European Federation of Pharmaceutical Industries and Associations

EFPIA Report on Ethics & Compliance Activities

June 2021

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 – 2020 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 2020 and into mid-2021.

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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 its mandate, the CodCom focused on the following topics in 2020 and into 2021:

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

EFPIA Secretariat, in partnership with the member associations, has 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.
This analysis has been based on the English version of the national codes, and additional Code guidance if they are binding and transparent for the members companies.
The Codes Committee has identified few priority topics for the transposition: the extension of the gift and promotional aids prohibition for the patient organisations, the full alignment with the IFPMA Code for the logos on the educational materials and items of medical utility, the integration of ethical principles in the introduction of the codes, the integration of the 3 EFPIA binding annexes, and the removal of the reference to the consent (as the sole legal basis) in the disclosure provisions.

On 28 national codes analysed so far:
- 25% of the codes are fully transposed (this represents 7 national codes)
- 39% of the codes include more than 90% of the new EFPIA Code provisions
- 22% include between 80% and 90%

- **e4ethics**

In 2011, EFPIA established an independent assessment of European events according to the EFPIA Code requirements. While the assessment served as a reference for individual member companies to organize and/or support such events and attendance, it remained the decision of each Member Company to take the assessment into consideration or not.

In March 2020, EFPIA decided to make the e4ethics platform binding, meaning that sponsoring, participating or collaborating in an event that has not been approved or has been qualified as non-compliant by e4ethics, would be considered a breach to the EFPIA Code which could be enforced by the competent national Code authorities.

EFPIA and MedTech Europe decided to merge the assessments of e4ethics and the Conference Vetting System. Building on existing capacities to create efficiency, the objective of such a move is to ensure consistency and harmonisation across the healthcare industry, for the benefit of all stakeholders involved.
This joint venture on congress assessments started on the 1st of January 2021 with a testing period of 6 months.

- **Disclosure**
  - Disclosure deviations

Based on Article 23.02 of the EFPIA Code and due to equivalent legal requirements in place in Portugal, the CodCom has submitted to the Board a request for a deviation of the application of the disclosure requirements for patient organisations.
The Board members approved the extension to patient organsiations of the disclosure deviation previously granted for Portugal.

b. Ethics & Compliance Committee

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 2020, EFPIA has started collaborations with other organisations (joint guidance or common congress assessments), and with stakeholders by organizing roundtable on Code topics.
The E&CC aims at expanding these types of collaborations across industry and among stakeholders.

For 2021-2023, the E&CC has decided to focus on two important priorities:

1. **Analysing the next steps for disclosure**

This priority aims to improve the disclosure figures and access, to analyse how to leverage value of the disclosure, and to understand the current challenges and emerging societal expectations.
All the options for improving the disclosure will be assessed and will include a specific timeline for implementation and a feasibility's study.

2. **Strengthening the communication including the collaboration with our stakeholders**

The E&CC would like to demonstrate our commitment to self-regulation by communicating on our contribution for driving high ethical standards and by sharing evidence of our societal role engagement.

2. e4ethics 2020 report

by Cristina I. Revilla - Ethics and Compliance at Farmaindustria - Spain

The health crisis caused by COVID-19 resulted in a notable decrease in the number of scientific-professional meetings held during 2020. Many of the planned meetings were canceled or postponed and others could finally be held in a virtual or telematic format.

Faced with this situation, the review and analysis work carried out through the e4ethics platform was reduced to a total of 84 meetings at European level (which represents 45% less than the number of meetings analyzed during 2019), no making it necessary to prevent pharmaceutical companies from the existence of elements contrary to the applicable codes in 49 of them (which represents 58% adequacy).

For 20 scientific-professional meetings, it was not possible to issue an evaluation report, as there were postponed until 2021 and even 2022.

ANNEX 1: 2020 NATIONAL CODE REPORTS

AUSTRIA – Pharmig

Code authority activity

In 2020, PHARMIG examined one new complaint. In another one, initiated in 2019, the final decision after appeal was rendered in 2020 by the National Code Authority. 100% of the complaints were introduced by pharmaceutical companies.

One complaint was closed as unjustified. In the other complaint the Code provisions have been breached with regards to the Articles 4 & 5 (information on medicinal products/advertising medicinal products).

