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CODE OF CONDUCT

Medicines for Europe

Follow us on
@medicinesforEU

Rue d'Arlon 50 - 1000 Brussels – Belgium
T: +32 (0)2 736 84 11- F: +32 (0)2 736 74 38
www.medicinesforeurope.com

Code of Conduct

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1. Introduction and Purpose

Medicines for Europe endorses the "List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector" under the Corporate Social Responsibility Platform by the European Commission. In order to ensure good governance, interactions should be based on fundamental principles of integrity, mutual respect, responsiveness, accountability, collaboration and transparency. The Medicines for Europe Code also addresses the core values of independence, fair market value for services obtained, and up to date scientific documentation for interactions with Healthcare Professionals, Healthcare Organisations, Patients and Patient Organisations. These values are defined in the Section on Definitions.

This Medicines for Europe Code of Conduct on Interactions with the Healthcare Community (The Medicines for Europe Code) aims to set a framework of standards and principles that promotes trust, responsible behaviour, and respect, between pharmaceutical companies and the Healthcare Community, including Healthcare Professionals, Healthcare Organisations, patients and Patient Organisations.

2. Preamble

Medicines for Europe is a non-profit, non-governmental organisation representing industry associations and companies from across Europe. Medicines for Europe Members are committed to the ethical standards set out in Medicines for Europe Code.

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, the Medicines for Europe Code. 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.

Medicines for Europe member companies are accountable for addressing and correcting infringements under the Medicines for Europe Code and/or the codes implemented by Medicines for Europe national associations. Companies that are not members of Medicines for Europe or its member associations may nonetheless follow the Medicines for Europe Code and/or the codes implemented by Medicines for Europe national associations.

The principles set forth in the Medicines for Europe Code are mandatory and shall be implemented by all Medicines for Europe Members. However, where Applicable rules and requirements related to Medicines for Europe Members are more stringent than the principles in the Medicines for Europe Code, those applicable rules and requirements shall prevail.

3. Applicability of Medicines for Europe Code

The Medicines for Europe Code only applies to prescription-only medicines.

The Medicines for Europe Code applies to 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.

A Medicines for Europe national association must either adopt the Medicines for Europe 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 the 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 the Medicines for Europe Code. The subsidiaries of Medicines for Europe member companies must either adopt the Medicines for Europe Code or the code that has been adopted by the Medicines for Europe national association.

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 the Medicines for Europe Code are relevant to all companies in all countries, since certain activities may not be undertaken. Nevertheless, the Medicines for Europe Code applies in its entirety and should be read in the spirit in which it is intended.

4. Guidelines

4.1. Patients and Patient Organisations

- Non-promotion of prescription-only medicines

EU and national legislation and codes of practice, prohibiting the advertising of prescription-only medicines to the general public, apply.

- Written agreements

When companies provide financial support, significant indirect support and/or significant non-financial support to Patient Organisations, they must have in place a written agreement. This must state the amount of funding and also the purpose (e.g. unrestricted grant, specific meeting or publication, etc). If applicable, it must also include a description of significant indirect support (e.g. the donation of public relations agency's time and the nature of its involvement) and significant non-financial support. Each company should have an approval process in place for these agreements.

- Use of logos and proprietary materials

The public use of a Patient Organisation's logo and/or proprietary material by a company requires written permission from that organisation. In seeking such permission, the specific purpose and the way the logo and/or proprietary material will be used must be clearly stated.

- Editorial Control

Companies must not seek to influence the text of Patient Organisation material they support in a manner favourable to their own commercial interests. This does not preclude companies from correcting factual inaccuracies. In addition, at the request of Patient Organisations, companies may contribute to the drafting of the text from a fair and balanced scientific perspective.

- Transparency

Each company must make publicly available a list of Patient Organisations to which it provides financial support and/or significant indirect/non-financial support. This should include a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the significance of the support. The description must include the monetary value of financial support and of invoiced costs.

For significant non-financial support that cannot be assigned a meaningful monetary value the description must describe clearly the non-monetary benefit that the Patient Organisation receives. This information may be provided on a national and/or European level and should be updated at least once a year.

Companies must ensure that their sponsorship is always clearly acknowledged and apparent from the outset.

Each company must make publicly available a list of Patient Organisations that it has engaged to provide significant contracted services. This should include a description of the nature of the services provided that is sufficiently complete to enable the average reader to form an understanding of the nature of the arrangement without the necessity to divulge confidential information. Companies must also make public the total amount paid per Patient Organisation over the reporting period.

