European Federation of Pharmaceutical Industries and Associations

EFPIA Code
Report on Ethics & Compliance Activities
July 2025

At EFPIA, the Ethics & Compliance activities are organised within the framework of the Codes Committee (composed of the representatives from the Member Associations) and the Ethics & Compliance Committee (composed of the representatives from the Member Companies and Associations).

Based on the EFPIA Code requirements, the Codes Committee must publish an **annual code report** which summarizes the work and activities which have taken place in connection with the implementation, development, and enforcement of the various national codes during the applicable year, based on the country reports provided by the Member Associations (**2024 National Code reports**).

In addition to these national Code reports, EFPIA includes in this report an overview of the Ethics & Compliance activities conducted by EFPIA during 2024 and into mid-2025.

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1. Codes Committee and Ethics & Compliance Committee Activities

a. Codes Committee

The role of the EFPIA Codes Committee (CodCom) is to assist the Member Associations in their national compliance activities and to monitor the adoption of compliant national Codes in line with local requirements.
In line with its mandate, the CodCom focused on the following topics in 2024 and into 2025:

- **Legal and compliance provisions applying to medical congress**

The CodCom members and IPCAA co-created a document summarizing the legal and compliance provisions applicable to medical congress organisation. The objective of this document is to explain the complex nature of medical congress to people outside the pharmaceutical industry.
The document is annexed to this report.

- **Code monitoring activities**

Based on the EFPIA Ethics & Compliance priority related to self-regulation credibility, EFPIA Secretariat monitored the national Codes activities.
For 2024, the CodCom members decided to verify the 2 following provisions:

- The transposition of the samples provision
- The implementation of the host country principle

Results from 2024 monitoring were shared back with the Member Associations to highlight areas where provisions had not been adopted into local Codes so action could be taken.

For 2025, the provisions to monitor are:

- Informational or educational materials, items of medical utility (Article 17)
- Promotional information provided during international Events (Article 8)

EFPIA Secretariat will also closely monitor national Code updates and share information with the E&C community. To this end, a dedicated section has been added in the national code reports.

- **Communication**

The CodCom members decided to write and publish 2 blogs:

- One explaining the concept of self-regulation, written by Alex Fell and Julie Bonhomme, published in December 2024
- Another one on the legitimate need of promotion in the pharmaceutical industry, written by José Zamarriego and Santiago Páramo and published in April 2025

- **Member Associations roundtable**

During each CodCom meeting, the Member Associations are invited to share their priorities or national topics. This roundtable is crucial to get information on ethics & compliance activities happening in Europe and identify emerging risks, trends and good practices.

- **e4ethics**

The CodCom members have decided to strengthen the collaboration with Ethical MedTech in the context of e4ethics. Quarterly meetings will be organised to discuss our respective positions.
They have also clarified EFPIA position related to the provision of childcare services during medical congress. The following position has been shared with the Ethical MedTech team and will be included in the EFPIA Code FAQ:

> "Appropriate childcare services may be proposed at a reasonable cost, provided that the healthcare professionals cover the expense and the congress organiser does not actively promote these services."

- **Update of the countries in scope of the EFPIA Code**

Due to the compliance risks associated with current sanctions prohibiting the provision of services to Russian entities, EFPIA Secretariat removed the Russian Member Association (AIPM) from the list of countries in scope of the EFPIA Code (footnote on page 5).

b. Ethics & Compliance Committee activities

The mission of the Ethics & Compliance Committee (E&CC) is to "contribute to enhance ethical behaviour within a self-regulation framework to increase reputation and credibility of the pharmaceutical sector for the benefit of patients."
In 2024 and into 2025, in addition to the EFPIA Ethics and Compliance priorities, the E&CC has focused on the following projects:

- **E&CC priorities**

The E&CC members agreed to prioritise on the development of compliance tools and identified three key areas:

- Communication
- Collaboration
- Training

- **Patient Solutions Guidelines**

In December 2024, the E&CC approved the Patient Solutions Guidelines.
This document includes recommendations for companies when designing, implementing or commissioning any types of services/programs/solutions aiming to benefit any actual or potential individual patient.
The document is annexed to the EFPIA Code (as a non-binding Annex) and published on the EFPIA website.

- **Disclosure**

In 2021, the E&CC has set up a Disclosure Task Force (TF) with the mission to investigate how to improve transparency and leverage value of our disclosure efforts, and to analyse the current challenges and evolving societal expectations.
This year, the E&CC members decided to implement 2 of the TF's proposals aiming to harmonise the information related to disclosure data:

- Implement a disclosure unified format (downloadable and searchable) and a publication standard (in the absence of a governmental or national platform) at the latest for the 2027 disclosure of 2026 data.
- Standardise the terminology and layout of the methodological notes at the latest for the 2026 disclosure of 2025 data.

Communication plan for the 10th disclosure
For the 10th publication, EFPIA Secretariat has developed a communication plan with the support of EFPIA members and some key stakeholders.

- 4 Blogs have been published
  - A general blog on the why, the achievements and future developments
  - A joint-patient blog co-authored by Magdalena Kołodziej and Antonella Cardone explaining the benefits of this initiative, how they use the data
  - A blog from the UK Academy of Medical Royal Colleges (AoMRC) showcasing how self-regulation has improved in the past 5 years thanks to the support of UK physician authority
  - A blog on the Spanish self-regulation mechanism: How FARMAINDUSTRIA has succeeded in maintaining self-regulation and solved the consent rates

- 2 videos

    - 1 with Nathalie Moll, based on the general blog
    - 1 with José Zamarriego on the Spanish self-regulation model

  - Toolkits for EFPIA members
    - The disclosure leaflet and disclosure external FAQ have been updated

- **Monitoring legal developments impacting E&C activities**

The E&CC has also monitored the following developments of legal initiatives that can impact Ethics & Compliance activities:

  - An update on the status of the General Pharmaceutical Legislation review has been presented during each E&CC meetings, with a special focus on the Advertising Chapter of the EU Directive 2001/83, which forms the basis of the EFPIA Code and the national codes.
  - The European Directives on Corporate & Sustainable Reporting and Corporate & Sustainable Due Diligence including the definition of mandatory reporting standards.

- **HETHICO – Healthcare Ethics & Compliance Conference**

EFPIA, with MedTech Europe, will organize the third edition of the European Healthcare Ethics & Compliance conference “HETHICO”, in Brussels.
It will take place from 7-8 October 2025 at The Hotel in Brussels.
All the information related to this conference is available here: https://www.hethico.org/

2. Annex 1: LEGAL AND ETHICAL RULES GOVERNING MEDICAL CONGRESS

How to set up a medical congress?

Introduction

The objective of this document is to explain the legal and ethical rules applying to medical congresses that are sponsored by EFPIA Member Companies.
The primary intended audience for this document is the medical societies and other organisations that may be unfamiliar with European legislation and the EFPIA Code.
The document includes the minimum standards of rules applying at the European level. National laws and regulations can be stricter; therefore, we recommend always verifying the national framework applying to medical congresses.

Structure of a medical congress

Medical congresses are generally organised in two parts:
1) The scientific program covers up to 95% of the entire program, is exclusively managed by the medical society without any pharmaceutical industry input. It typically includes keynote lectures, debates, plenary sessions, abstract, and poster presentations. This must be the main reason to attend the event.
To ensure the scientific purpose of the medical congress, there must be an independent scientific board that is responsible for the program review.

2) The pharmaceutical industry takes on the responsibility for satellite activities, including industry symposia and exhibitions, which complement the main congress agenda. These activities allow the industry to present their innovations and engage with healthcare professionals, while remaining separate from the core educational content led by the medical societies. The industry activities should represent a minor part of the entire program.

