CGR

(Dutch Foundation for the Code for Pharmaceutical Advertising)

General information about organising scientific meetings
and
Frequently Asked Questions

1. Introduction

In the Netherlands and abroad, specific rules apply for pharmaceutical advertising. In addition to rules for advertisements for and information on prescription-only medicinal products, the rules also cover payments by pharmaceutical companies which could promote the prescription, supply or use of a medicinal product. The rules on advertising must prevent that payments by pharmaceutical companies influence healthcare professionals in an undesired way. The rules also provide that certain payments by pharmaceutical companies must be disclosed in the Dutch Healthcare Transparency Register.

The rules on advertising also affect the organisation of scientific conferences and refresher training for physicians, other healthcare professionals and/or patients (to be further referred to as: "events") which are partly financed or organised by pharmaceutical companies. This will for instance be the case if a pharmaceutical company attends an event with a stand against payment. In such a case the rules on advertising claims must be complied with, but the conditions attaching to event sponsoring must also be met.

For a complete overview of the rules we refer to the Dutch Code of Conduct for Pharmaceutical Advertising (to be further referred to as: 'the Code of Conduct') of the CGR (the Dutch Foundation for the Code for Pharmaceutical Advertising) on the website www.cgr.nl. The CGR is the body that is responsible in the Netherlands for the self-regulation of pharmaceutical advertising recorded in the Code of Conduct. The Code of Conduct is based on the European Directive (2001/83/EC), the Dutch Medicines Act and the Policy Rules for Inducements and the EFPIA Codes of Conduct[1]. If the Code of Conduct is complied with, it can be assumed that the statutory standards are also complied with. The most important rules for the organisation of events will be explained in more detail below.

2. Advertising claims regarding prescription-only products

What the advertising rules come down to, in brief, is that *advertising* for prescription-only medicinal products is permitted only to persons who are authorised to prescribe and/or supply medicinal products ('healthcare professionals'). Advertising for prescription-only products may not target the other participants (non-healthcare professionals or 'the general public'). *Information* on prescription-only which is directed at the latter target group is permitted. The rules for advertising claims will be explained below.

a) Advertising to the general public for prescription-only medicinal products during events

[1] The European Federation of Pharmaceutical Industries and Associations (EFPIA).

In Europe advertising to the general public for prescription-only medicinal products is prohibited. Advertising to 'healthcare professionals' for prescription-only medicinal products is permitted.

Healthcare professionals are persons who are independently authorised to prescribe or supply prescription-only medicinal products. This group may differ per country. In the Netherlands the group of healthcare professionals comprises: physicians, physicians who are being trained to become a specialist ('*artsen in opleiding*'), pharmacists, pharmacist's assistants, obstetricians, dentists, physician assistants, nurse practitioners and specialised nurses.
Specialised nurses (limited to the lung, diabetes and oncology areas) only have independent prescription authority if they have completed a specific training programme for this purpose. The completion of this training is entered in the BIG register and so can be checked by anyone. This means that all of the other healthcare providers, such as regular nurses, dieticians, dental hygienists or supportive GP practitioners ('*praktijkondersteuners*'), are not healthcare professionals and so – just like patients – belong to the 'general public'. This group will be referred to below as 'non-healthcare professionals'.

The ban on advertising to the general public applies to all possible types of advertising for prescription-only medicinal products, such as showing the product name at stands (product stands), programme booklets, folders, scientific presentations, video messages and apps. This means that non-healthcare professionals may not be exposed to such advertising claims. Indirect advertising to the general public for prescription-only medicinal products is not permitted either. This can for instance be the case if a company advertises for an administration device (such as an injection pen or inhaler) which is used only in combination with certain prescription-only products. Advertising for the company itself ('corporate advertising') may be directed at the general public.

