

EFPIA Report on Ethics & Compliance Activities June 2020

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 – 2019 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 2019 and into mid-2020.

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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 2019 and into 2020:

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

The new provisions, introduced during the consolidation process of the EFPIA Code, are transposed in the 21 following countries: Austria, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Germany, Greece, Finland, Hungary, Iceland, Lithuania, Macedonia, the Netherlands, Norway, Romania, Russia, Serbia, Slovenia, Switzerland, Turkey.

Due to COVID-19, the CodCom decided to extend the transposition deadline (cf. **Annex 3**).

- **National complaint procedure implementation**

Based on a survey analysing the provisions in the national Codes, the CodCom decided to remind the applicable rules to the Member Associations and to maintain the current provisions in place.

The EFPIA Code provisions set 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, an annual report summarizing the work undertaken by it in connection with the implementation, development and enforcement of its National Code during the year.

- **Disclosure**

- Disclosure period

The CodCom has reminded to the Member Associations that the disclosure period for healthcare professionals (HCPs)/healthcare organisations (HCOs)/patient organisations (POs) must be aligned.

- The common reporting periods for publication of Transfer of Values (ToVs) to HCPs, HCOs and POs is set during the time interval from 20th to 30th June each year at the latest
- Where the Member Association Codes provide for a different time interval applicable in their countries, this should consistently apply to all disclosure obligations in application of the EFPIA Code

- Disclosure deviations

Based on Article 23.02 of the EFPIA Code and due to almost equivalent legal requirements in place in Latvia and Lithuania, the CodCom has submitted to the Board's approval a request for a deviation of the application of the disclosure Code requirements.

In Latvia, there is a legal framework but the company do not have to disclose the ToVs related to Research & Development (R&D) and the payment to the HCPs for the preparation of publications.

In Lithuania, the disclosure legal framework does not include the ToVs related to R&D and to the POs.

Both associations are committed, by discussing with the Ministry of Health or through completing the data via a mandatory self-regulation, to ensure that the disclosure will be equivalent with the EFPIA Code requirements.

- **e4ethics**

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

Recently, EFPIA has observed an increasing lack of commitment from EFPIA members and stakeholders in the compliance with the requirements laid out in the e4ethics assessments platform, as well as an increase of elements that may raise concern regarding the application of ethical rules during events.

Such developments combined with the current external environment relating to the reputation of the pharmaceutical industry led the ethics & compliance community to consider that it is time to strengthen EFPIA's self-regulation by reinforcing the e4ethics' events assessment platform by making adherence to it binding for EFPIA Member Companies.

b. Ethics & Compliance Committee

For 2019-2021, the E&CC has revised its priorities on the basis of E&CC members' outcomes as follows:

1. Enhancing self-regulation

This priority topic will focus on 2 areas:

(a) Communication & engagement:

- Two Code trainings were organised: one for the EFPIA members in charge of Ethics & Compliance on the 20th of February 2020 (with 150 participants) and another one for all EFPIA members on the 2nd of March 2020 (with 330 participants)
- The communication plan will include an interactive quiz, a video and a blogpost

(b) Content enhancement and transparency that includes the improvement of e4ethics scheme and the development of additional Code materials.

2. Embracing digital era

The previous Internet guidelines (Annex B of the HCP Code) have been revised and updated to a document that reflects the current digital environment.

The new document named Principles for the use of digital channels has been added as Annex G into the EFPIA Code (**Annex 2**).

This document includes the principles applicable to all types of communication, a section dedicated to the identification of the allowed information for the different digital channels and EFPIA guidance for the use of various digital channels.

3. Evolving ethical guidance

The focus is to provide a decision-making framework to embed our ethical principles in current and forward-looking challenges where the Code doesn't provide guidance.

2. COVID-19: EFPIA and IFPMA-EFPIA-PhRMA guidance

During the COVID-19 pandemic, EFPIA and its members remained fully committed to EFPIA Code requirements. We have continued implementing and applying the highest ethical standards as well as applicable laws and regulations such as competition, data protection, anti-bribery and anti-corruption legislation.

The EFPIA ethical principles have helped in assessing urgently the appropriateness of activities:

- **Patients first**
- **Integrity**
- **Respect**
- **Transparency**

Nevertheless, the COVID-19 pandemic has directly impacted the transposition of the EFPIA Code in the national Codes and the disclosure provisions.

Therefore, EFPIA has drafted guidance to extend certain time periods in relation to meeting commitments relevant to these two specific topics.

Due to the lockdown, the interactions and activities that are needed to maintain the scientific exchange, have moved to virtual to protect the health and safety of patients and healthcare professionals.

In addition to maintaining the EFPIA, IFPMA, and PhRMA Codes of Practice standards in virtual settings.

The 3 organisations have decided, for the first time, to jointly issue guidance on Virtual International Medical Congresses impacted by COVID-19, which will be in effect until December 31, 2020.

Besides this joint guidance, EFPIA guidance includes the decision endorsed by the EFPIA members in May to prohibit the provision of meals for the healthcare professionals attending individually a virtual congress.

The two guidance are in **Annex 3**.

3. e4ethics 2019 report

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

e4ethics is the EFPIA on-line platform including pre-assessment reports of events sponsored by industry and attended by HCPs in regard of EFPIA's 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 2019 the e4ethics platform was fully operational. 155 new events were pre-assessed, with 45 first pre-assessments, 104 second pre-assessments, 5 third pre-assessments and 1 fourth pre-assessment were conducted, bringing the total number of pre-assessments in 272.

303 emails were exchanged along the year with Medical and Scientific Societies and PCOs. The collaboration with them has been positive and regular. Some Medical and Scientific Societies have made changes to the organization of their congresses in order to be compliant with the EFPIA HCP Code provisions.

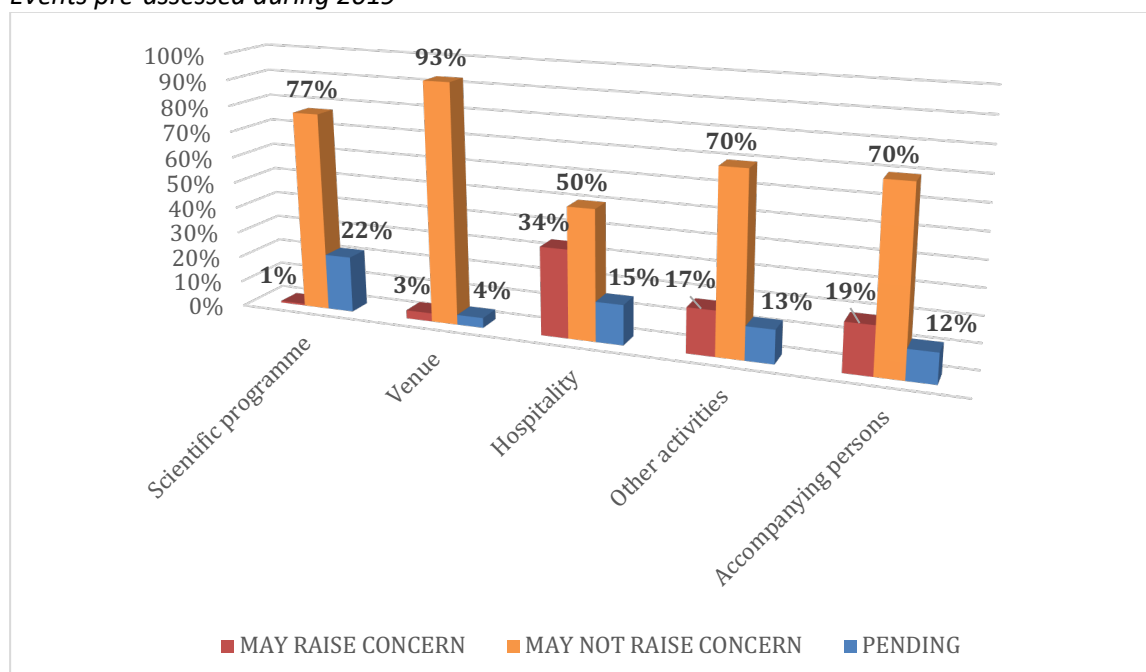
New events pre-assessed in 2019: 155 events

Total pre-assessments in this period: 272 pre-assessments

	MAY RAISE CONCERN	MAY NOT RAISE CONCERN	PENDING
Scientific programme	1	120	34
Venue	5	144	6
Hospitality	53	78	24
Other activities	27	108	20
Accompanying persons	29	108	18

