medicines for europe

better access. better health.

Code of Conduct

2020

Chapter 1

Introduction

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Chapter 1 Introduction

Medicines for Europe is a non-profit, non-governmental organisation that represents industry associations and companies from across Europe. Its members are committed to common ethical standards that govern the industry's interactions with the Healthcare Community and promote transparency in the pharmaceutical sector.

Ethics is a universal commitment, and Medicines for Europe has adopted the European Commission's 'List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector': integrity, mutual respect, responsiveness, accountability, collaboration and transparency.

This Medicines for Europe Code of Conduct ('the Code') sets out a framework of principles and standards that promote trust, responsible behaviour and respect between pharmaceutical companies and the Healthcare Community, including Healthcare Professionals, Healthcare Organisations, patients and Patient Organisations.

The Code is a self-regulatory standard and is without prejudice to any existing or future legislation. A Medicines for Europe national association is required to adopt a code that incorporates all standards and requirements of the Medicines for Europe Code and meets applicable national rules and requirements, and make it formally applicable to its member companies. Where there is any gap or inconsistency between standards, the stricter requirement shall always apply.

Medicines for Europe encourages competition and compliance with competition laws and regulations among pharmaceutical companies. The Code is not intended to address or regulate commercial terms and conditions relating to the price, sale and distribution of medicines and services by pharmaceutical companies, which must always be in compliance with applicable laws and regulations. Medicines for Europe expects companies to comply with all rules and requirements in the markets in which they operate, including data privacy legislation and competition law.

This version of the Medicines for Europe Code comes into effect on 1 February 2021. It supersedes all prior versions of the Code and its related Q&A and Enforcement Guidelines. Medicines for Europe National Association Members must transpose the standards and requirements of this Code into national codes to take effect on 1 January 2022. All Medicines for Europe Members must comply with this Code from 1 January 2022.

Chapter 2

Definitions

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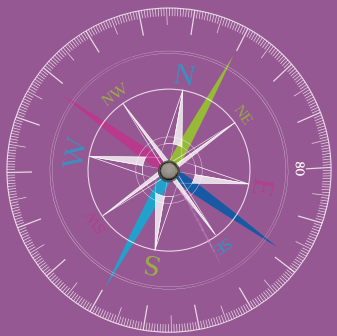

Chapter 2 Definitions

Healthcare community

Healthcare professionals, healthcare organisations, patients and patient organisations.

Also includes any other person or organisation that is involved in the regulation, approval, control or supply of medicines, or that communicates about medicines in a professional capacity (for example a medical journalist, but excluding member company representatives) to healthcare professionals, healthcare organisations or patient organisations.

Healthcare professional

A member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of their professional activities, may prescribe, dispense, purchase, supply, recommend or administer a medicinal product.

It includes any official or employee of a government agency or other organisation (whether in the public or private sector) who may purchase, supply, recommend or administer medicinal products. It also includes any employee of a pharmaceutical company whose primary occupation is that of a practising healthcare professional. It excludes other employees of pharmaceutical companies, and wholesalers or distributors of medicinal products.

Individual pharmacists are healthcare professionals.

Healthcare organisation

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. Also, any entity through which one or more Healthcare Professionals provide healthcare services.

Wholesalers, distributors, and similar commercial intermediaries are not considered Healthcare Organisations.

Pharmacy businesses are always healthcare organisations, even if they are retailers and regardless of their ownership or ownership structure.

Patient organisations

Not-for-profit organisations which are patient-focused, and in which patients or carers form a majority of the governing body.

Fair market value (FMV)
The amount payable for goods or services that would be expected to result from negotiation between independent and well-informed parties.

The calculation of FMV takes into account:

- the nature or quality of the goods or services to be provided, and the nature of the market;
- the qualifications and experience of the provider;
- the geographic location where goods or services are to be provided;
- the prevailing commercially reasonable rates for similar goods or services in the provider's country.

Where a person or their employer/organisation is to be paid for their time in providing a service, FMV must consider the prevailing rate in the individual's country of primary practice, even if the service is provided elsewhere.

Transfer of Value

Anything of value, including monetary payments or in-kind benefits, that is provided to a recipient by a company, either directly or via an intermediary.

Chapter 3

Scope and applicability of the Medicines for Europe Code

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Chapter 3 Scope and Applicability of the Medicines for Europe Code

Who must comply with the Medicines for Europe Code

The standards and requirements of the Medicines for Europe Code are mandatory for all Medicines for Europe Members, including Member Companies, National Association Members and Affiliate Members.

Members must not use their corporate structure to knowingly avoid their responsibilities under this Code or the relevant National Association Code.

Where national rules and requirements vary from those set out in the Code, the stricter requirements shall always apply.

Companies that are not members of Medicines for Europe or its member associations may voluntarily comply with the Medicines for Europe Code and/or relevant national association codes.

Whilst company business models differ, and regulatory, legal and market factors vary from country to country, nevertheless the Medicines for Europe Code applies in its entirety and should be read in the spirit in which it is intended.

Geographical scope

"Europe" for the purposes of this Code means the member states of the EU and EFTA as well as Albania, Bosnia-Herzegovina, Kosovo, Macedonia, Montenegro, Serbia and the United Kingdom.

Russia, Turkey, Ukraine and countries outside the geographical area of Europe are not in scope of the Medicines for Europe Code.

Product scope

The Medicines for Europe Code applies to all prescription-only medicines for human use, including innovative, generic and biosimilar products.

Over the counter (OTC) products, and interactions with Healthcare Professionals that solely concern OTC products, are outside the scope of this Code. However, if a Medicines for Europe affiliated national association code applies the same standard to prescription-only products and OTC products, then the rules of the national association code shall prevail. If a product is classified as a prescription-only medicine in one or more countries and as an OTC product elsewhere, it will be in scope of the Code (including for the purposes of disclosure) only in those countries where it is prescription-only.

Professional interactions are governed by the Code

The Medicines for Europe Code covers professional interactions with any person who, in the course of their professional activities, may prescribe, dispense, purchase, supply, recommend or administer a medicinal product.

To the extent that they prescribe, dispense, purchase, supply, recommend or administer a prescription-only medicinal product, professionals such as veterinarians, opticians, chiropodists, midwives, laboratory directors, bio-medical operatives, physiotherapists, nutritionists and the like may be in scope of the Code.

Other employees of pharmaceutical companies, and wholesalers or distributors of medicinal products, are not classed as healthcare professionals.

Chapter 4

Principles

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Chapter 4 Principles

Medicines for Europe has adopted the European Commission's 'List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector'. We recognise that adherence to the principles of good governance, ethics and transparency can have a profound positive impact on healthcare policy and practice, and ultimately on patient outcomes. The fundamental principles are:

Integrity

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.

Respect

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

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

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

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.

Transparency

In order to build trust with the public, the pharmaceutical industry commits to working together with all stakeholders to set out a clear approach to full transparency of financial transactions - including non-monetary benefits - and other declarations of interest. Companies must provide relevant, qualitative, transparent and complete information to the competent authorities.

Chapter 5

Standards

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Chapter 5 Standards

These standards apply to the conduct of all company activities that are in scope of the Code, including calls on healthcare professionals, company-organised meetings including virtual meetings, the use of online platforms, and other types of interaction with the healthcare community that are not specifically described in chapter 6. Companies are responsible for activities carried out on their behalf by agencies/consultancies and must ensure that they operate to the same standards and requirements.

5.1 Non-promotion to the public

5.1 In accordance with EU and national legislation, prescription-only medicines must not be advertised to the general public.

5.2 Independence of healthcare professionals

5.2.1 Pharmaceutical companies must respect the independence of healthcare professionals, and must not interfere with the relationship and trust that exists between patients and their healthcare professionals.

5.3 Promotional and non-promotional materials and information

5.3.1 Companies may promote pharmaceutical products by providing relevant information to healthcare professionals to assist in their decision-making. Materials and information must comply with local requirements in every country in which they are used or disseminated.