No sanctions were imposed because legal proceedings could be conducted with cease-and-desist declaration. The company in place had to pay the costs of the proceedings.

Code Report

PHARMIG published a Code Report which is also available online: https://www.pharmig.at/der-verband/pharmig-verhaltenscodex. The decisions by the National Code Authority are part of the Code Report in an anonymised way (available in German only).

The 2020 Annual Report is available on PHARMIG's website as well: https://www.pharmig.at/media/3895/pharmig-leistungsbericht-2020.pdf

Code awareness

PHARMIG organised training sessions and discussion platforms for member companies on a regular basis. PHARMIG provides plenty of information material to its members regarding the Code (e.g. fact sheets, FAQ, position papers).

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).

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BELGIUM – Pharma.be

Code authority activity

A complaint was lodged in 2020 before the Committee for Deontology and Ethics in the Pharmaceutical Industry and resulted in an amicable settlement between the parties.

Code report

- The **nominative decisions** are published on the Extranet of pharma.be (they are only available for members)
- The **references of each case** are published on the pharma.be public website

Code awareness

Pharma.be organised the following trainings:

- **02/03/2020: Knowledge session "Code of deontology and Infographics on ethics"**
  Programme:
  - Presentation of infographics on Ethics
  - Presentation of the new code of deontology
- **26-27/11/2020: 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

Pharma.be does not use EFPIA "e4ethics" platform, because in Belgium a mandatory visa procedure based on the Mdeon Code of Ethics applies. Each producer or supplier of medicinal products or medical devices wishing to invite a healthcare professional to take part in a scientific event which takes place during several consecutive calendar days, is required to have a prior visa. The visa procedure makes it possible to assess whether the hospitality offered as part of a scientific event complies with the cumulative conditions set out in Article 10 of the Belgian law on medicinal products.

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CROATIA – Innovative Pharmaceutical Initiative IF!

Code authority activity

3 complaints were received in 2020 and came from:

- Anonymous: 33%. One compliant was rejected, after the application for conducting professional lectures of the company in the hospital, during HCP's working hours. HCP meeting participants weren't found to have attended the meeting outside of their working hours.
- A publication on a newspaper website: 66%

Two cases refer to Hospitality and more specifically inappropriate form of entertainment during meetings with HCPs, organized by TPO/HCO (Popular Croatian pop/folk performers were included during dinner time). Given that these are frequent occurrences, involving several member companies with different statuses of participation in events, the President of the national Code authority decided, instead of conducting the procedure, to raise the issue to the level of the entire association, to prevent such behaviour in the future, since it was obvious additional education was needed.
Therefore, the Task Force Ethics & Compliance organized two thematic sessions, which proved to be purposeful and showed in these times of COVID pandemic, when there are no live events, that member companies took the time to think about the problem and to improve internal procedures and agreements when arranging sponsorships with event organizers to prevent of such potential breaching in the future.

2020 Disclosure of 2019 data

The figures are the following:

- R&D 18%
- HCOs 35%
- HCPs 47%

The percentage of positive consent is 11,6%.
The above-mentioned figures show that numbers are on last year's level - a fifth of the total transferred value has been invested in R&D, which enables the access of the latest therapies to the patients and provides the education of healthcare professionals about new and effective treatment methods.
Furthermore, in 2019, compared to the previous year, the level of positive consent of HCPs is almost the same. Unfortunately, Croatia is still at the bottom of the scale in terms of individual consents for which there is no particular explanation.

Code awareness

IF! has adopted the national Code in 9/2020, harmonized with the EFPIA Code, which entered into force on the 1st of January 2021. Task force Ethics & Compliance is in charge of the education about the new code and has already conducted 2 training meetings after the adoption of the Code, the first of which was held

in Q4 2020.
All members and associations of HCO and third-party event organizers were provided with everything necessary from the EFPIA presentation from December 2020 on the "*e4ethics / CVS demo session for EFPIA members*".

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CZECH REPUBLIC – AIFP

Code authority activity
1 complaint received in 2020 that came from:

- Pharmaceutical companies: 100%

The Code provision concerned by the complaint were related to Section 8 (Other Sponsorships).
The Code authority imposed Anonymous publication in annual report.

Code report
The Code report is not published.

