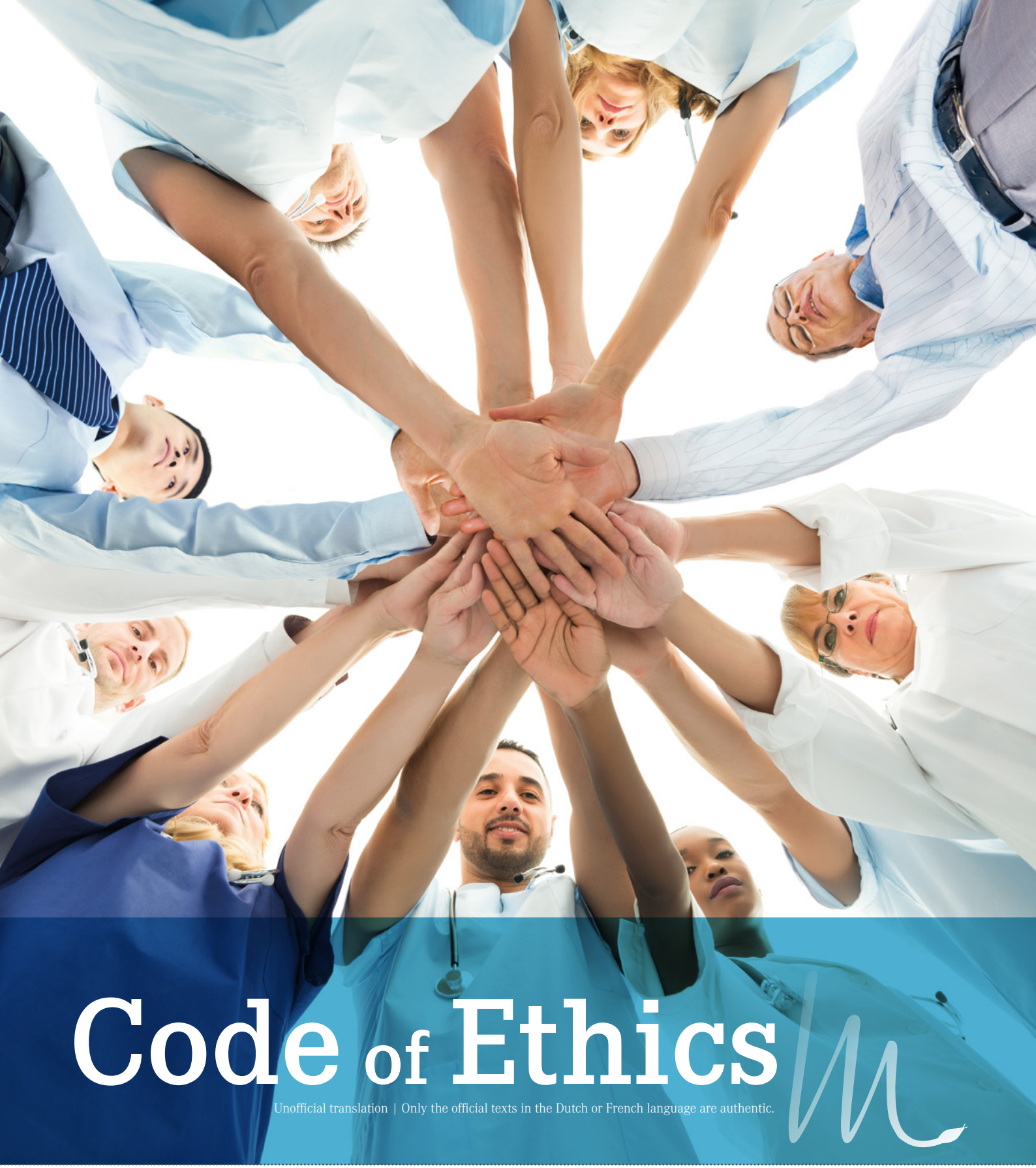


Code of Ethics

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

Ethical Health Platform

Medeon

Contents

Preface

As a qualified body under clause 10, §3, paragraph 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 clause 10, §3 of the law of 25 March 1964 concerning medicines, MDEON has a legal obligation, in accordance with clause 10,§3 of the above mentioned law, to consider visa applications presented by holders of a marketing authorization 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 targeted in clause 10, §2, paragraphs 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 granting of allowances of a scientific nature as defined in clause 10, §2, paragraphs 1 and 3 of the Law concerning medicines.

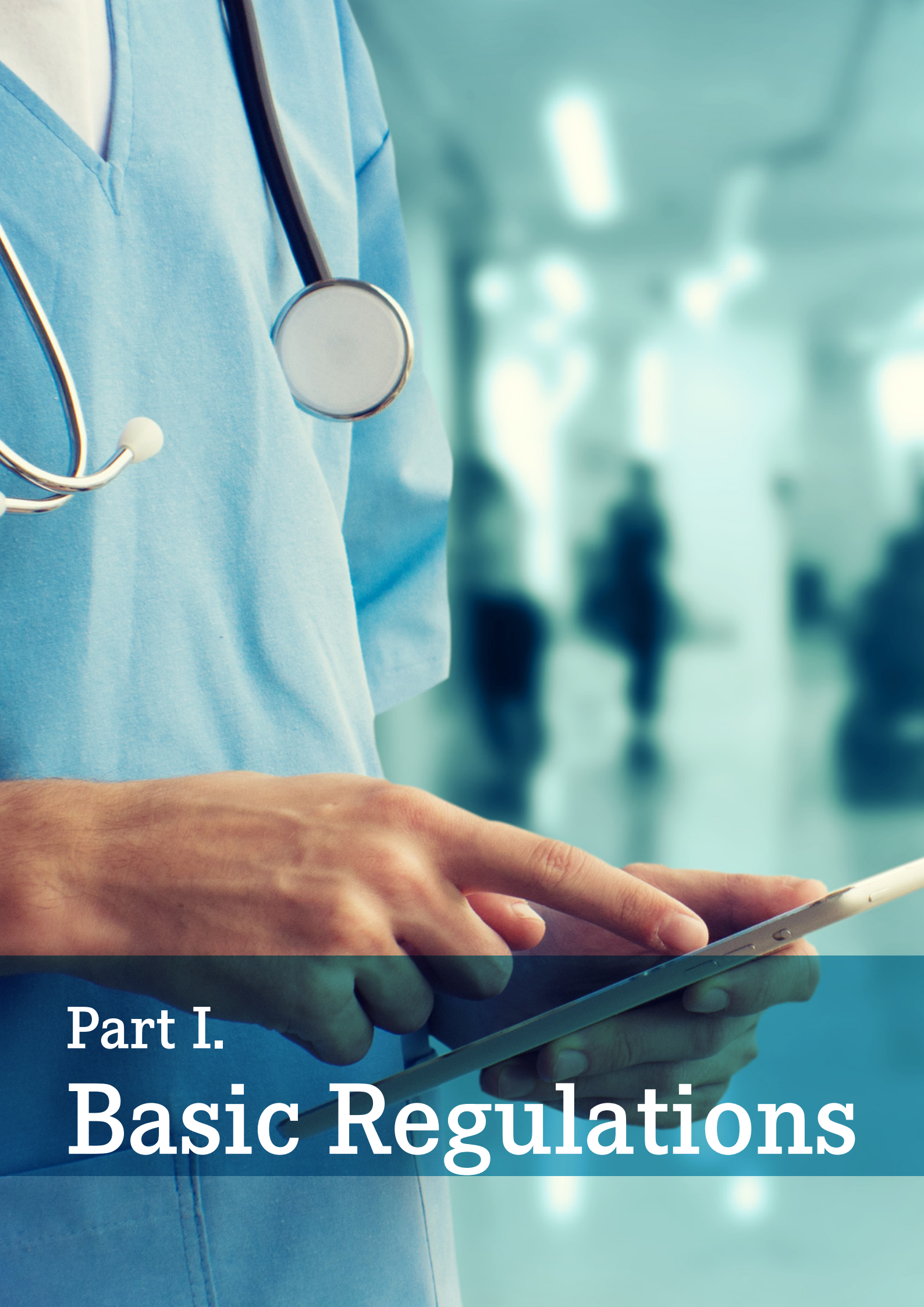
Within the framework of its legal requirement, MDEON examines whether or not scientific events which are taking place during several consecutive calendar days, including the related hospitality, and the financial support proposed by an industrial company meet the requirements of the criteria mentioned in clause 10, §2, paragraphs 1 and 2 of the aforementioned law and if, accordingly, a visa can be granted. Without this visa, the costs for attendance – including hospitality costs – may not be paid for by a company to any individual in accordance with clause 10, §1 of the aforementioned law.

