European Federation of Pharmaceutical Industries and Associations

EFPIA Report on Ethics & Compliance Activities

July 2022

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 (**Section 2 – 2021 National Codes reports and Code Authorities activities**).

In addition to these national Code reports, EFPIA includes in this report an overview of the Ethics & Compliance activities conducted by EFPIA during 2021 and into mid-2022.

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1. EFPIA Ethics & Compliance activities

a. Codes Committee activities

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 2021 and into 2022:

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

EFPIA Secretariat, in partnership with the member associations, has pursued the analysis of 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:

- 31,5% of the codes are fully transposed (this represents 11 national codes)
- 46% of the 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 27 countries by the member associations.

- **Code monitoring activities**

Based on the EFPIA Ethics & Compliance priority related to self-regulation credibility and EFPIA Code monitoring, EFPIA is currently monitoring the following national Codes activities:

- Verifying the national Codes authorities' governance and activities
- Assessing if some national Codes include provisions on individual patients interactions
- Analysing the definition and criteria applicable to information and promotion in the national Codes

- **Analysis of the disclosure reports of 2021**

Since the first disclosure in 2016, EFPIA has analysed the transfers of value (ToVs) disclosed by EFPIA member companies and the evolution of ToVs' amounts and consent levels.
While the survey is based on the public declarations of EFPIA member companies, the report is confidential and reserved for internal use only.
It presents a consolidated analysis of anonymized information collected, where individual statements/individual company positions cannot be identified or tracked.
This report helps EFPIA and its members to gain insight into the disclosure data and may allow understanding trends versus the previous disclosure periods.

- **Disclosure**
  - Disclosure deviations

In July 2020, the EFPIA Board agreed that disclosure provisions in place in **Latvia** are consistent with the EFPIA Disclosure Code, provided: (i) Member Companies include a hyperlink on their websites allowing access to disclosures accessible on the Health Inspectorate of Ministry of Health website; (ii) SIFFA reaches an agreement with the Health Inspectorate to add the ToVs related to R&D (in aggregate) and to the preparation of publications (on an individual basis) as well as reaching an agreement with the Ministry of Health to harmonize the disclosure of data on the state institution website in accordance with EFPIA Code of Practice.

On 31 August 2021, the Latvian legislation was amended to integrate the payment for publications and the amount spent on R&D in the material and other support provided to associations, foundations and medical institutions that have to be notified to the Health Inspectorate. In addition, the report to the Health Inspectorate will have to be submitted by 30 May, in order to comply with the Latvian Code of Ethics and to make the information publicly available by 30 June.

Therefore, the EFPIA Board updated the previously agreed deviation and agreed that disclosure provisions in place in **Latvia** are consistent with the EFPIA Disclosure Code, provided Member Companies include a hyperlink on their websites allowing access to disclosures accessible on the Ministry of Health's Health Inspectorate website.

- **Codes Committee involvement in other EFPIA projects**
    - Lifelong Learning in Healthcare

The Codes Committee has been involved in the changes introduced in Article 16 of the EFPIA Code and the publication of the guidelines related to Lifelong Learning in Healthcare.
In 2017, EFPIA recognized the importance of engagement in the field of medical education and the necessity to review and align on the Member Companies practices.
Therefore, guidelines have been drafted to provide explanations on the legitimate role of the pharmaceutical industry, define companies' minimum standards applying to Lifelong Learning in Healthcare, clarifies that any promotional activities are not in the scope of the guidelines and includes recommended standards and examples of processes ensuring the quality of learning.
The guideline and the changes in Article 16 have been approved by the EFPIA Codes Committee and Ethics & Compliance Committee.

- Involvement in Patient Think Tank projects

The Codes Committee is regularly consulted on projects related to the interactions with Patient Organisations, in scope of the EFPIA Code.
An on-going project is related to define best-practices for simplifying the contractual interactions between pharmaceutical companies and Patient Organisations.

b. Ethics & Compliance Committee activities

The mission of the 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 2021 and into 2022, the E&CC has focused on the following projects:

- Improving disclosure

The Ethics & Compliance Committee has set up a Disclosure Task Force with the mission to investigate how to improve transparency and leverage value of our disclosure efforts, to analyse the current challenges and evolving societal expectations.
Based on this analysis, the TF identified the following challenges and suggested some proposals :

- **To increase the level of individual data published**, explore the use of legitimate interest[1] and where legitimate interest is not possible, actively engage in activities to improve consent.
- Regarding the **research and development aggregate disclosure**, the TF recommends providing explanations regarding the types of expenditure included in R&D.
- Regarding the **disclosure accessibility**, EFPIA and its members are working to make the data easier for patients and others to access and help them understand the disclosure.

  Providing clearer guidance on how to implement a unified format and publication standard (in the absence of a governmental or national platform), on how to implement national platforms with a consistent format and structure that is also searchable and downloadable and how to publish all the disclosure (HCPs, HCOs and POs) in a central more accessible location are currently being explored by EFPIA and its members.

[1] The General Data Protection Regulation 679/2016 (GDPR) considers that companies can legally process the personal data if they rely on one of the legal bases: - Legal duty: there is a legislation in place allowing the personal data treatment - Consent: the individuals agree with the treatment of their personal data. - Legitimate interest ground: the data processor considers that there is a public interest higher than the private interests of the individuals.

