European Federation of Pharmaceutical Industries and Associations

EFPIA Code
Report on Ethics & Compliance Activities
July 2023

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 (**Annex 1 – 2022 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 2022 and into mid-2023.

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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 2022 and into 2023:

- **Transposition of the EFPIA Code provisions at national level**

EFPIA Secretariat, in partnership with the Member Associations, analysed the transposition in the 36 national Codes of the new provisions of the EFPIA Code, those introduced during the consolidation process of the 3 EFPIA Codes.
On 35 national Codes analysed:

- 40% of the national Codes include all the new EFPIA Code provisions (this represents 14 national codes)
- 40% of the national Codes include more than 90% of the new EFPIA Code provisions

In summary, more than 90% of the new provisions introduced in the EFPIA Code have been transposed in 28 countries by the Member Associations.

- **Code monitoring activities**

Based on the EFPIA Ethics & Compliance priority related to self-regulation credibility, EFPIA Secretariat monitored the following national Codes activities:

- Verifying the national Codes authorities' governance and activities especially the processing of industry and non-industry complaints, the appeal procedure and the publication of the decisions.
- Analysing the provisions on individual patients' interactions in the national Codes and related documents.

- **Impact of the inflation on the meals and drinks threshold**

Due to the inflation and the fact that some Member Associations have not updated their meals and drinks threshold during the last 10 years, 18 Member Associations have increased their thresholds.
The table with all the national meals and drinks thresholds is published here.

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 2022 and into 2023, in addition to the EFPIA Ethics and Compliance priorities, the E&CC has focused on the following projects:

- **Patient Support Program (PSP)**

The E&CC is currently developing a guidance related to PSP aiming to define the principles applicable to product related PSP in Europe (common definition, and alignment on criteria).

- **New ways of partnering**

The objective of this project is to create 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.

- **Qualifying communication & activities**

The purpose of this project is to create a "questions to consider" document that can be used to assess the companies' activities, in isolation and totality, and help them to qualify the nature of their communications and activities.

- **Disclosure**

European gateway

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 identified the challenges and suggested some proposals.
One of these proposals was to create a European gateway on the EFPIA website.
This European gateway, available here, includes a map with the links to the Member Associations gateways/platforms and below, the links to the EFPIA Member Companies european disclosure webpages via companies logo list on the same page.
A video, available here, has accompanied the launch of the gateway in June 2023.

Analysis of the disclosure reports

Since the first disclosure in 2016, EFPIA has analysed the transfers of value (ToVs) provided to Healthcare Professionals and 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.
For this year, 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.

- **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 European Directives on Corporate & Sustainable Reporting and Corporate & Sustainable Due Diligence including the definition of mandatory reporting standards.
- 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 proposal for an Anti-Corruption Directive.

- **Ethics & Compliance Committee involvement in other EFPIA projects**

The E&CC supported the Patient Think Tank project related to define best-practices for simplifying the contractual interactions between pharmaceutical companies and Patient Organisations.
This document "Best-Practice Principles - Working Together with Patient Organisations: Donations and Grants, Sponsorships and Contracted Services" is published on the EFPIA website.

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

Due to the retirement of the Professional Congress Organiser in charge of the International Pharmaceutical and Medical Device Ethics & Compliance Congress (former PCF conference), this one will no longer be organised.
EFPIA, with MedTech Europe and ETHICS, have decided to organise a one day ethics & compliance conference on 5 October, in Brussels.
All the information related to this conference is available here: https://www.hethico.org/

ANNEX 1: 2022 NATIONAL CODE REPORTS

AUSTRIA – PHARMIG

Code authority activity

In 2022 there was no complaint made under the PHARMIG Code of Conduct. Since PHARMIG heard that claims are filed at court instead we sent a reminder to our members, also highlighting the advantages of using the possibility of a procedure in front of the PHARMIG Adjudication and Appeal Boards.

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 2022 is available on PHARMIG's website: https://www.pharmig.at/media/5845/pharmig-leistungsbericht-2022.pdf (in German only).