In addition, this Code establishes the **procedure** which must be followed by the pharmaceutical or medical devices companies, as such as, eventually, in their quality of proxy, by the healthcare professionals themselves who organize a scientific event, with a view to the obtaining of a visa for the organising, sponsoring or the support for scientific events which are taking place during several consecutive calendar days, including the related hospitality.

Furthermore, MDEON has established a procedure to be followed in this Code which permits companies to **inform** of the organisation, the sponsoring or the support of scientific events not subject to visa requirements on the one hand and the granting of scientific advantages on the other.

Finally, this Code foresees the possibility for companies and healthcare professionals to obtain **advice** concerning the compatibility of other advantages or activities with the Code before their attribution or realisation.

Thanks to an efficient visa procedure, a straight forward means of notification regarding activities which does not require authorisation and to the possibility of obtaining advice, MDEON hopes to satisfy legal requirements in terms of requirements of preliminary control leading to openness in the promotion of medicines and medical devices.



Part I.
Basic Regulations

CHAPTER I.

Allowances and Advantages

ARTICLE 1. GENERAL PROHIBITION

1.1. Within the framework of the supplying, prescribing, deliverance or the administration of 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 qualified to prescribe, deliver or administer medicines or medical devices as well as institutions within which originate prescriptions, deliverance or administration of medicines or medical devices.

1.2. It is also forbidden, within the framework of the supplying, prescribing or the 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 particularly, to individuals targeted by clauses 1, 3 and 7 of the Law of 28 August 1991 concerning the practice of veterinary medicine.

1.3. This prohibition concerns – amongst others:

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

ARTICLE 2. EXCEPTIONS

However, the prohibition targeted in the above clause does not apply:

1° to gifts and advantages that are inexpensive and concern medical, dental or veterinarian 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”

GUIDELINES CONCERNING PREMIUMS AND BENEFITS OF NEGLIGIBLE VALUE

NEGLIGIBLE VALUE

- Of a nature which will have no influence on medical 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 as a whole entity and not on the value of its constituent 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. of the Healthcare professional or with the administrative activity relating to his or her work
- The gift is not intended for purely personal use

2° to the invitation and the payment of costs of participation in a scientific event – including hospitality costs – of healthcare professionals providing the event is in accordance with the conditions as described in clauses 3 to 8 of the present Code

3° to the indemnification of legitimate services of a scientific nature within the limitations of clause 9 of the Code.

- The giving of the gift is not associated with a private or personal event (birth, birthday, wedding, etc.)

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 voucher, reduction voucher, camera, bottles of wine, tickets for the theatre or other cultural, sporting or recreational events, mobile phone, scanner, radio, suitcase, sport/travel bag, alarm clock, cups, watch, etc.

CHAPTER II.

Scientific Events

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 to which healthcare professionals participate must be organised within a framework which does not bring into disrepute the scientific nature of the event.

3.2. The term "scientific event" includes all activities dispensing information, training courses, seminars, scientific meetings and congresses as well as all forms of scientific meetings 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 from Belgium or elsewhere.

PRACTICAL DIRECTIVES CONCERNING ARTICLE 3

The notion of "scientific event", as understood by the Code, includes all forms of scientific meetings such as congresses, gatherings, symposiums, scientific training courses, etc, which unite 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 giving an input. Events which are purely or mostly of a promotional nature cannot be granted a visa.

Scientific events, as understood by the Code, may be organised by pharmaceutical or medical devices companies or by third parties – for example: universities, local, national or international scientific associations, professional groups from the healthcare sector, etc.

Whoever the organiser, the event must take place within a qualifying framework which satisfies the requirements as stated in articles 4 to 8 of the Code, stated hereunder, in order that the medical industry is able to organise, sponsor or support in any other way such as that indicated above, or the individual participation of professional members of the sector at such an event.

Points to be noted 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.

ARTICLE 4. EXCLUSIVELY SCIENTIFIC NATURE

4.1. The event must be of an exclusively scientific nature and must be organised within a medical or pharmaceutical framework. From the moment of arrival until the time of departure, scientific activities must take up the majority of the time allocated each 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 to the scientific purpose of the event.

PRACTICAL DIRECTIVES CONCERNING ARTICLE 4

The law concerning medicines requires that scientific events – in whose framework companies sponsor certain healthcare professionals – must be of a purely scientific nature. When considering the granting of a visa, 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 practising of their profession and which can be considered necessary to the quality of the execution of their activities in the interest of their patients. In taking into consideration the fact that invited or sponsored participants may also be active in the domain of health other than in medicine or pharmacy, the strict sense of the term "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 merit in order to establish whether the exchange of certain professional information or a particular determined course actually presents a link sufficiently close to the practice of the concerned profession and is necessary in improving the quality in the exercise of the said profession. In this matter, the professional standing of the organiser, the qualifications of the speakers and the nature of the participants targeted. *E.g.:* management courses for nurses responsible for the operating theatre, pharmo-economy, etc.

Certain subjects, presentations or workshops may be of interest for participants but not enter into a medical or pharmaceutical framework. Such is the case for inputs concerning financial aspects or taxation and accountancy inherent in the managing of a medical practice. If such activities are organised, they must also be accompanied by scientific activities such as those indicated above and these must take up the major part of the daily timetable of the event.

The scientific nature of the event must make up the majority of the programme – in content and in timetable, as a whole and on an individual daily basis. Generally speaking, at least six hours per day must be devoted to scientific activities. Three hours may, however, be acceptable for the first and the last day to facilitate the arrival and departure of participants.

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 tackled, the speakers and the length of their input must always be stated in detail.

