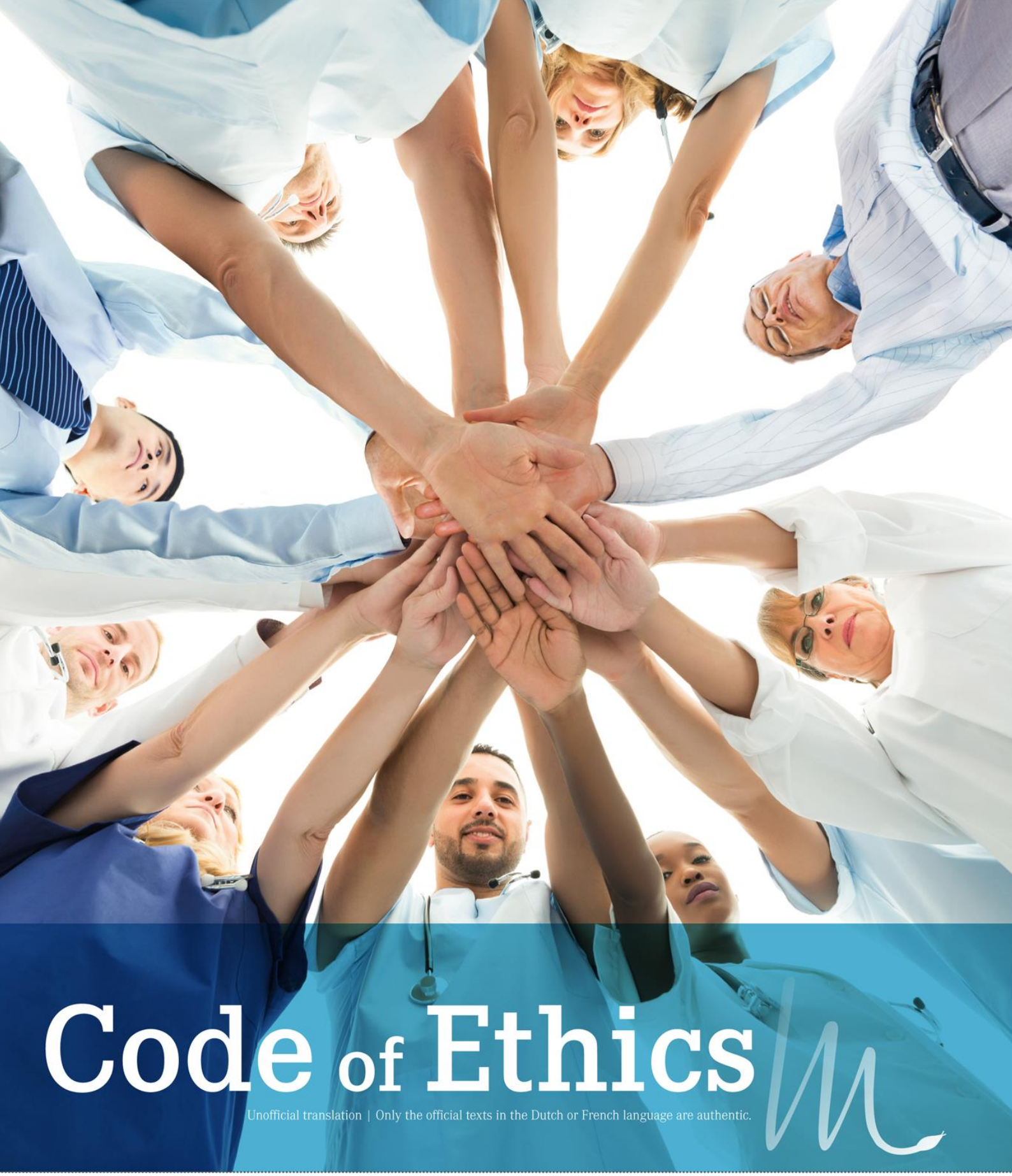


Code of Ethics

Unofficial translation | Only the official texts in the Dutch or French language are authentic.

Ethical Health Platform

Mdeon

Contents

Preface

As an authorised body under article 10, §3, subparagraph 5 of the Law of 25 March 1964 concerning medicines and of the Royal Decree of the 25 February 2007 concerning the authorisation of agents covered by article 10, §3 of the Law of 25 March 1964 concerning medicines, MDEON has a legal obligation, in accordance with article 10,§3 of the above mentioned law, to consider visa applications submitted by holders of a marketing authorisation or registration, manufacturers, importers and wholesalers of medicines and medical devices (hereafter referred to as "the pharmaceutical or medical devices companies") concerning scientific events, as referred to in article 10, §2, subparagraphs 1 and 2 of the above law, which are taking place during several consecutive calendar days, including the related hospitality.

The present Code of Ethics comprises, first of all, a certain number of rules which explain the legal basis with reference to scientific events and the compensation for services of a scientific nature as defined in article 10, §2, subparagraphs 1 and 3 of the Law concerning medicines.

Within the framework of its statutory task, MDEON must assess whether or not scientific events which are taking place during several consecutive calendar days, including the related hospitality, and the financial support proposed by the industry meet the criteria mentioned in article 10, §2, subparagraphs 1 and 2 of the aforementioned law and, where applicable, grant a VISA. Without this visa, the costs for attending the relevant event – including hospitality costs – may not be paid for by the industry to any legal or natural person referred to in article 10, §1 of the aforementioned law. In addition, this Code establishes the procedure which must be followed by the pharmaceutical or medical devices companies and where applicable by the healthcare professionals themselves who organise a scientific event as proxies, with a view to obtaining a visa for the organisation, sponsoring or support of scientific events which are taking place during several consecutive calendar days, including the related hospitality.

Moreover, this Code foresees the possibility for companies and healthcare professionals to seek ADVICE concerning the compatibility of other advantages or activities with the Code before they are awarded or carried out.

Thanks to an efficient VISA procedure and to the possibility of seeking advice, MDEON aims to effectively meet the legislator's expectations in terms of preliminary control and to foster greater transparency in the promotion of medicines and medical devices.

In addition to the authorisation granted pursuant to article 10, §3, subparagraph 5 of the Law of 25 March 1964 concerning medicines (see above), Mdeon also has an approval on the basis of the SUNSHINE ACT (Chapter 1 of the title 3 of the Law of 18 December 2016 regarding various provisions on health, *Belgian Official Journal* of 27 December 2016) and the Royal Decree of 31 July 2017 approving the organisation referred to in Article 44, §1 of the Law of 18 December 2016 regarding various provisions on health. This Royal Decree mandates Mdeon to perform the tasks entrusted to the FAMHP by the Sunshine Act. Mdeon specifically manages the publicly accessible website (www.betransparent.be) on which are published each year the premiums and benefits that pharmaceutical or medical device companies offer to healthcare professionals, healthcare organisations and patient organisations.

Part I.

Article 10 of the Law concerning Medicines

CHAPTER I.

Basic Regulations

Section 1. General Prohibition

ARTICLE 1.

1.1. In the context of supplying, prescribing, dispensing or administrating medicines or medical devices it is forbidden to supply, offer or promise – directly or indirectly – gifts, pecuniary advantages or benefits in kind to wholesalers, persons involved in brokering activities, persons qualified to prescribe, deliver or administer medicines or medical devices as well as institutions where medicines or medical devices are prescribed, delivered or administered.

1.2. It is also forbidden, in the context of supplying, prescribing or administering of medicines or medical devices for veterinary use, to supply, offer or promise – directly or indirectly – gifts, pecuniary advantages or benefits in kind to individuals procuring medicines or medical devices for veterinary use and, more specifically, to individuals targeted by articles 1, 3 and 7 of the Law of 28 August 1991 concerning the practice of veterinary medicine.