2022 Disclosure of 2021 data

In 2021 ToV of 105,2 Mio. EUR to HCP, HCO and PO were made by pharmaceutical companies in Austria. Regarding 97,2 % of the ToV the recipients were HCP and HCO. The 102,4 Mio. were split as followed:

- 78,4 Mio. EUR (74,5 %) R&D
- 3,4 Mio. EUR (3,3 %) events
- 14,2 Mio. Euro (13,5 %) fees for services and consultancy
- 6,4 Mio. Euro (6 %) donations and grants

Regarding the 2,8 Mio. (2,6%) PO received these were split as followed:

- 2,6 Mio financial support
- 900.000 non-financial support
- 730.000 fees for services and consultancy

The yearly graphic of the disclosure overview can be found on PHARMIG's website: https://www.pharmig.at/media/5034/pharmig_grafik_disclosure_2021_e.pdf

Code awareness

PHARMIG organised virtual training sessions and discussion platforms for member companies on a regular basis. This included Q&A on current questions of Code interpretation in practice, a session on e4ethics and exchange on sponsorship of medical education.

PHARMIG provides plenty of information material to its members regarding the Code (e.g. fact sheets, checklists, notes for guidances, sample contracts). The FAQ regarding the Code (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); an *introduction seminar regarding our Code as well as the rules on advertising in the Austrian Medicinal Products Act* for newcomers in the pharmaceutical industry or in their role in legal and/or compliance legal and other *compliance seminars focusing on a specific topic*.

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BELGIUM – Pharma.be

Code authority activity

No complaint has been lodged in 2022 before the Committee for Deontology and Ethics in the Pharmaceutical Industry.

However, a complaint launched in 2021 resulted in the case being brought before the Chamber of Appeal. This has been ruled in 2022.

Code report

According to art. 41 of the pharma.be code of Deontology and art. 42 of the pharma.be code of Deontology Animal Health:

- The **nominative final decisions** taken by the DEP Committee and the Chamber of Appeal are publicly disclosed on the extranet of pharma.be (they are only available for members)
- The final decisions taken by the DEP Committee and the Chamber of Appeal are **referenced** on the pharma.be public website: https://pharma.be/fr/jurisprudence-du-code-de-deontologie

Code awareness

Pharma.be organised the following trainings:

- **17/11/2022: PharmAcademy "ABC of Ethics"**

"The aim of this module is to give the trainees a clear and general insight into existing legislation and self-regulation on compliance for pharmaceutical companies and the tools for practical implementation. Focus will be on the relations with HCPs & HCOs and publicity for medicinal products. The target group are junior profiles in these domains, as well as new employees in the pharmaceutical industry."

The "Bureau for control of the written communication" is an independent deontological body that reviews the conformity of the written communication of pharma.be member companies intended for HCPs with the provisions of the code of deontology, the legal provisions and regulations. Each year, the Bureau issues a report containing an overview of its decisions and some guidelines for companies. This annual report is published on the Extranet of pharma.be.

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BULGARIA – Association of the Research-based Pharmaceutical Manufacturers/ARPharM

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

Ethical cases reviewed:

- EK 0057 - the proceedings in the case have ended due to lack of quorum.
- EK 0058 - the proceedings in the case were concluded without finding a violation.

- EK 0059 - the proceedings in the case were concluded without finding a violation.

2022 Disclosure of 2021 data

The figures are the following:

- R&D 80%
- HCOs/HCPs 17%
- PO 3%

The estimated percentage for positive consent is:

- HCOs 100% (no consent by HCOs required by law)
- HCPs 75 %

Code awareness

- **Distributed letter (03.04.2023)** to the governing bodies of medical unions and technical event organizers, **re-addressing** them to **the standards adopted by ARPharM** members regarding sponsoring and support of scientific events for medical professionals;
- Recommendation to include a **text** in the sponsorship contracts of the Companies, **which prevents support for events within the framework of which entertainment** (based on the texts of the observation index) **is organized**, regardless of whether it is announced in the program or not.
- Recommendation to include in the events' sponsorship contracts of the Companies provisions for **refund/money back** in case of hidden activities organised.
- Launching a procedure for discussion by e-mails the application of the Observation index in accordance with the norms adopted by EFPIA, namely **changing the character of the index from recommended to mandatory**.

Code related activities

- **ARPharM's Code of Ethics - new THRESHOLDS FOR MEALS & DRINKS as of 1 of April 2023**

New MEALS & DRINKS thresholds: (Art. 10.06)

Lunch	Dinner	Per Day
BGN 80	BGN 120	BGN 200

- **Synchronization of the ARPharM with the latest updates to the EFPIA Consolidated Code.**

Removal Article 1.03. Promotion and advertising of a Medicinal Product or therapeutic indication of a Medicinal Product is prohibited before the issuance of the marketing authorization, allowing its sale or delivery. This prohibition is not intended to prejudice the right of the scientific community and the public to be fully informed of scientific and medical progress. It does not aim to restrict the full and accurate exchange of scientific information concerning a Medicinal Product, including the presentation of relevant scientific facts in specialized **or mass media** and at scientific conferences. It should also not restrict the communication to shareholders and others of information about a Medicinal Product in accordance with the requirements or recommendations of the law, rules or regulations.