- Contracted Services

Contracts between companies and Patient Organisations under which they provide any type of services to companies are only allowed if such services are provided for the purpose of supporting healthcare or research. It is permitted to engage Patient Organisations as experts and advisors for services such as participation at advisory board meetings and speaker services. The arrangements that cover consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

a) A written contract or agreement is agreed in advance which specifies the nature of the services to be provided and, subject to clause (g) below, the basis for payment of those services;

b) A legitimate need for the services has been clearly identified and documented in advance of requesting the services and entering into the arrangements;

c) The criteria for selecting services are directly related to the identified need and the persons responsible for selecting the service have the expertise necessary to evaluate whether the particular experts and advisors meet those criteria;

d) The extent of the service is not greater than is reasonably necessary to achieve the identified need;

e) The contracting company maintains records concerning, and makes appropriate use of, the services;

f) The engaging of Patient Organisations is not an inducement to recommend a particular medicinal product;

g) The compensation for the services is reasonable and does not exceed the Fair Market Value of the services provided. In this regard, token consultancy arrangements must not be used to justify compensating Patient Organisations;

h) In their written contracts with Patient Organisations, companies are strongly encouraged to include provisions regarding an obligation of the Patient Organisation to declare that they have provided paid services to the company whenever they write or speak in public about a matter that is the subject of the agreement or any other issue relating to that company;

i) Each company must make publicly available a list of Patient Organisations that it has engaged to provide paid-for services.

- Single company funding

No company may require that it be the sole funder of a Patient Organisation or any of its major programmes.

4.2. Fee for Service and Consultancy

The expert advice and support by Healthcare Professionals and Healthcare Organisations are important to help companies make decisions and take actions that benefit the patients and the Healthcare Communities they serve.

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 educating on products.

In all cases, a company must have a legitimate need for the service, pay no more than fair market value and retain only the appropriate number of Healthcare Professionals or Healthcare Organisations necessary to effectively fulfil the service. Healthcare Professionals must only be selected and engaged as service providers based on their qualifications, expertise and abilities to provide the service.

An engagement must not be offered or entered into with the intention to induce the Healthcare Organisation or Healthcare Professional to supply, dispense, promote, prescribe, approve, reimburse, purchase, or recommend a particular product, influence outcomes of clinical trials, or otherwise improperly benefit business activities.

All engagements, regardless of extent, must be confirmed in writing or contract, with a clear description of the services and the compensation. In addition, the consultant should, whenever possible, be required to disclose the engagement to the consultant's employer.

Payment shall only be made for work performed.

4.3. Meetings and Hospitality

Meetings between companies and Healthcare Professionals and Healthcare Organisations (to the extent that the participants from the Healthcare Organisations are Healthcare Professionals) facilitate the beneficial and

essential interactions amongst them. Meetings may be held for educational, scientific or research purposes, and promotional purposes. Reasonable hospitality may be provided in connection with such meetings.

Depending on the nature of the meeting, hospitality may include hotel accommodation, meals and drinks, and must always be necessary, incidental, reasonable, and secondary to the main purpose of the meeting. Stand-alone hospitality or entertainment, not connected to any work-related meeting, is prohibited.

- Location

A meeting 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. Locations primarily known for their touristic or recreational character are prohibited.

- Venue

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.

- Hospitality

Companies may provide hotel accommodation, meals and drinks in connection with a meeting, as long as such hospitality is necessary, incidental, reasonable, and secondary to the main purpose of the meeting. Hospitality must not be lavish or luxurious, must be reasonable and proportionate, and may only be extended to the persons who qualify as participants in their own right.

- Travel

Travel should always be on the most direct and logical route, taking into account costs to the company. Stop-overs, side trips and trip extensions funded or facilitated by a company are prohibited. Arrival and departures should, whenever logistically possible, coincide with the beginning and end of the meeting. Flights should be booked in economy class; business class may only be compensated in exceptional circumstances, if justified.

4.4. Educational Support for Healthcare Professionals

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.

A company may provide educational support by paying registration costs, travel and accommodation and reasonable hospitality to support an individual Healthcare Professional to attend events that educate them in areas relevant to their field. Educational support may be provided for company-organized events or for congresses and conferences organized by third parties.

