

# EFPIA Code Report on Ethics & Compliance Activities July 2024

At EFPIA, the Ethics & Compliance activities are organised within the framework of the Codes Committee (composed only 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 (2023 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 2023 and into mid-2024.

# **Table of contents**

1.	Codes Committee and Ethics & Compliance Committee Activities	2
a.	Codes Committee	2
b.	Ethics & Compliance Committee activities	2
2.	2023 National Code reports	5

# 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 2023 and into 2024:

# • Sponsorship/support for organisations

The CodCom members analysed the type of support provided to an event and the company responsibility for compliance of the activity with the Code. It was recognised that there may be different interpretations within EFPIA countries based on national laws.

# • 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

# • Communication

The CodCom members decided to write and publish a blog explaining the concept of self-regulation. The blog is almost finalized and will be published in September.

# • 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.

# **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 2023 and into 2024, in addition to the EFPIA Ethics and Compliance priorities, the E&CC has focused on the following projects:

# • Qualifying communication & activities

In July 2023, the "questions to consider" document has been approved and shared with the E&CC members. The document provides a list of criteria to be assessed to qualify the nature of a communication or an activity. It is a non-binding document reserved for EFPIA members' internal use only.

# • New ways of partnering

In February 2024, the guidelines applicable to multi-parties partnering with stakeholders in scope of the EFPIA Code or collaboration with other types of counterparts that are established for the purpose of supporting healthcare, research or education have been approved and shared with the E&CC members.

# • Patient Support Program (PSP)

Initially, the E&CC initiated a working group in charge of drafting a guidance on PSP related to prescribed medicines that aims to define the principles applicable to PSP in Europe (common definition, alignment on criteria and impact measurement).

In October 2023, the E&CC asked for the extension of the scope of the PSP guidance to the extent that it will ensure the efficiency of the guidance and its relevance to current and future developments. Therefore, the new guidance is currently being finalized for a E&CC approval in November 2024.

# • 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.

Based on this analysis, the TF suggested proposals, some of which are summarized below:

- For the improvement of the individual data disclosed
- The TF recommend, when possible, changing the disclosure legal basis.

The EFPIA Data Governance Working Group created a toolkit to support companies and associations that would like to move to legitimate interest (LI) as a legal basis for disclosure. This toolkit includes a LI table.

- To ease the access to disclosure data

The format of the standardized disclosure template will be harmonized with a searchable pdf.

The <u>EFPIA gateway</u>: European gateway with a map with the links to the Member Associations gateways/platforms and the links to the EFPIA Member Companies European disclosure webpages via companies logo list on the same page has been created in June 2023 and is regularly updated.

# Analysis of the disclosure reports

Since the first disclosure in 2016, EFPIA has analysed the transfers of value (ToVs) provided to Healthcare Professionals and Healthcare Organisations and disclosed by EFPIA Member Companies.

This yearly report helps EFPIA and its Members to gain insight into the disclosure data and may allow understanding trends versus the previous disclosure periods.

In 2023, the E&CC has decided to extend the scope of this report and to also include the analysis of the data disclosed for the Patient Organisations (PO).

Based on the PO disclosure data analysis especially the variety of categories and lack of alignment, the E&CC members mandated the Disclosure TF to look into the harmonisation of categories and submit recommendations.

# • 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:

- The General Pharmaceutical Legislation review which includes some modifications in the Advertising Chapter of the EU Directive 2001/83, which forms the basis of the EFPIA Code and the national codes. The European Parliament included an amendment introducing transparency requirements whose developments will be monitored.
- The European Directives on Corporate & Sustainable Reporting and Corporate & Sustainable Due Diligence including the definition of mandatory reporting standards.

# • HETHICO – Healthcare Ethics & Compliance Conference

In October 2023, EFPIA, with MedTech Europe and ETHICS, organised the first European Healthcare Ethics & Compliance conference "HETHICO", in Brussels. 150 participants attended the conference.

The next edition of the HETHICO conference will take place from 5-6 November 2024 at the <u>Hotel Le Plaza</u> in Brussels.

All the information related to this conference is available here: <u>https://www.hethico.org/</u>

# • E&CC brainstorming

Every 2 years, a brainstorming is organized during the E&CC to define the priorities and organize the E&CC working groups.

The latest one identified 3 interesting topics:

- Social media
  - Interpretation of promotion vs information: consequences of posting information, liking a post, etc.
  - Analysis of intended audience, jurisdiction
  - Influencers and remuneration criteria
- AI
- $\circ$   $\;$  Risks associated with the use of chatbot and AI in external interactions.
- o Chat GPT: development of internal tools at company level

# - Patient organisations interactions

- Rationale for collaboration
- PSP vs patient services: Extension of the EFPIA guidelines
- o Interactions with individual patients

# 2. 2023 National Code reports

#### **AUSTRIA – PHARMIG**

#### Code authority activity

In 2023 there were two complaints filed under the PHARMIG Code of Conduct (CoC "VHC"). One was on the provision that information and statements about medicinal products must not be misleading (Art. 4.6). The parties agreed on a dispute resolution procedure (Art. 10 Rules of Procedure of the PHARMIG Code Adjudication and Appeal Boards). No sanctions were imposed since the Board did neither see a severe nor a repeated breach of the Code. The company in place signed a cease-and-desist declaration and had to pay the costs of the proceedings.

The other complaint was filed anonymously. The complaint mentioned several alleged breaches of the provisions on promotion (Art. 5). However, Art. 5.4 Rules of Procedure of the PHARMIG Code Adjudication and Appeal Boards says that anonymous complaints can only be filed regarding breaches of Art. 7 (events for HCP) and Art. 11 (benefits). Hence, the PHARMIG's Executive Committee decided not to start legal proceedings.