e4ethics related activities

- **By recommendations of the Ethical Commission regarding companies' financial support of medical scientific events featuring hidden entertainment activities**
    - In the Observation index introduced additional criterion: Orange colour of preliminary/ final assessment:

Section IV. Other Activities

Scientific event for which there is available information (photo and video materials) of hidden entertainment activities within the framework of a previous event of the same organizer - Hospitality shall not include sponsoring or organising entertainment (e.g., pre-congress sightseeing tours or post-congress sightseeing tours, concerts, theatre or similar spectacles, museum visits, sporting) events;

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CYPRUS – KEFEA

Implementation and Development of a new KEFEA Code of Conduct

1. A new Code of Conduct was adopted by the KEFEA Board of Directors on 15 December 2022. It repealed and replaced any and all previous versions of the KEFEA Code of Conduct, the KEFEA Disclosure Code and the KEFEA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations.
2. ComCom clarified that there would be a grace period of three months after the Code's adoption by the KEFEA Board of Directors for KEFEA members to update their processes from the previous version of the KEFEA Code of Conduct to this one.
3. The KEFEA Code has been translated into Greek for its members' ease of reference and it is pending proofreading and uploading onto the KEFEA website. It was clarified that in the event of any discrepancy between the Greek and the English versions of the Code, the English version shall prevail.
4. The Code of Conduct can be found here: http://kefea.org.cy/wp-content/uploads/2023/01/CY-KEFEA-Code-final-version-15.12.22-English.pdf

Enforcement of the KEFEA Code of Conduct

No complaints were received in 2022.

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DENMARK – ENLI (LIF)

Executive Summary (Annual Report 2022)

In 2022 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 more than 100 pharmaceutical companies on the Danish market.
For further information about the ethical codes, please visit www.enli.dk/en.

Significant matters in 2022

In 2022, approx. 412 promotional activities were self-reported to ENLI each month, as required (pre-vetting procedure). Of these, the Investigator Panel has reviewed approx. 38% of the reports in a random control, and 96% of the activities were approved, whereas sanctions were decided in 4% of the evaluated reports.

One complaint was processed and decided on against an affiliated pharmaceutical company in 2022. The complaint was upheld.

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-amil, and many companies consult ENLI on marketing compliance issues.

In 2022, companies requested 90 pre-approvals of promotional activities, which is a decrease of 16 requests compared to 2021. Of the pre-approval requests in 2022, 69% were approved.

From the total amount of 107 decisions that ruled against an affiliated company, six decisions were appealed to the Board of Appeal, which corresponds to approx. 5,6% of all relevant decisions. The Board of Appeal thus handled six cases in 2022. Five decisions from the first instance were upheld.

ENLI has continued to prioritize preventive activities. In 2022, ENLI has published 79 decisions (including 42 administrative reprimands), and 4 newsletters. Furthermore, ENLI has conducted 10 courses in the regulation, primarily the Promotional Code, and 4 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.

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FINLAND - PIF

Code authority activity

PIF handled 9 complaints in 2022:

- Inspection Board I (marketing and information to the consumers): 9 cases
- Inspection Board II (marketing to the HCP's): None
- Supervisory Commission (complaints of the decisions made by Inspection Boards): 1 case

The complaints came from:

- All cases at *the Inspection Board I* were initiated through self-monitoring process. All cases referred to collaboration with Patient Organizations.
- Pharmaceutical companies: None
- HCP: None

The Code provisions have been breached in 8 cases.

Supervisory Commission: The Code provisions have been breached in 1 case (there was only one case).

The following provisions were breached:

The events organised in collaboration with the patient organisations must be arranged in line with the instructions related to health awareness information and other information on health and diseases targeted at consumers. It was ruled in the decisions, that the companies clearly had *supported* the event and therefore are also liable for the content of the program including any third party presentations, which did have some pre-marketing elements.

The pharmaceutical company is always responsible for the compliance of its marketing with the PIF Code, even when sponsoring the events of the patient organisations. The programme and other arrangements of the events must in all respects comply with the principles included in the PIF Code regarding the equitableness and matter-of-factness of the information.