Disclosure
The figures are the following:

- R&D 70 %
- HCOs 13 %
- HCPs 17 %

The percentage of positive consent is:

- HCPs 19 %
- HCOs 100 %

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

Code awareness
On Thursday, November 26th, 2020, the 10th Day with the AIFP Ethics Committee for the representatives of AIFP member companies was held. The meeting was held in the virtual environment due to persisting government restrictions due to the COVID-19 situation. The meeting's main topics were the New AIFP Code of Practice, Virtual Congresses, AIFP Disclosure projects and the New casuistries of the AIFP Ethics Committee.

AIFP organized 10 regular examinations of sales representatives of the AIFP member companies in 2020

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DENMARK – ENLI (LIF)

Executive Summary (Annual Report 2020)
In 2020 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 2020
In 2020, approx. 354 promotional activities were self-reported to ENLI each month, as required (pre-vetting procedure). Of these, the Investigator Panel has reviewed approx. 42% of the reports in a random control, and 98,7% of the activities were approved, whereas sanctions were decided in 1.3% of the evaluated reports.

Five complaints were filed against an affiliated pharmaceutical company. Complaints led to sanctions in four cases.

Affiliated medicinal companies continue to exhibit a strong focus on achieving compliance to ENLI's regulation. In 2020, companies requested 126 pre-approvals of promotional activities, which is a decrease of 45 requests compared to 2019 (primarily due to COVID-19). Of the pre-approval requests in 2020, 67% were approved.

From the total amount of 66 decisions that ruled against an affiliated company, one decision was appealed to the Board of Appeal, which corresponds to approx. 1,5% of all relevant decisions. The Board of Appeal handled two cases in 2020 - one appeal was based on a decision from 2019. From the two appeals that have been decided, both decisions from the first instance was in whole or partially upheld.

ENLI has continued to prioritize preventive activities. In 2020, ENLI has published 24 decisions (including 7 administrative reprimands), 7 newsletters and updates to the Promotion guidelines. Furthermore, ENLI has published revisions of several guides. Moreover, ENLI has conducted 8 courses in the regulation, primarily the Promotional Code, and 6 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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ESTONIA – APME

Estonian Ethics code is fully harmonized with EFPIA Code and can be found on our website here: http://rtl.ee/en/apme-code/.
In 2020 there were no breach notifications submitted to APME Ethics Committee, but Ethics Committee did answer some APME members clarifying questions.

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FINLAND - PIF

Code authority activity
PIF received 4 complaints in 2020:

- Inspection Board I (marketing and information to the consumers): 3 cases
- Inspection Board II (marketing to the HCP's): no cases
- Supervisory Commission (complaints of the decisions made by Inspection Boards): 1 case

The complaints came from:

- Pharmaceutical companies: 50% (2 cases)
- National Code Committees: 25% (1 case)
- HCP: 25% (1 case)

The Code provisions have been breached in 4 cases:

- Inspection Board I: 3 cases
- Inspection Board II: -
- Supervisory Commission: 1 case

The following provisions were breached:

- Concerning RX-products: informing the nurses of other issues than information on the correct and safe use of the medicine.
- (in Finland nurses are not counted as HCP's in relation to marketing, it is permissible to provide the nurses with information on the correct and safe use of the medicine if they need such information to assist the patients in the correct use of the product. The material promoting the correct and safe use of the medicine includes the summary of product characteristics (SPC) and the package leaflet as well as the patient instructions intended to be handed out to them.)
- Using social media channels as marketing channel of RX-medicines.

The sanctions imposed were:

- request to abstain from incorrect activity
- sanction payments between 5.000 – 45.000 euros per case
- processing charges 2.000 euros or 5.000 euros per case

Code report

A Code report was published including decisions made by PIF Inspections Boards/Supervisory Commission at:https://www.laaketeollisuus.fi/media/julkaisut/toimintakertomukset/laakemarkkinoinnin-valvontakunnan-toimintakertomukset/lmvk-toimintakertomus-2020.pdf (only in Finnish).

2020 disclosure of 2019 ToVs

The figures are the following:

- R&D 63%
- HCOs 18%
- HCPs 19%

The percentage of positive consent is 68.5%.