ALL GREEN 45

Events pre-assessed during 2019



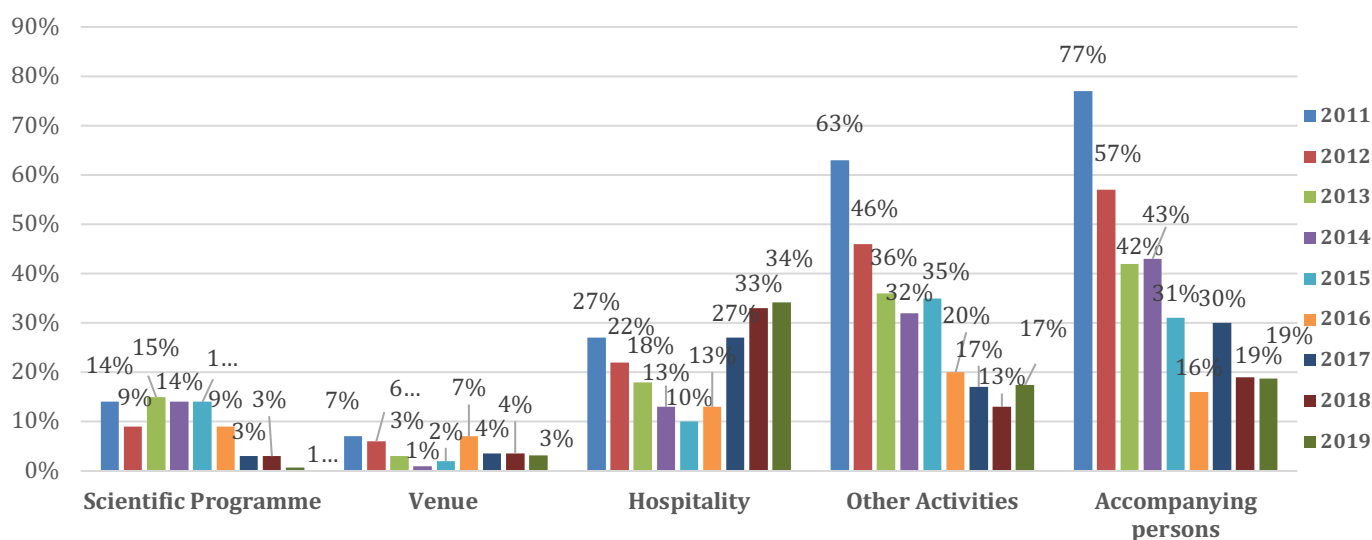
26 of 36 EFPIA Member Associations received draft pre-assessments regarding events taking place in their countries. 10 of them (Austria, Czech Republic, Finland, France, Greece, Norway, Portugal, Serbia, Spain, Sweden) replied several times to the requests for input.

9 national code warning messages¹ were issued by 7 countries during the events' pre-assessment of 2019; 2 comments regarding other activities, 5 for the area of Hospitality provided (directly or indirectly) to HCPs, 2 warnings for accompanying persons (one of them regarding stricter national regulation).

The collaboration with Member Associations is crucial because it facilitates the pre-assessment process and clarifies issues where it is recommended to check the rules prevailing under applicable national codes.

The overall view of the events pre-assessed during 2019 was quite satisfactory comparing to the previous years. Improvements were done in the area of Other Activities. The statistical data of the platform below reveal that the percentage of elements that raised concern in events has been halved in less than 9 years but still need to be improved.

Elements that may raise concern



The most problematic area during the events' pre-assessment in 2019 was Hospitality, where elements that raised concern have risen from 10% in 2015 to 34% in 2019. Comparing to last year we have an increase from 33% to 34%, but 27% to 34% from the beginning. In many cases we have established a positive relationship of mutual collaboration with the organizers, which have introduced changes in order to be compliant with EFPIA Code provisions, but numbers still remain negative.

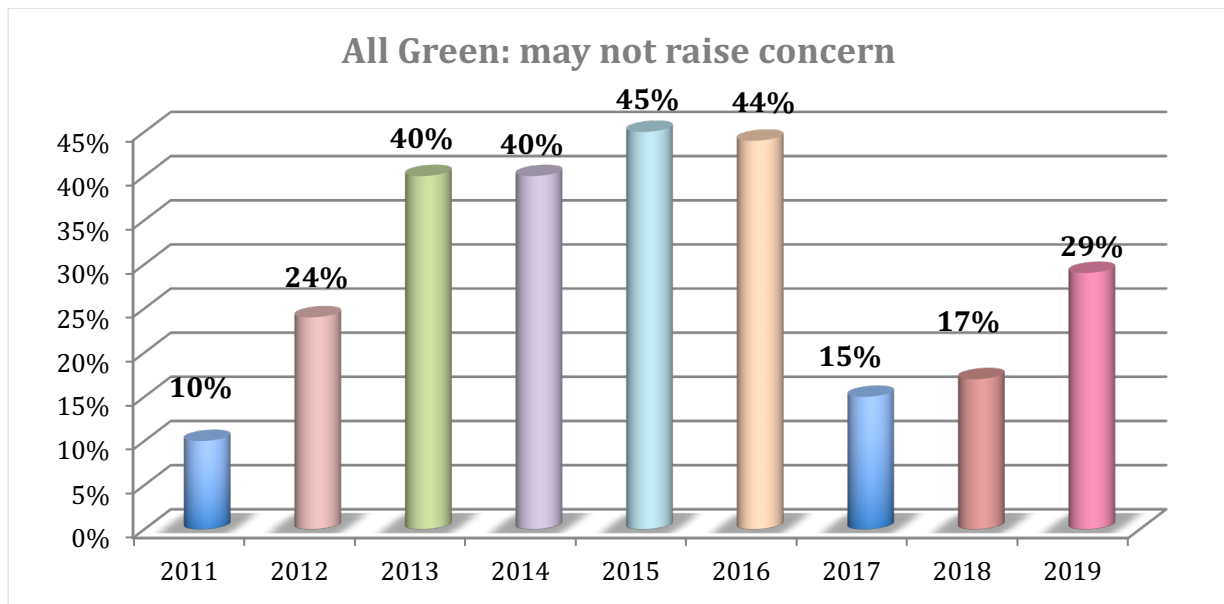
Venue and Scientific Programme remain the same comparing to last year. 5 of 155 events organised or sponsored by or on behalf of a company have not been held in an "appropriate" venue that was conducive to the main purpose of the event.

¹ Where the Member Association of the event's hosting country provides comments regarding stricter national laws, regulations and/or codes, these will be shared with the organizer and reflected in the sixth area of the pre-assessment report: National Code Provisions

Accompanying people had a positive change from 30% in 2017 to 19 % in 2019. A positive impact was also registered for the area Other Activities. Nevertheless, the percentage of elements raising concern still remains quite high. This last year has increased to 17%.

2019 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 155 events pre-assessed during 2019 only 45 of them had ALL the sections in green.



Recommendations:

- Improve collaboration with stakeholders including the organisation of collaborative sessions aiming at explaining the EFPIA Code requirements
- More implication at national level
- Reintroduce the site visits with the support of Member Associations
- Make e4ethics binding

ANNEX 1: 2019 NATIONAL CODE REPORTS

AUSTRIA – Pharmig

Code authority activity

In 2019, Pharmig examined 3 complaints in 1st instance and 1 in 2nd instance that is not finished.

All the complaints were introduced by pharmaceutical companies.

The Code provisions have been breached in 1 case with regard to the Article 5 on Advertising for Medicinal Products (off-labelling promotion).

Given that the sanctions are only imposed for serious violation, no sanctions were imposed in 2019. In 1 case the Code of Conduct Committee gave warning to the company concerned and the company concerned had to sign a cease-and-desist declaration. Furthermore, the company concerned had to pay the costs for the proceedings (€ 3.500).

Code report

The Code Decisions are published on the Pharmig Website (anonymised, available in German): <https://www.pharmig.at/der-verband/pharmig-verhaltenscodex/> - scroll to “VHC-Entscheidungssammlung”

The Annual Report provides a statistical report as well as Members of the CoC Committee of Experts of the 1st and 2nd instance: <https://www.pharmig.at/media/2947/pharmig-leistungsbericht-2019.pdf> (available in German).