Within the framework of evaluation of the scientific content of the event, the Visa Bureau will notably analyse the added value for healthcare participants. In the case of a visit to a production site or R&D site of a hospital, a medical centre or other health dispensary, companies are obliged, when applying for a visa, to clearly state the added interest for the participants of such a visit in scientific terms. Precisely in this case, this clear statement of the added value is an essential element in the justification of the attendance of participants at such a centre – especially when the centre is situated abroad.

Points to be noted in the preparation of a visa request:

- The programme sufficiently detailed (subjects to be covered, speakers, length of time allocated to these aspects by each speaker).
- An explanation, where necessary, concerning the links between the themes under discussion and their actual practice by the profession.
- Particular qualifications of the speakers and of the added value of their input to specific participants.
- The avoidance of subjects being duplicated unnecessarily in the scientific programme – even in a modified form.
- The coherence between different subjects. For example, that one particular theme be dealt with at one moment during one

ARTICLE 5. HOSPITALITY

5.1. The hospitality provided to healthcare professionals within the framework of scientific events must always be reasonable and remain of a subsidiary nature in terms of 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* in this matter.

5.2. Hospitality offered directly or indirectly to healthcare professionals by pharmaceutical or medical devices companies must be limited to the participation in travel expenses, meals, overnights and registration fees for the event and must not include any period of stay beyond the official duration of the event.

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

meeting and then again, for even longer, during another different meeting.
- Qualified speakers.
- A qualified chairperson with clear themes and aims for question time, group discussions, round-tables, etc.
- In the case of visits to production sites, hospitals, medical centres, etc. that there be clear objectives, a sufficient scientific framework and scientific explanations furnished by qualified speakers.

FREQUENTLY ASKED QUESTIONS CONCERNING ARTICLE 4

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

PRACTICAL DIRECTIVES CONCERNING ARTICLE 5

The hospitality reserved for healthcare professionals within the framework of scientific event must remain subordinate 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 must always remain a subsidiary activity. It must never be the primary aim of an event, nor even be on a par with the scientific aim. This rule will be clearly broken if the majority of the participants take part in the event because of the gastronomic, cultural, recreational or sporting qualities on offer rather than its scientific interest.

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

The hospitality offered within the framework of a scientific event must always be restricted to the organisation of travel arrangements, meals, overnight stays and course registration.

The hospitality offered cannot be extended to a period longer than 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 free time or of its being made available between arrival of a participant and the official opening of the event or that between the official closing and the actual departure of a participant is only authorised in the case of specific travel constraints such as a lack of an earlier or later flight.

Hospitality costs must remain reasonable; local prices should be assessed and taken into consideration in order to ensure the application of reasonable hospitality costs.

Hospitality services must in no case include payment for any form of sporting or leisure activities.

Points to be noted in the preparation of a visa request:
- Hospitality costs should be limited to enrolment, travel, meals and overnight stays in so far as the latter are necessary within

ARTICLE 6. PLACE, DATE AND DURATION OF THE EVENT

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

6.2. The location chosen for the event and the travelling arrangements to the event must be justified.

6.3. In the case of the organisation, sponsoring or support for scientific events taking place in another country or the organisation, sponsoring or support accorded to healthcare professionals taking part in scientific events abroad, it is a requirement that:

a. the majority of participants taking part in the event be not from Belgium. Good sense requires that, from a logistical point of view, such an event be held in another country.

b. there be present at the event a pertinent managing body or infrastructure so that from a logistical point of view it makes good sense to hold the event in a country other than Belgium.

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

the framework of the event and only for the duration of the event.
- Hospitality costs must remain reasonable and linked to local prices.
- The organisation and the funding of social, tourist, sporting and leisure activities are formally forbidden.
- The hospitality on offer must in no way prejudice of 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

PRACTICAL DIRECTIVES CONCERNING ARTICLE 6

The place chosen for the scientific event and travel arrangements to the same 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 most participants originate from, it is deemed more reasonable, logistically, to organise the event in another country,
- a pertinent competency or infrastructure is available at the place where the event is planned in such a way that it would be more logistically reasonable to organise the event in this said place rather than in Belgium.

The organisation of a scientific event abroad is justified if it targets participants coming from several different countries. If the event is organised by *the Head Office or sister company situated abroad*, the international nature of the said event must be clearly stated in the request submitted – as, for example, through informing of 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 place for the event must be seen to be coherent.

Travel abroad cannot be justified if the participants at a scientific event are all or mostly from Belgium, except, in scientific terms, there exists a sufficient number of reasons linked to the choice of the place, for instance: a visit to a research centre or to a hospital reputed for a particular aspect (see criteria n° 2 in point 1). In these cases the justification for the choice of the place relies directly on the added scientific value of this visit for the participants (please consult the commentary in section 2 above "Exclusively scientific nature of the event"). In addition, it is indispensable that the visit to a hospital or institution concerned justifies travelling abroad for the whole of the duration of the event. With

ARTICLE 7. PEOPLE ACCOMPANYING PARTICIPANTS

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

7.2. In the case where participants are accompanied no financial support may be given towards the expenses of those accompanying. Pharmaceutical or medical devices companies must make every effort to ensure that this requirement is clearly respected and adhered to.

7.3. No alternative programme shall be prepared for people accompanying participants at the event.

this in mind, a two-hour visit to a university centre would not justify the event being held abroad over three days.

The chosen place for the event, whether in Belgium or abroad, must not give rise to confusion or doubts as to the scientific nature of the event. When searching for a suitable place for the organisation of an event the Code explicitly requires manufacturers, importers or wholesalers of medicines or medical devices to avoid places reputed for their sporting activities or other attractions.

Points to be noted in the preparation of a visa request:

- justification of the place chosen for the event, and more particularly if the event is to be organised for abroad.
- coherence between the countries from which participants originate and the chosen place for the event (when a scientific event targets members from different countries)
- the added value of a visit to a particular centre justified by its degree of competence or the existence of a pertinent infrastructure of interest to the participants
- the visiting of such a centre or infrastructure will be justified if such a visit lasts for the whole duration of the event
- companies are specifically required to avoid choosing places for a scientific event which are reputed for their sporting or leisure activities.

PRACTICAL DIRECTIVES CONCERNING ARTICLE 7

Responsibility for participants' costs, including reception costs, cannot be extended to individuals other than healthcare professionals actually participating in the scientific event. Additional individuals accompanying healthcare professionals must finance all costs linked to their participation themselves.

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

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

Companies will not organise activities for individuals accompanying, even if these individuals are bearing the cost of the same.

Points to be noted by the companies in the preparation of a visa request:

- Avoid all forms of solicitation, encouragement or of sponsoring of participation by third parties in a scientific event.
- Submit invitations in such a way that they are addressed uniquely to healthcare professionals and not to their spouses or other individuals closely related to the healthcare individuals.
- Do not organise an alternative programme for spouses or other accompanying individuals – even if these individuals bear the cost of such a programme.
- If the healthcare professional participant's spouse is also a healthcare professional in his or her own right, the company

ARTICLE 8. PROLONGATION OF STAY

Pharmaceutical or medical devices companies shall not participate in the organisation of extending of stays for personal reasons by participants and shall not contribute to the financial costs thereby incurred. Manufacturers, importers or wholesalers in medicines or medical devices shall take all necessary measures to ensure the complete transparency in such matters.

may only bear that person's costs if he or she is a full participant at the scientific event and not there simply in the quality of an accompanying spouse.