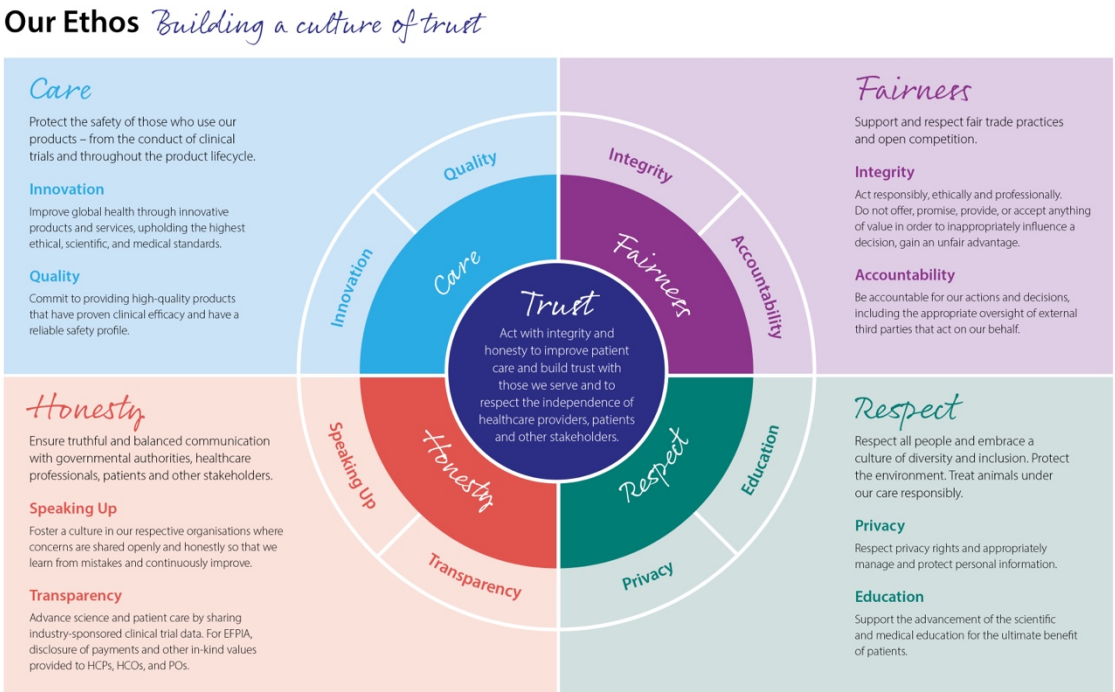
- <u>e4ethics</u>

EFPIA e4ethics is the independent platform assessing major European events according to the EFPIA Code requirements.
Since September 2021, event submission to e4ethics is mandatory and the final e4ethics decision is binding for EFPIA Members Companies.
As a consequence, sponsoring, participating or collaborating in an eligible event that was not submitted and approved as compliant by e4ethics would be considered a breach to the EFPIA Code that could be enforced by the competent national Code authorities.
To ensure the efficiency of the e4ethics platform hosted by Ethical MedTech:

- Several trainings were organized: webinars in November 2021 and January 2022, and a live Q&A session in March 2022 gathering 1550 participants
- Presentations were organised at the request of EFPIA Member Associations and Companies
- e4thics was presented at various conferences (e.g., IPCAA, MedTech Forum)
- The platform was strengthened with new functionalities (i.e., EFPIA Members can subscribe and follow events' status changes)

- <u>Alignment of the EFPIA Ethical principles with the IFPMA ETHOS</u>

Due to the willingness of global ethical alignment, the E&CC members decided to integrate the IFPMA ETHOS (published in 2019) in the EFPIA Code and to remove the EFPIA ethical principles (approved in 2016).
The principles mentionned in these 2 documents were perfectly aligned apart the scope of the transparency principle.
Therefore, and with the objective of reflecting the EFPIA requirements for disclosure of certain transfers of value, the ETHOS with a reference to the disclosure of payments to HCPs/HCOs and POs has been integrated in the EFPIA Code.



- Involvement in other projects

The E&CC has been informed and monitors the impact of European legal developments e.g., the whistle-blower Directive, the Corporate and Sustainable Reporting Directive and the Corporate and Sustainable Due Diligence Directive.

The E&CC has also been involved in the development of the EFPIA Value Framework, especially for advising which are the appropriate proof points for the responsible innovation part of the EFPIA Value Framework in relation to the work to drive high ethical standards for industry with stakeholders.

2. 2021 National Codes reports and Code Authorities activities

AUSTRIA – PHARMIG

Code authority activity

In 2021 there was one new complaint made under the PHARMIG Code of Conduct. It was initiated by a pharmaceutical company and concerned a reproached breach of the Articles 4 & 5 (information on medicinal products/advertising medicinal products). The parties settled the dispute via the procedural advisor according to Article 10, 10a of the Rules of Procedure of the PHARMIG Adjudication and Appeal Boards. Hence there was no decision rendered regarding this case by the Adjudication Board and no sanctions were imposed. The procedural costs were divided equally and the parties agreed on how the information and promotional material in question will be amended.

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 2021 is available on PHARMIG's website: https://www.pharmig.at/media/4880/pharmig_leistungsbericht-2021.pdf (in German only).

Code awareness

PHARMIG organised virtual training sessions and discussion platforms for member companies on a regular basis. This also included a session on e4ethics. Additionally, the member companies were invited to join the webinars organised by Ethical MedTech.
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, a special certificate course "Compliance & CoC" (4 different modules: Basics, Advertising, Events, Disclosure) and other legal and compliance seminars were provided by "PHARMIG Academy" (open to anyone interested).

