Dedicated to Life

Innovative Medicines for Luxembourg

Innovative Medicines for Luxembourg

Code of ethics

Amended by the General Meeting
of 17 April 2023

DISCLAMER

This translation of the Code of Ethics in English is proposed only for the convenience of the members. IML's Code of Ethics in its French version is the binding code in the event of divergence.

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PREAMBLE

The preamble to this Code of Ethics ("Code") forms the basis of the ethical concepts to which the Member Companies adhere.

IML'S ETHICAL PRINCIPLES

IML Member Companies invest in medical and biopharmaceutical research and are committed to developing innovative solutions for unmet medical needs. They are also committed to offering their medicines in compliance with all applicable local and international rules and regulations, within a global ethical framework.

Their priorities are the health and well-being of patients and the quality of the healthcare they receive. IML Member Companies adopt the following ethical principles:

1. Member Companies aim to provide medicines that meet the highest standards of quality, safety and efficacy, as determined by the regulatory authorities.

2. Member Companies aspire to provide their stakeholders with reliable, balanced and scientifically valid data about their medicines.

3. Member Companies aspire that the information contained in promotional material promotes a fair balance between the risks and benefits of their medicines and their proper use. Promotion is ethical, reliable, balanced and must not be misleading.

4. Member Companies endeavour to be open and transparent in their dealings with stakeholders and Healthcare Professionals, in accordance with applicable legislation. Interactions between Member Companies and stakeholders are ethical, appropriate and professional. As described in applicable legislation, nothing is offered or provided by a company in a manner or on condition that would have an inappropriate influence.

5. All clinical trials and scientific research sponsored or supported by Member Companies are conducted with the sole aim of developing knowledge that will benefit patients and advance science and medicine. Member Companies are committed to the transparency of industry sponsored clinical trials in patients.

ETHOS IFPMA

Member Companies endorse the Ethos of IFPMA. This Ethos underpins the rules of this Code and provides a framework to behave with integrity in all circumstances. It serves to instil a culture of ethics and integrity needed to guide Member Companies business behavious and the interactions with the healthcare community.

Our Ethos. Building a culture of trust

TRUST

Act with integrity and honesty to improve patient care, establish a relationship of trust with the people we serve, and respect the independence of healthcare professionals, patients and other stakeholders.

CARE

Protect the safety of those who use our products - from clinical trials onwards and throughout the product lifecycle.

Innovation

Improve global health through innovative products and services, upholding the ethical, scientific and medical standards.

Quality
Commit to providing high-quality products that have proven clinical efficacy and have a reliable safety profile.

HONESTY

Ensure truthful and balanced communication with the authorities, healthcare professionals, patients and other stakeholders.

Speaking up
Foster a culture within our respective organisations that allows us to share our concerns openly and frankly, so that we can learn from our mistakes and continuously improve.

Transparency
Advance science and patient care by sharing industry-sponsored clinical trial data responsibly, accurately and appropriately.

FAIRNESS

Support and respect fair trade practices and free competition.

Integrity
Act responsibly, ethically and professionally. Not offer, promise, provide or accept anything of value in order to improperly influence a decision or gain an unfair advantage.

Responsibility
To be accountable for our actions and decisions, ensuring the appropriate oversight of third parties that act on our behalf.

RESPECT

Respect each individual and embrace a culture of diversity and inclusion. Protect the environment. Treat animals under our care responsibly.

Privacy
Respect the rights to privacy and **appropriately** manage and protect personal information.

Education
Support the **advancement** of the scientific and medical education for the ultimate benefit of patients.

Source https://www.ifpma.org/subtopics/ifpma-ethos/

DEFINITIONS

Applicable codes :

(a) the present Code; and
(b) in the case of the promotion or interaction does not take place in Luxembourg, the National Code that applies in the country where the promotion or interaction takes place.

In case of an event that does not take place in the Grand Duchy of Luxembourg for which a Member Company sponsors the attendance of a Healthcare Professional or a Representative of a Patients' Organisation, such funding is subject to the rules of the National Code of the country where such Healthcare Professional or Representative of a Patients' Organisation carries out his/her profession or has its main location,, as opposed to those in which of the international event takes place.

When, on the basis of the previous paragraphs, several national codes of deontology apply, the most constraining provision shall apply in the event of contradiction between the applicable provisions, except for the application of Section 10.05, where the monetary threshold set in the country where the event takes place (i.e. the "host country") shall prevail.

Member Company: as defined in the IML's bylaw, the term Member Company refers to legal entities active in Luxembourg in the field of medicinal products for human use or goods and services related to the use of medicinal products for human use, from research through production to marketing, whose purpose is to place the above-mentioned products on the market themselves or via third parties, and who have been admitted as members of the IML by the General Assembly of the IML.

European Federation of Pharmaceutical Industries and Associations (EFPIA): is the representative body of the pharmaceutical industry in Europe.

Lifelong learning in healthcare: Medical training aims to increase the scientific knowledge and skills of healthcare professionals in order to improve medical practice and patient care.

Hospitality: Coverage of meal, travel, accommodation and/or registration costs to facilitate the participation of a Healthcare Professional or a representative of a Patient Organisation in an Event organised by a Company Member and/or a Third Party.

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA): Is the representative body of the pharmaceutical industry worldwide.

Objects of medical utility: Inexpensive objects directly intended for the training of Healthcare Professionals and for patient care and which are not normally charged to Healthcare Professionals as part of their normal practice. The amounts for these items are set out in Appendix 2 of this Code.

Patient organisation: any not-for-profit association (including the umbrella organisation to which it belongs), with or without legal personality, primarily composed of patients and/or (non-professional) caregivers, which serves and/or supports the needs of patients and/or (non-professional) caregivers.

Healthcare Organisation: any association or organisation active in the healthcare, medical or scientific field, regardless of its legal or organisational form, as well as any legal entity through which one or more Healthcare Professionals provide services, with the exception of Patient Organisations.

Healthcare professional (HCP): any natural person practising **medical, dental, pharmaceutical or nursing art who**, as part of their professional activities, may prescribe, purchase, deliver, recommend, lease, use or administer medicines or medical devices.

For the purposes of Chapter 1"Promotion of prescription-only medicines to healthcare professionals", the term "healthcare professional" refers to any natural person qualified to prescribe or supply a medicinal product.

Promotion: includes any activity carried out, organised or sponsored by a Member Company and directed towards Professionals in the healthcare sector with the aim of promoting the prescription, advice, dispensing, administration or consumption of its pharmaceutical products, by any means of communication, including the internet or via social networks.

Patient Organisation Representative: a person who is mandated to represent and express the collective views of a Patient Organisation on a specific issue or therapeutic area.

SCRIP: a trusted, comprehensive source of business critical market and competitor insights for the commercial pharmaceutical industry.

APPLICABILITY OF THE CODE

In addition to complying with extensive legal requirements (i.e. laws and regulations applicable to the pharmaceutical industry such as pharmaceutical legislation, competition law, intellectual property law and data protection law, as well as anti-bribery legislation), Member Companies have agreed to comply with additional standards in the present Self-Regulatory Code.

The present Code applies to promotion and interactions that are undertaken, sponsored or organised by, with or on behalf of a Member Company.

The present code applies without prejudice of and supplements all legal and regulatory provisions on the subject of promoting and providing information on medicinal product for human use as well as those related to interactions with Healthcare Professionals and organizations, and Patient organizations, which must be respected under all circumstances.

The disciplinary bodies referred to in articles 58 and 59 are competent to deal with any offence committed by a Member Company with regard to aforementioned promotion, provision of information and interactions in accordance with chapter 6 of the present Code.

SCOPE OF THE CODE

The present Code concerns medicinal products for human use, as defined by Article 1 of the law of 11 April 1983 regulating the marketing and advertising of medicinal products. Unless explicitly stated otherwise, the provisions of the Code apply to all medicinal products, whether subject to prescription or not, and whether reimbursable or not.

Where it is specified that a rule is only applicable in respect of medicinal products which can only be supplied on presentation of a medical prescription (hereafter "prescription-only medicinal products"), Member Companies are strongly encouraged to comply with this rule in respect of their other products as well.

The present Code applies to all means implemented with a view to promoting or providing information on medicinal products, to interactions between Member Companies and Healthcare Professionals, Healthcare Organisations and Patient Organisations. In particular, it contains rules relating to :

- Promotion of prescription-only medicines to Healthcare Professionals (whether orally, in writing or by any other means);
- interactions between Member Companies and Healthcare Professionals, Healthcare Prganisations and Patient Organisations;
- and disclosure of of transfers of value from Member Companies to Healthcare Professionals, Healthcare Organisations and Patient Organisations.

Member Companies are responsible for the obligations imposed under any relevant applicable Code, even if they commission a third party to design, implement or undertake activities covered by the Applicable Code on their behalf .

In addition, Member Companies must take the necessary steps to ensure that any other parties that they commission to design, implement or undertake activities covered by the Applicable Code but that do not act on behalf of the Member Company (e.g. joint ventures, licensees, etc.) comply with the applicable Codes.

CHAPTER 1: PROMOTION OF PRESCRIPTION-ONLY MEDICINES TO HEALTHCARE PROFESSIONALS

SECTION 1: PROMOTION IN GENERAL

The promotion of prescription-only medicines to Healthcare Professionals is subject to Luxembourg legislation and in particular to the conditions laid down in the law of 11 April 1983 regulating the marketing and advertising of medicines and the Grand-Ducal Regulation of 15 December 1992 on the marketing of medicines.

The following requirements apply in addition to these texts.

ARTICLE 1 - ACCEPTABILITY OF PROMOTION

Member Companies must maintain high ethical standards at all times. Promotion must:

a. Never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry;

b. Be of a nature that recognises the special nature of of Medicinal products and the professional standing of the intended audience;

c. Not likely to cause offence.

ARTICLE 2 - PROMOTION AND ITS SUBSTANTIATION

1. Promotion must capable of substantiation which must be promptly provided in response to reasonable requests from Healthcare Professionals. In particular, promotional claims concerning side effects must reflect available evidence or be capable of substantiation by medical experience. Substantiation need not be provided, however, in relation to the validity of elements approved in the marketing authorization.

2. Attention must be paid to ensure that the visual material such as graphs, illustrations, photographs or tables is not used to misleading effect, either with regard to the nature of a medicinal product (for example whether or not it is suitable for children) or any claims or comparisons (for example by using incomplete information or information of no statistical significance or uncustomary scales).

3. Whenever published studies are mentioned in the promotional material, clear references shall be given.

4. The terms "safe" or "without danger" or any other term expressing a similar concept may not be used unless they are clearly defined.

The word "new" must not be used to describe any medicinal product or presentation which has been generally available or any therapeutic indication which has been generally promoted, for more than one year.

