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CODE OF CONDUCT Q&A

Medicines for Europe

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Code of Conduct Q&A

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Introductory / General Questions

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

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 Medicines for Europe Code of Conduct promotes core values: integrity, mutual respect, responsiveness, accountability, collaboration and transparency.

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

Medicines for Europe Code of Conduct on Interactions with Healthcare Professionals comes from work on Ethics and Transparency in the pharmaceutical sector with the European Com- mission 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.

What was the rationale of having a Medicines for Europe Code?

Following endorsement by Medicines for Europe members of the EU Guiding Principles [explained below in this document], Medicines for Europe and all stakeholders of the Ethics and Transparency Platform committed to raising awareness of these Guiding Principles and to taking an additional step by integrating 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 member firmly wish to strengthen their ethical commitment towards a common set of rules with the objective of promoting transparency in the pharmaceutical sector.

What is the purpose of the Q&A Document?

The Q&A document is Medicines for Europe Code of Conduct's accompanying document to facilitate its understanding and thereby the implementation of rules and principles by MEDICINES FOR EUROPE Members. The Q&A is provided as a high quality service to Medicines for Europe members and will stand du- ring the whole working process of Medicines for Europe Code of Conduct.

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

Medicines for Europe Code applies to all 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 Medicines for Europe Code of Conduct to be implemented?

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

Which are the professions' interactions are concerned and covered by Medicines for Europe Code of Conduct?

As pointed out in Section 3, Medicines for Europe Code covers professions' interactions with any natural person that is a doctor, a member of 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.

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?

Medicines for Europe Code applies to all European[1] operations of 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 member associations adopt Medicines for Europe Code of Conduct in full, and that member companies comply with the national codes (even in those countries where they are not a direct member of the relevant member 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-Herzegovnia, Albania, Macedonia and Kosovo.

Introduction and Purpose

What is Medicines for Europe understanding of the Fundamental principles of:

Integrity[2]

Stakeholders should consistently practise their standards, values and procedures and communicate them appropriately. They should respect the integrity of the standards, values, procedures and decision processes of other stakeholders.

Mutual respect[3]

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.

Responsiveness[4]

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.

Accountability[5]

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.

Collaboration[6]

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

Interaction between pharmaceutical companies and the Healthcare Community must be transparent and comply with applicable rules and requirements. This section will be further clarified with 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 organisations[7]

As pointed out in Section 6, 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.

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

How were the Guiding Principles Elaborated?

The Platform brought together all relevant stakeholders to openly discuss a joint set of ethical and transparency principles and recommendations, based on voluntary cooperation. The result of such an endeavour is a List of Guiding Principles governing the interactions between healthcare professionals and patients' organisations, competent authorities, and the pharmaceutical industry. The List of Guiding Principles elaborated under this platform made use of the expertise of multiple stakeholders and public administrations in a combined effort, under the coordination and with the political support of the European Commission[6]. The EC Guiding Principles endorsed by Medicines for Europe Board led Medicines for Europe reflection and outcome of Medicines for Europe Code of Conduct on Interactions with the Healthcare Community.

It is a requirement of Medicines for Europe membership that Medicines for Europe national associations accept the conditions of the Medicines for Europe 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. 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.

Medicines for Europe Code of Conduct does not 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

Why would 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.

Regarding the applicability of Medicines for Europe code to prescription-only medicines, does it mean that the mentioned restrictions of gifts and medical utility items do not apply to OTC line? Are OTC allowed to deliver gifts which are not allowed to be delivered from 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, Medicines for Europe Code does not regulate interactions with Healthcare Professionals that concern OTC products. Local rules or regulations may be applicable.

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

The stricter rules from the national codes prevail.

How should 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 Medicines for Europe Code. Where Medicines for Europe Code is stricter, this principle should be implemented in the national Code.

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.

Guidelines

Patients and Patient Organisation

When does the patient organisation reporting obligation come into force and when must companies do their first report?

At the moment, in certain markets, companies and patient organsiations 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 Medicines for Europe Board.

Fees for services and consultancy

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

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

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

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

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, any natural person that is a doctor, a member of 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.

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 the deliverables that have been provided in an amount that reflects fair market value for the deliverables.

Meetings and hospitality

Which meetings between a pharmaceutical company and HCP and HCO are considered to facilitate the beneficial and essential interactions amongst them?

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

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. This should be defined by national associations.

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.

Are social activities permitted?

As pointed out in section 4.3 of 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 4.5 of 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 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 other funds than those issuing from medical devices or pharmaceutical companies.

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

Cost-ceiling and overnight stays should be consistent with local norms and applicable rules and requirements.

Can a member use a meeting venue outside of Europe?

As pointed out in Section 4.3 of 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.

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 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.

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 Medicines for Europe Code, luxury hotels, resorts, venues known for their entertainment or recreational value, or extravagant venues are never appropriate.

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 should always be on the most direct and logical route, taking into account costs to the company.

Education support for healthcare professionals

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

As pointed out in Section 4.4 of 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 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.

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 visit

Which 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).

Are social activities permitted?

As pointed out in section 4.3 of 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 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 other funds than those issuing from medical devices or pharmaceutical companies.