2021 Disclosure of 2020 data

In 2020 ToV of 102 Mio. EUR to HCP and HCO were made by pharmaceutical companies in Austria.

- 66 Mio. EUR (65 %) R&D
- 19 Mio. EUR (18 %) events
- 12 Mio. Euro (12 %) fees for services and consultancy
- 5 Mio. Euro (5 %) donations and grants

Additionally, ToV of 1,8 Mio. EUR were made to Patient Organisations. PHARMIG will analyse these transfers of value in more detail in future.
The yearly graphic of the disclosure overview can be found on PHARMIG's website: https://www.pharmig.at/media/4068/pharmig_grafik_disclosure_2020_e.pdf.

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BELGIUM – pharma.be

Code authority activity

Three complaints have been lodged in 2021 before the Committee for Deontology and Ethics in the Pharmaceutical Industry resulting in

- two definitive decisions from the Committee
- the third case being brought before the Chamber of Appeal (not ruled in 2021)

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

2022 disclosure of 2021 data (on the basis of the Belgian legal requirements)

The figures are the following:

CATEGORIES SUNSHINE ACT	BENEFICIARIES		TOTAL	
SCIENTIFIC RESEARCH	*Aggregate*		174.254.150 €	68%
SCIENTIFIC MANIFESTATIONS	*HCO**	23.836.336 €	27.129.289 €	11%
	*HCP**	3.292.953 €		
DONATIONS AND GRANTS THAT SUPPORT HEALTHCARE	*HCO*		21.381.575 €	8%
FEE FOR SERVICES AND CONSULTANCY	*HCP*	10.417.451 €	19.524.385 €	8%
	HCO	8.624.673 €		
	*PO**	482.260 €		
OTHER SUPPORT	*PO*		13.131.161 €	5%
TOTAL			255.409.559 €	

Link toward betransparent.be press release :

- Dutch: https://betransparent.be/nl/vijfde-openbaarmaking-van-de-samenwerkingen-tussen-bedrijven-zorgverstrekkers-zorginstellingen-en-patientenverenigingen/
- French: https://betransparent.be/fr/cinquieme-publication-des-collaborations-entre-entreprises-prestataires-de-soins-institutions-de-soins-et-organisations-de-patients/

Code awareness

Pharma.be organised the following trainings:

- **18/11/2021: 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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CROATIA – Innovative Pharmaceutical Initiative IF!

Code authority activity

What has been the predominant code violation in previous years is the inadequacy of the hotel and the inadequate hospitality. Considering COVID and the post-COVID period, there have been no complaints of breaches of the code this year. Namely, live congresses and event scene was mostly quiet for the above reasons. However, there were some announcements and attempts to organize events, but they were mostly postponed or turned into online meetings.

What was interesting during these attempts was the growing awareness of the organizers (Third party) who wanted to remove any doubts in advance about some venues (hotels) and seasonality that seemed borderline in appropriateness, so there were ad hoc changes in locations and venue and location.

In our opinion, this can be attributed to the activities of the Code authority, which worked hard to raise awareness especially among organizations of Congress organizers (Third party) to whom it sent circular notices of Code of Conduct and CVS/e4ethics conference assessment rules when choosing hotels for congresses and hospitality organizations. As for other segments of possible violations of the Code, there were no complaints, but there is a noticeable disagreement of some members regarding interactions with POs, more specifically regarding individual patients who do not belong to any PO, which has been clarified and prevented, so that they would know how to act.

2021 Disclosure of 2020 data

The figures are the following:

- R&D 23%
- HCOs 40%
- HCPs 37%

The percentage of positive consent is 25,3%

The Innovative pharmaceutical industry in Croatia last year invested a fifth of the total amount in R&D, which, in monetary terms, represents an increase of almost 20% compared to last year.

At least 37% of the total amount was transferred to healthcare professionals and 40% of the total amount was transferred to healthcare professionals. In accordance with regulations guaranteeing the protection of personal data, 25.3% of healthcare professionals have voluntarily provided their data for the individual publication of value transfer data which is a significant increase compared to the previous years (more than 100%).

Code awareness

Croatian Association (IF!) has taken into account all the comments made in the review of the transposition of the EFPIA Code into national codes, which relate to the IF! National Code. In this regard, the IF! Code Authority has updated the provisions of the Code according to the above remarks and introduced new terms and definitions presented by the EFPIA, which new and updated national code IF! plans to submit to EFPIA in Q3 2022.

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CZECH REPUBLIC – AIFP

Code authority activity

AIFP received 0 complaint in 2021.

Code report

The Code report is not published.

Disclosure

The figures are the following:

1. R&D 81 %
2. HCOs 12 %
3. HCPs 7 %

The percentage of positive consent is:

1. HCPs 22 %
2. HCOs 100 %

Compare to the previous years, the level of positive consent of HCPs is comparable.

Code awareness

An annual event called "A Day with AIFP Ethics Committee" was held on 30th November 2021 for the representatives of AIFP member companies. The main topics of the meeting were Activities of the AIFP Ethics Committee in 2021, Digital era, Cooperation with HCOs, Virtual Events, Promotion vs. Non-promotional communication, Patient support programs, Surveillance over advertising, Conflict of Interests and e4ethics.

An event called "A Day with the State Institute for Drug Control" was held on 19th January 2022 in the AIFP premises. High representatives of the Czech regulatory drug agency, including the Director of the agency Irena Storová, attended and discussed current issues in medicines regulation, including Advertisement Law with the AIFP members. More than 100 representatives of the AIFP companies joined the event and their feedback was very positive.