5.3.2 Consistent with EU and national legislation, “off-label” promotional messages are prohibited. Companies may promote only the particulars listed in the applicable summary of product characteristics (SmPC) for their products.

5.3.3 Promotional claims and comparisons must always be scientifically up-to-date, referenced, clinically relevant, and consistent with the licensed indication and prescribing information in the relevant country.

At international congresses, including virtual international congresses, companies must make it clear which country's label is the basis for their promotional materials and remind delegates to refer to the prescribing information for their own country.

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

5.3.5 Companies should bear in mind that digital platforms are simply a channel of communication, and that requirements applicable to physical meetings or other forms of media apply also to digital and virtual interactions. Companies must ensure that their representatives use only company approved materials, whether the interaction is a conventional meeting or online.

5.3.6 Companies must not promote prescription medicines to patients or any other person that is not legally qualified to receive the information.

Company websites and other digital channels must clearly indicate content that is intended only for healthcare professionals and, to the extent required by local laws, must restrict access to the appropriate audience.

Companies may promote their corporate brand, their company and the generic industry to the public, to the extent permitted by law in the relevant countries.

5.4 Use of social media

5.4.1 Social media messages must comply with the standards set out in clause 5.3 above. Companies must be careful to ensure that materials and information is available only to appropriate recipients and that each post is acceptable when read as a standalone communication.

5.4.2 Companies should have an appropriate social media policy for their employees, to ensure that individual employee interactions with the company's social media (including forwarding, retweeting, comments and likes) do not bring content to the attention of inappropriate audiences.

5.5 Approval and withdrawal of materials for external use

5.5.1 Companies must ensure that all materials and information for use outside the company are reviewed and approved by competent reviewers before they are disseminated or used. Procedures for approval, and the identification of competent reviewers, should be consistent with local norms and applicable rules and requirements.

5.5.2 Companies must regularly review and where necessary update their materials to ensure they remain relevant and consistent with current available scientific knowledge.

5.5.3 Companies must have procedures in place, consistent with local norms and applicable rules and requirements, to withdraw outdated or superseded materials and to prevent their further use.

5.6 Location and venue

5.6.1 Meetings should be held in a location that makes the most logistical sense, considering the location of the attendees or resources necessary for the meeting. This could include major transport hubs and cities with appropriate business infrastructure.

5.6.2 A meeting may be held outside Europe in appropriate circumstances, for example if the majority of non-company attendees are based outside Europe.

5.6.3 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, regardless of facilities or price.

5.7 Hospitality

5.7.1 Companies may provide travel, hotel accommodation, meals and drinks (collectively "hospitality") in connection with a meeting, as long as such hospitality is necessary, incidental, reasonable, and secondary to the main purpose of the meeting.

5.7.2 Hospitality must be reasonable and proportionate, and never lavish or luxurious:

- Accommodation must comply with clause 5.6.3;
- Flights should be booked in economy class. Business class flights may be funded by companies only in exceptional circumstances, where justifiable and in accordance with country requirements.

5.7.3 Travel should always be on the most direct and logical route, taking into account costs to the company. Arrivals and departures should, whenever logistically possible, coincide with the beginning and end of the meeting. Companies must not fund or facilitate stop-overs (except where logistically unavoidable), recreation, side trips and trip extensions.

5.7.4 Companies should implement cost limits for hotels and meals that are consistent with the relevant countries' norms and requirements.

5.7.5 Hospitality must be offered only to people who qualify as participants in their own right. Companies must not offer, fund or facilitate 'plus ones' for any member of the healthcare community or provide such uninvited guests with anything of value, except in those rare instances where a service provider with a disability genuinely requires a carer to enable them to travel. Companies should actively discourage the accompaniment of uninvited guests on company-funded travel.

5.7.6 Companies must not provide or fund any stand-alone hospitality that is not in relation to, and necessary for, a professional meeting. The provision or funding of entertainment is never permitted.

5.7.7 Companies must not provide or fund any food or drinks for individual virtual attendees at a meeting.

If sponsoring or organising a meeting where some delegates and/or company representatives are attending virtually, companies may provide or fund appropriate food and drinks only for those healthcare professionals who are physically present as a group in an appropriate meeting location.

5.8 Fair Market Value

5.8.1 Remuneration to the healthcare community for provision of a service must be at a rate that is fair market value considering the skills, experience, job role, prominence and location of the individual performing the work.

5.8.2 Where a company sponsors an activity, the amount paid must be fair market value considering the nature and scale of the activity and any commercial benefit available to the company.

5.8.3 Where a company provides a contribution to support a healthcare organisation or patient organisation's activities, the amount must be fair market value considering the market rates for the goods or services funded.

5.8.4 The principle of fair market value also generally applies to other transfers of value to members of the healthcare community.

5.9 Cross-border activities

5.9.1 When engaging the services of or providing any transfer of value to a member of the healthcare community from a different country, companies must ensure that all applicable requirements of the individual's country of primary practice (country of registration if recipient is an organisation) are met, as well as the local country requirements.

5.9.2 When providing hospitality to a member of the healthcare community from their own country, and the individual is travelling to a different country, the rules of the host country (where the event is held) will apply as regards hotels and meals, unless the law or Code of the individual's country dictates otherwise.

5.10 Planning and documentation of activities

5.10.1 In order to respect the time and professional priorities of professionals and ensure compliance with this Code, companies should have procedures and practices in place that facilitate timely advance review of activities.

5.10.2 Companies must adequately document their interactions with the healthcare community, entering into contracts and written agreements where appropriate. They must retain appropriate records and evidence of activities and engagements, such as copies of agreements, meeting reports, proofs of service, invoices, travel arrangements, and requests for donations or other support.

5.10.3 Companies should consider whether additional internal approvals or safeguards may be appropriate for activities where company representatives, third party speakers or meeting attendees are not physically present, such as virtual conferences. This includes controls to ensure attendance only by appropriate delegates, and addressing the data protection risks inherent in digital interactions.

5.11 Transparency and Disclosure

5.11.1 Being transparent about relations or interactions between companies and the healthcare community helps to prevent unethical and illegal behaviour. Companies must therefore adhere to all disclosure requirements in the countries in which they operate. Disclosures must always comply with data privacy legislation and competition law.

5.11.2 Companies should disclose engagements and transfers of value to healthcare professionals and healthcare organisations that could potentially pose a conflict of interest, and should encourage the recipients of the transfers of value to also disclose them where this would be in the

best interest of patients or the public. For example, it is good practice (and sometimes a legal requirement) for organisations to disclose industry support on their website, and for healthcare professionals to disclose industry-funded consultancies and sponsorships in speaker slides.

Disclosure procedures for companies, and transfers of value within scope, are set out in chapter 7 of this Code.

5.11.3 Activities that fall outside the scope of the Medicines for Europe Code, for example commercial rebates to pharmacy customers, must always be in compliance with applicable rules and requirements but are by definition not disclosable under this Code.

Chapter 6

Requirements for specific types of company activities

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Chapter 6 Requirements for specific types of company activities

All company activities in scope of the Medicines for Europe Code, including those not specifically described in this chapter, must be conducted in accordance with all applicable standards set out in chapter 5.

Meetings between companies and healthcare professionals (including employees of healthcare organisations) can be mutually beneficial. Meetings may be held for educational, scientific, research, or promotional purposes, but meetings and other company activities must never be used to improperly influence any member of the healthcare community.

6.1 Sponsorship of third party activities

6.1.1 Where locally permitted, companies may sponsor meetings, events or projects directed at healthcare professionals that are relevant to the company's therapeutic areas or business interests. The sponsorship may be direct, by providing funding to the organising healthcare institution, association or medical society, or indirect via that organisation's agency. An example of event sponsorship would be for a company to pay for an exhibition table or booth space, or to fund the meeting catering.