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

10 complaints received in 2020 that came from:

- Pharmaceutical companies: 2
- Third parties: 8

In 2020, the breach of Code provisions has been stated in 4 cases (e.g. inappropriate hospitality at congress stand). 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/fsa-jahresbericht

2020 Disclosure of 2019 ToVs
The figures are the following:

- R&D 64,3%
- HCOs 17%
- HCPs 18,7%

The percentage of positive consent is around 19%.
The overall figure of the three main areas have proven to be stable over the years. The level of positive consent slightly fell from 21 to 19% compared to 2019. 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 (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 organisers and of medical societies via several webinars on the code rules.

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GREECE - SFEE

A. SFEE CODE OF ETHICS
The New SFEE's Code of Ethics, in full alignment with EFPIA's Code of Ethics (both in terms of content and in terms of layout and format) is in effect as of 1/8/2020 (Exception: in ANNEX I, the limits for sponsorships and registration to web scientific events are applicable to scientific events with EOF filling date on or after 29/6/2020). There are no proposals for any amendments thereof during the General Assembly's meeting which is scheduled to take place on June 17th 2021.

B. SANCTIONS
During 2020, neither the First Instance Committee nor the Second Instance Committee for Code Compliance examined any cases, as there were no allegations/complaints filed.

C. DISCLOSURE
The National Disclosure of Transfers of Value to HCPs and HCOs from Pharmaceutical Companies in Greece, for ToVs that took place during year 2020, on the "National Organization for Medicines" web-site is still pending as the deadline for the pharmaceutical companies to file such ToVs is 30/6/2021.

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IRELAND - IPHA

Code authority activity
IPHA received 0 complaint in 2020.

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

2020 Disclosure of 2019 data

The figures are the following:

- R&D 59 %
- HCOs 22 %
- HCPs 12 %

The estimated percentage for positive consent is:

- HCOs 100 %
- HCPs 62 %

There was an increase in HCP Consent Rates for ToV Disclosure of 3% compared to 2018 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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ITALY – FARMINDUSTRIA

Code authority activity

In 2020, 6 cases of violation of the Code provisions were declared (participation in events not appropriate locations, presentation of promotional material not in line with current regulations).

The sanctions imposed consisted of warning and censorships without the application of monetary sanctions.

The associated companies were informed of the results through the publication of the cases.

Code report

Farmindustria provides information on all final decisions relating to Code violations on its website, in the section reserved to member companies.

2020 Disclosure of 2019 data

With regard to the publication of transfers of value to HCPs and HCOs in 2020, 72% of the HCPs provided their consents for the publication of the data.

The overall number of consents has proved to be stable over the years.

Institutions and media greatly appreciated the initiative to publish data and the awareness efforts to explain the initiative and persuade more HCPs to give their consent.

The Association intends to increase its efforts regarding transparency.

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LATVIA – SIFFA

Code authority activity

SIFFA examined 4 complaints that came from:

Pharmaceutical companies: 50%

Healthcare Organisations: 25%

Others (media) 25%

The Code provisions have been breached in 4 cases and relate to medicines advertising. As a sanction, the decision has been made to publish information regarding the examined case in the minutes 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
Promotional material and references were incomplete which misleads professionals. The company stopped distributing this advertising material. Additional recommendation of the Commission: would be good practice not to advertise brand names of medicinal products in the guidelines so that the guidelines can be used objectively.

Code awareness
The issues considered by the Ethics commission were discussed at the general meetings of the members of the association (06.07., 16.09., 19.10., 30.11.20.). New national Code of Good Practice and Ethics as well as the Implementing Rules and the Complaints Procedure were approved on 01.12.2020. Hospitality rules developed during virtual events at the Covid-19 time. Discussed new *e4ethics* rules. In co-operation with the MoH and Health Inspectorate, work was carried out on the harmonization of regulatory enactments with the requirements of the EFPIA Code whereas the EFPIA Board decided (July, 2020) to allow disclose data to be published only on the website of a public health authority.

Others topics
Working group of the Ethics Commissions finalised project of the National Code accordingly to the EFPIA Code of Practice (February, 2020) and submitted to SIFFA Board for approval by association members (March, 2020).
SIFFA turned to EFPIA Board (07.01.2020.) with a request to consider the question of the publication of annual data on the basis of Article 25.02. and 23.01. of the EFPIA Code of Practice, namely: to disclose information to the members of the association only in one publicly accessible platform, in accordance with the laws and regulations specified in Latvia, which are provided by the State supervisory authority – Health Inspectorate of the Ministry of Health in order not to duplicate information to be made public by industry. Since data are published in several countries only in accordance with the provisions laid down in national laws and regulations, SIFFA Board requests the EFPIA Board to consider the possibility of introducing such practices also in Latvia.
EFPIA Board agrees (01.07.20.) 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.