The faculty who is, in general, composed of the speakers, moderators or anyone involved in the scientific program of the medical congress may access sessions in which they have an active role even if they are not qualified as HCPs.

Definitions and legal provisions relevant for medical congress

Directive 2001/83/EC[1] regulates the interaction between pharmaceutical companies and person that can prescribe or supply medicinal products. The Directive also mentions information that can be shared with the public. Interactions with patients/Patient Organisations are not mentioned. Therefore, the provisions applicable to the public apply to these interactions.

Title VIII in Directive 2001/83/EC[2] sets the rules on advertising. It prohibits the advertising of prescription products to the general public[3].

Advertising of medicinal products is any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; including visits by medical sales representatives, the supply of samples, sponsorship of promotional meetings, sponsorship of

[1] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32001L0083
[2] Art. 86 – 100, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32001L0083
[3] Ibid. art. 88

scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.[4]

Non-promotion, as per the definition in the Directive[5], is the labelling and the accompanying package leaflets, correspondence to answer a specific question about a particular medicinal product, factual, informative announcements and reference material, trade catalogues and price lists, statements relating to human health or diseases, provided there is no reference, even indirect, to medicinal products.

Definitions included in the **EFPIA Code of Practice**[6]:

Healthcare Professional (HCP): any natural person that is a member of the medical, dental, pharmacy or nursing professions[7] or any other person who, in the course of his/her professional activities, may prescribe, purchase, supply, recommend or administer a Medicinal Product and whose primary practice, principal professional address or place of incorporation is in Europe. For the purpose of this Code, the definition of HCPs includes: (i) any official or employee of a government, agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply, recommend or administer Medicinal Products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of Medicinal Products.

Healthcare Organisation (HCO): any legal person/entity (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for POs within the scope of article 21) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.

Self-regulation provisions related to medical congress

Article 10 of the EFPIA Code defines the requirements applicable to pharmaceutical companies when organising events (all professional, promotional, scientific, educational meetings, congresses, conferences, symposia, and other similar events organised or sponsored by or on behalf of a Member Company) and/or providing hospitality during these events (paying for travel, meals, accommodation and genuine registration fees).

In addition, Member Company must submit or verify that the European congresses they organise or sponsor has been assessed by e4ethics and has received a positive assessment.

Self-regulation provisions related to the interactions between the pharmaceutical sector and the POs

The EFPIA Code includes a recognition of these interactions between the pharmaceutical sector and the Patient Organisations.[8]
It applies to **Patient Organisations**: non-for-profit legal person, mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and to **POs representatives:** a person mandated to represent and express the collective views of a PO on a specific issue or disease area.

[4] Ibid. Art. 86
[5] Ibid. Art. 86 paragraph 2
[6] EFPIA Code of Practice, https://www.efpia.eu/relationships-code/the-efpia-code/
[7] Local restrictions may apply i.e. in some countries, nurses are not considered as HCPs
[8] EFPIA Code of Practice, https://www.efpia.eu/relationships-code/the-efpia-code/

Questions

1. Which category of participants generally attend medical congresses?

- Healthcare Professionals
- Healthcare Organisations
- PO, patient advocates, patients
- Member of the public
- Journalists
- Staff of supporting companies and exhibitors
- Researchers, academic representatives
- Students[9]

2. Which type of activity are accessible for each category?

a. Exhibition area (with direct or indirect promotion)

- Healthcare Professionals
- Exhibitors

b. Medical society scientific session (without direct or indirect promotion)

- All registered delegates

c. Industry satellite symposia

- Healthcare Professionals
- Staff of the company organising the symposia

3. Why are non-HCP delegates unable to access some congress activities?

As mentioned above, Directive 2001/83/EC only regulates interactions with person qualified to prescribe or purchase a Medicinal Product or communication with the public. Interactions with patients/POs are not mentioned. Therefore, for communication to patients/POs, it is the provisions for public that apply.
Title VIII in Directive 2001/83/EC [10] sets the rules on advertising and prohibits any promotional communication of prescription products to the general public[11].
As described above, some parts of the medical congress include promotional information and can only be accessible to person qualified to prescribe or purchase a Medicinal Product.

4. Are non-HCPs allowed to visit or to have a booth in the exhibition area?

As described above, it is not acceptable to have non-HCPs visiting the exhibition area.

To ensure patient organisations have access to medical congresses, and whilst respecting the prohibition of promotion to public, some medical congresses have two different exhibition areas: one part with materials intended for HCPs (which may include promotional material) and another part with material intended also for the public (without any form of direct or indirect promotion).

[9] Local specificities may apply as in some countries, students are considered as HCPs.
[10] Art. 86 – 100, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32001L0083
[11] Ibid. art. 88

As an example, a PO can have a booth with materials intended for public/patients as long as the booth is in a separate non-promotional exhibition area.

5. What safeguards can medical congress organisers put in place to respect laws and regulation?

Medical societies must ensure that non-HCP delegates are not exposed to promotional materials.
As an example, they can provide different coded lanyards/badges so that non-HCP delegates do not enter promotional areas or organise two separate exhibition spaces (if any exhibitors have materials intended for the public).

3. 2024 National Code reports

AUSTRIA – PHARMIG

Code authority activity
In 2024 there was one complaint filed under the PHARMIG Code of Conduct (CoC "VHC").

The complaint focused on three topics: advertising of prescription-only-medicines to the general public (Art. 5.9 VHC; § 51ff Austrian Medicinal Products Act "AMG"); covering adequate travel and accommodation costs for participating HCP in case of need (Art. 5.9, 7.1 VHC; VHC Board Guidance 1/2015 Art. 2.2; § 55a Abs 3 Austrian Medicinal Products Act "AMG"); standard of the hotel that was used as the venue for this company owned event (Art. 7.4 VHC; VHC Board Guidance 1/2015 Art. 2.5, Art. 3).

The PHARMIG Code Adjudication Board decided: There was a breach of the ban of prescription-only-medicines advertising to the general public since even in case the advertisement was not intended to Non-HCP there was no (technical) barrier that prevented the general public of having access to it. There was a breach of the rules on covering costs for HCP attending an event since – according to the company concerned – it was not an exclusively scientific and/or educational event but one day scientific and the other day promotional. The hotel as the event venue was seen as compliant with the Code.

No sanctions were imposed since the Board did neither see a severe nor a repeated breach of the Code. The company concerned signed a cease-and-desist declaration and had to pay the costs of the proceedings.

Code report
PHARMIG publishes the decisions made by the National Code Authority on its website in an anonymised way: https://www.pharmig.at/der-verband/pharmig-verhaltenscodex.
The Code activities are also part of PHARMIG's Annual Report. The report is available for member companies only.

2024 Disclosure of 2023 data
In 2023 ToV of 150 Mio. EUR to HCP, HCO and PO were made by pharmaceutical companies in Austria. Regarding 98,2 % of the ToV the recipients were HCP and HCO. These 147,3 Mio. were split as followed:
- 78,6 Mio. EUR (52,3 %) R&D
- 50,6 Mio. EUR (33,7 %) events
- 13,5 Mio. Euro (9 %) fees for services and consultancy
- 4,6 Mio. Euro (3,1 %) donations and grants

Regarding the 2,7 Mio. (1,8 %) of ToV received by PO, these were split as followed:
- 2,5 Mio. EUR financial support
- 80.000 EUR non-financial support
- 111.000 EUR fees for services and consultancy

The yearly graphic of the disclosure overview can be found on PHARMIG's website:
PHARMIG_Grafik_Disclosure_2023_E_RZ.indd

Code awareness
PHARMIG organised virtual training sessions and discussion platforms for its member companies on a regular basis. PHARMIG provides plenty of information material to its members regarding the CoC (e.g. fact sheets, checklists, notes for guidances, sample contracts). The FAQ regarding the CoC (available as an internal guidance for members only) are regularly updated by questions submitted by member companies.