On 13th October 2021, a mediation session was held between three AIFP member companies who jointly reached out to AIFP to facilitate the mediation meeting to answer the question of how to define an educational material that can be provided to patients through HCPs/HCOs. Patrik Kastner, Chair of the AIFP Ethics Committee, and David Kolář, General Secretary of AIFP, were designated as the mediators.

The AIFP Representative Certification Project has been suspended for 2021 due to government restrictions associated with the COVID-19 pandemic. However, this forced break was used to review and update the certification process. The training materials were updated, and a new technical solution was prepared to conduct the certification solely online. The new, virtual certification process was launched in February 2022.

To complement the EFPIA Disclosure, the AIFP is operating two additional projects to further deepen transparency in the relationship between HCPs and the pharmaceutical industry.

1. CME Disclosure
    a. AIFP members' sponsored participation in congresses organized by specialized agencies (so-called PCO, Professional Congress Organizer) is published in the CME Disclosure database.
2. Congress Database
    a. The database of world medical congresses contains an overview of world congresses organized by third parties, where Czech physicians are sponsored by AIFP member companies.

In both databases, in addition to the name of the event, the date and place of the event, the organiser and a link to the congress website are also published. This makes it possible to find out detailed information about the organising company, the agenda of the event or the speakers. Every visitor to the website can thus easily find all the important details about the professional event.
The data for the individual databases are provided by all AIFP member companies, always retrospectively for a period of one calendar year. The data are published by the end of June every year.

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DENMARK – ENLI (LIF)

Executive Summary (Annual Report 2021)

In 2021 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.

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

Significant matters in 2021

In 2021, approx. 402 promotional activities were self-reported to ENLI each month, as required (pre-vetting procedure). Of these, the Investigator Panel has reviewed approx. 39% of the reports in a random control, and 97.5% of the activities were approved, whereas sanctions were decided in 2.5% of the evaluated reports.

No complaints were decided on against an affiliated pharmaceutical company in 2021. However, ENLI did ex officio start three cases in 2021 - two as a direct consequence of stories in the press. All three cases led to sanctions.

Affiliated medicinal companies continue to exhibit a strong focus on achieving compliance to ENLI's regulation. In 2021, companies requested 106 pre-approvals of promotional activities, which is a decrease of 20 requests compared to 2020. Of the pre-approval requests in 2021, 61% were approved.

From the total amount of 87 decisions that ruled against an affiliated company, eight decisions was appealed to the Board of Appeal, which corresponds to approx. 9,2% of all relevant decisions. The Board of Appeal handled eight cases in 2021. Five decisions from the first instance was in whole or partially upheld.

ENLI has continued to prioritize preventive activities. In 2021, ENLI has published 36 decisions (including 16 administrative reprimands), 6 news letters and a Nordic Q&A on Nordic rules. Furthermore, ENLI has conducted 10 courses in the regulation, primarily the Promotional Code, and 3 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 received 5 complaints in 2021:

- Inspection Board I (marketing and information to the consumers): 1 case
- Inspection Board II (marketing to the HCP's): 3 cases
- Supervisory Commission (complaints of the decisions made by Inspection Boards): 1 case

The complaints came from:

- Pharmaceutical companies: 80% (4 cases)
- HCP: 20% (1 case)

The Code provisions have been breached in 4 cases:

- Inspection Board I: 1 case
- Inspection Board II: 3 cases
- Supervisory Commission: no breach of provisions

The following provisions were breached:

- Marketing may not refer to a clinical trial in such a way as to give an erroneous impression of the outcome, scope or significance of the trial.
- All information provided in connection with marketing must comply with the latest SPC, off label marketing not allowed.

The sanctions imposed were:

- request to abstain from incorrect activity
- sanction payments between 20.00 – 45.000 euros per case
- processing charges 2.000 euros or 3.000 euros per case

Code report

The Code Report 2021 including decisions made by PIF Inspections Boards/Supervisory Commission published at:
https://www.laaketeollisuus.fi/media/julkaisut/toimintakertomukset/laakemarkkinoinnin-valvontakunnan-toimintakertomukset/lmvk-vuosikatsaus-2021-id-139630.pdf

2021 disclosure of 2020 ToVs

The figures are the following:

- R&D 75%
- HCOs 14%
- HCPs 11%

The percentage of positive consent is 70.3%.

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

During the reporting period, 9 complaints were submitted to the FSA by third parties, seven of which were anonymous and two open. No complaints were received from pharmaceutical companies. 8 of the complaints were inadmissible for formal reasons. One complaint led to nine proceedings against member companies. In the course of the investigations, the Arbitration Board was able to establish that this complaint was unfounded. The main focus was on two complaints against three member companies from previous years. The main issues were the assumption of accommodation costs for an internal training event and the distribution of care products and food in a so-called therapy management set as a breach of the ban on gifts. On its website, the FSA provides regular information on all decisions of the First and Second Instances 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:
https://www.fsa-pharma.de/de/mitteilungen/presse/archiv/fsa-pharma-jahresbericht-2021/

2021 Disclosure of 2020 ToVs
The figures are the following:

- R&D 73,2%
- HCOs 16,8%
- HCPs 10%

The percentage of positive consent is around 20%.
The overall figure of the three main areas have proven to be stable over the years. With 20 % the level of positive consent is slightly above the previous year´s value of 19%. It has to be stated that besides the exceptional circumstances related to COVID-19, 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 members do not let up in their efforts to explain the initiative and to convince more HCPs to give their consent.