2020 Disclosure of 2019 Data

The percentage of positive consent is:

- * HCPs 18,5%
- * HCOs 72%

In general, the level of positive consent remained quite stable over the last few years. In 2019, there was a slight decrease of positive consent from HCPs, but with a view to the Corona crisis and the impact on healthcare, this was expected. Some companies have made a conscious decision not to obtain consent declarations from mid-March in order not to generate additional administrative work in this difficult situation.

Due to data protection obligation the consent of HCPs and HCOs is required for disclosure. Due to negative press coverage back in 2016 most HCPs are concerned and refuse their consent for disclosure.

Pharmig established a new standing committee for ethic and compliance topics. A small working group within this standing committee aims to address the disclosure topic to reach better figures.

Furthermore, Pharmig and the Medical Chamber are working on this topic to raise awareness and increase positive consent. Joint publication (brochure) with Medical Chamber has been updated and distributed via the Austrian Medical Journal in April 2020 to reach every single HCP.

For more information on disclosure:
https://www.pharmig.at/media/3043/pharmig_grafik_disclosure_2019_e_print.pdf

Code awareness

Pharmig organised:

- training sessions and discussion platform on a regular base (for Member Companies only).
- special certificate course “Compliance & Code of Conduct” (4 different modules: Basics, Advertising, Events & Disclosure) and other compliance specific courses provided by “Pharmig Academy” (open to anyone interested)

BELGIUM – Pharma.be

Code authority activity

Pharma.be did not receive complaints in 2019.

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 SUNSHINE ACT	BENEFICIAIRES		TOTAL	
RECHERCHE SCIENTIFIQUE	<i>Aggrégé</i>		124.565.831 €	57%
MANIFESTATIONS SCIENTIFIQUES	<i>HCO*</i>	25.820.806 €	40.287.182 €	18%
	<i>HCP*</i>	14.466.376 €		
DONATIONS ET SUBVENTIONS QUI SOUTIENNENT LES SOINS DE SANTE	<i>HCO</i>		23.715.604 €	11%
SERVICES ET CONSULTANCE	<i>HCP</i>	11.633.376 €	20.694.259 €	9%
	<i>HCO</i>	8.899.579 €		
	<i>PO*</i>	161.304 €		
AUTRES SOUTIENS	<i>PO</i>		9.925.750 €	5%
TOTAL			219.188.627 €	

Pharma.be and betransparent.be developed press releases after the 2019 disclosure.

The disclosure of transfers of value in Belgium is a legal obligation, 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 were inserted in the pharma.be code of deontology in 2019 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:

- **25/03/2019: Info Session "Ethics and Compliance"**

Programme:

- o Bureau van Toezicht op de Geschreven Communicatie (BTGC) / Bureau de Contrôle de la Communication Écrite (BCCE) (by Mr. Marc Vangrimbergen, Lawyer)
- o Update van de pharma.be code of deontology: criteria grants & donations (by Mrs. Marie-Charlotte Destrée and Mrs. Charlotte Weyne, Legal Counsels at pharma.be)

- EFPIA Codes Consolidation (by Mrs. Julie Bonhomme, Legal Affairs & Compliance Director, EFPIA)
- **29/11/2019: 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.

BULGARIA – ARPharM

Code authority activity

1 complaint was received in 2019 and came from a pharmaceutical company.
 The Code authority considered that no Code provisions have been breached.

2019 Disclosure of 2018 data

The figures are the following:

- * R&D – 57,55%
- * HCOs – 17,25%
- * HCPs – 25,20%

The percentage of positive consent is 58,49%.

Code awareness

ARPharM organized joint meetings of the compliance people of all member-companies and ARPharM Director delivered presentations in front of the compliance departments of couple of member-companies in the company’s premises.

ARPharM uses the EFPIA “e4ethics” platform and also provides input to the assessments made by the platform as Host Country when requested.

On the 10th of June 2020, the General Assembly of ARPharM adopted the consolidated Code of Ethics of the Research-based Pharmaceutical Industry in Bulgaria, based on transposition of the current three HCP, Patients’ and Disclosure codes. The new Consolidated Code takes effect since 1st of January, 2021.

CROATIA – Innovative Pharmaceutical Initiative IFI

Code authority activity

3 complaints were received in 2019 and came from:

- * National Code Committee: 33%

- * Anonymous: 33%
- * A publication on a newspaper website: 33%

One refers to Article 11.2. d) concerning Hospitality and more specifically meetings with HCPs. The sanction imposed were a warning, taking into account whether the member has been previously sanctioned.

Most cases concern violations of Hospitality provisions, especially during the meetings of HCPs. Namely, there were a few cases where famous Croatian pop/folk performers were included during dinner time. The association intends to prevent such cases in the future.

2019 Disclosure of 2018 data

The figures are the following:

- * R&D 17%
- * HCOs 38%
- * HCPs 45%

The percentage of positive consent is 12,7%.

The above-mentioned figures show that 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 2018, a little more than 1 percent fewer healthcare professionals gave their consent for the individual disclosure of the transfer of value than in 2017. Unfortunately, Croatia is at the bottom of the scale in terms of individual consents. The number of consents for the disclosing of personal data is in line with the general social climate, as economic and political stability and trust in institutions are important factors in the decision to make personal data available to the public. Given the current economic and social situation, which has led to a further loss of confidence in the institutions and values of society as a whole, such a rate is expected. However, we believe that over time, with the strengthening of political stability, and thus the dignity of institutions, and with better education of both the public and healthcare workers, doctors will be more encouraged and motivated to participate in increasing transparency of public and private sector cooperation.

No media coverage was recorded which proves that there is no reason to be afraid of full transparency in disclosing transfers of value because we managed to create a positive association of transfers of value of pharmaceutical companies to investments in the education of healthcare professionals in previous years. 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 in June 2019. Companies shared their best practices, found possible solutions to improve the consent rate. A communication strategy for the upcoming disclosure was presented at the workshop as well. In addition to the workshop, newsletter for iF! members and proactive and reactive Q&A documents for iF! members and general public were prepared. 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 provides input to the assessments made by the platform as Host Country when requested.

In Autumn 2019, the Task Force Ethics & Compliance adopted the plan of transposition of the new EFPIA Code into the national code with the aim of adopting a new Code by June 2020 and its full implementation by January 2021.

CZECH REPUBLIC - AIFP

Code authority activity

2 complaints received in 2019 that came from:

- * Pharmaceutical companies: 50%
- * AIFP office: 50%

The Code provisions concerned by the complaints were related to Sections 1.1 (Responsibility), 1.3 (False or Misleading Claims), 1.4 (Unapproved Products and Indications) and 1.8 (Comparative Advertising) of the AIFP Code of Conduct, as well as Section 2.02 of the AIFP Disclosure Code (Time of Disclosure).

The Code authority imposed fines, and the request to terminate the usage of the promotional material.

Code report

The Code report is not published.

Disclosure

The figures are the following:

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

The percentage of positive consent is:

- * HCPs 20 %
- * HCOs 99 %

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 with PCOs that was held on 5th December 2019 in AIFP office. The main topic of this event was to introduce and discuss AIFP Principles for Sponsorships by AIFP Member Companies at Congresses with Social Programs. More than 25 PCO companies participated. AIFP received very positive feedback from side of participants. On Thursday, November 28th, 2019 in residence of member company Pfizer, the 9th Day with AIFP Ethics Committee for the representatives of AIFP member companies was held. The main topics of the meeting were New AIFP Code of Practice, AIFP Principles for Sponsorships by AIFP Member Companies at Congresses with Social Programs, Academy of Patient Organizations, Patients support programs, Relationship between pharmaceutical industry and patient organisations, Status of nurses regarding communication with pharmaceutical industry, Off-label promotion, Annual report of State Institute for Drug Control, Priorities of Trust & Reputation Working Group and Annual report of AIFP Ethics Committee activities. AIFP organized 12 regular examinations of sales representatives of the AIFP member companies in 2019.

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)

Executive Summary (Annual Report 2019)

In 2019 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 regulation, please visit www.enli.dk/en.

Significant matters in 2019

In 2019, approx. 428 promotional activities were self-reported to ENLI each month, as required (pre-vetting procedure). Of these, the Investigator Panel has reviewed 48.8% of the reports in a random control, and 98.4% of the activities were approved, whereas sanctions were decided in 1.6% of the evaluated reports.