5. It must not be stated that a medicinal product has no side effects, toxic hazards or risk of addiction or dependency.

ARTICLE 3- USE OF QUOTATION IN PROMOTION

Citations shall not be invoked in a tendentious manner out of context and shall remain true to the spirit of their author.

Use of quotations in promotion

ARTICLE 4 - DISTRIBUTION OF PROMOTION

Promotion must be presented objectively and in accordance with good practice, avoiding the use of misleading pictures or exaggerated descriptions. It must be presented in such a way that does not conceal its real purpose.

Information or promotion relating to medicinal products may only be addressed to Healthcare Professionals who may reasonably be assumed to need or be interested in such information.

The use of digital communications for promotion is only allowed with the valid consent and/or at the request of the recipient.

ARTICLE 5 - TRANSPARENCY OF PROMOTION

Promotional material for medicinal products must always be identifiable as such.

Clinical assessments, post-marketing surveillance and experience programmes and post-authorisation studies (including those that are retrospective in nature) must not be disguised promotion. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose.

Where a Member Company pays for or otherwise secures the publication of promotional material in in journals, such promotional material must be clearly distinguishable from independent journalistic articles.

Material relating to medicinal products and their use, whether promotional in nature or not, sponsored by a Member Company must clearly indicate that it has been sponsored by that Member Company.

ARTICLE 6 - PERSONAL MEDICAL MATTERS

In the case of requests for advice on personal medical matters from individual members of the general public, the enquirer must be advised to consult a Healthcare Professional.

ARTICLE 7 – RESPONSIBILITY OF THE MEMBER COMPANY

The Member Company must appoint at least one "senior" employee who must be responsible for the supervision of the Member Company and its subsidiaries to ensure that the standards of the Applicable Code(s) are met.

SECTION 2. MEMBER COMPANY STAFF

ARTICLE 8 - MEDICAL REPRESENTATIVES

Member Companies exercise control over and assume responsibility for the actions of their personnel. This responsibility continues to apply even if the medical representatives fails to respect the instructions given to them.

They must ensure that their medical representatives, including personnel to which there is recourse on the basis of an agreement with third parties, and all the other company representatives who are in contact with Healthcare Professionals in the framework of the promotion of medicinal products, are familiar with the relevant provisions of the Applicable Code(s), as well as with the applicable legal provisions and regulations.

The marketing authorisation holder checks that the medical representatives employed by its company have received adequate training and respect the obligations incumbent upon them.

The obligations of the medical representatives are the following:

a. Medical representatives must comply with all relevant requirements of the Applicable Code(s) and all applicable laws and regulations, and Member Companies are responsible for ensuring **their compliance**.
b. Medical representatives must approach their duties in a responsible and ethical manner.
c. Medical representatives must ensure that the frequency, timing and duration of visits to Healthcare Professionals, pharmacies, hospitals and other healthcare facilities, and the manner in which they are carried out, do not cause inconvenience.
d. Medical representatives must not use inducements or subterfuge to obtain an interview.
e. During an interview, or when seeking an appointment for an interview, medical representatives must, from the outset, take reasonable steps to ensure that they do not mislead as to their identity or that of the Member Company they represent.

ARTICLE 9 - SCIENTIFIC SERVICE

In addition to the conditions laid down in article 29 of the Grand-Ducal Regulation of 15 December 1992 on the marketing of medicinal products, the scientific service organised by the Member Company must include a doctor or a pharmacist.

The Scientific service is responsible for the review and certification of information on medicinal products and the company's promotional material, and the approval and supervision of non-interventional studies carried out by or with the support of the holder of the authorisation (cfr. Section 7 of Chapter 2).

CHAPTER 2: INTERACTIONS WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

SECTION 1: BAN ON GIFTS

ARTICLE 10 - GIFTS

With regard to **prescription-only** medicines, the offer, granting or promise of any gift, direct or indirect, to a Healthcare Professional or to a member of a Healthcare Organisation is prohibited, even if its value is negligible and it relates to the practice of the medical, dental or pharmaceutical profession, in particular:

- Gifts for personal benefit (such as tickets to sporting or entertainment events, or social courtesy gifts);
- Cash, cash equivalents or personal services. For these purposes, personal services are any type of service **unrelated to the profession and** that confers a personal benefit on the recipient;
- Promotional objects or gadgets. For these purposes, a promotional object is a non-monetary item given away for promotional purposes.

SECTION 2: INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY

ARTICLE 11 - COMPUTER OR EDUCATIONAL EQUIPMENT AND ITEMS OF MEDICAL USE

1. Member Companies may only provide Healthcare Professionals and members of Healthcare Organisations with informational or educational material when this material is:

(i) of limited value;
(ii) directly relevant to the practice of medicine or pharmacy;
(iii) directly beneficial to the care of patients.

2. Items of medical utility may only be provided for Healthcare Professionals and members of Healthcare Organisations when these items are:

(i) intended directly for the training of Healthcare Professionals and the care of patients;
(ii) of limited value; and
(iii) not part of the basic materials and equipment which every Healthcare Profesionnal needs for his or her routine practice.

3. The term "of limited value" as mentioned in points 1 and 2 above is determined in Annex 2 to this Code.

4. Informational or educational materials and items of medical utility can include the name of the Member Company, but must not be product branded, unless the medicinal product's name is essential for the correct use of the material or item by the patient.

5. The nature of the informational or educational material and items of medical utility mentioned above may not constitute a circumvention of the prohibition on offering gifts defined in Article 10. Under no circumstances may this material be provided with the intention of encouraging the recommendation, prescription, purchase or sale, supply or administration of a medicinal product.

SECTION 3. SCIENTIFIC EVENTS AND HOSPITALITY

The sponsorship and the organisation of scientific meetings by or on behalf of Member Companies are subject to Luxembourg legislation and in particular to the conditions set out in article 25 of the Grand-Ducal Regulation of 15 December 1992 on the marketing of medicinal products.

ARTICLE 12 - SCIENTIFIC EVENTS AND HOSPITALITY

Member Companies must comply with the following.

1. Scientific events, supported or organised directly or indirectly by Member Companies and attended by Healthcare Professionals, shall be held in a quality and appropriate setting, which is conducive to the main purpose of the event, avoiding those which are known for their entertainment facilities or which are extravagant.

Where a scientific event does not take place in the Grand Duchy of Luxembourg, this event must also, in accordance with the definition of "Applicable code(s)", meet the criteria laid down by the code of ethics that applies in the country where the event takes place.

2. The hospitality made available will always be limited to that which the Healthcare Professionals who benefit from it would reasonably be prepared to pay themselves.

3. Hospitality at events must be limited to travel, meals, accommodation and actual registration fees.

4. The public use of the Healthcare Organisation logo and/or any other proprietary material by a Corporate Member requires written permission from that organisation. In seeking such permission, the precise purpose and manner in which the logo and/or proprietaty materials will be used must be clearly stated.

5. Member Companies must ensure that their sponsorship to Healthcare Organisations is always clearly acknowledged and apparent from the outset.

6. Hospitality must not include the sponsorship or the organisation of entertainment events (e.g. sporting or leisure events).

7. Without prejudice to the application of the definition of "Applicable Code", Member Companies are obliged, if they invite Healthcare Professionals to participate in a scientific event taking place abroad or if they sponsor the participation of Healthcare Professionals in such events, to inform any local company concerned and linked to it or, where appropriate, to seek advice locally.

SECTION 4. CONTRACTED SERVICES

The conclusion of contracts with Healthcare Professionals for the provision of scientific services is subject to Luxembourg law (Civil Code).

ARTICLE 13 - CONTRACTS

Notwithstanding the legal provisions, contracts between Member Companies and institutions, organisations or associations of Healthcare Professionals by the terms of which such institutions, organisations or associations provide services to companies, are only allowed if such services:

1° support health care or scientific research ;

2° do not constitute an inducement to recommend, prescribe, purchase, sell, supply or administer medicinal products.

ARTICLE 14 - CONSULTANCY

1. A Member Company may engage one or more Healthcare Professionals as consultants for services such as speaking at or chairing scientific meetings, involvement in medical/scientific studies, clinical trials or training courses, participation in advisory board meetings or participation in market research, where such participation involves remuneration and/or hospitality.

2. The arrangement made in this respect must meet the following conditions:

a. A legitimate need justifying the services is clearly identified and documented before retaining the Healthcare Professionals and making arrangements in this respect;
b. The criteria for the selection of consultants are directly related to the legitimate need as referred in clause a. and the persons responsible for the selection of consultants have the expertise necessary to evaluate whether the contracted Healthcare Professionals meet those criteria;
c. The number of Healthcare Professionals retained and the extent of the services doeds not exceed what is reasonably necessary to meet the identified need;
d. Before the services are performed, a written agreement must be drawn up specifying the nature of the services to be provided by the Healthcare Professionals and, without prejudice to the application of clause g. below, the basis for compensation for their services;
e. The Member Company maintains records concerning the services provided and makes use of them;
f. The engagement of Healthcare Professionals for the provision of services is not an inducement to recommend, prescribe, purchase, sell, supply or administer medicinal products; and
g. The remuneration for the services provided is reasonable and reflects the usual market value of these services.

3. The compensation arrangement may include reimbursement of reasonable expenses, including travel, meals and accommodation.

4. For the purposes of transparency, Member Companies are strongly encouraged to include in the written contracts as mentioned above in paragraph 1.d., a provision regarding the obligation of the the Healthcare Professional in question to declare that he/she is fulfilling a consultancy or advisory mission for the Member Company whenever he/she speaks in public or publishes on matters that are the subject of the agreement or any other issue relating to that company.

Similarly, Member Companies that employ Healthcare Professionals on a part-time basis who also have their own practice are strongly encouraged to impose on such persons the obligation to declare their employment arrangement with the company whenever they speak in public or publish on matters that are the subject of their employment arrangement or on any other issue relating to that company.

5. Limited market research, such as telephone interviews or surveys by post, e-mail or Internet are excluded from the scope of Article 14.2, provided that the Healthcare Professionals or members of the Healthcare Organisation concerned are not consulted on a recurring manner (either with respect to the frequency of calls generally or of calls relating to the same research) , and that the remuneration is minimal.

6. When a Healthcare Professional attends a scientific event as a consultant or advisor, the Section 3 of Chapter 2 of the present Code apply.

7. No payment must be offered simply to compensate for time spent by the HCP or Patient Organisation representative attending events.

SECTION 5: PROVISION OF MEANS

ARTICLE 15 - MEMBER COMPANIES FUNDING

No Member Company may require that it be the some funder or sponsor a Healthcare Organisation or any of its programmes. Members Companies welcome broad funding and sponsorship of Healthcare Organisations from multiple sources.