Code awareness
FSA conducted two meetings of the compliance officers 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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ITALY – FARMINDUSTRIA

Code Authority activity
During the 2021, 6 reports were received on alleged violations of the Code from as many Member Companies.
In total, 4 sanctions were applied by the Single-Judge Tribunal, after the analysis of the preliminary investigation of the Supervisory Committee:
1) warning with a request to cease any behavior, if still in use, and ban it completely if necessary;
2) written reprimand for some promotional material, not in line with the applicable law and the Code;
3) written reprimand for some promotional material, not in line with the applicable law and the Code;
4) written reprimand for some promotional material, not in line with the applicable law and the Code.

Code report
Member Companies publish the report in their own website relevant section.

Disclosure
As for the transfers of value to HCPs and HCOs in 2021, the data relating to the consent for the publication by the HCPs is around 72%.
The percentage is in line with the 2020, 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.

Consequences of Code Authority activity

Some changes were made to the Farmindustria Code between 2021 and 2022.
Some of those changes are reported below:
2021:
- regulation of hybrid events (participation both face-to-face and via web);
- Professional updating and scientific cooperation;
- articles 9, 10 and 12 on the methods of operation of the deontological activity.
2022:
- loans for use and acts of liberality relating to instruments strictly related to the medical profession;
- Patient Support Programs;
- interactions with other non-prescribers involved in the administration of therapies;
- interactions other than medicine promotion;
- relations between Pharmaceutical Companies, Patient Associations and Expert Patients
Furthermore, the Supervisory Committee updated the Questions & Answers section, published on the Association's website in the section reserved for Member Companies.

Code awareness
Following the changes to the Code and in order to clarify the related application, the Supervisory Committee on June 2022, organized a seminar for Member Companies.

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IRELAND - IPHA

Code authority activity
IPHA received 1 complaint in 2021.

Code report
IPHA publishes a Code report that is available on request.

2021 Disclosure of 2020 data

Report Details

Submission Period	# Companies with Submissions	Generated
01 January 2020 - 31 December 2020	44	13 May 2022 16:29:21

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	€302,770	€178,230	€843,669	€30,355	€1,355,024
	HCP – Aggregate	N/A	N/A	€124,188	€105,250	€491,071	€29,624	€750,133
HCOs	HCO – Individual	€4,440,897	€2,886,398	€17,060	€0	€167,959	€0	€7,512,314
	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	€27,881,068
	Grand Total	**€4,440,897**	**€2,886,398**	**€444,018**	**€283,480**	**€1,502,699**	**€59,979**	**€37,498,539**

The estimated percentage for positive consent is:
HCOs - 100%
HCPs - 68%

There was an increase in HCP Consent Rates for ToV Disclosure of 9% compared to 2019 data.

Code awareness

IPHA runs multiple virtual training sessions annually 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 our members 24/7, 365 days a year at www.iphacode.ie. Bespoke training is also available for companies, where IPHA provides specific bespoke training for individual companies at a location of choosing by the company (this training is also available remotely).

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LATVIA – SIFFA

Code authority activity

SIFFA examined 1 complaint that came from industry.
The principles set out in the Code of Ethics of the Latvian Media Ethics Council (LMEC) have been violated:
- *integrity* - an unilateral opinion expressed in an article (in one clinical study) that may intentionally or covertly affect an audience;
- *diversity* - the article expresses an opinion from only one source, diversity of opinion is not ensured.
As a sanction, the decision has been made to publish information regarding the examined case in the webpage of LMEC for all media as well as to inform the members of SIFFA about the reviewed complaint without naming the defendant.

Code report

The annual report of the Ethics Commission was presented at the general meeting of the members of the association, but was not published on the SIFFA website.
The national Code is available in English here: https://www.siffa.lv/en/etika-un-atklatiba/

Consequences of Code authority activity

SIFFA informed the Health Inspectorate (HI) and the LMEC about violations of ethical rules.

Code awareness

Regarding disclosure, the companies publish data only on the website of a state institution, placing a link to this website on their websites. Data on the HI website are presented in an excel spreadsheet. The consent of specialists is not required, as regulatory enactments require them to be made public. Companies publish data on cooperation with patient organizations on their websites.
Non-duplication of data is possible on the basis of a deviation granted by the EFPIA Board decision (01.07.2020.), as well as taking into account that the Latvian regulatory enactments now fully reflect the appropriate disclosure of the information specified in the EFPIA and national Code.

In August 2021, the last amendments to regulatory enactments were made, which allow full disclosure of the information specified in the Code, including supplementing the publication of data on the HI website with payments for publications to HCS (on individually basis) and R&D (in agregate form), and stipulating that HI collect the data before May 30 and publish them no later than 30 June in accordance with the Code.
Already in 2022, companies reported 2021 in compliance with all the provisions of the Code (with the exception of the payment for publications, only this time in aggregate form).
In March of 2022, the amendment to Article 16 of the National Code was also adopted on the basis of EFPIA Board decision (01.12.2021.).

Others topics

Guidelines for advertising of medicinal products (both Rx and OTC) have been developed by HI in co-operation with industry, which will help guide the media and drug manufacturers in the development and publication of advertisements.

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MACEDONIA - Farmabrend Nova (FBN)

Code authority activity
No complaint has been examined in 2021.