PRACTICAL DIRECTIVES CONCERNING ARTICLE 8

1. If the duration of the stay is to be lengthened for personal reasons, the healthcare professional concerned must formulate a request. The company may not suggest such a prolongation even if the same is offered as an option and if the costs incurred are to be borne by the healthcare professional.

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

2. Companies must restrict their payment of transportation and board and lodging costs to those linked exclusively with attendance at and for the strict duration of the scientific event. The healthcare professional must always finance him or herself all costs liked to any prolongation of his or her stay for personal reasons (overnight stays, meals, social or cultural activities, etc.).

3. In this context, the stay may be prolonged to take place prior to or following the scientific event. In both cases, all costs linked to this prolongation must be taken on board by the healthcare professional – be he invited or sponsored.

4. It is permissible that the company bears the whole travel expenses to and from the scientific event, even if the stay is prolonged by the participant for personal reasons, with the proviso that 1) these costs are not greater than those for attendance at the scientific event without such a prolongation and 2) the duration of the prolongation is accessory in comparison with the duration of the scientific event. In this case, it can be considered that the journey is linked entirely to attendance at the scientific event and that the prolongation is simply an accessory event.

On the other hand, in the case of a lengthy prolongation, the company who issued the invitation or who sponsored the healthcare professional may not wholly pay the travel costs but must limit its obligations in this matter to that part of the travel expenses linked to participation at the scientific event. To the extent where travel expenses are inherent to the duration of the stay on a purely private basis, the company concerned may not assume the costs without granting the healthcare professional an illegal advantage.

From a practical point of view, the following rule has to be applied: the inviting or sponsoring company must limit its liability in funding travel expenses to the fraction of the total cost obtained through multiplying the total travel costs by a fraction of which the numerator corresponds to the official duration of the scientific event in days, and the denominator corresponds to the total duration of the stay, also counted in days.

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

Points to be noted in the preparation of a visa request:

- The arrival and departure dates must coincide as closely as possible with the commencement and finishing of the scientific event.
- Companies may not prolong the duration of a stay – even if such a prolongation is to be paid for by healthcare professionals attending the scientific event. Companies must only organise the journey of healthcare professionals participating in the scientific event, and this, during the time of its taking place. 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 must ensure that they limit their financial liability to that part of those travel expenses which are linked proportionately and exclusively to attendance at the scientific event.

FREQUENTLY ASKED QUESTIONS CONCERNING ARTICLE 8

- FAQ 12. Extending of a Stay

CHAPTER III.

Benefits of a Scientific Nature

ARTICLE 9.

9.1. Healthcare professionals may be rewarded by pharmaceutical or medical devices companies as payment for legitimate scientific acts on behalf of the above with the condition that these payments remain reasonable.

9.2. "Acts of a scientific nature" should notably be interpreted as being the collaboration of healthcare professionals taking part in clinical trials as laid down by the Law of 7 May 2004 concerning human experiments, the giving of scientific papers during teaching lectures, seminars, symposiums or congresses and the execution of contracts of consultations of a scientific nature.

9.3. However, no payment may be effected, under any conditions, uniquely for attendance at a scientific event such as that laid down by clause 3 of the Code.

PRACTICAL DIRECTIVES CONCERNING ARTICLE 9

1. BENEFITS TARGETED

Apart from the collaboration which healthcare professionals offer in the framework of clinical studies or other scientific studies, benefits which are specifically targeted are: the sharing of scientific explanations during a conference, a symposium, etc., and the execution of consultancy services as per contract.

2. SCIENTIFIC NATURE OF BENEFITS

Pharmaceutical or medical devices companies may only remunerate healthcare professionals for services of a scientific nature. As far as trials or studies arising from the application of legislation relating to human experiments[1], it is possible that within the framework of assessment of their scientific nature, reference may be made to the opinion of the ethics committee in consideration of the trial or study in question. For all other benefits, the scientific nature must be assessed on the basis of concrete circumstances according to each specific case. Healthcare professionals will not, under any circumstances, be indemnified for their services in return for collaboration 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 engendered. To the extent that they have provided a real and legitimate scientific service, they may be remunerated. In the framework of assessment of the legitimate nature of the services rendered, it is essential to ensure that no remuneration be accorded which, in reality, amounts to grants or advantages which are not permitted - leading to suspicion of doubt as to the objectivity of the studies or services rendered or indeed as to the independence of the authorship. It is contrary to the rules to indemnify healthcare professionals in any way which cannot be justified by legitimate services of a scientific nature.

4. REASONABLE REMUNERATION

Remuneration accorded to healthcare professionals providing aforementioned scientific services must always remain within

1. Law of May 7, 2004 relating to human experiments.

the bounds of reasonableness and proportional to the extent of the services provided.

5. NO COMPENSATION FOR LOSS OF REVENUE

Healthcare professionals may under no circumstance be remunerated for the time they spend at 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 ban in principle of grants and benefits as stated in the first article of the Code.

GUIDELINE CONCERNING FEES FOR SCIENTIFIC SERVICES

WRITTEN AGREEMENT

A written agreement has to be established in advance of the commencement of the services which clearly specifies in detail the nature and the content of the services to be provided, as well as the basis for payment of those services.

TRANSPARENCY

In the interests 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 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?

By scientific services is meant the involvement of Healthcare professionals in clinical trials, the giving of scientific papers during teaching lectures, 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 corresponds to a real need of the company
- it is provided for the purpose of supporting healthcare or research
- it is not an inducement to influence the prescription-, supply-, administration-, recommendation-, or using’s behavior of the consultant
- it is performed by a qualified consultant who has the required expertise
- and it is effectively performed.

REASONABLE FEE?

The compensation for the services has to be reasonable and reflects the *fair market value* of the services provided. The market of reference is the *Belgian* market.

The compensation is calculated on the basis of multiple criteria 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 past or future volume of prescription of the consultant is not a relevant criteria.

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

The compensation should be *consistent*. To identical services and situations, identical compensation.

HOSPITALITY ?
If hospitality is offered to the consultant in addition to the fees (meals, overnight stays or transport), this has to be *reasonable*.

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

Part II.
Procedure

CHAPTER I.

Visa Bureau

ARTICLE 10. TASKS

A Visa Bureau is part of the MDEON, the role of which is to:

1° by virtue of clause 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 clause 10, §2, paragraph 1, 2° of the above law concerning medicines and, if in conformity with the conditions and criteria legally laid-down and as stated in clauses 3 to 8 of the Code, to give a visa.

2° to record notifications given by pharmaceutical or medical devices companies concerning:

a. scientific events such as those identified in clause 10, §2 paragraph 1, 2° of the law of 25 March 1964 concerning medicines, which are not subject to visa requirements, and which they wish to organise, sponsor or support in another way and,

b. indemnities which they wish to grant for the execution of benefits of a scientific nature, such as those identified in clause 10, §2, paragraph 1, 3° of the abovementioned law,

3° at their request, to advise pharmaceutical or medical devices companies as well as healthcare professionals on the question of conformity with the dispositions of this Code for a subsidy, 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 is made up of two or more chambers; one of these (the Appeals Chamber) is exclusively charged with dealing with appeals lodged in accordance with clause 21 of the Code.