ARTICLE 16 - SUBSIDIES AND SPONSORSHIP

1. Notwithstanding the applicable legal provisions, Member Companies are free to make financial resources or other means of functioning available to third parties.

For the purposes of this Article, "financial or other operating means" includes subsidies, sponsorship and the provision of services for humanitarian purposes.

Where these means are made available to institutions, organisations or associations made up of Professionals from the healthcare sector and/or who provide healthcare or are active in research, these means may only be provided for the purpose of promoting healthcare or scientific research and not for the purpose of induce the recommendation, prescription, purchase or sale, dispensing or administration of medicinal products.

Under no circumstances may the means referred to in the previous paragraph be provided to individual Healthcare Professionals.

If means are made available in the context of continuing medical training (CMT), the primary goal of the meetings is to strengthen medical knowledge.

2. The Member Company making means available to third parties shall ensure that this is laid down in writing and takes all useful measures to ensure it is informed of the destination and use of the means made available.

If the means made available are for activities linked to information and promotion concerning the medicinal products, the Member Companies themselves shall remain responsible for ensuring that the third parties comply with the rules laid down in the code.

When a Member Company contributes to the content of training activities or programmes (CMT) the materials supplied must be honest, balanced and objective and included in such a way that they enable various theories and recognised views to be expressed. The content must consist of medical, scientific or other information that can contribute to improving patient care.

ARTICLE 17 - DONATIONS AND GRANTS

The provision of financial resources or any other operating, as donation or grant, to institutions, organisations or associations that are made up of Healthcare Professionals and/or that provide

healthcare or conduct research, with the exception of means made available as part of scientific experiments[1] is only allowed under the following conditions:

a. Under no circumstances may such means be provided to individual Healthcare Professionals, either directly or indirectly;
b. Such means can in no way constitute an inducement to recommend, prescribe, purchase, sell, supply or administer medicinal products;
c. Requests for such means should be unsolicited, meaning that the need for such means is expressed by the Healthcare Organisation;
   Requests in response to scientific awards, for which the submitted projects are reviewed by an independent and competent medical or scientific panel, are exempted from this condition;
d. The means may not impair the independence, the integrity and the credibility of the beneficiary;
e. It is only allowed to make such means available for the purpose of supporting healthcare, scientific research or education;
f. Such means can only finance activities that are not funded or not funded fully via normal channels;
g. The beneficiary of such means cannot be, either directly or indirectly, a group practice (i.e. a group of Healthcare Professionals organised under a same practice, with shared earnings and logistics) or other for-profit organisation;
h. Such means can only be granted for projects that are specific, well-defined, and well framed, budgeted and documented;
i. The provision of means can not require obligations on behalf of the beneficiary, except for a reference to the company and/or reporting by the beneficiary;
j. The Member Company making means available shall ensure that this is laid down in writing and takes all useful measures to ensure it is informed of the destination and the use of the means made available. It also ensures that it has an appropriate non-commercially driven internal review and approval process, including adequate documentation, overseen by an appropriate signing authority.

SECTION 6. LIFELONG LEARNING IN HEALTHCARE

ARTICLE 18 - PURPOSE OF LIFELONG LEARNING IN HEALTHCARE

Lifelong learning in healthcare ("healthcare learning") aims to increase the scientific knowledge and skills of Healthcare Professionals in order to improve medical practice and patient outcomes . Member Companies may be engaged in different types of Medical education, but these activities must be exclusively scientific in nature.

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[1] The notion of scientific experiments to the following experiments:
- Experiments on human beings
- Non-clinical studies as defined in the OECD Principles on Good Laboratory Practice
- Clinical trials

When funding independent medical education or organizing medical education activities directly or in collaboration with third parties, Member Companies must ensure that their participation and role is clearly acknowledged and apparent from the outset.

When organizing medical education activities in which Member Companies have input in the content, they are responsible for what is communicated during the activities. Such content must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognized opinions.

SECTION 7. NON-INTERVENTIONAL STUDIES

Non-interventional studies are subject to Article 27 of the Act of 8 March 2018 on hospitals and hospital planning.

ARTICLE 19 - QUALITY FRAMEWORK

Non-interventional studies (NIS) shall be conducted within a quality framework.

A non-interventional study is understood to mean a study in which the medicinal products are prescribed in the usual manner, in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current medical practice and the decision to prescribe the medicinal product is clearly separated from the decision to include a patient in the study. The patient in question must not be subject to additional diagnostic or monitoring procedures and epidemiological methods shall be used for the analysis of collected data.

ARTICLE 20 - SCIENTIFIC PURPOSE

Non-interventional studies must be conducted with a primarily scientific purpose and must not be disguised promotion.

ARTICLE 21- DATA COLLECTION

Non-interventional studies involving the collection of patient data from or on behalf of individual Healthcare Professionals or groups of Healthcare Professionals must meet all of the following criteria:

a. A written scientific protocol shall provide a detailed description of the purpose sought and methodology implemented; the aforementioned purpose and methodology shall always be coherent with one another;

b. The scientific protocol must be approved in advance by the Member Company's scientific service as referred to under Article 9 of the present Code and this service must supervise the conduct of the study;

c. A written contract shall provide a detailed description of the services expected from the investigators as well as of the amount and the procedures for remunerating the investigators;

d. The remuneration is commensurate with the services requested and reflects the fair market value thereof;
e. The future use of the data collected shall be stated clearly described in the protocol;
f. The study results must be analysed and reports thereof must be submitted within a reasonable period of time to the Member Company's scientific service which shall maintain these reports for a reasonable period of time;
g. The Member Company must send the study results to all Healthcare Professionals who participated in the study; if the study shows results that are important for the assessment of the benefit-risk ratio of the studied medicinal product(s), these results should be immediately forwarded to the competent authority;
h. Medical sales representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the Member Company's scientific service that will also ensure that the medical sale representative are adequately trained. Such involvement must not be linked to the promotion of any medicinal product;
i. When required by an ethics committee, the study plan must be submitted to the ethics committee for review.

The scientific service as referred to in Article 9 of the Code will be responsible for the approval and the supervision of any non-interventional study (including the review of any responsibilities relating to such studies, particularly with respect to any responsibilities assumed by medical sales representatives). Such person must certify that he or she has examined the protocol relating to the non-interventional studies and that, in his or her opinion, it complies with the requirements of all relevant Codes, laws and regulations.

SECTION 8. SAMPLES

The provision of free samples of medicinal products by Member Companies is regulated by article 27 of the Grand-Ducal regulation of 15 December 1992 on the marketing of medicinal products.

ARTICLE 22 - DELIVERY OF FREE SAMPLES

1. Without prejudice to legal and regulatory obligations, samples will only be given to persons authorised to prescribe medicines, after they have sent a written, dated and signed request to the Member Company.
2. Unless there are legal or regulatory exceptions, samples may only be given to enable the doctor to become familiar with the medicine in question, and then only for as long as is necessary for this purpose.
3. Samples may not be provided for the purpose of encouraging the recommendation, prescription, purchase or sale, dispensing or administration of medicines.
4. Each sample must be accompanied by a summary of the product characteristics.
5. Member Companies are required to have an appropriate system for controlling the distribution of medical samples.
6. The words "free sample - cannot be sold" or any other words with equivalent content must appear on the outer packaging of the samples.

7. In accordance with national and/or European laws and regulations, a limited number of medical samples may be provided on an exceptional basis and for a limited period. A reasonable interpretation of this provision is that each person authorised to prescribe medicinal products should receive a maximum of 8 samples per package per year.
8. Member Companies must have adequate control and accounting systems for the samples they distribute and for all medicinal products handled by their medical representatives. This system must also clearly establish, for each HCP, the number of medical samples supplied.

CHAPTER 3: INTERACTIONS WITH PATIENT ORGANISATIONS

SECTION 1: GENERAL PRINCIPLES

ARTICLE 23 - INDEPENDENCE

In their interactions with Patient Organisations, Member Companies undertake to respect the following principles:

1. The independence of patient organisations, in terms of political judgement, policies and activities, must be guaranteed.
2. All interactions between Patient Organisations and Corporate Members must be based on mutual respect, with the opinions and decisions of each partner having equal value.
3. Member Companies must not request, and Patient Organisations must not undertake, the Promotion of a prescription medicine.
4. The objectives and scope of any collaboration must be transparent. Financial and non-financial support provided by Member Companies must always be clearly acknowledged.

ARTICLE 24 - WRITTEN AGREEMENT

Where Member Companies provide financial support, significant indirect support and/or significant non-financial support to Patient Organisations, they must have in place a written agreement that includes as a minimum:

1. The amount of the founding or, in the case of indirect or non-financial support, a precise description of the support;
2. purpose of the funding, such as the allocation of an “unrestricted grant”, support for a particular meeting or publication, etc. and
3. The code(s) of ethics applicable to support as defined in the "Definitions" section of the present Code.

Each Member Company shall have an internal approval process in place for these agreements.

ARTICLE 25 - MULTIPLE SOURCES

No Member Company may require that it be the sole funder or sponsor of a Patient Organisation or any of its programmes. Member Companies welcome broad funding and sponsorship of Patient Organisations from multiple sources.

ARTICLE 26 - USE OF THE LOGO

Notwithstanding the application of legal provisions and regulations, a Member Company is only allowed to publicly use a Patient Organisation’s logo or proprietary material with the written

permission from that organisation. In this permission the purpose and the way the logo or proprietary material will be used must be clearly stated.

ARTICLE 27 - TEXTS AND DOCUMENTS

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

SECTION 2: BAN ON GIFTS

ARTICLE 28 - GIFTS

The offer, granting or promise of any gift to a Representative of a Patient Organisation is prohibited, in particular:

- Gifts for personal benefit (such as sporting or entertainment tickets, social courtesy gifts);
- Cash, cash equivalents or personal services. For these purposes, personal services are any type of service unrelated to the profession and that confer a personal benefit to the Recipient.
- Promotional aid or gadget. For these purposes, a promotional aid is a nonmonetary item given for a promotional purpose (e.g. mugs, memory sticks, diaries, calendars, thermometers, ...).

SECTION 3. EVENTS AND HOSPITALITY

ARTICLE 29 - FINANCIAL SUPPORT

1. Member Companies may financially support events that are organised by Patient Organisations provided that the main purpose of the event is of a professional, educative and scientific nature or in some other way supports the mission of the Patient Organisation. Under no circumstances shall the offer of hospitality include sponsoring or organising entertainment events (e.g. sporting or leisure activities).

2. Events for patients that are sponsored or organised by or on behalf of a Member Company will always be held in venues that are appropriate and conducive for the main purpose of the event. Locations that are known for entertainment or that are extravagant must be avoided.

3. Hospitality that is extended by the Member Companies to Patient Organisations and their representatives must always be appropriate and otherwise comply with the provision of any Applicable code.