1.3. This prohibition concerns inter alia:

- offering or granting personal gifts, such as tickets to sportive or other entertainment events;
- offering to pay for, or paying, all forms of hospitality beyond those accepted by article 3 of the Code within the framework of a scientific event.

1.4. However, the prohibition referred to above does not apply:

1° to gifts and advantages that are inexpensive and concern medical, dental, pharmaceutical or veterinary practice;

FREQUENTLY ASKED QUESTIONS CONCERNING ARTICLE 1

- FAQ 1. Healthcare Professionals Concerned
- FAQ 2. Companies Concerned
- FAQ 3. The Concept of “event of several days”

2° to the invitation and the payment of costs of participation in a scientific event – including hospitality costs – of healthcare professionals provided that the event meets the conditions as described in articles 3 to 8 of the present Code;
3° to the compensation of legitimate services of a scientific nature within the limitations of article 9 of the Code.

Section 2. Premiums and Benefits of Negligible Value

ARTICLE 2.

The prohibition targeted in article 1 does not apply to gifts and advantages that are inexpensive and which are related to the medical, dental, pharmaceutical or veterinary practice.

GUIDELINES CONCERNING PREMIUMS AND BENEFITS OF NEGLIGIBLE VALUE

NEGLIGIBLE VALUE

- Of a nature which will have no influence on therapeutic 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 taken as a whole, and not on the value of its different components/parts

LINK WITH THE 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. or with the administrative activity relating to this activity
- The gift is not intended for mainly personal use
- The gift is not offered in connection with a private or personal event (birthday, birth, wedding or other)

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

EXAMPLES OF ACCEPTABLE GIFTS

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.

EXAMPLES OF UNACCEPTABLE GIFTS

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

Section 3. Scientific Events

The prohibition referred to in article 1 is also not applicable to the invitation and the payment of costs of participation in a scientific event – including hospitality costs – of healthcare professionals, provided that the event meets the conditions as described in articles 3 to 8 of the present Code.

ARTICLE 3. FRAMEWORK OF THE EVENT

3.1. Scientific events organised, sponsored or otherwise directly or indirectly supported, in Belgium or abroad, by pharmaceutical or medical devices companies in which healthcare professionals participate must be organised within a framework which does not jeopardise the scientific nature of the event.

3.2. The term "scientific event" includes all information sessions, training courses, seminars, scientific symposiums and congresses as well as any other form of scientific meeting organised on the one hand by scientific organisations, hospital services, faculties, medical circles or others, or on the other hand by pharmaceutical or medical devices companies, either in Belgium or elsewhere.

PRACTICAL DIRECTIVES CONCERNING ARTICLE 3

The notion of "scientific event", within the meaning of the Code, includes all forms of scientific meetings such as congresses, meetings, symposiums, scientific training courses, etc., which bring together healthcare professionals. The title or qualification given to the event is of little importance. The scientific nature of the event must be assessed on the basis of the content of the programme, taking into account the role and the independence of the speakers. Events which are purely or mostly of a promotional nature cannot be granted a visa.

Regarding scientific training courses specifically, such trainings should always aim at the continuing medical education of the healthcare professionals. It should therefore be possible to combine the training course with the exercise of their profession without interrupting it for a long time. Long-term scientific training courses (i.e. more than three weeks) cannot therefore be sponsored by the industry (e.g. fellowship of several months, additional year of study) since these are not scientific events within the meaning of article 10 §2 of the Law concerning medicines.

Scientific events, within the meaning of the Code, may be organised by pharmaceutical or medical devices companies or by third parties such as, for example, universities, local, national or international scientific associations, professional groups from the healthcare sector, etc. Regardless of the organiser, the event must take place within a quality framework which satisfies the requirements laid down in articles 4 to 8 of the Code hereunder, in order for the medical industry to be able to organise, sponsor or support in any other way such

ARTICLE 4. EXCLUSIVELY SCIENTIFIC NATURE

4.1. The event must be of an exclusively scientific nature and must be organised in the context of the medical and pharmaceutical science. From the moment of arrival until the time of departure, activities with a scientific purpose must take up most of each event day.

4.2. The notion of scientific activities covers the 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.

4.3. The event must take place at a suitable location that is appropriate considering the scientific purpose of the event.

as that indicated above, or the individual participation of professional members of the sector at such an event.

Key points to consider in the preparation of a visa request:

- The scientific programme is the essential aspect of the event
- It is supposed that speakers, in view of their function, will be scientific and objective.

PRACTICAL DIRECTIVES CONCERNING ARTICLE 4

The Law concerning medicines requires that scientific events – in the context of which companies sponsor certain healthcare professionals – must be of a purely scientific nature. When considering requests, the Bureau will apply the following criteria.

The aim of the event must be to inform healthcare professionals of subjects which have a direct link to the exercise of their profession and which are necessary to ensure a qualitative exercise of the profession in the interest of patients. Because invited or sponsored participants may also be active in healthcare sectors other than medicine or pharmacy in the strict sense, the concept of “medical and pharmaceutical sciences” must also be understood in the wider sense to include veterinary, dental, nursing and paramedical sciences.

It is essential to consider each case on its merits in order to establish whether the exchange of certain professional information or whether a specific training course has a sufficiently close connection to the practice of the concerned profession and is necessary to improve the quality of the exercise of said profession. In this assessment, the following elements will be taken into account: the professional standing of the event organiser, the qualifications of the speakers, the target pubic, the link between the subjects, and the tasks of the participating professionals. E.g.: management courses for those responsible of the operating theatre, pharma-economy, etc.

Certain subjects, presentations or workshops may be of interest for participants but do not concern the medical or pharmaceutical sciences. Such is the case for example, for information about financial,

taxa and social aspects inherent to the management of a medical practice, or even « train the trainer » sessions. If such activities are organised, they must also be accompanied by scientific activities such as those indicated above. These scientific activities must take up the most of each event day.

The scientific nature of the event must be predominant – taking into account the programme content and timetable – which must be regarded as a whole and on an individual daily basis. Generally speaking, at least six hours per day must be devoted to scientific activities, during normal office hours. Three hours may, however, be acceptable for the first and the last day to facilitate arrival and departure.

The scientific nature of the event must be clearly established. A detailed programme, with a timetable, must be communicated – even in the case of "internal" meetings such as investigator's meetings, advisory boards and others. The themes to be addressed, the speakers and the duration must always be stated in detail.

In assessing the scientific content of the event, the Visa Bureau will inter alia analyse the added value for the participating professionals from the healthcare sector. In case of a visit to a hospital, a medical centre or another healthcare organisation, companies are obliged, when applying for a visa, to clearly demonstrate the added value of such a visit for the participants from a scientific perspective. In this situation, demonstrating the added value is essential to justify the venue where the event is organised, especially when such event is held abroad.

Key points to consider in the preparation of a visa request:

- Sufficiently detailed programme (subjects that will be covered, speakers, duration per subject and per speaker).
- An explanation, where necessary, of the link between the themes under discussion and the exercise of the profession.
- Particular qualifications of the speakers and added value of the event for the specific group of participants.
- No identical subjects being unnecessarily repeated in the scientific programme – even in a modified form.

- Coherence between different requests. For example, avoid that one theme be dealt with for an hour in meeting A, whereas it is discussed for two hours during an identical meeting B.
- Sufficiently qualified speakers.
- Qualified moderator, clear subjects and objectives for the Q&A session, group discussions, round-tables, etc.
- In case of visits to hospitals, medical centres, etc.: clear objectives, sufficient scientific framework, and scientific explanations provided by qualified speakers.
- If there is too much jargon or too many unusual abbreviations, they should be explained.

