

Codes Committee

Activities Report – June 2019

The EFPIA Codes Committee shall 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.

This report provides an overview of activities conducted by the EFPIA Codes Committee during 2018 and into 2019, as well as a summary of the national Codes' reports (**Annex 1 – 2018 National Code reports**).

The report has been complemented with key issues reviewed by the Ethics & Compliance Committee, and that are relevant to further developments in the code implementation and enforcement areas.

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1. Codes Committee and Ethics & Compliance Committee Activities

The role of the EFPIA Codes Committee is to assist member associations in their national code compliance activities, the EFPIA Codes Committee shall monitor the adoption of compliant national codes.

The EFPIA Codes Committee (CodCom) and Ethics & Compliance Committee (E&CC) activities in 2018 focused on the **consolidation of the three EFPIA Codes into one simplified version**.

The **structure of activities and work programmes** of the CodCom and the E&CC is provided hereafter.

a. Codes Committee priorities

In line with its mandate, the CodCom has decided to focus on 4 key priorities for the mandate 2017-2019:

- **National complaint procedure implementation**
The EFPIA Code sets that each Member Association is required to:
 - **Establish national procedures and structures to receive and process complaints, to determine sanctions and to publish appropriate details** regarding the same including, at a minimum, a national body of the Member Association that is designated to handle complaints and consists of a **non-industry chairman** and, besides any industry members, **membership from other stakeholders**;
 - Ensure that its National Code, together with its administrative procedures and other relevant information, are easily accessible through, at a minimum, publication of its National Code on its website; and
 - **Prepare, and provide to the EFPIA Codes Committee (defined below), an annual report** summarizing the work undertaken by it in connection with the implementation, development and enforcement of its National Code during the year.
- **Analysis of cases and infringements occurred at national level**
- **National Code trainings**
- **e4ethics report**

The **CodCom priorities for 2019-2021** will be to support the Member Associations:

- in the transposition of the new Code's provisions at national level, and
- for the national Codes' implementation and enforcement

b. Ethics & Compliance Committee priorities

For 2017-2019, the following E&CC priorities were defined on the basis of E&CC members' outcomes and were dedicated to the following topics (the priorities achieved are in bold):

1. Enhancing self-regulation

- (a) Providing strategic input in Codes consolidation based on the following approach:
 - **EFPIA principles (applying to the 3 codes)**
 - **Consolidation of the 3 codes in ONE simplified code (based on the EFPIA principles)**

This consolidation's process is described in the point 2 of the report.

- Additional guidance (to complement the Code)
- (b) Promoting common understanding of EFPIA Code principles
- (c) Developing capacity building towards/with stakeholders

2. Embracing digital era (EDE)

- (a) Defining direction for appropriate self-regulation
 - **Inputs provided during the Codes consolidation on the way to address digital activities in the Code**
 - Update of the Internet guidelines (Annex B of the HCP Code)
- (b) **Developing and sharing intelligence on digital environment development relevant to our industry**
 - **Analysis of companies practices in digital communication and digital innovation**

The overall objective of the EDE WG is to contribute to making it more visible to external stakeholders that the EFPIA members are pursuing digital opportunities in accordance with a set of ethical principles that supplement applicable legislation.

- (c) Identifying collaborations to ensure compliance with principles from external companies (i.e. outside pharmaceutical sector)

This long term and cross-sectorial project will be conducted in collaboration with other organizations like the IFPMA working group related to Future Health Technologies.

3. Developing ethical guidance

- (a) Identify new or increasing activities
 - Patient engagement

The objective of this workstream is to develop a “Questions to consider” document that could help when developing projects involving patients. It could be used by EFPIA, and serve as a reference for EFPIA Members.

- **Review of the patient remuneration document**
- **Position related to the definition of information vs. promotion provided during the Codes consolidation**

- (b) Define a methodology to assess and identify relevant ethical guidance

The scope of the “Question to consider” when interacting with patients will be extended to all type of activities and stakeholders.

The **E&CC priorities for 2019-2021** will be defined in Q3 2019.

The first ones will be to finalize the 2017-2019 remaining actions and to define actions aiming at ensuring an improvement for the Disclosure implementation.

2. Consolidation of the 3 EFPIA Codes

a. Process

On 13 April 2018, the EFPIA Board approved the initiation of the project to consolidate the 3 EFPIA Codes into 1 simplified Code for approval by the EFPIA General Assembly in 2019.

Regarding the timing for the implementation of the consolidated Code, the CodCom and E&CC members have planned the following:

- On 27 June 2019, submission of the consolidated Code to the General Assembly
- Transposition by members associations within a year
- Implementation at the latest in January 2021

A communication plan (including webinars, communication during EFPIA General Assembly and publication on EFPIA website) will be developed with the support of the EFPIA Communication team.

b. Main changes

Concept simplification

This simplification exercise, including the introduction of common definitions, has been conducted to update the Code provisions for a better concept alignment. It will allow EFPIA to promote the common understanding of the Code by stakeholders and the general public aiming to improve adherence to the Code.

The EFPIA Ethical Principles, approved by the Board on 16 June 2016, have been integrated in the introduction of the Code. To ensure alignment with the new IFPMA Ethos Charter, it has been suggested to add the notion of trust and to describe the self-regulation.

A new structure was defined to cover all type of interactions and bring clarity on the interactions:

- o Common principles for interactions with healthcare professionals (HCPs)/healthcare organisations (HCOs)/patient organisations (POs)
- o Specific requirements for interactions with HCPs and HCOs or POs

All the relevant existing guidance have been integrated into the Annexes.

Removal of repetitive provisions

The 3 Codes contained repetitions mainly in the introduction, scope, applicability, and enforcement sections, as well as in the annexes related to implementation and procedure rules (repeated 3 times). All these parts have been consolidated in the relevant sections.

Additionally, the provisions related to hospitality and contracted services of the HCP and PO Codes were similar and have been merged.

When redundant, outdated or inaccurate provisions have been identified, they have been deleted (e.g. in the articles related to non-interventional studies, medical samples, member company staff and disclosure.)

Content clarification

This consolidation exercise led the CodCom and E&CC members to review the 3 Codes in depth. Before modification, each principle or requirement has been analysed as well as the consequences of such a change for the sector.

The definition of HCP was found to be different depending on the Code. Members decided to use the one with the broadest scope (coming from the Disclosure Code). It includes any official or employee of a

government, agency or other organisation that may prescribe, purchase, supply, recommend or administer medicinal products.

To reflect the current collaboration between member companies and POs, the CodCom and E&CC members have decided to include the notion of "Patient Organisation Representative".

With the same objective of reflecting current business development, the notion of "Personal Health Data" has been integrated in the Ethical Principles. The aim of this reference is to take into consideration the current regulation related to data protection and its impact on pharmaceutical activities.

To make clear that the Code's provisions are mandatory, the term "shall" has been replaced by "must".

The scope of the following provisions has been extended:

- The gift prohibition is now applicable to POs' representative. The objective of this extension is to reinforce the legitimacy of the interactions with patients and demonstrate our ethical commitment. Finally, to ensure alignment with the IFPMA Code, it has been agreed with IFPMA to replace the current provision by the new IFPMA one.
- The requirements related to Donations & Grants and Sponsorship have also been extended to POs and their representatives.
- The provision on the use of logos and proprietary materials applicable to POs has been extended for application to HCO.
- The principle related to member company funding in the current PO Code is now also applicable to HCOs.

The provision related to sponsorship in the current HCP Code covers two different concepts that have been distinguished: Contribution to costs related to Events provided to HCPs and Sponsorship provided to HCOs. This change is aligned with the current Disclosure Code which contains this distinction.

Regarding medical education, EFPIA had no article in its Codes and believes this is an important topic that must be addressed. In addition, introducing this topic allows alignment with the IFPMA Code which already includes some information about medical education. This article sets basic principles and common standards applicable to medical education activities.

To align EFPIA requirements with the new IFPMA Code provisions, the prohibition of product branded has been introduced in the article related to informational and educational materials and items of medical utility.