Furthermore, via "PHARMIG Academy" seminars open to the public are offered. Among those there is a special certificate course Compliance & CoC (4 different modules: Basics, Advertising, Events, Disclosure) as well as an introductiory seminar for newcomers in the pharmaceutical industry or employees new in their role in legal and/or compliance. One of the six parts of this introductiory seminar is on the international self-regulation of the pharmaceutical industry, compliance in general, the Austrian CoC as well as the rules on advertising in the Austrian Medicinal Products Act. Besides, there are other legal and compliance seminars focusing on specific topics such as the use of Social Media in information and marketing of pharmaceutical companies.

In 2024 PHARMIG offered a special deep dive seminar on events for member companies as well as stakeholders via PHARMIG Academy.
Additionally, in 2024 PHARMIG gave a Country Code Update at an IPCAA webinar.

In order to prevent misunderstandings about Code requirements right from the start PHARMIG presented the Code rules on events to Professional Congress Organisers (PCO) at their annual conference in 2024.

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BELGIUM – Pharma.be

Code authority activity

Complaint procedure

In 2024, no ethical cases were submitted or reviewed, and there were no recorded violations of the Code of deontology.
Anyone who believes they have observed a breach of the rules outlined in the pharma.be Code of deontology can file a complaint. This complaint will be impartially reviewed by the Committee for Deontology and Ethics in the Pharmaceutical Industry, hereinafter referred to as the "DEP Committee," and, if deemed admissible and well-founded, may result in the sanctions provided for in the Code.
In 2021, three complaints were filed with the secretariat of the Code of deontology.
In accordance with Article 41 of the Code of Ethics, the final decisions made by the DEP Committee and the Appeals Chamber are referenced on the pharma.be website.
It is possible to obtain an excerpt of the decision upon request. The communication of an excerpt is always done with the consent of the parties involved.

Monitoring of Written Communication by the BCWC

Since 2010, the Bureau for the Control of Written Communication (BCWC), an independent body, has been ensuring the quality of written information sent by members of pharma.be to healthcare professionals. Each month, BCWC experts analyse communications related to five medicines randomly selected from those marketed by members of the association.
The BCWC ensures that these documents comply with both the applicable legal and regulatory provisions, as well as the pharma.be Code of deontology (Articles 46 and following).
The BCWC 2024 annual report is available upon request by contacting pharma.be at the following address: deonto@pharma.be. The BCWC 2024 annual report will be available upon request by contacting the same contact details as of the end of June 2025.

Disclosure

The data related to the year 2024 will be available on the following link https://betransparent.be/en/ as of the end of June 2025.

National Code provisions update

The pharma.be Code of deontology was thoroughly revised in 2020 to bring it into line with the then newly introduced version of the EFPIA Code of Practice. pharma.be took this opportunity to review and update its Code in general.

New amendments to the Code were necessary due to the further increase in interaction between pharma.be and patients and/or patient organisations. The Code as approved by the General Assembly on 13 March 2024 has been updated to improve how it handles complaints from patients and patient organisations: a new free, informal process allows open discussion and possible resolution with member companies, without lawyers and is overseen by the Bureau for Control on Written Communication (BCWC). If unsuccessful, parties can still pursue the formal DEF procedure or go to court.
In an effort to enhance the accessibility and clarity of the Code, a series of administrative updates have now been implemented. These improvements include the adoption of a new layout template across the English, French, and Dutch versions, the finalization of the English version of the Code, and the correction of article references where necessary. Additionally, the address of pharma.be has been updated to reflect current information, and an interactive table of contents has been introduced to facilitate easier navigation of the document. These changes aim to make the Code more user-friendly and ensure consistency across all language versions.
These proposed amendments (in the French, Dutch and English versions) are pending final approval of the Code by the General Assembly on June 11, 2025. The link to this updated version of the Code will thereafter be available on pharma.be's website.

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CROATIA - Innovative Pharmaceutical Initiative (iF!)

Code authority activity
There was one recorded code violation in 2024.
One member of the association was found guilty of advertising a prescription-only medicine in a business magazine that was not intended exclusively for healthcare professionals, and since they stated that they had taken action to have the disputed pages removed, the mildest type of sanction was imposed – a warning.

2024 Disclosure of 2023 data
The figures are the following:
⇒ R&D 25 %
⇒ HCOs 33%
⇒ HCPs 38 %
⇒ POs 4 %

The percentage of individual positive consent is 16,3 %.
Members of the Innovative Pharmaceutical Initiative (iF!) recorded nearly 26 million euros in transferred value in 2023 to healthcare organizations and healthcare professionals, patient associations, and investments in research and development, which enable patients to access the latest therapies and educate doctors on new and effective treatment methods.
Of the total amount, the innovative pharmaceutical industry in Croatia invested 6.5 million euros in research and development in 2023, which is 1.1 million euros more than in 2022. Transfers of value to healthcare professionals amounted to at least 8.5 million euros, and to healthcare organizations at least 10 million euros, representing 39 percent of the total transfer. In accordance with regulations that ensure the protection of personal data, 16.3 percent of doctors voluntarily provided their data for the individual disclosure of value transfers.

Code awareness
In order to resolve all uncertainties regarding the appropriateness of event organization, a meeting is planned with the national MedTech association, intended for professional congress organizers.

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CZECH REPUBLIC - AIFP

Code authority activities

Ethics Committee of AIFP (hereinafter as "EC") received 0 complaints in 2024.

However, Ethics Committee amended Code of Practice and few documents related to it (for more information, please see below) and very actively provides guidance to member companies in connection with concrete provisions of AIFP Code of Practice.

2025 Disclosure of 2024 data

- R&D: 73 %
- HCOs: 12 %
- HCPs: 15 %

Code awareness

- The Day with the Ethics Committee – event organized by the EC for member companies in order to discuss and present topics of the year 2024 (advertising vs. information, ESG, venues, lobbying act, Ethical limits on financing of medical care etc.)

Code related activities

- AIFP Code of Practice was amended in connection with marching EFPIA Disclosure and CME Disclosure (AIFP's initiative to disclose also ToV to PCO) – newly the EFPIA Disclosure is broadened by ToV to PCO.
- Guidance for venues of professional events according to the AIFP Code of Practice.
- Guidance of AIFP Ethics Committee of creating non-advertising communication.
- Guidance of AIFP Ethics Committee to the UST-27 document (UST-27 document is an interpretative guideline provided by State Institute for Drug Control that should interpret concrete parts of Advertising Regulation Act that unfortunately brought more questions than answers and that is why AIFP Ethics Committee decided to issue this guidance) – interpretative document is issued by the AIFP Ethics Committee in connection with the modification of selected parts of the AIFP Code of Practice that concern the issue of advertising and distribution of promotional materials.

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GERMANY – FSA

*(Freiwillige Selbstkontrolle für die Arnzeimittelindustrie e.V. – „Voluntary self-regulation of the pharmaceutical industry")***/VFA** *(Verband Forschender Arzneimittelhersteller e.V. – „German association of research-based pharmaceutical companies")*

Code authority activities

In the 2024 reporting period, 12 complaints were submitted to the FSA Arbitration Board (all from third parties). These complaints all related to possible non-compliance with the provisions of the FSA HCP/HCO Code.