Three complaints were filed against an affiliated pharmaceutical company. Complaints led to sanctions in two of the decided cases.

Affiliated medicinal companies continue to exhibit a strong focus on achieving compliance to ENLI's regulation. In 2019, companies requested 181 pre-approvals of promotional activities, which is an increase of 10 requests compared to 2018. Of the pre-approval requests in 2019, 74% were approved.

From the total amount of 83 decisions that ruled against an affiliated company, three decisions were appealed to the Board of Appeal, which corresponds to approx. 3.6% of all relevant decisions. The Board of Appeal handled four cases in 2019 - one appeal was based on a decision from 2018. From the four appeals that have been decided, three decisions from the first instance was in whole or partially upheld, while one appeal led to a revoked decision.

ENLI has continued to prioritize preventive activities. In 2019, ENLI has published 36 decisions (including 22 administrative reprimands), 7 newsletters and updates to the Promotion guidelines. Furthermore, ENLI has published a guide regarding documentation and substantiation (for now only in Danish). Moreover, ENLI has conducted 8 courses in the regulation, primarily the Promotional Code, and 4 presentations to collaborative partners, networks, medical societies etc.

All decisions which impose a sanction on a company are published (in Danish) on ENLI's website, www.enli.dk, where also all ethical codes and guidelines can be found. In 2019 ENLI launched its website in an English version as well. Please visit www.enli.dk/en for more information on ENLI, the codes and guidances.

FINLAND - PIF

Code authority activity

PIF received 8 complaints in 2019:

- * Inspection Board I (marketing and information to the consumers): 4 cases
- * Inspection Board II (marketing to the HCP's): 2 cases
- * Supervisory Commission (complaints of the decisions made by Inspection Boards): 2 cases

The complaints came from:

- * Pharmaceutical companies: 50%
- * National Code Committees: 50%

The Code provisions have been breached in 9 cases:

- * Inspection Board I: 4 cases
- * Inspection Board II: 1 case
- * Supervisory Commission: 2 cases

The following provisions were most frequently breached:

- * informing nurses of the price and reimbursement conditions of RX-products (*in Finland nurses are not counted as HCP's in relation to marketing, it is permissible to provide the nurses and 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.*)

The sanctions imposed were:

- * request to abstain from incorrect activity
- * sanction payments between 5.000 – 15.000 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: https://extranet.pif.fi/sites/default/files/vuosikatsaus_lmvk_2019.pdf (only in Finnish).

2019 disclosure of 2018 ToVs

The figures are the following:

- * R&D 62,5%
- * HCOs 15%
- * HCPs 22,5%

The percentage of positive consent is 67%.

Code awareness

PIF organized:

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

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

GERMANY – FSA/VFA

Code authority activity

40 complaints received in 2019 that came from:

- * Pharmaceutical companies: 6
- * Third parties: 34

In 2019, 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/schiedsstelle/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/mediencenter#jahresberichte>

Disclosure

The figures are the following:

- * R&D 64,6%
- * HCOs 18,8%
- * HCPs 16,6%

The percentage of positive consent is around 21%.

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 slightly raised from 20 to 21%. However, the negative press coverage from the first disclosure years (e.g. the Spiegel data base and the articles based

on it), the anticorruption law that came into force in 2016 and general data protection fears are still of influence on HCPs. FSA/vfa and their members again 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

On the occasion of the 15th anniversary of the FSA the association organized a commemorative event with representatives from politics, external stakeholders and member companies. The 10th year of disclosure of ToV to patient organisations gave cause for a workshop with representatives of patient organisations. FSA also conducted two meetings of the compliance officers to inform them about latest developments and share best practice. Several webinars were organized on current issues as well as monthly update webinars. Furthermore, in 2019 the new EFPIA Code of Practice has been successfully transferred to the regulations of the FSA.

GREECE - SFEE

A. AMENDMENT OF CODE OF ETHICS

SfEE's Code of Ethics was amended during the works of the General Assembly that took place on Friday 26th of June 2020. The new Code is currently being translated in English. In the meantime, please kindly see a brief presentation of the modifications in the attached document.

B. SANCTIONS

FIRST INSTANCE COMMITTEE

During 2019, the First Instance Committee for Code Compliance examined, in total two (2) cases of allegations/complaints about Code violations from SfEE Member-Companies.

*Decision 1/2019: **** vs ****:* Complaint filed by a SfEE Member-company against another SfEE Member-company for disguised and unlawful promotion of a competitive product, violating article 8 para. 1 and 3 and article 20.1. based on the reference of the active substance of a unique medicinal product of the defendant to an article of a National newspaper accessible to the public. The Committee concluded that given the fact that the claim concerned a product that has not been included yet in the positive list, the objective of promotion is not possible to be proven. In addition, it could not be proven whether the journalist was acting on his own initiative or under the impetus of the defendant company. Hence, the Committee rejected the complaint and closed the case.

Decision 2/2019: During the hearing of the 1st complaint before the First instance Committee, the defendant company referred to an Article published on a news web-site accessible to the public, with reference to the brand name of a medicinal product of the claimant company, without however requesting for any sanctions to be imposed to the claimant. The Committee considered such reference to be an anonymous complaint and reviewed the case. As reference to the brand name of the medicinal product was made further to a press release of the parent company with registered seat in the USA, where promotion of prescription only medicines is allowed, the issue under consideration was whether this constituted a violation of Art. 20.1. of SFEE's Code of ethics by the SfEE-member company. Further to the examination of the defendants allegations, the Committee concluded that in this case as well, it could not be proven whether the journalist was acting on his own initiative or under the impetus of the defendant company and therefore, held that the defendant company did not violate Art. 20.1. of SfEE's Code of Ethics.

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 2019, was concluded on Friday 29/5/2020 on the "National Organization for Medicines" web-site:

http://www.eof.gr/web/guest/home;jsessionid=0147fd9644ac46e09b1b2738e7c1?p_p_id=62_INSTANCE_0eNL&p_p_lifecycle=0&p_p_state=maximized&p_p_mode=view&p_p_col_id=column-2&p_p_col_count=11&_62_INSTANCE_0eNL_struts_action=%2Fjournal_articles%2Fview&_62_INSTANCE_0eNL_groupId=12225&_62_INSTANCE_0eNL_articleId=4984540&_62_INSTANCE_0eNL_version=1.0

IRELAND - IPHA

Code authority activity

IPHA received 3 complaints in 2019 that came from pharmaceutical companies.

The Code provisions have been breached in 2 cases and relate to Annex V, Clauses 7.1,7.2, 5.5, 5.2, 5.1 and Clauses 4.3, 4.4 of the National Code.

As a sanction, the remedial measures which have been introduced by the company involved should be immediately incorporated into the company's Standard Operating Procedures.

The promotional material claim must be amended to reflect the supporting evidence.

One company had to write to all HCPs affected by an error.

Code report

IPHA publishes a Code report that is available on request.

Consequences of the Code authority activity

The publication of erroneous HCP transfer of value amounts on the IPHA disclosure platform (www.transferofvalue.ie) resulted in adverse publicity for some healthcare professionals in both social media platforms and national print media. An error of one hundred-fold resulted in a grant of €10,000 being recorded as €1,000,000, for example. This was due entirely to one company loading incorrect data. The company was required to correct the information, contact all those affected and advise of the error and revise internal SOPs. As an additional precautionary measure, the Irish disclosure site (www.transferofvalue.ie) has now been amended so that decimal places cannot be loaded (the issue with the company data related to their decimal place nomenclature).

2019 Disclosure of 2018 data

The figures are the following:

- * R&D 51 %
- * HCOs 27 %
- * HCPs 22 %

The estimated percentage for positive consent is:

- * HCOs 99 %
- * HCPs 64 %

There was an increase in HCP Consent Rates for ToV Disclosure of 6% compared to 2017 data. HCO continue to be high at >99%.

Code awareness

IPHA runs multiple face to face 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).

LATVIA - SIFFA

Code authority activity

SIFFA examined 6 complaints that came from:

- * Pharmaceutical companies: 5
- * Healthcare Organisations: 1

The Codes provisions have been breached in 2 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.

Consequences of Code authority activity

The highlighted statement in the promotional material indicates the exaggerated properties of the medicine, as well as the statement was misleading in nature. There were no comparative studies to prove this. The statement was quoted from the website of the international award ceremony, where it was difficult to assess the significance of such an award.