The current template for written agreement with POs is removed.

Regarding the disclosure requirements, the main change is the removal of the references to the HCPs' consent. With the General Data Protection Regulation, the disclosure can be based on legal basis other than consent. EFPIA does not want to restrain these other bases that an EFPIA member can choose for its disclosure. For consistency with what is required for HCPs/HCOs disclosure, a methodological note explaining the disclosure is now also required for POs. A template for PO's disclosure is going to be created, its use will be optional.

The guidelines for Internet websites available to HCPs, patients and the public in Europe are removed from the consolidated Code. It will be updated when the current practices in this area are better defined.

c. Stakeholders feedback on the consolidated Code

EFPIA sent the draft consolidated Code to the following stakeholders: the Standing Committee of European Doctors (CPME), BioMed Alliance, the patient organisations represented in the Patient Think Tank and the

International Pharmaceutical Congress Advisory Association (IPCAA). The objectives were to inform them of this project before finalization and give them the opportunity to share any concerns before the Board approval.

EFPIA received mainly positive feedback from BioMed Alliance, European Men's Health Forum, Mental Health Europe and IPCAA.

d. Additional documents

The following pre-existing documents have been integrated in the Code:

- * Board Disclosure Guidance
 - * NIS disclosure - Disclosure date - Indirect ToVs through PCOs
- * Board Disclosure Recommendation
 - * Member Associations gateways
- * SOP Complaints

The E&CC members agreed that the following documents need to be updated or created:

- * Internet guidelines
- * PO Disclosure template
- * FAQs on HCP and Disclosure Codes

3. Disclosure Code report

a) Background

Working in partnership with various stakeholders including healthcare professionals (HCPs), healthcare organisations (HCOs), patient organisations (POs), regulatory authorities, governments and the public, improves health, quality of life, and contributes to the value of future research. A more open and transparent interaction between the stakeholders involved in the healthcare system benefits the whole society.

EFPIA aims to foster an environment where the public can be confident that choices regarding their medicines are being made on the basis of the merits of each product and the healthcare needs of patients. Consequently, EFPIA and its Member Associations, have adopted deontological Codes to ensure that these interactions take place in an ethical and transparent manner and meet the high standards of integrity that patients, governments and other stakeholders expect.

In 2014, EFPIA adopted the **Code on the Disclosure of transfers of value from pharmaceutical companies to HCPs and HCOs**. The Disclosure Code requires Member Companies and companies that are members of Member Associations to disclose transfers of value¹ made to HCPs and HCOs. This disclosure includes, by HCP or HCO, the total amounts of value transferred, by type of activity, which could consist of, for instance, a grant to an HCO, a consultancy fee for speaking or registration fees to attend a promotional, scientific or professional event. Member companies began disclosing in 2016 the transfers of value provided during the calendar year 2015.

Rationale for disclosure through self-regulation

Bringing greater transparency to this already well-regulated and vital relationship, builds understanding of industry-POs and HCPs/HCOs collaboration and, in the context of increasing societal expectations on transparency, directly addresses public concerns about interactions between the medical community and the pharmaceutical industry.

Increasing transparency through the disclosure of transfers of value is a step towards building stable and important collaboration between all stakeholders involved in the healthcare system. Nevertheless, the disclosure landscape is complicated by the existence of diverse legislation related to disclosure in some European Countries, including the adoption of central platforms² as well as the inclusion of other sectors and partners. Some countries have chosen to enshrine transparency requirements in legislation depending on the political context, national attitudes to transparency and national data privacy regulations.

The disclosure includes personal data e.g. the names, the address of the HCPs and the amounts of transfers of value provided to them.

The General Data Protection Regulation 679/2016 (GDPR) considers that companies can legally process the personal data (that do not contain sensitive personal data) if they rely on one of the 8 legal bases. Of these EFPIA believes the following three would be most relevant in this context:

- Legal duty: there is a legislation in place allowing the personal data treatment i.e. transparency legislations
- Consent: the individuals agree with the treatment of their personal data. This consent must be specific, unambiguous, informed and freely given.
- Legitimate interest ground: the data processor considers that there is a public interest higher than the private interests of the individuals.

¹ Transfers of Value are direct and indirect payment, whether in cash, in kind or otherwise or reimbursement provided to HCPs and HCOs.

² A central platform is one single, searchable database at a national level where users can search by HCP and/or by company. EFPIA supports the creation of mechanisms such as gateways and portals collating links to company disclosure pages as a minimum standard in order to make the data more accessible.

The appropriateness of these legal bases may differ between Member States.

For the Disclosure Code implementation, EFPIA considers that the consent basis is the most prudent approach though the legitimate interest ground can also be used after consulting the national Data Protection Authority.

For example, the legitimate interest ground has been endorsed by the Spanish Data Protection Authority³ that has granted a waiver for the implementation of the Disclosure Code meaning that consent is not needed for the disclosure in Spain.

Additionally, the Dutch self-regulation regime and the national transparency laws have also acknowledged that there is a clear societal interest for the disclosure of individual information.

At the European level, since the first disclosure in 2016, EFPIA observed some variances in rates of consent between countries, HCPs areas of specialty, etc. These differences depend on the levels of engagement on disclosure with the HCP/HCO community, mixed reactions from the medical and media communities and cultural attitudes to transparency.

EFPIA strongly believes that transparency is best achieved without legislation.

Experience of existing national legislation demonstrates significant inconsistencies in the scope and approach of disclosure requirements. Each legal framework has its own specificities preventing a global and consistent approach for companies across Europe and common understanding for the public.

For these reasons, EFPIA and its members are fully committed to self-regulation as the optimal way to define, implement and enforce the highest ethical standards including for disclosure of transfers of value. Member states that value the transparency of these relationships over and above the individual's privacy rights have the option to endorse the legitimate interest approach to disclosure through their data protection authorities, negating the need for individual consent.

In order to continue to be successful, transparency requirements need to respond to the evolving demands of society and to solve the discrepancies emerging during their application. Self-regulation is ideally suited to address the continuous challenge and proactive adaptation.

There are significantly different socio-economic and cultural attitudes to transparency across Europe which can be reflected through self-regulation approach but that would make drafting and implementing a European legal framework costly and problematic.

b) Enforcement of the Disclosure requirements

Each year, EFPIA Member Companies **self-certify their Disclosure report**, the letters are available on EFPIA website: <https://www.efpia.eu/relationships-codes/healthcare-professionals-hcps/commitment-letters/>

Since the first disclosure in 2016, EFPIA mandated **Ernst & Young** to assess the transfers of value (ToVs) disclosed by EFPIA members companies and analyse the evolution of ToVs' amounts and consent levels.

The survey is based on the information sent by the EFPIA Member Companies. In 2018, 34 out of 40 members participated in this survey.

The objective of this survey is to direct EFPIA's future work to strive toward success in the implementation of the Disclosure Code. It provides a sound basis of comparison for the evolutions in HCP/HCO level of disclosure consent and ToVs since June 2016.

³ The Spanish DPA considered that the individual disclosure of the transfers of value is justified on the legitimate interest ground because it is essential (i) to decrease the perception risk on the influence that the HCP might have received to carry out a specific prescription, dispensing and administration of medicines; (ii) to promote a culture of integrity in transactions with HCPs and (iii) to promote the confidence of the general public in the integrity and independence of the HCPs.

The countries analysed are the ones where the Disclosure Code is implemented in full: Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, Norway, Poland, Russia, Serbia, Slovenia, Spain, Sweden, Switzerland, Ukraine and the United Kingdom.

The excluded countries, based on a deviation recognising the equivalence between the national legal/self-regulation requirements and the Disclosure Code, are: Belgium, Denmark, France, the Netherlands, and Portugal.

In Romania and in Slovakia, there are 2 deviations approved with additional requirements because some activities are excluded from the scope of the legislation (for R&D in Romania and for HCOs in Slovakia).

In Turkey, the Disclosure Code implementation has been suspended.

c) Disclosure convergence

EFPIA fully supports cross-sectorial approaches, especially in the field of Ethics & Compliance where the public and patients consider us as healthcare companies.