6.1.2 In return for sponsorship, a company generally receives commercial benefits such as advertising opportunities, booth or exhibit space, distribution of promotional material, company branding of banners and materials, or similar acknowledgments. Companies must consider the appropriateness of sponsor benefits and ensure that they are commensurate with the amount of sponsorship and the size and nature of the meeting.

6.1.3 Before committing to sponsoring any event, companies should ensure they have sufficient detail about the nature of the event, the programme content and any associated hospitality. Companies are responsible for ensuring that their sponsorship will be used only for the stated purpose and will not subsidise activities that do not meet the standards and requirements of the Medicines for Europe Code.

6.1.4 Companies are forbidden to provide standalone hospitality or entertainment for members of the healthcare community, therefore company sponsorship must not directly or indirectly fund or subsidise recreational or entertainment activities for delegates. The organising institution or association must finance any cultural or social aspects of the event programme from other funds and not from pharmaceutical company sponsorship.

6.1.5 Transfers of value to healthcare organisations and patient organisations under clause 6.1 are disclosable in accordance with chapter 7 of this Code.

6.2 Educational support for healthcare professionals

6.2.1 Where locally permitted, companies may support scientific, medical, pharmaceutical and professional education by funding individual healthcare professionals to attend meetings and conferences that educate them in areas relevant to their field. Educational support may be provided to attend appropriate company-organised events as well as for congresses and conferences organised by third parties. Meetings, congresses and conferences may be face to face, virtual (online) or a combination of both.

6.2.2 Any physical or virtual meeting which a company supports a healthcare professional to attend must:

- primarily consist of scientific, educational and professional content;
- be in a therapeutic area in which the healthcare professional currently practises; and
- be directly related to the company's therapeutic areas.

6.2.3 Companies may cover the costs of event registration, travel, accommodation and reasonable hospitality, all of which must comply with the standards set out in chapter 5 of this Code, including in particular clauses 5.6 Location and venue, 5.7 Hospitality, and 5.9 Cross-border activities.

6.2.4 Decisions about who receives educational support must be based on objective criteria related to the educational needs of the recipient and the educational value of the programme. The selection criteria might include, for example:

- the healthcare professional's existing knowledge and experience, and relevant educational needs;
- their reputation and standing in the scientific or medical community, along with the likelihood that they will willingly and effectively share the knowledge gained with other healthcare professionals;
- the resources of the institution that employs them;
- the location and convenience of the event relative to their usual place of work;
- for meetings abroad, whether an alternative event in their home country might offer similar educational opportunities; and
- the potential impact on the quality of patient care.

A healthcare professional's experience with the sponsoring company's products may be taken into consideration, but not their prescribing behaviour or volume of prescriptions.

6.2.5 Companies must not finance the attendance of individual healthcare professionals on courses certified by accredited institutions of further education (for example Masters degrees, asthma diplomas) or modules contributing to postgraduate qualifications, because these are not educational meetings or conferences, and they would provide a significant personal benefit to the individual which is not permissible under the Medicines for Europe Code.

This clause does not preclude the funding of appropriate educational grants or scholarships to healthcare organisations or relevant academic institutions where the company has no involvement in the selection of the individual recipients. Companies must not proactively engage with individual beneficiaries for the duration of their studies, and not subsequently improperly differentiate them from other healthcare professionals on the basis of the grant/scholarship.

6.2.6 Transfers of value to healthcare professionals under clause 6.2 are disclosable in accordance with Chapter 7 of this Code.

6.3 Site visits

6.3.1 A tour of a company's manufacturing, distribution or R&D facilities can help healthcare professionals and customers to better understand a company's core manufacturing capabilities, technology and operations, which supports their decision-making. As such, site visits must have genuine educational value and should not be organised as a promotional opportunity.

6.3.2 All site visits must have a specific and detailed agenda that correlates with the defined educational objective. The agenda should include a full timetable, sufficient description of each session's content, the title of every presentation and, if possible, the name and job title of all speakers.

6.3.3 Companies should invite healthcare professionals to visit only the site that is the most logistically practical to fulfil the educational objectives. If it is crucial for a company to organise a site visit outside the healthcare professionals' home country in order to do so, this is permissible so long as the arrangements comply with all applicable rules and requirements including the standards set out in this Code.

6.3.4 It is rarely acceptable for companies to arrange a site visit as an “add on” to congress attendance or to organise an advisory board meeting in conjunction with a site visit. Attendees for each separate activity must be appropriate, and therefore must be selected in accordance with the same criteria as would be applied to a standalone event.

6.3.5 Transfers of value to healthcare professionals under clause 6.3 are disclosable in accordance with Chapter 7 of this Code.

6.4 Fee for service and consultancy

6.4.1 Expert advice and support from healthcare professionals, healthcare organisations and patient organisations helps the industry to make decisions that ultimately benefit patient care. Companies may engage appropriate experts from these segments of the healthcare community to provide necessary services, including:

- serving as experts on advisory boards
- speaking engagements
- participating in research
- participating in focus groups or market research
- training and educating on products.

6.4.2 A company must have a legitimate business need for the particular service and intend to make appropriate use of the work done. This need for the services must have been identified and documented before the company makes any arrangements. Companies must not create meetings or work for the sake of it, as a means of paying experts or keeping them engaged.

6.4.3 Market research must not be used as a mechanism for channelling non-disclosable payments to a particular group of healthcare professionals. If a company provides the agency with a list of potential targets (for example a customer satisfaction survey conducted with pharmacies), this cannot be considered truly anonymous if a significant proportion of those listed will be respondents.

6.4.4 Experts must be selected and engaged as service providers based only on their qualifications, expertise and abilities to provide the service. Company personnel responsible for selecting experts must have the expertise necessary to evaluate whether the proposed experts are appropriate considering the specific identified need.

6.4.5 When companies organise fee for service activities in conjunction with congress attendance or a site visit, the attendees for each separate activity must be selected in accordance with the same criteria as would be applied to a standalone event.

6.4.6 Companies should engage only as many experts as are necessary, and only for as long as is reasonably necessary, to achieve the identified business need.

6.4.7 Companies must be mindful of healthcare professionals' reputation and not engage any individual with a frequency that could be viewed as excessive, bearing in mind the availability of alternative experts.

6.4.8 All engagements must be confirmed in writing, clearly detailing the services and amount of compensation.

6.4.9 Wherever possible, an expert should be contractually obliged to (a) 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; and (b) if applicable, disclose the engagement to their employer.

6.4.10 In accordance with clause 5.8.1 of this Code, companies must pay no more than fair market value for services, and pay only for work performed. Where it has been not possible for an expert to complete all their contracted deliverables, the company may pay fair market value for those deliverables that have actually been provided.

6.4.11 Sometimes healthcare professionals or other experts providing contracted services ask for their fee to be donated to charity. Companies are prohibited from doing this.

6.4.12 Transfers of value to healthcare professionals, healthcare organisations and patient organisations under clause 6.4 are disclosable in accordance with Chapter 7 of this Code.

6.5 Educational materials, medical utility items, promotional items and gifts

6.5.1 Companies may occasionally provide educational materials, inexpensive medical utility items and inexpensive promotional items (for example a pen) to individual healthcare professionals, where legally permitted and in accordance with national requirements and norms.

6.5.2 All such items must be:

- aimed directly at the education of healthcare professionals and patient care; or
- relevant to a healthcare professional's professional duties and ultimately benefit patients, patient care or the practice of medicine or pharmacy.

They must never provide a personal benefit to healthcare professionals or be used to improperly influence them.

6.5.3 Companies must not provide items that would offset the routine costs of operating a healthcare practice, so it is forbidden to give medical supplies that are normal and necessary for the day-to-day practice of medicine such as tongue depressors, latex gloves, masks, wipes, dressings and similar items.

An occasional inexpensive item will not be considered as offsetting the costs of practice, but even an item that is acceptable when provided singly will be inappropriate if given in large quantities or on a frequent basis.