#### Code report

PHARMIG publishes the decisions made by the National Code Authority on its website in an anonymised way: <u>https://www.pharmig.at/der-verband/pharmig-verhaltenscodex</u>.

The Code activities are also part of PHARMIG's Annual Report. The report 2023 (2023 version only available beginning of June) is available on PHARMIG's website: <u>https://www.pharmig.at/media/5845/pharmig-leistungsbericht-2022.pdf</u> (in German only).

#### 2023 Disclosure of 2022 data

In 2022 ToV of 112 Mio. EUR to HCP, HCO and PO were made by pharmaceutical companies in Austria. Regarding 97,3 % of the ToV the recipients were HCP and HCO. These 109 Mio. were split as followed:

- 50,9 Mio. EUR (46,7 %) R&D
- 38,6 Mio. EUR (35,4 %) events
- 14,2 Mio. Euro (13 %) fees for services and consultancy
- 5,3 Mio. Euro (4,9 %) donations and grants

Regarding the 3 Mio. (2,7%) of ToV received by PO, these were split as followed:

- 2,1 Mio financial support
- 662.000 non-financial support
- 224.000 fees for services and consultancy

The yearly graphic of the disclosure overview can be found on PHARMIG's website: <u>https://www.pharmig.at/media/5945/pharmig\_grafik\_disclosure\_2022\_en.pdf</u>

#### Code awareness

PHARMIG organised virtual training sessions and discussion platforms for its member companies on a regular basis. This included in 2023 Q&A on current questions of Code interpretation in practice and special sessions on sponsorship of medical education.

In order to also train the contractual partners of our member companies, an information campaign on events compliant with our CoC was rolled out towards HCP, PCO and PO.

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 introductory seminar for newcomers in the pharmaceutical industry or in their role in legal and/or compliance legal regarding our Code as well as the rules on advertising in the Austrian Medicinal Products Act. Besides, there are other compliance seminars focusing on specific topics.

#### \*\*\*\*\*

# **BULGARIA – Association of the Research-based Pharmaceutical Manufacturers (ARPharM)**

On the 29<sup>th</sup> of May on the Annual General Assembly Meeting of ARPharM, new members of the Ethical committees were elected due to an execution of the 2-yer-mandate. (available here: <u>https://www.arpharm.org/en/ethical-committee</u>)

#### Code authority activity

Full compliance with EFPIA Code requirements for Independence criteria for the national Code authority – Ethical committees

Composition criteria

- Non-industry chairman
- Industry members + membership from other stakeholders

Appeal procedure

- Established effective procedures for appeal at national level
- Processing of industry and non-industry complaints

Independence assessment

- Composition of the national code authority non-industry Chairman
- Composition of the appeal instance two more non-industry members

#### Code report

During 2023 no Ethical cases were submitted and reviewed.

#### 2024 Disclosure of ToV for 2023 data

On the 30<sup>th</sup> of June 2024, the links of ToV reports for 2023 of 23 ARPharM member-companies and one nonmember were published on the ARPharM platform: <u>https://www.transparencybg.org/en/opovestenni-danni</u> (new, updated platform)

#### ARPharM's e4ethics new, updated platform

The e4ethics platform of ARPharM was also revised, updated and with new design and functionalities: <u>https://www.arpharm-e4ethics.org/en</u>

Report for upcoming event banner: <u>https://www.arpharm-e4ethics.org/en/report-for-event</u>

Alleged violations of the Code during an event banner: <u>https://www.arpharm-e4ethics.org/en/report-for-problen-in-event</u>

\*\*\*\*\*

#### **CROATIA - Innovative Pharmaceutical Initiative (iF!)**

<u>Code authority activity</u> There were no recorded code violations in 2023. In 2023, a decision was made to reject the code violation report that was received the previous year, concerning a potential code violation related to the promotion appropriateness and off-label promotion of a pharmaceutical product in a reputable magazine, as it was determined that no violation had occurred. To prevent potential code violations, the TPOs' preventive inquiries about the appropriateness of meeting locations remain omnipresent.

# 2023 Disclosure of 2022 data

The figures are the following:

- R&D 28 %
- HCOs 36,7 %
- HCPs 35,3 %

The percentage of individual positive consent is 22,9 %.

The Innovative pharmaceutical industry in Croatia last year invested more than a quarter of the total amount in R&D, which, in monetary terms, represents an increase for the third consecutive year.

At least 36,7% of the total amount was transferred to healthcare organisations and 35,3% of the total amount was transferred to healthcare professionals. In accordance with regulations guaranteeing the protection of personal data, 22.9% of healthcare professionals have voluntarily provided their data for the individual publication of value transfer data which represents a slight decrease compared to the previous year.

#### Code awareness

As IFI decided that it is more purposeful to proceed with extensive changes to the current code, regarding the comments made in the review of the transposition of the EFPIA Code into national codes provided by IQVIA, the new code was adopted at the beginning of 2023. The period of adaptation to the new changes in the code has passed without major ambiguities and any possible ones were quickly resolved.

#### \*\*\*\*\*

# CYPRUS – KEFEA

<u>Code authority activities</u> No complaints were received in 2023.

\*\*\*\*\*

# **CZECH REPUBLIC - AIFP**

#### Code authority activities

Ethics Committee of AIFP (hereinafter as "EC") received 2 complaints in 2023 according to the advertising activities of two member companies. In one case a fine was imposed and an appeal was submitted against the decision. The appeal was discussed by the appeals committee and the decision was partially changed. In addition to complaints, two mediations took place as well regarding the (1) use of comparison in presentations on congresses and (2) terms of sponsorship of a congress.

#### 2023 Disclosure of 2022 data:

- R&D: 73 %
- HCOs: 13 %
- HCPs: 14 %

#### Code awareness:

• A series of webinars covering the topic of sponsorship on congresses (convener vs. organizer, venues, programs on congresses, trade displays, symposiums, support of HCP, non-HCP on congresses) were organised.