The FSA Arbitration Board concluded these 12 proceedings in 2024. 10 were discontinued for material reasons (no breach of the Code). In two proceedings, member companies were sanctioned for a breach of the Code (one case, which concerned the inappropriate geographical location of a scientific event sponsored by a member company, was decided by the 1st Instance of the FSA Arbitration Board; the other case, which concerned an inappropriate venue for a company-owned scientific event, was decided by the 2nd Instance of the FSA Arbitration Board).

The sanctions pronounced are monetary fines with publication of the cases with full disclosure of the relevant member companies.

On its website, the FSA provides regular information on all decisions of the 1st and 2nd Instances of the FSA Arbitration Board concerning violations of the Codes: Fachkreise - Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.

National Code report

FSA published a Code report which also informs about all decisions of the FSA Arbitration Board: FSA-Jahresbericht_2024_Digital.pdf

2024 Disclosure of 2023 ToVs

The FSA has reported publicly on the yearly disclosure of its member companies:
Transparenzveröffentlichungen 2024 - Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.
The overall figure of the three main areas have proven to be stable over the years (R&D: 68,5%; HCO: 19,2%; HCP: 12,3%).
The level of positive consent is with 23% just as high as last year. It has to be stated, that the special situation in Germany with respect to individual consent of HCP continues (general sensitivity when it comes to data protection and data privacy; negative press coverage from the first disclosure years).
FSA/VFA and member companies continue to advocate to HCP to participate in the transparency initiative and support the efforts of pharmaceutical companies by giving their individual consent (e.g. FSA brochure explaining the transparency initiative of the research-based pharmaceutical companies and promoting the involvement of HCPs in this joint effort: FSA-Ihr-Beitrag-fuer-mehr-Transparenz_2025.pdf.

Code awareness

In 2024, the FSA celebrated its twentieth anniversary. For 20 years now, the FSA stands for successful self-regulation of the pharmaceutical industry in Germany. Therefore, 2024 was a year in which the FSA was even more committed than usual to explaining – and, where necessary, discussing – why compliance, ethics, and transparency are so important to the FSA and its member companies. The positive reactions from politicians, stakeholders, and partners in the healthcare sector confirm that we are on the right track.
As every year, the FSA conducted two meetings of the compliance officers of the member companies in Berlin to inform them about latest developments and share best practice. Several webinars were organized on currents issues as well as monthly update webinars. Furthermore, the FSA trained representatives of congress organizers and of medical societies via several webinars on the code rules. Moreover, the FSA regularly presents the compliance activities and objectives of the research-based pharmaceutical companies in Germany to the outside world, e.g., via presentations at third-party events, through debate contributions, FSA-podcasts and social media.

National Code provisions update

The FSA and its member companies addressed the increasing digitalization of the healthcare sector and extended the FSA regulations to digital health applications („DiGA“). DiGA within the meaning of Section 33a of the German Social Code, Book V (SGB V) are specific digital health applications that can be prescribed by healthcare professionals in the German healthcare system and are reimbursed by statutory health insurance providers).
Based on a resolution passed by the General Assembly in March 2024, the FSA's proven compliance standards for cooperation between our member companies with healthcare professionals (HCP), healthcare organisations (HCO) and patient organisations now also apply to DiGA within the meaning of Section 33a of the German Social Code, Book V (SGB V). This is a consistent step for the FSA, which we have also implemented at the association level by opening up membership in the FSA not only to pharmaceutical companies, as was previously the case, but now also to DiGA companies.

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GREECE – SFEE

Code authority activities

i. Case 64/2025

On 1/4/2025 took place a **mediation procedure**. According to article 33 par. 1 a' and 34 par. 8 and 10 of the Code of Ethics, regarding a. no. 63/13-12-2024: (Novo Nordisk Hellas *filed a complaint against Pharmaservice-Lilly, as the responsible representative of the MAH of the Product under the trade name* ***Mounjaro®*** *(tirzepatide),* which was given protocol number SFEE 63/2024, *and*

b. no. 64/14-3-2025: (*PHARMASERV – LILLY S.A. filed a* ***counter-*** *complaint against Novo Nordisk Hellas for promoting "****Ozempic****" (semaglutide) to the public and off-label use allegations*), which was given protocol number SFEE 64/2025.

The companies PHARMASERV - LILLY S.A. and Novo Nordisk Hellas were jointly invited to a hearing before the Chairman of the Compliance Committee, emeritus Judge Mr. Stylianos Paterakis, on Tuesday, April 1, 2025, in the context of the attempt to resolve the dispute amicably. Following the necessary clarifications, both companies have decided to amicably resolve the dispute between them and to waive their complaints and claims, as described in detail in the **private settlement agreement**, which has been signed by the parties.

ii. Case 65/2025

MSD member Company filed a complaint dated 29-4-2025 against **BMS** as the authorized MAH of the Chemotherapeutic Product under the trade name ***"YERVOY"*** (*ipilimumab®),* which received SFEE protocol number SFEE 65/2025. The companies MSD and BMS were jointly invited to a hearing on June 4, 2025. Following the necessary clarifications, both companies have decided to amicably resolve the dispute between them and to waive their complaints and claims, as described in detail in the **private settlement agreement**, which has been signed by the parties.

Disclosure

A. Transfers of Value (ToVs) from Pharmaceutical Companies to HCPs, HCOs and POs that took place during the year 2024, **WERE DISCLOSED** on **Sunday 30.06.2025** on the "National Organization for Medicines" platform, according to paragraph 7a of article 66 of Law 4316/2014 (A' 270), regarding the obligation to disclose, on the national platform: https://services.eof.gr/greseis-ext/expenses-report.xhtml. All disclosed items will be published by EOF at the end of September 2025/ October 2025.

The disclosure data entries should include the HCPs/ HCOs TOVs data, as well as the POs data.

Finally, it is noted that each SFEE member Company is required to post on an annual basis on its website and send to SfEE Legal dpt. at sfee@sfee.gr the corresponding link entitled "Annual Contributions to POs" as a way of safeguarding compliance to disclosure for this category of TOVs too, given that this category is excluded from the Law 4316/2014 span of application.

B. Deviation request

Given that the Greek law 4316/2014 art. 7a is stricter than the consent request to disclose, as per the Efpia Code, we had considered that there is no need to request for a deviation from Efpia, as there is no gap in disclosing TOVs in Greece. In any case, we submit a tentative request for deviation from the EFPIA Code of Ethics disclosure obligations, should Efpia Legal dpt. considers that the Greek Law does not include an exhaustive disclosure pattern. For this reason, we attach the Greek Law translated in English and the exchange of information on the issue, dated 6-5.2015.

Article 66(7) of Law 4316/2014 states the following:

«a. Disclosure requirement

Each pharmaceutical company shall disclose on its website and on the designated website of EOF, no later than six months of the end of each calendar year, any transfer of value it has made [during the reference year] to healthcare professionals (HCPs) and healthcare organisations (HCOs), including, but not limited to: donations; sponsorships; registration fees to attend conferences and scientific events for the medical community, as such events are specified in circulars issued by EOF from time to time; travel and accommodation; as well as any other transfer of value under contractual arrangements or of a

voluntary nature in respect of the promotion of prescription medicines. Transfers of value relating to research and development activities, as well as non-interventional studies (pharmacy-based or otherwise), shall be disclosed on an aggregate basis by each pharmaceutical company. The scope of the disclosure requirement shall explicitly exclude any costs arising from market research, meals and drinks, as well as items of medical or educational utility of negligible value that are closely related to the day-to-day medical practice of Healthcare Professionals and Healthcare Organisations, in accordance with Ministerial Decision ΔΥΓ3α/ΓΠ 3221/2013 (Government Gazette B 1049). Item of negligible value means any item whose value does not exceed fifteen (15) euro, including VAT. According to the provisions of Joint Decision Υ6α/οικ. 121863/11.12.2002 of the Ministers of Economy and Finance, Development and Health and Welfare issued under authority of Article 49(1) of Law 2519/1997 "Development and modernisation of the National Health System, organisation of health services, provisions regarding medicinal products", as amended by Joint Decision Υ6α/οικ. 121 863/11.12.2002 by the same Ministers, the costs specified therein shall be deducted from the gross income of pharmaceutical companies.

b. Sanctions

Responsibility for supervising compliance with this provision shall lie with the National Organisation of Medicines. Non-compliant persons shall be liable to administrative sanctions in the form of a fine of between €30,000 and €100,000 in favour of the Treasury".