Medicines for Europe and MedTech have also implemented disclosure requirements for their members.

While we all share the same ethical principles and transparency's objectives, our respective disclosure requirements were designed to reflect the specificities of each sector.

d) Disclosure awareness

While the national media coverage of the Disclosure is low, there are some initiatives from Patient associations or organisations aiming to raise awareness on transparency.

An example is the **Shedding light initiative**: a project conducted by Mental Health Europe that aims at raising awareness about the importance of transparency in the field of mental health and to encourage the adoption of sunshine and transparency laws across Europe.

During 2018, EFPIA took part in multi-stakeholders' meetings organised by Mental Health Europe, provided information on the Disclosure Code and contributed to the report "Shedding light on transparent cooperation in healthcare", published in January 2019.

e) Hurdles impacting transparency and the Disclosure Code implementation

The **main hurdles** to achieving transparency through the Disclosure Code's implementation are:

- Inconsistencies in the legal and self-regulation framework
- Consent issues in general but also by country and by speciality
- Lack of external knowledge of this pharmaceutical initiative

f) Actions introduced to improve Disclosure figures

To solve these issues in implementing the Disclosure Code, EFPIA introduced the following **clarification**:

- The Board guidance related to disclosure date alignment for POs and HCPs/HCOs
- The Board guidance on indirect ToVs through PCOs
- The Board guidance related to non-interventional studies' disclosure
- The Board recommendation related to national gateways on association's websites including links to companies' disclosure reports and the CodCom additional recommendation to include a link to governmental platforms and add the PO's disclosure data

EFPIA developed a **communication** plan that includes a video, a messaging guide, info-graphics, leaflet, Q&A, documents explaining the interactions (advisory boards, grants and donations, consultancy), a document compiling the external positive statements at national level.

g) How to ensure successful disclosures in the future?

While EFPIA members dedicated a lot of resources and energy to the implementation of the Disclosure Code, this EFPIA initiative can be enhanced, and more promoted and valued, both internally and externally.

In addition, the accessibility and explanation related to disclosure can be improved.

Few patients know that Member Companies disclose the data related to their interactions with HCPs, HCOs and POs, and they are not aware that this initiative comes from the pharmaceutical industry itself.

Regarding the disclosure accessibility, we must make the data easier for patients to access and help them understand them.

Thus, the content, accessibility and communication related to the disclosure can easily be improved by EFPIA. These improvements can have a positive impact on the reputation and credibility of the sector.

The main topics for EFPIA and its members to consider are:

- **Ensure understanding**
 - Explain to HCPs why we have voluntarily implemented disclosure requirements
 - Reinforce communication: using existing documents – after updating - related to disclosure
 - Explain R&D figures and why they are disclosed in aggregate
 - Ask an HCP to be a spokesperson for disclosure
 - Prepare a patient case for transparency that shows how society/patients benefit from the interaction between the industry and HCPs. This could be used in the communication with the medical association

- **Share best practices**
 - Be more demanding and robust on the pharmaceutical industry's position. Request support from medical associations
 - When legislations are planned, national associations should use the Disclosure Code as a reference for the law to be adopted (cf. Belgium model). National associations should also guarantee the level playing field
 - Share/publish national disclosure reports (including main figures and consent rates)
 - Initiate a concerted/coordinated action through the national associations (and the local Member Companies) with the aim of getting more acceptance from HCPs to individual disclose

- **Meaningful individual figures**
 - Increase the level of positive consent (e.g. Spanish consent waiver, legitimate interest)
 - Improve the information provided in the methodological note and provide infographics explaining the activities related to the disclosure figures and how these activities contribute to patient care

- **Improve access**
 - Create platforms with searchable tool

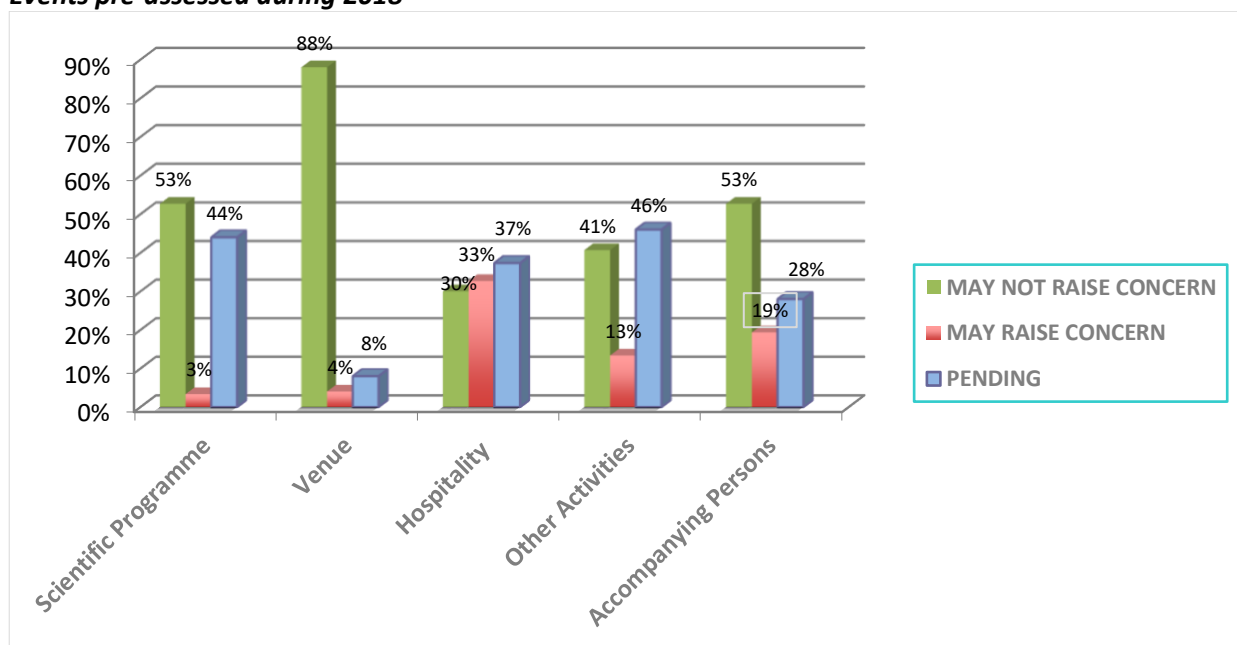
4. e4ethics 2018 report

e4ethics in the EFPIA on-line platform including pre-assessment reports of events sponsored by industry and attended by HCPs in regard of EFPIA's HCP Code. Its purpose is to serve as a reference for the EFPIA membership. Companies belonging to the EFPIA membership should be mindful of the rules and provisions applying when deciding about sponsoring, participating or collaborating in an event. **It is however the company's individual decision to decide to sponsor / participate in the event.**