b) Meetings with a 'mixed' target group

If an event is attended by both healthcare professionals and non-healthcare professionals, the latter group may not be exposed to advertising claims for prescription-only medicinal products. This does not mean that no advertising for prescription-only products is allowed *at all*, but if it *is* done, additional measures must be taken by the organisation. In this case the organisation has the following options:

i. Pharmaceutical companies must not advertise for prescription-only products, except in their 1-to-1 contacts with healthcare professionals. So prescription-only medicines may be promoted in talks with healthcare professionals and advertising materials may be handed to them. In addition, pharmaceutical companies may elect to only advertise for prescription-only products inside their stands ('stand-in-stand'), but in that case they may only allow healthcare professionals into their stand. Advertising statements of pharmaceutical companies that everyone can take note of must be restricted to corporate advertising.

ii. The event is divided by the conference organisation into a part with and a part without advertising for prescription-only products. In this case the organisation must actively see to it that non-healthcare professionals do not have access to the closed part where prescription-only products are being advertised.

In both situations clear agreements must be made between the attending pharmaceutical companies and the conference organisation, so that there is no

unintended advertising to the general public. Healthcare professionals and non-healthcare professionals must be recognisable as healthcare and non-healthcare professionals respectively by wearing badges. This requires that the conference organisers must know in advance which participants are healthcare professionals and which participants are not. As for the badges, it must also always be clear for which pharmaceutical company the representative in question is working.

c) Large-scale international conferences

In the case of large-scale international medical-scientific meetings or conferences for healthcare professionals, it will not always be possible to completely screen off the small group of attending non-healthcare professionals from advertising claims. If the following conditions are satisfied, the organisation does not have to take additional measures to prevent non-healthcare professionals from being exposed to advertising for prescription-only medicinal products:

- the conference primarily targets healthcare professionals;
- large groups of speakers and participants from countries other than the Netherlands are attending the conference;
- participation is open only to healthcare professionals and other healthcare providers (professional representatives of patient organisations are deemed to belong to the latter group), but not to non-professional target groups, such as patients;
- the majority of the participants are healthcare professionals (and so are authorised to prescribe or supply prescription-only medicinal products).

In these circumstances it will be assumed that the pharmaceutical advertising targets the healthcare professionals who will attend the conference, and not the small group of other healthcare specialists. In the case of a conference that (also) specifically targets non-healthcare professionals, then the promotional claims made during this conference will also be deemed to be directed at non-healthcare professionals, which would result in a violation of the ban on advertising to the general public for prescription-only products. So in these circumstances the conference organisers must take additional measures to prevent non-healthcare professionals from being confronted with advertising for prescription-only medicinal products. The exception for large-scale international conferences set out above, incidentally, does not apply to conferences which are predominantly attended by Dutch speakers and participants.

If there is doubt as to whether a large-scale international conference comes under the exception, the conference organisers can ask the CGR for its view so that the CGR can confirm this in writing. This request can be submitted via cgr@cgr.nl and this view can only be requested in the case of large-scale international conferences. For other events the CGR's regular procedure for an opinion should be used, which will be discussed below.

d) Employees

The ban on public advertising does not apply to the attending employees of pharmaceutical companies, the conference organisers, the conference venue and the catering.

e) Patient representatives and the press

Journalists of the specialised press covering the event for healthcare professionals may be exposed to advertising for prescription-only medicinal products. This does not apply to patient representatives and the regular press serving the general public or the specialised press targeting non-healthcare professionals.

f) Requirements for advertising to healthcare professionals for prescription-only products

Specific rules are in place for advertising to healthcare professionals for prescription-only products. A professional may never be misled (wrongfooted) by the advertisement. If a claim about the efficacy of a prescription-only product is made, that claim must be up-to-date, correct and verifiable. The rules also prescribe that written advertisements must include the information in the SPC (package leaflet) of the product (in condensed form). If only the brand name is mentioned (for instance a product logo on a stand), the substance name must also be stated, but the information in the SPC does not have to be included. Advertising for medicinal products not authorised in the Netherlands or for an indication or indications other than those authorised is prohibited. Advertising for medicinal products not (yet) registered in the Netherlands is permitted only during international conferences, provided the product has been authorised in another industrialised country where adequate procedures for the market authorisation of medicinal products are in place. However, such advertising may not specifically target the Dutch participants.