4. The hospitality that is offered in connection with an event shall be limited to the organisation, travel, meals, accommodation and genuine registration fees.

5. Hospitality may only be offered to participants in the event. In exceptional cases of established health needs (e.g. disability or injury), the travel, meals, accommodation and genuine registration fee costs of an accompanying person can be reimbursed within the same parameters.

6. All forms of hospitality offered to Patient Organisations and their representatives must be "reasonable" in level and strictly limited to the main purpose of the event. As a general rule, the hospitality provided must not exceed what those individuals would normally be prepared to pay for themselves.

7. A Member Company may not organise or sponsor events that do not take place on the territory of the Grand Duchy, unless :
    - Most of the invitees are from outside Luxembourg and given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country; or,
    - Given the relevant expertise or infrastructure at the location of the event, it makes greater logistical sense to hold the event in another country.

8. Member Companies must comply with criteria governing the selection and support of Patient Organisation representatives to attend events, as provided in, or in connection with, any Applicable Code.

9. No payment must be offered to compensate merely for the time spent by the Patient Organisation representative for time spent attending events.

10. Member Companies must ensure that their sponsorship to POs is always acknowledged and apparent from the outset.

SECTION 4. CONTRACTED SERVICES

ARTICLE 30 – CONTRACTED SERVICES

Contracts between Member Companies and Patient Organisations or their representatives in which the latter undertake to perform particular services for the former are only allowed if these services:

a. Are provided to support healthcare, research or education; and
b. Do not constitute an inducement to recommend, purchase or use specific medicinal products.

ARTICLE 31 - CONSULTANCY

1. Member Companies may engage one or more Patient Organisations or their Representatives as consultants for services such as speaking at or chairing scientific meetings, or general consultancy activities where such a contract involves remuneration and/or hospitality.

2. Contracts in which such genuine consultancy or other services are regulated must, insofar as they are relevant, comply with the following conditions:

a. Prior to the start of the services a written contract must be drawn up in which the nature of the services to be provided is specified and, subject to clause g. below, the basis for the remuneration for these services;

b. A legitimate need for the services has been clearly identified and documented before the services are requested and before entering into the agreement;

c. The criteria for selecting the consultants are directly linked to the identified need mentioned in clause b. and the people who are responsible for selecting the consultant possess the necessary expertise to evaluate whether the particular consultant satisfies the criteria;

d. The number of consultants retained and the scope of the service does not exceed what is reasonably necessary to meet the identified need;

e. The Member Company keeps a report of the services provided and use it appropriately;

f. The engagement of the consultant to provide the relevant service is not an inducement to recommend and/or purchase or use a particular medicinal product;

g. The remuneration for the services is reasonable and reflects to the fair market value of the serces provided. Consultancy contracts made may not be used as a justification for remunerating Patient Organisations or their members.

ARTICLE 32 - CONSULTANCY DISCLOSURE

In their written contracts with consultants, Member Companies are strongly encouraged to insert a clause concerning the obligation of the consultant to declare that they are consultant to the Member Company concerned whenever they write or speak in public about a matter that forms the subject of the contract or about any other matter in connection with the company.

ARTICLE 33 - MARKET RESEARCH

Limited market research, such as one-off phone interviews or mail/e-mail/internet questionnaires are excluded from the scope of this session, provided that the Patient Organisation or their members are not consulted in a recurring manner (either with respect to the frequency of calls generally or of calls relating to the same research) and that the remuneration is minimal.

ARTICLE 34 - PARTICIPATION IN AN EVENT

If a Patient Organisation's representative attends an event (an international event or otherwise) in a consultant capacity, the relevant provisions of Section 3, Chapter 2 must apply.

SECTION 5. DONATIONS AND GRANTS

ARTICLE 35 - DONATIONS AND GRANTS

Donations and grants (in cash, in kind or otherwise) to Patient Organisations are only allowed if:

a. They are made for the purpose of supporting healthcare, research or education;
b. They are documented and kept on record by the donor/grantor; and
c. They do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicinal products.

Donations and grants to individuals are not permitted.

SECTION 6: TRANSPARENCY

ARTICLE 36 - TRANSPARENCY

Notwithstanding legal and regulatory provisions, in particular those relating to the promotion of medicinal products, each Member Company will ensure that its sponsorship is always clearly acknowledged and apparent from the outset.

CHAPTER 4: TRANSPARENCY

ARTCLE 36bis - TRANSFERS OF VALUE DISCLOSURE

1. Without prejudice to the application of legal and regulatory provisions, in particular with regard to the protection of privacy, Member Companies are required to document and publish the transfers of value that they make, directly or indirectly, to the benefit of Healthcare Professionals or to Healthcare Organisations.

Whether directly or indirectly, when deciding how a statement of value should be disclosed, Member Companies should, as far as possible, identify and publish individual statements of value.

Where the beneficiary has its principal place of business or registered office in Europe, the documentation and publication of transfers of value will be carried out in accordance with the rules and procedures described below.

2. For the purposes of this chapter, the following definitions shall apply:

- Transfers of value: any direct or indirect transfer of value, whether in cash, in kind or otherwise, made, for promotional purposes or otherwise, in connection with the development and sale of prescription medicines for human use;

- Direct transfers of value: transfers of value made directly by a Member Company for the benefit of a Healthcare Professional or a Healthcare Organisation;

- Indirect transfers of value: transfers of value carried out on behalf of a Member Company for the benefit of a Healthcare Professional or Healthcare Organisation, as well as transfers of value carried out by an intermediary when the Member Company knows or can identify the Healthcare Professional or Healthcare Organisation that will benefit from the transfer of value.

3. The obligation described in point 1 of this Article is not applicable to Transfers of Value which either (i) relate solely to non-prescription medicines, or (ii) are not listed in Article 36quater of the present Code, such as objects of medical utilitý, meals and beverages, samples, or form part of customary transactions for the purchase and sale of medicines by a pharmaceutical company or between the latter and a Healthcare Professional, e.g. a pharmacist, or a Healthcare Organisation.

4. In respect of the Transfers of value relating solely to non-prescription medicines, Member Companies are, however, strongly encouraged to comply with the obligation described in paragraph 1 of this Article in respect of their other products.

ARTICLE 36 ter - ANNUAL CYCLE

1. Annual disclosure cycle: The Transfers of Value referred to in Article 36bis 1 must be published annually. Each reporting period will cover a full calendar year (the "Reporting Period").

2. Publication must take place within six months of the end of the reference period concerned. Without prejudice to the application of legal and regulatory provisions, in particular with regard to the protection of privacy, the information must remain publicly accessible for a period of at least three years from the date of its first publication in accordance with Article 36 ter 4.

3. Template : For reasons of consistency, publication must be made in accordance with the scheme set out in Annex 3 to the present Code.

4. Publication on a centralised platform: Value Transfers are published on or via the website of a central platform set up for this purpose. The practical elements relating to this platform will be determined by guidelines available on the IML website, in the Code of Ethics section.

5. Language of publication: The data is published in French. It is racommended that Member Companies also publish data in English.

6. Documentation and record keeping: Member Companies are required to document all Transfers of Value that are required to be published in accordance with Article 36bis 1 and to keep evidence that they have fully and correctly complied with their publication obligation for at least five years after the end of the relevant reporting period, without prejudice to applicable legal and regulatory provisions on privacy or otherwise.

ARTICLE 36 quater: INDIVIDUAL AND AGGREGATED INFORMATION

1. Except in the cases referred to in Article 36 ter 3 and 5, Transfers of Value shall be published on an individual basis. Each Member Company shall publish for each identifiable beneficiary the amounts of Value Transfers made to that beneficiary during the reference period which can reasonably be allocated to one of the categories listed below. These Transfers of Value may be aggregated by category, it being understood that a detailed publication must be made available if the beneficiary concerned or the competent authorities so request.

2. The categories of Transfers of Value referred to in Article 36 quater 1 are as follows:

I. With regard to Transfers of value to Healthcare Organisations:

a. Donations and grants that support healthcaree, including donations and grants, whether in cash or in kind, to institutions, organisations or associations made up of Healthcare Professionals and/or that provide healthcare, referred to in Article 16 of the Code.

b. Contributions towards the costs of scientific events, including sponsorship offered to Healthcare Professionals for the purpose of participating in these events, such as :

i. Registration fees ;
ii. Sponsorship agreements with health sector organisations or with third parties appointed by these organisations to manage a scientific event; and
iii. Travel, meal and accomodation expenses as referred to in Article 29 of the present Code.

c. Fees for services and consultancy. This category includes Transfers of Value resulting from or related to contracts between Member Company and institutions, organisations or associations of Healthcare Professionals according to which these institutions, organisations or associations provide a service to a Member Company, as well as any other type of financing not covered by the previous categories. Fees and Value Transfers relating to reimbursements of expenses agreed in the written agreement covering the activity will be published separately.

II. With regard to Transfers of Value to Healthcare Professionals :

a. Contributions towards the costs of scientific events, such as :

i. Registration fees; and

ii. Travel, meal and accomodation expenses as referred to in Article 29 of the present Code.

b. Fees for services and consultancy. This category includes Value Transfers resulting from or related to contracts between Member Company and Healthcare Professionals under which the latter provide a service to a Member Company, as well as any other type of financing not covered by the previous categories. Fees and Transfers of Value relating to reimbursements of expenses agreed in the written agreement covering the activity will be published separately.

3. If, for legal reasons, certain information concerning Transfers of Value which can reasonably be allocated to one of the categories listed in Article 36 quarter 2 cannot be published on an individual basis, the Member Company shall publish the amounts corresponding to such Transfers of Value for each reference period on an aggregated basis. This aggregated publication will include, for each category, (i) the number of beneficiaries it comprises, expressed both as an absolute number and as a percentage of the total number of beneficiaries, and (ii) the total amount of Transfers of Value to these beneficiaries.

4. Where a Transfer of Value to be published in accordance with Articles 36 quater 1 or 3 above, is effected indirectly, through a Healthcare Organisation, for the benefit of a specified individual Healthcare Professional, this Transfer of Value shall only be published once. As far as possible, the publication will be made in the name of the Healthcare Professional beneficiary following the categories provided for in Article 36 quater 2, II above.

5. Transfers of Value concerning research and development carried out during the reference period will be published by each Member Company on an aggregated basis. Costs related to scientific events

which are clearly linked to activities referred to in this paragraph may be included in the aggregated amount to be published in the category of Transfers of Value concerning research and development.

Transfers of Value relating to research and development means transfers of value to Healthcare Professionals or Healthcare Organisations relating to the planning or execution of (i) non-clinical studies (as defined in the OECD Principles on Good Laboratory Practice), (ii) clinical trials (as defined in Regulation (EU) No 536/2012) or (iii) non-interventional studies as referred to in Article 19 of the present Code.