11.2. Without prejudice to clause 1, 9° of the Royal Decree of 23 November 2006 as executed in clause 10, §3 of the Law concerning medicines of 25 mars 1964, each chamber is made up of three members (natural persons), namely:

a. a lawyer who is not a Company employee is the Chair of the Chamber;

b. a member with extensive experience of the pharmaceutical sector but who no longer works for a pharmaceutical or medical devices company.

c. a member with a certain amount of professional expertise in the Health Sector.

11.3. Each member has a substitute and receives an allowance.

11.4. Chairpersons, members and their substitutes 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 clause 21 of the MDEON Statutes. The duration of a mandate is three years, with the possibility of mandates being renewed; they may also be revoked at any moment.

11.5. The mandates of the different Chambers of the Visa Bureau may be cumulated but when a case is being dealt with in Appeal, members who sat in the Chamber initially dealing with the case are excluded from sitting in the Appeals Chamber, in accordance with clause 21 of the Code.

ARTICLE 12. SECRETARIAL SERVICE

12.1. The Visa Bureau is supported by a Secretariat, the role of which is to deal with the administrative activities of the Office and to manage notifications and requests for authorisations. This service is carried out in a strictly neutral fashion and the service is not concerned in any way with the decision-making process of the Visa Bureau.

12.2. The organism mandated to deal with the daily routine management of MDEON has the responsibility of managing the secretariat.

ARTICLE 13. WORKING METHODS

13.1. Each Chamber 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 meet if the three members are present. In the absence of a consensus, decisions are reached on the basis of a simple majority. In the case of the same number of votes for as against, the Chairperson has the casting vote.

13.3. The Chair is unquestionably sovereign in his or her Chamber in all procedures and decides on what measures are best adapted to the circumstances.

13.4. For particular precisions on a matter, the Chairperson seeks the advice of an expert of his or her choice. The organism mandated to deal with the daily routine management of MDEON constitutes a list of experts in the medical devices sector and pharmaceutical industry and this list is readily available to all Chairpersons of the different Chambers.

13.5. Each individual member of the Authorisation Bureau acts independently and if there is a conflict of interest, the member(s) concerned abstains from taking part in the proceedings concerned; this member will then call upon a substitute to replace him or her.

13.6. Members of the Bureau undertake, at the risk of being dismissed from the Chamber by the MDEON, if they do not respect the confidentiality of all information in their possession relating to data, documents and other items concerning their activities within the framework of their mandate.

13.7. Any Member of the Visa Bureau who is absent from three consecutive meetings to which he has been summoned, excepting in exceptional circumstances, will be regarded as no longer being a member. He or she will immediately 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 procedures, notification or requests for advice of the Visa Bureau must be addressed to the secretary of the Visa Bureau situated at: MDEON asbl, 64 Avenue du Roi Albert Ier in 1780 Wemmel.

14.2. If proceedings need to be dealt with in situ, they must be presented during opening hours as indicated on the MDEON internet site.

ARTICLE 15. COMMUNICATION

All correspondence issuing from the Visa Office – including notification of decisions – may be sent to the companies concerned by post, fax, e-mail or other forms of communication adapted to the circumstance.

CHAPTER II.

Visa Procedure

ARTICLE 16. FIELD OF APPLICATION

16.1. Invitations of healthcare professionals and the consideration of their possible participation in a scientific event such as indicated by clause 10, §2, paragraph 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 procedure for the obtaining of prior visa described as follows – independently of the fact that the above-mentioned professionals be present as participants or as speakers.

16.2. Both the direct and indirect funding of costs of participation of healthcare professionals in a scientific event are subject to the granting of prior visa. It follows that the financial support of the organiser of a scientific event (for example, the hiring of a stand) is also subject to the visa procedure.

The sponsoring of the organiser of a scientific event comes under the requirement of visa 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 organizer still requires the granting of a visa 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 from MDEON, the applicant implicitly accepts the application of the Code - including both conditions and criteria to which the event must conform and the procedure which must be adhered to in view of the obtaining of 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. To this effect, pharmaceutical or medical devices companies must apply for a visa.

Pharmaceutical or medical devices companies may apply under the aegis of a third party in their name. In particular, when several companies are concerned in sponsoring the same scientific event together (for example the hiring of a stand or stands), the

FREQUENTLY ASKED QUESTIONS CONCERNING ARTICLE 17

- FAQ 13. The Procedure

organiser may submit a group application to include all of the companies sponsoring the event and who have mandated the applicant to so do on their behalf.

17.3. The application is not receivable if it is submitted later than 15 working days before the start of the scientific event and after all healthcare professionals have been invited to participate. The date the application is received by the Visa Office - as indicated by clause 18.4 - is the official date of acknowledgment.

17.4. However, in the following situations, the applicant may submit its visa application at the latest six working days before the start of the event:

- the scientific event concerns 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, within the frame of a Scientific Event, is providing scientific acts on behalf of the organizer 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 when authorisation has already been granted (see clause 22)
- the applicant submits a new visa application following a refusal.

When an applicant opts to make use of this shortened period of application, it must not be forgotten that it may not be possible to lodge an appeal in the case of a refusal given that the Appeal Chamber would not be able to grant authorisation after the start of a scientific event.

17.5. The whole of the procedure is carried out exclusively in written form.

ARTICLE 17*BIS*. COLLECTIVE VISA

17*bis*.1. A visa request can only apply to a scientific event which has been well-defined.

17*bis*.2. However, when a well-defined scientific event is repeated several times, a single visa may be delivered for the ensemble of events, with the provision that:

- the events are identical (same programme, same content, same duration, same place, same conditions of hospitality and the same planning and same travel arrangements),
- all of the events take place within one calendar year counting from the date of reception as indicated in clause 18.4,
- the exact number of planned events, the number of participants, the periods during which – and if possible – the dates to which the different events will take place, being clearly stated in an appendix of the application for authorisation.

17*bis*.3. In addition, when a company invites a healthcare professional to present several lectures and takes on board the lecturer's hospitality costs, it is recommended that the company applies for a visa which re-groups together the lectures which attract the same degree of sponsorship.

ARTICLE 18. METHOD OF REQUESTING VISA

18.1. All visa requests must be done through the website of MDEON using the official application form supplied by MDEON, to which should be appended all information and documentation which prove that clause 10, § 2, paragraph 1, 2°, of the law of 25 March 1964 concerning medicines and clauses 3 to 8 of this Code is being adhered to.

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

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

- A complete description of the applying company.
- A complete and accurate title of the scientific event, the dates and the place when and where the event will take place.
- Proof of where the event is to take place.
- The dates, the duration and the chosen mode of return transport arrangements concerning the event.
- In the event where the date and time of arrival or departure do not coincide with the commencement or ending of the event, the reasons must be stated.
- The number of participants to be invited or sponsored and their professional capacity must be stated.
- If the healthcare professionals are invited as consultants, a description of the scientific acts they will execute in the frame 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 activity of the participants.
- The scientific programme of the event itemised on a daily basis in terms of content and from a timetabling point of view.
- A brief description of the measures of hospitality being offered, detailed per day with indication of the timetable.
- The event subscription fees, the costing for transport and hospitality fees requested by the organising company per applicant
- A justificatif of what is included in the registration's fees in scientific events organized by (associations of) healthcare professionals
- A justificatif of the cost and the class of the chosen flight ticket.