- Types of Meetings

Companies may sponsor Healthcare Professionals to attend company-organized meetings, as well as recognized conferences and congresses, provided that the meetings have material scientific, educational and professional content, are in therapeutic areas in which the Healthcare Professional currently practices and are directly related to the company's therapeutic areas.

- Invitees

Appropriately qualified Healthcare Professionals may be invited to meetings and conferences and receive hospitality and travel support. Guests, spouses, family members, or friends of Healthcare Professionals may not be invited to meetings and conferences and may not receive any hospitality or travel or anything else of value. A company cannot facilitate and should actively discourage the accompaniment of uninvited guests on company funded travel.

The decision about who shall receive educational support shall be based on objectively defined criteria that are directly related to the educational needs of the recipient and the educational value of the program.

4.5. Site Visits

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.

Visits to a company's facilities must have educational value and may never be provided as a means of improperly influencing a Healthcare Professional. Healthcare Professionals should only ever be taken to visit the most logistically logical site that can demonstrate the core manufacturing capabilities or technology that is crucial to the educational objectives.

All site visits must have a specific and full agenda. As a general matter, such 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.

4.6. Sponsorship of Events

Subject to the Applicable rules and requirements, companies may provide financial sponsorship to third-party organisations for meetings, events or projects directed at Healthcare Professionals, provided the events are relevant to the company's therapeutic areas or business interests. In recognition of their support, they can receive commercial advertising opportunities, booth or exhibit space, distribution of promotional material, company branding of banners and materials, and similar acknowledgments

Before committing to sponsoring any event, companies should take care to understand the nature of the event, the program content and any associated hospitality. Companies must ascertain that the sponsored funds will only be used for the stated purpose.

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.

4.7. Social Contributions

As responsible corporate citizens, companies may contribute to the communities they serve.

Contributions may be provided to recognized charities, civic organisations and not-for-profit institutions, but never to natural persons or for-profit entities. Contributions can take the form of financial and in-kind donations for the purpose of supporting scientific research, medical education, patient education, patient access to healthcare, and the overall development of healthcare systems. A company may also support community and charitable initiatives.

Contributions must be supported by an unsolicited and independent request from the institution, including a detailed description of their needs, the program or project, and the budget. Contributions, including details of the program or project, must be memorialized in writing. This requirement may be deemed to be fulfilled where a company is responding to a public appeal by a charity of national or international renown. A company must ensure it has a sufficient understanding of how the funds will be used.

Contributions to Healthcare Organisations must serve the purpose of supporting healthcare goals, like research and education, and are documented and kept on record. They must never be provided as a means of improperly influencing a Healthcare Professional or Healthcare Organisation, and must not influence decisions on research programmes and on persons benefitting from donations (unrestricted grants). With the exception of legitimate research and/or educational grants, donations/grants to individual Healthcare Professionals are not allowed. Unrestricted contributions to Healthcare Organisations that are not tied to a specific project or activity are prohibited.

4.8. Educational Materials, Medical Utility Items and Inexpensive Gifts

Companies may occasionally provide educational materials, medical utility items and inexpensive gifts to a Healthcare Professional in accordance with Applicable rules and requirements.

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.

Gifts and medical utility items may not offset the costs of operating a Healthcare Professional's practice. Therefore providing medical supplies that are normal and necessary for the day-to-day practice of medicine (e.g. tongue depressors, latex gloves, etc.) are prohibited. Items that could be easily resold or used to generate income are also prohibited. Gifts must not be given in the form of cash or cash equivalents.

4.9. Samples

Samples of prescription-only medicinal products may only be provided on an exceptional basis to help Healthcare Professionals who are authorized to prescribe them to familiarize themselves with certain products and acquire experience in dealing with them.

Samples cannot financially enrich a Healthcare Professional and cannot be re-sold by the Healthcare Professional. Healthcare Professionals must be informed of this and the packaging must clearly indicate this.

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.

Companies must establish and maintain appropriate controls for distribution of samples.

4.10. Promotional Materials and Information

Companies may promote pharmaceutical products by providing relevant information to healthcare professionals and assisting their decision-making.
Companies may not promote prescription medicines and products to patients, the public or any other person that 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.

All promotional materials and information (whether printed, electronic or oral) must be clear, legible, accurate, up-to-date, balanced, fair, and sufficiently complete to enable the recipient to form his or her own opinion. It must not be misleading and must encourage the rational use of medicinal products by presenting them objectively and without exaggeration.

