

Questions and Answers (version 4)

Medicines for Europe

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Code of Conduct Q&A

Draft Version 4

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General Questions

What is the Medicines for Europe Code of Conduct on Interactions with the Healthcare Community?

The Medicines for Europe Code of Conduct aims to set high ethical standards for the European generic and biosimilar medicines industries when interacting with the healthcare community. Ethics is a universal commitment and the Medicines for Europe Code of Conduct promotes core values: integrity, mutual respect, responsiveness, accountability, collaboration and transparency.

Where does the Medicines for Europe Code come from? Who created it?

The Medicines for Europe Code of Conduct on Interactions with Healthcare Professionals results from work on ethics and transparency in the pharmaceutical sector with the European Commission as well as with a dedicated Medicines for Europe Working Group, bringing together global and EU compliance experts to communicate a strong set of ethical rules for the generic and biosimilar medicines industries in Europe, while promoting transparency in the pharmaceutical sector.

Why have a Medicines for Europe Code?

Following endorsement by members of Medicines for Europe of the EU Guiding Principles [explained below -], Medicines for Europe and all stakeholders of the Ethics and Transparency Platform committed to raising awareness of these Guiding Principles and to taking a further step to integrate them into the organisation's Code/guideline or set of rules. Medicines for Europe responded to this engagement by developing a universal set of rules for the European generic and biosimilar medicines industries.

Medicines for Europe members firmly wish to strengthen their ethical commitment towards a common set of rules in order to promote transparency in the pharmaceutical sector.

What is the purpose of the Q&A Document?

The Q&A document is an accompanying document to facilitate understanding of the Code of Conduct and thereby the implementation of the rules by Medicines for Europe members. The Q&A is provided as a high quality service to Medicines for Europe members and will continue throughout the whole working process.

Who has to abide by the rules of the Medicines for Europe Code of Conduct?

The Medicines for Europe Code applies to all its members, including Medicines for Europe Member Companies, Medicines for Europe Member Company Affiliates, Medicines for Europe National Association Members and Medicines for Europe National Association Affiliate Members.

How is the Code of Conduct to be implemented?

A national association member of Medicines for Europe must either adopt this Code or a comparable code that is at least as strict as the Medicines for Europe Code, or make it formally applicable to its member companies. Medicines for Europe member companies must directly apply the rules and requirements of our Code to their activities or apply rules and requirements that are consistent with, and at least as comprehensive as, the rules and requirements of the Medicines for Europe Code. The subsidiaries of Medicines for Europe member

companies must either adopt our Code or the code that has been adopted by a Medicines for Europe national association

What professional interactions are concerned and covered by the Medicines for Europe Code of Conduct?

As pointed out in Section 3, the Medicines for Europe Code covers professional interactions with any natural person that is a doctor, a members 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 or administer a medicinal product. For the avoidance of doubt, the definition of a Healthcare Professional includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, dispense, purchase or administer medicinal products and (ii) any employee of a pharmaceutical company whose primary occupation is that of a practising Healthcare Professional, but excludes (x) all other employees of a pharmaceutical company and (y) a wholesaler or distributor of medicinal products.

These professions could include without limitation: doctors, pharmacists, nurses, vets, dentists, opticians, chiropodists, midwives, laboratory directors, bio-medical operatives, physiotherapists, nutritionists, etc.

Which pharmaceutical companies are concerned?

The pharmaceutical companies concerned are Medicines for Europe Member Companies and Medicines for Europe National Association Member Companies.

Where will the Code apply?

The Medicines for Europe Code applies to all European¹ operations of all Medicines for Europe Members, including Medicines for Europe Member Companies, Medicines for Europe Member Company Affiliates, Medicines for Europe National Association Members and Medicines for Europe National Association Affiliate Members.

As pointed out in Section 3, it is a condition of Medicines for Europe membership that associations adopt the Medicines for Europe Code of Conduct in full, and that companies comply with the national codes (even in those countries where they are not a direct member of the relevant member association).

The Code is currently in English only. What if I need clarification about the text of the Code?

Please contact the Secretariat of Medicines for Europe, which can provide clarification or referrals to other sources, for example, to the respective local generics association.

¹ For purpose of Medicines for Europe Code, Europe includes the Member States of the EU, Members of the EFTA (Norway, Liechtenstein, Switzerland and Iceland) as well as Serbia, Bosnia-Herzegovina, Albania, Macedonia and Kosovo.

Introduction and Purpose

Our fundamental principles:

Integrity²

Stakeholders should consistently uphold their standards, values and procedures and communicate them appropriately. Accordingly, they should respect those of other stakeholders.

Mutual respect³

Stakeholders should promote an attitude and environment of mutual respect for other stakeholders, for different cultures, for different socio-economic environments, for different views, for diverse ways of working and for the decision-making processes of competent authorities.

Responsiveness⁴

Stakeholders should make clear in which respect they will collaborate with other stakeholders, and indicate who is responsible for this within the organisation. They should also be prepared to responsibly and accurately answer questions in this context and to indicate a reasonable time-frame within which a response can be expected.

Accountability⁵

Stakeholders should aim to identify those who are likely to be affected by their decisions, where possible communicate their intentions and if necessary engage in an exchange of views with them. They should also justify their objectives, and assume responsibility for the foreseeable and/or actual consequences for them, regardless of whether these concern actions, products, or policies.

Collaboration⁶

Stakeholders are encouraged to collaborate with other fellow stakeholders, for instance via public-private partnerships when appropriate, to achieve their goals. The public-private partnerships should be based on clear, transparent, good governance principles. In the context of these partnerships, the participants should share information about their objectives if needed.

