

# **CHECKLIST FOR COMPLETING A VISA APPLICATION V2**

# PRELIMINARY

# When should a V2 visa application be submitted?

In every situation in which one or several companies will sponsor the organisation of a scientific event by for example covering the costs of flyers, badges, etc.: In that case it is up to the scientific organizer of the event to submit the visa application, featuring all the event sponsors.

A scientific event is subject to a visa V2 requirement if it runs in its entirety over several consecutive calendar days and if it is either 1) organized by an association managed by a majority of healthcare professionals practicing their profession in Belgium and/or if 2) the majority of the participants are healthcare professionals practicing their profession in Belgium.

## What should be done with the obtained visa number?

The visa number provided then has to be mentioned in any correspondence with the sponsors who have to be able to verify whether their sponsoring is consistent with the relevant legislation and ethical codes. The sponsors are indeed co-responsible with the organizers with regard to the respect of the visa obligation. The visa has to be obtained before any funding is made available to the organizer.

A sponsoring company inviting a number of participants at the same time has to submit a visa application (V1) separate from the collective visa application made for sponsoring the organizer.

## What is a substantial modification and when do you need to submit a new (additional) V2 visa application?

If you have received a visa number, you have to submit a new visa application if your project of sponsorship undergoes a *substantial modification* between the moment of submitting the visa application and the beginning of the scientific event (art. 22.1 of the Code of Ethics). In this case a new visa application may be submitted **at the latest the 6th working day prior to the day the event starts** (art. 17.4 of the Code of Ethics). In general is considered as *substantial* every modification of which we can reasonably presume that the Visa office should take it into consideration in order to take a decision with full knowledge of the case.

Here are a few examples a substantial modifications, not limitative:

• substantial modification of the budget:

## additional sponsor(s)\*

- extra costs in the budget (e.g. addition of a social activity
- o etc.
- alteration of the scientific program
- alteration of the location of the event
- the dates of the scientific event alter and this altering has an impact on the sponsoring.

Version July 2024 - Document subject to change - Check regularly for the latest update

\* The grouped visa number obtained by the organizer **covers only the companies mentioned in the visa application** and afterwards in the decision. If one or more sponsors present themselves later their sponsorship will have to be subject to a new visa application (substantial modification). This application can be submitted by the organizer as well as by the company itself. In this last situation, the file number of the organizer has to be mentioned in the visa application in order to allow the Visa Office to link the different applications.

## What am I allowed to do with the sponsorship money?

Sponsoring of events by the pharmaceutical and medtech sector can only happen if the sponsorship money is exclusively used to sponsor the organization of the scientific program. In order to be able to demonstrate that the sponsorship money was exclusively used to finance the scientific part of the programme, organizers must be able to prove each item of expenditure separately on the basis of a quote, cost, invoices, receipts, origin of the money, sponsorship, profits, ... If it is not possible to demonstrate this unambiguously in this way, sponsorship is completely excluded if non-scientific elements, such as a social activity, are also present.

# Deadline for submitting a visa application V2

Each visa application must be submitted at the latest on the **15<sup>th</sup> working day** preceding the day of the start of the scientific event and before the deposit of monetary amounts to the organizer. By "working day" is meant Monday, Tuesday, Wednesday, Thursday and Friday, with an exception for public holidays.

If it is a resubmission (after a refusal or approval), a submission deadline of **6 working days** must be respected.

In case of urgency, the urgency procedure may also be invoked. In that case there is a shortened submission deadline of at least **2 working days**, meaning that the visa application must reach the Secretariat at the latest at 12:00 (noon) of the second working day preceding the day of the start of the scientific event. An urgency procedure can be initiated via the red link in your account: "Visa application - Urgency procedure" (click here for more info on the urgent procedure).