FREQUENTLY ASKED QUESTIONS CONCERNING ARTICLE 18

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

b) In the case of sponsoring 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 title of the scientific event, the dates when and the place where the event will take place
- An estimate of the number of participants attending,
- The scientific programme, detailed on a day-to-day basis in terms of content and timing,
- a brief description of the added value of the event for participants,
- the amount to be contributed by the applicant company towards the organisation of the event (in the case of a request for authorisation on behalf of a group of companies, the sum to be paid by each individual company must be mentioned),
- a detailed budget for the scientific event, listing the different sources of the sums paid and the associated expenses,
- a declaration by the scientific organiser stating that 1) the sponsorship amounts will only be used in the financing of scientific activities or for legitimate hospitality expenses by virtue of clause 5.2 of the Code and 2) that the eventual profit will be used conform article 10 of the Law of March 25, 1964 on the medicinal products
- an undertaking 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.

18.3. The secretariat of the Visa Bureau will issue an acknowledgment of receipt for each request and will issue a registration number.

18.4 All applications received before midday will be acknowledged on that day ; requests received after midday will be acknowledged on the following working day. The date of sending of an acknowledgement is an important aspect in terms of the delay as stated in clause 17.3.

ARTICLE 19. EXAMINATION OF VISA REQUESTS

19.1. The Visa Bureau firstly decides if the request is in order, and if so proceeds to establish if the request is in accordance with the criteria in clause 10, § 2, paragraph one, 2°, of the law of 25 Mach 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 is in order, and that it conforms to the dispositions listed in the first paragraph, visa is granted. In this case, a registration number is allocated by the Office. This number must be referred to in all correspondence established within the framework of the project concerned following reception of the visa.

19.3. If the Visa Bureau deems the project as described in the request is not in order or does not conform to the dispositions as listed in the first paragraph, visa is refused. An explanation for a refusal accompanies the notification of refusal. In the case of a refusal, the sponsoring concerned may not be attributed to individuals identified in clause 10, § 1, of the law of 25 March 1964 concerning medicines.

19.4. All visa granted by the Bureau are done so on the presumption that the projects requested are in conformity with the dispositions in clause 19.1., but the requests must be complete and must correspond to the reality and without prejudicing the dispositions in clause 22 of this Code.

ARTICLE 20. COMMUNICATION RELATING TO THE BUREAU'S DECISION

Applicants will be informed of the Visa Bureau's decision no later than five working days following confirmation of the reception of the said application in accordance with clause 18.4 of the Code, with the reminder that the fifth working day ends at midnight. The absence of any communication of a decision within the time stated does not mean the application has been authorised.

ARTICLE 21. PROCEDURE FOR APPEAL

21.1. All applications that are not granted visa may go into appeal and be considered by the Chamber of Appeal of the Visa Bureau.

21.2. In order to be receivable, the appeal must be accompanied by an explanatory note within five working days of the refusal and sent to the Bureau by registered post, with the postmark giving proof of the date of posting.

The secretariat of the Visa Bureau acknowledges receipt of all appeal requests. Requests for appeal received before midday will be acknowledged on that day; those received after midday will be acknowledged on the next working day.

21.3. The Chamber of Appeal examines the original application as presented by the requesting party, who may, if he or she desires, provide additional information in support of the original application with the proviso that nothing be altered. If the request is to be modified, this constitutes a new request and must be submitted as such to the Visa Bureau.

21.4. The Chamber of Appeal takes into consideration the new elements included in the request and verifies that the request as described satisfies the conditions and criteria as defined in clause 10, §2, paragraphs 1, 2° of the Law of 25 March 1964 concerning medicines in clauses 3 to 8 of the Code.

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

21.6. If the Chamber of Appeal deems that the project is not in accordance with the requirements as listed in clause 21.4, visa is refused. A motivation for the refusal is provided.

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

21.8. The application for an appeal procedure must be provided in writing.

ARTICLE 22. MAJOR 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 major change or changes between the moment of the granting of the first authorisation and the date of the scientific event.

22.2. By "major change or changes" it is understood that substantial alteration has been made to the project of which the Visa Bureau should be made aware so that they can reasonably take into consideration such a change or changes in line with the preceding paragraph.

22.3. A special dispensation – in accordance with clause 17.3 of the present Code – can be granted to the applicant who has substantially modified his or her project; such a request must be made at the latest the sixth 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 in such a way that the latter be in a position to exercise its legal requirement of control:

- Refusals
- Late Requests
- Refusals transformed into Appeals
- Irregularities detected by MDEON concerning the respecting of the procedure of requesting and granting of visa.

FREQUENTLY ASKED QUESTIONS CONCERNING ARTICLE 23

- FAQ 14. Overseeing of Visa Requirements

CHAPTER III.

Procedure for Notification

SECTION 1. SCIENTIFIC EVENTS NOT SUBJECT TO VISA REQUIREMENTS

ARTICLE 24.

24.1. In the event of a Scientific Event not subject to visa requirements, the pharmaceutical or medical devices companies may inform directly the Visa Bureau that they have invited healthcare professionals to attend the event in accordance with clause i 10, §2, line 1, 2° of the law of 25 March 1964 concerning medicines.

24.2. By doing so, the company concerned expressly understands and undertakes to follow the procedure at stated down in the first paragraph of the Code.

ARTICLE 25.

25.1. The Visa Bureau must be notified at the latest by the tenth day before the start of the Event.

25.2. Such notification must be sent by electronic means on a completed application form obtainable by the pharmaceutical or medical devices companies exclusively on the MDEON website.

25.3. This form must include at least the following information:

- Complete identity of the notifying enterprise,
- The complete and accurate name of the Scientific Event, where it is to take place and the planned dates,
- A description of the nature of the Scientific Event and its duration,
- The number of participants to be invited or sponsored together with their professional domain of expertise,
- A summary of the hospitality to be accorded to invited participants as well as a timetable of activities,
- The sums of financial allocation to each participant within the overall financial arrangements of the organisation or the registration fees, transportation subsidies and hospitality offered to participants.

ARTICLE 26.

26.1. An electronic acknowledgement of receipt is sent to all applicants in accordance with clause 24 once the application has been received by the Visa Bureau. This message is purely a receipt and in no way confirms that the application for the Scientific Event satisfies the criteria and conditions as listed in clause 10, §2, paragraph 1, 2° of the law of the 25 March 1964 concerning medicines and of clauses 3 to 8 of the Code.

26.2. The information which figures in these notifications is not used by the Visa Bureau other than for internal use – notably with a view to developing new propositions of directives in relation to the application of the Code to the Board of Directors.

SECTION 2. BENEFITS OF A SCIENTIFIC NATURE

ARTICLE 27.

27.1. The pharmaceutical or medical devices companies may directly inform the Visa Bureau of advantages which they wish to give, directly or indirectly, to healthcare professionals in exchange for scientific services such as those described in clause 9.2 of this Code, in addition to their contractual work.

27.2. Through informing the Visa Bureau in this way, as described in the first paragraph, the enterprise expressly accepts the application of this Code concerning the procedure to be followed.

ARTICLE 28.