6. Each Member Company shall publish a note summarising the methods used to prepare the publication and to allocate the Transfers of Value to the different categories listed in Article 36 quarter 2. This note shall in particular contain a description of the valuation methods that have been applied as well as the ways in which contracts with a duration of more than one year, VAT aspects or aspects relating to other taxes, monetary aspects and any other problems relating to the timing and amount of the Transfers of Value have been dealt with, as the case may be.

ARTICLE 36 quinquies: CONSENT OF BENEFICIARIES

Member Companies are strongly encouraged, when transferring value to Healthcare Professionals or Healthcare Organisations, to include in their contracts with them clauses which record the consent of the recipients to the publication referred to in this chapter. They are also strongly encouraged to renegotiate existing contracts with a view to including clauses to this effect.

III. DISCLOSURE OF SUPPORT AND SERVICES TO PATIENT ORGANISATIONS

Each Member Company must disclose a list of Patient Organisations to which it provides financial support and/or significant indirect/non-financial support, or with which it has entered into contracts involving Transfer of Value.

This disclosure must include a description of the nature of the support or services provided that is sufficiently comprehensive to allow an idea of the nature of the support or agreement without having to refer to the information provided.

In addition to the name of the Patient Organisation, the following information must be included:

- For support :
  - the monetary value of financial support and invoiced costs
  - the non-monetary benefit
- For contractual services: the total amount paid per Patient Organisation during the reference period.

This information must be published on the Member Company's website, either at national or European level, on an annual basis and each reference period must cover a full calendar year.

Methodology. Each Member Company must publish the methodologies it uses in preparing disclosures and identifying the support and services provided.

CHAPTER 5: SUPERVISION - PENALTIES

Without prejudice to the powers granted by laws and regulations to the competent authorities, the present Code provides for measures in the event of non-compliance with legal and regulatory provisions and with the present Code.

SECTION 1: GENERAL INFORMATION

ARTICLE 37 - SANCTIONING BODIES

In order to ensure that the rules of the Code are complied with and properly applied, IML relies on the following bodies:

A. Secretariat ;

B. two disciplinary bodies :

I. The Committee for Deontology and Ethics in the Pharmaceutical Industry, hereinafter referred to as the "DEP Committee"; and
II. The Chamber of Appeal.

ARTICLE 38 - SECRETARIAT

A. The Secretariat is tasked with general management duties and overseeing the organisation and administration of the deontological scheme. It assists the disciplinary and supervisory bodies in the performance of their duties. Since strict neutrality and independence must be maintained at all times, it does not intervene in the decision-making process of any of the disciplinary or supervisory bodies.

B. IML assumes material responsibility for the Secretariat.

ARTICLE 39 - RULES APPLICABLE TO SANCTIONING BODIES

A. The president of each disciplinary body shall have sole discretion for ruling on procedural issues.

B. The president of the disciplinary bodies may call in, at its own initiative or at the request of the parties, an expert of its choice, at any stage of the proceedings, to provide an opinion on any specific question, noting that said individual shall be bound by a confidentiality obligation.

C. The members of the disciplinary bodies expressly undertake, under penalty of possible exclusion from the relevant body decided by the Board of Directors, to guarantee the confidentiality of all data, information, exhibits, acts, documents and any other elements of which they become aware in the course of exercising their mandate.

D. Each member of a disciplinary body must act with complete neutrality, independence and impartiality. In the event of any (perceived) lack of neutrality, independence or impartiality, the relevant member shall refrain from participating in any phase of the proceedings or handling of the case at stake. On this basis, for example, where a member of one of the disciplinary bodies belongs to the same company – or the same interest group – as one of the parties involved in the proceedings, said member shall refrain from involvement in the relevant phase of the proceedings or the handling of the case at stake. The president - or the other members of the disciplinary body if the president is targeted - may, on his/her/their own initiative or following a substantiated request made by one of the parties, if applicable in accordance with Article 58, B, of the present code, exclude any member of the relevant body from the proceedings or the handling of the case at stake in the event of any lack of neutrality, independence or impartiality. Any decision taken in this context shall be promptly notified and cannot be appealed.

E. In reaching its decision, the disciplinary body concerned will not accept any instructions from IML members or other IML bodies.

ARTICLE 40 - PROPOSED AMENDMENTS TO THE CODE

Where necessary, the presidents of the various bodies, accompanied by any other members of these bodies wishing to attend, shall meet to study how professional ethics have evolved, particularly in light of legislation and case law. They shall submit any proposed modification of this code that they consider necessary to the Board of Directors, with subsequent submission to the IML General Assembly in mind.

ARTICLE 41 - PUBLICATION OF DECISIONS

In compliance with privacy regulations, the final decisions taken by the DEP Committee and the Chamber of Appeal in the context of a complaint for violation of the present code are made public on the IML Intranet. These decisions are also referenced on the IML public internet site, with the possibility of obtaining an extract of the decision on request. Disclosure of an excerpt of the decision is contingent on consent being provided by the relevant parties. The decisions (whether or not in the form of excerpts) are solely intended for internal use and may not be disclosed to any third parties except with the consent of the parties involved.

ARTICLE 42 - CORRESPONDENCE

Unless otherwise specified in this code, all correspondence may be sent to the relevant parties by postal mail, email, fax or any other means of communication.

ARTICLE 43 - INTERNAL DISTRIBUTION

Without prejudice to the publication and communication measures referred to in Articles 41, 69 and 71, any document (complaint, brief, exhibits, decision, etc.) communicated to the parties in the course of any proceedings is strictly confidential and may not be disclosed by the parties except with the express written consent of the president of the relevant body and, where applicable, the party having originally issued said document. It cannot, under any circumstances, be used for commercial purposes.

ARTICLE 44 - DEADLINES

A. Except where otherwise specified, the time limits referred to in this code are absolute. They run from zero hours on the day following that of the act and expire as of midnight on the final day of the specified period

B. If the latter day is a Saturday, Sunday or public holiday, the expiry of the period shall be automatically extended to the next working day.

C. Any period due to commence or expire during the months of July and August shall be suspended until 1 September and deemed to recommence from said date, unless otherwise decided by the president of the relevant body.

D. Any acts having to be fulfilled at the Secretariat can only be carried out at the Secretariat may only be done on days when the IML offices are open, between 9 a.m. and 5 p.m.

ARTICLE 45 - CORRESPONDENCE ADDRESS

All correspondence concerning the application of the present Code should be addressed to :

Code of Ethics Secretariat
7 Rue Alcide de Gasperi
L 1615 Luxembourg
Luxembourg
contact@iml.lu

SECTION 3. COMPLAINTS PROCEDURE

SUBSECTION 1. DISCIPLINARY BODIES

ARTICLE 46 - DISCIPLINARY BODIES

The DEP Committee :

A. decides on the admissibility of any complaint;

B. deals with complaints;

C. performs conciliation duties pursuant to Article 53, B.

ARTICLE 47 - APPEALS AGAINST DECISIONS

The Chamber of Appeal shall adjudicate any appeal made against decisions taken by the DEP Committee. In the event of an appeal, the Chamber of Appeal is tasked with assessing the merits of the case and shall reconsider whether to confirm or reform the decision incumbent on it. It shall under no circumstances refer the case back to the DEP Committee.

ARTICLE 48 - COMPOSITION OF CHAMBERS OF DISCIPLINARY BODIES

A. To be validly convened, the chambers of the disciplinar y bodies must respectively comprise:

I. a president who is not actively involved within the pharmaceutical industry;

II. a member representing the industry for pharmaceutical products for human use; and

III. a member, not involved in the industry, representing either the medical profession or the pharmaceutical profession.

B. Each member of the disciplinary body, at the time of designation, must report in writing that he/she does not have any conflict of interests with regard to the case he/she has been seized upon and shall report any circumstances which may raise doubts over its neutrality, independence or impartiality in the sense of Article 39, E. The Secretariat shall annex said declaration to the notice of hearing referred to in Article 58, B, to ensure the parties are made aware of the same.

ARTICLE 49 - RESERVE OF PARTICIPANTS

A. **A reserve is established to allow the setting up of the chambers of the disciplinary bodies called upon to decide, in accordance with Article 48 of this Code.** This reserve shall comprise the following full members :

I. two lawyers based in Luxembourg who are not active in the pharmaceutical industry;

II. two members representing the industry for pharmaceutical products for human use;

III. two members representing the medical profession, not involved in the industry ;

IV. two members representing the pharmaceutical profession, not involved in the industry.

B. The number of substitute members must be equivalent to that of full members.

C. The members referred to in point A, I, are designated by the other members of the disciplinary bodies on the basis of a list presented by the Board of Directors. The same applies for the corresponding substitute members.

The members referred to in point A, II are elected by the Board of Directors. To the extent possible, attempts shall be made to ensure that at least one third of the members of the disciplinary bodies elected in this manner are not employees of companies represented in the Board of Directors of pharma.be (on the day of the election).

Among the elected individuals, those ranked most highly shall become full members and all subsequent individuals shall become substitute members, taking into account, to the extent possible, the allocation key of a third of employees of companies that are not represented in the Board of Directors of pharma.be (on the day of the election) for each list of full/substitute members.

In the event of a voting tie, the vote cast by the most senior individual in terms of the exercising of the mandate or the most senior shall prevail. The surplus members shall be placed on a waiting list, with an order of precedence determined on the basis of total votes obtained, to ensure replacements in the event that the position of a serving member becomes vacant or any full or alternate members are rendered unavailable.

The members referred to in point A, II may under no circumstances exercise a commercial function or hold a position within the marketing department of a pharma.be member. However, persons who hold the title of Chief Information Officer, who perform the function of Compliance Officer or who are part of the medical or legal department of a pharma.be member are eligible. The same applies to the corresponding substitute members.

The members referred to in points A, III and IV are appointed by one or more associations or organisations concerned. The same applies to the corresponding alternate members. As far as possible, the distribution of the mandates referred to in points A, III and IV shall take into account the representativeness of the associations from which the aforementioned members are drawn.

ARTICLE 50 - MANDATE

A. The mandates of the members of the disciplinary bodies shall be three years and may be renewed. The mandates may be revoked ad nutum.

B. When a members representing the pharmaceutical products industry resigns or can not/no longer continue his/her mandate, said member shall be automatically excluded from the reserve referred to in Article 49 and replaced by the next incumbent member in the relevant category, in terms of the total votes obtained in the election referred to in Article 49, C, subparagraph 2.
Any replacement member of a disciplinary body shall be appointed for the remaining term of mandate of its predecessor.

C. If the president is absent or otherwise incapacitated, the meetings of the disciplinary bodies shall be chaired by the deputy presidient.