The Explanatory Memorandum of the aforementioned provision states, inter alia, the following: *"Safeguarding public health, protecting the patient's right to know the relationship between the pharmaceutical industry and the scientific community, and constantly promoting innovation and research in the pharmaceutical market all necessitate equality and transparency among pharmaceutical companies in the area of scientific information of healthcare professionals and healthcare organisations in respect of prescription medicines. Consequently, it is deemed necessary to establish a requirement of detailed disclosure of the amount and nature of transfers of value, in cash or in kind, from pharmaceutical companies to healthcare professionals and healthcare organisations, in the context of collaborations and sponsorships. By this measure, the State seeks to ensure transparency and build trust in the relationship of pharmaceutical companies in the country with healthcare professionals, healthcare organisations and the society at large"*.

The requirement introduced by this provision shall take effect as from 1 July 2016.

Code awareness

Throughout the year, several meetings were held with the participation of members of the Code of Ethics and Transparency Committee, which included training sessions to promote compliance with the SfEE Code of Ethics and promote best practice.

National Code provisions update

SFEE's Code of Ethics was amended during the works of the General Assembly held on 8 April 2025.
Finally, the General Assembly decides that the new Code of Ethics will enter into force on 1/7/2025.

N.B. All the thresholds in Annexes I & II are indicative and work as consultation tools. They are set after consultation with the member companies and academia and reflect fair market values. Some of those are provided by EOF. Ethical interactions are at the heart of self-regulation. Industry standards frequently exceed legal requirements.

The objective of self-regulation in the pharmaceutical sector is to promote the appropriate and legitimate use of medications and ensure high-quality patient care, while enhancing trust and improving public perceptions.

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IRELAND - IPHA

Code authority activity

The Irish Pharmaceutical Healthcare Association (IPHA) received no complaints in 2024.

Code report

IPHA publishes a Code report (Publication of Findings) that is available upon request.

2025 Disclosure of 2024 data

ToV Rollup Report Results

		Donations and Grants	Contribution to Costs of Events			Fee for Service and Consultancy		TOTAL
			Sponsorship	Registration Fees	Travel & Accomm.	Fees	Related Expenses	
HCPs	HCP – Individual	N/A	N/A	€1,087,744	€2,771,702	€1,446,487	€174,498	€5,480,431
	HCP – Aggregate	N/A	N/A	€20,817	€61,702	€84,219	€11,431	€178,169
HCOs	HCO – Individual	€2,019,148	€5,406,627	€2,774	€0	€1,181,008	€8,841	€8,618,398
	HCO – Aggregate	€0	€0	€0	€0	€0	€0	€0
R&D	R & D	N/A	N/A	N/A	N/A	N/A	N/A	€18,288,926
	Grand Total	€2,019,148	€5,406,627	€1,111,335	€2,833,404	€2,711,714	€194,770	€32,565,924

For 2024 data, the individual (named) level of disclosure is as follows:

- Healthcare Organisations (HCOs) - 100%
- Healthcare Professionals (HCPs) – 98% (a 2% increase for 2024 data compared to 2023 data).

National Code provisions update

A new version of the IPHA Code of Practice for the Pharmaceutical Industry became effective on 1st June 2025. The changes to the previous version were reviewed, deliberated upon and considered by IPHA's Board and took into consideration new European requirements, amended working practices and the need for clarification on many points.

The key changes relate to Clauses 7. 2 (conditions for adding a QR Code to promotional and informational materials); Clause 9 (conditions around the placement of reimbursement status notifications in medicine advertisements); Clause 16.3 (an increase to €90 [from €80] of the threshold for the provision of a meal); Clause 16.9 (simplifying the wording and requirements regarding the sponsorship of meetings convened by HCPs); Annex III, Patient Organisations (clarifying the restrictions around funding); Annex VI, Advisory Boards (clarification that a note taker can attend Advisory Board meetings in addition to the other attendees). There are other changes but many of these are administrative (addition of specific definitions, rewording etc). For transparency, a clean version of the new Code, a tracked changes version and a document outlining the key changes to the Code are available at www.ipha.ie/codes-of-practice.

Code awareness

IPHA conducts multiple training sessions annually, for full and affiliate members, on the most up to date version of the *IPHA Code of Practice for the Pharmaceutical Industry* and the Irish Legislation. Furthermore, access to IPHA Code e-Learning is available to all members 24 hours a day and 365 days a year at www.iphacode.ie. Training is also provided to MSc students and Diploma students in two Universities in Ireland.

Additionally, bespoke training is available for all member companies. This is where IPHA provides tailored training for individual companies at a location of choosing by the company (remote or in person). Furthermore, training aimed specifically for nurses working in the industry is also provided annually as is training specifically for medical directors of IPHA member companies.

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ITALY – FARMINDUSTRIA

Code Authority activity

During the 2024, four reports were received on alleged violations of the Code from as many Member Companies.

Among the four reports received, three were archived and one was closed with the sanction of written reprimand.

Code report

The Code Report is published on the area of the website reserved for the members of our Association.

Disclosure

As for the transfers of value to HCPs and HCOs in 2024, the data relating to the consent for the publication by the HCPs is around 72%.

The percentage is in line with the 2023, so the overall number of consents has proved to be stable over the years.

As for the HCOs, please note that the Italian legislation does not require the consent for the publication of relevant data.

Institutions and media greatly appreciated the data publication initiative and the commitment to encourage HCPs to agree for the consent for the publication of data.

The Association will continue to carry out activities for increasing transparency for next year.

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NORWAY - LMI

Code Authority activity

In 2024 the Code Authority (Rådet) handled the following activities:

The Code Authority handled 4 cases and 5 Advanced statement cases. The Code provisions were breached in 3 of 4 complaint cases. 3 of 4 complaints was made by the Secretariat, and one by a pharmaceutical company. The provision in the case were LMI Industry Rules 7.1 (plain, factual balanced, objective) 7.2 (mandatory Information) and 14.4 (international congress)

The sanctions imposed was a total of NOK 245.000.

Code report

The full Code report is published in Norwegian here: https://www.lmi.no/lmi/fagomrader/lover-og-regler/lmis-regelverk/

The cases are published in Norwegian here: Avgjøresler i rådet for legemiddelinformasjon

Code trainings

5 different trainings were organized:

- 1 Advertising trainings (1-day)
- 2 Law and Industry Trainings (3 days)
- 1 Specialist Training 2 days (for compliance officers)

LMI also has a mandatory e-learning for all employees of the member companies.

National Code provisions update

There were few substantial changes in the regulations for 2024, but a lot of cleanup and editing were done to make the regulations better and more readable.

Some changes were made regarding digital reminder ads (advertising), ad plugs (non-advertising), and small/large digital ads (advertising).

In Chapter 15, which concerns contact with healthcare personnel at public hospitals, several changes have been made. All information and invitations must now be sent to the central mail reception, but with a possible copy directly to the employee (provided consent for the use of email is given).