- 1:1 meetings regarding the reporting of EFPIA Disclosure and CME Disclosure (= disclosure of ToV to continuing medical education initiated and organized by professional congress organizers) were organised.
- The Day with the Ethics Committee event organized by the EC for member companies in order to discuss and present topics of the year 2023 (advertising vs. information, comparative advertising, venues, etc.)

#### Code related activities:

- Change of the AIFP Code of Practice EC has the competence to initiate the proceeding for the breach of AIFP Code of Practice from its own initiative: "Rules for submitting and processing complaints, rules for commencement of the proceedings for violation of the AIFP Code on the Ethics Committee's own initiative as well as for imposing sanctions for breach of the AIFP Code are specified in Annex A of the AIFP Code".
- The change of meal limits was repeatedly discussed in 2023. Outcome: the limit for meals on congresses longer than 6 hours were increased from the amount of 3 000 CZK (120 €) to the amount of 3 600 CZK (144 €). This change was implemented into the internal guidelines in 2024.
- The AIFP Code of Practice won in the competition "Law of the year, section non-state regulatory action" organized by Deloitte company.

\*\*\*\*\*\*

# DENMARK – ENLI (LIF)

# **Executive Summary (Annual Report 2023)**

In 2023 ENLI has continued its control and sanctions of the affiliated pharmaceutical companies to ensure that they comply with Danish law and the international, mainly European, business ethics codes particular to the pharmaceutical industry. The regulatory basis regulates the cooperation and exchange of information between the pharmaceutical companies and healthcare professionals, hospitals, patient organizations and public decision makers. Should the regulations be violated by an affiliated company, ENLI can impose fines and a number of other strict sanctions such as withdrawal of promotional material, require public corrections or similar sanctions appropriate to the specific violation.

ENLI's jurisdiction covers 110 pharmaceutical companies on the Danish market.

For further information about the ethical codes, please visit www.enli.dk/en.

#### Significant matters in 2023

In 2023, approx. 400 activities aimed at HCPs were self-reported to ENLI each month, as required (prevetting procedure). Of these, the Investigator Panel has reviewed approx. 35% of the reports in a random control, and 97% of the activities were approved, whereas sanctions were decided in 3% of the evaluated reports.

One complaint was filed in the end of 2023 which ended with a fine.

Affiliated pharmaceutical companies continue to exhibit a strong focus on achieving compliance to ENLI's regulation. ENLI's secretariat is available to affiliated companies every weekday by phone or e-mail, and many companies consult ENLI on marketing compliance issues.

In 2023, companies requested 59 pre-approvals of promotional activities, which is a decrease of 31 requests compared to 2022. Of the pre-approval requests in 2023, 71% were approved.

From the total amount of 67 decisions that ruled against an affiliated company, one decision were appealed to the Board of Appeal, which corresponds to approx. 1,5% of all relevant decisions. The Board of Appeal handled two cases in 2023 (one case regarded activities from 2022). Both decisions from the first instance were upheld.

ENLI has continued to prioritize preventive activities. In 2023, ENLI has published 50 decisions (including 18 administrative reprimands), and 4 newsletters. Furthermore, ENLI has conducted 8 courses in the regulation, primarily the Promotional Code, and 5 presentations to collaborative partners, networks, medical societies etc.

All decisions which impose a sanction on a company are published (in Danish) on ENLI's website, www.enli.dk, where also all ethical codes and guidelines can be found. Please visit www.enli.dk/en for more information on ENLI, the codes and guidances.

#### \*\*\*\*\*\*

#### **FINLAND - PIF**

#### Code authority activity

The year was characterised by the trend, where several member companies split their OTC portfolios to new entities. These entities left the self-regulation system, at least for now.

PIF handled 1 complaint in 2023:

- Inspection Board I (marketing and information to the consumers): none
- Inspection Board II (marketing to the HCP's): 1
- Supervisory Commission (complaints of the decisions made by Inspection Boards): none

The complaints came from:

Health care professional: 1

The Code provisions have been breached in 1 case.

The following provisions were breached:

The case was on a company product presentation in a clinic. The slide show didn't have any sources on the slides. When this was pointed out by a participant, the sales representative didn't provide further material or updated slides.

The sanctions imposed were: Sanction payment 10.000 euros Processing charges 3.000 euros per case

#### Code report

The Code Report 2023 including decisions made by PIF Inspections Boards/Supervisory Commission published in Finnish at: <u>https://www.laaketeollisuus.fi/vastuullisuus/laakkeiden-markkinointi/laakemarkkinoinnin-valvonta.html</u>

#### 2023 Disclosure of 2022 data

The figures are the following:

- R&D 76.5%
- HCOs 10.5%
- HCPs 13%
- The percentage of positive consent was 82%.

# Code awareness

PIF organized:

- several information meetings/trainings for our members on a yearly basis.

- 1 webinar and 4 short presentations with a commercial training organization (Pharmaca Health Intelligence)

- a yearly remote meeting for companies offering marketing services to pharma companies explaining the Code of Ethics and sharing best practices.

#### \*\*\*\*\*

# **GERMANY – FSA/VFA**

#### Code authority activity

In the 2023 reporting period, 22 complaints were submitted to the FSA Arbitration Board, including one from a member company and 21 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 32 proceedings in 2023 (from 2023 and previous years). 21 were discontinued for material reasons (no breach of the Code). In 11 proceedings, member companies were sanctioned for a breach of the Code (in 9 proceedings by the 1st instance, in 2 proceedings by the 2nd instance of the FSA Arbitration Board). The main issues were the appropriateness of venue and location in the case of sponsoring of a third party scientific event.