The sanctions imposed were:
Sanction payments 8.000 euros per case
Processing charges 2.000 euros or 5.000 euros per case

Code report

The Code Report 2022 including decisions made by PIF Inspections Boards/Supervisory Commission published at:

https://www.laaketeollisuus.fi/media/julkaisut/toimintakertomukset/laakemarkkinoinnin-valvontakunnan-toimintakertomukset/lmvk-vuosikatsaus-2023-final-id-141468.pdf

2022 Disclosure of 2021 data

The figures are the following:

- R&D 77.5%
- HCOs 10.5%
- HCPs 12%
- The percentage of positive consent is 72.7%.

Code awareness

PIF organized:

- information meetings/trainings for our members on a yearly basis.
- a yearly remote meeting for companies offering marketing services to pharma companies explaining the Code of Ethics and sharing best practices.

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GERMANY – FSA/VFA

Code authority activity

In the 2022 reporting period, the FSA Arbitration Board dealt with 37 complaints, of which 28 were submitted by third parties and 9 by member companies. 1 of the complaints was inadmissible for formal reasons, 17 of the complaints were unfounded.

The main issues were the appropriateness of venue and location in the case of sponsoring of a third party scientific event and the question of admissibility of statements in a video directed at patients, produced on behalf of and at the expense of a company.

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:

https://www.fsa-pharma.de/de/schiedstelle/berichterstattung/fachkreise

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 Code authority:

23-03-28_fsa_jahresbericht_2022.pdf (fsa-pharma.de)

2022 Disclosure of 2021 ToVs

The FSA has reported publicly on the yearly disclosure of its member companies: Transparenzveröffentlichungen 2022 (fsa-pharma.de)

The overall figure of the three main areas have proven to be stable over the years (R&D: 72,5%; HCO: 17,1%; HCP: 10,4%).

The level of positive consent is with 22% slightly above the previous year´s value of 20%. It has to be stated that as in the past the special situation in Germany with respect to individual consent of HCP continues (negative press coverage from the first disclosure years, the anticorruption law that came into force in 2016 and general data protection fears). FSA/vfa and their member companies do not let up in their efforts to explain the initiative and to convince more HCPs to give their consent. The FSA Transparency Code and the objective of creating transparency on collaboration and ToV together with HCP via an annual publication are regularly the subject of presentations and training sessions by the FSA Managing Director with HCP and HCO in Germany.

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.

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GREECE - SFEE

A. AMENDMENT OF CODE OF ETHICS

SFEE's Code of Ethics was amended during the works of the General Assembly held on **30 March 2023**. Relevant modifications were communicated to EFPIA.

B. FIRST INSTANCE COMMITTEE

During 2023, the First Instance Committee for Code Compliance examined, in total one (1) case of allegations about Code violations from SFEE Member – Companies. The case includes claims of **off-label promotion** and **exaggerative non-objective allegations.**

C. CODE TRAINING

On May 11th, 2023 SFEE participated at **Roche Compliance Week** and provided extensive training.
A new training is scheduled on 28th September 2023 for **MSD** at their offices.

D. DISCLOSURE

The Disclosure of Transfers of Value to HCPs and HCOs from Pharmaceutical Companies that took place during the year 2022, was compiled on Friday 30.06.2023 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 2023/October 2023

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IRELAND - IPHA

Code authority activity

IPHA received zero complaints in 2022.

Code report

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

2022 Disclosure of 2021 data

Submission Period	# Companies with Submissions	Generated
01 January 2021 - 31 December 2021	44	16 February 2023 11:46:46

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	€665,944	€28,197	€1,020,431	€2,523	€1,717,095
	HCP – Aggregate	N/A	N/A	€293,193	€24,085	€506,010	€20,638	€843,926
HCOs	HCO – Individual	€2,553,925	€2,378,446	€76,989	€0	€295,872	€0	€5,305,232
	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	€16,278,225
	Grand Total	€2,553,925	€2,378,446	€1,036,126	€52,282	€1,822,313	€23,161	€24,144,478

The individual level disclosure is:
HCOs - 100%
HCPs - 69% (a 2% increase in individual level HCP Disclosure for 2021 data compared to 2020 data).

Code awareness
IPHA runs 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 24/7, 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, where IPHA provides tailored training for individual companies at a location of choosing by the company (this training is also available remotely). Training aimed specifically for nurses working in the industry is also provided annually as is training for medical directors of IPHA member companies.

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ITALY – FARMINDUSTRIA

Code authority activity
During the 2022, 2 reports were received on alleged violations of the Code from as many Member Companies.
1 report has been archived and 1 is under investigation.