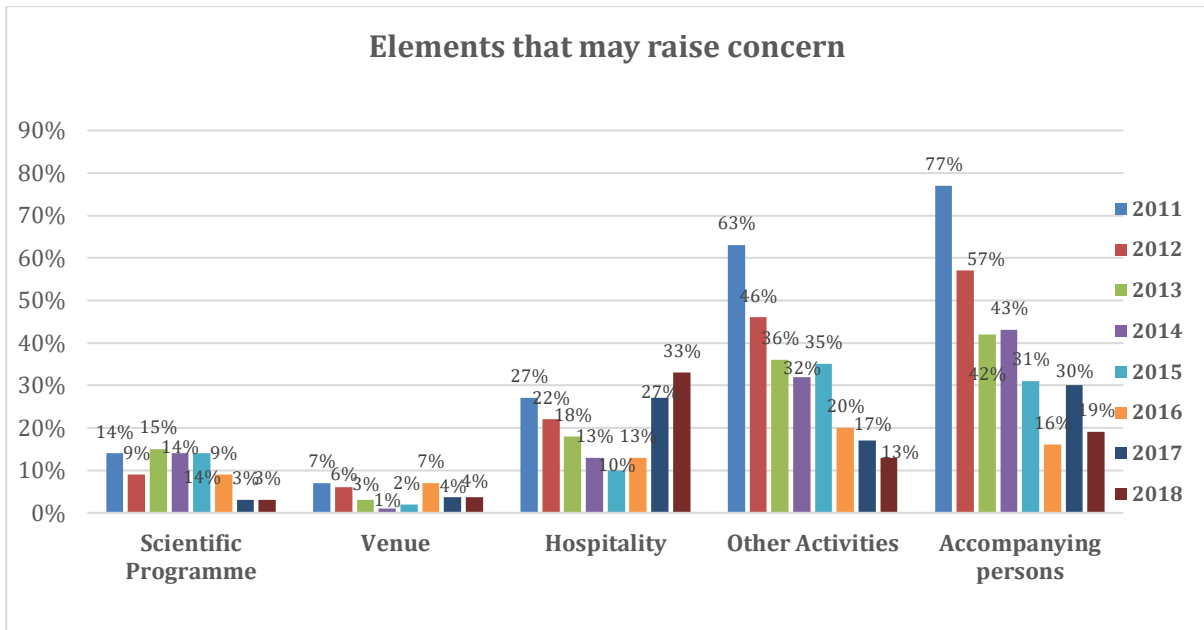
During 2018, the e4ethics platform was fully operational. 150 new events were pre-assessed and 54 second pre-assessments were conducted, bringing the total number of pre-assessments in 204.

The collaboration with Medical and Scientific Societies has been positive and regular. Few Medical and Scientific Societies have made changes to the organization of their congresses in order to be compliant with the EFPIA HCP Code provisions.

Events pre-assessed during 2018



The overall view of the events pre-assessed during 2018 was quite satisfactory compare to the previous years. Improvements were done in the area of Other Activities and Accompanying persons. The statistical data of the platform below reveal that the percentage of elements that raised concern in events has been halved in less than 5 years but still need to be improved.



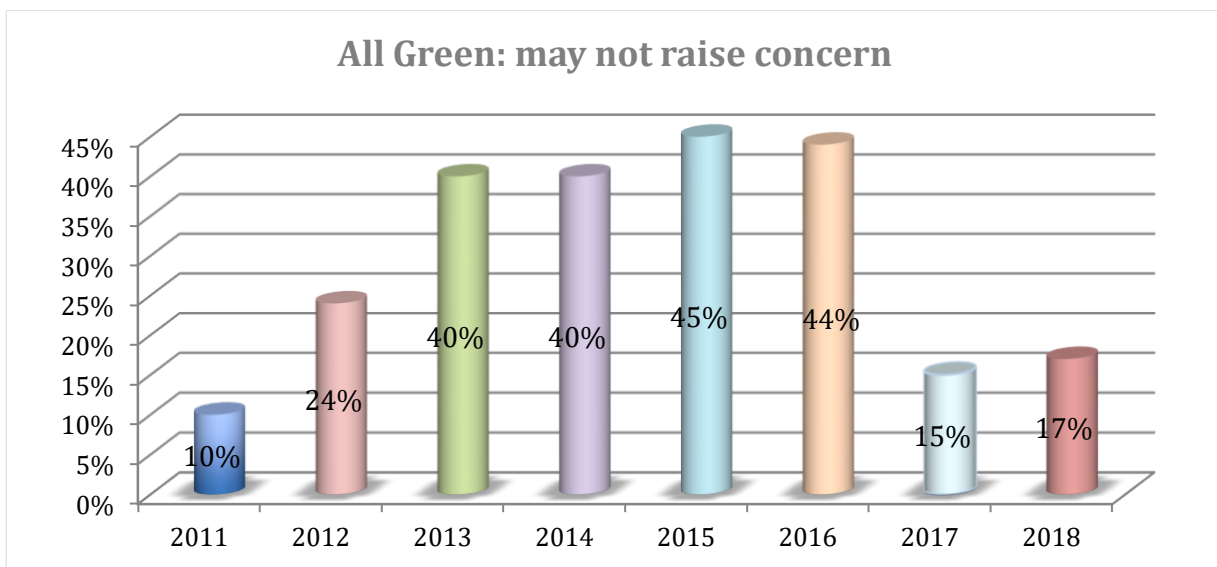
The most problematic area during the events' pre-assessment in 2018 was Hospitality, where elements that raised concern have risen from 10% in 2015 to 33% in 2018. In many cases we have established a positive relationship of mutual collaboration with the organisers, which have introduced changes in order to be compliant with EFPIA HCP Codes' provisions.

Accompanying person had a positive change from 30% in 2017 to 19% in 2018.

A positive impact was also registered for the area Other Activities.

2018 has been a positive year comparing to the previous years, but there are few elements that raise concern. Numbers are still in a negative trend.

From all the 150 events pre-assessed during 2018 only 25 of them had ALL the sections in green.



Recommendations:

- Improve collaboration with stakeholders
- More implication and coordination at national level during the validation process and national requests
- Reintroduce the site visits with the support of Member Associations
- Engaging in the reflective process of making e4ethics a binding system

ANNEX 1: 2018 NATIONAL CODE REPORTS

AUSTRIA – Pharmig

Code authority activity

In 2018, Pharmig examined 5 complaints: 4 proceedings have been initiated and 1 complaint did not fulfil formal requirements. 60% of them were introduced by pharmaceutical companies and 40% on an anonymous basis.

The Code provisions have been breached in 2 cases with regard 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 and alternative dispute resolution.

Code report

Pharmig published a Code report that includes decisions of the National Code Authority, this report is available on the website: <https://www.pharmig.at/der-verband/pharmig-verhaltenscodex/>.

The Code decisions (anonymised) are part of the Code report and are published on the website: <https://www.pharmig.at/der-verband/pharmig-verhaltenscodex/>.

The 2017 Code report is available here: https://www.pharmig.at/media/1321/pharmig_jahresbericht_2017_final_22194_de.pdf

Disclosure

The figures are the following:

- * R&D 64%
- * HCOs 22,50%
- * HCPs 13,50%

The percentage of positive consent is:

- * HCPs 18,8%
- * HCOs 67,7%

Details available on the website (German only): <https://www.pharmig.at/pharmaindustrie/transparenz/>.

Pharmig developed a brochure with the Medical Chamber to raise awareness and increase disclosure at individual level. It was distributed to all practitioners by the Medical Chamber and it is available at congresses as well as on the Pharmig website (https://www.pharmig.at/media/1484/pharmig_vhc_booklet-zusammenarbeit-aerzte_industrie-2018_de.pdf).

Code awareness

Pharmig organised training sessions for member companies on a regular base and provides several information materials. A special training course “Compliance & Code of conduct” was provided by “Pharmig Academy” (4 modules).

BELGIUM – Pharma.be

Code authority activity

Pharma.be did not receive complaints in 2018.

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

The last complaint dates from 2017 and ended with an amical settlement. It is referenced as follows on pharma.be public website: <https://pharma.be/fr/pharma-be/code-de-deontologie.html>.

Disclosure (on the basis of the Belgian legal requirements)

The figures are the following:

CATEGORIES	BENEFICIAIRES		TOTAL	
RECHERCHE SCIENTIFIQUE	Aggrégé		115.648.996 €	57%
MANIFESTATIONS SCIENTIFIQUES	HCO	23.781.539 €	39.033.549 €	19%
	HCP	15.252.010 €		
DONATIONS ET SUBVENTIONS QUI SOUTIENNENT LES SOINS DE SANTE	HCO		21.268.155 €	10%
SERVICES ET CONSULTANCE	HCP	10.092.864 €	19.541.705 €	10%
	HCO	8.089.930 €		
	PO	1.358.911 €		
AUTRES SOUTIENS	PO		7.779.325 €	4%
TOTAL GENERAL			203.271.730 €	

Pharma.be and betransparent.be developed press releases after the 2018 disclosure.

The disclosure of transfers of value in Belgium is a legal obligation (→ Sunshine Act), so no consent is required from HCPs.