² http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/outcomes_et_en.pdf

³ http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/outcomes_et_en.pdf

⁴ http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/outcomes_et_en.pdf

⁵ http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/outcomes_et_en.pdf

⁶ http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/outcomes_et_en.pdf

Transparency

Interactions between pharmaceutical companies and the Healthcare Community must be transparent and comply with applicable rules and requirements. This section is further clarified in the Medicines for Europe Disclosure Rules.

Independence

Pharmaceutical companies must respect the independence of Healthcare Professionals and not interfere with the relationship and trust that exists between patients and their Healthcare Professionals

What is fair market value?

As pointed out in Section 6, where members of the Healthcare Community are engaged to perform a service, or where sponsorships or contributions are provided, the remuneration and payments must be fair market value. This is understood as the value that would be paid as a result of bona fide discussions between well-informed parties in arm's-length transactions for the goods or services to be provided. The value shall consider the nature or quality of the goods or services to be provided, the qualifications and experience of the provider, the geographic location where goods or services are to be provided, the nature of the market for the goods or services to be provided, and the pre-vailing rates for similar goods or services.

Up-to-date documentation for interactions with healthcare professionals, healthcare organisations, patients and patient organisations⁷

As pointed out in Section 6 of the Code states that pharmaceutical companies shall adequately document their interactions with the Healthcare Community by entering into contracts and written agreements, where appropriate, and keeping and maintaining appropriate records and evidence of activities and engagements, such as copies of agreements, related reports, and invoices.

Preamble

What are the Guiding Principles?

The List of Guiding Principles is based on recognition by all participants of the need to go beyond bilateral relationships and to address the quintessential role of good governance in the pharmaceutical sector. Adhering to principles of good governance, ethics and transparency, can have a profound positive impact on healthcare policy and practice, and ultimately on patient outcomes.

How were the Guiding Principles established?

Our platform brought together all relevant stakeholders to openly discuss a joint set of principles and recommendations on ethics and transparency, based on voluntary cooperation. This resulted in a [List of Guiding Principles](#) governing the interactions between healthcare professionals and patients' organisations, competent authorities, and the pharmaceutical industry. This List of Guiding Principles made use of the

⁷http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/process_on_corporate_responsibility/platform-ethics/index_en.htm

expertise of multiple stakeholders and public administrations in a combined effort, with the coordination and political support of the European Commission⁶. The EC Guiding Principles, endorsed by the Medicines for Europe Board, has led to the Medicines for Europe Code of Conduct on Interactions with the Healthcare Community.

It is a requirement of Medicines for Europe membership that national associations accept the conditions of the Code and, subject to Applicable rules and requirements, adopt codes that meet both applicable rules and requirements and are consistent with, and at least as comprehensive as, Medicines for Europe Code.

Medicines for Europe national associations will have to implement Medicines for Europe Code and transpose it at national level by 2015. Applicable laws and regulations will prevail, however, where no rules are in place, national associations will apply Medicines for Europe Code as a minimum standard.

The Code is intended to be a self-regulatory standard and is without prejudice to any existing or future legislation.

The Code sets standards for pharmaceutical companies with regard to ethical interactions with the Healthcare Community. The Medicines for Europe Code is not intended to address or regulate commercial terms and conditions relating to the price, sale and distribution of medicines, which must always be in compliance with applicable rules and requirements.

Neither does it intend to address competition law issues. Therefore, pharmacists are considered as healthcare professionals and not as business partners/retailers.

Applicability of the Medicines for Europe Code

1. Why does the Medicines for Europe Code not address OTC products?

OTC products which are self-care products based on patients' choice are outside of the scope of Medicines for Europe Code of Conduct.

2. Regarding the applicability of the Medicines for Europe Code to prescription-only medicines, does this mean that restrictions of gifts and medical utility items do not apply to OTC lines? Are OTC allowed to deliver gifts which are not allowed to be delivered by RX?

OTC products, which are self-care products based on patients' choice, are outside of the scope of Medicines for Europe Code of Conduct. Therefore, the Code does not regulate interactions with Healthcare Professionals that concern OTC products. Local rules or regulations may be applicable.

3. What happens if a national association Code covers both prescription and OTC products?

The stricter rules from the national codes prevail.

4. How should the Medicines for Europe Code be implemented in a country where ethical codes already exist with other healthcare stakeholders?

The national ethical code should be compared with the Medicines for Europe code. Where Medicines for Europe Code is stricter, this principle should be implemented in the national code.

5. Define Medicines for Europe Affiliate Members

Membership categories Affiliate Company or Affiliate Association, are open to those who only wish to enjoy limited benefits of membership, or b) have more limited resources or c) whose commercial activities are not deemed by Medicines for Europe Board to be directly or solely related to the development, production or marketing of generic medicines or APIs. All receive the regular Medicines for Europe EU Brief and reduced members' rates for participation at Medicines for Europe and IGBA conferences, however, participation in the decision-making bodies and related activities is more limited than Ordinary Membership. They may be a part of Medicines for Europe delegations representing the industry in various events and meetings if it brings an added value to the meeting and is agreed by the Chair of the relevant group.

It is acknowledged that the business practices and business models of Medicines for Europe Members vary from country to country, due to regulatory, legal and market factors. Not all of the provisions of Medicines for Europe Code are relevant to all companies in all countries, since certain activities may not be undertaken. Nevertheless, Medicines for Europe Code applies in its entirety and should be read in the spirit in which it is intended.

6. Medicines for Europe is only for European markets. If a doctor is hired in a country where Medicines for Europe has no national association to speak on behalf of a subsidiary (for example, our Dubai office hires an Emirati physician to speak at a satellite symposia for our company), does this fall outside of the medicines for Europe's scope?

This is correct.

7. What is Europe for Medicines for Europe? What about Ukraine, Russia?

Ukraine and Russia are not Europe in the scope of the Medicines for Europe Code. See Q&A, version 2.