When medical utility items are needed during public health emergencies or disaster relief, deviations from this clause will be permissible only to the extent agreed upon by Medicines for Europe. In general the recipients will be healthcare organisations or governmental agencies rather than individual healthcare professionals, and such benefits in kind will be disclosable as donations in accordance with chapter 7 of this Code unless classified differently under local law.

6.5.4 Companies must not give cash or cash equivalents. Items that could be easily resold or used to generate income are prohibited.

6.5.5 Personal gifts to healthcare professionals, such as flowers or chocolates to mark a birthday, festival or national holiday, are prohibited in all countries.

6.5.6 Items provided to individual healthcare professionals in accordance with this clause are not disclosable under the Medicines for Europe Code, although they may require disclosure under national rules and requirements.

6.6 Samples

6.6.1 The purpose of medical samples is to help authorised prescribers familiarise themselves with certain products and acquire experience in dealing with them. Samples of prescription-only medicinal products may be given only to prescribers.

6.6.2 Samples may be provided only in response to an unsolicited written request from the healthcare professional.

6.6.3 Companies may provide medical samples only by exception and on an occasional basis, in accordance with local legal restrictions on amounts and frequency.

6.6.4 Samples must not be resold by the healthcare professional and the product packaging must clearly indicate this. Medical samples are not disclosable under this Code.

6.6.5 Companies must establish and maintain appropriate controls for distribution of samples. Arrangements for delivery must comply with national legislation.

6.7 Social contributions

6.7.1 Companies may contribute to the communities they serve by making financial and in-kind donations to healthcare organisations and patient organisations to support healthcare goals. Legitimate purposes include support for:

- scientific research;
- medical education;
- patient education;
- patient access to healthcare; and
- the overall development of healthcare systems.

6.7.2 A company may also support community and charitable initiatives. Contributions may be provided to recognised charities, civic organisations or not-for-profit institutions.

6.7.3 All recipients of contributions must have as their primary purpose a charitable or philanthropic objective.

Contributions may be provided to a for-profit healthcare entity only if it passes its entire profit to the government or a public institution. Companies must not subsidise or contribute to the profitability of a private enterprise, therefore donations are prohibited (a) if the entity has private shareholders, or (b) if any healthcare professional would benefit financially.

6.7.4 Contributions must never be provided to individuals, or for the benefit of specific individuals (except for the donating company's employees and their families).

Even though a cash donation to cover the same activity would not be permissible under this Code, company provision of appropriate screening services and the like in primary care (general practice) may be acceptable where permitted by national laws and guidance, and on condition that no healthcare professional would benefit financially. This type of support is a disclosable in-kind donation to the practice (organisation) rather than to the requesting healthcare professional.

Note that research grants, and educational sponsorship for healthcare professionals, are not deemed to be 'contributions' for the purposes of this clause.

6.7.5 Companies may give a contribution only in response to an unsolicited and independent request from the potential recipient; that is, a request initiated by the organisation without any prompting from the company. A public appeal by a charity will meet this requirement.

In exceptional circumstances, companies may proactively donate if:

- all other requirements of section 6.7 are met; and
- the donor company does not have, and is not reasonably likely to have, any commercial interest in relation to the recipient organisation's activities.

Deviations from this clause for the purposes of public health emergencies or disaster relief will be permissible only to the extent agreed upon by Medicines for Europe.

6.7.6 Unrestricted contributions to healthcare organisations, meaning donations that are not tied to a specific project or activity, are prohibited. A company must therefore ensure it has a sufficient understanding of how the funds are intended to be used. The request must include a detailed description of the organisation's needs, the programme or project, and the overall budget, as well

as the amount being sought from the company. This requirement is considered to be met where a company is responding to a public appeal by a charity of national or international renown.

6.7.7 Companies should perform sufficient due diligence on a proposed recipient to assure the legitimacy of the organisation, its financial stability, and that the contribution would not present a conflict of interest risk.

6.7.8 Companies must have an approval process for contributions. The approval process must be independent of all commercial considerations, and sales personnel must not be involved.

6.7.9 Transfers of value to healthcare organisations and patient organisations under clause 6.7 are disclosable in accordance with Chapter 7 of this Code.

6.8 Interactions with patients and patient organisations

6.8.1 To maintain the independence and credibility of patient organisations, no company may seek to be the sole funder of a patient organisation or any of its major programmes.

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

6.8.3 If requested by a patient organisation, a company may contribute to the drafting of material from a fair and balanced scientific perspective. Companies may also correct factual inaccuracies. However, companies must not have editorial control over the text of patient organisation material they support and must not seek to influence the content in a manner favourable to their own commercial interests.

6.8.4 The public use of a patient organisation's logo or proprietary material by a company requires written permission from that organisation. When seeking permission, the company must clearly state the specific purpose and how the logo or proprietary material will be used.

6.8.5 When a company provides financial support, significant non-financial support (for example product or equipment) or significant indirect support (for example the donation of a public relations agency's time) to a patient organisation, there must be a written agreement that clearly sets out:

- the amount of funding;
- the purpose e.g. unrestricted grant, sponsorship of a specific meeting, or to support a publication;
- if applicable, a description of any significant non-financial support; and
- if applicable, a description of any significant indirect support including the specific nature of the other party's involvement.

6.8.6 Sponsorship and contributions must comply with the requirements set out in clauses 6.1 and 6.7 respectively.

6.8.7 Companies are permitted to engage patient organisations to provide services only for the purpose of supporting healthcare or research. For example, patient organisations may supply experts to participate in advisory board meetings or as a speaker at an educational meeting. Fee for service arrangements must comply with the requirements set out in clause 6.4.

6.8.8 Companies must have an approval process for donations to, sponsorship of, and contracted services from patient organisations. The approval process for donations must be independent of all commercial considerations, and sales personnel must not be involved.

6.8.9 Transfers of value to patient organisations under clause 6.8 are disclosable in accordance with chapter 7 of this Code.

6.8.10 Patient support programmes (PSPs) are company-funded non-promotional arrangements that help consenting patients or carers, either directly or via their doctor, to better understand and/or manage their disease. Examples of PSPs include the provision of third party nurses to assist individuals with drug administration, a patient helpline, or periodic contact to check adherence to medication. The arrangements for PSPs must comply with all relevant standards and requirements of this Code.

Selection and management of PSP vendors, and decision-making about PSPs, are typically within the company's medical function with significant support from pharmacovigilance, and must be independent of sales and marketing personnel.

Chapter 7

Disclosure procedures

Code of Conduct 2020

Chapter 7 Disclosure procedures

This chapter applies to the disclosure of transfers of value from 1 January 2021, when this version of the Medicines for Europe Code comes into effect. Transfers of value relating to 2020 activities and disclosed in 2021 are governed under the prior version of this Code.

7.1 Responsibility for disclosing transfers of value

7.1.1 Transparency about interactions between companies and the healthcare community helps to prevent unethical and illegal behaviour. The Medicines for Europe Code therefore requires companies to disclose the types of transfers of value where there might be a conflict of interest.

7.1.2 A company must disclose transfers of value made by third parties on its behalf, if the company knows or has access to the identities of the recipient(s). These indirect transfers of value are to be treated for disclosure purposes as though they were made directly by the company.

The status and nature of the intermediary party (for example travel agency, events management company or distributor) is immaterial. If the transfer of value arises from an activity in scope of this Code and ultimately under the pharmaceutical company's control, then the company must disclose it. Companies should ensure that their intermediaries' obligation to provide data to them for disclosure reporting is addressed in their contractual arrangements.

7.1.3 A company must report transfers of value that are within scope of this Code made by its head office, regional office or other country offices of the same company, regardless of the member company's local office involvement in the activity."

7.1.4 Where this chapter states that the nature of the transfer of value must be described, the description given must be sufficiently complete to enable a member of the public to understand what the arrangement between the company and the recipient was. There is no need and no obligation to divulge confidential information.