g) Information or education on prescription-only medicinal products targeting all participants

Education and information on prescription-only medicinal products targeting all the groups of participants at an event is permitted. Information can easily become promotional in nature and will then be advertising. The essence in the case of *education* is that the medicinal product should not be promoted and that not only its positive features must be highlighted. In the case of *information* specific requirements must also be met; it must concern factual information presented in a neutral and balanced way.
'Balanced' also means that complete information is given about all the relevant treatments and treatment options for a certain disorder in a well-balanced way. If the information concerned is provided to a patient (or to his or her carer or healthcare provider) to whom the prescription-only product was already prescribed, the information may be limited to technical and specific user information about the product concerned. This means that information on the safe administration and use of a medicinal product *can* be provided, but that restraint must be exercised here, because information on a prescription-only product can easily be considered as advertising.

h) Rules for presentations

The scientific content of the conference must also be compliant with the rules for advertising. It is therefore important that the speakers are familiar with these rules and know the target group of the conference. The most important requirement is that presentations may not include advertising for prescription-only medicinal products if the audience also includes non-healthcare professionals. In addition, the speakers must have disclosed their ties with the business community before holding their presentations. For this purpose a specific format has been developed, the 'disclosure slide', which can be found on the CGR website at http://cgr.nl/en-GB/Medische-congressen/Format-of-disclosure.

3. Event sponsoring

As for sponsoring by the pharmaceutical industry, there are also rules that organisers must allow for. The most important rules concern the content of the programme, the venue of the event and the costs that are paid. These rules will be explained below.

a) Programme

As for the sponsoring of events, it is important that the (scientific) content of the meeting occupies central stage. So the scientific content and the total duration of the programme must be well-balanced, meaning that breaks should not be unnecessarily long and 'peripheral issues', such as social activities, may not become a reason for participating in the event. If participants must travel to events taking place abroad, care should also be taken that the journey does not take place well before or long

after the event. If a participant wants to stay on after the event (for other purposes), there is a risk that the participant will actually decide to attend because of the extended stay, rather than because of the event itself. The conference organisers of a sponsored meeting must take this into account when they plan the programme and the journey. The travelling costs or other parts of the event itself may not be paid for the partners of participants wishing to join.

b) Venue

The sponsored event must be held at a suitable venue. The term 'suitable' applies to both the facilities and the location of the venue. This criterion serves to keep the hospitality within certain bounds and to prevent excesses. Venues with a luxurious feel must therefore be avoided.
Regular conference venues will normally be permitted, but modesty is required, in line with what is customary in the Netherlands. Venues that are so attractive that the venue alone might be a reason for participants to attend the event must not be chosen. Luxury hotels or resorts known for their excellent facilities and/or the entertainment offered will not be suitable, in view of the perception they create on the part of the participants, regardless of whether these facilities will actually be used and even if the (negotiated) costs per participant remain within the imposed limits. Although the number of stars or other rankings of a particular venue are not decisive, a high score may be an indication of how the venue will be perceived by participants. The requirement of a suitable venue, incidentally, applies to all the elements of the programme, so including the dinners and hotel stays.

c) Costs for participants

Events may be sponsored, but only within certain limits. The most important rules with regard to financial contributions by pharmaceutical companies are:

- social/recreational costs may not be paid for;
- the participants' travel expenses, accommodation costs and registration fees ('hospitality costs') must remain limited to what is strictly necessary for their participation in the event;
- the speakers' fees must be reasonable in relation to the services they provide;
- as a matter of principle, a surplus/positive balance without a specific destination is not permitted, if it is formed by the sponsoring of pharmaceutical companies. In any event such a surplus/positive balance may not be used for social/recreational activities.