On its website, the FSA provides regular information on all decisions of the First and Second Instances of the Arbitration Board concerning violations of the Codes: <u>Fachkreise - Freiwillige Selbstkontrolle für die</u> <u>Arzneimittelindustrie e.V. (fsa-pharma.de)</u>

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

# Code report

FSA published a Code report which also informs about all decisions of the FSA Arbitration Board: <u>Veröffentlichung des Jahresbericht 2023 - Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V. (fsa-pharma.de)</u>

# 2023 Disclosure of 2022 ToVs

The FSA has reported publicly on the yearly disclosure of its member companies: <u>Transparenzveröffentlichungen 2023</u>: Die wichtigsten Inhalte auf einen Blick - Freiwillige Selbstkontrolle für <u>die Arzneimittelindustrie e.V. (fsa-pharma.de)</u>

The overall figure of the three main areas have proven to be stable over the years (R&D: 67,3%; HCO: 20,5%; HCP: 12,2%).

The level of positive consent is with 23% slightly above the previous year's value of 22%. 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: pioniere muessen sich nicht verstecken fsa 2020 pdf-1.pdf (fsa-pharma.de)).

#### Code awareness

The FSA conducted two meetings of the compliance officers of the member companies 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.

\*\*\*\*\*

# **GREECE - HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES (SFEE)**

#### A. AMENDMENT OF CODE OF ETHICS

SFEE's Code of Ethics was amended during the works of the General Assembly held on 19 April 2024. Relevant modifications were communicated to EFPIA.

#### **B. SECOND INSTANCE COMMITTEE**

On 27/03/2024, the Secondary Committee for compliance with the SfEE Code of Ethics issued its decision No. 1/2024, accepting the application of Gilead Sciences Hellas M.Ltd. for violation of the provisions of article 1, paragraphs 1.1. & 1.2., 1.3. & 1.6., article 3, paragraph 3.4.14. and article 19, paragraph 19.9.2B., against Glaxo SmithKline M.A.E.B.E.

The decision upheld the decision of the First Instance Committee No. 1/2023 imposing a total fine of twenty thousand euros ( $\leq 20,000$ ) for all the infringements against the latter. The case includes claims of off-label promotion and exaggerative non-objective claims.

Decision 1/2024 will be published on the SfEE's locked domain, in accordance with the operative part of the decision of the Secondary Committee, the provisions of the SfEE Code of Ethics and the provision of the EFPIA Code (article 28.04.f), in a summary of its main points, indicating the names of the companies.

#### C. CODE TRAINING

Participation of SfEE to the 4th HEALTH LEGAL AND COMPLIANCE FORUM on 2<sup>th</sup> July 2024. New projects are discussed form September 2024, onwards.

# D. DISCLOSURE

The Disclosure of Transfers of Value to HCPs and HCOs from Pharmaceutical Companies that took place during the year 2023, was compiled on Sunday 30.06.2024 on the "National Organization for Medicines" platform, according to paragraph **7a of article 66 of Law 4316/2014 (A' 270),** on the obligation to disclose, on the national platform:

https://services.eof.gr/greseis-ext/expenses-report.xhtml

All data items will be published by EOF at the end of September 2024/ October 2024.

#### \*\*\*\*\*

# **IRELAND - IPHA**

Code authority activity

The Irish Pharmaceutical Healthcare Association (IPHA) received zero complaints in 2023.

Code report

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

#### 2024 Disclosure of 2023 data

01 January 2023 - 31 December 2023

# Companies with Submissions

Generated 28 June 2024 17:18:19

#### 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	€1,153,057	€2,931,999	€1,419,169	€83,437	€5,587,662
HC	HCP – Aggregate	N/A	N/A	€31,262	€155,801	€152,079	€26,632	€365,774
HCOs	HCO – Individual	€2,637,396	€5,041,550	€15,625	€1,614	€1,194,253	€2,320	€8,892,758
HC	HCO – Aggregate	€O	€0	€0	€0	€0	€0	€0
R&D	R & D	N/A	N/A	N/A	N/A	N/A	N/A	€14,193,107
	Grand Total	€2,637,396	€5,041,550	€1,199,944	€3,089,414	€2,765,501	€112,389	€29,039,301

For 2023 data, the individual (named) level of disclosure is as follows:

- Healthcare Organisations (HCOs) 100%
- Healthcare Professionals (HCPs) 96% (a 16% increase for 2023 data compared to 2022 data).

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

#### \*\*\*\*\*

#### ITALY – FARMINDUSTRIA

#### Code Authority activity

During the 2023, no reports were received on alleged violations of the Code from as many Member Companies.

#### Disclosure

As for the transfers of value to HCPs and HCOs in 2023, the data relating to the consent for the publication by the HCPs is around 72%.

The percentage is in line with the 2022, 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.

#### Code Authority activity and status of the transposition of the EFPIA Code in Farmindustria Code

As anticipated in the Code Report 2022, in November 2023 Farmindustria published the new version of the Code in compliance with EFPIA requests related to the transposition of EFPIA Code provisions in the national Codes.

For instance, the new version of Farmindustria Code includes a specific section for Definition; the EFPIA ethical principles (integrity, respect, transparency, patient first), the alignment of the principles applicable to all types of interactions (HCPs and POs) and of the time period for disclosure to HCPs, HCOs, and Pos (at the end of June); the written permission from HCOs in case of use of its proprietary material by a M ember Company.

Furthermore, the point 3.25 of the Code has been changed with the specification that the limit of 150 euro for the hospitality of the other non-prescribers subjects involved in the administration of therapies is referred only to CME events.

#### \*\*\*\*\*

# LATVIA – SIFFA

# Code authority activity

Ethics Commission of the Association of International Innovative Pharmaceuticals Producers (SIFFA)<sup>1</sup> examined 6 complaints that came from industry (including 2 complaints where no violation was found) regarding:

- advertising of prescription (Rx) medicine by media, including *off-label* use, to the public 50%;
- advertising of Rx medicine by patient organisation to the public 25%;
- inappropriate distribution of calendars with advertisements of over the counter (OTC) and Rx medicine, including to the public 25%.