ARTICLE 51 - VOTING

Decisions within the chambers of the disciplinary bodies are taken by a simple majority of the members. Only the members present during the most recent hearing and who were present throughout the relevant discussions shall be entitled to vote. If the composition of a disciplinary body

varies between two hearings, all debates must be restarted from scratch. Votes by procuration are prohibited.

ARTICLE 52 – EXCLUSIVITY OF THE MANDATE

The members of the disciplinary bodies are not allowed to sit in both the DEP Committee and the Chamber of Appeal when both entities are addressing the same case. The same applies to members belonging to the same company or organisation as a member who has already sat in the concerned case.

SUBSECTION 2. GENERAL RULES OF PROCEDURE

1. CONCILIATION

ARTICLE 53 – CONCILIATION

A. Before initiating a complaint procedure before the DEP Committee, the parties must attempt to settle their disputes amicably.

B. At any stage of the complaint procedure, the president of each disciplinary body may engage in conciliation attempts or appoint a member to do likewise. The president may convoke the parties for this purpose.

2. FILING A COMPLAINT

ARTICLE 54 – PERSON ENTITLED TO LODGE A COMPLAINT

A. Any individual or legal entity who/that observe a violation of the rules of deontology as laid down in the present code, except in the preamble section, may file a written complaint against any member of IML with the Secretariat, for the attention of the DEP Committee.

The plaintiff must substantiate its complaint with the available evidence. The complaint must be filed in person or sent by registered mail to the Secretariat. It must also be emailed to the Secretariat. It cannot exceed 25 pages (A4, Verdana 9, single-spaced).

B. The plaintiff must also concomitantly send a copy of the complaint and any annexes to the defendant by registered mail.

C. The complaint shall only be registered and conveyed to the DEP Committee after receipt of payment of the registry fee in the bank account of IML. The plaintiff shall include proof of said payment with the complaint.

The registration fees amount to :

- 1,250 euros for legal entities (excluding VAT);
- 60 euros for natural persons (excluding VAT).

D. The Secretariat shall confirm receipt of the complaint with the relevant parties as soon as possible.

ARTICLE 55 – ADMISSIBILITY OF COMPLAINTS

A. To be declared admissible, the complaint must:

I. Clearly identify the plaintiff and the defendant;

II. Include a statement of relevant facts and a description of the alleged claims, making explicit reference to the relevant provisions of this code of Deontology;

III. Be accompanied by a declaration with which the plaintiff undertakes to comply with the rules prescribed by this code unless adherence to the present code is already confirmed in accordance with the rules laid down in Article 73; and

IV. Be accompanied by evidence that conciliation, e.g. as referred to in Article 53, A, has been attempted or, where applicable, evidence of the defendant's refusal to participate in said conciliation.

B. The plaintiff must also specify which measures are being requested in its complaint, as referred to in Article 69 of the present code.

ARTICLE 56 – LANGUAGE

A. Under penalty of inadmissibility, the plaintiff is obliged to formulate its complaint in French.

B. The proceedings shall be carried out exclusively in French in accordance with point A of this article.

C. The briefs and any other observations of the parties sent to the disciplinary bodies and other parties must be communicated in French, under penalty of exclusion from the debates. Unless otherwise specified by the president of the relevant disciplinary body, the exhibits brought by the parties must also be prepared or translated in French, except for documents originally drawn up in English.

3. PREPARING AND SETTING UP OF A HEARING

ARTICLE 57 - REPAIR

A. No later than the seventh calendar day following confirmation by the Secretariat of the registration of complaint in accordance with Article 54, D, the parties must inform the Secretariat whether or not they intend to file written briefs and/or exhibits during the proceedings and, if necessary, whether

they have mutually concluded and agreed on a timetable for the exchange of their written briefs/exhibits.

B. The maximum period allowed for the exchange of briefs/exhibits shall be 4 weeks from the date of notifying said timetable to the Secretariat. However, subject to mutual agreement, the parties may arrange a shorter or longer timetable, as required. Provided the parties agree on a timetable, they shall notify the details to the Secretariat within the period referred to in point A of this Article. In the absence of agreed timetable notified to the Secretariat within the time limit referred to in point A. of this Article, the president of the DEP Committee shall impose, at its sole discretion and without any recourse, a timetable, which shall in any event not exceed 4 weeks (as from the time the decision is communicated to the parties). The president may, where applicable, impose very strict time limits for the exchange of briefs/exhibits based on the circumstances of the case.

ARTICLE 58 – NOTICE OF MEETING

A. The parties shall be convoked before the DEP Committee within a time limit and in a manner commensurate with the circumstances and, where applicable, depending on the established timetable. Efforts shall be made, depending on circumstances, to ensure a reasonable period of time is allowed between the filing of the last brief and the date of appearance at the hearing.

B. The notice of hearing indicates the date, time and composition of the chamber of the disciplinary body before which the relevant parties must appear. Annexed to this is the declaration referred to in Article 48, B. If a party wishes to remove a member of the disciplinary body pursuant to Article 39, E, of this Code, it shall notify the specific reasons for its request to the members of the disciplinary body, through the Secretariat, as well as all parties involved as soon as it is informed of the composition of the seat of the body, in accordance with this paragraph and no later than the time of commencement of the first hearing. This request shall be handled in accordance with Article 39, E.

ARTICLE 59 – SUPPORTING DOCUMENTS

A. Each party shall provide all other parties with a copy of its entire set of exhibits or briefs at the same time it submits such exhibits or briefs to the Secretariat. The exhibits and briefs must in any event be emailed to the Secretariat (in WORD format for briefs and PDF format for exhibits). The exhibits must be properly itemised and numbered.

B. Except where exceptional circumstances apply, any briefs or exhibits filed or notified belatedly or outside the established timetable shall be excluded from the debates.

C. The briefs of the parties may not exceed 25 pages (A4, Verdana 9, single-spaced).

ARTICLE 60 - CONSULTATION OF THE FILE

The parties may consult the file in the Secretariat at any time, by appointment.

4. HANDLING OF COMPLAINTS BY THE DISCIPLINARY BODIES

ARTICLE 61 - HANDLING COMPLAINTS

A. The president of the disciplinary body shall open, preside over and close the debates. The president may also order the reopening of discussions. The president shall take all measures deemed necessary to ensure the proceedings function smoothly. If nothing is specified in the code, the president shall have sole discretion to decide how to follow up each procedural issue. Although the provisions of the Judicial code are not applicable, the president may nevertheless decide to proceed in line with the same.

B. At any stage of the proceedings, the president of the disciplinary body may convoke and hear the relevant parties within a reasonable time. The president may also order the production of documents within a specified time limit to obtain additional information.

ARTICLE 62 - CONTRADICTORY PRINCIPLES

A. The parties shall cooperate in the proper conduct of the proceedings and shall respect the rights of the defence and the adversarial principle. In the absence of a party duly summoned to the hearing, the proceedings shall be deemed to be adversarial and no opposition shall be possible.

B. In principle, no remission will be granted. However, a reasoned request may be submitted to the president of the body concerned, who will make a decision without appeal, respecting the parties' rights of defence.

C. The parties may be represented by counsel or a lawyer.

ARTICLE 63 - HEARINGS

A. Hearings before disciplinary bodies are organised virtually. They shell not be not public, unless otherwise asked by the defendant at the start of the hearing.

B. Any party who wishes a third party to be heard may lodge a substantiated request with the president of the disciplinary body, who shall decide at its sole discretion and without any recourse. In light of the rights of defence, the president shall ask the opposing party to provide its arguments over whether or not said hearing should proceed.

C. the debates shall be held in French, in accordance with Article 56, unless the president of the relevant body authorises the parties or third parties concerned to express themselves in another language.

ARTICLE 64 - TAKING OF EVIDENCE

At the request of a party and after adversarial scrutiny, the disciplinary bodies shall exclude any evidence gathered by unlawful means from the file.

ARTICLE 65 – REQUALIFICATION

The disciplinary bodies may qualify the facts themselves or otherwise requalify them.

ARTICLE 66 – SUSPENSION

A. When the same case is heard between the same parties before disciplinary bodies and any body external to IML, for example a judicial or administrative authority or an arbitration body, handling of the same case by the disciplinary bodies can be suspended until a verdict is rendered by the relevant judicial or administrative authority.

B. Any party involved in a case brought before the disciplinary bodies shall promptly notify the latter if the same case is brought before a body external to IML.

The application of this Article 66 leads to a separate decision by the president of the disciplinary body. There is no right of appeal against this decision before the Chamber of Appeal.

5. SPECIFIC RULES GOVERNING THE APPEAL PROCEDURE

ARTICLE 67 - CHAMBER OF APPEAL

A. Any decision taken by the DEP Committee can be appealed against to the Chamber of Appeal. Decisions made on procedural issues cannot be appealed.

B. Under penalty of inadmissibility, the appeal must be made in French and, either hand-delivered to the Secretariat or sent to the Secretariat by registered mail, within ten calendar days from the date of receipt of the decision of the DEP Committee sent in accordance with Article 68, B, of the code. The appeal shall also be notified to the Secretariat by email.

C. The appellant is also obliged to send a copy of its appeal and any annexes by registered mail to the defendant in appeal.

D. The appeal shall only be registered and conveyed to the Chamber of Appeal after receipt of payment of the registry fee in the bank account of IML. The appellant shall include proof of said payment with the appeal.

The registry fees shall amount to:

- 3,000 euros for legal entities (excluding VAT);
- 100 euros for natural persons (excluding VAT).

E. The Secretariat shall confirm receipt of the appeal with the relevant parties as soon as possible.

F. To be deemed admissible, the appeal must outline the set of claims put forward by the appellant in response to the decision of the DEP Committee. The appellant must also specify which measures are being requested in its appeal, as referred to in Article 69 of the present code.

G. Under penalty of exclusion from the debates, the defendant in appeal shall have a maximum period of 10 days from the notification of the Secretariat referred to in point E of this Article to transmit to the latter and the other relevant parties its written observations, the scope of which must be limited to the grievances set out in the appeal. The appeal and observations, as well as any exhibits, must at least be emailed to the Secretariat (in WORD format for briefs and PDF format for exhibits). The exhibits must be properly itemised and numbered. The appeal of the appellant and the observations of the defendant in appeal may not exceed 25 pages (A4, Verdana 9, single-spaced).

H. The parties shall be convoked before the Chamber of Appeal within a time limit and in a manner commensurate with the circumstances. Efforts shall be made, depending on circumstances, to ensure a reasonable period of time is allowed between the filing of the observations of the defendant in appeal and the date of appearance at the hearing. The notice of hearing indicates the date, time and composition of the chamber of the disciplinary body before which the relevant parties must appear. Annexed to this is the declaration referred to in Article 48, B. If a party wishes to remove a member of the disciplinary body pursuant to Article 39, E of this code, it shall notify the specific reasons for its request to the members of the disciplinary body, through the Secretariat, as well as all parties involved as soon as it is informed of the composition of the seat of the body, in accordance with this paragraph and no later than the time of commencement of the first hearing. This request shall be handled in accordance with Article 39, E.