28.1. The notification must be made before the end of the tenth day before any benefits are accorded.

28.2. A notification can only be done by electronic means through the sending of a completed form, an example of which, available to pharmaceutical or medical devices companies, can be found on the MDEON website.

28.3. This form must include at least all of the following information :

- The identity of the contractor,
- The number of persons who will distribute the benefits and their professional quality,
- A complete detailed description of the scientific benefits, the dates of their being distributed and the amount of time devoted to them,
- A brief description of the added value of the scientific benefits in the contractor's list,
- The fees paid by the contractor to the agents and the means of payment.

ARTICLE 29.

29.1. The Secretariat of the Visa Bureau informs of the reception of the notification by electronic means, in accordance with clause 27. This receipt is purely for administrative purposes and in no way suggests that the payments satisfy the criteria listed in clause 10, §2, line one, 3° of the law of 25 March 1964 concerning medicines or of clause 9 of this Code.

29.2. The information contained in these notifications will only be used by the Visa Bureau for internal purposes – namely with a view to the developing of new propositions of directives in relation to the application of the Code to the Board of Directors.

CHAPTER IV.

Requests for Advice

ARTICLE 30.

30.1. Pharmaceutical or medical devices companies as well as healthcare professionals may request advice concerning grants, benefits, events or, more generally, all activities from the Visa Bureau prior to their submission, organisation or acceptance in terms of conformity to the Code.

30.2. The advice indicated above does not apply to scientific events subjected to the visa procedure in accordance with clause 16 of the Code.

CHAPTER V.

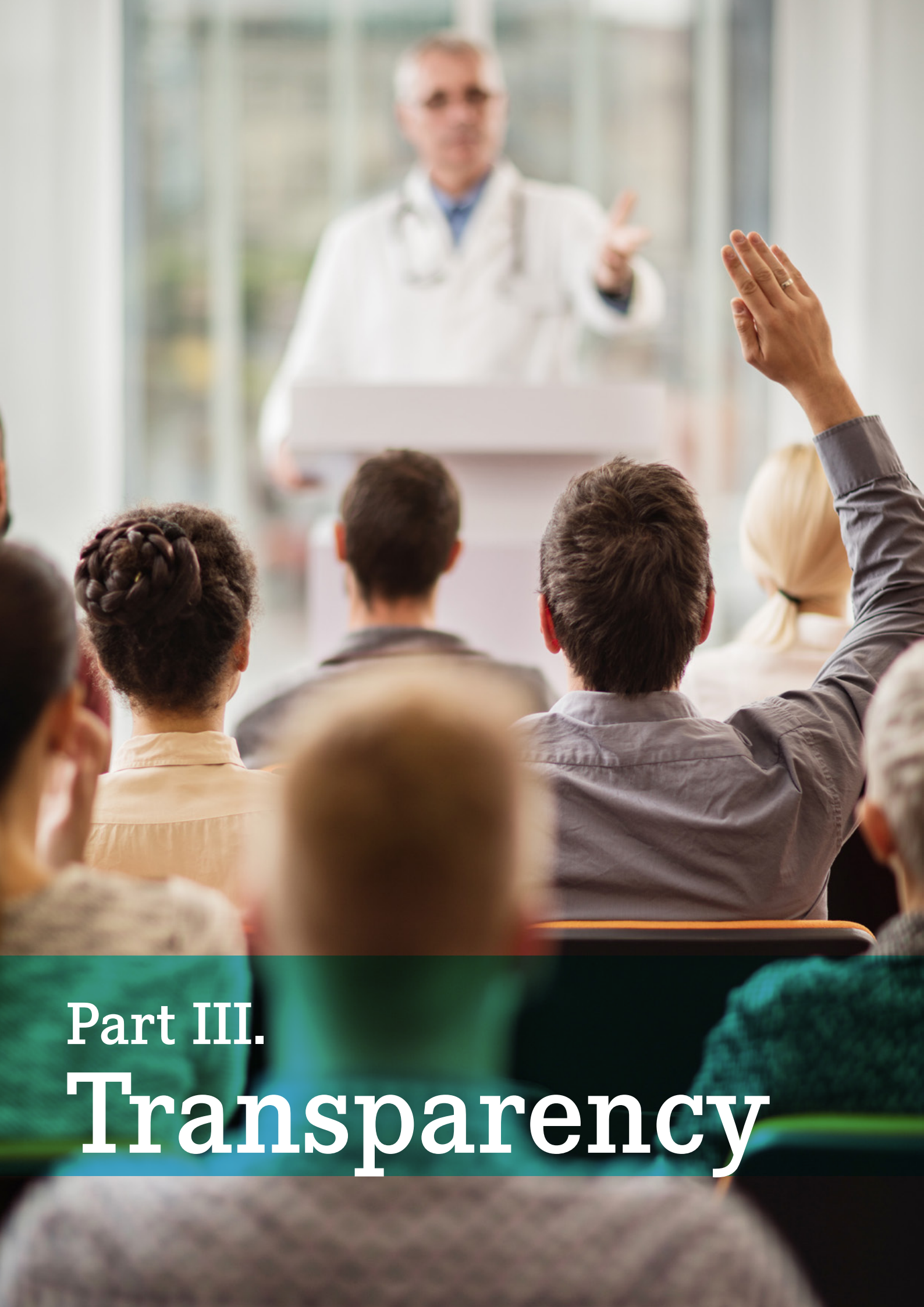
Procedural Costs

ARTICLE 31.

31.1. All visa requests in accordance with clause 16 of this Code are subject to the payment of a fee of which the amount is fixed annually by the Board of Directors of MDEON in line with the running costs of the Association.

31.2. The fees referred to in the preceding paragraph may vary according to the different criteria in operation, thereby ensuring a fair distribution of running costs for the Association.

31.3. Fees thus identified in this clause are payable and paid at the same time as a visa application is submitted, or at the moment when advice is sought, independently of whether authorisation is granted or not, or if advice is given. Such fees are not refundable.



Part III.
Transparency

ARTICLE 32

PRINCIPE

32.1. Notwithstanding the application of legal and regulatory provisions, and in particular those that relate to the protection of privacy, pharmaceutical or medical devices companies shall document and disclose transfers of value they make, directly or indirectly, for the benefit of a healthcare professional or organisation.

When the recipient has its principal professional address or place of incorporation in Belgium, the documenting and disclosure of the transfers of value must be made in accordance with the rules and procedures as set out below.

DEFINITIONS

32.2. For the application of the provisions in this Part III of the Code, the following terms are to be understood as defined below:

- *Transfers of value:* any direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of medicinal products or medical devices for human use;
- *Direct transfers of value:* transfers of value made directly by a pharmaceutical company for the benefit of a healthcare professional or organisation;
- *Indirect transfer of value:* transfers of value made on behalf of a pharmaceutical or medical devices company for the benefit of a healthcare professional or organisation, or transfers of value made through an intermediate and where the pharmaceutical or medical devices company knows or can identify the healthcare professional or organisation that will benefit from the transfer of value.
- *Healthcare professional:* any natural person who is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend, rent, use or administer a medicinal product or medical devices and whose primary practice, principal professional address or place of incorporation is in Belgium. This definition of healthcare professional includes (i) any official or employee of a government agency or other organisation (whether in the public or private sector) who may prescribe, purchase, supply, recommend, rent, use or administer medicinal products or medical devices and (ii) any employee of a pharmaceutical or medical devices company whose primary occupation is that of a practising healthcare professional. All other employees of a pharmaceutical or medical devices company and wholesalers or distributors are excluded from this definition.
- *Healthcare organisation:* (i) any association or organisation active in the field of healthcare or at the medical or scientific level, irrespective of the legal or organisational form, such as a hospital, foundation, university or other teaching institution or learned society (except for patient organisations) whose business address, place of incorporation or primary place of operation is in Belgium, and (ii) any legal entity through which one or more healthcare professionals provide services.