The principles set out in the Code of good practice and ethics (further – Code) of SIFFA have been violated:

- Introduction of the Code: EFPIA and its members are conscious of the importance of (i) providing accurate, fair and objective information about Medicinal Products so that rational decisions can be made as to their use, (ii) <u>ensuring that interactions with HCPs</u>, HCOs and <u>POs take place in an ethical manner, which is key for sharing knowledge and improving the quality of patient care</u>, and (iii) introducing greater transparency regarding the pharmaceutical industry's interactions with HCPs, HCOs and POs;
- Scope of the Code: <u>Member Companies are responsible for fulfilling their obligations under the</u> <u>Applicable Codes even if they have authorised a Third Party to prepare and carry out activities or</u> <u>engage in activities relevant to an Applicable Code</u>. In addition, Member Companies must take reasonable steps to ensure that any other parties that they commission to prepare, implement or engage in activities covered by an Applicable Code but that do not act on behalf of the Member Company (..) comply with the Applicable Codes;
- Article 6.01 of the Code and its applicability: advertising and cooperation that takes place in Europe must comply with the requirements of the applicable regulations and comply with the requirements of the applicable Codes; <u>the advertisement should be addressed only to those HCP who can</u> reasonably be assumed to be interested in or need this information;
- Article 11.01 of the Code: it is prohibited to directly or indirectly offer, promise or present <u>gifts</u> [f.e., calendars etc.] intended for the personal use of HCP, HCO or PO representatives (..).

<sup>&</sup>lt;sup>1</sup> SIFFA and Latvian Generics Medicine Association (LPMA) have a common Code and Ethics commission.

Violations by third parties (media, publisher) have been reported to the Health Inspectorate, which is entitled to take measures in connection with violations of regulatory acts. As a sanction, a decision was made to inform SIFFA members about the reviewed complaint without naming the defendants, as well as to publish information about the reviewed case on the SIFFA website: https://www.siffa.lv/lv/etikas-komisijas-lemumi/.

#### Code report

The annual report of the Ethics Commission was presented at the general meeting of the members of the association on 19.01.2024; it is not published on the SIFFA website.

National Code web link (English version): https://www.siffa.lv/en/etika-un-atklatiba/

# Consequences of Code authority activity

The Commission has discussed violations of the Code with drug manufacturers, including explanations in the area of enforcement of the Code and regulatory acts.

# 2023 Disclosure of 2022 data

Companies publish data only on the platform of a state institution (Health Inspection) https://www.vi.gov.lv/lv/pazinojums-par-biedribam-nodibinajumiem-un-arstniecibas-iestadem-sniegto-

materialo-vai-cita-veida-atbalstu-2, placing a link to this website on their websites. Data on the Health Inspection website are presented in an excel spreadsheet. The consent of HCPs is not required, as regulatory enactments require them to be made public.

Non-duplication of data is possible on the basis of EFPIA Board decision (01.07.2020), as well as taking into account that the Latvian regulatory enactments fully reflect the appropriate disclosure of the information specified in the EFPIA Code and national Code.

The requirements for data disclosure are the same for all pharmaceutical manufacturers.

Health Inspection collects data by 30 May, compiles and publishes them no later than 30 June to comply with the Code.

In 2022, companies have declared support for 10,34 millions euros, incl. R&D sum (in 2021 – 6,35M, 2020 – 4,47M euros).

Companies publish data on cooperation with patient organizations on their websites.

#### **Others topics**

Updated guidelines on the application of Article 11 of the Code (prohibition of gifts) and the corresponding regulatory act (Cabinet rules nr.378), which materials HCPs may and may not hand out during individual visits, conferences and billboards, including training and demo-materials.

In communication with the *EFPIA CodCom*, comments and opinions were provided on the planned changes in the pharmaceutical legislation regarding medicinal product advertising in Directive 2001/83/EC and their compatibility with the Code and national regulations.

In order to inform HCPs about industrial ethical issues (implementation of *ETHOS* principles in the Code; distribution and use of drug samples; *off-label* use of drugs; aspects of drug promotion, including advertising distribution), 4 publications were published in the doctors' magazine "Latvijas Ārsts" (*Latvian Physician*) and 2 – in the pharmacists' magazine "*Materia medica*".

Negotiations continues with the Association of Latvian Doctors regarding the revision of the existing "Declaration on the interaction and ethical principles of doctors and the pharmaceutical industry".

#### \*\*\*\*\*

#### LUXEMBOURG – IML

Code authority activity

No complaint has been lodged in 2023 before the Committee for Deontology and Ethics in the Pharmaceutical Industry.

#### Code awareness

IML's code of ethics is available on the association's website: <u>https://www.iml.lu/en/our-points-view/code-ethics</u>. With the support of EFPIA each year, the code is updated, and the changes proposed by the Board of Directors are approved by the General Assembly. The updated version is shared with all members of the association by email.

#### \*\*\*\*\*

# **MACEDONIA - Farmabrend Nova (FBN)**

#### Code authority activity

No complaints or reports for FBN Code violations were received in 2023. Members' activities were at a minimum due to low access to innovative medicines (positive list not updated for 15+ years).

<u>2024 Disclosure of 2023 data</u> Disclosure is going according to plan. No negative feedback has been received so far.

#### Code awareness

The Code is published on FBN website here: <u>https://fbn.mk/?attachment\_id=3306</u>

\*\*\*\*\*\*

#### **NORWAY - LMI**

Code Authority activity

In 2023 the Code Authority (Rådet) handled the following activities:

The Code Authority handled 1 case and 6 Advanced statement cases. The Code provisions were breached in 1 of 1 complaint cases. The complaint was made by the Secretariat. The provision in the case were LMI Industry Rules 23.1 Disclosures of Transfers of Value. The sanctions imposed a fine of NOK 200.000.