SUBSECTION 3. DECISIONS AND MEASURES UPON NON-COMPLIANCE WITH THE CODE

ARTICLE 68 - APPEAL PROCEDURES

A. The proceedings before the DEP Committee and the Chamber of Appeal may give rise to the following decisions:

I. The complaint/appeal, being declared admissible, is well founded and a violation of the code is established, possibly with the pronouncing of one of the measures provided for in Article 69;

II. The lack of admissibility or grounds for the complaint/appeal;

III. The statement that the dispute has ended, where applicable, by implementing an amicable agreement between the parties. In the latter case, the parties are solely responsible for reaching such agreement, even after conciliation by the president.

B. The decisions of the DEP Committee and the Chamber of Appeal are expressly substantiated and notified to the parties by registered mail with acknowledgment of receipt.

C. The decisions of the DEP Committee are deemed final in the absence of any appeal filed within the period referred to in Article 67, B, of the present code.

ARTICLE 69 - MEASURES AND EFFECTS

A. When the DEP Committee or the Chamber of Appeal declares that a violation is established, it shall order immediate cessation of the infringing activities and shall urge the relevant party to undertake in writing to take the necessary measures to prevent any recurrence.

B. When the DEP Committee or the Chamber of Appeal declares that a violation is established, it may also impose the following measures against the party that it deems to have contravened the rules of deontology referred to in the present code:

I. a reprimand; and/or

II. a corrective measure; and/or

III. a supervisory measure; and/or

IV. a financial indemnification measure.

C. The term “corrective measure”, as referred to in point B., includes for example:

I. Correction of infringing material;

II. insertion of a corrective statement and/or issuing an amended version of the infringing material;

III. recall of any infringing material already distributed;

IV. direct communication by letter to the medical and/or pharmaceutical profession of the decision of the DEP Committee or of the Chamber of Appeal or of an excerpt from the same;

V. removal of a link to a website.

D. The term “supervisory measure”, as referred to in point B, includes for example:

I. communicating the details of the organisation of an upcoming event and any other relevant information relating thereto;

II. recommendations for transparency or clarity;

III. requiring the submission, by a specified deadline, of a detailed plan of concrete measures that the relevant party intends to undertake to comply with the decision or to improve its internal control process.

E. The term “financial indemnification measure” refers to a reasonable financial compensation for any damage suffered by the pharmaceutical industry as a result of a violation of the rules of deontology referred to in the present code. The amount of the latter shall be fixed at the sole discretion of the DEP Committee or the Chamber of Appeal. When determining said amount, the DEP Committee or the Chamber of Appeal shall take account of any damage suffered by the pharmaceutical sector, including to its reputation. The amount of compensation shall vary between 5,000 euros and 50,000

euros depending on the violation and must be paid in the bank account of IML specifically reserved for this purpose (as communicated by the Secretariat) within a period of 30 calendar days from the date of the written notice issued by the Secretariat. If this is not done, late payment interest shall be levied at the legal interest rate applicable to civil matters. The financial indemnification referred to in this paragraph shall be repaid by IML to the pharma. be to Cancer Foundation.

F. The DEP Committee or the Chamber of Appeal may also order the nominative publication of a summary of the decision in French, in certain journals, subject to the agreement of the journal in question. As regards the decisions of the DEP Committee, any publication shall only take place after time limit for appeal, as referred to in Article 67, B of the present code, has elapsed and provided that no appeal has been filed. In the event of a subsequent violation within two years after a breach of this code has been established by the DEP Committee or the Chamber of Appeal in a final decision or in the event of a serious breach of the rules of deontology referred to in this code, the nominative publication of a summary of the decision shall also proceed in English in SCRIP. In assessing whether or not a breach is serious in the context of the preceding paragraph, the DEP Committee or the Chamber of Appeal, whichever is applicable, may refer to the guidelines on this subject, appended to this code in annex.

All publications contain the following statement: "*The DEP Committee and the Chamber of Appeal are bodies created by pharma.be with a view to ensuring the correct application of the rules of its code of deontology as well as the IML code. These committees comprise both members not involved in the pharmaceutical industry (lawyers and members of the medical profession, the pharmaceutical profession, or from scientific or academic backgrounds), and a representative of the pharmaceutical industry; all of whom operate with total independence pursuant to the code. The decisions of the DEP Committee and the Chamber of Appeal are taken by a simple majority of the members present, relate solely to the facts submitted to them and concern only the parties directly involved in the cited dispute. IML oversees the administrative management of the deontological system. To consult the IML Code of eEthics, visit www.iml.lu ".*

G. The costs associated with the **cessation, measures, publication** shall be borne by the party against whom they are delivered, without prejudice to the application of Article 72.

SUBSECTION 4: EXECUTION OF DECISIONS

ARTICLE 70 - EXECUTION OF MEASURES

Except in the case of publications referred to in Article 69 F, of the code, decisions taken by the DEP Commission are in principle enforceable by provision, notwithstanding appeal, unless the DEP Commission decides otherwise, by way of a specially substantiated decision. The provisional execution of the decision shall take place at the sole risk of the party pursuing the same.

ARTICLE 71 - INFORMATION FOR THE BOARD OF DIRECTORS

A. The Board of Directors shall be informed of any final decision of the disciplinary bodies which results in a violation of this Code being established.

B. The measures which may be imposed under Chapter 5 of this code shall not, regardless of circumstances, prejudice the possibility for the Board of Directors of IML to propose the exclusion of any member to the General Assembly pursuant to Article 7 of the bylaws.

CHAPTER 6. COSTS OF PROCEEDINGS

ARTICLE 72 - DEFINITION OF PROCEDURAL COSTS

A. In the sense of the present Article, the term “costs of proceedings” refers to all costs linked to the proceedings referred to in Chapter 5, section 3.

B. The party deemed to have committed a violation by a final decision and, where applicable, against which a measure is imposed, shall bear the costs of proceedings. The plaintiff shall bear the costs of proceedings where, after a final decision, no violation is established or measure imposed against the original defendant. Unless otherwise agreed by the parties, the plaintiff shall bear the costs of proceedings when the disciplinary body concerned acknowledges that the dispute has ended before a decision has been made.

C. The party bearing the costs of proceedings is obliged:

- to pay the lump sum as published on the public website of IML ;

- where applicable, to make payment of expert fees arising pursuant to Article 39, C, of this code;

- where applicable, to refund the plaintiff /appellant for the equivalent amount spent by the latter on registry fees, as referred to in Articles 54, C, and 68, D, of this Code.

D. In view of the circumstances, the disciplinary body may order the party that has committed a violation to pay a procedural allowance of between 1,500 and 4,500 euros. In its assessment, the disciplinary body shall take account of:

- the complexity of the issue;

- any patently unreasonable aspect of the situation.

E. Each disciplinary body may, in any case not provided for under this Code, fix the allocation of costs of proceedings to the parties.

F. In derogation of the preceding rules, individuals shall not be required to bear any costs of proceedings.

CHAPTER 7:

GENERAL PROVISIONS - ENTRY INTO FORCE - TRANSITIONAL MEASURES

ARTICLE 73 - COMPULSORY MEMBERSHIP

Adhesion to the Code, that is an inherent part of the IML by-laws, becomes effective at the time of membership of IML. It is a necessary condition for becoming a member of IML.

ARTICLE 74 - VERSIONS

The Code of Ethics, as originally conceived, came into force on 3 November 2012. The current revised version of the Code comes into force

- As regards the ethics complaint procedure, on 1er January 2024
- For the rest, 1er May 2023.

ARTICLE 75 - COMMUNICATION

IML will be responsible for communication in connection with the present code. This communication will be addressed to all interested parties as well as to members of the pharmaceutical industry, Healthcare Professionals, including representative organisations, patients and the authorities.

ARTICLE 76 - RESIGNATION, EXCLUSION

The resignation or exclusion of a Member Company when a case of concern to it is in progress does not halt the proceedings, or the implementation of measures pronounced against it. This Member Company also remains liable for any costs of proceedings (or other sums) established in accordance with Article 72.

ARTICLE 77 - MERGER and ACQUISITION

In the event of the accession of a new Member Company or the merger/acquisition of a non-member undertaking by a Member Company of the IML, the first reference period referred to in Article 36ter.1 shall coincide, for this new Member Company or for the merged/acquired undertaking, at the latest, with the calendar year following the first year of accession or the year of the merger/acquisition respectively.

APPENDIX S

APPENDIX 1 TO THE IML CODE OF ETHICS

Guidelines for determining the facts that are to be considered a "serious breach of the rules of deontology " under Article 69, F of the Code.

BACKGROUND

In accordance with article 69, F of the Code, when the DEP Committee or the Chamber of Appeal declares a "serious breach" established in the sense referred to above, a summary of the decision appears in English in SCRIP.

GUIDELINES

It is clear that the question of whether or not certain facts constitute a "serious breach" in the aforementioned context will always have to be judged on a case-by-case basis and that it is ultimately up to the deontological body to which the matter has been referred (the DEP Committee or the Chamber of Appeal) to pronounce on this question in complete independence but nevertheless in a reasoned manner.

Without wishing to call into question the freedom of judgement of the bodies mentioned, a number of points are proposed below for consideration:

- Medicines are supposed to help preserve and restore what is most precious to human beigns: their health and quality of life.
  - The pharmaceutical industry has a major responsibility in this respect. For this reason, any action that could jeopardise a patient's health could be considered a "serious breach".

  The following may be considered as acts likely to endanger a patient's health:
  - deliberate falsification of the results of a study;
  - falsification of the expiry date of medicines.

- The information provided by Member Companies concerning the products they place on the market must be correct and objective. Patients must be able to be certain that they are receiving the medicinal product that is best suited to their needs.

  Consequently, any failure by a Member Company to influence the prescribing or dispensing behaviour of Healthcare Professionals which, if made known to patients, could compromise the relationship of individual trust between patients and Healthcare Professionals may be considered a "serious breach".

  The following may be considered as breaches intended to influence the prescribing or dispensing behaviour of Hralthcare Professionals and which, if made known to patients,

could compromise the relationship of individual trust between the latter and Healthcare Professionals:

- the granting to the doctor of a benefit in cash or in kind for each prescription he writes.

- For adequate healthcare, it is also important that patients, authorities and Healthcare Professionals can trust in the pharmaceutical industry and its products in general. Consequently, breaches that are highly visible, either to Healthcare Professionals, the general public or the authorities, will very often have a greater (negative) impact on general confidence in the pharmaceutical industry and may therefore generally be regarded as "serious breaches". In this context, the fact that the breach could possibly be reported by the media must therefore be taken into account.