Advice and Control

During 2024 The Secretariat provided advice to pharmaceutical companies regarding the industry rules on regular basis.

The Secretariat carries out frequent controls to find deviations/breaches from the Code. The Code Authority (Rådet) and the Norwegian Medicines Agency (DMP) both have access to the same electronic archive where advertising material is submitted.

For national events, LMI has its own "Concept Approval" with a digital application form.

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POLAND - INFARMA

Code authority activity

The Disciplinary Court of the Employers' Union of Innovative Pharmaceutical Companies INFARMA acts in accordance with the Statutes and the Rules of the Disciplinary Court.

The Disciplinary Court of INFARMA has two instances. The adjudicating panel is as follows:

- 3 Court Members – in the first instance,
- 5 Court Members – in the second instance.

On 21 June 2022, at the meeting of the General Assembly of INFARMA, the composition of the INFARMA Disciplinary Court has been approved for the cadences 2022-2025. The members of the Disciplinary Court include the Chairman, Vice Chairman and two members outside the member companies. Elections for the next mandate of the Disciplinary Court will be held in June 2025.

In 2024, no case was investigated by the Disciplinary Court.

Code report

The association does not publish a Code report but information on each violation of the provisions of the Union's Statutes, resolutions of the Union's governing bodies or Principles of Ethics established by the final adjudication of the Court and on the implemented sanctions is published in the newsletter issued by the Union.

All adjudications of the Court are available to Member Firms via the Ethics and Transparency Group's Intranet and can be used by Member Firms or the Union for internal training purposes.

The annual report of INFARMA's activities presented at the General Assembly includes information on the activities of the Disciplinary Court, the observance of the Code implementation and a summary of the activities of INFARMA and the Ethics and Compliance Group.

2024 Disclosure of 2023 data

The figures are the following:

- R&D 76%
- HCOs 13,4%
- HCPs 10,6%

The total value of payments made by Code signatories in 2023 increased by 22% compared to 2022.

The estimated percentage for positive consent is:

- HCOs 94,4%
- HCPs 24,3%

Annual reports published on the website: https://www.kodeksprzejrzystosci.pl/raport-przejrzysto%C5%9Bci/

In 2024 no significant changes in comparison with 2023 ToV, but an increase of HCP consents was noted. The overall figure of the three main areas has proven to be stable over the years.
General trends (2016-2024):

- Increase of HCP consents from 25% to 31% in 2021 and decrease from 2022 to 2024 to 24,4%
- Stable level in TOTAL ToV amount with the tendency to increase
- Relatively stable proportions of ToV distribution (in share / %)
- Annual increase in R&D expenditure in Poland

On 26-30 June 2024, the Signatories of the Transparency Code published on their websites reports on the scope and value of collaboration with the medical community, medical professionals and healthcare organizations, as well as aggregated data concerning allowances for research and development activities. On 4 July 2024, the aggregate data was published on INFARMA's website: www.kodeksprzejrzystosci.pl

Code awareness

The INFARMA Code of Good Practices

In 2020 the INFARMA Code of Good Practices was adopted by 28 Signatories of the Code – 25 INFARMA member companies and 3 Signatories of the existing Codes. The Code is effective as of January 1, 2021.

Activities related to the Code in 2024:

1. Transparency - enhancing the medical community's awareness of transparency.
2. Education of the medical community (continued cooperation with the Supreme Medical Chamber).
3. Proper implementation of the Code and ongoing updating of the Q&A document to INFARMA Code of Good Practice.
4. 4.Effective operation of the Event Certification System – education on INFARMA standards among both event organisers and INFARMA member companies.

INFARMA was involved in promoting the Code and idea of transparency. The association shares its experience in self-regulation, and presents good practices that contribute to building an ethical and transparent healthcare system and to giving the patients access to the most effective treatment.

The Event Certification System

The Event Certification System was introduced by INFARMA based on a decision of the member companies. INFARMA launched a pilot event certification system in 2017 with the aim to improve the functioning of the system and to implement the application in the full scope in 2018. In 2024, 1830 events were recorded in the certification system (similar level than in 2022).

In 2024 maintaining an efficient Event Certification System that involved:

- ongoing improvements;
- effective education of all system participants (including periodic newsletters);
- update to the Terms and Conditions on the non-subject matter elements in the event program.

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SLOVAKIA – AIFP

Code authority activities

In 2024, the AIFP Ethical Committee (EC) received one complaint concerning a violation of the AIFP Ethics Code from the public representative (third party). The next complaint was delivered to EC from member company. Complaints were proceeded according to Complaints review procedures. The EC meetings were held 3 times per year.

Upon the requests from members and third parties, EC assessed the venues and leisure activities of the professional events supported by member companies.
The part of the regular EC agenda is monitoring and assessment of the Non-interventional Clinical Trials (NCT). There has been 0 NCT reported in 2024.

Code report
The annual 2024 report of the EC was presented at the AIFP General Assembly meeting and was published on the AIFP intranet for all members.

Code Awareness
The Head of the Ethics WG, who is also a member of the AIFP EC, informs compliance leaders, members of the Ethics WG and General Managers about the activities of the Ethical Committee after every EC meeting and retrospectively brings topics from WG to EC. The chairman of the EC supported the discussion and proposed to discuss the topics at the Ethics WG.

National Code provisions update
The following amendments to the AIFP Code of Conduct have been approved in 2024:
The definition of Healthcare professional was changed in Annex 1 – Definitions:
"Healthcare professional" means any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his/her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in the Slovak Republic. Persons listed in Section 27 of the Act 578/2004 Coll. on Healthcare Providers, Healthcare Professionals, Professional Organisations in the Healthcare, and on amendment to and supplementation of certain acts, as amended shall also be considered a Healthcare professional. 2For the avoidance of doubt, the definition of healthcare professional includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a Member whose primary occupation is that of a practising healthcare professional, but excludes (x) all other employees of a Member and (y) a wholesaler or distributor of medicinal products. This amendment to the AIFP Ethics Code was approved by the AIFP General Assembly.

Other activities – educational activity
Members of EC participated in a lecture and discussion panel on the topic - Ethics of a Healthcare Professional, which was prepared by members of the AIFP Ethics Working Group. JUDr. Polakovič – AIFP attorney-at-law and expert in the field of pharmaceutical and medical law and member of the AIFP Ethics Committee introduced the first half of the event with a practical lecture dedicated to the ethics of the healthcare professional from the perspective of the Slovak law. The discussion panel was dedicated to questions of attendees. The AIFP EC President welcomes the organisation of this educational activity and recommends the continuation of this activity in the next period.

Code report
The annual 2024 report of the EC was presented at the AIFP General Assembly meeting and was published on the AIFP intranet for all members.

Code Awareness
The Head of the Ethics WG, who is also a member of the AIFP EC, informs compliance leaders, members of the Ethics WG and General Managers about the activities of the Ethical Committee after every EC meeting and retrospectively brings topics from WG to EC. The chairman of the EC supported the discussion and proposed to discuss the topics at the Ethics WG.

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SLOVENIA – FarmaForum

Code authority activity
No complaint has been received in 2024.

Disclosure
The final report on Transfers of Value data for 2024 will be available from 7 July 2024.

Code awareness
Regular meetings with members of the Transparency Group. Ongoing updates to general managers on all changes to the Code.