Code awareness

A meeting on data disclosure was held in cooperation with the Health Inspectorate (16.10.2019.) as well the issues considered by the Ethics commission were discussed at the general meeting of the members of the association (09.12.2019.). Publications on the implementation of the new code of ethics were prepared in the journal "Latvijas Ārsti" (Latvian Physicians) for doctors and "Materia Medica" - for pharmacists.

Others topics

- The working group of the Ethics Commissions finalised project of the National Code accordingly to the EFPIA Code of Practice on February, 2020 and it was submitted to SIFFA Board for approval by association members (possible in April, 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.

LITHUANIA - IFPA

Code authority activity

IFPA examined 9 complaints in 2019 that came from:

- * Pharmaceutical companies: 78%
- * Healthcare Professionals: 11%
- * National agencies: 11%

The Code provisions have been breached in 3 cases and relate to "Regulations of promotion of medicinal products".

The sanctions consisted in writing recommendations for pharmaceutical companies.

Code report

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

MACEDONIA - Farmabrend Nova

Code authority activity

No complaint has been examined in 2019

2019 disclosure of 2018 data

The disclosure was not introduced in 2019.

In June 2020, it will be the first disclosure in Macedonia.

Code awareness

Farmabrend Nova provided two internal trainings to promote the compliance with the National code, one for the people responsible for compliance, the other one for all employees of the member companies supported by Sani Pogorilic from IFI. In addition, the plan for implementation of disclosure was discussed and approved by the members of the FBN Assembly, as well as the supportive tools and materials translated on Macedonian language for external communication.

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

VIG examined 16 complaints in 2019 (4 ordinary cases and 5 pre-assessment cases) that came from:

- * Pharmaceutical companies: 70%
- * Healthcare Professionals: 12%
- * Healthcare Organisations: 6%
- * National Code Committees: 6%
- * Others (please specify): 6%, by the company itself

The Codes provisions that have been breached in the 13 cases are related to the promotion of Prescription Only Medicines to the HCPs.

The sanctions imposed were reprimands, publication, rectification.

Code report

The Code report is available here: <https://www.cgr.nl/getattachment/Nieuws/Jaarverslagen/Jaarverslag-2018/De-CGR-in-2018.pdf.aspx>

Consequences of the Code authority activity

One case concerned a complaint by a HCP against promotional messages of patient organisations of a new pharmaceutical product. CGR investigated whether the pharmaceutical company had any influence on these messaging. There was no proof there was, so the complaint did not lead to an infringement of the pharmaceutical company. CGR addressed the patient organisations to delete the promotional messages, being an infringement of the ban on public advertising of POM. The Inspectorate of Health (governmental agency) did a follow up and visited the patient organisations. This has led to a new consciousness of patient

organisations that the advertising regulations of POM also apply to them. CGR is now in consultation with the sector organisation of patient organisation to join CGR. Several meetings took place to inform patient organisations on their responsibilities.

This case has been relayed in the media and discussed in Parliament.

2019 disclosure of 2018 data

The figures are the following:

- * R&D 63 %
- * HCOs 32 %
- * HCPs 5 %

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

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

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.

Congress evaluation

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

NORWAY - LMI

Code authority activity

LMI examined 9 complaints in 2019 (4 ordinary cases and 5 pre-assessment cases) that came from:

- * Pharmaceutical companies: 2
- * Healthcare Professionals: 1
- * National Code Committees: 1

The Codes provisions that have been breached in the 4 cases are related to Articles 8.2 (mandatory information), 8.4 (balanced and factual information) and Chapter 5 (digital information of the Norwegian Code).

The sanctions imposed were fines between NOK 25.000 and NOK 150.000.

As a consequence of cases occurred, the Council places stringent requirements on the safety information contained in the advertising online. The online advertising should be easily accessible. The information provided must be highlighted and spaced in such manner that the reader can perceive the advertisement's message easily and clearly.

Code report

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

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

2019 disclosure of 2018 data

The percentage of positive consent is 71%.

After consultation of the national data protection authority, the association have decided to base the disclosure on the legitimate interest for the 2021 disclosure of 2020 data.

Code awareness

5 different trainings were organised:

- 2 Advertising trainings (1 day, approx. 50 participants each)
- 2 Law and Industry Trainings. (3 days each, for new employees, approx. 50 participants each)
- 1 Specialist Training 2 days, (for compliance officers, approx. 35 participants)
- 1 e-learning Training (with usually 1200 users before each update)

The Code Authority (Rådet) and Norwegian Medicines Agency have access to an Electronic Archive where all information from the companies are uploaded. The Secretariat provides ongoing advice in response to questions related to industry rules. The secretariat takes samples to check for compliance with the Code.

Congress evaluation

LMI has its own "Concept Approval" (national version of e4etics), it has developed its own electronic Concept Approval application procedure.

LMI evaluated 108 cases in 2019.

International Congresses in Norway should apply for e4ethics.

When applicable, LMI provides input to the e4ethics assessments as Host Country.

POLAND - INFARMA

Code authority activity

In 2019, 3 cases were submitted to the Disciplinary Court, one of which was not considered due to the fact that the subject matter of the application was outside the scope of the Code of Good Practices. The 3 cases came from the pharmaceutical companies.

The Codes provisions have been breached in the 2 cases and are related to Art. 10 paragraph 1, 2, 3 and 5, art. 12 paragraph 1, art. 19 paragraph 1 point a, art. 21 paragraph 2 points a-g of the Code of Good Practice in connection with its dissemination of materials.

The court imposed on the company XYZ admonition and obligated to inform the scientific societies about the fact of arbitrary use logos of these societies in materials distributed by the company on Polish territory.

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

In 2019, continuation of the case in which 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 (Disciplinary Court granted the company reprimand in connection with advertising activities conducted during Congress based on art 10 paragraph 1 of the Code of Good Practice).

2019 Disclosure of 2018 data

The figures are the following:

- * R&D 66 %
- * HCOs 18 %
- * HCPs 16 %

The estimated percentage for positive consent is:

- * HCOs 84 %
- * HCPs 23 %

In 2019 no material or significant changes in comparison with 2018 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 (2016-2018):

- 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 (2016-2018)

Code awareness

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 2019, the certification covered 1396 scientific events organised by third parties addressed to medical professionals (with 1207 such events in 2018).

In 2019, the Certification Task Force and INFARMA met the following objectives and completed tasks associated with the Event Certification System:

- Improvement of the certification system: clarification of criteria, implementation of an efficient IT system,
- Cooperation with the stakeholders: other industry organisations and scientific societies and events organisers,
- Communication activities.

The Code of Practise

In 2019, work was started on the implementation of the new EFPIA Code of Practice. In 2019, INFARMA was involved in promoting the Code of Good Practices and the Transparency 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.

INFARMA uses EFPIA “e4ethics” platform for international congress that take place in Poland and provide input to the assessments as Host Country.

SLOVENIA – FarmaForum

Code authority activity

No complaint has been received in 2019.

Disclosure

A whole report on Transfers of Value data for 2019 will be available from 10 July 2020.

Code awareness

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

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

SPAIN – FARMAINDUSTRIA

Code authority activity

Farmaindustria examined 10 cases in 2019 that came from:

- * Pharmaceutical companies: 70%
- * National Code Committees: 30%. Issued by the Code of practice Surveillance Unit.

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

- * Article 1. Marketing Authorization for Medicines (EFPIA Code Article 1 Marketing Authorization)
- * Article 3. Information on Medicines and its Substantiation (EFPIA Code Article 3 Promotion and its Substantiation)
- * Article 4. Acceptability of Promotional Material (EFPIA Code Article 5 Acceptability of Promotion)
- * Article 5. Transparency in promotion of Medicines (EFPIA Code Article 7 Transparency of Promotion)
- * Article 7. Distribution of Promotional Materials for Medicines (EFPIA Code Article 6 Distribution of Promotion)
- * Article 10. Guarantees of Independence (EFPIA Code Article 11 Prohibition of Gifts)

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 promotion of a prescription-only medicine, before having the Marketing Authorization. Moreover, such promotion was directed to the general public.

Due to this situation FARMAINDUSTRIA communication working group, decided to revise, reinforce and improve, the “guidelines for communication and for the interaction with the media”

2019 disclosure of 2018 ToVs

The figures are the following:

Transfers of Value (TOTAL: 564 million euro)

- * R&D 43,38%
- * HCOs 24,79%
- * HCPs 31,83%

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.