8. Applicability/Scope – Section 3 states that the Code is applicable to prescription-only medicines. At the same time, how do we apply Rx and OTC regulations?

The Medicines for Europe Code of Conduct applies to prescription-only medicines (Code, art. 3). When a product is qualified in one country as Rx product and in another county as OTC product a member company should disclose only Transfer of Value related to this product in the country where this product has Rx status.

Guidelines

Patients and Patient Organisations

1. When do the patient organisations' reporting obligations come into force and when must companies make their first report?

At the moment, in certain markets, companies and patient organisations have a legal obligation to disclose. Medicines for Europe Members operating in these markets are expected to comply with these legal obligations. Further disclosure rules will be clarified following adoption by the Medicines for Europe Board.

Fees for Services and Consultancy

1. Could you provide some examples where a company has a legitimate need for a service?

Companies may engage Healthcare Professionals and Healthcare Organisations to provide necessary services, such as serving as experts on advisory boards, speaking engagements, participating in research, participating in focus groups or market research, training and education on products.

Define Fair market value

Where members of the Healthcare Community are engaged to perform a service, or where sponsorship or contributions are provided, the remuneration and payments must be at a fair market value. This is understood as the value that would be paid as a result of bona fide discussions between well-informed parties in arm's-length transactions for the goods or services to be provided. The value shall consider the nature or quality of the goods or services to be provided, the qualifications and experience of the provider, the geographic location where goods or services are to be provided, the nature of the market for the goods or services to be provided, and the prevailing rates for similar goods or services.

2. Could the country of residence of the service provider be taken into account when determining the fair market value to be attributed to a service?

As set out in Section 6 of the Medicines for Europe Code, the prevailing rates for similar goods or services should be taken into consideration when determining the fair market value. The country of residence of the person providing the service must be a factor in determining the prevailing rate.

3. Please provide an example of healthcare professionals being selected and engaged as service providers based on their qualifications, expertise and abilities to provide the service.

As pointed out in Section 3 of the Code, any natural person that is a doctor, 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 or administer a medicinal product. For the avoidance of doubt, the definition of Healthcare Professional includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, dispense, purchase or administer

medicinal products and (ii) any employee of a pharmaceutical company whose primary occupation is that of a practising Healthcare Professional, but excludes (x) all other employees of a pharmaceutical company and (y) a wholesaler or distributor of medicinal products.

4. What does it mean to pay for “work that is performed”?

In those instances where it is not possible to perform the full contract obligation, payment may be made for deliverables that have been provided of an amount that reflects their fair market value.

Meetings and Hospitality

1. What meetings between a pharmaceutical company and HCP and HCO are considered to facilitate the beneficial and essential interactions between them?

Meetings may be held for educational scientific research and promotional purposes.

2. What is reasonable hospitality?

Reasonable hospitality should be defined on a national level depending on applicable local norms, according to the applicable rules and requirements. These should be defined by national associations.

3. What would be considered “exceptional circumstances” that would justify booking business class for a flight?

Flights should be booked in economy class; business class may only be compensated in exceptional circumstances, if justified. Justification should be defined on a national level based on applicable rules and requirements.

4. Are social activities permitted?

As pointed out in section 4.3 of the Medicines for Europe Code, stand-alone hospitality or entertainment which is not connected to any work-related meeting, is prohibited. Any social activities should be consistent with local norms and applicable rules and requirements.

As pointed out in section 4.5 of the Medicines for Europe Code, site visits should be limited in duration to closely coincide with their purpose and may not include any side trips, trip extensions, stop-overs or any recreation or entertainment. The arrival and departure of participants should closely coincide with the start and finish of the meeting.

As pointed out in Section 4.6 of the Medicines for Europe Code, companies must not use sponsorship as a way to indirectly fund or support any activity that they could not legitimately undertake themselves. A company must not provide sponsorship that funds or subsidises recreational or entertainment activities for Healthcare Professionals.

If the event is to be organised by Healthcare Professionals or other associations independent of companies, it is important that any cultural or social activity be financed from funds other than those issuing from medical devices or pharmaceutical companies.

5. Is there a cost-ceiling for meals and overnight stays?

The cost-ceiling for meals and overnight stays should be consistent with local norms and applicable rules and requirements.

6. Can a member use a meeting venue outside of Europe?

As pointed out in Section 4.3 of the Medicines for Europe Code, meetings should be held in a location that makes the most logistical sense in light of the location of the attendees or resources necessary for the meeting. This could include major transport hubs and cities with appropriate infrastructure. In appropriate circumstances, a meeting could be held outside Europe, consistent with applicable rules and requirements.

7. Provided that the location is appropriate, are top category or luxury hotels suitable venues for conferences attended by the Healthcare Community?

As pointed out in Section 4.3 of the Medicines for Europe Code, venues must be appropriate and conducive to the main purpose of the meeting. Appropriate venues may include clinical, laboratory, educational, conference or healthcare settings, or business locations such as business hotels or conference centres. Luxury hotels, resorts, venues known for their entertainment or recreational value, or extravagant venues are never appropriate.

8. Is use of a luxury hotel as a venue acceptable if it has appropriate meeting room facilities and offers a better deal than a non-luxury hotel?

No, as set out in Section 4.3 of the Medicines for Europe Code, luxury hotels, resorts, venues known for their entertainment or recreational value, or extravagant venues are never appropriate.

9. Should the prohibition of “Stop-Overs” be read as prohibiting stop-overs for a personal program in the stop-over location, but not stop-overs for logistical reasons?

The prohibition of “stop-overs” should be understood as prohibiting stop overs that are not connected to the business purpose of a meeting, such as for the purpose of a personal programme. It is not intended to prevent lay-overs for connecting flights or other travel-related logistical reasons, provided that the travel is always on the most direct and logical route, taking into account costs to the company.