As pointed out in 4.5 of 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.

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

Cost-ceiling and overnight stays should be consistent with local norms and applicable rules and requirements.

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 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 circumstance and consistent with applicable rules and requirements.

Sponsorship of events

Are social activities permitted?

As pointed out in section 4.3 of 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 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 other funds than those issuing from medical devices or pharmaceutical companies.

As pointed out in 4.5 of 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.

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 organizer and is therefore not subject to the code.

Social Contributions

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

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

Who is the recipient of the grants and donation?

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

According 4.7. Social Contributions, "Contributions may be provided to recognized charities, civic organizations and not-for-profit institutions, but never to natural persons or for-profit entities."

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 eligible to receive donations. The purpose and spirit of this statement of Medicines for Europe Code is to prevent subsidizing the profitability of a private enterprise. If the benefit goes to the government or public then, the legal status of the entity likely does not matter. However, if private shareholders or Healthcare Professionals may also benefit financially then such donations would be prohibited

Educational material, medical utility items and inexpensive gifts

Define 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

Define expensive gift

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

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 pro- duct in practice, for example in large quantities or on a continuous basis.

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 it or releasing it?

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

Are inexpensive items such as pens or notebooks considered to be 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 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.

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 Anniversary)?

No. The giving of flowers, chocolates, and similar items is prohibited. Gifts must meet the criteria set forth in Section 4.8 of 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 a personal benefit to a Healthcare Professional and must never be provided as a means of improperly influencing the Healthcare Professional.

Samples

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 needed and desirable to pursue to deliver samples to healthcare prescribers who explicitly request for them. Delivery of samples must comply with national legislation quotas.

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

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

Promotional materials and information

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

As pointed out in Section 4.10 of Medicines for Europe Code, companies may promote pharmaceutical products by providing relevant information to healthcare professionals and assist their decision-making. Companies may not promote prescription medicines and products to patients, the public or any other person does not qualify as a Healthcare Professional. Companies may promote their corporate brand, their company and the generic 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 situation[8].

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

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.

Who are the competent reviewers?

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

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

Transparency

What does Medicines for Europe Code understand by Transparency?

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

What will be the items/ payments for disclosure?

Items and payments for disclosure will be defined at a later stage.

What are the timelines for disclosure?

Medicines for Europe Board committed to provide guidance for disclosure by December 2015 and timelines will be defined by then.

What items/ payments will be disclosed?

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

What is the definition of Transfer of Value?

A Transfer of Value can include anything of value that is provided (or “transferred”) by an 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 Transfer of Value specified in section 7.1 must be disclosed.

What is 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.

What is understood by transition or implementation period for Medicines for Europe National Associations?
MEDICINES FOR EUROPE National Associations will have a 6 month implementation period to adopt Medicines for Europe disclosure requirements in their Code/ statutes starting from the date of adoption by 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.

What are the timelines for disclosure?

The first required disclosure on Transfer of Value provided from Medicines for Europe member companies to the healthcare community starting January 2018 and at the latest 30 June 2018 with 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.

What is Medicines for Europe recommended platform for disclosure?

Medicines for Europe gives its members the option of how to disclose, as long as the general public can easily access such information. In section 7.4 Medicines for Europe Code suggests some ways of disclosure like Member Company’s website or a central platform.

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

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

What should be the accompanying document for Disclosure?

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

What additional information about the disclosure chapter?

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

Enforcement Procedure

How to constitute the Review Committee?

As pointed out in Section 5 of Medicines for Europe Code, Medicines for Europe member companies should follow, in the first instance, the enforcement procedures set forth 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 Medicines for Europe national association does not have adequate enforcement procedures, the following procedures apply. A national association may also transfer a claim to Medicines for Europe Secretariat for adjudication.

More details with Medicines for Europe enforcement guidance will be provided when adopted by Medicines for Europe Board in 2015.

Starting when a company can put forward a complaint based on Medicines for Europe Code against another Medicines for Europe member?

As 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 procedures provided that the matter could not be resolved through the inter-company dialogue to companies’ mutual satisfaction.

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 exists in an EU member state, the complaint may be directly filed with Medicines for Europe[9].

Could we extend the adoption period for one National association if the code of conduct was not adopted during the initial agreed period?

No. Medicines for Europe Code is implemented by national associations and member companies as of 31st July 2015.

How to proceed, if a Medicines for Europe Member Company or subsidiary violates Medicines for Europe code, but is not a member of national association?

Medicines for Europe Code applies to all European operations of MEDICINES FOR EUROPE members, including MEDICINES FOR EUROPE member companies, MEDICINES FOR EUROPE member affiliates, MEDICINES FOR EUROPE national association members and MEDICINES FOR EUROPE national association affiliate members. The subsidiary of MEDICINES FOR EUROPE member companies must either adopt Medicines for Europe Code or the Code that has been adopted by Medicines for Europe national association.

Therefore, if a Medicines for Europe company or subsidiary violates Medicines for Europe Code, this is subject to Medicines for Europe Enforcement Guidelines.

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

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

[9] Enforcement Guidelines, Medicines for Europe Rules of Procedures, Version 1, July 2014


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