7.2 Scope of disclosure

7.2.1 Companies must publish disclosure data relating to the following transfers of value (whether directly or indirectly funded) made to healthcare professionals, healthcare organisations or patient organisations:

- Fee for service (excluding associated expenses)
  except fees paid in connection with research & development activities or anonymous market research;
- Registration fees to attend a third party congress/conference;
- Travel and accommodation provided to delegates to attend a meeting – including third party meetings, company organised meetings and site visits;
- Grants and donations, both financial and in-kind, to organisations that are part of the healthcare community;
- Sponsorship of healthcare organisations' and patients organisations' activities and events.

7.2.2 The research & development exception applies only to fees paid. Equipment provided to a healthcare organisation for the purposes of a study does not need to be disclosed as long as the equipment is taken back at the end of the activity. If equipment is left in the possession of the healthcare organisation, it must be disclosed as a donation at the current fair market value of the equipment.

7.2.3 The market research exception in respect of fees applies only to genuinely anonymous market research where it is not possible for the company to know or deduce the identity of respondents.

7.2.4 If there is no direct cost (other than food and drinks) connected to a meeting, there is no transfer of value to disclose. For company organised meetings, items such as room rental and audiovisual support do not confer any benefit to individual delegates and are not transfers of value.

7.2.5 Transfers of value relating solely to OTC products and other non-prescription medicines are out of scope of this Code and therefore out of scope of disclosure, unless national requirements or local codes require them to be included.

7.2.6 If a company's product portfolio includes both prescription-only and non-prescription-only products, then meetings, activities and transfers of value that solely or partly involve prescription-only medicines are to be regarded as being fully within scope of disclosure under this Code.

7.2.7 Activities outside the scope of the Code, for example rebates, or the sale of advertising space not linked to sponsorship of materials, are by definition out of the scope of disclosure.

7.3 Period and frequency of disclosure

7.3.1 The reporting period for transfer of value disclosures is the full calendar year.

7.3.2 Disclosure data must be published annually.

7.3.3 Companies should disclose as early as possible, and by no later than 30 June of the year following the reporting period. In some countries, local requirements may dictate an earlier deadline.

7.4 What to disclose and how – healthcare professionals

Fee for service

7.4.1 Fee for service is always disclosed on an individual named basis (unless the healthcare professional refuses consent for disclosure in accordance with clause 7.7.2 below).

7.4.2 The amount disclosed for each healthcare professional is the total of all honoraria for the reporting period.

7.4.3 Expenses directly related to performance of the contracted service (for example travel, accommodation and meals) are not disclosable.

7.4.4 If a healthcare professional provides contracted services through a consultancy or personal services company controlled by them or their family, then for disclosure purposes the engagement is to be treated as if the transfer of value was made to the individual.

7.4.5 If the company contracts with an organisation for the services of a specific healthcare

professional whom they employ, then for disclosure purposes the engagement is to be treated as if the transfer of value was made to the individual, even if the individual performing the service was not directly compensated.

Support to attend meetings as a delegate

7.4.7 In this category, 'support' refers to transfers of value during the reporting period in the form of:

- Registration fees to attend a third party congress/conference, including virtual meetings;
- Travel and accommodation to attend a meeting – including third party meetings, company organised meetings and site visits.

7.4.8 Companies must choose one of two options for presenting their disclosures in this category:

- 7.4.8.1 Option 1 – disclosing how many events each named healthcare professional has been supported to attend, without giving any financial information.

  For each healthcare professional state:
  - The healthcare professional's name
  - Number of third party meetings attended in their country of primary practice (includes provision of registration to virtual meetings)
  - Number of third party meetings attended elsewhere within Europe
  - Number of third party meetings attended outside Europe
  - Number of site visits attended in their country of primary practice
  - Number of site visits attended elsewhere within Europe
  - Number of site visits attended outside Europe
  - Number of company organised meetings attended in their country of primary practice
  - Number of company organised meetings attended elsewhere within Europe
  - Number of company organised meetings attended outside Europe

- 7.4.8.2 Option 2 – disclosing the total cost of each specific meeting, and the total number of healthcare professionals supported to attend, without naming the delegates.

  For each meeting state:
  - The name of the congress, meeting or site visit
  - The total spent on registration fees*, travel and accommodation for all healthcare professionals
  - Number of healthcare professionals financially supported to attend

  *Refer to clause 7.4.10 as regards the disclosure value of 'free' conference registrations.

7.4.9 Meals included as part of a conference registration 'package' are relatively insignificant and should not be deducted.

7.4.10 Where a company receives a number of free conference registrations as part of a sponsorship package and gives these to healthcare professionals, the deemed value of the transfer will be the price that individual recipients would have paid for themselves at the time the arrangements were made.

7.5 What to disclose and how – healthcare organisations

7.5.1 Transfers of value to healthcare organisations must be disclosed on a named basis. No consent is required.

Fee for service

7.5.2 The amount disclosed for each healthcare organisation is the total of all honoraria for the reporting period.

7.5.3 Expenses directly related to performance of the contracted service (for example travel, accommodation and meals) are not disclosable.

7.5.4 If the company contracts with an organisation for the services of one or more healthcare professionals whom they employ and there is no requirement for specific individuals to perform the work, then for disclosure purposes the engagement is to be treated as if the transfer of value was made to the organisation.

Grants and donations

7.5.5 The amount disclosed for each healthcare organisation is the total of all contributions in the reporting period made in accordance with clause 6.7 of this Code.

7.5.6 For each healthcare organisation, companies must include a brief description of the nature of the contribution(s) (for example research grant, equipment donation, product donation) and, where not obvious, its purpose (for example "to increase lung cancer screening capacity" or "to support pandemic relief").

7.5.7 In-kind contributions to a healthcare organisation must be disclosed at fair market value, even if the donating company has written off all or part of the value in its own books.

Sponsorship of activities and events

7.5.8 The amount disclosed for each healthcare organisation is the total of all sponsorship for the reporting period made in accordance with clause 6.1 of this Code.

7.6 What to disclose and how – patient organisations

7.6.1 Transfers of value to patient organisations must be disclosed on a named basis. No consent is required.

Fee for service

7.6.2 The amount disclosed for each patient organisation is the total of all honoraria for the reporting period.

7.6.3 Expenses directly related to performance of the contracted service (for example travel, accommodation and meals) are not disclosable.

7.6.4 For each organisation, companies must include a brief description of the nature of the services provided.

Support in the forms of grants, donations and sponsorship of activities and events

7.6.5 The amount disclosed for each patient organisation is the total of all sponsorship support and contributions in the reporting period made in accordance with clauses 6.1 and 6.7 of this Code.

7.6.6 For each patient organisation, companies must include a brief description of the nature of the sponsorship or contribution(s) (for example to fund a disease awareness day, to cover the cost of a newsletter, or general support for the organisation's running costs).

7.6.7 In-kind contributions to a patient organisation must be disclosed at fair market value, even if the donating company has written off all or part of the value in its own books.

7.6.8 Where exceptionally a company gives significant non-financial support that cannot be assigned a meaningful monetary value, it must clearly describe the non-monetary benefit that the patient organisation receives.

7.7 Privacy and consent

7.7.1 In accordance with clause 5.11.1 of this Code, companies must ensure that their disclosures comply with data privacy requirements. Subject to national legislation and codes within each country, companies must have informed consent from an individual before publishing on a named basis the transfers of value made to them.

7.7.2 If local rules permit opt-out and a healthcare professional does not consent to named disclosure, the company must publish that person's disclosure data without identifying them. If multiple healthcare professionals refuse consent, their transfers of value must be aggregated by category and the number of recipients in aggregate indicated as is shown in the disclosure template (appendix 1).

7.7.3 If a healthcare professional withdraws consent for the disclosure of their data, the reporting company must update the published disclosure report with that person's data aggregated as soon as possible, and within 30 days after receiving the withdrawal request

7.8 Company's methodological note

7.8.1 Along with its disclosure data, each company must publish the methodology which they have applied in preparing the disclosure and identifying transfers of value in each category. The methodological note should also explain the treatment of:

- multi-year contracts;
- taxes, including whether or not VAT has been included;
- currency and exchange rate where applicable;
- issues related to the timing and amount of transfers of value for the purposes of disclosure – for example, the company's approach where an event happened during the reporting year (so liability to pay was incurred) but the speaker has not yet invoiced the company.