10. Can a promotional face to face meeting between a medical representative and a doctor be considered as to be reported under Section 4.3 (Meetings and Hospitality)?

Section 4.3 does not address disclosure or reporting. Section 4.3 provides rules that relate to all sorts of meetings and hospitality.

Section 7 addresses disclosure, but only the specified meetings need to be disclosed. Meetings would only need to be disclosed if they involve an overnight stay or air travel (as well as congress sponsorships and site visits).

Educational Support for Healthcare Professionals

1. Is it permissible under the Code for member companies to finance the attendance of individual Healthcare Professionals on courses of further education, for example, Master degree courses or modules of such courses?

As pointed out in Section 4.4 of the Medicines for Europe Code, companies may support scientific, medical, pharmaceutical and professional education in the communities they serve. By inviting and funding Healthcare Professionals to attend meetings and conferences, companies contribute to the advancement of scientific knowledge and the improvement of patient care and are subject to applicable rules and requirements.

2. What are the relevant selection criteria and factors to take into account when deciding who shall receive educational support?

Examples of selection criteria might be:

- Therapeutic areas of interest to the company;
- Healthcare Professional's expertise, knowledge, experience, areas of scientific or medical interest, and related educational needs;
- Geographic location of the Healthcare Professional and distance to the educational event;
- Alternative educational opportunities;
- The reputation, means and need of the institution employing the Healthcare Professional;
- Reputation and standing of the Healthcare Professional in the scientific or medical community
- Experience with a company's products may be considered in connection with company-sponsored third party events and company-Organized Meetings;
- Potential impact on the quality of patient care; and
- The ability, willingness and likelihood of the recipient to further share the knowledge gained with others.

Site Visits

1. What elements should a site visit agenda contain?

As pointed out in Section 4.5 of the Medicines for Europe Code, visiting and touring a company's manufacturing and R&D facilities helps Healthcare Professionals to better understand the efficacy and quality of a company's products and operations. This assists in building understanding and faith in generic and biosimilar medicines and supports the Healthcare Professional in making decisions for the benefit of patients and the public.

The agenda should closely relate with the purpose of the visit. The agenda should include a detailed time table, a detailed content (not only the nature of the sessions but also the title of each scientific address and, if possible, the names of the speakers).

2. Are social activities permitted?

As pointed out in section 4.3 of the Medicines for Europe Code, stand-alone hospitality or entertainment, not connected to any work-related meeting, is prohibited. Any social activities should be consistent with local norms and applicable rules and requirements.

As pointed out in Section 4.6 of the Medicines for Europe Code, companies must not use sponsorship as a way to indirectly fund or support any activity that they could not legitimately undertake themselves. A company must not provide sponsorship that funds or subsidises recreational or entertainment activities for Healthcare Professionals.

If the event is to be organised by healthcare professionals or other associations independent of companies, it is important that any cultural or social activity be financed from funds other than those issuing from medical devices or pharmaceutical companies.

As pointed out in 4.5 of the Medicines for Europe Code, site visits should be limited in duration to closely coincide with their purpose and may not include any side trips, trip extensions, stop-overs or any recreation or entertainment. The arrival and departure of participants should closely coincide with the start and finish of the meeting.

3. Is there a cost-ceiling for meals and overnight stays?

A cost-ceiling for meals and overnight stays should be consistent with local norms and applicable rules and requirements.

4. Is it appropriate for members to invite Healthcare Professionals on company plant or factory tours where the Healthcare Professionals reside outside the country of location of the plant or factory?

As pointed out in Section 4.5 of the Medicines for Europe Code, professionals should only be invited to visit the most logical site that can demonstrate the core manufacturing capabilities or technology that is crucial to the educational objectives.

Site visits could be held outside home countries in appropriate circumstances and consistent with applicable rules and requirements.

5. If we organize a site visit to one of our sites, sometimes no direct costs arise connected to that because:

travel will be organized by medical representatives' company cars, we do not have rental fees, we do not have other costs from services, and/or only costs connected to hospitality (meals, drinks) may arise.

We deleted "cost for hospitality" at the last working group meeting which means that our company does not have to disclose any costs of meals and drinks (hospitality).

The guiding principle is always that companies should disclose what can be reasonably allocated as a transfer of value to an HCP individually or a group of HCPs in the aggregate. The manner of this allocation can be explained in the methodological note.

Sponsorship of Events

1. Are social activities permitted?

As pointed out in section 4.3 of the Medicines for Europe Code, stand-alone hospitality or entertainment, not connected to any work-related meeting, is prohibited. Any social activities should be consistent with local norms and applicable rules and requirements.

As pointed out in Section 4.6 of the Medicines for Europe Code, companies must not use sponsorship as a way to indirectly fund or support any activity that they could not legitimately undertake themselves. A company must not provide sponsorship that funds or subsidises recreational or entertainment activities for Healthcare Professionals.

If the event is to be organised by healthcare professionals or other associations independent of companies, it is important that any cultural or social activity be financed from funds other than those issuing from medical devices or pharmaceutical companies.

As pointed out in section 4.5 of the Medicines for Europe Code, site visits should be limited in duration to closely coincide with their purpose and may not include any side trips, trip extensions, stop-overs or any recreation or entertainment. The arrival and departure of participants should closely coincide with the start and finish of the meeting.

2. Is the stand alone rental of a booth in the scope of this Code?

When the rental of the booth is a stand-alone engagement, not linked to other sponsoring activities, this is considered as a commercial activity with the event organiser and is therefore not subject to the code.

Social Contributions

1. What is an unsolicited and independent request from an institution for a contribution?

Requests for contributions should be initiated by the Institution and should not be based on a company's suggestion or recommendation.