The association is an active member of EFPIA e4ethics validation team and it always provides input to the assessments made by the EFPIA “e4ethics” platform as Host Country when requested.

SWEDEN – LIF

Code authority activity

LIF examined 48 (includes total number of assessed cases, where a large majority of 73 % originates from the continuous supervision and monitoring performed by our first instance, IGN)

In 2019, the complaints came from:

- * Pharmaceutical companies: 13%
- * Healthcare Professionals: 2%
- * National Code authority: 73% (IGN= first instance)
- * National agencies: 6 %
- * Anonymous: 2 %
- * Others (please specify): (2 %, researcher in academia)

The Code provisions have been breached in 44 cases and 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

The sanctions imposed were fines (in general 90 000 SEK).

Code report

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

Consequences of Code authority activity

As referred to in the 2018 Code report, we had a case in 2018 which concerned funding of patient organisation representatives to participate in a company organised Event abroad. The concerned company was found in breach of the code, which triggered an in-depth code revision assessment that was carried out by LIF during 2018 and 2019. The result is an updated code (entry into force by 01-May-2020) which clearly forbids companies to fund the mere participation of patient organisations in events. By that the same restrictions are being applied for patient organisations and patients, that has been enforced in Sweden since 2015 for HCPs/HCOs, i.e. not allowed to cover costs for travel, accommodation, registration, to attend medical/scientific events, congresses, or company sponsored events.

2019 disclosure of 2018 ToVs

The figures are the following:

- * R&D 80%
- * HCOs 80%
- * HCPs 20%

The percentage of positive consent is:

- * 86% (HCP/HCO ToVs in relation to consultancy engagements)

The strong figures for consent have been maintained during the years since the disclosure requirements were introduced in 2015, and does not seem to have been impacted negatively by GDPR-enforcement.

Code awareness

LIF organized:

- 5 Code Training sessions (2 days course, including formal test to get accredited in code compliance). Approximately 40 attendees each session.
- One half-day seminar (learnings from past 2 years of self-regulation, interesting cases, briefing about new/ongoing topics), approx 100 attendees
- One half-day seminar, approx. 100 attendees (patient organisations, politicians, HCO, pharma) about upcoming change (2020) of the code for interactions with patient org./patients

The association sometimes uses EFPIA “e4ethics” platform and provides input to the assessments made by the EFPIA “e4ethics” platform as Host Country when requested.

SWITZERLAND

The Swiss association publishes an annual report of the Pharma Code and the Pharma Cooperation Code each year, the 2019 annual report is available here:

<https://www.scienceindustries.ch/en/article/12674/annual-reports-of-the-codes-secretariat>

TURKEY – AIFD

Code authority activity

AIFD examined 1 complaint in 2019 that came from the national code authority.

The Code provisions that have been breached relate to hospitality provided to Turkish physicians in a congress in Germany (though allowed under Turkish code, a breach of more restrictive German Code).

The sanctions imposed was a warning.

Consequences of Code authority activity

The case permitted AIFD to emphasise the need to pay due attention not only to the local AIFD Code but also the Codes of the host countries.

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

Code issues and pertinent questions are evaluated and discussed in every monthly Compliance Managers Meetings in Istanbul (9 meetings in 2019).

No specific training session in 2019. Training sessions are planned for 2020 (September and December, postponed due to Covid-19)

AIFD shares the EFPIA “e4ethics” assessments with its members. The association provides input to the assessments as Host Country when requested.

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

ANNEX 2: EFPIA PRINCIPLES FOR THE USE OF DIGITAL CHANNELS

This document is intended as a supplement to the provisions of the EFPIA Code of Practice that apply to all types of communication including via digital channels.

As this document is non-binding, Member Companies and Associations may need to adapt it to meet their particular requirements and are encouraged to adopt additional measures which extend further than the provisions in this document.

This document describes the most commonly used digital channels and what to be aware of, when communicating to and with the public and/or HCPs.

1. Principles applicable to all types of communication

Compliance with laws, regulations and codes of practice

A digital channel is only a platform for communicating. Laws and regulations applicable to other platforms and media also apply to digital media. The content, target group and use of the platform are relevant factors to determine applicable rules, not the media as such.

Therefore, the provisions of the Directive 2001/83/EC related to the Medicinal Products' advertising and of the EFPIA Code of Practice apply to digital communication.

The processing of personal data must comply with applicable data protection regulations.

Responsibility

Member Companies are responsible for all material disseminated via any digital channel that is initiated, branded and/or sponsored by Member Companies, or any Third Party acting on their behalf, including promotion of Medicinal Products.

A Member Company owning the social media page or site is responsible for the content. E.g. any mention of a Prescription-Only Medicine is likely to be considered promotion of that medicine to the public and prohibited. Another example might be the use of social media directed to the public to alert HCPs about the publication of a study on a Medicinal Product which is also likely to be considered promotion of that Medicinal Product and therefore prohibited.

Member Companies may also have responsibilities when interacting on digital channels owned by other companies or organisations.

Member Companies are also responsible for information disseminated by Member Company staff who do so via their private social media channel including, a) when they can reasonably be perceived as representing the Member Company, or b) if they are instructed, approved or facilitated by the Member Company to do so. The Member Company should have internal guidelines in place on how its staff should behave on digital channels including their own personal account activities.

For digital channels owned by the Member Company, processes should be established to monitor, moderate and/or delete any inappropriate comments in a timely manner to the extent permitted by the data protection regulations and applicable laws and codes. Member Companies may need to have similar processes when using digital channels owned by other companies or organisations.

Pharmacovigilance

Member Companies should consider developing specific guidance for digital channels and contacting their pharmacovigilance experts for specific projects in order to meet their pharmacovigilance responsibilities including the obligation to record and report any adverse effects that are discussed about their Medicinal Products.

Transparency

Section 7.04 of the EFPIA Code of Practice requires Member Companies to clearly indicate when they have sponsored a communication. Whenever a Member Company or an individual or entity acting on behalf of a Member Company provides information on a digital channel, it should clearly state the involvement of the Member Company, including but not limited to defining content, funding in part or in totality.

In addition, the transfers of values to HCPs, HCOs and POs are reportable under the disclosure obligations as described in the EFPIA Code of Practice (Chapter 5).

When possible, the target audience of the channel should be clearly identified (e.g., HCPs and the public, or a combination thereof).

2. How to identify the allowed information for the different digital channels

It is important that the Member Company understands what content is appropriate for the different digital channels and the respective audience. All laws and regulations in this regard must be complied with in the same way as for other media.

Information included on a digital channel should be regularly updated and should clearly display, for each page and/or item, as applicable, the most recent date as of which such information was updated.

The following questions can be useful to assess risks associated with digital communication and appropriateness of digital channel content, access, set-up and maintenance:

- What is the objective of the communication (promote, inform, exchange)?
- What content will be made available on the digital channel?
 - Is the content related to Medicinal Products?
 - Is the content promotional or non-promotional?
 - Is the content related to disease awareness?
 - Is the content related to healthcare information e.g. in connection with diagnosis, treatment education, dietary support
 - Is the role of the Member Company providing/developing the content clear?
- Who is the intended audience? e.g. public, HCPs or both
 - Is verification of audience required?
 - If yes, how?
- What is the channel standard set-up?
 - Is the digital channel open to audience reaction such as sharing, commenting, exchanging?
 - How is the information cascaded across the digital channels?
 - Is the digital channel an open platform or for a closed audience?
 - Are there limitations in content size? e.g. Twitter
 - Are there any community guidelines applicable? e.g. Facebook, YouTube
 - How is the information about the channel audience processed?
- How is the content reviewed, approved and maintained including by the Member Company?

3. EFPIA guidance for members for various digital channels

Below is a short description of the general use of different types of digital channels. When deciding which digital channel to use and how to develop it, the principles set out above should be taken into account.

The content published by a Member Company on each channel must be appropriate and aligned with relevant regulations, laws and codes including the EFPIA Code of Practice.

Websites

Websites are classified as a channel that reaches the public, unless verification (e.g. pop-up for identification, or password) is required to access the website e.g. to HCPs. Some websites may include forums where the public can exchange or discuss topics.

Since many website visits are a result of using a search engine, keyword optimization has become an important tool. Member Companies can use appropriate search optimization to ensure that their websites are displayed high on the list of search results for relevant key words.