7.8.2 Companies must comply with the requirements and norms in each country as regards the

inclusion or exclusion of tax and VAT in the reporting data. Where no rules are in place, the company should decide on its approach and explain this in the methodological note.

It is worth considering that the value to an individual recipient of a benefit in kind (such as an event registration or flight) is the price that they would have paid personally, and this includes VAT and sales tax where applicable. In contrast, if a service provider has added VAT to their invoice, the VAT has to be paid forward to the country's tax authority, therefore it could be argued that the VAT is not a benefit to the recipient and does not form part of the value transferred to the individual. Different types of transfer of value may be treated in different ways; companies must decide on their approach for each class of activity and document this in the methodological note.

7.8.3 Companies must comply with the requirements in each country, where applicable, as regards the currency of disclosure. Otherwise and in general, where a transfer of value was not in the local currency (for example a fee paid to a speaker from another country), the company should convert the reportable amount into the currency used for disclosure and explain the approach in their methodological note

7.9 Platform, location and format of disclosure

7.9.1 Companies must disclose transfers of value so that the information is easily accessible to the public. Where locally required this should be the national platform designated by a government, regulatory authority body, or a Medicines for Europe national association. Alternatively (or additionally) companies may publish disclosure data on their own website.

7.9.2 For 2021 transfers of value (to be disclosed by June 2022), companies may elect to publish their disclosures either in the recipients' countries of primary practice, or in the countries of the contracting affiliates, or in the country where their European regional office is located.

For transfers of value on or after 1 January 2022 (to be disclosed by June 2023) and in subsequent years, companies must publish their disclosures in the recipients' countries of primary practice, except where there is no local commercial affiliate (see 7.9.3).

Companies may additionally publish disclosures in the countries of the contracting affiliates and/or in the country where their European regional office is located.

7.9.3 For transfers of value on or after 1 January 2022 (to be disclosed by June 2023) and in subsequent years, if a company is publishing transfers of value based on recipients' countries but the company does not have affiliates in all the relevant countries, they must publish those particular disclosures at European level.

Companies may additionally publish disclosures in the countries of the contracting affiliates.

7.9.4 Companies must comply with relevant national requirements in each country where they publish their disclosures, including the local Medicines for Europe national association's Code. Where there is no national association or local code, companies must follow the requirements of the Medicines for Europe Code.

7.9.5 This Code sets the minimum standard for disclosure of transfers of value. If local requirements differ, companies must always follow the stricter requirements. Any such differences should be

addressed in the company's methodological note.7.9.6 Where national disclosure requirements do not address all categories of disclosure required by this Code, for example as regards patient organisations, companies must disclose these additional transfers of value on their own website or in another appropriate manner.

7.9.7 The Medicines for Europe disclosure template (appendix 1) provides an appropriate format that clearly distinguishes between categories of recipient (healthcare professional, healthcare organisation or patient organisation) and between different types of transfer of value. Companies may use this or a similar presentation, so long as the disclosure data described in clauses 7.4-7.6 is clearly set out and the format readily understandable to the general public.

7.9.8 It is acceptable for companies to publish their disclosure report in the form of a searchable database, where locally permitted, provided it is searchable both (a) by a recipient's name and (b) by their location or professional registration number/organisation registered number.

'Location' means the city where an individual practises professionally or where an organisation is registered or operates.

Database search results must include:

- recipient's name (except healthcare professionals who have not consented to disclosure);
- disclosure data for that recipient, as set out in clause 7.4, 7.5 or 7.6 as applicable;
- the total transfer of value amounts by type for all healthcare professionals, healthcare organisations or patient organisations as applicable.

In countries where companies require healthcare professionals' consent to disclosure, a search for an individual whose name is not in the report should display the aggregated healthcare professional disclosures. The individual may not have received any transfers of value from the company, or they may have refused to consent to disclosure; it should if possible be made clear to the reader that no assumption either way can be made.

7.10 Other acceptable forms of disclosure

7.10.1 Medicines for Europe member companies do not need to disclose transfers of value under the Medicines for Europe Code if they fully report the same transfers of value in accordance with:

- either the transparency reporting regime of another self-regulatory association (such as EFPIA or one of its national associations)
- or national laws and regulations governing transparency.

This is on the condition that the scope and substance of the reporting is at least as thorough and detailed as is required in this Code, and that the disclosure data is publicly available.

7.10.2 If the local disclosure regime does not fully cover the requirements set out here, companies must additionally report transfers of value in accordance with this Code.

7.11 Retention requirements

7.11 Companies are responsible for ensuring that their disclosure information is accessible online for at least one year, when it should be replaced by the next year's data. In some countries, local law or regulations may require a longer retention period.

Chapter 8

Enforcement procedures

Code of Conduct 2020

Chapter 8 Enforcement procedures

Member companies are accountable for addressing and correcting infringements of the Medicines for Europe Code and/or the codes of national associations, and are encouraged to report potential violations.

The Medicines for Europe Code enforcement procedure is without prejudice to the rights of member companies and national associations to also bring matters to the attention of competent regulatory authorities. However, complainants should not initiate enforcement proceedings under this Code where a case on substantively the same matter has already been brought under another applicable code of conduct (for example EFPIA or one of its member associations).

Medicines for Europe national associations are obliged to have procedures in place for complaint, appeal and enforcement procedures. The preference is for a self-regulatory process, except where national requirements necessitate additional co-regulatory mechanisms. Companies must follow the enforcement procedures set out by the relevant Medicines for Europe national association. Note that occasionally a national association may transfer a claim to the Medicines for Europe Secretariat for adjudication. However, companies may not appeal the enforcement decisions of national associations, whose appeal process is final.

Where exceptionally there is no Medicines for Europe national association, or no effective and operational national complaint and enforcement procedure, the complaint may follow the Medicines for Europe process summarised below and detailed in the rules of procedure (appendix 2).

If the company alleged to have breached this Code is not a member of a national association, but is (or its parent is) a Medicines for Europe member, it will be subject to this Medicines for Europe process.

Non-member companies, healthcare organisations, patient organisations, healthcare professionals, members of the public, company employees or other stakeholders may make a complaint either under the national procedure (where permissible) or following the process below. For further details on managing each stage of the process please refer to the detailed requirements and guidance given in the enforcement rules of procedure (appendix 2).

Where it is in the best interests of an individual complainant to withhold their identity from the company alleged to be in breach, they may raise the complaint directly to the national association or to the Medicines for Europe Secretariat, who must protect the complainant's confidentiality. Individual complainants who wish to remain completely anonymous in accordance with Directive (EU) 2019/1937 (the 'Whistleblower Directive') are encouraged to report their concerns to the competent local regulator or to the relevant company's whistleblowing hotline.

Inter-company dialogue

A complainant who believes that a company has violated this Code should in the first instance report the alleged violation to the company in breach, at an appropriate level of seniority. The two parties shall work to resolve the matter between themselves, in good faith and in the spirit of the Medicines for Europe Code. Inter-company dialogue is confidential between the parties and the correspondence should be limited to what is necessary to discuss and where possible resolve the alleged violation, in compliance with competition law. In any event, discussions between companies will take place in compliance with competition law.

Formal complaint

If they cannot resolve the matter to their mutual satisfaction, either party may escalate it to the Medicines for Europe Secretariat. The complainant must submit a detailed written complaint.

Case preparation

Upon receipt of a complaint, the Medicines for Europe Secretariat will coordinate preparations for a hearing. The parties to the complaint must comply with all deadlines for information and responses advised by the Secretariat.

Complaint hearing

Complaint cases are heard by a review committee of three people who have no conflicting interests with the parties involved in the matter. The complainant and the respondent company are entitled to be represented. The review committee will adjudicate on the complaint and put its findings in writing.