2. Who is the recipient of the grants and donation?

Contributions may be provided to recognised charities, civic organisations and not-for-profit institutions.

According to section 4.7 of the Code regarding Social Contributions, "Contributions may be provided to recognised charities, civic organisations and not-for-profit institutions, but never to natural persons or for-profit entities."

3. Due to the local legislation of some countries, the public (municipal) hospitals as well as the private hospitals are for-profit entities. May contributions be provided to public (municipal) and/or private hospitals?

If the "for-profit" governmental hospital provides its total profit to the government, then they are likely to be eligible to receive donations. The purpose and spirit of this statement of the Medicines for Europe Code is to

prevent subsidising the profitability of a private enterprise. If the benefit goes to the government or to the public, then the legal status of the entity is unlikely to matter. However, if private shareholders or Healthcare Professionals may also benefit financially then such donations would be prohibited.

4. In the social contributions section (4.7.) what happens if we are not directly paying such event, but we give a mandate to an organizing company which will ultimately organize the event for us on our behalf? In this case, the purpose is clearly for promoting the social benefit but we are not funding it directly (but through a for-profit organization). How shall we evaluate this matter?

Section 4.7 provides limits on providing direct contributions to third party non-profit charities and civic organizations. For indirect contributions, the rules of the Code also apply to persons and entities acting on behalf of a pharmaceutical company (such as employees and agents). This is because the underlying goal is to facilitate transparency to the extent possible. If the pharmaceutical company knows or is informed which non-profit organization receives funding, the funding should be disclosed.

5. To what extent are donations to natural persons prohibited? With the strict interpretation of the Article 4.7, they should be banned in all cases?

Donations to natural persons are prohibited. Section 4.7 states in part: “Contributions may be provided to recognized charities, civic organisations and not-for-profit institutions, but never to natural persons or for-profit entities” (emphasis added).

Educational Material, Medical Utility Items and Inexpensive Gifts

1. Define a medical utility item:

Items of medical utility aimed directly at the education of healthcare professionals and patient care can be provided if they are “inexpensive” and do not offset routine business practices of the recipient.

2. Define an inexpensive gift:

Inexpensive gifts should be defined under local norms, applicable rules and requirements.

3. Define the offset the cost of operating a healthcare professional practice

Gifts and medical utility items should not be given to cover the normal usage of the product in practice, for example in large quantities or on a continuous basis.

4. How will the transitional period for educational materials, medical utility items and inexpensive gifts concretely take place? Does the pharmaceutical company have to stop producing or releasing them?

From 2015, date of the implementation of the Medicines for Europe Code, gifts, educational materials and medical utility items can only be given to healthcare professionals as long as they comply with the Medicines for Europe Code of Conduct.

5. Are inexpensive items such as pens or notebooks considered being relevant to Healthcare Professional duties and do they offset the cost of operating a practice?

Inexpensive items may be provided to Healthcare Professionals, as long as they do not offset the costs of operating a Healthcare Professional's practice. Providing medical supplies that are normal and necessary for the day-to-day practice of medicine, in a form and quantity that an HCP would normally purchase are prohibited. Therefore, an occasionally given inexpensive item will not be considered to offset the costs of operating a practice.

6. Small value gifts given to Healthcare Professionals (for example, pens given to the Healthcare Professional by field force members) are not required to be disclosed. Is that correct?

Yes, that is correct. Please see Section 7.1 of the Code of Conduct, which describes which Transfers of Value need to be disclosed, and notes that "Transfers of Value that are not listed below, do not need to be disclosed under this Code." For more details on Inexpensive Gifts please refer to Section 4.8 of the Code of Conduct.

However, please also remember that the trend in the pharmaceutical industry in the foreseeable future is to eliminate providing gifts.

7. Our standpoint is that commercial rebates given, for example, to pharmacies are not required to be disclosed. Is that correct?

Yes, that is correct. As stated in the Preamble, the Code of Conduct sets standards for pharmaceutical companies with regard to ethical interactions with the Healthcare Community. "The Medicines for Europe Code of Conduct is not intended to address or regulate commercial terms and conditions relating to the price, sale and distribution of medicines, which must always be in compliance with applicable rules and requirements".

8. Are fully depreciated items (for example, old computers, the book value of which is zero) given to a Patient Organisation or a Healthcare Organisation to be disclosed? At what value are these to be disclosed, if the book value is zero?

Yes, in-kind contributions to a Healthcare Organisation or a Patient Organisation must be disclosed. Please refer to Section 7.1 of the Code of Conduct. The amount of the Transfer of Value must be at Fair Market Value (see section 6 of the Code of Conduct). For example, although the book value for a company on an old computer may be zero, an HCO or PO would otherwise have to purchase equipment at some FMV rate.

9. Are occasional personal gifts, that are not related to an HCPs professional duties, allowed to be delivered to Healthcare Professionals (e.g. flowers or chocolates in case of National Holidays or an Anniversary)?

No. The giving of flowers, chocolates, and similar items is prohibited. Gifts must meet the criteria set forth in Section 4.8 of the Medicines for Europe Code. All such items must be relevant to a Healthcare Professional's professional duties and ultimately benefit patients, patient care or the practice of medicine or pharmacy. Such items should never provide personal benefit to a Healthcare Professional and must never be provided as a means of improperly influencing the Healthcare Professional.

Samples

1. How do samples provide societal benefits such as quicker access to treatment/ greater access to medicines for patients?

Samples can only be given to prescribers and they are responsible for providing samples according to patient needs. Samples represent an important societal role. It is necessary and desirable to continue to deliver samples to healthcare prescribers who explicitly request them. Delivery of samples must comply with national legislation quotas.