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SPAIN – FARMAINDUSTRIA

Code authority activity.
Farmaindustria examined 3 cases in 2024 that came from:

- Pharmaceutical companies: 66,67%
- Code of Practice Surveillance Unit: 33,33%

The Code provisions that have been breached in the 3 cases are the following:

- Article 3. Information on Medicines and its Substantiation (EFPIA Code Article 3 Promotion and its Substantiation)
- Article 5. Transparency in Promotion of Medicines (EFPIA Code Article 7 transparency of Promotion)
- Article 7. Distribution of Promotional Materials for Medicines (EFPIA Code Article 6 Distribution of Promotion)
- Article 8. Digital Environment (EFPIA Code Annex 2 Principles for the Use of Digital Channels)

The three cases were settled by a mediation agreement between the parties.

Code report
The Code report is available here: https://www.farmaindustria.es/web/

Consequences of Code authority activity
No relevant consequences.

2024 disclosure of 2023 ToVs
The figures are the following:
Transfers of Value (TOTAL: 698 million euros)

- R&D 47,99%
- HCOs 26,51%
- HCPs 25,50%

The percentage of positive consent is 100%.
For transparency initiative success, we encourage countries to approach Personal Data Protection Authorities to be able to disclose all the ToVs individually based on the “legitimate public interest ground”.

Code awareness
During 2023 the Code of Practice Surveillance Unit launched an initiative that aims to certify the degree of knowledge of the Spanish Code of Practice for the Pharmaceutical Industry.
During 2024 the 2nd edition of such a certification took place on April.

Detailed information available at:
https://www.codigofarmaindustria.org/sites/sarfi/certificacion.html

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SWEDEN – LIF

Code authority activity

The first instance (IGN) in Lif self-regulation system examined 68 cases.
The second instance (NBL) in the Lif self-regulation system examined 8 cases. 4 cases were assessed directly by the second instance (NBL), including 1 originating from National Agency (Regulatory Authority). The part originating from the continuous supervision and monitoring performed by IGN represents 62.5 % of the total case volume.
The Code provisions have been breached in 34 cases, as assessed by IGN, and in general relate to reporting in Lif's official collaboration database and that promotion is not consistent with SmPC, misleading, not truthful information, abbreviated prescribing information is missing, insufficient or has poor readability.
The second instance, NBL (handling escalations from first instance, and appeals), 7 cases assessed a breach, and in 1 case the outcome was non-breach.
The sanctions imposed were fines (in general 110 000 SEK).
A recurring issue this year involved the distinction between promotional and non-promotional materials, such as press releases.
All decisions with a sanction are published in a database on Lifs website (https://www.lif.se/etik/ign-och-nbl/). On the same page more information about the Lif ethical code as well as a page for FAQ can be found.

Code report

The Code report is available at: https://www.lif.se/etik/ign-och-nbl/verksamhetsberattelser/

2024 disclosure of 2023 ToVs

The figures are the following:

- R&D 79,0 %
- HCOs 17 % (consultancy fees and associated expenses, sponsorships, donations)
- HCPs 4,0 % (consultancy fees and associated expenses)

The percentage of individual disclosure is:

- 95 % of recipients (HCP and HCO combined; ToVs in relation to consultancy fees and associated expenses)
- 92 % of recipients (HCP only; ToVs in relation to consultancy fees and associated expenses)

The proportion of individual disclosure has been maintained during the years since the disclosure requirements were introduced in 2015 and does not seem to have been impacted negatively by GDPR-enforcement.

Code awareness

Lif organized:
4 Code Training sessions (2-day course, including formal test to get accredited in code compliance). Three sessions where in person trainings and one session was digital, and in total 145 attendees participated.
Upon request, Lif organized training for individual member companies.

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SWITZERLAND

Pharma Code and Pharma Cooperation Code in 2024
Annual report of the Code Secretariat

Introduction

For many years, the Swiss pharmaceutical industry has applied internationally coordinated (see IFPMA[12], EFPIA[13]) self-regulation that goes beyond the law with the Pharma Code (PC[14]) and the Pharma Cooperation Code (PCC[3]). Pharmaceutical companies can voluntarily agree to abide with these codes (see lists of signatories [15]). The supporting organisation for pharmaceutical self-regulation in Switzerland is scienceindustries, whereby its Code Secretariat is responsible for the implementation of the codes. It follows the principle of non-adversarial conflict resolution in the case settlement and thus primarily takes on a mediating role. In 2024 too, its neutral assessment was always accepted by the parties involved in individual cases and the Code-compliant state was quickly restored in each case.

Implementation of the Pharma Code

The number of proceedings dealt with in connection with the PC decreased slightly (2024: 100; 2023: 103), while the number of reports from competitors fell more significantly (2024: 29% / 29 cases; 2023: 38.2% / 39 cases). One company reported itself (2023: 1). Once again, no proceedings were classified as potentially hazardous to health and therefore as serious.

The average duration of proceedings decreased to 6.7 days in 2024 (2023: 8.1 days).

In 2024, 100 proceedings were opened, which corresponds to the long-term average. The 72 proceedings in 2021 appear to have been an exception due to the pandemic. Of the 100 proceedings, 91 (91%, 2023: 91.2%) were concluded after the advertising in question was corrected or the infringement was acknowledged and measures were implemented. In 9 cases (9% / 2023: 8.8%), no conduct in breach of the Code was identified. In four cases, there were delays due to the complexity of the issues (duration of proceedings > 40 days). As in the previous reporting year, no company had to be warned for not submitting the requested statement on time.

The Code Secretariat did not carry out any mediation in 2024 (2023: 1), but was informed of 10 bilateral settlements (2023: 5), which means the double amount compared to 2023.

In the reporting year, 79 pharmaceutical companies (2023: 91) sent a total of 13,460 specimen copies (2023: 12,581) of their promotional material and information; 99.1% of these were sent electronically (2023: 96.9%). Only 120 specimen copies reached the Code Secretariat by post. 23 companies now send their specimen copies to the Code Secretariat via the new Sharepoint set up in 2024.

Identified violations of the Code

In total, 30 (2023: 34) different PC sections were examined as part of the 100 (2023: 103) procedures mentioned above. In 21% of cases, only one section was in dispute (2023: 25%); 10% involved two sections (2023: 9.7%) and 69% of cases involved three to eight sections (2023: 65.3%; 3 to 8 sections). The PC sections that were frequently objected to are listed below:

- Principle of professional promotion (PC 24.1): decrease to 12 violations (2023: 20).
- Unsubstantiated advertising claims and incorrectly cited references (PC 24.2): slight decrease to 79 violations (2023: 82)
- Promotional materials that did not contain all the minimum information on the medicinal product required by the PC (PC 24.4, 24.5): sharp decrease to 8 violations (2023: 23).
- Incomplete or inadmissible literature references (PC 25, excluding PC 25.1, 25.4.3, and 25.7): slight increase compared to the previous year with 19 infringements (2023: 15).

[12] IFPMA
[13] EFPIA
[14] The provisions of the two codes are referred to in the Annual Report by “PC” and “PCC” with the relevant section number.
[15] Signatories of the Pharma Code / Signatories of the Pharma Cooperation Code

- Missing indication that references can be requested from healthcare professionals (PC 24.2, 25.1, 25.4.3, and 25.7): remained almost the same with 50 violations; these were systematically sanctioned for the first time in 2022 (49 cases in 2023).
- Reports of unqualified superlatives and comparatives (PC 25.8, 25.9): slight increase with 16 violations (2023: 10).
- Ban on gifts (PC 15.1, 15.2 and PC 15.3): Increase to 8 violations (2023: 1, only related to PC 15.2).
- Promoting medicinal products or indications not yet authorized (PC 23.1, 23.2): sharp decrease to 5 violations (2023: 13).
- Differences between the promotional claims and the medicinal product information as approved by Swissmedic at the time of authorisation (PC 23.3): slight decrease to 6 violations compared to 8 in 2023.