FREQUENTLY ASKED CONCERNING ARTICLE 4

- FAQ 4. Scientific Programmes
- FAQ 5. Types of Scientific Events

ARTICLE 5. HOSPITALITY

5.1. The hospitality provided to healthcare professionals within the framework of scientific events must always be reasonable and remain secondary to the scientific aims of the event. It must not bring into disrepute the good reputation of the industry and the healthcare professionals.

5.1*bis*. The value of the meals provided, drinks included, may under no circumstances exceed the limits laid down in the Frequently Asked Questions on this matter.

5.2. Hospitality offered directly or indirectly to healthcare professionals by pharmaceutical or medical devices companies must be limited to the organisation or sponsoring of travel expenses, meals, overnight stays and registration fees for their participation to the event and should not extend beyond the official duration of the event.

5.3. Hospitality shall not include sponsoring or organising of sporting or leisure events or any other form of entertainment.

PRACTICAL DIRECTIVES CONCERNING ARTICLE 5

The hospitality reserved for healthcare professionals in the context of a scientific event must remain secondary to the scientific aims of the event. Hospitality must never be an end in itself. Given the fact that scientific activities must always predominate, hospitality arrangements must always remain a subsidiary activity and it must never be the primary aim of an event, nor even be on a par with the scientific aim. It is clear that this condition is not met if the majority of the participants take part in the event because of the gastronomic, cultural, recreational or sporting activities rather than scientific aspects.

The hospitality offered must never bring into disrepute the medical industry or healthcare professionals.

The hospitality offered in the context of a scientific event must always be restricted to the organisation or sponsoring of travel arrangements, meals, overnight stays and registration fees for the event.

The hospitality offered cannot be extended beyond the official duration of the event. This implies that the arrival and departure times for the participants must, as far as possible, coincide with the official

opening and closing of the event. As a matter of principle, the allocation of – or possibility to take – free time, between the arrival on site and the official opening of the event, or between the official closing of the event and the departure off site, is only authorised in case of specific travel constraints such an earlier or later flight being unavailable.

Costs of hospitality arrangements must remain reasonable; local standards should be taken into consideration to assess the reasonable character of hospitality arrangements.

Hospitality will in no event include financial sponsoring or organisation of sporting or leisure activities, or any other form of entertainment.

Key points to consider in the preparation of a visa request:

- Hospitality limited to registration, travels, meals and overnight stays in so far as they are necessary for the event and only for the duration of the event.
- Reasonable and moderate hospitality base on local standards.
- The organisation and sponsoring of social, touristic, sporting and leisure activities are formally forbidden.
- The offered hospitality must in no way bring into disrepute the good reputation of the medical industry or healthcare professionals.

FREQUENTLY ASKED QUESTIONS CONCERNING ARTICLE 5

- FAQ 7. Arrival and Departure – Days and Times
- FAQ 8. Midday and Evening Meals and Overnight Stays
- FAQ 9. Registration Fees
- FAQ 10. Transport Costs
- FAQ 11. The Concept of Hospitality

ARTICLE 6. VENUE, DATE, AND DURATION OF THE EVENT

6.1. The venue, date and duration of the event must not lead to any confusion regarding the scientific nature of the event.

6.2. The venue chosen for the event and the travel arrangements to the event must be justified.

PRACTICAL DIRECTIVES CONCERNING ARTICLE 6

The venue chosen for the scientific event and travel arrangements in the context of such event must be justified.

Travel abroad can only be justified if:

- the majority of participants are not from Belgium and if, in view of the country where

6.3. The organisation, sponsoring or support of scientific events abroad, or the organisation, sponsoring or support of healthcare professionals' attendance to scientific events abroad, must be justified by:

a. the fact that the majority of participants taking part in the event are not from Belgium. Common sense requires that, from a logistical point of view, such an event be held in another country, namely that where the majority of the participants live.

b. a relevant knowledge or infrastructure being present at the event so that – from a logistical point of view – it makes more sense to hold the event in another country.

6.4. The pharmaceutical or medical devices companies must avoid organising scientific events in venues well-known for sporting or leisure opportunities.

most participants originate from, it is deemed more reasonable, logistically, to organise the event in another country,
- a relevant knowledge or infrastructure is available at the event venue, so that it would be more reasonable, logistically, to organise the event in said venue rather than in Belgium.

The organisation of a scientific event abroad is justified if it targets participants coming from different countries. If the event is organised by a company's head office or sister company located abroad, the international nature of said event must be clearly evidenced in the request, for example by indicating the total number of participants, their countries of origin and the countries of origin of the speakers.

If a scientific event is targeted at participants from different countries, the countries of origin of the different participants and the chosen venue must be coherent.

Travel abroad cannot be justified if all or most of the participants of a scientific event are from Belgium except if, from a scientific standpoint, there are enough connecting factors with the choice of the venue, for instance: a visit to a reputed hospital (see second criteria in article 6.3). In such case, the justification for the choice of the venue relies directly on the added scientific value of this visit for the group of participants (please consult the commentary related to article 4: "Exclusively scientific nature of the event"). In addition, it is indispensable that the visit to the hospital or institution in question justifies travelling abroad for the full duration of the event. Bearing this in mind, a two-hour visit to a university centre would not justify the event being held abroad over three days.

The venue chosen for the event, whether in Belgium or abroad, must not give rise to confusion or doubts as to the scientific nature of the event. The Code explicitly requires pharmaceutical or medical devices companies to avoid venues reputed for their sporting or leisure activities.

Key points to consider in the preparation of a visa request:
- Justification of the venue chosen for the event, and more particularly if the event is organised abroad.

- Coherence between participants' country of origin and the chosen venue (when a scientific event targets participants from different countries)
- The added value of on-site visit for a group of participants, if the choice of venue is justified by a relevant knowledge of infrastructure
- Such knowledge or infrastructure justifies travelling to the venue for the whole duration of the event
- Companies are specifically required to avoid choosing venues which are reputed for their sporting or other leisure activities.

ARTICLE 7. PEOPLE ACCOMPANYING PARTICIPANTS

7.1. Invitations to attend scientific events as well as their organisation, sponsoring or support, or the attendance to such events, must be strictly limited to healthcare professionals only.

7.2. For any accompanying persons, no expenses may be borne. Pharmaceutical or medical devices companies must take every necessary measures to ensure as much transparency and clarity as possible in this regard.

7.3. Pharmaceutical or medical devices companies shall not provide an alternative programme for persons accompanying participants.

PRACTICAL DIRECTIVES CONCERNING ARTICLE 7

Sponsoring of participation costs, including reception costs, cannot be extended to individuals other than healthcare professionals taking part to the scientific event. Persons accompanying healthcare professionals must finance themselves all such related costs, including costs linked to reception costs.

All invitations to participate in a scientific event must exclusively be addressed to healthcare professionals.

Logistical support is permitted for transport arrangements and overnight stays, on the condition that the company notifies the number of accompanying individuals to Mdeon via e-mail, before the commencement of the scientific event.

Companies shall refrain from organising or providing for a programme for accompanying persons, even if participation costs in such programme are fully borne by the accompanying persons

Key points to consider by companies in the preparation of a visa request:

- Avoid all forms of inducement, encouragement or sponsoring of participation by third parties in the scientific event.
- Draft invitations in such a way that they are addressed uniquely to healthcare professionals and not to their spouse or other individuals in their close environment.
- Do not organise an alternative programme for spouses or other accompanying persons – even

if these persons fully bear the participation cost in such a programme.