2. How will the transitional period for samples concretely take place? Does the pharmaceutical company have to stop producing or releasing them?

From 2015, date of the implementation of the Medicines for Europe Code, samples can only be given to healthcare professionals as long as they comply with the Medicines for Europe Code of Conduct.

3. Are free medicines samples given to Healthcare Professionals required to be disclosed?

No. Please see Section 7.1 of the Code of Conduct, which describes which Transfers of Value need to be disclosed, and notes that “Transfers of Value that are not listed below, do not need to be disclosed under this Code.”

The Code of Conduct also states that medical samples should only be given on an occasional basis, in line with applicable legal limits on amounts and frequency, and only upon the prior written request of the Healthcare Professional. For more details on Samples, please refer to Section 4.9 of the Code of Conduct.

Promotional Materials and Information

1. What type of relevant information could assist healthcare professionals in their decision-making?

As pointed out in Section 4.10 of the Medicines for Europe Code, companies may promote pharmaceutical products by providing relevant information to healthcare professionals in order to assist their decision-making. Companies may not promote prescription medicines and products to patients, the public or any other person who does not qualify as a Healthcare Professional. Companies may promote their corporate brand, their company and the generic medicines industry to the public through normal advertising and promotional channels, to the extent permitted by Applicable rules and requirements.

As stated in the EU Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, (52) Persons qualified to prescribe or supply medicinal products must have access to a neutral, objective source of information about products available on the market. Whereas it is nevertheless for the Member States to take all measures necessary to this end, in the light of their own particular situation⁸.

⁸ http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/outcomes_et_en.pdf

2. What is the procedure to follow for a pharmaceutical company to ensure that all materials are reviewed by competent reviewers before the dissemination?

Procedures to ensure that all materials are reviewed by competent reviewers should be consistent with local norms and applicable rules and requirements.

3. Who are the competent reviewers?

Competent reviewers should be identified in accordance with local norms and applicable rules and requirements.

4. What kind of company procedures must be in place to withdraw outdated or superseded materials and to prevent their further use?

As pointed out in Section 4.10 of the Medicines for Europe Code, companies must ensure that all materials and information are reviewed by competent reviewers before they are disseminated or used. They must regularly review their materials to ensure they remain relevant and consistent with current available scientific knowledge. Companies must have procedures in place to withdraw outdated or superseded materials and to prevent their further use. Procedures to withdraw outdated or superseded materials should be set in accordance with local norms and applicable rules and requirements.

How will the transitional period for promotional materials and information concretely take place? Does the pharmaceutical company have to stop producing or releasing them?

From 2015, date of the implementation of the Medicines for Europe Code, promotional materials and information can only be given as long as they comply with the Medicines for Europe Code of Conduct.

Transparency

1. How does Medicines for Europe Code define Transparency?

Transparency is defined in the Medicines for Europe Code. Interaction between pharmaceutical companies and the Healthcare Community must be transparent and comply with Applicable rules and requirements.

2. What items/ payments will be disclosed?

The items/ payments for disclosure are in details set in section 7.1 “disclosing transfer of value”.

3. What is the definition of a Transfer of Value?

A Transfer of Value can include anything of value that is provided (or “transferred”) by a Medicines for Europe member company (directly or indirectly via a third party acting at its direction) to a recipient, including monetary payments or in-kind benefits. Only Transfers of Value specified in section 7.1 must be disclosed.

4. What is the Medicines for Europe transition or implementation period for companies to disclose?

As set in section 7.6, Medicines for Europe member companies will have a 12 month implementation period starting from the date of adoption of the disclosure paragraph (December 2015), which corresponds to January 2017. All relevant Transfers of Value allocated in 2017 will have to be disclosed during the following reporting period, starting from January 2018 and at the latest by 30 June 2018.

5. What is the transition or implementation period for Medicines for Europe National Associations?

Medicines for Europe national associations will have a 6 month implementation period to adopt the Medicines for Europe disclosure requirements in their Code/ statutes starting from the date of adoption by the Medicines for Europe General Assembly (8 December 2015), which corresponds to 30 June 2016. This includes a notification to Medicines for Europe on the preferred platform for disclosure.

6. What are the timelines for disclosure?

The first required disclosure on Transfers of Value provided by Medicines for Europe member companies to the healthcare community starting January 2018 and at the latest 30 June 2018 from the data collected in the 2017 calendar year. Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year.

7. What platform for disclosure is recommended by Medicines for Europe?

Medicines for Europe gives its members the option on how to disclose, as long as the general public can easily access such information. Section 7.4 of the Medicines for Europe Code suggests some ways to disclose such as via a member company's website or a central platform.

8. How to manage when existing national disclosure requirements do not address the Medicines for Europe minimum disclosure standards? [E.g. Patient Organisations]

Where the Medicines for Europe Code is stricter (e.g. than patient organisations), the members should disclose Transfers of Value relating to such a category on their individual website or in another appropriate manner.

9. What document should accompany the Disclosure?

Companies shall publish a note summarising how data have been prepared for disclosure in accordance with section 7.2 "Company Methodological Note".

10. What additional information should be provided on disclosure?

Medicines for Europe will develop a recommended disclosure table that may be used by their members when publishing transfers of value to the healthcare community.

11. If a HCP is operating through a company/or is an individual entrepreneur, is he/she considered to be a HCO despite of the fact that he/she is a natural person?

The underlying goal of transparency in the Code is to facilitate disclosure of transfer of value to the extent possible. Generally, this means the specific HCP, HCO, or PO recipient.

Solution 1: The pharmaceutical company contracts with an individual HCP who either is working independently or as sole owner of the HCP's company. In this case, the HCP's company and the HCP are the same. Disclosure of the HCP under an individual, named basis (if consent has been obtained where legally required), or of the company under an aggregated basis (if no consent has been obtained) is appropriate.