In order to judge whether sponsoring is permitted, a budget must be prepared before the event and a final settlement must be made after the event. For monitoring purposes all the revenues and costs must be divided into a limited number of income and cost categories in accordance with the following format:

Revenues	Costs
Contribution from the organisation itself Sponsoring by the business community Contributions from participants: - healthcare professionals - nurses without prescription authority - other participants Other revenues	
	General organisational costs, including: - speakers' fees - speakers' expenses Hospitality costs Recreational/social costs Unforeseen costs
Balance	**Balance**

Based on this format it is possible to determine whether the sponsoring stays within reasonable bounds and whether the total sponsoring amount received from pharmaceutical companies is permissible. Below the sponsoring of the various categories of costs will be explained in more detail.

i. Recreational/social costs

The recreational and social costs (such as entertainment) during the event may in no case be sponsored by pharmaceutical companies. Examples are gala dinners, festive evenings or museum visits. Such activities are actually only permitted during an event sponsored by pharmaceutical companies *at all* when the role they play, considering the programme as a whole, is limited and if the budget shows that these activities are fully paid for out of the participants' own contributions.

ii. Hospitality costs

Restrictions apply for the payment of the travel expenses, accommodation costs and registration fees of the participants ('hospitality costs'). In general, any costs that can be traced to an individual will be seen as hospitality costs. Examples are meals (such as a buffet) and drinks for participants, the hotel stays and travelling expenses (such as air fares) of participants, but also the costs of printing hand-outs, programme booklets and conference bags for participants. The criterion for the payment of these costs is that they should be limited to what is 'strictly necessary' for participating in the event. Modesty is required, in line with what is customary in the Netherlands. It is also necessary to determine whether the sponsoring of the hospitality costs concerned is justified *at all* in relation to the programme.

The sponsoring of hospitality costs must be commensurate with the duration of the programme. Additionally, the sponsoring of the hospitality costs of healthcare professionals may in no event exceed a certain amount per person. In the case of an event which is scientific in nature that maximum has been fixed at € 500 per occasion or else the participant must bear at least one half of the hospitality costs him- or herself. In the case of scientific meetings this maximum also applies to nurses without prescription authority. For meetings with non-healthcare professionals hospitality may be offered only if that hospitality does not constitute an 'inducement' (so without the evident object of sales promotion). It will be assumed that hospitality at a meeting is not an inducement if it is limited to a cup of coffee and a simple sandwich. If the hospitality costs (and any social/recreational costs) can be paid in full from the participants' contributions, then these costs are not being sponsored and the sponsoring will therefore remain under the

permitted limits for hospitality. Another requirement is that the value of an individual meal within the scope of events held in the Netherlands may never exceed € 75. When determining the value of a meal, allowance must be made for the list prices a healthcare professional would have to pay him- or herself (excluding tips and negotiated discounts, and including the costs for drinks).

If pharmaceutical companies sponsor hospitality costs for healthcare professionals, the healthcare professionals must be informed about this in retrospect by the organisation. This concerns the total amount of hospitality offered by the pharmaceutical companies. The reason for this is that healthcare professionals must be able to check whether they are not receiving more hospitality than the annual maximum (a total of € 1,500 for scientific meetings per pharmaceutical company).

iii. General organisational costs

The general organisational costs of an event are generally costs that cannot be individualised, such as the costs of hiring conference rooms, the employee costs of the organiser, preparations, the profit margin for the conference organisation and the costs and expenses of the speakers. The costs of printing and sending invitations are also seen as general organisational costs.