2022 disclosure of 2021 data
Macedonian Ethics Code is fully harmonized with EFPIA Code and can be found on our website here: https://fbn.mk/?p=3257. Member reports can be found on: https://fbn.mk/?p=3257 and will be available end of June at latest.

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The NETHERLANDS - VIG

Please note that the Dutch Code of Conduct for Pharmaceutical Advertising is founded and controlled by the Foundation for the Code for Pharmaceutical Advertising "CGR". The CGR is a multi-stakeholder platform. The Dutch association ("VIG") is one of the participants. The part of the report related to the Netherlands is checked by CGR and VIG.

Code developments
Most important development in 2021 is the update of the system of maximum reasonable renumeration for service by the different healthcare professionals. CGR new a system of maximum rates for different professions since 2012. These rates were never indexed. An independent advisory committee advised on a future proof system, not based on specific professions, but on categories based on education. The rates 2022 are the indexed rates of 2012 and will be indexed annually. The new rate system is summarised as follows:

Category	Indexed maximum hourly rate, as per 01.01.2022	Explanation in relation to prior proposal
1. Professor	€ 253	Indexation conform original proposal in the Newsletter (current: € 200)
2. University + healthcare-related education > 3 years	€ 177	Indexation conform original proposal in the Newsletter for medical specialists (current: € 140)
3. University + healthcare-related education ≤ 3 years	€ 127	Indexation conform original proposal in the Newsletter for category medical/university (current: € 100 for GP + pharmacist)
4. University/master without additional healthcare-related education	€ 108	Indexation of current hourly rate for dentist (current: € 85)
5. HBO/bachelor	€ 95	Indexation of amount for current last category (current: € 75)
6. Other	€ 82	New proposal

Code authority activity
Like last year, the activities of the CGR foundation were dominated by the COVID-19 pandemic. During the pandemic it was not possible to provide sessions on location; these were kept digitally. The number of requests for advice and filed complaints was relatively low.
In 2021, a total of 4 complaints were handled by the CGR, three of which were cases according to the serious signal procedure and one according to the regular complaint procedure at the Code Committee. No appeals

were lodged with the Appeals Committee. One complaint procedure related to media presence of a pharmaceutical company during the pandemic, dealing with COVID-19 medication.

Below is an overview of the treatments of advice in 2021:

Submitted:	14
Advice issued:	13
Withdrawn:	1
Positive:	11
Negative:	2
Inadmissible:	0
Published:	8

The total number of requests for advice is lower than in 2020 and significantly lower than 2019. Due to the corona crisis, many foreign meetings did not take place. These meetings normally accounted for the bulk of mandatory advice requests (61 out of 75 in 2019). In 2021, about half of the advice related to foreign meetings. The other subjects on which advice is requested vary. As usual, the largest number of opinions were requested by marketing authorization holders.

Code report

The Code report 2021 is available here.

Consequences of the Code authority activity

The CGR has received reports of a possible violation of the Code of Conduct by a pharmaceutical company that cooperated with the national news to broadcast information on the development of a new COVID-19 medicine. The messaging was based on a news report of the USA headquarters about the development of the product. In the news item on national television, the effectiveness of product in development was compared with authorised products. The news item was deemed a prohibited advertising of a non-authorised medicinal product. The company should not have cooperated on this item, but should have warned that the news report from the USA headquarters is considered prohibited advertising in the Netherlands. The company agreed with this reasoning. The complaint was therefore settled with a publication of the facts and payment of the costs incurred by the CGR.

2021 disclosure of 2020 data

In July 2021, the financial relationships reported for the 2020 calendar year were published in the Healthcare Transparency Register (see newsletter 2/2021). The relationships reported by the pharmaceutical companies show an decrease of 9% compared to 2019. In total, the companies have reported relationships worth €59 million. The decrease has entirely occurred in relations with HCP and around meetings. The sponsorship relations on projects with healthcare institutions, partnerships of healthcare providers and patient organizations doubled in value compared to 2019.

The figures are the following:

- R&D 69,5 %
- HCOs 28 %
- HCPs 2,5 %

In the Netherlands, all relations with HCPs are published on the individual name, without needing positive consent. The basis for public disclosure (under the GDPR) is found in the necessity to perform the agreements involved.

Summary table per category of financial relation 2020

Type relation	Beneficiary	Amount (€)	Total (€)	(%)
Research & development	Aggregated		€ 135.000.000	68%
Services fees	HCP HCO	€ 3.070.614 € 1.759.813	€ 4.830.427	2,5%
Services expenses	HCP HCO	€ 169.911 € 148.791	€ 318.702	0%
Sponsoring project	HCP HCO	€ 9.508 € 30.257.822	€ 30.267.330	15,5%
Sponsoring events and hospitality	HCP HCO	€ 322.122 € 23.739.597	€ 24.061.719	12,5%
Total			**€ 194.478.178**	**100%**

The trend is that the value of financial relations with HCO grows and with HCP decreases.

Code awareness

Together with the medical devices sector, CGR initiated a new website for HCP how to secure independence when entering into a contract with a pharmaceutical or medical devices company. The website hoeblijfikonafhankelijk.nl was launched in January and is accompanied by campaigns form the HCP organisations. CGR also organised frequent online training sessions on the application of the Code. Next to these public sessions, CGR also gave these online training for individual companies (in-house trainings).