  The following may be considered to be breaches with a high profile:
  - sponsoring/supporting an event attended by a large number of Luxembourg doctors abroad (e.g. in the French Champagne region), without any justification being given as to the location;
  - inviting a large number of doctors to a sporting or cultural event.

- Medical products are not simply consumer goods. It can only be placed on the market after an in-depth procedure designed to guarantee the quality, safety and efficacy of the product (MA = marketing authorisation). Alongside the MA, a Summary of Product Characteristics (SPC) and a package leaflet are drawn up to inform the Healthcare Professional and the patient respectively. Any marketing technique aimed at encouraging patients to use medicinal products by offering them gifts or any other economic advantage and whereby the purchase and, where applicable, the prescription or dispensing of the medicinal product are no longer (mainly) motivated by reasons set out in the package leaflet/SPC but rather by commercial impulses may therefore be considered a "serious breach".

  The following may be considered to be breaches that consist in stimulating the use of medicinal products by offering advantages to the patient:
  - the organisation of a competition for patients who use a certain medicine;
  - the introduction of a system whereby, after the tenth purchase, the pharmaceutical company offers the patient an eleventh medicine free of charge.

- The law on medicinal products is the cornerstone on which interactions between the pharmaceutical industry and Healthcare Professionals are based. A breach of this article - which prohibits the pharmaceutical industry from granting bonuses and benefits, with certain exceptions - is therefore likely to constitute a "serious breach". The following may be considered to be breaches of the law on medicinal products:
  - inviting Healthcare Professionals to sporting or cultural events;
  - inviting professionals from the healthcare sector to a seminar abroad, without the location being justified in any way;

- overcompensating a doctor for his contribution to a scientific study, by granting compensation that is disproportionate to the nature and duration of the work provided;
- inviting healthcare professionals to restaurants, provided that this is not done in the context of medical or pharmaceutical science or provided that the medical-pharmaceutical communication is only secondary to the facts as a whole.

The notion of "serious breach" as described above is part of IML's ethical arsenal. The facts charged must therefore constitute a breach of the provisions of the Code of Ethics, whether or not they are legally sanctioned.

However, the fact that the charges may be punishable under criminal law because they also breach one or more legal provisions is a factor that should be examined when assessing their seriousness.

APPENDIX 2 TO THE IML CODE OF ETHICS

Guidelines (Annex CB of the EFPIA Code)

The purpose of this document is to guide IML members in their interpretation and application of the provisions of the IML Code of Ethics relating to bonuses and benefits of negligible value, as well as reasonable hospitality towards Healthcare Professionals.

Clarifications to article 12 and 29: Hospitalityy

For the purposes of Articles 12.1 and 29.2, the terms "appropriate", "renowned for their entertainment facilities" and "extravagant" are intended to ensure that the location, date and duration of the event do not create confusion about its scientific nature.

An "appropriate" venue is one that corresponds to the objective of the event, whether in terms of its proximity to a scientific or business centre, its ease of access or its capacity. Destinations that are characterised solely by their tourist appeal and have no connection with the scientific objective of the event should be avoided.

Venues that do not have facilities for hosting scientific events are "reputed for their entertainment facilities" or considered to be "extravagant". The venue hosting the event must not include any sports or leisure facilities. This excludes, for example, golf clubs, fitness centres, or venues with a recreational or festive purpose (e.g. amusement parks, wineries, concert halls).

Under Article 12.2, Member Companies are permitted to offer hospitalityy to Healthcare Professionals, provided that such hospitalityy remains at a reasonable level.
By a reasonable level is meant for:

1. A scientific event without overnight stay Meals
2. Scientific event with overnight stay Meals

The maximum amounts for hospitality are defined in guidelines published on the IML website.

These same values may be used as a frame of reference for relations with patient organisations (article 29.6 of this Code).

Clarifications to Article 11: Informational or educational material and objects of medical use

Member Companies are permitted to provide informative or educational material and items of medical utility to Healthcare Professionals, provided that these are of negligible value.
By negligible value, is considered :

o The equipment or object is not of a nature to influence the therapeutic choice;
o Maximum 50 EUR per object (market value, VAT included);
o Maximum 125 EUR per year, per Healthcare Professional and per firm (VAT included).

The negligible value is determined on the basis of the object as a whole and not on the basis of any individual components/parts.

APPENDIX 3 TO THE IML CODE OF ETHICS (MANDATORY)

Annexe 2 - SCHEMA DE PUBLICATION DES TRANSFERTS DE VALEUR

Article 44ter.3 — *Date de publication: .....*

	Nom complet *(Art. 44bis)*	**PSS**: Commune et code postal du cabinet principal **OSS**: Commune et code postal du siège principal *(Art. 44quater)*	Pays du cabinet principal *(Art. 44bis.2)*	Adresse (rue/numéro/bte) du cabinet principal *(Art. 44quater)*	Numéro unique d'identification *OPTIONNEL* *(Art. 44quater)*	Donations et subventions *(Art. 44quater.2.I.a)*	Contributions aux frais relatifs à des manifestations scientifiques *(Art. 44quater.2.I.b & 44quater.2.II.a)*			Honoraires pour services et consultance *(Art. 44quater.2.I.c & 44quater.2.II.b)*			**TOTAL** *OPTIONNEL*
							Conventions de sponsoring avec OSS / des tiers désignés par OSS pour gérer une manif. scientifique	Coûts d'inscription	Frais de voyage et de séjour	Honoraires	Frais liés inclus dans la rémunération ou convenus dans la convention de consultance, y compris frais de voyage et de séjour liés à la convention		
PSS	***PUBLICATION INDIVIDUELLE NOMINATIVE - une ligne par PSS*** *(tous les transferts de valeur durant l'année effectués au profit d'un PSS seront additionnés - une publication détaillée ne devrait être rendue disponible que pour le bénéficiaire concerné ou pour les autorités compétentes qui le demandent)*												
	Dr A					N/A	N/A	*Montant annuel*	*Montant annuel*	*Montant annuel*	*Montant annuel*		
	Dr B					N/A	N/A	*Montant annuel*	*Montant annuel*	*Montant annuel*	*Montant annuel*		
	etc.					N/A	N/A	*Montant annuel*	*Montant annuel*	*Montant annuel*	*Montant annuel*		
	AUTRES, NON INCLUS CI-AVANT - Si les informations ne peuvent être publiées sur une base individuelle pour des raisons légales												
	Montant agrégé des transferts de valeur à ces bénéficiaires *- Art. 44quater.3*					N/A	N/A	*Montant agrégé*	*Montant agrégé*	*Montant agrégé*	*Montant agrégé*		*Optionnel*
	Nombre de bénéficiaires *(liste nominative si indiquée) - Art. 44quater.3*					N/A	N/A	*nombre*	*nombre*	*nombre*	*nombre*		*Optionnel*
	% du nombre de bénéficiaires inclus dans la publication agrégée dans le nombre total de bénéficiaires publié *- Art. 44quater.3*					N/A	N/A	%	%	%	%		N/A
OSS	***PUBLICATION INDIVIDUELLE NOMINATIVE - une ligne par OSS*** *(tous les transferts de valeur durant l'année effectués au profit d'une OSS seront additionnés - une publication détaillée ne devrait être rendue disponible que pour le bénéficiaire concerné ou pour les autorités compétentes qui le demandent)*												
	OSS 1					*Montant annuel*	*Montant annuel*	*Montant annuel*	*Montant annuel*	*Montant annuel*	*Montant annuel*		*Optionnel*
	OSS 2					*Montant annuel*	*Montant annuel*	*Montant annuel*	*Montant annuel*	*Montant annuel*	*Montant annuel*		*Optionnel*
	etc.					*Montant annuel*	*Montant annuel*	*Montant annuel*	*Montant annuel*	*Montant annuel*	*Montant annuel*		*Optionnel*
	AUTRES, NON INCLUS CI-AVANT - Si les informations ne peuvent être publiées sur une base individuelle pour des raisons légales												
	Montant agrégé des transferts de valeur à ces bénéficiaires *- Art. 44quater.3*					*Montant agrégé*	*Montant agrégé*	*Montant agrégé*	*Montant agrégé*	*Montant agrégé*	*Montant agrégé*		*Optionnel*
	Nombre de bénéficiaires *(liste nominative si indiquée) - Art. 44quater.3*					*nombre*	*nombre*	*nombre*	*nombre*	*nombre*	*nombre*		*Optionnel*
	% du nombre de bénéficiaires inclus dans la publication agrégée dans le nombre total de bénéficiaires publié *- Art. 44quater.3*					%	%	%	%	%	%		N/A

R&D	***PUBLICATION AGREGEE***		
	Transferts de valeur concernant la recherche et le développement tels que définis à l'art. 44quater.5	*MONTANT TOTAL*	*OPTIONNEL*

APPENDIX 4: GUIDANCE ON TRANSFERRING THE VALUE OF NON-INTERVENTIONAL STUDIES :

TRANSFER OF VALUE FROM NON-INTERVENTIONAL STUDIES :

Transfers of value relating to non-interventional studies (NIS) that do not comply with the definition of R&D Transfers of value in the IML Code must be declared individually.

Foresight	Retrospective
Prospective cohort studies in which the prescription of the medicinal product is independent of the patient's inclusion in the study A retrospective study to which a prospective element is subsequently added Long-term extension studies with patient follow-up Patient follow-up beyond the duration specified by the trial protocol for observation and active collection of additional data	Examination of a purely observational and/or research database Retrospective examination of recordings where all the events of interest have already occurred *e.g. case-control, cross-sectional and purely retrospective cohort studies* Studies in which the prescriber becomes an investigator, but the prescription has already been issued *for example, collection of retrospective data from individual medical records on the investigator's site*

For the sake of clarity, activities that do not fall under the definition of R&D ToVs, including NIS that are not conducted to maintain a marketing authorisation (pursuant to and following the definitions in the Clinical Trials Regulation Regulation 536/2014), will be disclosed under the heading "consultancy/fee-for-services".

TRANSFER OF VALUE INDIRECTLY OR BY THIRD PARTIES

Third parties provide support to Member Companies in various capacities, with varying degrees of impact on the conduct of activities regulated by the IML Codes. Such activities would be declared as Indirect Transfers of Value (ToVs) under the provisions of the IML Code.

Where Member Companies provide support / sponsorship to Patient Organisations involved in the organisation of Scientific Events, it is understood that these are Indirect Transfers of Value.

Indirect transfers of securities are those made in the name of a member company to a beneficiary, or Transfers of Value through an intermediary.

In view of the legal problems that may arise when declaring Transfers of Value via distributors on behalf of a Member Company, the declaration of such Transfers of Value is outside the scope of this guide.

Where appropriate, the IML may consider developing further guidelines for this category (and other categories of third parties involved in ToV).