If people are engaged to provide services, such as speaking during the meeting, who work in the Netherlands, then the maximum payment that is permitted is a market-conforming fee.
In the case of healthcare professionals, maximum hourly rates have been fixed for this purpose. In addition, the costs that were actually incurred may be reimbursed, provided they are reasonable. In a newsletter the CGR has set out the maximum hourly rates permitted for every profession and what the term 'reasonable expenses' should be understood to mean.[1] Also, the agreements that pharmaceutical companies, conference organisations, scientific associations and/or healthcare institutions make with healthcare professionals must be recorded in advance in a written, signed agreement in which the service and the fee, length, place and time of the service are set out. In some cases the service to be provided may also have to be registered in the Healthcare Transparency Register.

No limits have been set for the level of the sponsoring of other general organisational costs.

iv. Budget surplus

After all the revenues and costs of the event have been settled, it may happen that a surplus ('profit') is left. This surplus must be distinguished from the fee (or profit margin) paid to the conference organisation, which is part of the general organisational costs of the event. If this surplus has been partly sponsored by pharmaceutical companies, then these companies have apparently also contributed to other activities not included in the budget. The unfamiliarity with these activities makes their sponsoring by pharmaceutical companies problematical, in particular if it concerns a grouping of healthcare professionals or a body in which they participate. After all, it is difficult to judge in advance what the surplus will be spent on, so that it is impossible to judge whether the sponsoring of these activities is compliant with the advertising rules. It is therefore advisable to agree that repayments will be made to the sponsors in the case of a budget surplus. Alternatively, agreements can be made on the destination of any surplus to guarantee that it will be used in a way that is compliant with the advertising rules (for instance that it will be used for hospitality at a next meeting or to sponsor a healthcare project).

[1] The maximum hourly rates for services can be found here (pages 20/21)

d) Self-assessment regarding 'inducements' if accreditation for refresher training is applied for

If an application is submitted via the regular KNMG Accreditation Portal (GAIA) for the accreditation of the event, the applicant must answer a number of questions about the degree of sponsoring of the event by the industry. If the sponsoring is substantial, additional information on the meeting must be provided (including the budget in the format set out above). The assessment of the meeting will then in the first instance be carried out via automatic means. The successful completion of the self-assessment will provide an indication of the admissibility of the meeting. Although the completion of the self-assessment is mandatory, it does not have the same status as an opinion given by the CGR Code Commission. In some cases a manual assessment of the meeting within GAIA will be required additionally, before the application can be sent to the Accreditation Committee. The costs of a manual assessment are € 100 (exclusive of VAT). To help applicants seeking accreditation, the CGR has prepared the Self-Assessment Manual, which will limit the delays and costs of a manual assessment to the maximum possible extent.

e) Compulsory request for an opinion for events abroad

In the case of an event abroad that will be sponsored by pharmaceutical companies for the benefit of Dutch healthcare professionals, the CGR Code Commission must be asked for its opinion. The costs of such an opinion are € 700 (exclusive of VAT), and € 400 (exclusive of VAT) if the same set-up was already assessed previously. In the case of an event which is international in nature and which has been accredited or is being organised by an independent organisation, the preventive assessment by the CGR Code Commission will generally not be required.

4. Healthcare Transparency Register

The Healthcare Transparency Register is a central public register in which financial relationships between pharmaceutical companies and healthcare professionals (or groupings and institutions comprised of healthcare professionals) and patient organisations are disclosed. The aim of the register is to allow patients to ask their healthcare professionals questions about their relationships with pharmaceutical companies. Although the amount shown in the Register for a particular person or institution will not necessarily have been paid to the healthcare professional him- or herself, it *will* provide an indication of the intensity of that cooperation. The entries in the Register will help to prevent a conflict of interest or the suggestion of a conflict of interest.

A financial relationship must be reported to the Dutch Foundation for the Healthcare Transparency Register, if the Code of Conduct requires that this relationship must be recorded in writing. A threshold of € 500 per healthcare provider applies for the total of the financial relationships with any pharmaceutical company, before the relationships with that company must be registered.

If a pharmaceutical company is the only external financier of the event, it is assumed that the relationships the organisation enters into with healthcare professionals are entered into with that pharmaceutical company directly. In that case these relationships must be reported on behalf of the pharmaceutical company and in the names of the healthcare professionals concerned, provided they are also relationships which must be recorded in writing according to the Code of Conduct and the threshold of € 500 per year is reached.