Following the adoption of the Sunshine Act, an internal analysis was done to evaluate the ethical safeguards that the pharma.be code of deontology offers for each category of transfer of value published on the betransparent.be platform. Following this analysis, pharma.be's Task Force Ethics took the initiative to work on more detailed safeguards with regards to Grants and Donations. A strong deontological framework and clear criteria for the provision of Grants & Donations to HCOs was drafted and approved by the Task Force Ethics and by the pharma.be's Board and General Assembly. Those criteria will be inserted in the pharma.be code of deontology with the purpose of ensuring a framework for an ethical and responsible provision of Grants & Donations by the member companies.

Code awareness

Pharma.be organised the following trainings:

* **"Pharmacademy Compliance"**

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 is on the relations with HCPs & HCOs, publicity for medicinal products and Risk Minimisation Activities (RMA). 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

* Info session: "Working together with patient groups: overview of the current guidelines and principles"

Over the last couple of years pharmaceutical industry and patient organisations interact more and more together.

It is only through open and transparent dialogue between patient organisations and industry that it can be ensured that the patient perspective becomes an integral part on how medicines are researched, developed and delivered to patients.

This info session aims to give an update on the current Belgian framework and an insight on the EFPIA document “Working together with patient groups”. This document, which is the first one in his kind in Europe, was co-created by the representatives of the Patient organisations and the research-based pharmaceutical industry through the EFPIA Patient Think Tank with support from EFPIA’s Ethics and Compliance Committee.

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.

CROATIA – IF!

Code authority activity

One anonymous complaint was received in 2018 and is not yet solved. it refers to Article 11.2. d) concerning Hospitality and more specifically meetings with HCPs.

Disclosure

The figures are the following:

- * R&D 24,3%
- * HCOs 31,4%
- * HCPs 44,3%

The percentage of positive consent is 14 %.

The above-mentioned figures show that a quarter 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. Also, the innovative pharmaceutical industry in Croatia invested 14 percent more in R&D in 2017 than in 2016 which represents an additional confirmation of trust in Croatian HC professionals and institutions.

Furthermore, in 2017, 3 percent more healthcare professionals gave their consent than in 2016 which shows that HCPs are increasingly supporting public disclosure and full transparency of their cooperation with the pharmaceutical industry.

A higher percentage of consent can easily be linked to the positive media coverage of public disclosure. A positive association of transfers of value of pharmaceutical companies to investments in the education of healthcare professionals was achieved. Transfers of value were associated with the education of HCPs, investing in innovation and effective therapeutic procedures.

Code awareness

IF! organized the ‘*transfer of value*’ workshop for iF! member companies.

The use of EFPIA “e4ethics” platform by IF! is limited to queries concerning some international meetings taking place in the Republic of Croatia. The association also provide input to the assessments made by the platform as Host Country when requested. No feedback from IF! Member companies has been received.

CZECH REPUBLIC - AIFP

Code authority activity

3 complaints received in 2018 that came from:

- * Pharmaceutical companies: 66,6 %
- * Patients Organisation: 33,3 %

The Code provisions concerned by the complaints were related to Section 1.3 of the AIFP Code of Conduct (False or Misleading Claims) and the principle n° 2 of the Patient Code. In one case, the Code authority imposed a fine and in two cases, the request to terminate the usage of the promotional material.

Code report

No annual report was published.

Disclosure

The figures are the following:

- * R&D 68 %
- * HCOs 18 %
- * HCPs 14 %

The percentage of positive consent is:

- * HCPs 16 %
- * HCOs 97 %

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

Code awareness

AIFP Ethics Committee members participated on the AIFP workshop “Continuing Medical Education (CME) Disclosure” that was held on 24th and 25th April 2018 in AIFP office. The main topic of this event was to introduce this initiative to Professional Congress Organizers (PCOs). AIFP received very positive feedback from side of participants.

On Thursday, November 22nd, 2018 in residence of member company Shire, the 8th Day with AIFP Ethics Committee for the representatives of AIFP member companies was held. The main topics of the meeting were Transparency in Pharmaceutical Industry, Topical compliance issues , Compliance within the pharmaceutical industry – panel presentation, Opinion of the State Prosecutor to marketing activities within the pharmaceutical industry, Patients support programs, Relationship between pharmaceutical industry and patient organisations, Status of nurses regarding communication with pharmaceutical industry, Scientific-exchange vs. Off-label promotion and Annual report of AIFP Ethics Committee activities.

AIFP organized 41 regular examinations of sales representatives of the AIFP member companies in 2018.

AIFP uses occasionally EFPIA “e4ethics platform” and provide input to the assessments made as Host Country. Members of the Trust & Reputation platform discussed request received from EFPIA “e4ethics platform” and how to proceed these requests in the future.

DENMARK – ENLI (LIF)

Code authority activity

14 complaints were received in 2018 (please note that companies are obliged to report all activities aimed at HCPs to ENLI – we examine approx. 2.000 cases each year. Only 14 of these cases in 2018 started as a complaint). All of them were submitted by pharmaceutical companies.

The Code provisions have been breached in 11 cases (one case is not final yet – awaiting the appeal board’s decision). These breaches relate mostly to Art. 4(2) which states that the promotion of a medicinal product must be sufficiently complete and objective, and it must not mislead or exaggerate the properties of the

medicinal product. Information in promotion material must be in accordance with the approved summary of product characteristics of the medicinal product.

The sanctions pronounced are mostly fines.

Code report

The Code report, in Danish, is available here: <http://www.enli.dk/media/49795/aarsberetning-2018.pdf>.

The executive summary, in English, here: <https://documentcloud.adobe.com/link/track?uri=urn%3Aaaid%3Aascds%3AUS%3A618453d0-70fa-4c92-8f10-3a35a3bcabed>

Consequences of the Code authority activity

On the therapeutic areas where the competition is strong, we see the most complaints. Cases that are reported by the industry-media are mostly regarding non-compliant advertisements (and mostly the story of the competing companies) and – if any – use of non-compliant meeting venue.

Some cases received media attention – but mostly it is the story of the two competing companies that is interesting to the media.

Disclosure

Disclosure in Denmark is by law, administered by the Government: Danish Medicines Agency.

Code awareness

Code trainings

Basic training in promotional activities towards HCPs – both advertising and educational meetings/training sessions

- * 5 hours in one day
- * The course is offered 4 times a year
- * We touch upon all the rules in the Danish Promotion code (equivalent to EFPIAs HCP Code)

Advanced training in promotional activities towards HCPs – both advertising and educational meetings/training sessions.

- * 5 hours in one day
- * The course is offered 2 times a year
- * We touch upon grey areas and the training revolves around recent rulings from the Ethical Committee

Nordic compliance course – Denmark, Sweden, Norway and Finland are represented

- * 7 hours in one day
- * The course is offered once a year
- * We touch upon grey areas and the training revolves around hot topics in the Nordic countries, so that the participants can get an insight on how each of the Nordic countries assess e.g. a specific commercial or postings on LinkedIn or other Social Media.

1-2 half or full day training sessions a year in pharmaceutical companies who have requested this - tailored specific to the needs of the company.

The Danish association uses EFPIA “e4ethics” platform and contribute to providing input to the assessments through the validation team and as Host Country when requested. No feedback has been received from Member Companies.

FINLAND - PIF

Code authority activity

12 complaints received in 2018:

- * Inspection Board I (marketing and information to the consumers): 2 cases
- * Inspection Board II (marketing to the HCP's): 6 cases

- * Supervisory Commission (complaints of the decisions made by Inspection Boards): 4 cases

The complaints came from:

- * Pharmaceutical companies: 90%
- * National Code Committees: 10% (1 case)

The Code provisions have been breached in 9 cases:

- * Inspection Board I: 1 case
- * Inspection Board II: 5 cases
- * Supervisory Commission: 3 cases

The following provisions were most frequently breached:

- * using study results in a misleading way
- * using arguments which are not in line with SPC

The sanctions imposed were:

- * request to abstain from incorrect activity
- * order to rectify and correct the measures taken
- * sanction payments between 5.000 – 40.000 euros per case
- * processing charges 2.000 euros, 3.000 euros or 5.000 euros per case

Code report

A Code report was published including decisions made by PIF Inspections Boards/Supervisory Commission at:

http://www.laaketeollisuus.fi/sites/default/files/attachments/laakemarkkinoinnin_valvontakunnan_toimintakertomus_2018.pdf (only in Finnish).