Solution 2: The pharmaceutical company contracts with an entity for services. The entity employs or uses more than one HCP to provide services and the services are not associated with a specific HCP. In this case, disclosure of the entity under an aggregated basis is appropriate.

Disclosure shall include Transfers of Value made by a third party on behalf of a Medicines for Europe member company for the benefit of a recipient and where the Medicines for Europe member company knows or is informed about the recipient who will benefit from the Transfer of Value, using the same analysis above.

12. Is a pharmacy considered to be an HCO?

Yes, a pharmacy likely falls in the definition of HCO, to the extent that it is an organization “through which one or more Healthcare Professionals provide healthcare services”, as defined in section 6 of Medicines for Europe’s Code.

13. What happens if the doctor requests Medicines for Europe’s members to support his/her practice or company generally in order to perform screening activities? Shall we disclose such financial supports? If so, under which sub-category?

Support should be provided, limited, and directly related to the specific activity requested. Additional “general funding” requests could be considered a request for a bribe, and paying it could be considered a bribe. The category of transfer of value disclosure depends on the nature of the support.

14. Is market research subject to the transparency reporting?

As indicated in Section 7.1 “Fees paid in connection with research & development activities or market research, are excluded from the scope of this disclosure.”

15. Are distributors vs. meeting planners and KOL agencies to be considered as “third party acting on the company behalf”?

As a rule, the Medicines for Europe Code of Conduct is not intended to address or regulate commercial terms and conditions relating to the price, sale and distribution of medicines, which must always be in compliance with applicable rules and requirements (Code Preamble, paragraph 3). However in some countries distributors offer additional services of promotional nature.

This is why from a disclosure perspective it is important to know the scope of the interaction as well as the legal status of the the contractor (licensee, agent, distributor, etc.). In general terms, if a pharmaceutical company controls actual activities performed through third parties and falling within the scope of the Medicines for Europe Code, these activities must be disclosed, even if a a third party is a distributor.

On the other hand, travel agencies or event planners hired by a pharmaceutical company as a rule are required to collect transparency data that arises in the course of their business and provide it to the pharmaceutical company for reporting. This results from the nature of services they offer. Since third party relationship require case by case assessment, you would need to consult with your legal counsel.

16. HCP provides services in Italy for an Italian company. Do we disclose in Italy or France?

Companies must consider the rules of both the home country of the HCP and the place where services are provided: Section 7.4 states «Disclosures shall be made pursuant to the national rules and regulations, including

the Medicines for Europe national association’s code, in the country where the Medicines for Europe member company or the affiliate holding the contractual relationship with the recipient is located, or where the physical address of the recipient is located.” The company may elect one of these options.

17. How should companies manage consent collection with HCPs that work with both with on and off patent medicines and the ethical divisions of the same pharmaceutical company?

This decision is left to the companies. There are various software tools and companies that can provide this service or advice on how best to collect the consents.

18. Does a Medicines for Europe member company need to report Transfers of Value made by parent or sister companies of the Medicines for Europe member company, which are not made on behalf of the Medicines for Europe member company and over which the Medicines for Europe Member company has no influence?

No. According to section 7.1, only Transfers of Value provided (or “transferred”) by a Medicines for Europe member company (directly or indirectly via a third party acting at its direction) to a recipient, must be disclosed.

19. Not all countries have a local association which will implement a local transparency code. What disclosure rules apply to our subsidiaries in those countries?

In countries without a national association, the member company will follow the Medicines for Europe Code. Under Section 3, the Code states “The subsidiaries of Medicines for Europe member companies must either adopt the Medicines for Europe Code or the codes that has been adopted by the Medicines for Europe national associations.”

20. Is it required to sum up the total Transfer of Value given to a Healthcare Professional in different categories? In case of Healthcare Professionals who provide services through their company, the name of the company will be listed in this category (without the indication of the name of the Healthcare Professional) and the name of the Healthcare Professional will be listed in the category of event participation. Is that correct or should the name of the Healthcare Professional also be included besides the name of their company?

Please see answer to question 1 above.

21. If certain Healthcare Professionals refuse the consent to the disclosure, the Transfer of Value given to such Healthcare Professionals may be aggregated. This would result in a name based disclosure in respect of only those Healthcare Professionals who gave their consent and an aggregated disclosure in respect of those who refused the consent. Is that correct?

Yes, that is correct. In the situation of an aggregated disclosure, the number of HCP recipients should be indicated in the table as provided by the template. Please refer to section 7.3 of the Code of Conduct. Also see answer to question 1 above.

22. How much time will the organization have to update information in the report in case the healthcare professional (HCP) withdraws consent for disclosing?

In case the HCP withdraws consent for disclosing data, the organization must update the report as soon as possible, but no later than 30 days from the date the withdrawal request was received.

23. The Code of Conduct states that the inclusion of VAT is recommended. Would it be acceptable to disclose the net amounts and describe the applicable taxes in the methodological note?

Yes, that would also be correct.

24. Since we deleted “hospitality” from the new template, what kind of costs should be disclosed in the template on transfer of value to HCPs?

Under Option 1 on transfers of value to HCPs for meetings, educational support, and site visits, the Code of Conduct does not require disclosure of monetary values.

Under Option 2, the Code of Conduct requires an aggregate amount of support provided to HCPs. For example, this would be the total amount of all HCP-related costs at a conference or seminar including travel, accommodation, registration fees, and meals that are not included as part of the conference “package”. The reason for this is pragmatic. If the aggregated amounts transferred are in line Code of Conduct, the disclosure of detailed costs would not make a difference.

However, the guiding principle is always that companies should disclose what can be reasonably allocated as a transfer of value to HCPs. The manner of this allocation can be explained in the methodological note.