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LITHUANIA - IFPA

Code authority activity
IFPA examined 6 complaints in 2020 that came from:

- Pharmaceutical companies: 100%

The Code provisions have been breached in 5 cases and relate to “Regulations of promotion of medicinal products”.

The sanctions consisted in writing recommendations for pharmaceutical companies, in 4 cases without publishing of name of the Company and product, 1 case with publishing of Company's name and details of the breach of the Code. The material of 1 case was for forwarded to the State Medicines Control Agency at Ministry of Health of Republic of Lithuania.

Code report
IFPA Code report is available here: https://www.vaistukodeksas.lt/pranesimai-apie-pazeidimus/

2020 Disclosure of 2019 data
The figures are the following:

- R&D 39 %
- HCOs 30 %
- HCPs 31 %

Others topics
The working group of the Innovative Pharmaceutical Industry Association (IFPA), Local American working Group (LAWG) pharmaceutical committee and Medicines Manufacturing Association (VGA) Joint Ethics & Compliance Committee finalised project of the National Code accordingly to the EFPIA Code of Practice and it was adopted by IFPA General Assembly in 18th of June, 2020 and by VGA General Assembly in 25th of June, 2020, as well as the supportive tools and materials (Q&A, addendums, etc.) translated into Lithuanian language for external communication.

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MACEDONIA - Farmabrend Nova (FBN)

Code authority activity
No complaint has been examined in 2020.

2020 disclosure of 2019 data
The first disclosure in Macedonia was in June 2020. All members disclosed the reports for ToVs within the deadline. Links to the reports can be find on: https://fbn.mk/?p=3257.
All planned activities of FBN, related to the disclosure, were executed. We did not receive any reaction, positive or negative, from healthcare authorities, medias or public.

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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 authority activity
Despite the COVID-19 pandemic, the CGR foundation has been able to perform its work relatively well. During the corona period it was not possible to provide sessions on location; these are kept digitally. The corona crisis has led to a drastic decrease in the number of requests for advice for the assessment of (foreign) meetings. Instead, questions arose about the preconditions for organizing or sponsoring online refresher courses. For the case histories, please refer to the advisory opinions section, which is explained in more detail in this annual report.

In 2020, a total of 7 complaints were handled by the CGR, three of which were cases according to the serious signal procedure and three according to the regular complaint procedure at the Code Committee. One complaint has been withdrawn. In 2020, three appeals were lodged with the Appeals Committee. One of these cases was ruled in 2020, the other two rulings will take place in 2021. All complaint procedures related to statements.

As of 2020, the CGR advisory opinions will be issued on behalf of the Inspection Council. Requests for advice are treated on a confidential basis and, insofar as relevant, published in an anonymous form on the website of the CGR. Advisory opinions on foreign meetings are no longer published (and numbered differently). Below is an overview of the treatments of advice in 2020:

Submitted:	35	
Advice issued:	34	
Withdrawn:	1	
Positive:	26*	of which 14 conditional.
Negative:	6	
Inadmissible:	2	
Published:	16	

About 76% of the proposed actions that were submitted have received a positive decision. The total number of requests for advice is significantly lower than in 2019. Due to the corona crisis, many foreign meetings did not take place. These meetings normally accounted for the bulk of advice requests (61 out of 75 in 2019). In 2020, about half of the advice related to foreign meetings. Almost all requests for foreign meetings were made in the first quarter of 2020. Requests for advice on other subjects mainly took place in the first and last quarter of 2020. 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 is available here:
CGR nieuwsbrief 1-2021 De CGR in 2020

Consequences of the Code authority activity

The CGR has received reports of a possible violation of the Code of Conduct by a radio commercial about a vaccine against shingles. In the commercial, the public is actively invited to inquire about this treatment option with the general practitioner. The commercial is considered to be promotional for the shingles vaccine, despite the intention to inform only and the shingles vaccine is not mentioned. The CGR has ruled that there is public advertising and the commercial is therefore in violation of the Code of Conduct. The relevant marketing authorization holder has taken various measures to prevent further distribution of the commercial and will reassess the material. The complaint was therefore settled with a publication of the facts and payment of the costs incurred by the CGR.