Disclosure

The figures are the following:

- * R&D 59.4% (19.3 mil euros)
- * HCOs 13.2% (4.3 mil euros)
- * HCPs 27.4% (8.9 mil euros)

The percentage of positive consent is 68% (same as previous year);

As the R&D figure is relatively high and represent 60 % of the total, it raises the question if all the ToV's in this category are reported correctly.

Code awareness

PIF organises information meetings/trainings for our members on a yearly basis.

PIF organises, also on a yearly basis, a meeting for companies offering marketing services to pharma companies explaining the Code of Ethics and sharing best practices.

PIF provides input to the assessments made by the EFPIA "e4ethics" platform as Host Country when requested. No feedback was received from Member Companies.

FRANCE - Leem

Code authority activity

No complaints received in 2018. There was one mediation.

Code report

The 2017 Code report is available at: <https://www.leem.org/rapport-dactivite-2017-du-codeem> The 2018 report will be published in May 2019.

Code awareness

Leem uses the EFPIA e4ethics platform and provides input to the assessments as Host Country when possible. No feedback received from Member Companies on the platform.

GERMANY – FSA/VFA

Code authority activity

36 complaints received in 2018 that came from:

- * Pharmaceutical companies: 42%
- * Anonymous: 36%
- * FSA Management Director: 22%

The Code provisions have been breached in 4 cases. These breaches relate to missing “appropriate” venues for events, prohibition of gifts, inconvenience caused by medical sales representatives to HCPs.

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: www.fsa-pharma.de/downloads

Consequences of the Code authority activity

A member company invited HCP’s to a promotional and scientific meetings, held in a hotel at the shores of the Chiemsee, a well-known area for leisure and holidays, at the countryside close to Austria. A breach was found because the invitees did not come from the neighborhood of the place but from all parts of the south of Germany.

The perception of the meeting was more liked to leisure activities for HCP’s, nut not to the training of HCPs in scientific areas.

Disclosure

The figures are the following:

- * R&D 65,8%
- * HCOs 16,9%
- * HCPs 17,3%

The percentage of positive consent is around 20%.

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 year. The level of positive consent went down from 25 to 20%. This development mainly results from the negative press coverage of the Spiegel data base and the articles based on it. Another aspect was still the anticorruption law that came into force in 2016 and the national implementation of the GDPR which brought the value of individual data again to the mind of HCPs. FSA/vfa and their members did a lot of outreach efforts to explain the initiative and to convince more HCPs to give their consent. The association increases its efforts for the next transparency period.

Code awareness

The association organized two workshops for external stakeholders and 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.

FSA promotes the EFPIA e4ethics platform towards the FSA membership and provides input to the assessments as Host Country when requested. No feedback received from Member Companies.

GREECE - SfEE

Code authority activity

During 2018, the 1st Instance Committee:

- * examined one complaint filed from one member company and
- * investigated one case on its own initiative

The complaint contained allegations of breach of art. 6.2, 6.5.1., 6.5.3, 6.6. and 6.8.1. of the SfEE Code of Ethics.

The investigation was initiated based on art. 2 of the SfEE Code of Ethics.

No sanctions were imposed as:

- * in the case of the complaint, the case was closed through an amicable settlement of the parties involved.
- * in the case of the investigation, the Committee did not find proof of violation and the case was closed.

Code report

SfEE published a Code report including decisions prepared by the National Code Authority at the following links:

- * <https://www.sfee.gr/category/ipefthinotita/diafania-kodikas-deontologias/apofaseis-a-epitropis-kwdika-deontologias/>
- * <https://www.sfee.gr/category/ipefthinotita/diafania-kodikas-deontologias/apofaseis-b-epitropis-kwdika-deontologias/>

However, access is available only to member-companies through a password provided to them by SfEE.

Disclosure

The figures are the following:

- * R&D 20%
- * HCOs 50%
- * HCPs 30%

Disclosure in Greece takes place based on a legal provision, so the HCPs consent is not required.

Further to the above, Disclosure in Greece, pursuant to the provisions of art. 66 para. 7a of Law 4316/2014, for ToVs that took place during years 2016 and 2017, and where the prior consent of the HCP was not obtained, was made following the DPA's Opinion, only for ToVs related to promotional events.

However, on 6/6/2018, EOF, the competent supervisory Authority for the implementation of art. 66 para 7a of L. 4316/2014, issued an announcement requesting the Disclosure of any ToV made within the context scientific event/advisory board that took place in Greece during 2018.

Following such announcement, some Pharma companies disclosed individually all ToVs to HCPs, related to any kind of scientific events (both promotional and non-promotional) that took place during 2018, even where the HCPs prior consent was not obtained (abiding to EOF's announcement), while other Pharma companies proceeded to individual disclosure of ToVs related solely to promotional events that took place during 2018, where the HCPs prior consent was not obtained (abiding to the DPA's opinion).

Code awareness

In March 8th, 2018 SfEE, committed to the constant request of its members for more focused information, organised the "2nd SfEE Congress Pharma Law & Compliance" a daily congress on the latest legal, regulatory, tax, development and compliance issues, affecting our sector Europe-wide, with special reference to issues having particular importance for the Greek market and great gravity for our member companies.

SfEE uses the EFPIA e4ethics platform and helps providing input to the assessments as Host Country when requested. We receive feedback from SfEE's Congress Evaluation Committee.

HUNGARY - AIPM

Code authority activity

No complaints were received by the association in 2018.

Code report

The association does not publish a Code report.

Disclosure

The figures are the following:

* R&D 67%

* HCOs 23%

* HCPs 10%

The percentage of positive consent is:

* HCOs: 59%

* HCPs: 43%

The AIPM put in place a gateway that was created on the Hungarian transparency website (<http://transzparencia.org/kozzeteteli-adatok>).

Code awareness

AIPM organised two workshops for external stakeholders. The association also conducted two meetings of the compliance officers to inform them about latest developments and share best practice. It also organised several webinars on current issues as well as monthly update webinars.

ICELAND - Frumtok

Code authority activity

No complaints received by Frumtok in 2018.

Code report

Frumtok does not publish a Code report

Disclosure

The figures are the following:

* R&D 62%

* HCOs 7%

* HCPs 31%

IRELAND - IPHA

Code authority activity

Between July 2017 and June 2018, the Code Council adjudicated upon two referrals and one Complaint. The Code Council found that Code had been breached in both cases. One of the referrals was appealed and the Appeals Board concurred that the Code had been breached in that case.

Code report

IPHA does not publish a Code report.

Code awareness

IPHA organized trainings related to the Code.

LATVIA - SIFFA

Code authority activity

SIFFA examined 6 complaints that came from:

- * Pharmaceutical companies: 2 (incl. 1 non-association member)
- * Healthcare Organisations: 2
- * Journalist articles on the Internet: 2

The Codes provisions breached relate to non-regulatory drug advertising:

- * Advertising of prescription (Rx) medicines to the public in the media and social networks;
- * Incompatible measure organizing.

As a sanction, communication with Medical Professional Organizations and Media Representatives on Advertising Rules for Medicines as well as with pharmaceutical companies (incl. one company non-association member), reminding them of the arrangements for organizing events for HCP.

Code report

The decisions of the National Code Authority were not published.

Consequences of Code authority activity

The journalist interviews HCP by advertising prescription drugs.

The content of the information and the way in which it is presented shall be deemed to be advertising within the meaning of Advertising Act as well as Medicine Advertising Rules, in which Prescription medicines, included in the Latvian Medicines Register, medical practitioners advertise to society; this may harm the public's use of inappropriate medicines and impact reputation of the industry.

The involved media representative disagreed with the Ethics Commission's opinion, so the Commission asked the health inspectorate to inform this media about compliance with the advertising rules. This case was not discussed further in the media.