Hearings are conducted in English and, unless all parties agree otherwise, will be held in Brussels.

Findings and sanctions

Following the conclusion of the case and if applicable any appeal, a company found in breach of the Code must take corrective actions to immediately stop the non-compliant activities or practices. To prevent recurrence of the breach, the company must implement any further remedial measures imposed by the review committee.

The committee may recommend further sanctions against a member in egregious or repetitive cases, or in circumstances where a company's activities have been such as to potentially bring the pharmaceutical industry or the generics and biosimilars sector into disrepute. In these circumstances, Medicines for Europe members may, in accordance with Medicines for Europe's bylaws and the applicable legislation, expel a company from membership.

Publication of case reports

Complaint decisions are made public. A case report summarising the essential details will be published promptly on the Medicines for Europe website, and will be reproduced in the Medicines for Europe annual report and on the relevant national association websites.

Appendix 1

Disclosure template

Code of Conduct 2020

Appendix 1 Disclosure template

Name of Recipient	Location of the Organisation	Date	Location of the Event	Purpose/ Description of the ToV	Expense Details	Aggregated Amount/ Value
Total						

Appendix 2

Enforcement rules of procedure

Code of Conduct 2020

Appendix 2 Enforcement rules of procedure

A2.1 Form and content of a complaint

A2.1.1 Complaints must be in writing and in English.

A2.1.2 Complaints may be sent either by email to complaints@medicinesforeurope.com or by post to:

Director General
Medicines for Europe
50 Rue d'Arlon
Brussels 1000
Belgium

A2.1.3 Complaints from companies or organisations must be signed by an appropriate legal representative.

A2.1.4 For a complaint to be admissible, the complainant must set out their concerns in sufficient detail as follows:

- Complainant's full name and contact details;
- Name the Medicines for Europe member company (and if applicable its relevant subsidiary);
- Set out specific allegations, including facts relating to location and date of the alleged breach(es);
- Clearly specify which clauses/paragraphs of the Code have allegedly been breached;
- Include concrete evidence to substantiate the complaint. To ensure procedural fairness, complaints without supporting evidence will not be accepted;
- If inter-company dialogue has failed, include evidence of this and provide contact details of the person at the respondent company who participated in the inter-company dialogue.

A2.1.5 If the complainant is a pharmaceutical company, there will be an administrative fee of 2,500 euro for each Code clause alleged to have been breached. The respondent company will be liable for payment of the complaint fee in respect of those allegations that are subsequently upheld.

A2.2 Case and hearing preparation

A2.2.1 All complaints and related documents must be treated confidentially throughout the process and will be marked as confidential when distributed to parties involved in managing the case.

A2.2.2 The Medicines for Europe Director General will acknowledge receipt of a complaint within 5 working days.

A2.2.3 If the complainant is an individual, the Medicines for Europe Secretariat will check their credentials before proceeding with case preparation, and may ask the complainant for proof of their identity. Further deadlines will run from when the Secretariat has verified the complainant's identity.

A2.2.4 Within a further four weeks, the Medicines for Europe Director General will enact the Medicines for Europe Executive process to jointly assess the admissibility of the complaint.

A2.2.5 If the complaint is out of scope of this Code, the Secretariat will write to the complainant explaining why it will not be further processed.

If the complaint requires further explanation or clarification, or if insufficient evidence has been provided by the complainant, the Secretariat will write to them requesting further information. Further deadlines will run from when this is received.

If after this there is insufficient evidence of a Code breach and it is, on balance, unlikely that the complaint would be upheld at a hearing, the Medicines for Europe Director General may nonetheless if it is appropriate write to the company alleged to be in breach offering guidance and reminders on the relevant standards and requirements of this Code. The complainant will not be identified and no case report will be published, however, the Executive may take further steps such as an investigation if there are multiple similar reports relating to a member company.

A2.2.6 If the complaint is admissible, the Secretariat will promptly send a copy of it by registered post to the company alleged to be in breach. The covering letter will give the respondent company a deadline of four weeks from the date of the letter to provide a full written response.

Copies of the letter and complaint will be sent by registered post to the complainant and to Medicines for Europe Executives.

Where the complainant is an individual (healthcare professional, member of the public or company employee) who wishes their identity to be withheld from the respondent company, the Secretariat is responsible for ensuring that identifying details are redacted from all correspondence.

A2.2.7 The respondent company must reply to the Secretariat by the deadline, using registered post, with their full response to the complaint.

A2.2.8 The Secretariat will send copies of the response by registered post to the complainant and to Medicines for Europe Executives.

A2.2.9 If the respondent company has admitted to the breach and given an appropriate and adequate undertaking to end, correct or otherwise mitigate the breach, then no hearing will be necessary. The respondent company will be liable to pay the complaint fees and a case report will be published in accordance with section A2.6.

A2.2.10 Whilst awaiting the respondent company's response, Medicines for Europe Executives will select and appoint a review committee of three people to adjudicate the case:

- One Medicines for Europe Secretariat member,
- One Medicines for Europe national association,
- One external independent expert (arbitrator or lawyer) to chair the hearing.

Committee members must confirm that they have no conflicting interests with the parties involved in the matter.

The Medicines for Europe Executive Committee may periodically appoint a standing review committee.

A2.2.11 The review committee may define specific rules of procedure for the case, seek additional clarifications from the parties involved, and request that specific company representatives appear at the hearing in person.

A2.2.12 The complainant and the respondent company must submit all information and evidence by the deadlines set by the review committee. Failure to meet the deadlines will not subsequently be any basis for appeal.

A2.2.13 The review committee is entitled to engage external experts in relation to the case if required.

A2.2.14 The cost of the hearing consists of the fee of the independent review committee member, and travel and accommodation costs for all three members of the review committee.

If the complaint is upheld, the respondent company will bear the cost of the hearing.

If the complainant is a pharmaceutical company and the complaint is not upheld, the complainant will bear the cost of the hearing.

If a pharmaceutical company complaint alleges breaches of multiple clauses of this Code and some but not all are upheld, they will bear a reasonable and proportionate share of the hearing costs, as determined by the review committee. This will be subject to appeal only to the extent that the number of breaches ruled is changed by the outcome of the appeal.

A2.2.15 The chair of the review committee, in consultation with the parties and any appointed experts, will determine the date and time of the hearing and confirm it by email to all concerned. In principle the hearing should occur within 12 weeks from when the Secretariat receives the respondent company's defence, but after consultation with the parties the review committee may extend this by a maximum of four weeks.

Exception: where legal proceedings have been initiated on the same matters, the hearing must be postponed until after a final enforceable decision has been reached in the legal case. At this point, the parties must promptly provide Medicines for Europe with a copy of the ruling in English. The Medicines for Europe Director General will evaluate the merits of resuming the procedure and will promptly inform the parties of its decision. If the complaint resumes, the timelines given here will begin to apply.

A2.2.16 Unless all parties agree otherwise, the hearing will take place at Medicines for Europe's premises in Brussels.

A2.2.17 At least five working days before the hearing, the complainant and the respondent company must deliver to the review committee and the other party the names of (i) all people who will speak on their behalf and (ii) others who will attend the hearing.

An individual complainant who wishes to withhold their identity from the respondent company may appoint a representative to attend on their behalf, and must ensure that the representative's details are submitted via the Secretariat at least two working days earlier, to allow for the information to be shared with the review committee and the respondent company.

A2.2.18 All documentation to be reviewed at the hearing must be available to both parties. However, where applicable, the Secretariat must redact identifying details to the extent necessary to withhold the identity of an individual complainant from both the review committee and the respondent company.

A2.2.19 No additional documentation or evidence will be considered unless it has been made available to the review committee and the other party at least five working days before the hearing.

An individual complainant who needs to submit additional information via the Secretariat must allow at least additional two working days for this.

A2.3 Hearings

A2.3.1 Hearings are conducted in English. If any party requires the services of translators, they must arrange this at their own cost.