2020 disclosure of 2019 data

In July 2020, the financial relationships reported for the 2019 calendar year were published in the Healthcare Transparency Register (see newsletter 3/2020). The relationships reported by the pharmaceutical companies show an increase of 2% compared to 2018. In total, the companies have reported relationships worth €64 million. The increase has entirely occurred in sponsor relationships for organizing meetings by healthcare institutions, partnerships of healthcare providers and patient organizations.

The figures are the following:

- R&D 68 %
- HCOs 29 %
- HCPs 3 %

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.
The association observed a trend that the value of financial relations with HCO grows and with HCP decreases.

Summary table per category of financial relation

Type relation	Beneficiary	Amount (€)	Total (€)	(%)
Research & development	Aggregated		€ 135.000.000	68%
Services fees	HCP HCO	€ 2.886.035 € 4.424.825	€ 7.310.860	3,5%
Services expenses	HCP HCO	€ 2.135.445 € 1.001.336	€ 3.136.781	1,5%
Sponsoring project	HCP HCO	€ 32.544 € 14.126.963	€ 14.159.507	7%
Sponsoring events and hospitality	HCP HCO	€ 1.697.831 € 37.861.343	€ 39.559.174	20%
Total			**€ 199.166.322**	**100%**

Code awareness
CGR organises frequent training sessions on the application of the Code. Next to these public sessions, CGR also gives these training for individual companies (in-house trainings). Further, sessions are organised for patient organisations and medical students. The CGR training courses (basic course and in-depth course) were given online during the COVID-19 pandemic. Although the added value of physical meetings is recognized, the benefits of online meetings are also recognized. There are calls for offering both physical and online meetings in the future. Physical meetings work well to exchange experiences and ideas. Online meetings could be held for case histories updates.

Congress evaluation
When applicable, the association provides input to the e4ethics assessments as Host Country.

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NORWAY - LMI

Code authority activity
In 2020 the Code Authority (Rådet) received 7 complaints from:
- Pharmaceutical companies: 5
- Healthcare Professionals: 1
- National Code Committees: 1

The Code Authority handled 5 cases. The Code Appeal Board handled 2 cases.
The Code provisions was breached in 3 cases. These were Articles 4.1 (timing of product marketing), 8.2 (mandatory information in advertising), 8.4 (balanced and factual information) and 29.6 (duty to upload advertising material to the Norwegian electronic archive).

The sanctions imposed were fines between NOK 100.000 to NOK 150.000.
Due to these cases, the Council places stringent requirements to that the information must be in line with the marketing authorization and that it is not permitted to use statements in a Medicinal Product's Advertising which do not agree with information in the SmPC.

Code report
The 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

2020 disclosure of 2019 data
The percentage of consent was 76%.
Due to a transition period disclosure for 2020-data disclosed in June 2021 will partly be based on the legitimate interest. As of disclosure June 2022 (2021-data) Norway expects 100% disclosure due to use of the legal basis legitimate interest.

Code awareness
3 different trainings were organized:
- 1 Advertising trainings
- 1 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.

The Code Authority (Rådet) and the Norwegian Medicines Agency both have access to the electronic archive where advertising material is submitted.
The Secretariat continuously provides advice pharmaceutical companies regarding the industry rules. The secretariat carries out controls looking for compliance with the Code.

Congress evaluation
International Congresses in Norway apply for e4ethics.
For national events, LMI has its own "Concept Approval" with a digital application form.
Normally there are around 100 + applications per year both for physical and digital third-party meetings. In 2019 however LMI evaluated only 40 cases, this due to the pandemic. When the pandemic is over, we expect the number of approvals to increase.

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POLAND - INFARMA

Code authority activity
In 2020, the Rules of the Disciplinary Court were updated because of the implementation of the EFPIA Code and the adoption of a new INFARMA uniform Code of Good Practices by the INFARMA member companies.
The Disciplinary Court of INFARMA has two instances. 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.
In 2020, the Disciplinary Court investigated one case, which was received by the Court in 2019. The proceedings were conducted in the first and second instance.
The decision of the second instance has upheld the decision of the first instance. The Disciplinary Court assessed the violation of the company XXX in accordance with Article 8(1) and Article 12(1) of the Code of Good Practices – through the conduct of advertising activities of medicinal product and ordered a notice to an related entity.