The shift to more objectionable sections per case is due to the fact that a frequent objection (lack of indication that references can be requested) led to a violation of four different sections: PC 24.2, 25.1, 25.4.3 and 25.7. As in previous years, it can also be stated for 2024 that the violations of the PC that were objected to in each case could not be qualified as gross. The threat of forwarding a case to the competent state authority (PC 75.10) was again not necessary in 2024.

Support for further education and training events (section 3 PC)

In recent years, there has been an increase in interventions by companies and the Code Secretariat in the implementation of the requirements for supporting continuing and further education events. In order to provide organisers and professional associations in particular with a simple guide, a "Checklist for pharmaceutical companies and organisers to check whether events for the purpose of postgraduate medical training or continual medical education may be supported" was published in 2023.

Although this has well been taken into consideration, there are still repeated discussions, particularly with regard to the conference venue and the conference location. In 2024, the Code Secretariat again reviewed a large number of training and further education events on its own initiative and at the request of companies or event organisers to determine whether they meet the requirements of self-regulation and based its assessment on the long-established international benchmarks (in particular IPCAA[16] and e4ethics[17]).

The Code Secretariat has also compiled a list of cases to supplement the checklist. This summarises important individual case decisions made by the Code Secretariat and is intended to serve as a decision-making aid for PC signatories when assessing a specific request for support. The Code Secretariat was and is also in regular contact with numerous organisers and professional associations, with the mutual aim of ensuring that events are organised in accordance with the Code, so that support for meaningful continuing education by the industry ultimately remains possible in the interest of patients.

Implementation of the Pharma Cooperation Code

Between 20 and 30 June 2024, the signatory companies of the PCC disclosed the pecuniary benefits granted in 2023 to healthcare professionals (HCP - primarily doctors and pharmacists), healthcare organisations (HCO - primarily hospitals and specialist organisations) and patient organisations (PO) on their websites for the ninth time. This involved compensation granted directly or indirectly for cooperation in connection with prescription-only medicinal products in human medicine. All companies submitted their data on time.

The Code Secretariat compiled the figures for the 64 PCC signatory companies and arrived at the following picture for Switzerland by the end of July 2024: a total of CHF 242.3 million in transfers of value (ToV) were disclosed for 2023. In 2022, the figure was CHF 216.7 million, which corresponds to an increase of CHF 25.6 million. At CHF 8.1 million, slightly more benefits were paid to HCP than in the previous year (CHF 7.4 million). ToV to HCO also increased to CHF 128.3 million compared to CHF 120.3 million in the previous year. ToV for R&D services increased significantly from CHF 89 million in 2022 to CHF 106 million in 2023.

With an increase of 0.7 million in 2023, cooperation grants to HCP remained at a comparable level to 2022. Once again, there was a certain shift from direct support for HCP to HCO. Cooperation grants to HCO

[16] https://www.ipcaa.org/public/international-healthcare-congress-guidelines/

[17] https://www.ethicalmedtech.eu/e4ethics/about-e4ethics/

increased accordingly by more than CHF 8 million to a good CHF 128 million. Grants for research and development increased significantly by CHF 17 million in 2023. In this area, the picture of grants from individual companies fluctuating sharply from year to year was once again confirmed, which can be explained, among other things, by the varying intensity of activities in the area of clinical research.
To ensure as much transparency as possible, disclosure should be made on an individual basis, i.e. by naming the person who received a benefit, which for reasons of data privacy requires the recipients to agree to the disclosure. Overall, the average consent rate in relation to HCP increased once again in 2023, from 92.4% to 94.9%. The median rate was as high as 100%, which means that half of the PCC signatory companies were able to report HCP consent rates of 100%. The average consent rate for HCO also increased further, from 97.2% to 98%. The median here was again 100%. Overall, the consent rates once again developed in a positive direction, with a few companies able to achieve even better values. There are some significant discrepancies in the consent rates among the individual companies, which do not appear to be fully comprehensible. Five companies that achieved an HCP consent rate of less than 80% for the reporting year were therefore listed by name on the scienceindustries website (for reporting year 2022: 9 companies) and asked to identify measures to increase their consent rates. This shows a welcome development, as the number of companies that had achieved less than 80% was almost halved.
scienceindustries was again in contact with affected parties and interested media regarding the disclosure and explained the transparency initiative of the pharmaceutical industry.

Inquiries and training on the Pharma Codes
In 2024, the Code Secretariat responded to over 330 written or telephone inquiries in accordance with section 8 PC / section 6 PCC (previous year: around 240). Of these, 294 related to the PC and 35 to the PCC. The introduction of Sharepoint led to some additional correspondence, which was not included in the inquiry statistics. The significant increase in inquiries is partly due to the area of support for further education and training events. These inquiries meant a large additional advisory effort. In 2024, the Code Secretariat again conducted two online training courses on promotional activities for healthcare professionals with a total of 96 participants and two on pharma compliance with a total of 63 participants. In addition, scienceindustries, in its capacity as the self-regulatory body of the Swiss pharmaceutical industry, gave presentations on various topics and answered media inquiries.

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UK – PMCPA

Code authority activity
The PMCPA publishes an annual report each year when all the complaints received in that year are completed. The PMCPA also publishes detailed case reports on its website pmcpa.org.uk.

National Code provisions update
The ABPI Code of Practice was updated in October 2024 following an extensive public consultation.

Major updates were made to Clause 12, including the introduction of QR codes to access prescribing information on certain promotional materials. The rationale was to provide an option whereby scanning a QR code would always directly access the up-to-date version of the prescribing information.

Other changes to the 2024 ABPI Code included making gateway links from Disclosure UK to patient organisation and member of the public disclosure information on the pharmaceutical company's website a mandatory requirement, and mandating a written agreement when a company provides support to an individual health professional or other relevant decision maker to attend an event/meeting.

The PMCPA Constitution and Procedure was also updated with the goal of

- Further embedding the operational independence of the PMCPA into the structure of the ABPI/PMCPA model in line with the regulatory principle of transparency and the public law principles of procedural fairness and lack of bias.
- Adopting a more proportionate approach to the resolution of certain complaints through the introduction of an abridged complaints procedure.
- Making other changes to the PMCPA Constitution and Procedure, governance arrangements and administration of the ABPI/PMCPA model to improve the robustness (including from a public law perspective) and efficiency of the complaint's procedure

Disclosure – 2024 data disclosed in 2025[18]

- Total disclosed value, including R&D and non-R&D, increased by 17% to £813.3 million in 2024, from £692.5 million in 2023, and £642.1 million in 2022.
- Total R&D value was £554.0 million in 2024, up from £467.0 million in 2023, and £440.6 million in 2022. The percentage split of R&D vs non-R&D remains similar.
- Total non-R&D value was £259.2 million in 2024, up from £225.5 million in 2023, and £201.6 million in 2022.
- Of the total non-R&D value, 98.5% is published against a named person or organisation, which is higher than the 95.8% for 2023, and 95.1% for 2022.
- The estimated percentage of healthcare professionals named against non-R&D values has increased to 91.9%, from 80.8% for 2023, and 78.8% for 2022.
- More than 50 companies used the lawful basis of Legitimate Interests to publish information about healthcare professionals.

Enquiries and Training on the Code

- During 2024, the PMCPA responded to 180 queries on the ABPI Code.
- New guidance was issued to assist with implementation of the new Code including updating of all the FAQs on the PMCPA website.
- A new e-learning portal was implemented with a free ‘e-learning’ module on the ABPI Code and on-demand webinars to explain the changes to the Code
- Two in-person training days were held with over 150 delegates.
- PMCPA held its 2nd annual Patient Organisations Day to enable compliant interactions between the pharmaceutical industry and patient organisations.

[18] Source Disclosure UK