Code report

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

The cases are published in Norwegian here: <u>http://reklameregler.lmi.no/avgjorelser</u>

#### Code trainings

5 different trainings were organized:

- 2 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.

#### Advice and Control

During 2023 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.

#### \*\*\*\*\*\*

#### **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. In 2023, 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.

#### 2023 Disclosure of 2022 data

The figures are the following:

- R&D 73,2%
- HCOs 15,5%
- HCPs 11,3%

The estimated percentage for positive consent is:

- HCOs 93,4%
- HCPs 28,6%

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

In 2023 no significant changes in comparison with 2022 ToV, but an increase of HCP consents was noted. The overall figure of the three main areas have proven to be stable over the years.

General trends (2016-2023):

- Increase of HCP consents from 25% to 31% in 2021
- Stable level in TOTAL ToV amount
- Relatively stable proportions of ToV distribution (in share / %)
- Slight decrease in R&D investments noticed in last years (in %) but an increase in R&D activities last four years

On 26-30 June 2023, 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 3 July 2023, 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 2023:

- 1. Further development and implementation of the Q&A document to the INFARMA Code of Good Practices.
- 2. Improvement of the Event Certification System education in the field of INFARMA standards, both among parties organizing events and INFARMA member companies.
- 3. Identification of risk areas and creation of thematic subgroups dedicated to specific areas: education of the medical community, working with Digital Opinion Leaders, compliance conflict of interest of healthcare professionals, cooperation with Patients/Patient Organisations.

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 2023, 1883 events were recorded in the certification system (5% more than in 2022).

In 2023 the INFARMA met the following completed tasks associated with the Event Certification System:

- on-going improvements,
- effective education of all system participants (including regular newsletters),
- introduction of the first elements of monitoring of events with INFARMA certificate,
- exchange of experience with other industry organizations national and international.

#### \*\*\*\*\*\*

# SLOVAKIA – AIFP

#### Code authority activities

In 2023, the AIFP Ethical Committee (EC) received only one complaint concerning a violation of the AIFP Ethics Codefrom a member company. Due to the end of the year, EC has proceeded to the required actions in the next year 2024. The EC meetings were held 4 times per year.

Upon the requests from members and third parties, EC assessed the venues of the scientific events supported by member companies and even the social programs.

The most significant part of the regular EC agenda is monitoring and assessment of the so-called Other studies (marketing surveys among HCP, epi surveys, FE monitoring, retrospective data analysis without the direct impact of its result on the patient, monitoring of therapeutic procedures for the treatment of the disease without monitoring the effects of specific drugs etc.). The aim of the Other studies carried out or sponsored by the member may be the acquisition of scientific, professional and other information following the legitimate business needs of the submitter. EC assessed 22 Other studies. (In total, EC has assessed 429 Other studies till the overall operation of EC).

EC also opened on her own initiative the question of modification of the explanatory notes on the topic of donations to a private hospital provider vs. sponsoring the education of such a provider, where the provision of the AIFP Code of Ethics referred to the possibility of making donations only to public hospitals, but not to the prohibition of supporting the education of such a provider. This amendment to the AIFP Ethics Code was approved by the AIFP General Assembly.

The following amendments to the AIFP Code of Conduct have been approved in 2023:

Upgrade of the hospitality amount offered in the form of meals has increased to € 150 for an all-day meal in the Slovak Republic, provided when the event lasts longer than 6 hours.

The use of digital tools has been approved. The rule governing the use of Product Information must apply to the full and abridged Product Information, as well as in printed and digital form. Digital tools are, for example, QR codes or hyperlinked Internet links.

The next amendment of the AIFP Ethics Code was related to hospitality offered exclusively to qualified professional event participants (healthcare professionals).

The last amendment, approved by the General Assembly at the end of the year, was the cancellation of the Section related to reporting on the Other studies (reporting of Other studies on the AIFP intranet, see above). The proposal was made due to changes in legislation at the EU level related to the provisions of Competition law.

#### Code report

The annual 2023 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.

#### \*\*\*\*\*

#### **SLOVENIA – FarmaForum**

<u>Code authority activity</u> One complaint has been received in 2023. The breached provision was Article 10.1.

#### <u>Disclosure</u> A whole report on Transfers of Value data for 2023 will be available from 5 July 2023.

#### Code awareness

Internal guidelines are given to Forum members compliance leaders and General Managers at multiple sessions.

#### \*\*\*\*\*

#### **SPAIN – FARMAINDUSTRIA**

#### Code authority activity.

Farmaindustria examined 7 cases in 2023 that came from:

- Pharmaceutical companies: 42,86%
- Code of Practice Surveillance Unit: 57,14%

The Code provisions that have been breached in the 7 cases are the following:

- Article 1. Marketing Authorization for Medicines (EFPIA Code Article 1 Marketing Authorization)
- Article 3. Information on Medicines and its Substantiation (EFPIA Code Article 3 Promotion and its Substantiation)
- 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)
- Article 10. Guarantees of Independence (EFPIA Code Article 11 Prohibition of Gifts).
- Article 11. Scientific and Professional Meetings (EFPIA Code Article 10 Events and Hospitality)

One case was filed, four settled by a mediation agreement between the parties, and two solved by the Jury.

#### Code report.

The Code report is available here: <a href="https://www.farmaindustria.es/web/">https://www.farmaindustria.es/web/</a>

<u>Consequences of Code authority activity</u> No relevant consequences.

2023 disclosure of 2022 ToVs

The figures are the following: Transfers of Value (TOTAL: 667 million euros)

- **\*** R&D 46,93%
- **\*** HCOs 28,49%
- **\*** HCPs 24,58%

The percentage of positive consent is 100%

For transparency initiative success, we encourage countries to approach Personal Data Protection Authorities in order to be able to disclose all the ToV 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.