2022 Disclosure of 2021 data
As for the transfers of value to HCPs and HCOs in 2022, the data relating to the consent for the publication by the HCPs is around 72%.
The percentage is in line with the 2021, 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
In 2023 the point 3.16 of Farmindustria Code has been changed with reference to the limit of hospitality, meals and drinks offered by member companies during events.
The threshold of 60 euro per each HCP has been raised to 70 euro in consideration of the increased cost of living.
As for the status of the transposition of the EFPIA Code in Farmindustria's, the Code Authority has carried out an analysis of the changes required by EFPIA.
The points that will be amended have been shared with EFPIA. The new version of the code will be published by the end of 2023.

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LATVIA – SIFFA

Code authority activity
Ethics Commission of the Association of International Innovative Pharmaceuticals Producers (SIFFA)[1] examined 2 complaints that came from industry regarding:

- advertising of prescription (Rx) drugs in a press release to the public 50%;
- over the counter (OTC) medicine sample improper distribution 50%.

The principles set out in the Code of good practice and ethics (further – Code) of SIFFA have been violated:
- Article 19 of the Code, including improper distribution and labeling of OTC medicine samples for HCP and society;
- 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; the advertisement should be addressed only to those HCP who can reasonably be assumed to be interested in or need this information.
As a sanction, a decision was made in both cases to inform SIFFA members about the reviewed complaint without naming the defendant, 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 12.12.2022; 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
Drug manufacturers have provided assurance and taken appropriate actions to prevent the probability of occurrence of risks associated with violations of the code and regulatory acts.

Code awareness
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-0 , 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.

[1] SIFFA and Latvian Generics Medicine Association (LPMA) have a common Code and Ethics commission.

The requirements for data disclosure are the same for all pharmaceutical manufacturers.
Health Inspection collects data every year by 30 May and publishes no later than 30 June to comply with the Code. In 2021, companies have declared support for 6,35 millions euros (in 2020 – 4,47M euros).
Companies publish data on cooperation with patient organizations on their websites.

In March of 2022, the amendment to Article 16 (Lifelong learning in healthcare) of the National Code was also adopted on the basis of EFPIA Board decision (01.12.2021.).
Amendments to the national Code, based on the amendments of the EFPIA Code of Practice entered into force on January 1, 2023, including:

- introducing ethical principles of ETHOS;
- the Code has been supplemented with new annexes:
  i) e4ethics rules and procedure;
  ii) principles of using digital channels;
  iii) guidelines on basic principles of quality in lifelong learning in health care;
- amendments to the numbering of annexes and some terms in Annex C (Guidance Obligations for Member Associations Under the EFPIA Code).

Others topics
Since 2022, decisions of the SIFFA Ethics Commission have been made public on the website of the association: https://www.siffa.lv/lv/etikas-komisijas-lemumi/ .

Scorecard Food and beverages: revised hospitality limits in July 2022.

Negotiations were held 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".

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MACEDONIA - Farmabrend Nova (FBN)

Code authority activity
No complaints or reports for FBN Code violation were received in 2022.
Re-training of FBN members on the EC requirements (internal training) as well as promotion/information to external stakeholders on transparency and ethics as self-regulating process of innovative industry should take place in H2.

2022 Disclosure of 2021 data
Disclosure is going according to plan. No negative feedback was received so far. More details about the figures will be available after June 30, 2023.

Code awareness
The Code is published on FBN website here: https://fbn.mk/?attachment_id=3306

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NORWAY - LMI

Code Authority activity
In 2022 the Code Authority (Rådet) handled the following activities:
The Code Authority handled 1 case. 6 Advanced statement cases were also handled by the Code Authority.
The Code provisions were breached in 1 of 1 complaint cases. 1 complaint was made by the Secretariat. The

provisions in the cases were Articles 8.1 (balanced and factual information), and Article 8.7 use of references in advertising.
The sanctions imposed a fine of NOK 225.000.

Code report
The full Code report is published in Norwegian here: download.php (lmi.no)
The cases are published in Norwegian here: http://reklameregler.lmi.no/avgjorelser

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 2022 The Secretariat provided advice to pharmaceutical companies regarding the industry rules on regular basis.

The secretariat carries out controls to find deviations/breaches from the code. The Code Authority (Rådet) and the Norwegian Medicines Agency both have access to the same electronic archive where advertising material is submitted. In 2022, the number of controls was increased and the feedback to the companies on their advertising has become more frequent.

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.
In 2022, 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.