However, Member Companies need to ensure that the use of keyword optimization is appropriate for the intended audience. For example, optimized search through use of key words directed to websites with therapy-oriented information for the public or websites aimed at HCPs, where such websites can only be accessed by the authorized individuals.

Member Companies may sponsor website material to be produced by a Third Party in which the role of the Member Company must be made clear. If the Member Company i) is initiating the material, or the concept for it; ii) is influencing the content of the material in any way; iii) is selecting or directly paying the authors; then the Member Company is very likely to be liable for the contents of the website. If the reverse is true, and there is a strictly arm's length arrangement with the Member Company just providing a grant, then the Member Company may not be liable.

Member Companies should be confident about the choice of linked websites and that these do not promote Prescription-Only Medicines to the public. If a Member Company includes website addresses in an advertisement of a Prescription-Only Medicines to HCPs, the core principles apply, of ensuring the content of those websites is appropriate.

Social media

In general, social media are digital channels that are considered to be aimed at the public.

Social media are websites or applications on which people can interact in social networks (e.g. Facebook, Twitter, Snapchat, LinkedIn, YouTube, Instagram). In most cases social media are used to reach or interact with the public. A social media platform can be an open channel for the public or a closed channel for a targeted audience where verification of the audience is required before providing access.

Blogs

The difference between a text on a website and on a blog is that a blog is usually owned and updated by a person or a group of people who posts on the blog regularly.

A blog can be owned by the Member Company or the Member Company may engage (either through sponsorship or consultancy fees) the owner to write on a blog (such as "social influencers"). In both cases, the blog should clearly state the involvement of the Member Company.

Given that, by its very nature, a blog is for contributors to freely and spontaneously express their personal views on a subject, Member Companies should not sponsor such blogs if they were intended, or could reasonably be expected, to promote Prescription-Only Medicines and their uses.

Podcasts

A Member Company can have its own podcast which should follow the same rules as for websites.

A podcast can be downloaded from any podcast distributor. Core principles apply, of ensuring the recipient is well defined and targeted and that content is appropriate. E.g. a podcast promoting Prescription-Only Medicines should only be accessed by HCPs.

Applications (Apps)

An application, usually referred to as an “app”, is to be downloaded on an electronic device (e.g. smartphone, computer or tablet).

A Member Company can develop apps for the use of external stakeholders (e.g. HCPs, HCOs, patients, payers), provided that they follow the same rules as for websites. Also, they should consider potential regulatory requirements if the app fulfils the requirements for a medical device. Core principles apply, including ensuring the audience is well defined and targeted.

An app can also be developed to improve compliance with a treatment method. If an app targets a specific group (e.g. HCPs, patients, caregivers), it is important that only this group is offered access to the app content.

Webinars

A webinar is an on-line event conducted via the internet and it can be either performed as a live streaming event or as an on-demand service.

A Member Company can be the direct organiser of a webinar and/or use a Third Party facilitator to run the event. The Member Company is responsible for these webinars including the content and ensuring that the audience is well defined and targeted. Similar arrangements apply to Third Party webinars sponsored by Member Companies

Such webinars can be for the communication with external stakeholders (e.g. HCPs, HCOs, patients, payers) provided, that they follow the same rules as for websites.

Direct channels

These are one-to-one or one-to-many channels, which are targeting selected recipients; these are most commonly private, not visible to non-selected recipients; they could be replies on social media channels to an individual.

Member Companies should ensure they have the consent of the recipients to be in contact with them, and the recipients should be able to stop receiving messages easily. Appropriateness of the frequency of contact should be borne in mind.

Discussion forums

If a Member Company facilitates a discussion forum on either a Third Party platform, or hosts a forum on its own platform, the Member Company must be confident that they can moderate the site such that the content complies with relevant regulations, laws and codes including the EFPIA Code of Practice. The intended audience should be identified so that relevant requirements are complied with. If discussion forums are used for market research, Member Companies should ensure these are compliant with relevant legal and ethical guidelines.

ANNEX 3: EFPIA CODE OF PRACTICE: ETHICAL GUIDANCE IN LIGHT OF COVID-19 + JOINT GUIDANCE ON VIRTUAL INTERNATIONAL MEDICAL CONGRESSES IMPACTED BY COVID-19 BY IFPMA, EFPIA AND PhRMA

During the COVID-19 pandemic, EFPIA and its members remained fully committed to EFPIA Code requirements. We have continued implementing and applying the highest ethical standards as well as applicable laws and regulations such as competition, data protection, anti-bribery and anti-corruption legislation.

The EFPIA ethical principles have helped in assessing urgently the appropriateness of activities:

- **Patients first**
- **Integrity**
- **Respect**
- **Transparency**

Nevertheless, the COVID-19 pandemic has directly impacted the transposition of the EFPIA Code in the national Codes and the disclosure provisions. Therefore, EFPIA has drafted guidance to extend certain time periods in relation to meeting commitments relevant to these two specific topics.

Due to the lockdown, the interactions and activities that are needed to maintain the scientific exchange, have moved to virtual to protect the health and safety of patients and healthcare professionals.

In addition to maintaining the EFPIA, IFPMA, and PhRMA Codes of Practice standards in virtual settings.

The 3 organisations have decided, for the first time, to jointly issue guidance on Virtual International Medical Congresses impacted by COVID-19, which will be in effect until December 31, 2020.

Besides this joint guidance, EFPIA guidance includes the decision endorsed by the EFPIA members in May to prohibit the provision of meals for the healthcare professionals attending individually a virtual congress.

This guidance could be amended to take into consideration concrete experiences occurring in the coming weeks/months.

1. Transposition of the new EFPIA Code provisions introduced during the consolidation

The EFPIA Code of Practice was agreed in 2019 with Member Associations asked to transpose the revised EFPIA Code provisions by 30 June 2020 and implement the EFPIA Code by no later than 31 December 2020. Member Associations started this work and although some have finished, others are still working on changes to their local codes.

In light of the COVID-19 Pandemic, Member Associations, which have not completed work on their national code, are asked to use their best efforts to implement the EFPIA Code and to inform the EFPIA secretariat of any delay in transposing or implementing the Code provisions.

Member Associations are expected to have transposed at the latest by 31 December 2020 and work to ensure that implementation is completed at the latest by 30 June 2021

2. Disclosure provisions (Articles 22-23-24 of the EFPIA Code of practice)

a. 2020 disclosure of 2019 ToV

Based on the current information and feedback received from some companies and associations, the disclosure period is not postponed and should happen between the 22nd and the 30th of June 2020.

Nevertheless, and due to the exceptional circumstances related to COVID-19 (including that it is inappropriate to contact the Healthcare Professionals and Healthcare Organisations to obtain consent), **Member Companies that cannot satisfy the requirements of the data protection regulations should disclose the data in aggregate and provide explanations for this aggregate disclosure in their methodological notes. EFPIA asks them to complete the disclosure with individual data when it will be possible.**

b. 2021 disclosure of 2020 data

Disclosure requirements remain unchanged, as a reminder each Transfer of Value made in 2020 with an identifiable recipient must be disclosed in June 2021 such as donations and grants, contributions to costs related to Events, fees for services.

c. Disclosure of ToVs related to Events cancelled

Even if an Event is cancelled, the Transfers of Value related to the Event must be disclosed if they can be attributed to a recipient. Planned Transfers of Value for educational support to Events should only be disclosed if a recipient received the benefit e.g. if Event was cancelled and no Transfer of Value occurred to an individual then no disclosure required, if an Event was converted from face to face to virtual and recipient will receive a Transfer of Value via a virtual registration that Transfer of Value must be disclosed.

d. Disclosure of registration fees for recorded Event (Section 23.05)

The registration fee for an Event, live and/or recorded, is a Transfer of Value that must be disclosed.

e. Methodological note

Member Companies must provide detailed explanations on the consequences of COVID-19 on the disclosure data in their methodological note.

3. Events and hospitality (Article 10 of the EFPIA Code of practice)

The rules applicable to the virtual Events² organized by a third-party are described in the Joint Guidance on Virtual International Medical Congresses impacted by COVID-19 in Annex.

Regarding the hospitality provided during virtual Events, Member Companies cannot provide hospitality for the Healthcare Professionals attending individually a virtual third-party organized Event.