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.

2020 Disclosure of 2019 data

The figures are the following:

- R&D 64 %
- HCOs 18 %
- HCPs 18 %

The estimated percentage for positive consent is:

- HCOs 95 %
- HCPs 22 %

In 2020 no material or significant changes in comparison with 2019 ToV.

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 few years.

General trends (2016-2019):

- 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 23% of HCPs (2016-2019)

Code awareness

The Code of Practise

In 2020, intensive works were carried out on the implementation of the new EFPIA Code of Practice and on the adoption of the new INFARMA Code of Good Practices. 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.

Activities involving the signatories' adoption of the new INFARMA Code of Good Practices were implemented:

- implementation workshops devoted to the new Code for INFARMA members were held.
- positions and recommendations with respect to the application of the provisions of the Code (Q&A).

In 2020, an IT tool – Transparency Code platform – was developed and implemented, thanks to which the member companies can enter and update data regarding reports on an ongoing basis; data is automatically generated on the website

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.

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 2020, 1766 events were recorded in the certification system.
In 2020, the Certification Task Force and INFARMA met the following objectives and completed tasks associated with the Event Certification System:

- adapting the system to the epidemiological situation - virtual event evaluation,
- a recommendation on hospitality during virtual meetings was developed,
- communication activities.

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SERBIA - INOVIA

Code Authority Activity
No complaints were filed in 2020.

2020 Disclosure
There were 30.27% contracts with positive consent but with huge variation between member companies. One member company had 100% of positive consent ("no consent no contract" principle) while three additional member companies had more than 80% of positive consent. At the other end of the spectre two member companies had 1% or less of positive consent, while all others were between 24-54% of positive consent.
As for the disclosed amount, it was distributed in the following way:

- HCPs 35%
- HCOs 16%
- R&D 49%

Code Awareness
INOVIA organized first Compliance Day on November 4th. It was organized by our Compliance Working Group with strong support from INOVIA Managing Board with the idea of promoting best practice in gaining positive consent. Three most successful companies were given the opportunity to present how they are achieving high positive consent percentages, followed by Q&A session afterwards. It was highest attended event INOVIA ever organized with more than 170 participants from our member companies present over Zoom platform. The idea is to make this an annual event.

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SLOVAKIA – AIFP

Code authority activity
AIFP Ethical Committee (EC) did not receive any complaints in 2020.
Based on a case from 2019 – a complaint submitted by a member company against the action of another member company, EC prepared an amendment to the AIFP Code of Conduct. It has addressed provisions concerning the possibility to appeal against the resolution of the EC.
EC has also assessed a motion from the external environment asking to evaluate specific activities of a member company.
Suitability assessments of three venues for professional and educational events were performed based on requests submitted by professional medical societies or on their behalf.

Code report
The annual report of the Ethical Committee was presented at the AIFP General Assembly meeting and it was published on the AIFP intranet.

Code awareness

The Head of the ethics working group, who is also a member of the AIFP Ethical Committee, informs compliance leaders and General Managers about the activities of the Ethical Committee regularly. Together with other internal members of the committee, they are preparing the case studies from the issues solved at the committee (project starting in 2021).

AIFP prepared the notifications to alert member companies on the need to train and to certify or re-certify eligible employees on the field of compliance and Code of Conduct knowledge.

Others topics

The National Code of Conduct amendment ensuring alignment with the EFPIA Code of Practice has been prepared by the end of 2020, and it was approved, together with other changes, by the General Assembly on March 1st, 2021.

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SLOVENIA – FarmaForum

Code authority activity

No complaint has been received in 2020.

Disclosure

A whole report on Transfers of Value data for 2020 will be available from 9 July 2021.

Code awareness

Internal guidelines are given to Forum members compliance leaders and General Managers at multiple sessions. Information about the new Code was sent to Patient Organisations (68 recipients) on 11 January 2021.

e4ethics requirements are implemented and mandatory for all member companies. Information was also distributed to all relevant stakeholders on March 23rd, 2021.

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SPAIN – FARMAINDUSTRIA

Code authority activity

Farmaindustria examined 5 cases in 2020 that came from:

- Pharmaceutical companies: 20%
- National Code Committees: 80%. Issued by the Code of practice Surveillance Unit.

