times still be inappropriate due to for instance a festival or other occasion. **Inclusion on the list of appropriate locations does not exclude the need for evaluation of appropriateness of the event, the lodging and hospitality, etc.**

Hospitality Limits

If you are planning to host an event in a given country the **general principal is that hosting country limits apply**. However if the country of a participating HCP has **specified abroad limits** this means that these limits, based on law, regulation or industry code of conduct, travel with the HCP when abroad. **In such cases the most restrictive limit applies.**

Belgium

LOCATIONS



Appropriate Conditions apply Inappropriate

Antwerp



Brussels



Gent



Leuven



Luik (Liège)



HOSPITALITY IN COUNTRY

Meals & beverages

Country	Currency	Breakfast	Lunch	Dinner	Max/days	Snacks	Tax	Laws & Regulations
Belgium	EUR	25,-	40,-	80,-			Incl.	→

Hotel

Country	Currency	Limit	Tax	Breakfast included	Laws & Regulations
Belgium	EUR	250,-	Incl.	✓	→

HOSPITALITY ABROAD

Meals & beverages

Country	Currency	Breakfast	Lunch	Dinner	Max/days	Snacks	Tax	Laws & Regulations
Belgium	EUR	25,-	40,-	80,-			Incl.	→

Hotel

Country	Currency	Limit	Tax	Breakfast included	Laws & Regulations
Belgium	EUR	250,-	Incl.	✓	→

TRAVEL

Air travel <

Business Class flight only allowed if HCP is a consultant and flight time is more than 6 consecutive hours. If HCP is participant, no business flight allowed irrespective of destination or duration of flight.

Train travel <


Non-economy class train travel will be permitted when the cost of the travel does not exceed that of the lowest logical airfare to the same destination.

Ground transportation <


HCC approval required

Laws & Regulations 

GIFTS

	Currency	Allowed	Limit	Tax	Description	Laws & Regulations
Life events	EUR	X		Excl.		
Cultural gifts	EUR	X		Excl.		
Branded items	EUR	✓	15,-	Incl.	corporate branding only, no product branding	

OTHER PROVISIONS

	Currency	Allowed	Limit	Tax	Description	Laws & Regulations
Educational	EUR	✓	50,-	Incl.	Only educational gifts related to practice of medicine. Max. 50€/HCP - Max. 3x/year Attention !!! total per year max. = 125€/year (tax reasons) • Company branding only • No product branding	

LAWS & REGULATIONS

Hospitality

Meal limit: includes drinks, tips, tax and room rental

Hotels: Deluxe hotels are not permitted. Five Star hotels only upon HCC approval. For international J&J events, Hotel evaluation should be undertaken in line with Health Care Business Integrity Guide and MedTech Europe Code requirements.

Direct sponsorship of HCP's attendance to third party organized educational conferences taking place after 31 December 2017, is no longer allowed.

ATTENTION !!! CROSS BORDER REVIEW IS APPLICABLE FOR BELGIUM

Health Care companies are subject to MDEON regulation when interacting with Belgian HCPs (consultancies, support of attendance to educational events, congresses, etc).

WHAT IS AN MDEON VISUM/APPROVAL?

- Mdeon is a Belgian industry governance body which provides formal approvals to companies for offering hospitality (Travel /Meals/ Overnight stay) to Belgian HCPs .
- This "visum" is not a "travel visum" but a formal approval. **Without Mdeon visum, we cannot pay for any travel & hospitality to the Belgian HCP(s).**
- Deviations are subject to inspections by the FAMHP (Federal Agency for Medicines and Health Products) and possible penalties (fines, jailtime).
- In case of not complying with the Mdeon requirements, both J&J company AND the HCP are held responsible (Co responsibility).

WHEN IS MDEON VISUM REQUIRED?

- Mdeon visum is required when a HCP is invited as a consultant and/or as a participant to an activity which last longer than one day and for which travel & hospitality is provided (travel, registration, meals and/or lodging).
- Activity means the scientific event as such, as well as the stay necessary to take part in the event.

In case of doubt, please contact the Benelux HCC team to advise you on the Mdeon requirements.

WHAT IS THE PROCESS TO OBTAIN AN MDEON VISUM/APPROVAL?

For all J&J Affiliates outside Belgium, Netherlands, Luxemburg (Benelux) = Mdeon submissions will be done centrally by a dedicated person.

Business partners to follow the process steps below:

1. Due to central submission, we need 6 weeks to ensure the Mdeon approval.
2. Complete the request form. [Link](#)
3. Provide a printscreen of the flights with class + departure/arrival time.
4. Provide a printscreen of the registration's fee. It must include the cost of registration and what the registration covers (access to sessions, lunches, dinner, overnight stay, etc.).
5. Submit your request to: BelgiumHCP_approval@its.jnj.com
6. The dedicated HCC person (submitter) will do the Mdeon submission for you.
7. You will receive formal confirmation about the outcome (approval or refusal by Mdeon)
8. **In case of refusal by Mdeon**, there are 2 options:
 - a. The submitter will contact you to see if the request can be submitted a second time and will confirm final outcome to you.
 - b. **If there is no appeal possible or if we receive a final Mdeon refusal:** you will not be allowed to support travel & hospitality of the Belgian HCP. The Benelux HCC Officer will decide how and when to communicate to the HCP that we cannot support the HCP. Business partners will be copied in this communication.