Disclosure

In view of the provisions on advertising of medicinal products, which provide detailed disclosure of data in Latvia, it is advisable not to duplicate the disclosure under the Disclosure Code, similar as in some EU countries.

Code awareness

Contrary to previous years, no training was organised in 2018 by SIFFA.

SIFFA provides answers to members' questions, publishes Q&A.

LITHUANIA - IFPA

Code authority activity

IFPA examined 14 complaints in 2018 that came from:

- * Pharmaceutical companies: 86%
- * Healthcare Professionals: 7%
- * National agencies: 7%

The Code provisions have been breached in 12 and relate to “Regulations of promotion of medicinal products”.

The sanctions consisted in warning of companies including announcements in national Code weblink with or without Companies names.

Code report

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

Disclosure

The figures are:

- * R&D 5,4 mln. eur
- * HCOs/HCPs 2,9 mln. Eur (social projects and education)
- * Total IFPA members, 17th company’s investment in Lithuania 41,4 mln. EUR (out of which- 33,1 mln. EUR Taxes paid to the State)

Code awareness

Every employee of our companies is obliged to make certification on EFPIA code annually.

IFPA uses EFPIA “e4ethics” platform but does not provide input to the assessments as Host Country. The association receives feedback from Member Companies.

NORWAY - LMI

Code authority activity

LMI examined 8 complaints in 2018 (5 by the Committee for Drug Information, 3 by the Appeal Board) that came from:

- * Pharmaceutical companies: 2
- * Healthcare Professionals: 2
- * National Code Committees: 4

The Codes provisions that have been breached in the 8 cases are related to the Article 8.4 of the Norwegian Code (Balanced information).

The sanctions imposed were fines between NOK 25.000 and NOK 130.000 (EUR 2500 – EUR 13.000).

Code report

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

English and Norwegian version of the Code report is published here: <https://www.lmi.no/lmi/fagomrader/lover-og-regler/lmis-regelverk/>

Disclosure

The figures are the following:

- * R&D 72%
- * HCOs 15%
- * HCPs 13%

The percentage of positive consent is 76%.

The Companies, most HCPs, the Medical Association and Hospital owners support disclosure.

Code awareness

5 different trainings, with approximately 250 participants, were organised.

E-learning, mandatory for most employees in the member companies, was organised with approximately 1300 participants during the last two years.

LMI has its own “Concept Approval”, (national version of “e4ethics”). International Congresses in Norway should apply for e4ethics.

LMI provides input to the assessments made by the EFPIA “e4ethics” platform as Host Country when requested.

No Member Companies feedback on e4ethics but a very high support to the national concept approval system.

POLAND - INFARMA

Code authority activity

INFARMA examined 2 complaints in 2018 made by pharmaceutical companies.

The Codes provisions have been breached in the 2 cases.

The sanctions imposed were the following:

- * Disciplinary Court at the Employers of Innovative Pharmaceutical Company INFARMA in Warsaw (1st Instance) granted the company XYZ reprimand in connection with advertising activities conducted during the XIX Scientific Congress of the Polish Diabetes Association based **on art 10 paragraph 1 of the Code od Good Practice.** The court obliged the parties to the dispute to develop guidelines regarding the involvement of publicly known persons in educational events for doctors.
- * Two disciplinary court sessions (1st and 2nd Instance) - Disciplinary Court of Second Instance at the Employers' Association of Innovative Pharmaceutical Companies INFARMA in Warsaw, dismissed the appeal of XYZ and upheld the decision of the Disciplinary Court of First Instance, dated 19.06.2018, in which the Disciplinary Court recognized XYZ was found guilty of having violated **of Article 10 paragraph 2, 3, 4; Art. 15 paragraph 1; Article 16; Article, 18 paragraph 1 and 2; 19 paragraph 1 of the Code of Good Practice.**

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 with the proper anonymization of individuals’ personal data ensured.

The adjudications which are made available are used by Member Firms or the Union for internal training purposes.

The evidence collected in the cases in which the Court adjudications were issued may also be used by the Union Office for training purposes, unless the use thereof causes the risk of a breach of any personal rights.

Consequences of Code authority activity

Disciplinary Court at the Employers of Innovative Pharmaceutical Company INFARMA in Warsaw (1st Instance) granted the company XYZ reprimand in connection with advertising activities conducted during the XIX Scientific Congress of the Polish Diabetes Association based on art 10 paragraph 1 of the Code od Good Practice. The court obliged the parties to the dispute to develop guidelines regarding the involvement of publicly known persons in educational events for doctors. Currently Ethics & Transparency Working Group finalizing the guidelines.

Disclosure

The figures are the following:

- * R&D 60 %
- * HCOs 20 %

- * HCPs 20 %

The estimated percentage for positive consent is (more details will be available by the end of April):

- * HCOs 80 %
- * HCPs 20 – 25 %

For the association, these results are similar to previous years.

Code awareness

In March, 2018 – training sessions for HCO to promote the Event Certification Process (good practices implementation in Poland)

Scope of the system:

- * scientific conferences for HCP taking place in POLAND
- * obligatory Certification is for national, regional and local scientific events which following criteria:
- * are organized by third parties (certification is not required for events where the organizer or co-organiser is a Member of INFARMA),
- * are addressed to healthcare professionals,
- * contain at least 3 (clock) hours of substantive lectures,
- * concern issues from the fields of medicine or pharmacy related to the treatment or prevention of diseases, or the use of specific medicinal products, treatment or diagnostic methods,
- * take place in Poland

Who can submit a conference for assessment?

- * professional congress organizing entities
- * hospitals
- * societies
- * foundations
- * universities / educational institutions
- * publishing agencies

USE OF THE CERTIFICATION SYSTEM:

- * it's necessary to set up a Certification System User account.
- * the first time System Users undergo an online training which is completed by taking a short test
- * Users can access the functions of the Event Certification System

Success:

Significant educational effect on event organizers & pharma industry

Website with all detailed information about System - <https://certyfikacja.infarma.pl/o-certyfikacji/kryteria/>

RUSSIA - AIPM

Code authority activity

AIPM examined 4 cases in 2018 introduced by pharmaceutical companies.

The Code provisions have been breached in 3 cases and relate to Clauses 2.3.2 and 2.3.4 of the AIPM Code of Practice.

The following sanctions were imposed:

- * To stop distribute advertising materials which do not comply with the AIPM Code of Practice provisions;
- * To oblige employees of the violating company to complete an online training session on the Code;
- * To inform the parent company about the violation;
- * To notify AIPM of the measures taken to implement the Special Panel within 10 working days.

Code report

The cases are published at:
http://www.aipm.org/netcat_files/364/353/h_1389378243ddf8a3253db753b7a20e67

Disclosure

The figures are the following:

- * R&D 44%
- * HCOs 30%
- * HCPs 26%

The percentage of positive consent is 18%.

Code awareness

AIPM has a Code on-line trainings platform (485 participants from 62 companies).

SERBIA - INOVIA

Code authority activity

One case introduced by a pharmaceutical company was examined by Inovia in 2018 but the Code was not found to have been breached. No sanctions were imposed and nor publication were made by the association.

Disclosure

The figures are the following:

- * R&D 48%
- * HCOs 18%
- * HCPs 34%

The percentage of positive consent is 30%.

The association notes a huge spread among member companies, from those below 5% of positive consent to those with more than 90% which indirectly shows that positive percentage is more company-related than market-related.

Code awareness

Inovia uses EFPIA “e4ethics” platform and provides input to the assessments as Host Country when requested but has no feedback form member companies.

SLOVENIA – Forum EIG

Code authority activity

Forum EIG examined one case in 2018 introduced by several members of the association. They informed Forum Board of potential violation of the Code and based on such information, the Board of the association filed an official complaint to the Ethic Committee for the Supervision of the Provisions of Ethical Codes. The Code provisions that have been breached are related to the “support of event at an inappropriate location”.

The following sanctions were imposed:

- * reminder to infringer with an order to cease with such violations and
- * pecuniary fine (10.000 EUR) as an accessory sanction.