If an event is being organised by a grouping of healthcare professionals or a body in which they participate and is being sponsored by pharmaceutical companies, the sponsoring must be disclosed in the Healthcare Transparency Register. This also

applies if the institution or grouping has engaged an external conference organisation. In this case the sponsoring must also be reported on behalf of the grouping/institution concerned.

If an event is being organised by a conference organisation acting in its own name and not at the instructions of a grouping of healthcare professionals or a body in which they participate, the sponsoring of this conference organisation by pharmaceutical companies may also have to be entered in the Register. That will be the case if the conference organisation uses all or part of the sponsoring by a pharmaceutical company for making payments to Dutch healthcare professionals (such as speakers or participants) and if these payments would have to be reported, if the pharmaceutical company had organised the event itself.

Pharmaceutical companies that organise the events themselves are required to report any payments made to individual healthcare professionals acting as speakers. The hospitality offered to Dutch healthcare professionals must also be reported, if hospitality costs are paid for their benefit which partly cover travelling expenses and/or overnight stays.

5. Responsibilities

The Code of Conduct is reciprocal, which means that both pharmaceutical companies and healthcare professionals must comply with the rules. The Dutch Medicines Act applies to everyone, including conference organisations. In order to prevent violations of the law, all the parties would do wise to comply with the Code of Conduct.

Generally, the initiator and any conferences organisations engaged will be held responsible for the compliance with the advertising rules. They must take measures to prevent advertising to the general public during events. This means that the pharmaceutical companies must be informed about the participating target groups and that organisational measures must be taken for non-healthcare professionals, with regard to both advertising for prescription-only medicines and hospitality. If the initiator engages an external conference organisation to organise the event, it is important that clear agreements are made about the responsibilities between these parties as well.

It is in the first place the responsibility of a pharmaceutical company that is represented at an event with a stand to ensure that non-healthcare professionals are not exposed to advertising for prescription-only medicinal products. That company must also check whether its sponsoring is compliant with the Code of Conduct. The hospitality offered by the company from the stand directly, such as meals and drinks, will, moreover, have to remain limited to what is ‘strictly necessary’ for participating in the event. A pharmaceutical company will also want to have information in advance about the programme, the speakers, the budget, etc. in order to check in advance whether its sponsoring satisfies the requirements of the Code of Conduct. It will also request a final settlement after the event has been held.

6. Enforcement and sanctions

In the Netherlands the IGJ (Health and Youth Care Inspectorate) monitors the compliance with the rules. It may impose a maximum penalty of € 830,000 for every violation of the Dutch Medicines Act. In addition, its inspection reports can be disclosed.

Complaints about parties who are subject to the Code of Conduct may be made via the CGR. The complaints will be considered by the independent Code Commission or, on appeal, by the Commission for Appeal. The decisions on complaints are published by the CGR on the CGR website. The Code Commission may also order the parties to pay the costs of the procedure or order corrective measures (including a rectification), but it cannot impose fines. The CGR may also decide to deal with reports made by natural

persons or the IGJ as if they were formal complaints.

If a party wishes to know whether an envisaged action is compliant with the Code of Conduct, the Code Commission may be asked for its opinion. The costs of such an opinion are € 2,000. The opinions are published in an anonymised form on the CGR website.

The CGR and the IGJ have made cooperation agreements for the purpose of the enforcement of the advertising rules and have agreed that primacy should be given to self-regulation.

7. Frequently asked questions

a) Claims

Who decides whether an advertisement concerns advertising for a prescription-only medicinal product? If an advertising claim relates to a prescription-only product, its promotional nature will easily be accepted and will therefore constitute advertising. The IGJ monitors compliance with these rules. The Code Commission or the Commission for Appeal of the CGR can also give a decision on this matter after a complaint has been filed or an opinion has been requested.