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

#### \*\*\*\*\*

# SWEDEN – LIF

#### Code authority activity

The first instance (IGN) in LIF self-regulation system examined 59 cases. The second instance (NBL) in the Lif self-regulation system examined 12 cases. 6 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 represent 83 % of the total case volume.

In 2023, the complaints came from:

- ★ Pharmaceutical companies: 1,4 %
- ★ Healthcare Professionals: 0 %
- ★ National Code authority: 83 % (IGN= first instance)
- \* National agencies: 1,4 % (including regional Formulary Committees)
- **\*** Anonymous: 0 %
- \* Others (please specify): 1,4 % (private person)

The Code provisions have been breached in 28 cases, as assessed by IGN, and in general relate to promotion 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), in 4 cases assessed a breach, and in 3 cases the outcome was non-breach.

The sanctions imposed were fines (in general 110 000 SEK).

#### Consequences of Code authority activity

More ascertain boundaries have been established regarding the broadening of article 2 in LER (the possibility to use new data that is not explicitly found in the SPC) and the cases regarding that have started to decrease. 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/

#### 2023 disclosure of 2022 ToVs

The figures are the following:

- **\*** R&D 77,0 %
- **HCOs** 10,7 % (consultancy fees and associated expenses, sponsorships, donations)
- **\*** HCPs 4,0 % (consultancy fees and associated expenses)

The percentage of individual disclosure is:

★ 93.3 % of recipients (HCP and HCO combined; ToVs in relation to consultancy fees and associated expenses)

★ 88,7 % 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 GDPRenforcement.

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 158 attendees participated. Upon request, Lif organized training for individual member companies. In addition, Code introduction sessions for new member companies were held in the first half of the year.

#### \*\*\*\*\*

#### **SWITZERLAND**

# The Pharma Code and the Pharma Cooperation Code in 2023: Annual Report of the Code Secretariat

#### Introduction

For many years, the Swiss pharmaceutical industry has applied internationally coordinated (see IFPMA<sup>2</sup>, EFPIA<sup>3</sup>) self-regulation that goes beyond the law with the Pharma Code (PC<sup>4</sup>) and the Pharma Cooperation Code (PCC<sup>1</sup>). Pharmaceutical companies can voluntarily agree to abide with these codes (see lists of

<sup>&</sup>lt;sup>2</sup> IFPMA

<sup>&</sup>lt;sup>3</sup> EFPIA

<sup>&</sup>lt;sup>4</sup> The provisions of the two codes are referred to in the Annual Report by "PC" and "PCC" with the relevant section number.

signatories<sup>5</sup>). The support organisation for pharmaceutical self-regulation in Switzerland is scienceindustries, while its Code Secretariat is responsible for the implementation of the codes. When dealing with disputes, the Secretariat primarily acts as an intermediary and applies the principle of the amicable settlement of conflicts. In 2023 too, its neutral assessment was always accepted by the parties involved in the individual disputes and the situation was soon returned to compliance with the codes.

# Implementation of the Pharma Code

The number of cases dealt with under the PC fell slightly to 103 from 107 last year. The number of complaints filed against competitors increased significantly (2023: 38.2% / 39 cases; 2022: 13.1% / 14 cases). One company reported itself (2022: 2). Once again, no cases were classified as potentially hazardous to health and therefore serious.

The average duration of proceedings increased to 8.1 days in 2023 (2022: 5.6 days) and thus corresponds again to the duration of proceedings in 2021 (8.2 days).

103 cases were opened in 2023. Of these, 94 cases (91.2%, 2022 83.2%) were closed after the contested advertising had either been corrected or removed. Nine cases (8.8% / 2022: 16.8%) were found not to be in breach of the Code. Two of these 9 cases were initiated by a competitor (2022: 1 of 18). There were delays in two cases due to the complexity of the issues. As in the previous reporting year, no company had to be warned for failing to submit the requested comments on time. In a complaint filed by a competitor, the Code Secretariat was not responsible for assessing the content of advertising to the general public.

The Code Secretariat conducted one mediation in 2023 (2022: 1) and took note of 5 bilateral agreements (2022: 3).

Ninety-one pharmaceutical companies (2022: 90) submitted a total of 12,581 specimen copies (2022: 13,724) of their promotional material and information; 96.9% (2022: 98.3%) were sent to the Secretariat electronically. Only a few specimen copies were sent to the Code Secretariat by post.

The number of cases opened was once again at the average level of recent years, with 72 cases in 2021 appearing to have been an exception. Competitor notifications increased again, as did reports of bilateral negotiations, but here an unknown number of unreported cases must still be expected. The time required for each case increased somewhat, which was due to the complexity of the issues involved.

# Established breaches of the Code

A total of 34 (2022: 45) PC requirements were mentioned in the 103 complaints (2022: 107). One requirement only was mentioned for 25.0% of the cases (2022: 33%); two requirements were mentioned for 9.7% (2022: 11.3%) and three to nine requirements were cited in 65.3% of cases (2022: 55.7%; 3 to 8 requirements). The following is a list of the PC requirements that were mentioned often:

- Principle of professional promotion (PC 24.1): further sharp increase to 20 breaches (previous year: 12).
- Unproven advertising statements and incorrectly cited references (PC 24.2): stable at 82 breaches (previous year 82).
- Promotional materials that did not contain all the minimum information about pharmaceuticals required by the PC (PC 24.4, 24.5): slight increase to 23 breaches (previous year: 19).
- Incomplete or impermissible references to literature (PC 25, excluding PC 25.1, 25.4.3, and 25.7): down on the previous year with 15 breaches (previous year: 29).
- Missing indication that references can be requested from healthcare professionals (PC 24.2, 25.1, 25.4.3, and 25.7): strong increase to 49 breaches; these were systematically warned for the first time in 2022 (29 cases in 2022).
- Notifications of unqualified superlatives and comparatives (PC 25.8, 25.9): slight increase to 10 breaches (previous year: 7).
- Obligations of pharmaceutical companies when implementing the PC (PC 6): slight decrease to 11 breaches compared with 14 in the previous year.
- Ban on gifts (PC 15.2): one identified breach (previous year: 1).