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NORWAY - LMI

Code authority activity

In 2021 the Code Authority (Rådet) handled the following activities:
The Code Authority handled 3 cases. The Code Appeal Board handled 1 case. 14 Advance statement cases was also handled by the Code Authority. The Code provisions were breached in 3 of 4 complaint cases. 1 complaint was made by HCP organization, 3 complaints from companies.
The provisions in the cases were Articles 1.13 (definition of advertising), 7.2 advertising to the general public, 4.1 (timing of product marketing), 8.2 (mandatory information in advertising), 8.4 (balanced and factual information), and 8.11 comparative advertising.
The sanctions imposed were fines between NOK 100.000 to NOK 150.000.

Code report

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

2021 disclosure of 2020 data

The percentage of consent was 85%. Due to a transition period disclosure for 2020-data disclosed in June 2021 are not 100%. Norway expects mainly 100% disclosure in 2022 due to use of the legal basis legitimate interest.

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)

Due to the pandemic all trainings were completed digitally.
LMI also has a mandatory e-learning for all employees of the member companies.

Advice and Control

During 2021 The Secretariat provided advice to pharmaceutical companies regarding the industry rules on regular basis.
The secretariat carries out controls looking for compliance with the Code. The Code Authority (Rådet) and the Norwegian Medicines Agency both have access to the same electronic archive where advertising material is submitted.
For national events, LMI has its own "Concept Approval" with a digital application form.

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POLAND - INFARMA

Code authority activity

The Disciplinary Court of the Employers' Union of Innovative Pharmaceutical Companies INFARMA acts in accordance with the Statutes and the Rules of the Disciplinary Court.
The Disciplinary Court of INFARMA has two instances. The adjudicating panel is as follows:

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

The Court Members are elected by the General Assembly. In 2020, during the General Assembly session held on 23 June, there took place an election of the Court Members for the next term of office of 2020-2022. On 23 June 2021, at the meeting of the General Assembly of INFARMA, the composition of the INFARMA Disciplinary Court was expanded by 2 persons from outside the member companies for the term of office 2020-2022.
In 2021, 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 Companies via the Ethics and Transparency Group's Intranet and can be used by Member Companies 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.

2021 Disclosure of 2020 data

The figures are the following:

- R&D 80%
- HCOs 13%
- HCPs 7%

The estimated percentage for positive consent is:

- HCOs 38% (*)
- HCPs 25%

(*) *Publication of HCO data takes into account the situation associated with COVID (part of the benefits reported as aggregate), without this change the consent rate would be 85%*

In 2021 no material or significant changes in comparison with 2020 ToVs.
The overall figure of the three main areas have proven to be stable over the years. However, we noticed an increase in R&D activities last four years.
General trends (2016-2020):

- 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 %)

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

On 26-29 June 2021, 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 2021, the aggregate data was published on INFARMA's website: www.kodeksprzejrzystosci.pl

Code awareness

1. 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 2021:

1. Development of a Q&A document for the newly implemented INFARMA Code of Good Practices (consistent with the EFPIA Code)
2. Improvement of the Event Certification System – education in the field of INFARMA standards, verification of the Certification Regulations, adaptation of the system to the epidemiological situation related to COVID-19.
3. Identification of risk areas and creation of thematic subgroups dedicated to individual areas

INFARMA was involved in promoting the Code. 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.

2. 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 2021, 1677 events were recorded in the certification system.
In 2021 the INFARMA met the following completed tasks associated with the Event Certification System:

- a change in the criterion of geographical location of events was introduced (exclusion of towns which are attractive to tourists and are not the seats of provinces),
- in response to the change in the forms of organization of events related to the epidemiological situation, the introduction of solutions for certification of events organized in the form of virtual, hybrid and traditional meetings was continued.

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ROMANIA - ARPIM

Code authority activity

In 2021 ARPIM received one new complaint. The complaint was analyzed thoroughly and remedial actions were identified as necessary to strengthen compliance with the Code, for the complained company. No sanctions were imposed but the complained company provided and implemented a remedial action plan to address the highlighted topics and strengthen compliance in its operating practices.

Code awareness

ARPIM further developed the yearly Code awareness training, exercise designed for all member companies employees. The yearly training exercise is now performed on a modern adult learning platform (Code of Talent). The platform is flexible in terms of the content to be delivered and is based on micro-learning. The content (training material) was developed especially for this purpose for ARPIM member companies, it is interactive and focuses on the Code principles as well as practical situations. The plan is to further enhance and develop the training content in order to continue the development journey of industry employees in terms of acting with integrity and in line with the industry standards.

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SLOVAKIA – AIFP

Code authority activity

AIFP Ethical Committee (AIFP EC) did not receive any complaints or any breaching notifications in 2021.
Due to the pandemic situation, all the AIFP EC meetings were held virtually.
Based on a discussion on the AIFP Ethics & Ways of working Working Group (Ethics WG), the AIFP EC prepared an amendment to the AIFP Code of Conduct (CoC) in the part where the CoC specifies the reporting of marketing research supported by member companies, and where added an explanatory note to specify an exception in this reporting, which is available on the AIFP intranet and the assessment is part of the regular agenda of the EC.
Members of the AIFP EC also discussed the initiative of the Ethics WG on the possibility of supporting a non-educational event by AIFP members, which could include healthcare providers at a site classified as inappropriate under the provisions of the AIFP CoC, as well as opportunities to support a professional event. whose sponsor is a non-pharmaceutical company offering promotional activities only to participants in such events, which have been linked to a possible inappropriate social program.
The AIFP EC as well as implemented the deviations the AIFP CoC had vs the EFPIA CoC.
Internal members of AIFP EC (elected from members of Ethics WG) prepared a series of virtual events for 3rd parties who organized virtual professional and educational events with the topic - conditions and law possibilities of such an event.