25. For company organized meetings, what kind of costs should be disclosed? Could you please specify and give some examples? What about rental for rooms/premises, costs of technical infrastructure (sound and light system services), travel (if any). Are these costs appropriate for disclosure?

Items such as room rental and technical infrastructure are basis costs of the meeting, and are not a value that is transferred to the benefit of the HCP. Under the Code of Conduct, transfers of values to the HCP include items such as travel, accommodation, and meals.

26. On the other hand, how should we proceed if there is no direct cost (other than hospitality) connected to the conference and meeting? If we do not have rental fees, no cost for infrastructure, because all of these items are in our possession (for example, our conference room is fully equipped and Budapest based doctors travel to us by their own car/public transportation). This would mean that we cannot indicate any “Yearly Amount” but only the “Number of Recipients”.

If there was no transfer of value, there is nothing to report. For purposes of good documentation, we recommend that your internal records reflect the number of participants and a “zero” value if that is the case, with an explanation as to why there was no transfer for value to the HCPs.

However, the guiding principle is always that companies should disclose what can be reasonably allocated as a transfer of value to an HCP individually or a group of HCPs in the aggregate. The manner of this allocation can be explained in the methodological note.

27. Transfer of Values to HCOs include fees for services and consultancy and grants and donations. There is an exception that R&D and market research is not to be disclosed. Does that mean that equipment donation for R&D activities provided to HCO are to be disclosed?

There are three parts to this question, and three answers. (1) Equipment provided for the purpose of typical R&D and market research activities does not need to be disclosed as long as the equipment is taken back at the end

of the activity. Otherwise the amount of the Transfer of Value must be at Fair Market Value of the equipment (see section 6 of the Code of Conduct). (2) Social contributions (whether funding or items) cannot be made to individuals or for-profit entities. (3) Social contributions of equipment under section 4.7 to charities, civic organisations, and non-profit institutions must be disclosed.

28. How long does a company need to retain information of the disclosure process?

For one year, unless a local law or regulations requires a longer retention period.

29. Is it mandatory to disclose Transfers of Value regarding OTC products?

No. OTC is out of scope of the Code of Conduct.

30. Can organization publish the disclosure report in a form of a searchable database?

Yes, provided that the searchable database must be available by:

- name of the HCP, HCO, or patient organization (PO),
- city where the HCP practices his/her profession or where the HCO/PO is based or by the HCP's licensing number if the city is not available. The use of a drop-down list of cities is suggested.

The report excerpt from the searchable database should provide information corresponding to the selected search as follows:

- For HCPs, HCOs, and POs who agreed to disclosure, information should be provided for the individual HCP, HCO, and PO and in the aggregate for all HCPs, HCOs, and POs.
- For HCPs, HCOs, and POs who did not agree to disclosure, information should be provided in the aggregate for all HCPs, HCOs and POs.

31. What should I do if the local association's rules or code of conduct have different disclosure requirements?

The Code of Conduct of Medicines for Europe sets a minimum threshold for disclosure of Transfers of Value. Local associations may have additional requirements. If you are a member of the local association, or have agreed to follow that association's rules, you must follow the more restrictive disclosure requirements. Please note the difference in the methodological notes in the disclosure report.

32. Do we have to disclose transfers of value to pharmacists?

If a pharmacy provides consulting or other services typical of those provided by HCPs or healthcare organizations (HCOs), then the Transfers of Value related to such services must be disclosed.

If the pharmacy provides standard commercial services (for example, placement of products on shelves at set rates), then these amounts do not need to be disclosed.

Enforcement Procedure

1. What is the Review procedure?

As pointed out in Section 5 of the Medicines for Europe Code, their member companies should follow, in the first instance, the enforcement procedures set out by the relevant Medicines for Europe national association. National associations should therefore establish enforcement, complaint and appeal procedures, preferably by self-regulatory mechanisms and if appropriate by additional co-regulatory mechanisms.

In the exceptional event that a Medicines for Europe national association member does not have adequate enforcement procedures, the following procedures apply. A national association may also transfer a claim to the Medicines for Europe Secretariat for adjudication.

2. From when can a member company put forward a complaint based on the Medicines for Europe Code against other Medicines for Europe member?

As the Medicines for Europe Code has been implemented by national associations and member companies as of 31st July 2015 a complaint can be put forward following the enforcement rules of procedure, provided that the matter cannot be resolved to the members' mutual satisfaction through inter-company dialogue.

Medicines for Europe member companies should follow the complaint and enforcement procedures set out by the relevant Medicines for Europe national association, or the national accepted procedure/guidelines as adopted by the relevant national association, where the alleged infringement occurred.

In the exceptional case where no Medicines for Europe national association or accepted national complaint and enforcement procedure exist in an EU member state, the complaint may be directly filed with Medicines for Europe⁹.

3. If the Code of Conduct has not been adopted during the initially agreed period, Can we extend the adoption period for a National association?

No. The Medicines for Europe Code has been implemented by national associations and member companies since 31st July 2015.

4. What is the procedure if a Medicines for Europe Member Company or subsidiary violates the Medicines for Europe code, but is not a member of a national association?

The Medicines for Europe Code applies to all European operations of all Medicines for Europe members. Subsidiaries of Medicines for Europe member companies must adopt either the Medicines for Europe Code or the Code that has been adopted by Medicines for Europe national association.

Therefore, if Medicines for Europe Member Company or subsidiary violates the Medicines for Europe Code, it will be subject to Medicines for Europe Enforcement Guidelines.

5. The code does not seem to take into account the possibility that a non-member company (or other stakeholder), may make a complaint.

Indeed, complaints from non-Medicines for Europe member companies may not be addressed under the enforcement procedure of the Medicines for Europe Code

