

FREQUENTLY ASKED QUESTIONS (FAQ)

PART I

APPROVED AT THE IFPA'S GENERAL ASSEMBLY ON 24 NOVEMBER 2020

APPROVED AT THE VGA'S GENERAL ASSEMBLY ON 25 NOVEMBER 2020

The following FAQs are related to the 2020 Code of
Conduct for Marketing of Medicinal Products

ARTICLE 10. EVENTS AND HOSPITALITY

QUESTION 1: Is the provision of catering for healthcare professionals allowed during remote Events?

ANSWER: This issue is defined in the procedure for the provision of catering services during remote Events.

PROCEDURE FOR THE PROVISION OF CATERING SERVICES DURING REMOTE EVENTS

DEFINITIONS

- ✚ **Remote Company Event** means an event organised by the Company (not a third party, such as HCO, university or scientific professional organisation) during which one or more participants (i) are in the Location other than the speaker, and (ii) attend the event via a remote access platform.
- ✚ **Remote Third-Party Event** means an event remotely held by a third party, not the Company. Where the Company organises a remote Event through a third party, such event is regarded as a Remote Company Event. Companies are prohibited from providing catering to Remote Third-Party Events.

EXAMPLES/TYPES OF REMOTE COMPANY EVENTS

- ✚ **Individual remote:** all participants access the Event remotely, and the Company organises the Event so that all participants are enabled to connect individually from different Locations via a remote access platform. If any of the participants decide, on their own initiative, to access the event from the same Location, such event will nevertheless be regarded as individual remote.
- ✚ **Hybrid:** some participants are in the same Location as the representative of the Company, while others connect individually from different Locations via a remote access platform.
- ✚ **Group remote:** a group of participants access the event via a remote access platform while being in the same room booked by the Company, such as a conference hall, while the speaker(s) and the representative of the Company stay in a different Location and attend the Event remotely.

REQUIREMENTS FOR A REMOTE ACCESS PLATFORM DURING REMOTE COMPANY EVENTS

A remote access platform must be technically capable of documenting the name and access time of each participant attending the Event remotely.

CATERING REQUIREMENTS DURING REMOTE COMPANY EVENTS

- ✚ Catering is prohibited during Remote Company Events.
- ✚ Hospitality during a Remote Company Event should be justified and strictly limited to the main purpose of the Event.
- ✚ Catering should be arranged only when the participation of healthcare professionals is reasonably expected throughout the duration of the Event.
- ✚ Catering during Remote Company Events is allowed only if the Company physically is in the Venue of the Event or virtually attends the Event.

- ✚ During Group Remote Company Events catering may be provided, where at least three participants attend the Event at the same Location.
- ✚ The number of participants of a Remote Company Event must be known in advance: (i) participants are extended personal invitations specifying the agenda, time and Venue of the Event, and (ii) should confirm their attendance.
- ✚ The provision of catering must be confirmed by signatures of the participants in the participant list. The participant list should contain the title, date and time of the Event, as well as participant names, surnames and signatures. The participant list with signatures may also be transmitted to the Company electronically, e.g. in the form of a picture or scanned image.
- ✚ Catering may only be organised in the planned Venue of the Event (e.g. doctor's office, hall), no home deliveries are allowed.
- ✚ Catering should only be ordered from catering suppliers to ensure quality and hygiene compliance. The Company should keep the order documentation, including details of the actual delivery place and time of meals.
- ✚ Meals should only be delivered on the Event day before or during the Event.

CHAPTER 5 DISCLOSURE OF TRANSFERS OF VALUE FROM COMPANIES

ARTICLE 22. DISCLOSURE OF TRANSFERS OF VALUE TO HEALTHCARE PROFESSIONALS, HEALTHCARE ORGANISATIONS AND PATIENT ORGANISATIONS

QUESTION 1: The Company signs a support agreement with a HCO, which, inter alia, requires direct payment to an HCP in the name of the HCO. Since the Company signs the support agreement with the HCO, this amount will be reported to the State Tax Inspectorate, and if the specific HCP is known, according to the new transparency requirements, such HCP must be individually disclosed. Also, even if a direct agreement is not concluded with the HCP, but the HCP is identified in the application, it gives rise to the individual disclosure obligation. How should it be reported?

ANSWER: It should be reported to both the State Tax Inspectorate and the State Medicines Control Agency. The report form to be submitted to the State Tax Inspectorate includes a special asterix referring to possible overlapping.

QUESTION 2: How should the Company sign agreements with a third party organising an Event in the name of an HCO if the exact HCO is not known? In the absence of a tripartite agreement, the final beneficiary(s) is/are not clear. How should it be reported? Should reference be made only to the third party? Or, as an option, should the beneficiary be identified in bilateral agreements and eventually confirmed by the third party?