EXCEPTIONS

32.3. The obligation described under point 1 of this article does not apply to transfers of value that

(i) either are not listed in article 34 of the present Code, such as premiums and benefits of limited value governed by article 2,2° and the meals and drinks governed by article 5.1*bis*,

(ii) or are part of ordinary course purchases and sales of medicinal products or medical devices by and between a pharmaceutical or medical devices company and a healthcare professional, such as a pharmacist, or a healthcare organisation.

ARTICLE 33

REPORTING PERIOD

33.1. The transfers of value as referred to in article 32 must be disclosed on an annual basis. Each period for which a report is made shall cover a full calendar year (the "reporting period").

DELAY

33.2. Disclosures shall be made within 6 months after the end of the relevant reporting period. Without prejudice to the application of the legal and regulatory provisions, in particular concerning the protection of privacy, the information must remain accessible to the public for at least three years after the date when such information is first disclosed, in accordance with point 4 of this article.

TEMPLATE

33.3. For consistency purposes, disclosures will be made using a structure set forth in annex 1 of the present Code.

CENTRAL PLATFORM

33.4. Transfers of value shall be disclosed on the website of a central platform set up for this purpose. The practical aspects linked to this platform will be determined by means of guidelines.

LANGUAGE

33.5. The information shall be disclosed in Dutch and French. Pharmaceutical and medical devices companies are encouraged to also make disclosures in English.

DOCUMENTATION

33.6. Pharmaceutical or medical devices companies must document all transfers of value that must be disclosed in accordance with article 32.1. They must retain the relevant proof that they have respected their disclosure obligations correctly and in full for a minimum of 5 years after the end of the relevant reporting period, notwithstanding the legal and regulatory provisions concerning the protection of privacy and other matters.

ARTICLE 34

PUBLICATION ON AN INDIVIDUAL BASIS

34.1. Except in the cases referred to in points 3 and 5 of this article, transfers of value shall be disclosed on an individual basis. Each pharmaceutical or medical devices company shall disclose for each identifiable recipient the amounts attributable to transfers of value during the reporting period for the benefit of this recipient which can be reasonably classed under one of the categories set out below. Such transfers of value may be aggregated on a category-by-category basis, provided that itemised disclosure is made available upon request by the relevant recipient, or the relevant authorities.

CATEGORIES OF TRANSFERS OF VALUE

34.2. The categories of transfers of value referred to above are as follows:

I. In regard to transfers of value to ***healthcare organisations***:

a. Donations and grants that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organisations or associations that are comprised of healthcare professionals and/or that provide healthcare

b. Contribution to costs of scientific events, including sponsoring of healthcare professionals to enable them to attend these events, such as:

i. Registration fees;
ii. Sponsorship agreements with healthcare organisations or with third parties appointed by these organisations to manage a scientific meeting; and
iii. Travel and accommodation as referred to in article 5 of the Code.

c. Fees for services and consultancy. This category includes transfers of value resulting from or related to contracts between pharmaceutical or medical devices companies and institutions, organisations or associations of healthcare professionals under which such institutions, organisations or associations provide any type of services to a pharmaceutical or medical devices company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand transfers of value relating to the reimbursement of expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

II. In regard to transfers of value to ***healthcare professionals***:

a. Contributions to costs related to scientific events, such as:

i. Registration fees; and
ii. Travel and accommodation as referred to in article 5 of the Code.

b. Fees for services and consultancy. This category includes transfers of value resulting from or related to contracts between pharmaceutical or medical devices companies and healthcare professionals under which such healthcare professionals provide a service to a pharmaceutical or medical devices company, as well as any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand transfers of value relating to the reimbursement of expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

PUBLICATION ON AN AGGREGATE BASIS

34.3. For transfers of value where certain information, which can be otherwise reasonably allocated to one of the categories set forth in point 2 above, cannot be disclosed on an individual basis for **legal reasons**, the pharmaceutical or medical devices company shall disclose the amounts attributable to such transfers of value for each reporting period on an *aggregate* basis. Such aggregate disclosure shall identify, for each category, (i) the number of beneficiaries covered by such disclosure, on an absolute basis and as a percentage of all recipients, and (ii) the aggregate amount attributable to transfers of value to such recipients.

34.4. Where a transfer of value required to be disclosed pursuant to points 1 or 3 above is made to an individual healthcare professional indirectly via a healthcare organisation, such a transfer of value shall only be required to be disclosed once. To the extent possible, such disclosure shall be made in the name of the individual healthcare professional in accordance with the categories set forth in point 2, II above.

34.5. Transfers of value relating to research and development in each reporting period shall be disclosed by each pharmaceutical or medical devices company on an *aggregate* basis. Costs related to scientific events that are clearly related to activities covered by this paragraph can be included in the aggregate amount under the "Research and Development" transfers of value category.

"Research and Development" transfers of value include transfers of value to healthcare professionals or healthcare organisations related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in European Directive 2001/20/EC); or (iii) non-interventional.

NOTE

34.6. Each pharmaceutical or medical devices company shall publish a note summarizing the methodologies used in preparing the disclosures and identifying transfers of value for each category described in point 2. The note shall include a description of the valuation methods applied and of the way in which, depending on the case, an agreement for more than one year, VAT and other tax aspects, currency aspects and other issues relating to the timing and amount of the transfers of value were handled.

ARTICLE 35

INFORMED CONSENT

35.1. In view of the legislation on the protection of privacy, informed consent of the healthcare professional is essential to publish the transfers of value on an individual basis.

35.2. In this regard and more generally, when transferring values to healthcare practitioners or organisations, pharmaceutical or medical devices companies are strongly encouraged to include, in their contracts with them, provisions relating to the recipients' consent to disclose transfers of value in accordance with this Part III of the Code. In addition, companies are strongly encouraged to renegotiate existing contracts to include clauses to this effect.

Part IV.
General provisions, entry into force and interim measures

ARTICLE 36.

36.1. The original version of this Code came into practice on 15 November 2006 with the understanding that scientific events which had commenced before 1 January 2007 would not come under the visa procedure as indicated in clause 16 of the Code. The present version of the Code, as approved by the Board of Directors on 24 November 2014, came into practice on April 1, 2015.

36.2. The first reporting period referred to in article 33.1 shall be the 2015 calendar year for the companies member of pharma.be and the 2016 or 2017 calendar year for the companies member of Unamec.

36.3. The companies member of Bachi and FeBelGen will comply with the transparency obligation under Part III of this Code under the suspensive condition of developing a roadmap preparing the evolutions in the obligation. The roadmap will be drafted in consultation with the two associations concerned and must be approved by the Board of Directors.

36.4. MDEON will undertake to execute 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.

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