The decisions are not published.

Consequences of Code authority activity

Several members were invited to sponsor an event taking place in a congress centre which is a part of the 5-star hotel. This venue has been a source of discussion in the past since its marketing staff argued that a congress centre without a categorisation of its own should not qualify as a 5-star location. The association

has taken an opposite standpoint and, in the past, already sent reminders to its members to that end. For the event at hand, all apart one member withdrew from sponsorship engagements.

The association does not believe there was much impact on reputation, in particular if the gravity of the infringement is taken into account. There was no media attention since the decision was never made public.

Disclosure

The figures are the following:

- * R&D 12%
- * HCOs 65%
- * HCPs 23%

The percentage of positive consent is relatively stable over the years and it is estimated on around one third of HCPs. The level of individual consent is constant over the last years.

FORUM MEMBERS (22 member companies, representatives of Innovative Pharmaceutical Industry in Slovenia + Forum as a business entity)

	2015		2016		2017	
	NET in €	SHARE (%)	NET in €	SHARE (%)	NET in €	SHARE (%)
TOTAL ToV disclosure amount on HCP level	1,6 mio	20,1 %	1,9 mio	22 %	2,1 mio	22,6 %
TOTAL ToV disclosure amount on HCO level	5,7 mio	69,9 %	5,5 mio	65 %	6 mio	65,2 %
TOTAL ToV disclosure amount for R&D	0,8 mio	10 %	1,1 mio	13 %	1,1 mio	12,2 %
TOTAL ToV disclosure amount on FORUM level; 23 companies	8,1 mio		8,5 mio		9,2 mio	

General trends:

- * Stable growth in TOTAL ToV amount
- * Relatively stable proportions of ToV distribution (in share / %)
- * Slight decrease in R&D investments noticed in 2018 (ToV report for the year 2017)
- * Positive consent rate is relatively stable over the years and it is estimated on around one third of HCPs

Code awareness

No trainings were organised in 2018. Info events were organized in 2016 before first ToV disclosure made public.

Forum EIG uses EFPIA “e4ethics” platform and knows that several members use the platform for assessment of international events. The association has recently put a link to the platform on Forum’s website. The association has recently assisted with pre-assessment of ESPID 2019 congress which will take place in Ljubljana in May 2019. No feedback was received from member companies so far.

SPAIN – FARMAINDUSTRIA

Code authority activity

Farmaindustria examined 6 cases in 2018 that came from:

- * Pharmaceutical companies: 50% (3)
- * National Code Committees: 50% (3). Issued by the Surveillance Unit.

The Code provisions that have been breached in the 6 cases are the following:

- * Article 1 Marketing authorization for medicines
- * Article 2 Information on medicines to be made available
- * Article 3 Information on medicines and its substantiation
- * Article 5 Transparency in promotion of medicines
- * Article 7 Distribution of promotional material for medicines
- * Article 8 Digital environment
- * Article 10 Guarantees of independence
- * Article 16 Services provided by healthcare professionals and healthcare organizations

Apart from its publication (*name and shame*), corrective measures were adopted and also, in some cases, pecuniary sanctions imposed.

Code report

Public information of all the cases is available at www.codigofarmaindustria.org.

The Code report including decisions prepared by the National Code Authority will be available as from July 1st 2019 here: <http://www.farmaindustria.es/web/documentos/memorias/>

Consequences of Code authority activity

A case related with digital environment and the use of social media by pharmaceutical companies and their representatives.

With the collaboration of different working groups, companies have realized and accepted the need to improve and reinforce internal procedures and measures on this regard.

The case impacted the industry's reputation positively. Our member companies have put in place a lot of efforts and corrective measures to do things correctly and respecting any applicable legislation or rule. A general principle/statement have been assumed: "activities or practices banned off-line must also be banned on-line". The case did not receive media attention. No English version of the case is available on the website.

Disclosure

The figures are the following:

Transfers of Value (TOTAL: 564 million euro)

- * R&D 251 million euro (44.50%)
- * HCOs 130.5 million euro (23.14%)
- * HCPs 182.5 million euro (32.36%)

The percentage of positive consent is 100% (thanks to the Spanish consent waiver).

No material or significant changes in comparison with 2016 ToV. The 100% positive consent for individual disclosure did not produce any impact on the interactions with HCPs. Therefore it demonstrates and reinforce that pharmaceutical companies interactions with HCPs and HCOs are legitimate and based on professionalism and responsibility principles.

Code awareness

The Code of Practice Surveillance Unit organises and participates in several training sessions (in-company training, courses, post-doctoral courses, etc.).

The association is an active member of EFPIA e4ethics validation team. It receives sporadically feedback from member companies. In some cases, when comparing e4ethics pre-assessments and Farmaindustria third parties event platform pre-assessments.

SWEDEN – LIF

Code authority activity

The Information Practices Committee (NBL) handled 13 complaints 2018 that came from:

- * Pharmaceutical companies: 47%
- * Healthcare Organisations: 15 %
- * National agencies: 15 %
- * Pharmacist: 8%
- * Industry's Information Examiner Committee (IGN): 15 %

The Code provisions have been breached in 8 cases and relate to the information provided by the pharmaceutical industry that, in connection with the marketing the medicinal products, is targeted at the general public.

The sanctions imposed were fines of 130 000 SEK.

Code report

The Code report is available at: NBL:
<https://lif.se/contentassets/411411b9069548419e08a73b22a5ff0b/nbl-verksamhetsberattelse-2018.pdf>

Consequences of Code authority activity

Roche organized a meeting in Athens where patient organizations attended. The case concerned whether the activity was to be regarded as consultation or participation in an educational activity. If the activity was to be regarded as a training activity, the companies could pay 50% of the total cost for the participant, otherwise 100%. The case was discussed in media but no impact on the industry reputation over time.

Several articles were published in the newspaper Dagens Medicin, which is aimed to, and well known by, healthcare professionals.

The case is available only in Swedish at: <https://www.lif.se/etik/ign-och-nbl/detaljer/?id=3317>

Disclosure

The figures are the following:

- * R&D 86%
- * HCOs 9%
- * HCPs 5%

The percentage of positive consent is:

- * HCP 79%
- * HCO 95%

The association notices a minor drop in consent from HCPs from 83 % in 2016 to 79 % in 2017.

Code awareness

Five training sessions were held in 2018 in the ethical regulations and 190 people attended.

SWITZERLAND

The Swiss association publishes an annual report of the Pharma Code and the Pharma Cooperation Code each year, the 2018 annual report is available here: <https://en.scienceindustries.ch/involvement/pharma-code-and-pharma-cooperation-code/code-secretariat-annual-reports>

TURKEY – AIFD

Code authority activity

AIFD examined 2 complaints in 2018 that came from:

- * Pharmaceutical companies: 2
- * Ex-employee: 1

The Code provisions have been breached in 1 case and relate to the accuracy of the promotional claims, incorrect referencing of scientific articles.

The sanctions imposed was a “warning”. The publication is not available outside member companies.

Consequences of Code authority activity

The one case which could have damaged the industry reputation was the complaint of an ex-employee, claiming that his previous company and other companies are in conflict of interest with HCPs, by helping them fulfil prescriptions; the ex-employee shared as video recorded with the hospital staff.

By conducting a swift, rigorous and professional investigation, the alleged member company had proven that the allegation was not correct. The complaint was sent to Presidential Complaint Board as well. The Board waited the conclusion of the AIFD Adjudication process. AIFD shared the report with the Board. No reaction. (we have assumed the Presidential Board also concluded that the allegation is not reflecting the reality.)

This case did not receive media attention. We do not publish cases on AIFD website.

Disclosure

In Turkey, there is no public disclosure but full reporting of ToVs to the Ministry of Health Agency, TITCK. 100% (No consent, no ToV rule of TITCK).

Code awareness

AIFD does not really use EFPIA “e4ethics” platform, because every congress participation needs to be approved by the MoH Agency, TITCK. The association provides input to the assessments as Host Country when requested. Feedback from Member companies are rare.

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.