2022 Disclosure of 2021 data
The figures are the following:

- R&D 74%
- HCOs 16%
- HCPs 10%

The estimated percentage for positive consent is:

- HCOs 68%
- HCPs 31%

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

In 2022, no significant changes in comparison with 2021 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 (2016-2022):

- Increase of HCP consents from 25% to 31%
- 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

Positive consent rate is relatively stable over the years and it is estimated on around 24% of HCPs (2017-2020) and increased in 2021 to 31%.

On 26-30 June 2022, 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 1 July 2022, 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.
National Code web link *(English version)*: http://en.infarma.pl/

Activities related to the Code in 2022:

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 individual areas: digital, patient advocacy groups, Patient Support Programs, non-promotional activities, contacts with external stakeholders.

INFARMA was involved in promoting the Code and idea of transparency. The Union 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 2022, 1784 events were recorded in the certification system (6% more than in 2021).

In 2022 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.

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SLOVAKIA – AIFP

Code authority activities

In 2022, AIFP Ethical Committee (EC) did not receive complaints or breaching notifications from member companies or an external environment.
Due to the pandemic situation, all the EC meetings were held virtually.
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 Other studies carried out or sponsored by the member may be the acquisition of scientific, professional and other information following the legitimate business need of the submitter.
EC also opened the question of the nurses´ education on scientific events since not all member companies believed such support is possible regarding legislation and the AIFP Code of Ethics. In the discussion, the members of the EC stated that as far as a professional, not an advertising part, is concerned, such a lecture is possible for any health professional. The chairman of the EC supported the discussion and proposed to discuss the topic primarily at the Ethics WG and prepare the explanatory notes to the AIFP Code of Conduct.

Code report

The annual 2022 report of the EC was presented at December´s 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.
Other sharing best practices are part of the regular agenda of the Ethics WG.

Other topics

The AIFP Code of Conduct amendment ensuring smooth process and progress (timelines) of the compliance issues submitted to EC was approved last year. Together with the deadlines for the complaints procedure, the function of the AIFP Supervisory Board as an Apealed Body was withdrawn, as the SB did not feel like the right institution for considering and correcting the decisions of EC. EC decisions are thus the final ones. We looked for other options, but since the status of the Apealed Body was not used often, we keep the status as it was approved in the Code of Conduct so far.

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SLOVENIA – FarmaForum

Code authority activity
No complaint has been received in 2022.

2023 Disclosure of 2022 data
A whole report on Transfers of Value data for 2022 will be available from 7 July 2023.

Code awareness
Internal guidelines are given to Forum members compliance leaders and General Managers at multiple sessions. FarmaForum also had a lecture about Code for HCPs at the event organized by Slovene Medical Chamber in November 2022.

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SPAIN – FARMAINDUSTRIA

Code authority activity
For the first time since the creation of the Code of Practice Surveillance Unit, no cases were examined in 2022.

Code report
The Code report is available here: https://www.codigofarmaindustria.org/servlet/sarfi/interes.html

Consequences of Code authority activity
Because of legislative changes and court rulings, Code new versions were approved in July and September 2021. These new versions include amendments and improvements regarding: Observational Studies related with medicines, and the start of the promotion for new medicines or indications (issue currently pending on court decision).

2022 disclosure of 2021 ToVs
The figures are the following:
Transfers of Value (TOTAL: 587 million euros)
* R&D 48,89%
* HCOs 28,20%
* HCPs 22,91%

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 ToV individually based on the "legitimate public interest ground".

Code awareness
The Code of Practice Surveillance Unit participated in seminars, Post-doctoral and Master courses, in-company training.

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SWEDEN – LIF

Code authority activity
The first instance (IGN) in LIF self-regulation system examined 84 cases. In addition, 1 case was assessed directly by the second instance (NBL), based on a complaint from the regulatory authority. The part originating from the continuous supervision and monitoring performed by IGN represent 80 % of the total

case volume.

In 2021, the complaints came from:
- Pharmaceutical companies: 1.2 %
- Healthcare Professionals: 0 %
- National Code authority: 80 % (IGN= first instance)
- National agencies: 1.2 %
- Anonymous: 0 %
- Others (please specify): (17.6 %, private individual)

The Code provisions have been breached in 54 cases, as assessed by IGN, and in general relate to promotion not consistent with the SmPC, misleading, not truthful information, abbreviated prescribing information is missing, insufficient or has poor readability.
In the second instance (NBL) (handling escalations from first instance, appeals, and direct complaints from authorities), 10 cases were assessed as breaches, and in 5 cases the outcome was non-breaches. 15 cases (complaints filed by a private individual) regarding insufficient disclosure of interactions/collaborations with patient organisations were referred by IGN to NBL but led to no decision. NBL instead directed an instruction to Lif to further clarify what is required to be disclosed by the companies.
The sanctions imposed were fines (in general 110 000 SEK), except for the cases that rendered a written warning (16 cases).