- If the healthcare professional's spouse is also a healthcare professional in his or her own right, the company may only bear the spouse's participation costs if he or she participates in the scientific event as a "participant" and not merely as a "spouse".

ARTICLE 8. PROLONGATION OF STAY

Pharmaceutical or medical devices companies shall not be involved, directly or indirectly, in the organisation of an extension of stay for personal reasons by participants, and shall not contribute to the financial costs thereby incurred.
These companies shall take all necessary measures to ensure the greatest level of transparency and clarity in such matters.

PRACTICAL DIRECTIVES CONCERNING ARTICLE 8

1. In case of an extension of stay for personal reasons, the healthcare professional concerned must formulate a request. The company may not suggest such an extension even if it is optional and if the costs incurred are to be borne by the healthcare professional.

All forms of sponsoring of extensions are forbidden – including logistically. In other words, any healthcare professional who wishes to extend his or her stay must personally organise and pay for his or her stay, as well as all travel arrangements associated with the extension.

2. Companies' contribution to the costs of transportation, meals, and overnight stays in the context of a scientific event must be strictly limited to the official duration of the event. The healthcare professional must always finance himself or herself all costs related to any extension of his or her stay for personal reasons (overnight stays, meals, social and cultural activities, etc.).

3. In this context, the stay may be extended to take place prior to or following the scientific event. In both cases, all costs linked to this extension must be borne by the healthcare professional – whether he is invited or sponsored.

4. It is permissible that the company bears all the travel expenses to and from the scientific event, even if the stay is extended for personal reasons, provided that these costs are not greater than they would have been without such a prolongation and that the duration of the extension is accessory in comparison with the duration of the scientific event. In such case, it can be considered that the travel arrangement is entirely linked to attendance at the scientific event and that the extension is merely incidental.

However, in case of a longer (and thus non-incidental) extension, the company who issued the invitation or who sponsored the healthcare professional may not pay the travel expenses in full, but must limit its contribution to that part of the travel expenses related to the participation to the scientific event. Should travel expenses be inherent to the duration of a stay for purely private reasons, any company compensating those expenses would be granting the healthcare professional an illegal advantage.

From a practical point of view, the following rule has to be applied: the contribution in the travel expenses of the company issuing the invitation or guaranteeing sponsorship is limited to a fraction of the total cost; this amount is obtained by multiplying the total travel costs by a fraction whose numerator is the official duration of the scientific meeting (expressed in days) and the denominator is the total duration of the stay (also expressed in days).

For example: a doctor participates in a three-day scientific event in Rome and then extends his stay by three days in order to privately visit the city. The total duration of his stay is six days. The company may only fund 3/6th or half of this healthcare professional's travel expenses, the other half being at the doctor's expense.

Key points to consider in the preparation of a visa request:

- The arrival and departure dates must coincide as closely as possible with the opening and closing of the scientific event.
- Companies may not organise an extension of a stay on site – even if such an extension is to be paid for by the participating healthcare professionals. Companies must only organise the travel and stay of healthcare professionals participating in the scientific event, and this, for the duration of the event. Companies must take measures to guarantee the greatest transparency in this matter.
- If a participant wishes to extend his or her stay by several days for personal reasons, companies should limit their contribution in the travel expenses proportionally to the segment equivalent to the time spent to attend the scientific event. It is not appropriate to sponsor only the outward or return journey.

- Extension of stay for professional reasons should be justified and evidenced.

FREQUENTLY ASKED QUESTIONS CONCERNING ARTICLE 8

- FAQ 12. Extending of a Stay

Section 4. Benefits of a Scientific Nature

ARTICLE 9.

9.1. Healthcare professionals may be compensated by pharmaceutical or medical devices companies for legitimate scientific services performed on behalf of the latter, provided that these payments remain reasonable.

9.2. "Scientific services" should notably be interpreted as including the collaboration of healthcare professionals taking part in clinical trials or other scientific studies as laid down by the Law of 7 May 2004 on experiments on human persons, giving scientific presentations during training courses, seminars, symposiums or congresses and the performance of consulting agreement of a scientific nature.

9.3. However, payment may under no condition be made solely to compensate the time spent by healthcare professionals to attend a scientific event as described in article 3 of the Code.

PRACTICAL DIRECTIVES CONCERNING ARTICLE 9

1. SERVICES CONCERNED

Apart from the collaboration which healthcare professionals offer in the context of clinical studies or other scientific studies, the following services are covered inter alia: providing scientific explanations during a conference, a symposium, etc., and the performance of services in the context of a consulting agreement.

2. SCIENTIFIC NATURE OF BENEFITS

Pharmaceutical or medical devices companies may only remunerate healthcare professionals for services of a scientific nature. With regard to trials or studies within the scope of the legislation relating to human experiments[1], reference can be made, during the assessment of the scientific nature, to the opinion of the ethics committee in consideration of the trial or study in question. For all other services, the scientific nature must be assessed on the basis of specific circumstances pertaining to each and every case.

Healthcare professionals will not, under any circumstances, be indemnified for providing cooperation to studies or services of which the scientific basis is contestable or which are motivated by commercial interests rather than scientific interests.

3. LEGITIMATE NATURE OF SERVICES

It is reasonable that healthcare professionals be remunerated for the time and energy they devote to a study or a service, for the responsibility they accept thereto and for their costs so incurred. To the extent that they have provided a real and legitimate scientific service, they may be remunerated.

1. Law of 7 May 2004 on experiments on human persons.

When assessing the legitimate nature of the services rendered, it is essential to ensure that no remuneration be granted which, in reality, amounts to premiums and benefits that are not permitted or that raise doubts as to the objectivity of the studies or services rendered or as to the independence of their author. It is prohibited to provide remuneration to healthcare professionals in a way that cannot be justified by legitimate services of a scientific nature.

4. REASONABLE REMUNERATION

Remuneration provided to healthcare professionals performing the aforementioned scientific services must always remain reasonable, having regard to the nature of the services provided, and proportional to their extent.

5. NO COMPENSATION FOR LOSS OF REVENUE

Healthcare professionals may under no circumstance be remunerated for the time spent attending a scientific event – even if the event satisfies the criteria indicated in articles 3 to 8 of the Code. In fact, such remuneration would infringe the principle ban on premiums and benefits referred to in article 1 of the Code.

GUIDELINE CONCERNING FEES FOR SCIENTIFIC SERVICES

WRITTEN AGREEMENT

A written agreement must be concluded before the commencement of the services, outlining specifically and in detail the nature and the content of the services to be provided, as well as the basis for compensation.

TRANSPARENCY

In the interest 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 or publishes a piece 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?

Scientific services means the involvement of healthcare professionals in clinical trials, giving scientific presentations during training courses, 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 satisfies a real need of the company
- it is provided for the purpose of promoting healthcare or scientific research
- it does not aim at influencing the consultant’s prescription, supply, administration, recommendation, or using behaviour
- it is performed by a qualified consultant who has the required expertise
- and it is actually performed.

REASONABLE COMPENSATION?

The compensation for the services has to be reasonable, i.e. it reflects the fair market value of the services provided. The market of reference is the Belgian market.

The compensation is calculated based on multiple criteria such 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 consultant’s past or future volume of prescription is not a relevant criterion.

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

Consistency must be ensured in calculating compensation; to identical services and situations, identical compensation.

HOSPITALITY?

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

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

CHAPTER II.