A2.3.2 All members of the review committee must attend all hearings in full.

A2.3.3 Before the start of a hearing, all three members of the review committee must sign a confidentiality agreement that contains adequate penalties for violations and is enforceable by the parties to the complaint. Other than information included in the public case report, review committee members must keep confidential the identity of the complainant and the respondent company, and matters discussed during the hearing and their deliberations.

A2.3.4 The complainant and the respondent company may attend the hearings along with their own advisers, experts or assistants. Regardless of the outcome of the case, each party will bear the costs of its own team.

A2.3.5 An individual complainant (healthcare professional, member of the public or company employee) is entitled but not obliged to attend the hearing. Otherwise, the review committee will not meet, hear or otherwise contact one party in the absence of the other.

A2.3.6 Hearings are closed sessions, unless all parties agree otherwise.

A2.3.7 The review committee will conduct the hearing fairly, ensuring that both the complainant and the respondent against are afforded sufficient opportunity to put their case.

A2.3.8 Each member of the review committee has an equal vote on the matters under review and where possible should endeavour to reach a unanimous decision on each element of the alleged breach(es).

A2.3.9 Either party may request an additional hearing, however the review committee has absolute discretion to refuse the request if it feels it has sufficient evidence to make a decision after one hearing.

A2.3.10 The decision of the review committee will be communicated in writing to the parties involved, the Medicines for Europe Executive and to Medicines for Europe Board. To protect the rights and confidentiality of individuals, people involved in the case will not be referred to by name in the report.

The review committee may make recommendations or impose sanctions and/or remediation measures on a respondent company found to have been in breach, to the extent permitted by this Code (see section A2.5).

A2.3.11 The correspondence communicating the outcome of the case must stipulate the deadline for requesting an appeal, which will be two weeks from the date of the letter (except during holiday periods when a longer deadline may be appropriate).

A2.3.12 The ruling is confidential pending the outcome of any appeal.

A2.4 Appeal procedure

A2.4.1 The only grounds of appeal are (i) procedural unfairness or (ii) incorrect interpretation of the Code by the review committee. There can be no appeal on the facts of the case.

A2.4.2 If the complainant or respondent company wishes to appeal, they must notify the Medicines for Europe Director General by the given deadline.

A2.4.3 The costs of an appeal, including the cost of external experts, will be borne by the losing party. See clause A2.2.11 for guidance as to the allocation of costs where an appeal is only partly successful.

A2.4.4 The Medicines for Europe Executive will initiate the appeal procedure, designating a group of Executive members to form an appeal panel. Members conducting the appeal must confirm that they have no conflicting interests with the parties involved in the matter.

A2.4.5 The Executive may engage external experts for advice on the correct interpretation of the Code.

A2.4.6 The complainant and respondent are not entitled to participate in or be present at appeal discussions.

A2.4.7 The appeal procedure should be completed and a final decision communicated to both parties within eight weeks of receiving the notification of appeal.

A2.5 Findings and sanctions

A2.5.1 The companies involved in the complaint are bound by the final case decision for the duration of their respective Medicines for Europe membership, unless the outcome is subsequently overruled by a court order or regulatory ruling.

A2.5.2 A company ruled in breach of this Code must take corrective actions to immediately stop the non-compliant activities or practices, and must implement any further remedial measures imposed by the review committee.

A2.5.3 In egregious or repetitive cases, or where a company's activities have been such as to potentially bring the pharmaceutical industry or the generics/biosimilars sector into disrepute, the review committee may recommend that Medicines for Europe members expel the company from membership, in accordance with Medicines for Europe's bylaws and the applicable legislation.

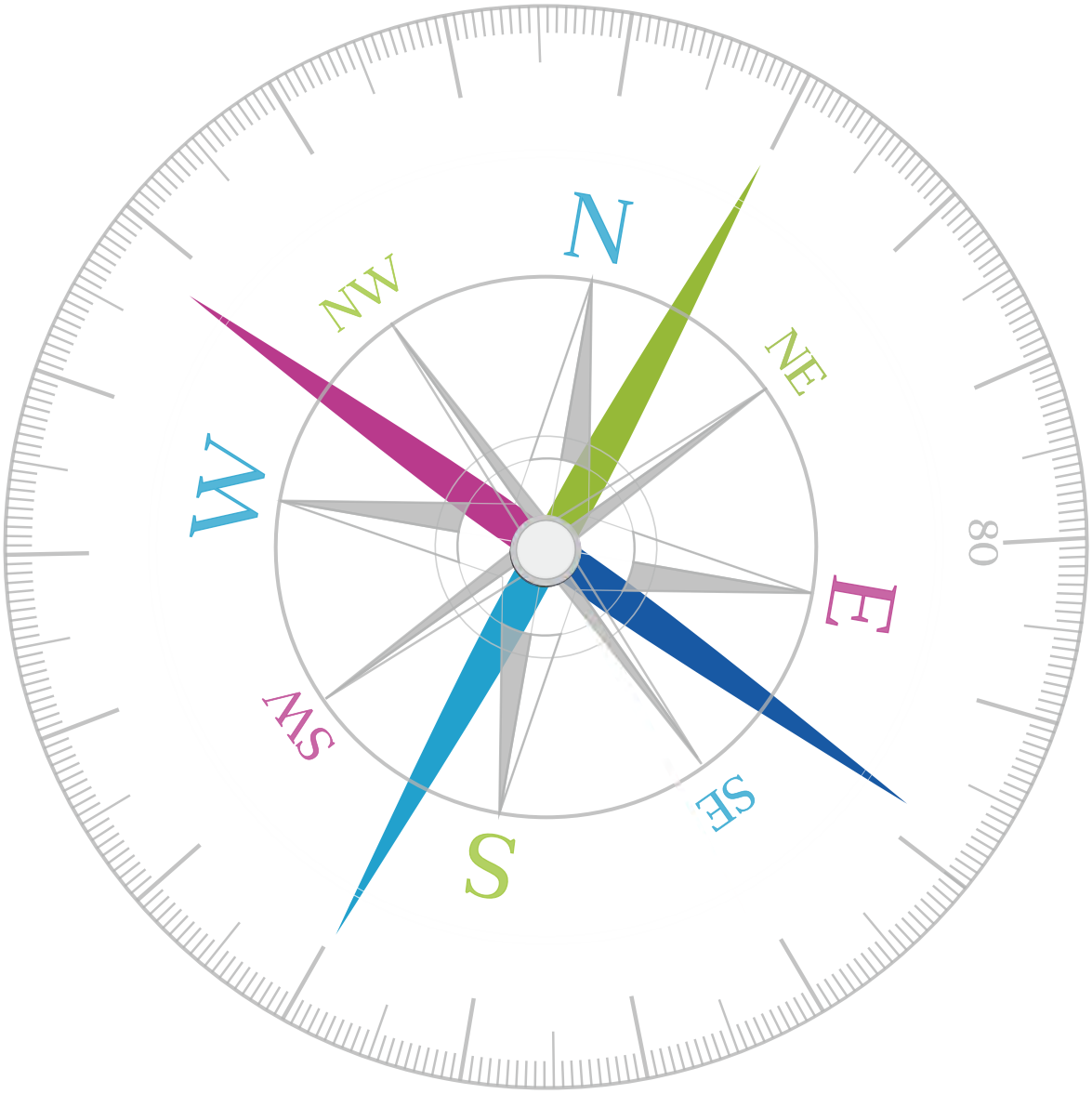
A2.5.4 Medicines for Europe does not have the power to levy fines or award damages.

A2.6 Publication of case reports

A2.6.1 After the complaint process has been concluded, a case report summarising the essential details will be published promptly on the Medicines for Europe website and national relevant national association websites.

Case reports will also be reproduced in the Medicines for Europe annual report.

A2.6.2 Medicines for Europe national associations should likewise share their case reports with the Medicines for Europe Secretariat for central publication. The Secretariat will redact all individuals' names from case reports.



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