Consequences of Code authority activity
Earlier decisions regarding poor readability of compulsory text in banner ads in 2021 appear to have contributed to better compliance in 2022 based on the statutory copies sent to IGN.
In 2022, several breaches were observed in editorial ads in general newspapers, namely patient testimonials, prelaunch, and advertising of prescription medicines to the public. Common denominators in these cases were that they concerned smaller biotech companies that used media agencies to promote what was claimed to be investor relations and disease awareness. IGN has communicated that editorial ads will be under specific scrutiny for the time being.

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

2022 disclosure of 2021 ToVs
The figures are the following:
- R&D 78.7 %
- HCOs 15.4 % (consultancy fees and associated expenses, sponsorships, donations)
- HCPs 3.5 % (consultancy fees and associated expenses)

The percentage of individual disclosure is:
- 89.3 % of recipients (HCP and HCO combined; ToVs in relation to consultancy fees and associated expenses)
- 81.9 % 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:
5 Code Training sessions (2-day course, including formal test to get accredited in code compliance). The sessions were digital due to Covid, and in total 164 attendees participated.
Upon request, Lif organised training sessions for several individual member companies as well as lectures

for a few HCOs and POs. In addition, Code introduction sessions for new member companies were held.

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SWITZERLAND

The Pharma Code and the Pharma Cooperation Code in 2022:
Annual Report of the Code Secretariat

Introduction

For many years, the Swiss pharmaceutical industry has applied internationally coordinated (see IFPMA[2], EFPIA[3]) self-regulation that goes beyond the law with the Pharma Code (PC[4]) and the Pharma Cooperation Code (PCC[3]). Pharmaceutical companies can voluntarily agree to abide with these codes (see lists of signatories [5]). 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 2022 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 increased to 107 from 72 cases last year. The number of complaints from competitors declined significantly in percentage terms (2022: 13.1% / 14 cases; 2021: 26.4% / 19 cases). Two companies reported themselves (2021: 0). Once again, no case was classified as potentially hazardous to health (2021: 0).

The average duration of proceedings fell sharply in 2022 to 5.6 days (2021: 8.2 days). In contrast to the previous year, only around 11% of cases required discussions with the affected companies; these had led to various extensions of deadlines in the previous year (2021: 20.9%).

107 cases were opened in 2022. Of these, 89 cases (83.2%, 2021 84.7%) were closed after the contested advertising had either been corrected or removed. In 18 cases (16.8%/2021: 15.3%) it was ultimately found that there had been no breach of the Code. One of these 18 cases was initiated by a competitor (2021: 2 of 11). There were delays in two cases due to the complexity of the case (2021: 0). In none of the cases did a company have to be warned for failing to submit the requested comments on time (2021: 2). In the case of one complaint from a competitor, the Code Secretariat did not consider itself responsible.

The Code Secretariat conducted one mediation in 2022 (2021: 1) and received notice of three bilateral negotiations (2021: 8).

90 pharmaceutical companies (2021: 82) submitted a total of 13,724 specimen copies (2021: 12,461) of their promotional material and information; 98.3% (2021: 88.6%) were sent to the Secretariat electronically. Only a few specimen copies were sent to the Code Secretariat by post. Both the number of submitting pharmaceutical companies and the number of submitted specimen copies increased further.

The number of cases opened was once again in line with the average for recent years; the 72 cases in 2021 seem to have been an exception. Competitor notifications continued to decline, as did reports of bilateral

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

negotiations, but here an unknown number of unreported cases has to be expected. The time required for each procedure decreased as the questions tended to be more concise and therefore fewer clarifying discussions with the companies were required.