ANSWER:

- ✚ The form of an agreement, whether bilateral or tripartite, is for the Company to decide.
- ✚ If an application for support of an Event arranged by an Event organiser does not indicate which HCO will take the role of a customer (i.e. which HCO will issue the certificate of participation), the Company should ask the Event organiser about it. The Company should not sign a support agreement or any other type of

agreement with the organiser arranging the Event in the name of the HCO without making any reference to the HCO concerned.

- ✚ In the case of a joint Event held in the name of a number of HCOs, the report should name all HCOs with the transfers of value proportionately distributed among them, as well as the Event organiser through which such value was transferred to the HCO.
- ✚ If an Event organiser arranges, in their own name (there is no other HCO supervising the Event), an Event for HCP which will result in the issue of certificates of continuous medical training acknowledged by the Ministry of Health, such Event organiser will play the role of an HCO.
- ✚ If an Event organiser arranges, in their own name (there is no other HCO supervising the Event), an Event for HCP without issuing certificates of continuous medical training acknowledged by the Ministry of Health, such Event will not be regarded as educational and scientific and should not be supported by the Company. If the Company provides support for such Event, it should be considered as a Promotional Event of the Company.

QUESTION 3: Should the sum of transfers of value be broken down, where the final beneficiary is the same HCO, but technical organisers are different?

No	Name of the legal entity	Legal entity number	Monetary value of the transfers of value to the legal entity during the year (EUR)	Name of the third party, legal entity number (indicated when item 2 is being filled in)	Purpose of the transfers of value to the legal entity
1	HCO	182935350	5000		1
			7000	Third Party Vendor 1 (123456), Third Party Vendor 2 (456321)	2
			1000		3
Total (EUR):			13000		

No	Name of the legal entity	Legal entity number	Monetary value of the transfers of value to the legal entity during the year (EUR)	Name of the third party, legal entity number (indicated when item 2 is being filled in)	Purpose of the transfers of value to the legal entity
1	HCO	182935350	5000		1
			4000	Third Party Vendor 1 (123456)	2
			8000	Third Party Vendor 2 (456321)	2
			1000		3
Total (EUR):			13000		

ANSWER: Yes, the sum of transfers of value should be broken down as illustrated in the table below.

QUESTION 4: If there are several payments via the same technical organiser and the final beneficiary is the same HCO, should the sum be given in the report as aggregate? For example, five payments of EUR 100 each made to technical organiser No 1, while the final beneficiary of all payments is the same HCO X.

ANSWER: Yes.

QUESTION 5: Should the sum of transfers of value to a legal or natural person be disclosed as the sum of all transfers of value in the reported year by the purpose of the transfer of value?

ANSWER: It should be reported as shown in the table, i.e. broken down by individual category and summed up within each category, if value is transferred to the same HCP within the same category or to the same HCO through the same third person.

QUESTION 6: What is the sum format used in reports? E.g. 123,456.78

ANSWER: Companies should choose the format at their own discretion. No definition of the format is provided in the legislation.

QUESTION 7: Which amount should be given in the report – GROSS or NET?

ANSWER: The gross amount (minus VAT, if recovered by the Company), i.e. the amount actually incurred by the Company, which corresponds to the transfer of value by the Company, should be reported. Taxes paid by the Company for the beneficiary is also considered as the transfer of value.

QUESTION 8: Which of them – the total sum for the report or sub-totals for each HCO or HCP – should be given in the line 'Total EUR' at the end of the reports?

ANSWER: The total sum for the entire report should be shown at the end of the report.

QUESTION 9: Do *cross border transactions* fall within the scope of such reports?

ANSWER: Yes, when Lithuanian HCP are hired by foreign subsidiaries of the Company.

QUESTION 10: In which language and format (excel, PDF) should the reports be submitted?

ANSWER: Reports should be submitted in the Lithuanian language, which is the national language. No definition of the format is provided in the legislation. The logical choice would be PDF.

QUESTION 11: Is it possible to send corrections in the case of a mistake identified following the publication of reports?

ANSWER: As it is not prohibited by law, such a possibility exists.

QUESTION 12: Are any penalties imposed for the late submission of reports?

ANSWER: No specific penalties are provided for in the legislation, however, general penalties apply for non-compliance with the laws.

ARTICLE 23. INFORMATION ON RESEARCH AND DEVELOPMENT TRANSFERS OF VALUE

QUESTION 1: Which report should be used to disclose transfers of values relating to non-clinical and non-interventional studies?

ANSWER: The law does not require disclosure of transfers of value relating to any research and development. Those should be disclosed on the companies' web pages together with R&D transfers of values, where studies are prospective. They should be included in the report submitted to the State Medicines Control Agency with regard to consultation services, where studies are retrospective. Non-clinical studies in the context of R&D should be disclosed together with R&D transfers of value.