Visa Obligation

Section 1. Visa Bureau

ARTICLE 10. TASKS

A Visa Bureau shall be established within MDEON, the role of which is to:

1° by virtue of article 10, §3 of the Law of 25 March 1964 concerning medicines, examine visa applications submitted by pharmaceutical or medical devices companies concerning scientific events which are taking place during several consecutive calendar days (including the related hospitality), as identified by article 10, §2, subparagraph 1, 2° of the above law concerning medicines and, if in conformity with the conditions and criteria legally laid-down and as stated in article 3 to 8 of the Code, to issue a visa.

2° at their request, advise pharmaceutical or medical devices companies as well as healthcare professionals on the question of conformity with the provisions of this Code of a premium, a benefit, an event or, more generally, on all acts or actions, prior to their being submitted, organised, carried-out or accepted.

ARTICLE 11. COMPOSITION

11.1. The Visa Bureau consists of two or more chambers; one of these (the Appeals Chamber) shall exclusively deal with appeals lodged in accordance with article 21 of the Code.

11.2. Without prejudice to article 1, 9° of the Royal Decree of 23 November 2006 implementing article 10, §3 of the Law concerning medicines of 25 March 1964, each chamber is composed of three members (natural persons), namely:

a. a legal professional who is not active within the industry;
b. a member having acquired extensive experience in the pharmaceutical or medical devices sector, but who no longer works for a pharmaceutical or medical devices company;
c. a member with professional expertise in the healthcare sector.

11.3. The mandates are remunerated.

11.4. Chairpersons and members of the Visa Bureau are nominated by the Board of Directors of MDEON. They are excluded from sitting on the Board of Directors of the association, from acting as a Board member and from representing a Board member as per article 21 of the MDEON Statutes. The duration of their mandate is three years, with the possibility of mandates being renewed; they may also be revoked at any moment by the Board of Directors.

11.5. The mandates within the different chambers of the Visa Bureau may be cumulated. However, when a case is being dealt with in appeal in accordance with article 21 of this Code, members who sat in the chamber initially dealing with the case in first degree are excluded from sitting in the Appeals Chamber.

ARTICLE 12. SECRETARIAT

12.1. The Visa Bureau is supported by a secretariat, the role of which is to deal with the administrative activities of the Visa Bureau and to manage administrative aspects of visa requests and requests for opinions. The secretariat is strictly neutral and is not involved in any way with the decision-making process of the Visa Bureau.

12.2. The body mandated to deal with the day-to-day management of MDEON has the responsibility of managing the secretariat.

ARTICLE 13. FUNCTIONING

13.1. Each chamber of the Visa Bureau meets as many times as there are requests to be dealt with.

13.2. A quorum for each chamber is reached once the chairperson and at least one of the two other members are present. However, the Appeals Chamber can only reach the quorum if all three members are present. In the absence of a consensus, decisions are reached on the basis of a simple majority. In case of a tie, the Chairperson has the casting vote.

13.3. The Chairperson of each chamber rules sovereignly on every procedural incident without the possibility of appeal. The Chairperson takes all measures he or she deems necessary to maintain orderly proceedings.

13.4. For particular questions relating to a certain matter, the Chairperson may seek the advice of an expert of his or her choice. The body mandated to deal with the day-to-day management of MDEON establishes a list of experts in the medical devices and pharmaceutical industries and makes this list available to all Chairpersons of the Visa Bureau.

13.5. Each individual member of the Visa Bureau acts independently. In a situation of conflict of interest, members shall refrain from taking part in any step of the proceedings. If necessary, such members shall be replaced.

13.6. Members of the Visa Bureau undertake, at the risk of being dismissed by the Board of Directors of MDEON, to uphold confidentiality of all data, information, exhibits, deeds, documents and any other information that comes to their knowledge in the context of their mandate.

13.7. Any Member of the Visa Bureau who is absent from three consecutive meetings to which he has been summoned, except in exceptional circumstances or justified absence, is deemed to have resigned. He or she will be replaced by a new member.

ARTICLE 14. ADDRESS OF THE SECRETARIAT AND ITS OPENING HOURS

14.1. All correspondence relating to the application or within the framework of the visa procedures or requests for advice must be addressed to the secretary of the Visa Bureau situated at: MDEON asbl, rue Belgica 1 b7 in 1930 Zaventem.

14.2. If proceedings are or should be dealt with *in situ*, they must be presented during opening hours as indicated on the MDEON website.

ARTICLE 15. COMMUNICATION

All correspondence originating from the Visa Bureau – including notification of decisions – may be sent to the applicants concerned by mail, e-mail or any other appropriate form of communication.

Section 2. Visa Procedure

ARTICLE 16. FIELD OF APPLICATION

16.1. Invitations of healthcare professionals and the sponsoring of their participation in a scientific event referred to in article 10, §2, subparagraph 1, 2° of the Law of 25 March 1964 concerning medicines and taking place during several consecutive calendar days, including the related hospitality, are subject to a prior visa procedure as described hereafter – independently of whether the above-mentioned professionals are present as participants or as speakers.

16.2. Both the direct and indirect sponsoring of costs of participation of healthcare professionals in a scientific event are subject to the granting of a prior visa. It follows that the sponsoring of the organiser of a scientific event is also subject to the visa procedure.

The sponsoring of the organiser of a scientific event is subject to the visa requirement if the event is organised by or on behalf of an association managed by a majority of healthcare professionals practising in Belgium. In the case where the scientific event is organised by or on behalf of an association which is not managed by a majority of healthcare professionals practising in Belgium, the sponsoring of the organiser remains subject to the visa requirement if the organiser may reasonably suppose that the event will attract a majority of healthcare professionals practising in Belgium.

16.3. In submitting a request for authorisation to the MDEON Visa Bureau, the applicant expressly accepts the application of the Code –both as regards the conditions and criteria which the event must meet, and the procedure which must be followed to obtain a visa.

FREQUENTLY ASKED QUESTIONS CONCERNING ARTICLE 16

- FAQ 1. Healthcare Professionals Concerned
- FAQ 2. Companies Concerned
- FAQ 6. Sponsoring of Organisers

ARTICLE 17. DELAY AND PROCEDURE

17.1. Visa must be obtained before the start of the scientific event and before healthcare professionals are invited to participate in the event.

17.2. For this purpose, pharmaceutical or medical devices companies must file a visa application with the secretariat of the Visa Bureau.

Pharmaceutical or medical devices companies may authorise a third party to file a visa application in their name and on their behalf.

In particular, when several companies sponsor the organiser of the same scientific event, the organiser may submit a group visa application to include all companies sponsoring the organiser's event and who have mandated the organiser to file the application in their name and on their behalf.

17.3. The application is not admissible if it does not reach the secretariat on the 15th business day before the start of the scientific event and in any case before healthcare professionals have been invited to participate in the event. The date –of acknowledgement of receipt indicated in article 18.4 is deemed the date of receipt of the application.
17.4. However, in the following situations, the applicant may submit its visa application at the latest six business days before the start of the scientific event:

- The scientific event involves in total a maximum of 15 participants and speakers
- The healthcare professional(s) who form(s) the subject of the application take(s) part in the scientific event as (a) consultant(s). A consultant is a healthcare professional who, during a scientific event, is providing scientific services on behalf of the organiser of the event or on behalf of a pharmaceutical or medical devices company
- The applicant submits a new visa application following a substantial change in arrangements after the visa has been obtained (see article 22) The applicant submits a new visa application following a refusal.