Established breaches of the Code

A total of 45 (2021: 33) PC requirements were mentioned in the 106 complaints (2021: 72). One requirement only was mentioned for 33.0% of the cases (2021: 59.7%); two requirements were mentioned for 11.3% (2021: 25.0%), and in 55.7% of cases, three to as many as eight requirements were mentioned (2021: 15.3%; 3 to 6 requirements). The following is a list of the PC requirements that were mentioned often:

- Principle of professional promotion (PC 24.1): sharp increase to 12 breaches (previous year: 3).
- Unproven advertising statements and incorrectly cited references (PC 24.2): sharp increase to 82 breaches (previous year 30), even considering that 29 cases were sanctioned in combination with three further PC requirements (see below).
- Promotional materials that did not contain all the minimum information about pharmaceuticals required by the PC (PC 24.4, 24.5): slight increase to 19 breaches (previous year: 13).
- Incomplete or impermissible references to literature (PC 25, excluding PC 25.1, 25.4.3, and 25.7): slightly up on the previous year with 29 breaches (previous year: 21).
- Missing indication that references can be requested from healthcare professionals (PC 24.2, 25.1, 25.4.3, and 25.7): 29 breaches; these were systematically sanctioned for the first time in 2022.
- Notifications of unqualified superlatives and comparatives (PC 25.8, 25.9): clear decline to 7 breaches (previous year: 14).
- Obligations of pharmaceutical companies when implementing the PC (PC 6): the number of breaches increased to 14 compared to 10 in the previous year.
- Ban on gifts (PC 15.2): one punished breach (previous year: 0).
- Promoting as yet unauthorised medicinal products or indications (PC 23.1, 23.2): unchanged at 3 breaches (previous year: 4).
- Promotional statements differing from the drug information for health professionals approved by Swissmedic at the time when marketing authorisation was given (PC 23.3): one breach compared to 4 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): no breach (previous year: 1).
- Marking mailings as “important notice” (PC 210): no breach (previous year: 0).
- Complaints regarding serious breaches of the Code (PC 74): no breach (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 2022 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 appropriate State authority (PC 75.10) in 2022 (2021: 1).

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

In 2022, 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[6] and e4ethics[7]). 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 2022, the companies that signed the PCC for the seventh time disclosed the pecuniary benefits granted in 2021 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. For eight companies (previous year two), there was a slight delay in the publication of their data; after the Secretariat intervened, complete data sets of good quality could be published just a few days after 1 July 2022.

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 87.8% to 90.4% in 2021. The median rate was as high as 97.3%, which shows that half of the PCC signatory companies had HCP consent rates of 97.3% or higher. The average consent rate for HCO also increased further from 94.9% to 95.8%. The median here remained at 100%. These rates are good in a European comparison and once again clearly higher than in other German-speaking countries. There are sometimes considerable discrepancies between the individual companies in terms of consent rates, which do not always appear to be comprehensible. Ten 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 (2020: 11 companies) and requested to implement measures to increase their consent rate.

The Code Secretariat compiled the figures of the 68 PCC signatory companies (previous period: 62) and by the end of July 2022, was able to put together the following statistics about Switzerland: Transfers of value (ToV) for a total of CHF 194.1 million were disclosed for 2021. In the previous year, the figure was CHF 182.5 million, which corresponds to an increase of CHF 11.6 million (+6.3%). At CHF 6.4 million, slightly more payments were made to HCP than in the previous year (CHF 6.0 million or +5.4%). The ToV to HCO also increased to CHF 106.1 million from CHF 90.0 million in 2020, which equals an increase of 14.1%. The ToV for R&D services decreased slightly from CHF 83.5 million to CHF 81.6 million (-2.2% compared to 2021).

Cooperation payments to healthcare professionals were therefore on a par with the previous year in 2021. The effect of the coronavirus pandemic seems to have continued in 2021. Once again, a certain shift in direct support from HCP towards HCO was observed. Cooperation payments to HCO increased by more than CHF 10 million to almost CHF 106 million. Grants for research and development decreased 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.

With regard to disclosure, scienceindustries was once again in contact with the stakeholders to explain the pharmaceutical industry's transparency initiative. Media interest in the topic was relatively low in 2022.

Pharmaceutical Code enquiries and training

[6] https://www.ipcaa.org/public/ipcaa-healthcare-congress-guidelines
[7] https://www.ethicalmedtech.eu/e4ethics/about-e4ethics/

In 2022, the Code Secretariat replied to 362 written or telephone enquiries pursuant to section 8 PC/section 6 PCC (previous year 328). Of these, 223 enquiries related to the PC and 87 to the PCC (previous year 191 and 124 respectively). An enquiry can concern the PC as well as the PCC. In 2022, the Code Secretariat conducted three online training courses on professional promotion (previous year 2) with a total of 123 participants, and two on pharma compliance (previous year 5) with a total of 67 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. Code Secretariat Dr. med. Daniel Simeon Zurich, February 2023Introduction

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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 pmcpa.org.uk.