Do the advertising rules also apply to participants from other countries?
The provisions of the Code of Conduct and the Dutch Medicines Act are aimed at the Dutch healthcare sector and so to persons working in the Netherlands. For participants from abroad the rules of their countries will apply. Because the European Medicines Directive also includes rules on advertising, the rules in other European countries will be more or less the same.

Is advertising for prescription-only products permitted during an event, if only a very limited group of non-healthcare professionals participate?
Non-healthcare professionals may not be exposed to advertising claims for prescription-only products. If an event is also targeted at this group, measures must be taken. An exception applies for persons who are inseparably connected with the operational implementation of the event, such as employees of pharmaceutical companies, the conference organisation, the conference location and the catering. In the case of large-scale international conferences, it will sometimes be permitted that a small part of the healthcare providers who are not ‘healthcare professionals’ can be passively exposed to advertising for prescription-only products at the event. This means they do not have to be kept away from the stand area (also see under chapter 2, paragraph c).

b) Venue

Is a 5-star hotel a suitable venue?
The number of stars will provide an indication of the facilities offered by a particular venue. A 5-star hotel will generally not be considered to be a suitable venue, but in the end the classification or any other ranking is not the deciding criterion.

Is an estate a suitable venue?
If the estate is known as an exclusive venue, it will generally not be a suitable venue.

c) Costs

What is the maximum amount of hospitality costs a pharmaceutical company may sponsor for non-healthcare professionals?
The sponsoring of hospitality costs for non-healthcare professionals is not permitted, if that sponsoring is evidently aimed at sales promotion. As long as the hospitality remains limited to a modest meeting arrangement with a simple sandwich, it will be assumed that there is no sales promotion object. If the hospitality goes beyond this, the person involved must pay for it him- or herself.

Does it make any difference whether an event is financed by pharmaceutical companies only partly or fully?
The most important difference is that in the case of multiple revenue sources, the amount sponsored by pharmaceutical companies can be lower than the costs of hospitality and speakers. In that case the assessment of whether the limits for hospitality and speakers' fees are complied with will have to be based on the level of that sponsoring. If there are no revenues in the form of contributions from the participants, this means that no recreational/social activities can take place.

What are the consequences if the final settlement for an event differs from the budget?
The decision whether the advertising rules have been complied with will be made on the basis of the actual expenditure. As opposed to the budget, the final settlement will give a picture of the actual costs. In the case of the mandatory prior assessments (for instance via GAIA or by the Code Commission) the budget will be taken as the starting-point and the data provided by the applicant will be deemed to be accurate. In retrospect the parties themselves continue to be responsible for the compliance with the rules (also see Chapter 3, paragraph c, under iv).

What is the maximum amount of sponsored hospitality a healthcare professional may receive per year?
For scientific events the sponsored hospitality an individual healthcare professional may receive is a maximum of € 1,500 per year per pharmaceutical company. It is up to the healthcare professional to ensure that this annual maximum is not exceeded. This means that healthcare professionals must be able to have insight into the sponsored hospitality. Sponsored hospitality does not in all cases count towards the annual maximum. If the healthcare professional has paid for at least one half of the hospitality costs, the hospitality for that event will not count towards the annual maximum. The pharmaceutical companies have a responsibility to check whether they are not paying a healthcare professional more than the annual maximum (directly) as an individual company.

Do the maximum hourly rates for services also apply to speakers from abroad?
No, the Dutch advertising rules have been introduced for the Dutch healthcare industry, so the maximum hourly rates apply to healthcare professionals working in the Netherlands, even if they give lectures abroad.
There may be rules on advertising in the speaker's country that actually impose restrictions on the fee that speaker may receive.