Scientific promotional claims and comparisons must always be scientifically up-to-date, referenced, clinically relevant and consistent with the licensed indication. “Off-label” promotional messages are prohibited
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.

Materials and information must comply with applicable rules and requirements in every country in which they are used or disseminated.

4.11. Transparency

Promoting transparent relations or interactions between companies and Healthcare Professionals / Organisations to relevant stakeholders assists informed decision-making and helps to prevent unethical and illegal behaviour.

Under various applicable rules and requirements, companies must disclose engagements, payments and other transfers of value to Healthcare Professionals and Healthcare Organisations, either publicly or directly to specific stakeholders. Companies must therefore adhere to all applicable disclosure rules and requirements.
Companies should disclose engagements and transfers of value that could potentially pose a conflict of interest or encourage the recipients of the transfers of value to disclose them, where such disclosure would be in the best interest of patients or the public.

4.12. Data Protection

If processing personal data received from, collected about or concerning Healthcare Professionals, Healthcare Organisations, Patients and Patient Organisations, applicable data protection laws must be complied with.

Any disclosure must be compatible with data privacy legislation.

5. Enforcement Procedures

Medicines for Europe member companies are encouraged to report potential violations of the 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 the Medicines for Europe national association 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.

Present enforcement procedure does not cause prejudice to nor limit the right of any Medicines for Europe Member to bring any matter at any time before competent jurisdictions or administrative authorities.

- Inter-company dialogue

If a company A believes a company B has violated the Medicines for Europe Code, company A should report such alleged violation to the company B. The two companies shall work to resolve the matter between themselves, in good faith and in the spirit of the Medicines for Europe Code. Inter-company dialogue shall be confidential between the involved parties and limited to what is necessary to discuss the alleged violation.

- Formal Complaint

If the companies cannot resolve the matter to their mutual satisfaction, either company may report it to the Medicines for Europe Secretariat. The company must file a detailed written complaint at the Medicines for Europe Secretariat. The Medicines for Europe Secretariat shall send the complaint by registered letter to the Medicines for Europe Executives and to the company alleged to be in breach. Within 30 days following the date of the registered letter, the alleged breaching company shall respond to this complaint in writing and per registered letter to the Medicines for Europe Secretariat. The Medicines for Europe Secretariat shall communicate this reply to the Executives and the claimant per registered letter.

- Adjudication and Records

Upon receipt by the Medicines for Europe Secretariat of a complaint, a review committee of 3 persons, appointed by the Medicines for Europe Executives, will be set-up to review the complaint and the reply. The review committee shall be composed one Medicines for Europe Secretariat member, one Medicines for Europe national association who has no conflicting interests with the parties involved in the matter to be adjudicated and one external independent expert (arbitrator, lawyer). The review committee may define specific rules of procedure, seek additional clarifications from the parties involved, invite the company representatives to appear in-person, or contract external experts, as needed. The language of the procedure before the committee will be English and, unless the parties involved and the review committee agree otherwise, the location of the procedure will be Brussels. The procedure before the committee will be suspended if a party to the procedure is pursuing a legal complaint before a court or an administrative authority directly related to the case pending before the committee until the final enforceable decision of the court or administrative authority.

- Findings and Sanctions

The review committee will issue its findings in writing and may make a recommendation or impose sanctions and/or remediation measures, in as far as and to the extent not prohibited by the Medicines for Europe Code. The decision of the committee is not open for appeal. The companies involved in the procedure are bound by the decision of the committee for the duration of their Medicines for Europe membership and unless such decision is contradicted by an order or decision of a competent administrative authority or court involving said companies. The companies commit to abide by the decision and to take the corrective actions to immediately cease the breach concerned and implement the remedial measures to avoid similar breaches of the Code in future. Medicines for Europe shall not have the power to levy fines or award damages. Medicines for Europe Members may however expel, in accordance with Medicines for Europe's bylaws and the applicable legislation, a company from the Association in egregious or repetitive cases and in circumstances where the company's activities have been such as to potentially bring the pharmaceutical industry or the generics and biosimilars sector into disrepute. The succumbing party will bear the costs related to the procedure before the committee, including the costs of the experts contracted by the committee, if any. Each party will however bear the costs of its own experts, counsels etc.