Unless prohibited by local laws and regulations (including individual company's position), the hospitality provided to a group of Healthcare Professionals attending a virtual Event together could be assimilated to a face-to-face meeting.

Therefore, the rules applicable to Events and hospitality (Article 10) apply and the Member Companies must implement processes to ensure compliance with those rules.

² As defined in the EFPIA Code of practice – Definitions section

Annex:
Joint Guidance on Virtual International Medical Congresses Impacted by COVID-19
by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the
European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical
Research and Manufacturers of America (PhRMA)

The COVID-19 pandemic has led to new ways of working for biopharmaceutical companies, which have replaced in-office visits and face-to face congresses with virtual engagements to maintain dialogue and scientific exchange with the medical community while protecting the health and safety of patients, healthcare professionals and their own employees. Even as economies open, it is anticipated that virtual meetings and congresses will continue.

The IFPMA's Ethos and Code of Practice set global standards for industry business practices, which must be maintained in the virtual setting. In response to Company and Association questions, IFPMA, EFPIA and PhRMA are issuing this guidance on Virtual International Medical Congresses impacted by COVID-19, which will be in effect until December 31, 2020. This provisional guidance may be amended to take into consideration experience in the coming weeks/months. Companies should adhere to the requirements established by their country's applicable laws, regulations, or industry codes of practice. In the event of a conflict between the provisions of the applicable laws, regulations, and codes, the more restrictive of the conflicting provisions should apply.

Scope of the Guidance

This guidance applies to all International Congresses organized by medical associations/societies involving HCPs from multiple countries, and activities organized by Companies at these congresses (e.g. exhibition stands, satellite symposia, poster sessions) that have been moved to a purely virtual format, and that are taking place between July 1 and Dec 31, 2020. The document additionally provides considerations for International Congresses scheduled after December 31, 2020. Specifically, this guidance sets out factors IFPMA/EFPIA/PhRMA member companies and non-member companies who are signatories to the PhRMA, IFPMA, or EFPIA Codes (collectively, "Companies") should consider when determining which code and/or label to use as reference for the Company activities at such Virtual International Congresses. All other congresses, such as national congresses organized by medical associations/societies in one country with a focus on HCPs from that country, company-organized meetings, etc. are excluded from the scope of this guidance.

Purpose of the Guidance

The pharmaceutical industry supports a wide range of local, national, and international meetings, organized by third parties, providing funding to assist in the medical education of HCPs, sponsorships to medical societies organizing events, hiring of exhibition space, support of speakers, etc. These activities are covered by Article 7 (Events and Meetings) of the IFPMA Code, Article 10 of the EFPIA Code and Articles 4, 5 and 7 of the PhRMA Code. While these requirements were originally drafted for in-person meetings, they apply similarly to virtual meetings and require that support and attendance be based on the event's educational value, considering the educational program, overall cost, nature of the audience, and cybersecurity and privacy arrangements, with attention paid to the overall impression given by all the various arrangements. Companies might find it helpful to clearly document their reasons for supporting events, including Virtual International Congresses.

IFPMA, EFPIA and PhRMA code provisions also cover the appropriate communication of promotional information during International Congresses, deferring to host country regulations in instances where medicine is not approved in the host country or not approved in the country of a participating HCP. In the

context of virtual meetings, the notion of host country is no longer applicable, and this guidance seeks to replicate the Codes' pragmatic approach in the virtual format. This guidance aims to inform other stakeholders such as medical associations/societies, third party organizers etc. about the arrangements Companies should fulfil in a virtual setting. Companies should also ensure they are aware of guidance issued by medical associations/societies etc. on organizing Virtual International Congresses.

Guidance

Short-term (until December 31, 2020)

Activities organized by a Company (e.g. exhibition stands, satellite symposia, poster sessions) associated with a Virtual International Medical Congress should comply with the following requirements:

- Given the global scope of the IFPMA Code, Companies are expected to use the IFPMA Code as the minimum standard. The EFPIA and PhRMA Codes reflect the principles and rules of the IFPMA Code and should be considered in conjunction with the IFPMA Code when the meeting is hosted by a European or American medical association.
- Companies should consider the code from the region from which the majority of delegates would be expected to come based on past experience. When there is no regional code, the IFPMA code applies. This particular code may be referred to for adjudication purposes, as may the code from where the individual attendees come from. When considering the distribution or display of promotional material at International Congresses and assuming the majority of delegates are expected to be from the US or Europe, Member Companies should consider the US and European label for the products being promoted.
- It is important for Companies to clearly state the label by which promotional materials were developed, to avoid any possible confusion. The promotional material must be accompanied by a statement indicating the countries in which the medicinal product is registered, and by an explanatory statement indicating that registration conditions differ internationally. Additionally, the statement should be prominently displayed (e.g. via a pop-up box or alternative display) informing delegates to refer to prescribing information from their home country as information may be different for each country (see Explanatory Statements/Disclaimer examples).
- Companies should ensure that a process is in place to confirm participants' status as HCPs/Non-HCPs (patient advocates, journalists, industry representatives, etc.). It is expected that they will work with the medical association to ensure that the congress' virtual platforms allow for participant categorization, and to work with the medical association/society (congress owner) to make reasonable efforts to restrict access to promotional material to HCPs only, where required by applicable rules and regulations. Where the medical association's platform does not have a categorization capability, Companies should consider alternative mechanisms to enable attendee classification for their promotional events.
- Congress attendees should sign a digital consent indicating awareness/acknowledging Virtual Congress terms and conditions, such as specific permission to access different virtual areas (lectures, commercial expositions, social engagement sites, the basis of promotional material development, etc.). Even if this is the responsibility of the medical association/society, Companies need to be aware of the content of these kinds of Explanatory Statements/ Disclaimers.

Mid- to long-term (post 2020)

Companies should explore putting in place systems to appropriately address the situation where HCPs view materials from countries other than their own. Of particular concern is potential promotion directed to people not qualified to receive such content and promotion of unlicensed medicines and/or indications. Companies should use the lessons learned from the July to December 2020 period to develop ways to address the concerns in a pragmatic manner together with medical associations/ societies. A Company sponsoring/collaborating with a booth at the virtual exhibition area should be able to identify those wishing to view its booth (HCP or Non-HCP) and therefore determine what information will be appropriate. Companies and medical associations/ societies (congress owners) are strongly encouraged to work together to share experiences and where possible jointly develop standards for all to follow.

Explanatory statements/Disclaimers

As stated above, Companies should include a statement explaining to delegates when entering their virtual booth/exhibition to help them understand the context by which the material was developed and to highlight that the content may not be applicable to their country.

Examples include:

- “You are viewing an International Virtual Congress run by [society name] and provided to international HCPs from around the world. Please note that prescribing information provided here may vary depending on local approval in each country. For purposes of [congress name], best efforts were undertaken by [society name] and congress sponsors to ensure compliance with [relevant code], however, you should review your local prescribing information and consult directly the local affiliate of the relevant Company to address any questions.”
- “The materials for [PRODUCT(S)] contained in this virtual exhibition are approved for use only in [COUNTRY]. Prescribing information may vary depending on local approval in each country. Therefore, before prescribing any product, always refer to local materials such as the prescribing information and/or the Summary of Product Characteristics (SPC).”

Definitions

- For purposes of this guidance an **International (Medical) Congress** is a scientific meeting organized by a medical association/society etc. for their members with the opportunity for industry to participate in the form of exhibition (medical and commercial), satellite symposia etc. The medical association/society is the owner of the congress and responsible for attendee management, access, and other relevant criteria, e.g. the scientific agenda. The Congress gathers a multinational group of medical experts and professionals with the objective to increase the knowledge about and expertise in a disease state and treatment, to facilitate exchange and ultimately to advance patient care. The delegates usually comprise of HCPs, researchers and other individuals who work in the healthcare and/or research environment.
- A **Virtual International (Medical) Congress** is an International Congress where all activities are virtual/digital without an in-person event linked to it. Companies have the opportunity to participate in the form of virtual exhibition stands as well as virtual satellite symposia.
- **Exhibition Stands** are areas in the context of an International Congress where pharmaceutical companies (and other organizations) can display their product material to delegates in the commercial booth and their scientific material in the medical exhibition area.
- A **Satellite symposium** is a Company activity which occurs immediately prior, during or immediately after the main scientific program in the context of an International Congress.
- A **Healthcare Professional (HCP)** means any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, sell or administer a pharmaceutical product.