Does a payment for a meal with a value under € 75 count towards the maximum hospitality costs a healthcare professional may receive in the case of scientific events (the maximum of € 500 or payment of 50% of the costs by the healthcare professional him-/herself)?
Yes, the limit for meal costs in the Netherlands applies in addition to the maximum amount for the total hospitality costs that may be sponsored for that meeting. The maximum of € 75 applies for every individual meal enjoyed (in the Netherlands). In addition, the payment of the meal costs must always be restricted to what is 'strictly necessary' for participating in the event.

Are there also rules for payments to conference organisations?
Yes, that is the case if a conference organisation is a grouping of healthcare professionals or a body in which they participate and is receiving sponsoring from the industry. In this case services are being provided for which no more than market-conforming rates may be paid. If the conference organisation is not a grouping of healthcare professionals or a body in which they participate, then the rules for advertising do not impose any payment limits.

d) Other questions

Can different terms be used to distinguish between 'non-healthcare professionals' and 'healthcare professionals'?
The law defines a 'healthcare professional' as a person who is authorised to prescribe and/or supply medicinal products. 'Non-healthcare professional' is not a legal term. The parties are free to make a distinction between healthcare professionals and other participants in the event using their own terms.

Which parts of the programme are accessible to stand holders?
Congress organisations must make agreements with the pharmaceutical companies about the access to the various parts of the programme for their representatives. The representatives must be recognisable as such (with badges).

What responsibility do professional conference organisations have for the compliance with the advertising rules?
The Code of Conduct is only binding for the members of the umbrella organisations associated with the CGR. Conference organisations are therefore not directly bound to the Code of Conduct, but *must* comply with the Dutch Medicines Act. In view of this, the conference organisation must ensure that proper organisational measures are taken so that the advertising rules are complied with. The organisation should for instance provide badges to the participants, guarantee that (signed) service provision agreements are concluded with the speaker, inform the healthcare professionals about the sponsored hospitality, compile a scientific programme, select a suitable venue, prepare a sound budget, etc.

Are physicians who are being trained to become a specialist 'healthcare professionals'?
Yes, they are medical practitioners with independent authority to prescribe prescription-only medicines. Medical students, including interns, are not healthcare professionals (yet).

Are pharmaceutical companies allowed to organise side-events?
Yes, side-events are generally sales-promoting manifestations, which must be seen as independent events for which specific rules apply, provided the side-event is completely separate from the main event. If pharmaceutical companies sponsor specific parts of an event (or main event), these are not side-events and the sponsoring must be seen as sponsoring from which the whole event benefits. Therefore this type of sponsoring must be made visible in one total budget for that event and no separate budgets may be used for this purpose.

What are the rules for online programmes?
For online programmes, the CGR principle applies that the same rules are applicable for offline and online interactions. Online training programmes (such as e-learnings) that are offered or co-financed by pharmaceutical companies must therefore comply with the rules

for hospitality. In case of online programmes, the hospitality costs may consist of printing costs for study materials and registration fees for the participants. When evaluating the content of an online program, special attention should be paid to the way the programme is offered to the participants, the prohibition on public advertising for prescription-only medicinal products and the requirement that advertising for prescription-only medicinal products (if present) should be recognizable as such.

May a follow-up/assessment talk be held with the sales department of the pharmaceutical company following the event?
Yes, but if the conference organisation is a grouping of healthcare professionals or a body in which they participate (such as a scientific association), restraint must be exercised. This type of contact must serve to assess the event that was held and may not have a sales promotion object.

Do the Dutch advertising rules also apply if foreign branches of pharmaceutical companies act as sponsor or organiser?
Yes. Based on the EFPIA HCP Code all the pharmaceutical companies associated with EFPIA are obliged to comply with the applicable self-regulation of the country in which the event is held.

How should amended legislation be dealt with in practice if a positive opinion has already given on the set-up of the event previously?
The event must be held in agreement with the advertising rules as they apply at the time of the event. If the Code of Conduct is amended, the CGR and the legislator will normally provide for a transitional period. This transitional period will allow the parties to make adjustments, if necessary, in the set-up of their event.