- Publication of Cases and Findings

Decisions of the committee will be published if agreed by both parties or, without their agreement, upon decision of the committee if repetitive and/or (a) serious breach(es) of the Code is/are concerned, on Medicines for Europe and national relevant national association websites. If, after the decision of the committee, a party to the procedure initiates a formal complaint before a court or administrative authority directly related to the case, the publication of the committee's decision will be delayed until the final enforceable decision of the court or administrative authority. The names of the companies and their location will be identified, but the identity of individual persons involved shall not be publicly disclosed. Confidential information will not be disclosed. The purpose of such publication shall be to provide information and guidance about the Medicines for Europe Code and its application to companies and the public. Medicines for Europe national associations shall also report breaches and cases to Medicines for Europe for publication.

6. Definitions

- Applicable rules and requirements

All laws (including national laws), regulations, codes of practices and standards that apply to a company or transaction in any given location or circumstance.

- EGA Code

This Medicines for Europe Code of Conduct on Interactions with the Healthcare Community.

- Medicines for Europe Members

Medicines for Europe member companies (including Medicines for Europe member company affiliates) and Medicines for Europe national associations (including Medicines for Europe national associations affiliate members).

- Healthcare Community

Healthcare Professionals, Healthcare Organisations, Patients and Patient Organisations.

- Healthcare Professional

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.

- Healthcare Organisation

Any entity (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society or (ii) through which one or more Healthcare Professionals provide healthcare services. For the avoidance of doubt, wholesalers, distributors, and similar commercial intermediaries are not considered Healthcare Organisations.

- Patient Organisations

Not-for-profit organisations which are patient-focused, and in which patients or their carers represent a majority of members in their governing bodies.

- 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.

- Transparency

Interaction between pharmaceutical companies and the Healthcare Community must be transparent and comply with Applicable rules and requirements.

- 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 bargaining 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.

- Documentation

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.

7. Transparency Rules and Requirements

7.1. Disclosing Transfers of Value

Transparent relations and interactions between companies and Healthcare Professionals/Organisations and Patient Organisations assist informed decision-making and help to prevent unethical and illegal behaviour. The Medicines for Europe Code therefore requires Medicines for Europe member companies to disclose Transfers of Value that could potentially pose a conflict of interest, or to encourage the recipients of the transfers of value to disclose them, where such disclosure would be in the best interest of patients or the public, further specified below. Such 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.

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, such as meals, travel, hospitality, etc.

Each Medicines for Europe member company shall disclose the amounts attributable to a Transfer of Value which can be reasonably allocated to one of the categories set out below. Transfers of Value that are not listed below, do not need to be disclosed under this Code.

Transfers of Value shall be disclosed on an individual, named basis:

- Transfers of Value to Patient Organisations:
    - Support: financial and in-kind support
    - Fee for services: contracted services per Patient Organisation, including a description of the nature of the Transfer of Value (educational summer camp, disease awareness world day, development of information brochures for an awareness campaign, etc.) and the amount provided.

- Transfers of Value to Healthcare Professionals:
    - Fees for services and consultancy: aggregated honoraria (excluding expenses such as meals and drinks, travel and accommodation) paid by a Company to a Healthcare Professional in exchange for the provision of services, such as serving as an expert on an advisory board, speaking at a company-organised educational event, participating in a focus group, etc. Fees paid in connection with research & development activities or market research, are excluded from the scope of this disclosure.

Meetings, educational support and site visits: Medicines for Europe member companies have two options for disclosure and may decide (for themselves and for their affiliates) which option to adopt for disclosure in this category:

OPTION 1

- Total number (but not actual monetary value) of events, for which an individual Healthcare Professional has received support (which may include payment of registration fees, travel and/or hotel costs). Support shall be disclosed per individual Healthcare Professional in the following categories and sub-categories:
    - Sponsorship for attending a third party organised congress (as per section 4.4), where the company pays for registration fees, travel or accommodation. Indicate whether each event is local/domestic, within Europe or outside of Europe.
    - Site visits (as per section 4.5).
    - Company organised meetings for which a Healthcare Professional receives company funded hotel accommodation and/or airplane travel (as per section 4.3).

OPTION 2

Aggregate total amount of support provided to Healthcare Professionals per individual conference or meeting as follows:

- Sponsorship for attending a third party organised congress (as per section 4.4):
    - name of congress,
    - aggregated amount spent for the congress, including the
    - number of Healthcare Professionals financially supported to attend.