When an applicant chooses to make use of this shortened period of application, he must be aware that it may not be possible to lodge an appeal in the

FREQUENTLY ASKED QUESTIONS CONCERNING ARTICLE 17

- FAQ 13. The procedure

case of a refusal, given that the Appeals Chamber is not able to grant a visa after the start of a scientific event.

17.5. The procedure before the Visa Bureau is exclusively conducted in writing.

ARTICLE 17*bis*. COLLECTIVE VISA

17*bis*.1. A visa request can only concern a scientific event that has been well-defined.

17*bis*.2. However, when a well-defined scientific event is organised several times, a single visa application can be filed for the group of events, provided that:

- the events are identical (same programme, same content, same duration, same venue, same hospitality and same travel planning and arrangements),
- all events take place within a period of maximum one year counting from the date of acknowledgement of receipt as indicated in article 18.4,
- the exact number of planned events, the number of participants, the periods during which – and if possible – the dates on which the different events will take place must be clearly stated in an appendix to the vis application.

17*bis*.3. In addition, when a company invites a healthcare professional to give several lectures and covers the lecturer's hospitality costs, it is recommended that the company files a visa application which re-groups together the lectures which present similarities with the level of the sponsoring related to it.

ARTICLE 18. METHOD OF REQUESTING VISA

18.1. All visa requests must be submitted through the website of MDEON using the official application form supplied by MDEON. All information and documentation providing evidence that article 10, § 2, subparagraph 1, 2°, of the Law of 25 March 1964 concerning medicines and articles 3 to 8 of this Code are being complied with, should be attached to the request

FREQUENTLY ASKED QUESTIONS CONCERNING ARTICLE 18

- FAQ 4. Scientific Programmes
- FAQ 6. Sponsoring of Organisers
- FAQ 9. Registration Fees
- FAQ 10. Transport Costs

18.2. Applications which do not contain the following items will not be admissible:

a. In the case of invitation or sponsoring of healthcare professionals taking part in a scientific event:

- The full identity of the applying company.
- The full and accurate name of the scientific event, the dates and the venue when and where the event will take place.
- Justification regarding the event venue.
- The dates, the duration and the chosen mode of transportation to and from the event, and, if applicable, transportation during the event
- If the date and time of arrival or departure do not coincide with the commencement or ending date of the event, the reasons must be stated.
- As the case may be, the number of participants to be invited or sponsored and their professional capacity.
- If the healthcare professionals are invited as consultants, a description of the scientific services they will provide in the context of the scientific event.
- A brief description of the added value of the event for participants.
- A brief explanation of the relationship between the object of the event and the professional activities of participants.
- The scientific programme of the event detailed by day both in terms of content and schedule.
- A brief description of the hospitality being offered to participants, detailed per day with indication of the timetable.
- The amounts of the event's organisation costs, registration costs, travel costs and accommodation costs detailed by participant, for which the applicant company will be involved
- A justification of what is included in the registration fees for scientific events organised by (associations of) healthcare professionals.
- A justification of the cost, the class and the days and hours of the chosen flight ticket.

b. In the case of sponsoring of the organiser of a scientific event:

- The identity of the company making the request (if the scientific organiser makes a group request in the name of, or on behalf of

several companies, the identity of each company must appear on the request),
- The complete name of the scientific event, the dates when and the venue where the event will take place,
- An estimate of the expected number of participants,
- The scientific programme of the event detailed by day with regard to content and schedule,
- A brief description of the added value of the event for participants,
- The amount to be contributed by the applicant company to the organisation of the event (in the case of a visa request filed in the name and on behalf of a group of companies, the amount to be paid by each individual company must be mentioned),
- A detailed budget for the scientific event, listing the various income and expense items and the amounts related thereto,
- A declaration by the scientific organiser stating that 1) the sponsorship amounts will only be used to finance scientific activities or legitimate hospitality expenses by virtue of article 5.2 of the Code and 2) the eventual profit will be used in accordance with article 10 of the Law of 25 March 1964 concerning medicines,A commitment to send the amount and the allocation of the closed account's result to the Mdeon Secretariat by e-mail within three months after the scientific event.

18.3. The secretariat of the Visa Bureau will issue an acknowledgment of receipt for each request and will provide the applicant with an identification number.

18.4. All applications received before 12:00 AM will be acknowledged on that day; requests received after 12:00 AM will be acknowledged on the following business day. The date on which the acknowledgement of receipt is sent is decisive for monitoring compliance with the deadline referred to in article 17.3.

ARTICLE 19. EXAMINATION OF VISA REQUESTS

19.1. The Visa Bureau firstly examines if the request is admissible, and if so, proceeds to establish if the request meets the criteria referred to in article 10, § 2, subparagraph one, 2°, of the Law of 25 March

1964 concerning medicines as described in articles 3 to 8 of the Code.

19.2. If the Visa Bureau deems the proposal as described in the request admissible and in accordance with the provisions listed in the first paragraph, a visa shall be granted. In this case, a visa number is allocated by the Visa Bureau. The applicant must refer to this visa number in all correspondence used in the context of the project concerned, after receipt of the decision of the Visa Bureau.

19.3. If the Visa Bureau deems the project as described in the request not admissible or in violation of the provisions referred to in the first paragraph, a visa is refused.
The reasons for refusal shall be given. In case of a visa refusal, the sponsoring concerned may not be offered to persons identified in article 10, § 1, of the Law of 25 March 1964 concerning medicines.

19.4. Any visa granted by the Visa Bureau constitutes a presumption that the project concerned is in conformity with the provisions listed in article 19.1., provided that the application is complete and reflects reality, without prejudice to article 22 of this Code.

ARTICLE 20. COMMUNICATION RELATING TO THE VISA BUREAU'S DECISION

Applicants will be informed of the Visa Bureau's decision no later than five business days following confirmation of the reception of said application by the secretariat in accordance with article 18.4 of the Code, it being understood that the fifth working day ends at midnight. The absence of any decision within the abovementioned time period does not mean the visa has been granted.

ARTICLE 21. PROCEDURE FOR APPEAL

21.1. All decisions containing a visa refusal from the Visa Bureau can be appealed before the Appeals Chamber of the Visa Bureau.

21.2. In order to be admissible, the appeal must be lodged by a reasoned request in writing, sent to the secretariat by registered mail no later than five

business days after notification of the contested decision. The mark on the post stamp serves as proof of the sending date.

The secretariat of the Visa Bureau acknowledges receipt of each appeal request. Requests for appeal received before 12:00 AM will be acknowledged on that day; those received after 12:00 AM will be acknowledged on the next business day.

21.3. The Appeals Chamber examines the original application as presented by the requesting party, who may, if he or she desires, provide some additional information in support of the original application with the proviso that nothing be altered. If the applicant wishes to modify his original visa application, he must file a new visa application.

21.4. The Appeals Chamber examines whether the project as described in the visa application satisfies the conditions and criteria as defined in article 10, §2, subparagraph 1, 2° of the Law of 25 March 1964 concerning medicines and article 3 to 8 of the Code. In doing so, it takes into consideration the explanation and the additional elements included in the request.

21.5. If the Appeals Chamber judges that the project as described in the application complies with the requirements listed in article 21.4, a visa is granted. In this case, a visa number is issued by the Appeals Chamber. The applicant is required to indicate this number on all correspondence related to the project concerned once the decision has been received from the Appeals Chamber.

21.6. If the Appeals Chamber deems that the project is not in accordance with the requirements listed in article 21.4, the visa is refused. The reasons for refusal shall be given.

21.7. The Appeals Chamber will make public its decision within five business days following the day of acknowledgment of receipt of the appeal, in accordance with article 21.2, with the proviso that the fifth day ends at midnight. An absence of a decision within that time period does not imply that a visa has been granted.