	SECTION A - GENERAL INFORMATION				
	CHECKLIST	FAQ	TIPS		
A.1	Applicant		Depending on who is submitting the V2 application, it must contain the details of:		
			<ul> <li>The scientific organizer: In this case, the organizer must include a list of the identity of each company and the amount sponsored by the company. In addition, the scientific program, the declaration and a detailed budget must be added (see below);</li> <li>The logistic organizer: In this case, the organizer must include a list of the identity of each company and the amount sponsored by the company. In addition, the scientific program, the declaration of the scientific organizer and a detailed budget must be added (see below);</li> <li>One of the companies which are sponsoring the scientific event: In this case, the company must refer to the visa number already obtained by the scientific organizer. In addition, the scientific organizer (see below) is not necessary in this case.</li> <li>In addition, it must be indicated whether or not the file has already been treated by the Visa Office. This is important and allows the Visa Office to check which submission deadline must be respected (15 working days (for a first submission) or 6 working days (for a resubmission)).</li> <li>Finally, a choice of language must be made (DU or FR). This choice is important for further communication (e-mails and decision) will take place in Dutch or French), further communication (e-mails and decision) will take place in Dutch or French.</li> </ul>		
A.3	Title and organizer of the scientific event		Here, in addition to the name of the scientific event (title), also the name of the scientific organizer (not of the logistic organizer) must be mentioned. If it is not clear who the scientific organizer is, please check the scientific program and / or the invitations sent by the scientific organizer.		
A.4	Location of the scientific event		The country, city and place (conference center, hospital, hotel, etc.) must be filled in.		
A.5	Dates and times of the scientific event		Has this section been filled in completely and correctly? No contradiction with annexes?		
A.6	Information about the participants		Are the correct specializations / professions filled in here? Estimated number?		

	SECTION B - DETAILED INFORMATION					
	CHECKLIST	FAQ	TIPS			
B.1.	Type of event		Here it must be indicated what kind of scientific manifestation is involved (for example: national manifestation, life surgery,). The option "virtual" is not (yet) available: mention this in section B.2.2.			
B.2	Scientific program	4 + 5	The general rules apply.			
	Scientific nature		<ul> <li>Clearly describe the <u>scientific</u> added value for the participants.</li> <li>If it concerns a virtual meeting, mention it here (B.2.2).</li> </ul>			
В.3	Detailed budget	6.4	<ul> <li>! Make sure that the budget contains at least two columns: income and costs. An example can be found by clicking on the following link: https://www.mdeon.be/wp-content/uploads/2017/01/model-detailed-budget_ENG.pdf</li> <li>! If the only source of income is coming from companies (industry) and the entire amount will be used by the organizers to cover all the costs, then the cost of the offered hospitality (lunch, dinner, lodging, etc.) must be detailed per unit, must respect the maximum amounts (see FAQ 8.1) and <b>no</b> social nor cultural activity may be foreseen.</li> <li>! If the above-mentioned maximum amounts are exceeded or if social activities are offered, the budget and application must show that this is financed with own funds or with registration fees of the participants.</li> <li>! The added budget is an estimation. The exact amount and allocation of the result of the closed accounts must be sent by email to the Secretariat of Mdeon within three months following the end of the scientific meeting.</li> </ul>			
	Income: Registration fee participants		The total amount paid by the participants in the scientific event must be indicated here. This amount must correspond with the amount indicated in the corresponding section in the attached budget. Obviously, this is an estimate of number of participants.			
	Income: Sponsoring from pharmaceutical or medical devices companies		The total amount obtained as sponsorship from pharmaceutical or medical device companies must be mentioned here. This amount must correspond with the amount indicated in the corresponding section in the attached budget.			
	Income: Other (own capital, sponsorship from non- medical companies, subsidies, etc.)		The total amount must be stated here that relates to own funds, sponsorship of non- medical companies, subsidies, and so on. This amount must correspond with the amount stated in the corresponding section in the attached budget.			