Code report

The annual report of the AIFP EC was presented at the AIFP General Assembly meeting, and it was published on the AIFP intranet.

Code awareness

The Head of the Ethics WG, who is also a member of the AIFP EC, informs compliance leaders and General Managers about the activities of the Ethical Committee regularly.
AIFP the notifications to alert member companies on the need to train and certify/re-certify eligible employees in the field of compliance and AIFP CoC knowledge were successfully implemented and the reports were welcomed by compliance managers.
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 AIFP EC is under preparation, with the expected approval in May 2022.

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SLOVENIA – FarmaForum

Code authority activity
No complaint has been received in 2021.

Disclosure
A whole report on Transfers of Value data for 2021 will be available in July 2022. It will be available here: https://www.farmaforum.si/sl/o-forumu/kodeksi

Code awareness
Internal guidelines are given to Forum members compliance leaders and General Managers at multiple sessions. It was also presented to external stakeholders at the event organised by Slovene Medical Chamber in December 2021.

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SPAIN – FARMAINDUSTRIA

Code authority activity
Farmaindustria examined 3 cases in 2021 (one is still pending on final resolution) that came from:

- Pharmaceutical companies

The Code provisions that have been breached in the 3 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 4. Acceptability of Promotional Material (EFPIA Code Article 5 Acceptability of Promotion)
- Article 5. Transparency in Promotion of Medicines (EFPIA Code Article 7 Transparency of Promotion)
- Article 17. Relationships with Patient Organisations (EFPIA Code Article 21 Interactions with POs).

One case was filed, other settled by a mediation agreement between the parties, and the third one is still pending on Jury Resolution.

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

Consequences of Code authority activity
A Code new version was approved in October 2020 and came into effect on January 1st, 2021. This new version transposed EFPIA Code and includes, among other, the following amendments and improvements:

1. Annex III “Practical guidance for communication and relations with the media concerning prescription-only medicines” (non-binding).
2. Annex IV “Practical guidance and criteria concerning services provided by Healthcare Professionals or by Healthcare Organisations” (binding).

2021 disclosure of 2020 ToVs
The figures are the following:
Transfers of Value (TOTAL: 529 million euros)

- R&D 54,44%
- HCOs 27,22%
- HCPs 18,34%

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
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 89 cases. In addition, 5 cases were assessed directly by the second instance (NBL), including 2 originating from National Agency (Regulatory Authority), and 3 from regional Formulary Committees. The part originating from the continuous supervision and monitoring performed by IGN represent 87 % of the total case volume.

In 2021, the complaints came from:
- Pharmaceutical companies: 5,3 %
- National Code authority: 87,2 % (IGN= first instance)
- National agencies: 5,3 % (including regional Formulary Committees)
- Others (please specify): (2,1 %, private person)

The Code provisions have been breached in 69 cases, as assessed by IGN, and in general relate to promotion not consistent with SPC, misleading, not truthful information, abbreviated prescribing information is missing, insufficient or has poor readability. There have also been several breaches related to the code requirement to disclose interactions/collaborations with patient organisations, and one case concerns non-allowed provision of virtual congress registration for Swedish HCPs.

The second instance, NBL (handling escalations from first instance, and appeals), in 4 cases assessed a breach, and in 4 cases the outcome was non-breach. In addition, for the 5 cases that were submitted directly to NBL as complaints, the outcome was: breach in 4 cases, non-breach in 1 case.
The sanctions imposed were fines (in general 110 000 SEK), except for the cases that rendered a written warning (13 cases) by IGN.

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

Consequences of Code authority activity

In 2021, IGN issued sanctions in several cases for poor readability of the abbreviated prescribing information for banner advertisements of Rx-products. Consequently, we have thereafter seen a general improvement in the last 3-4 months. By 01-July-2021, we introduced several changes to the Code, eg. regarding the possibility to use new data that is not explicitly found in the SPC, in promotion. Due to this change, we expect breaches concerning this provision to decrease in 2022. In 2020, IGN issued several sanctions regarding poor readability of abbreviated prescribing information for OTC advertisements (on TV, digital/ social media etc.), however this significantly improved in 2021.

In 2021, we also saw a new trend of "self-disclosure" of pharmaceutical companies, i.e. to voluntarily self-report company-identified breaches to IGN. Since 2020, 8 such self-disclosures have been submitted. The majority of the breaches self-disclosed were related to observed deficiencies for transparency requirements regarding interactions with patient organisations.

2021 disclosure of 2020 ToVs

The figures are the following:

R&D	80,9 %	
HCOs	16,3 %	(consultancy fees and associated expenses, sponsorships, donations)
HCPs	2,8 %	(consultancy fees and associated expenses)

The percentage of individual disclosure is:

90,7 % (HCP and HCO combined; ToVs in relation to consultancy fees and associated expenses)
83,5 % (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 180 attendees participated.

Upon request, Lif organised training for 5 individual member companies. In addition, Code introduction sessions for new member companies were held, and a presentation about the July 2021 Code update, was made on Lif CEO Forum.

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SWITZERLAND

The Swiss association publishes an annual report of the Pharma Code and the Pharma Cooperation Code each year, the 2021 annual report is available here:
https://www.scienceindustries.ch/en/article/12674/annual-reports-of-the-codes-secretariat

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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.

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