The Code provisions that have been breached in the 5 cases are the following:

- Article 3. Information on Medicines and its Substantiation (EFPIA Code Article 3 Promotion and its Substantiation)
- Article 7. Distribution of Promotional Materials for Medicines (EFPIA Code Article 6 Distribution of Promotion)
- Article 11. Scientific and professional meetings (EFPIA Code Article 10 Events and Hospitality).

The sanctions imposed were the admission of an infringement, implementation of corrective measures (i.e. internal procedures revision and update, in-company trainings), monetary sanctions, and publication (applicable to both, Mediation Agreements and Jury Resolutions).

Code report

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

Consequences of Code authority activity

The incorporation of a new Annex III "Practical guidance for communication and relations with the media concerning prescription-only medicines".

2020 disclosure of 2019 ToVs

The figures are the following:

Transfers of Value (TOTAL: 601 million euros)

- R&D 43,10%
- HCOs 25,79%
- HCPs 31,11%

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 120 cases (includes total number of assessed cases, where 89 % originates from the continuous supervision and monitoring performed by IGN). In addition, 3 cases where assessed directly by the second instance (NBL), including 2 originating from National Agency (Regulatory Authority, and 1 one from a regional Formulary Committee.

In 2020, the complaints came from:

- Pharmaceutical companies: < 1%
- Healthcare Professionals: 2,4%
- National Code authority: 89% (IGN= first instance)
- National agencies: 1.6%
- Anonymous: 3,3%
- Others (please specify): (2,4%, private person)

The Code provisions have been breached in 102 cases and in general relate to promotion not consistent with SPC, misleading, not truthful information, documentation not cited in a fair and balanced way (the statistical power of the data supporting the claim was not provided in promotion), abbreviated prescribing information is missing or insufficient. There have also been several fines for breaches related to the code requirement to disclose interactions/collaborations with patient organisations, and in one case for lack of disclosure regarding individual patients (the latter a new requirement effective by 01-May-2020).

The sanctions imposed were fines (in general 110 000 SEK), except for the cases that rendered a written warning (41% of total) 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 2020, IGN issued sanctions in several cases for poor readability of the abbreviated prescribing information in e.g. TV commercials (OTC only). Consequently, we have seen a general improvement the last 6-7 months, where such information is displayed more clearly nowadays. We are also in the process of updating the Code (effective by 01-July-2021), to address and clarify several issues with regards to rules for promotion of Rx-

pharmaceuticals to HCPs, e.g. need to include the abbreviated prescribing information also in invitations to meetings, if the invitation is containing promotional attributes (such as product logotype and/or product claims). In 2020, we have also monitored Code disclosure requirements, to improve the use of Lif´s public disclosure databases, and ensure that all interactions/collaborations with patient organisations, individual patients and caregivers, are correctly and timely disclosed, when applicable.

2020 disclosure of 2019 ToVs

The figures are the following:

* R&D 82%
* HCOs 14% (consultancy fees and associated expenses, sponsorships, donations)
* HCPs 4% (consultancy fees and associated expenses)

The percentage of individual disclosure is:

* 86,8 % (HCP and HCO combined; ToVs in relation to consultancy fees and associated expenses)
* 76, 85 % (HCP only; ToVs in relation to consultancy fees and associated expenses)

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

Code awareness

LIF organized:

- 4 Code Training sessions (2 days course, including formal test to get accredited in code compliance). Approximately 40 attendees each session, 3 of these sessions where digital (webinars) due to Covid.
- 2 half-day seminars in February, where companies were trained about the new Code (and Ethical agreement with public healthcare), that was implemented by 01-Jan-2020.
- One half-day seminar about the new Ethical agreement was co-organised with SALAR (the public healthcare central organisation) attended by regional compliance representatives from healthcare.
- One E-learning about rules for interaction with patient organisations, patients and caregivers was developed and launched in August. The course is available via Lif website, see link E-utbildning om samverkan mellan läkemedelsföretag, patientorganisationer och patienter (lif.se)
- Training to OTC companies in October: New guidelines for OTC advertisements on mobile platforms

Transparency seminar/training in December for companies (approx. 120-130 participants, all remotely).

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SWITZERLAND

The Swiss association publishes an annual report of the Pharma Code and the Pharma Cooperation Code each year, the 2020 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.