21.8. The appeal procedure is exclusively conducted in writing.

ARTICLE 22. SUBSTANTIAL MODIFICATIONS

22.1. If a visa has already been granted for a project the applicant must re-apply for a visa if the project has been subjected to any substantial change(s) between the moment where the first application was submitted and the date of the organisation of the scientific event. 22.2. Is considered “substantial” for the purpose of the previous paragraph every alteration that can reasonably be expected to be considered by the Visa Bureau in order to make a decision with full knowledge of the facts.

22.3. By way of derogation from article 17.3 of the present Code, the applicant who has substantially modified his or her project can file a new visa request at the latest the sixth business day preceding the start of the scientific event.

FREQUENTLY ASKED QUESTIONS CONCERNING ARTICLE 22

- FAQ 13. The procedure

ARTICLE 23. CO-REGULATION WITH THE FAMHP

MDEON is obliged to immediately communicate the following information to the Federal Agency for Medicines and Health Products to enable the FAMHP to exercise its statutory control:

- Refusal decisions
- Late requests
- Decisions reversed on appealIrregularities detected by MDEON concerning compliance with the visa procedure.

FREQUENTLY ASKED QUESTIONS CONCERNING ARTICLE 23

- FAQ 14. Overseeing of Visa Requirements

CHAPTER III.

Requests for Advice

ARTICLE 24.

24.1. Pharmaceutical or medical devices companies as well as healthcare professionals may request the Visa Bureau to advise on the conformity with the present Code of premiums, benefits, events or, more generally, any act or action prior to their submission, organisation or acceptance.

24.2. The advice indicated above does not apply to scientific events subjected to the visa procedure in accordance with article 16 of the Code. The opinion does not fall within Mdeon's approval related to the visa procedure, nor in the co-regulation with the FAMHP.

CHAPTER IV.

Procedural Costs

ARTICLE 25.

25.1. All visa requests submitted in accordance with article 16 of this Code and requests for advice submitted in accordance with article 24 of the present Code are subject to the payment of a fee of which the amount is fixed annually by the Board of Directors of MDEON linked to the operational costs of the association.

25.2. The fees referred to in the preceding paragraph may vary according to each criterion or combination of criteria allowing for a fair distribution of the association's operational costs

25.3. Fees thus identified in this article shall be payable and paid *per se* when the visa application is submitted or when advice is sought, regardless of the outcome of the visa application or request for advice. Such fees will not be refunded under any circumstances.

Part II.

Sunshine Act

ARTICLE 26. DEFINITIONS

For the purposes of this Part II of the Code, the following definitions apply:

- Sunshine Act: Chapter 1 of title 3 of the Law of 18 December 2016 regarding various provisions on health, *Belgian Official Journal* of 27 December 2016.

- RD Sunshine Act: Royal Decree of 14 June 2017 executing the Sunshine Act, *Belgian Official Journal* of 23 June 2017.

- Company subject to notification: any entity that carries out an economic activity, regardless of its legal form and the way in which it is financed, within the meaning of Title VII of the Treaty on the Functioning of the European Union, in particular marketing authorisation holders for medicinal products for human or veterinary use, importers, manufacturers and distributors of medicinal products for human or veterinary use, persons engaged in brokering activities relating to medicinal products for human or veterinary use, and distributors, retailers and manufacturers of medical devices (art. 41, §1, 1°, Sunshine Act);

- Beneficiary (art. 41, §1, 3°, Sunshine Act):
  - healthcare professional (see below)
  - healthcare organisation (see below)
  - patient organisation (see below).

- Healthcare professional: any natural person practicing medicine, dentistry, pharmacy, veterinary medicine or nursing or who, in the context of his professional activities, may prescribe, purchase, deliver, recommend, lease, use or administer medicinal products or medical devices and whose practice is established in Belgium (Art. 1, 4°, RD Sunshine Act).

- Healthcare organisation: any association or organisation active in the field of healthcare, medicines or sciences, regardless of its legal or organisational form, and any legal entity through which one or more healthcare professionals provide services (art. 41, §1, 2°, Sunshine Act).

- Patient organisation: a healthcare organisation that is responsible for patient representation (Art. 1, 5°, RD Sunshine Act).

- Scientific research: the experiments as referred to in article 2, 11°, of the Law of 7 May 2004 on experiments on human persons, non-clinical studies as defined in the OECD Principles on Good Laboratory Practice and clinical trials referred to in article 6quinquies of the Law of 25 March 1964 concerning medicines (Art. 1, 3°, RD Sunshine Act and Art. 42, §1, subparagraph 2, Sunshine Act):

- Period of reference: the full calendar year in which the premiums and benefits were granted (Art. 42, §2, Sunshine Act). The date which determines the reference year in which a premium or benefit was granted is the date of the financial transaction relating thereto and not the date on which the beneficiary benefited from the premium or benefit, in case it is different (Art. 3, clause 1, 6°, RD Sunshine Act). Companies subject to notification must notify these data by 31 May of the year following the reference year (Art. 42, §2, Sunshine Act). The data shall be published no later than 30 June of the year following the reference year (Art. 43, §1, clause 4, Sunshine Act).

ARTICLE 27. TRANSPARENCY OBLIGATION

The companies subject to notification, whether Belgian or foreign, must document and annually disclose in the Transparency Register of betransparent.be the premiums and benefits that they grant as from 1 January 2017

directly or indirectly to healthcare professionals, healthcare organisations or patient organisations with a practice or a registered seat in Belgium (art. 41, §2 Sunshine Act).

ARTICLE 28. CATEGORIES OF PREMIUMS AND BENEFITS

28.1. The categories of premiums and benefits as referred to in article 27 are the following (article 2 RD Sunshine Act):

1° Regarding the premiums and benefits granted directly or indirectly to healthcare professionals:
   a) The contributions to the costs of scientific events, such as registration costs, travel expenses and subsistence costs;
   b) The fees, payments and reimbursements of costs for services and consultancy;

2° Regarding the premiums and benefits granted directly or indirectly to healthcare organisations:
   a) Contributions to the cost of scientific events, such as registration costs, travel expenses and subsistence costs, and sponsorship agreements with healthcare organisations or with third parties appointed by these organisations to organise a scientific event.
   b) Fees, payments and reimbursements of costs for services and consultancy.
   c) Donations and grants that support healthcare.

3° Regarding the premiums and benefits granted directly or indirectly to patient organisations:
   a) Fees, payments and reimbursement of expenses for services and consultancy:
   b) Financial or other support.

28.2. The following categories of premiums and benefits do not have to be made public (art. 41, §3 Sunshine Act):

1° the gifts of negligible value related to the practice of the profession;
2° meals and beverages offered in the context of scientific events;
3° the economic margins and discounts that are part of the usual purchase and sales transactions for medicinal products or medical devices by a company subject to notification or between such company and a beneficiary;
4° samples within the meaning of article 12 of the Law of 25 March 1964 concerning medicines.

ARTICLE 29. ANNUAL PUBLICATION ON BETRANSPARENT.BE

29.1. YEAR OF REFERENCE

The premiums and benefits as referred to in article 28 must be made public annually. Each period will cover one entire calendar year (art. 42, §2, Sunshine Act).

29.2. TERM

The publication takes place on 30 June of the year following the end of the reference year at the latest (art. 43, §1, Sunshine Act). The published data stay publicly accessible during a period of three years from the date of their publication in accordance with point 4 of this Article (article 6 RD Sunshine Act).

29.3. TEMPLATE

The notification must take place in accordance with the template referred to in article 42, §2 of the Sunshine Act.