- Site visits (as per section 4.5): aggregated amount spent, including the number of Healthcare Professionals financially supported to attend.

- Company organised meeting: aggregated amount spent, including the number of Healthcare Professionals financially supported to attend.

- Transfers of Value to Healthcare Organisations:
    - Fees for services and consultancy: aggregated honoraria (excluding expenses such as meals and drinks, travel and accommodation) paid by a Company to a Healthcare Organisation in exchange for the provision of services, such as serving as an expert on an advisory board, speaking at a company-organised educational event, participating in a focus group, etc. Fees paid in connection with research & development activities or market research, are excluded from the scope of this disclosure.
    - Grants and donations: aggregated monetary amounts and a brief description of the nature of the grant or donation (e.g. research grant, equipment donation, product donation, etc.)

7.2. Company's Methodological Note

Along with its disclosure, each Medicines for Europe member company shall publish a note summarising the methodology which they have applied in preparing the disclosure and identifying Transfers of Value for each category. This shall describe the recognition methodologies and should include the treatment of multi-year

contracts, VAT plus other tax aspects, currency aspects and other issues related to the timing and amount of Transfers of Value for the purposes of this Code.

It is recommended to include VAT and any other taxes in the disclosure amount, as required by local laws and regulations. Where no rules are in place, the company should decide on VAT disclosure.

Medicines for Europe member companies are advised to disclose in Euro and in the local currency if required by the applicable law and regulations. Where the Euro is not the local currency, the company should decide on the currency used for disclosure.

7.3. Data Privacy and Consent

Each Medicines for Europe member company will respect the applicable data privacy laws and regulations. To the extent required and in compliance with applicable data privacy laws and regulations, companies should seek the required consent from individual Healthcare Professionals to publish Transfer of Value data regarding the individual Healthcare Professional concerned.

If a Healthcare Professional refuses to provide the consent required under applicable data privacy laws and regulations, the company concerned shall nonetheless publish the Transfers of Value related to the Healthcare Professional on an anonymous basis. If multiple Healthcare Professionals refuse consent, then the Transfer of Value data can be aggregated and shall indicate the total number of Healthcare Professionals included in the aggregation.

7.4. Platform for Disclosure

Medicines for Europe member companies should disclose Transfers of Value in a way in which the public can easily access such information. This means via the relevant company's website, and/or on a central platform (such as one provided by the relevant government, regulatory or professional authority body, or a Medicines for Europe national association).

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. If a Medicines for Europe member company decides to disclose Transfers of Value in the country where the recipient address is located but the company has no residency or affiliate in that country, the

Medicines for Europe member company shall disclose such Transfers of Value at European regional level.
It is the Medicines for Europe member company's responsibility to ensure that the information is accessible online for a reasonable period of time.

7.5. Other Acceptable Forms of Disclosure

Medicines for Europe member companies do not need to report under the Medicines for Europe Code if they are subject to, and currently report, Transfers of Value to Patient Organisations, Healthcare Professionals and Healthcare Organisations under either (1) the transparency reporting regimes of other self-regulatory associations (such as the EFPIA Transparency Code) or (2) local transparency reporting laws and regulations, provided that these alternate reporting regimes are at least as robust as the Medicines for Europe's, including public availability of reports.

7.6. Implementation Period

Medicines for Europe member companies will have a 12 month implementation period starting from the date of adoption of the disclosure paragraph, i.e. 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.

Medicines for Europe national associations will have a 6 month period for implementation of the disclosure requirements starting from the date of adoption by the Medicines for Europe General Assembly.

7.7. Frequency of Disclosing

Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year. The first reporting period shall be the calendar year 2017 and the first disclosures shall be made from January 2018. Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year. The first reporting period shall be the calendar year 2017 and the first disclosures shall be made from January 2018. Companies are encouraged to disclose as early as possible, and at the latest within 6 months after the end of the relevant reporting period.

Medicines for Europe Code of Conduct on Interactions with the Healthcare Community
Version 2 | Adopted by the Medicines for Europe General Assembly on 8 December 2015
Including Transparency Rules and Requirements for Disclosure Chapter
Medicines for Europe Code of Conduct on Interactions with the Healthcare Community

Medicines for Europe Code of Conduct on Interactions with the Healthcare Community
February 2015 Updated in January 2016


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