ATTENTION - MDEON REFUSALS TRIGGER INSPECTIONS BY THE FEDERAL AGENCY

Please note that any final Mdeon refusal triggers inspections by the Federal Agency who sends a formal communication to the J&J legal entity for whom the request has been submitted. In case you receive such a letter, please contact immediately Benelux HCC Officer who will handle the case. Under no circumstances, should the foreign J&J affiliate correspond with the Belgian Federal Agency.

Gifts & other provisions

Branded Items: corporate branding only, no product branding.

Educational:

Only educational gifts related to practice of medicine.

maximum of 3 times a year total maximum a year 125 EUR. (tax reasons)

- Company branding only
- No product branding
- HCPs may be provided with informational or educational materials and with items of medical utility aimed at the education of healthcare professionals and patient care provided that they are inexpensive and directly related to the practice of medicine or pharmacy and directly benefit patient care.
- The transmission of such materials or items shall not constitute an inducement to recommend, prescribe, purchase, sell or administer a Medicinal Product and do not offset routine business practices of the recipient.

Travel

Flight in Business Class: Business Class flight only allowed if HCP is a consultant and flight time is more than 6 consecutive hours. If HCP is participant, no business flight allowed irrespective of destination or duration of flight.

Train travel: Business/First class allowed

Car Rental: HCC pre-approval required

Travel- Use of personal HCP vehicle: HCC pre-approval required

See Mdeon requirements under 'Hospitality' Law & Regulations

Transparency requirements

As far as your interaction (direct or through any intermediary irrespective of their location) involves the Belgian HCPs/HCOs/POs (Patient Organizations) as the final beneficiaries, you are required to check here and follow the steps as there is a local transparency reporting law applicable

Note: if the paying OpCo / MRC is on Prizma already, follow the normal processes in Prizma. The system will collect the required data automatically. You don't have to report your interaction separately.

Please also check the Hospitality section to ensure you fulfil the Belgian Mdeon requirements if applicable.

Employer notifications

As of 01 January 2017, HCP's employer must be notified of the nature of the collaboration between the Company and the HCP. This applies to any Fee For Service Agreements (speaker agreements, consultancy agreements, etc.) and support of attendance to educational events in the broadest sense. This requirement does not extend to incidental business meals with an HCP.

For informing the HCP of this obligation please refer to this template.

For informing the Employer please refer to this template (individual HCP) or this template (group notification).

For any consultancies with Belgian HCPs working at University Hospitals, please contact the local HCC Team for further assistance.

Please check if Mdeon requirements apply. (see details under "Hospitality")

Contractual requirements

Cordis is no longer part of J&J Medical Belgium. For all Cordis Compliance matters, please contact Julie Tomlinson. Phone 614-757-6769; email: julie.tomlinson@cardinalhealth.com

In the case of direct sponsorship of participants, Mdeon visa number should appear in all correspondence exchanged between companies and healthcare professionals.

Direct sponsorship of HCP's attendance to third party organized educational conferences taking place after 31 December 2017, is no longer allowed.

As of 01 January 2017, data must be collected in regards to educational grants provided to Health Care Organisations (HCOs) based in the MedTech geographical area. This data should be provided to the medical device OpCo based in the same country as the HCO. Data must include at a minimum:

- purpose of educational Grant,
- full contact details of the HCO,
- amount of the Educational Grant and currency,
- specification on inclusion or exclusion of VAT (including VAT %)

In case where:

- J&J provides direct support of HCP attendance to third party organized educational conference, or
 - J&J provides direct support of HCP attendance to third party organized procedure training,
- the event must be positively evaluated by the EthicalMedTech Conference Vetting System (CVS).

For events taking place after December 31, 2017, in case where:

- educational grant is provided in support of an international third party organized educational event, or for support of HCP participation to such event, or
 - J&J organizes commercial activities during international third party organized educational event (e.g. promo booth),
- the event must be positively evaluated by the EthicalMedTech Conference Vetting System (CVS). Details around the Conference vetting System can be found [here](#).

Contractual requirements – **specifics for EVICEL**

For all Transfers of Value (TOV) as of 01 JAN 2015 that are in scope of EFPIA disclosure reporting (see also Transparency requirements section), include the appropriate Disclosure contract clause and consent form if applicable (that you will find [here](#)) and adapt it to your sector (without changing the actual privacy language).

Governmental requirements

Health Care companies are subject to MDEON regulation when interacting with Belgian HCPs. Please check the Mdeon requirements and process steps under "Hospitality"

- It is illegal to pay for any travel & hospitality to HCPs without upfront mdeon approval
- Deviations are subject to penalties by the authorities (fines, jailtime).
- Sanctions : fines of 1.100 up to 82.700 euro) and/or imprisonment of 1 month up to 1 year
- Strict application deadline to be respected
- Please note that in case of not respecting the Mdeon requirements, both J&J company AND HCP are held responsible (Co responsibility)