<sup>&</sup>lt;sup>5</sup> <u>Signatories of the Pharma Code</u> / <u>Signatories of the Pharma Cooperation Code</u>

- Promotion of as-yet unauthorised medicinal products or indications (PC 23.1, 23.2): up sharply at 13 breaches (previous year: 3).
- Promotional statements differ from the drug information for health professionals approved by Swissmedic at the time when marketing authorisation was given (PC 23.3): 8 breaches compared to 1 in the previous year.
- Use of expressions minimising possible risks (e.g. claiming that the medicinal product concerned does not induce addiction or is harmless (PC 24.3.3): 2 breaches (previous year: 0).

The shift to more disputed requirements per case is due to the fact that a frequent complaint (lack of indication that references can be requested) ultimately resulted in a breach of four different requirements: (PC 24.2, 25.1, 25.4.3, and 25.7). As in previous years, it can also be said for 2023 that the breaches of the PC for which complaints were received could not be qualified as gross breaches. There was no need to threaten to refer a matter to the competent state authority (PC 75.10) in 2023 too.

# Support for events promoting postgraduate medical training and continuing medical education (PC 3)

In 2023, the Code Secretariat of its own accord as well as at the request of companies or organisations again reviewed a number of events promoting postgraduate medical training and continuing medical education to check whether they meet the self-regulation requirements. In doing so, the Secretariat applied established international standards (in particular IPCAA<sup>6</sup> and e4ethics<sup>7</sup>). It had to intervene in two cases (2021: one). With the help of the Code Secretariat, certain events were restructured to comply with the codes, which then allowed company support. It has to be noted that the Code Secretariat on its own cannot obtain a complete overview of these activities. Here too it will continue to be dependent on questions or complaints received from the companies or the organisers themselves.

# Implementation of Pharma Cooperation Code

Between 20 and 30 June 2023, the companies that signed the PCC for the eighth time disclosed the pecuniary benefits granted in 2022 to healthcare professionals (HCP – mainly doctors and pharmacists), healthcare organisations (HCO – mainly hospitals and professional organisations) and patient organisations (PO) on their websites. These concerned direct or indirect payments for cooperation relating to prescription-only medicinal products for humans. Six companies (previous year: 8) were slightly behind in the publication of their data; after the Secretariat intervened, complete data sets of good quality could only be published in August 2023, which was very unsatisfactory.

The Code Secretariat compiled the figures of the 66 PCC signatory companies (previous period: 68) and by the end of July 2023, was able to put together the following statistics about Switzerland: Transfers of value (ToV) for a total of CHF 217.9 million were disclosed for 2022. In the previous year, the figure was CHF 194.1 million, which corresponds to an increase of CHF 23.8 million. At CHF 7.4 million, slightly more donations were paid to HCP than in the previous year (CHF 6.4 million). ToV to HCO also increased to CHF 121.5 million compared to CHF 106.1 million in 2021. The ToV for R&D services increased slightly from CHF 81.6 million to CHF 88.9 million.

Cooperation payments to HCP was therefore on a par with the previous year in 2022. The effect of the coronavirus pandemic therefore seems to have continued. Once again, a certain shift in direct support from HCP towards HCO was observed. Cooperation payments to HCO increased by more than CHF 14 million to almost CHF 120 million. Grants for research & development increased slightly again in 2022 after falling slightly in 2021. In this area, it seemed once again that annual contributions from individual companies fluctuate strongly from one year to the other, which can be explained, among other things, by varying levels of activity in the field 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. Seen overall, the average consent rate for HCP increased once again from 90.4% to 92.4% in 2022. The median rate was as high as 99.7%, which shows that half of the PCC signatory companies had HCP

<sup>&</sup>lt;sup>6</sup> https://www.ipcaa.org/public/international-healthcare-congress-guidelines/

<sup>&</sup>lt;sup>7</sup> <u>https://www.ethicalmedtech.eu/e4ethics/about-e4ethics/</u>

consent rates of 99.7% or higher. The average consent rate for HCO also increased further from 95.8% to 97.2%. The median here remained at 100%. Overall, consent rates continued to develop positively, and only a few companies can still achieve better results. In some cases, consent rates have resulted in considerable discrepancies between the individual companies, which are sometimes difficult to understand. Nine companies who achieved an HCP consent rate of less than 80% in the reporting year were therefore mentioned by name on the website of scienceindustries (2021: 10 companies) and requested to implement measures to increase their consent rate.

With regard to disclosure, scienceindustries was once again in contact with stakeholders and interested media and explained the pharmaceutical industry's transparency initiative.

#### Pharmaceutical Code enquiries and training

In 2023, the Code Secretariat replied to 242 written or telephone enquiries pursuant to section 8 PC / section 6 PCC (previous year 362). Of these, 162 enquiries related to the PC and 77 to the PCC. The significant decline in enquiries surprises the Code Secretariat insofar as a large amount of consulting work was nevertheless required in 2023. The situation will continue to be monitored. In 2023, the Code Secretariat conducted two online training courses on professional promotion with a total of 79 participants, and two on pharma compliance with a total of 62 participants. In its capacity as self-regulatory body for the Swiss pharmaceutical industry, scienceindustries also gave lectures about various topics and replied to media enquiries.

#### \*\*\*\*\*

#### UK – PMCPA

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 <u>pmcpa.org.uk.</u>