29.4. CENTRAL PLATFORM

Premiums and benefits are made public in the Transparency Register which is accessible on the website www.betransparent.be and which is managed by the non-profit association Mdeon (see the Royal Decree of 31

July 2017 approving the organisation referred to in article 44, § 1 of the Law of 18 December 2016 regarding various provisions on health).

29.5. LANGUAGE

The data are notified to the platform by the companies subject to notification in Dutch, French or English.

29.6. DOCUMENTATION

The companies subject to notification must document all premiums and benefits that must be published in accordance with article 27. They must retain evidence that they have fully and correctly fulfilled their publication obligation for at least 10 years after the end of the reference year (Article 43, §2, Sunshine Act).

29.7. EXPLANATORY NOTE

Each company subject to notification may publish an explanatory note summarising the methods used to prepare the publication and to distribute the premiums and benefits in the different categories. This note is also made public in the Transparency register.

ARTICLE 30. NOMINATIVE vs. AGGREGATE PUBLICATION

30.1. PUBLICATION ON AN INDIVIDUAL BASIS

All premiums and benefits are made public on an individual basis (in the name of the beneficiary who received them directly or indirectly) (article 43, §1, subparagraph 2 Sunshine Act). In particular, each company subject to notification shall make public, for each beneficiary, the amounts of the premiums and benefits granted to that beneficiary during a calendar year (article 3 RD Sunshine Act).

These premiums and benefits are grouped by category, so that a total amount per category and per beneficiary appears in the Transparency Register (article 3 RD Sunshine Act). The details of the publication shall be communicated by the company if the beneficiary concerned or the competent authority so requests.

30.2. PUBLICATION IN THE NAME OF THE BENEFICIARY

The publication shall always take place in the name of the beneficiary of the granted benefit, taking into account the following (see Art. 3, subparagraph 1, 4°, RD Sunshine Act):

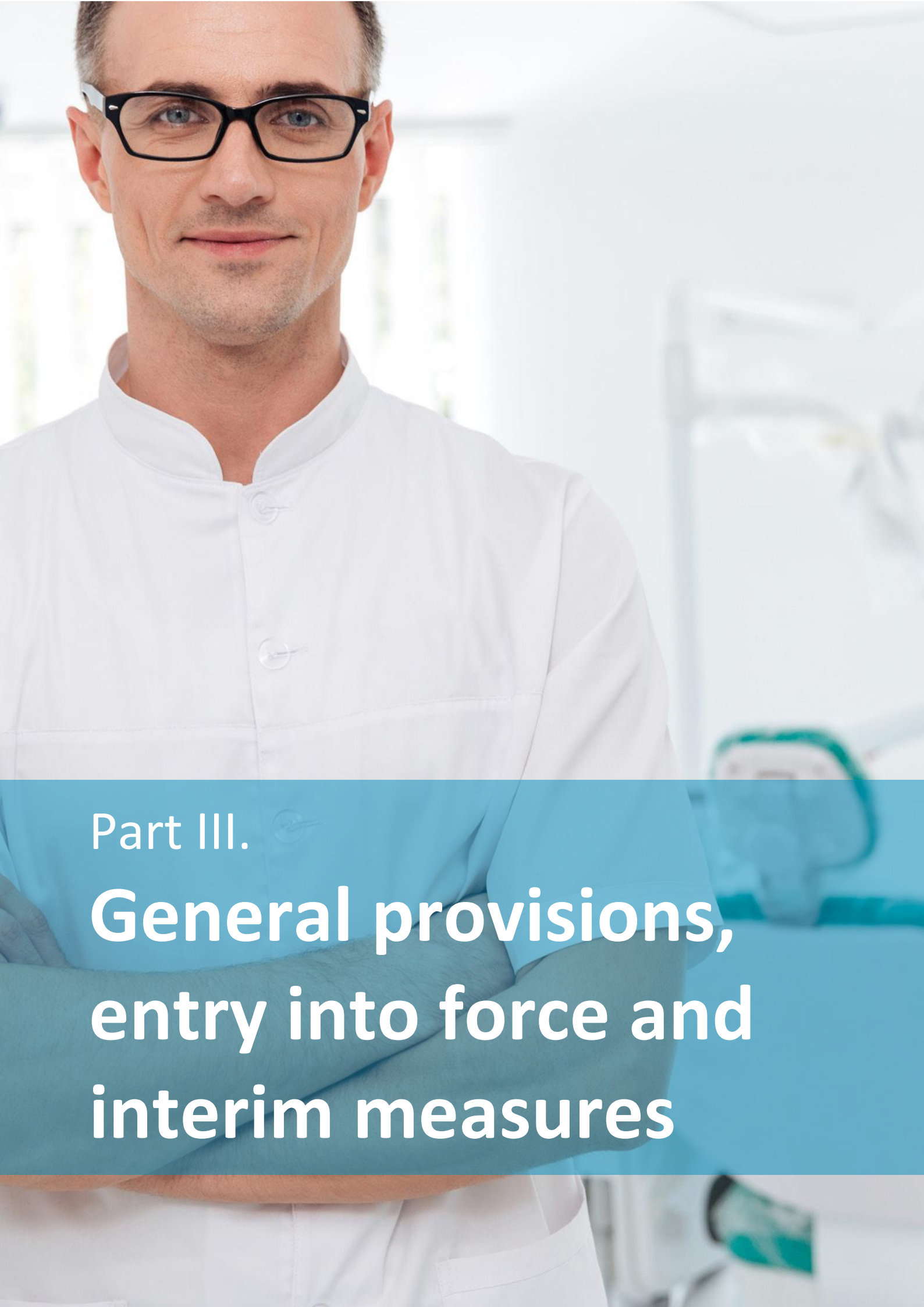
a) when fees, payments and reimbursement of costs for services and consultancy are accorded to healthcare organisations, the beneficiary is the healthcare organisation, except if it concerns a healthcare professional who acts as a company or who is part of a *de facto* association, in which case the beneficiary is the healthcare professional who provided the services that led to the fees and payments;

b) regarding contributions to the costs of participation in scientific events, the beneficiary is the healthcare professional who actually participated in the scientific event even if the healthcare professional has received this premium or benefit through a healthcare organisation;

c) regarding contributions to the organisation costs of scientific events, the beneficiary shall be the healthcare organisation or the patient organisation that received the contributions.

30.3. PUBLICATION ON AN AGGREGATE BASIS

The premiums and benefits granted in the context of scientific research are notified and published in aggregate. More particularly, such premiums and benefits are published in an aggregated (grouped), non-individual way, by the company subject to notification, without mentioning the identity of the beneficiaries (Article 42, §1, subparagraph 3, Sunshine Act). Each company will therefore make public one total amount for scientific research in Belgium each year (article 2, §2 RD Sunshine Act).



Part III.

General provisions, entry into force and interim measures

ARTICLE 31.

31.1. The original version of this Code entered into force on 15 November 2006 with the understanding that scientific events that began before 1 January 2007 are not subject to the visa procedure as indicated in article 16 of the Code. The present version of the Code, as approved by the Board of Directors on 13 November 2017, enters into force on 1 September 2018.

31.2. The first reporting period referred to in Part II is the calendar year 2018. By way of exception, an additional period is granted for premiums and benefits for medicinal products for veterinary use. Their first reference year is 2018, with a first publication in June 2019.

31.3. MDEON will take care of all communications relating to the Code. Such communication will be sent to all interested parties – pharmaceutical or medical devices companies, healthcare professionals, patients and Governmental departments.

Version 10 September 2018

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