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	Costs	The column with costs must list the total expenditure of the meeting, detailed by cost section and the corresponding amounts. This amount must correspond with the amount stated in the corresponding section in the attached budget.
	Result	The result should be included here (income minus costs). The budget must not be positive, negative or balanced. This amount must correspond with the amount stated in the corresponding section in the attached budget.
B.4	Amounts which will be paid to the organizer	There are two options: <b>Option a</b> : The visa application is submitted by <u>scientific or logistical organizer</u> of the event. In this case, in this section should be indicated the amount for which each company will contribute to the costs of the organization. This amount must correspond to the amount indicated in the corresponding section in the attached budget. Once the visa number has been obtained, it must be communicated to all the companies listed here. <b>Option b</b> : The visa application is submitted by <u>one of the companies sponsoring</u> the organizer of the event. This is the case where the organizer has already obtained a visa number V2 in which this additional sponsor was not yet included. The company must fill in the amount that it transfers to the organizer. In this case, a detailed budget must not be attached.
B.5	Allocation of the sponsored amounts	There are two options: <b>Option a</b> : Either the visa application is submitted by the <u>scientific</u> organizer: in that case it is sufficient to tick the boxes in section B.5 a) of the visa application; <b>Option b</b> : Either the visa application is not submitted by the scientific organizer, but by the <u>logistics</u> organizer: in that case it is mandatory to attach a signed statement from the scientific organizer to the file stating that (i) he undertakes 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. (ii) 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 Code (iii) any advantage realized will be allocated in accordance with Article 10 of the law of 25 March 1964 on medicinal products. This statement must be signed by the scientific organizer.



	SECTION C - ANNEXES				
	CHECKLIST	FAQ	TIPS		
	Did you add all required annexes?		<ul> <li>Scientific program,</li> <li>Declaration of the scientific organizer,</li> <li>Detailed budget.</li> </ul>		
<b>C.1</b>	Scientific program		General rules apply - See also higher section B.2.		
	Detailed	4.1	<ul> <li>In terms of content? Explain jargon and abbreviations! (also possible in section B.2 of the visa application)</li> <li>In terms of timetable?</li> <li>Tip: always add -if available- the link of the website of the scientific event</li> <li>Is the date mentioned on the program?</li> </ul>		
	Language		In a language that can be understood by the Visa Office? (DU – FR – EN – GE). If not, a translation must be added.		



# SUBMISSION OF YOUR VISA APPLICATION V2 - POINTS OF ATTENTION

#### How do I submit my visa application?

- Use Google Chrome

- After completing your visa application, you must click on "Print".
- You will be redirected to a web page to pay (for more info on fees, click <u>here</u>). Only a payment online (via Maestro, MasterCard, American Express or Visa) will lead to the submission of a visa application. It is impossible to work with a bank transfer.
- After payment, you should receive a total of **three emails** within two hours:
  - 1. An email from Ingenico confirming the payment: *Worldline Nouvelle commande mdeonbe PAYID: xxxxxxxxx / orderID: Wxxxx-xxxxx /00 / statut: 9*

Your visa number

Date of submission Your visa number

 An invoice from Mdeon: Mdeon – Invoice - Visa application V2/xx/xx/xx/xxxxxx

! If you didn't receive these three emails, your visa application has <u>not</u> been submitted. In that case, please contact Mdeon asap.

# **ATTENTION: 3 TYPES OF EVENTS**

## **1) Exclusively scientific events**

These are scientific events organized by a third party (not a pharmaceutical or medical device company) whose program is exclusively scientific.

In that case, the organization of and participation in the scientific event is its main purpose.

The organization of the scientific part of these conferences may be sponsored. This includes speaker fees, room rental, logistics, staff rental, catering, invitations, etc.

As the sponsoring company, you must ensure that you have an appropriate agreement with the organizer stating exactly what the sponsorship money will be used for.

Please note that the presence of booths is tolerated but the sponsorship itself must relate to the organization of the scientific part of the congress. Moreover, booths may only be present in a separate room and therefore not in the congress halls.



These are events organized by a third party (not a pharmaceutical or medical device company) whose program is not exclusively scientific. This is the case, for example, when the publicity stands are not ancillary to the scientific part.

In such events, science is not the main reason for the event.

Such events may not be sponsored at all, even if the participants themselves would pay for the non-scientific part.

Pharmaceutical and medical device companies may not have a booth because this is a sponsorship of a benefit in violation of article 10 of the Medicines Act dated March 25, 1964.

3) Pure promotional events

The aim of these events is not to pass on scientific information, but purely promotional. Examples include trade fairs and exhibitions.

At such events, companies may attend with a booth if the following conditions are respected:

- There can be no scientific program (otherwise it is considered a mixed event, see point 2);
- No benefit (such as a workshop or non-scientific program) or gift may be given to participating healthcare professionals, nor may hospitality be provided at the booths;
- Booths are neutral and sober;
- No social activities may be offered (no party, reception, etc.) nor organized.