EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations

(EFPIA HCP/HCO DISCLOSURE CODE)

Frequently Asked Questions – FAQ

It is understood that unless there is a strong legal mandatory requirement, no deviations from the EFPIA HCP/HCP Disclosure Code should be envisaged by the Member Associations, which were required to transpose the Code in full by 31 December 2013.

These FAQs provides clarification and interpretation of the EFPIA Code provisions. They are provided as guidance and in addition relevant national association codes and related guidance have to be considered.

It is recommended that companies carefully consider the content of their Methodological Notes to ensure they address some of the complex situations that cannot always be addressed in FAQs. Companies are also advised that, where there are doubts, the reasonable solution is to disclose unless the Transfer of Value is clearly out of scope. *Companies would not be criticized for over-disclosure, but are likely to be in breach of national codes for under-disclosure.*

This document replaces previous drafts and editions
Where the question is from previous drafts released, the batch or list and question number has been added for ease of reference (e.g. Batch/List x, Q.x).

Points of Clarification and Definitions

Transposition Expectation

The EFPIA Codes set out the minimum standards, which must apply to all countries with an EFPIA Member Association. The Member Associations are required to transpose the EFPIA Codes in their national codes, in line with applicable laws and regulations.

The Member Associations are expected:

- Where possible, to transpose the EFPIA Code in full (without deviations);
- Deviations from the EFPIA Code should not go beyond mandatory national laws & regulations;

Issues that will arise at the time of disclosure – i.e. potential implementation issues – should not be a barrier, to the transposition of the Code. Such issues, e.g. protection of personal data ("privacy" regulations), may be dealt with during the implementation phase. The Member Company (who owns the data) will be responsible to gain consent of the Recipient of a Transfer of Value, and will make its own decision on how it will comply with the Code.

However, with a view to simplifying the process of collecting consent from individual HCPs (and in some case, HCOs), EFPIA will support Member Associations in countries where consent issues may constitute a major hurdle to the implementation of the EFPIA Code in full.

Template

At its 18 December 2013 meeting, the Board acknowledged the value of making the Disclosure Template mandatory, which will therefore be referenced as "The Template". Deviations would only be acceptable where legal requirements justify that the EFPIA Code is not transposed in full, and therefore, in a given country, a single template shall apply.

For good understanding, the Template is made in a manner, which shows how the publications should be made. Nevertheless, other templates could be imposed by the relevant national authorities/codes, for instance for uploading data onto central platform.

The Template in place has been latest updated on 11 December 2013 (rev1).

Research and Development

Where questions arise relating to potential Research and Development activities, companies should first consider if the activity fulfils the definition of Research and Development, set out below:

- If the answer is **yes**, then the disclosure should be on an aggregate basis, as set out in Section 3.04, under the category "Research and Development Transfers of Value".
- If the answer is **no,** then the Member Company should declare, as required, on an individual basis as set out in Section 3.01.

The Disclosure Code defines "**Research and Development Transfers of Value**" as Transfers of Value to HCPs or HCOs related to the planning or conduct of:

i. **non-clinical studies** (as defined in *OECD Principles on Good Laboratory Practice*);
ii. **clinical trials** (as defined in Directive 2001/20/EC); or
iii. **non-interventional studies** that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study (*Section 15.01 of the HCP Code*).

Definitions in the relevant legal and regulatory instruments

i. Non-clinical studies as defined in the OECD Principles on Good Laboratory Practice

The OECD Principles on Good Laboratory Practice (as latest revised in 1997) define non-clinical studies as follows (Section I – 2. Definitions of Terms; section 2.3.1):
Non-clinical health and environmental safety study, henceforth referred to simply as "study", means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities.

For complete reference, see www.oecd.org

ii. Clinical trials (as defined in Directive 2001/20/EC)

The EU Directive 2001/20/EC (Article 2(a)) defines clinical trials as:
any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmaco-dynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy.

For complete reference, see http://eur-lex.europa.eu

iii. Non-interventional studies

The EU Directive 2001/20/EC (Article 2(c)) defines non-interventional trials as:
study(ies) where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data.

Non-interventional studies are subject to the provisions of the EFPIA HCP Code (Section 15.01).

Privacy law & regulations

Article 7 of Directive 95/46 EC on "Data Protection" states that Member States shall provide that personal data may be processed only if:

a) the data subject has unambiguously given his consent, or
b) processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract, or

c) processing is necessary for compliance with a legal obligation to which the controller is subject, or
d) processing is necessary in order to protect the vital interests of the data subject, or
e) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller or in a third party to whom the data are disclosed, or
f) processing is necessary for the purposes of the legitimate interests pursued by the controller or by the third party or parties to whom the data are disclosed, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection.

In application of these provisions, Member States have laid out the conditions for disclosure of personal data. Therefore, Member Companies are referred to national laws (including jurisprudence) in place, and will organise their disclosures in line with these laws and regulations.

As a general rule, each Member Company will therefore need to obtain the consent of each HCP (or HCO when privacy regulation also apply to organisations) to disclose their personal data. Where Transfers of Value to an HCP (or HCO, as applicable) occur in the context of a contract, the contract provides a ready mechanism to obtain the data subject's consent to the processing of his/her personal data. As a matter of good practice, companies should create and retain evidence showing that the consent was indeed given.

A company (as a data controller) may have legitimate interest in disclosing data – for instance: to promote confidence in its relationships with HCPs. This legitimate interest must be outweighed by the data subject's interests. The legal basis is significantly strengthened when a data controller can say that consent had been obtained.

There is no prescribed process for Member Companies to follow for handling HCP or HCO enquiries, nor are they obliged under the Code to validate data with HCPs or HCOs before disclosure. However, as a matter of good practice, companies are advised to put in place procedures for handling enquiries and for making HCPs / HCOs aware of the content of upcoming disclosures.

The Executive Committee has asked EFPIA to provide additional support to Member Associations and local operations in countries where consent issues may constitute a major hurdle to implementation of the EFPIA in full. EFPIA will intensify its efforts throughout 2015 towards resolution of outstanding hurdles.

Competition & regulation

The Code was drafted with the support of legal counsel, taking into account the relevant competition law considerations. This support gives EFPIA sufficient comfort as to conformity of the Code with applicable EU legislation.

In some countries, self-regulation is submitted to prior authorisation of Competition Authorities. For instance, in Germany, the Bundeskartellamt has approved the FSA Code. This gives additional comfort about the appropriateness of the EFPIA Code.

Cross Border Payments

Disclosures of Transfers of Value should be made pursuant to the national code of the country of the Recipient's Principal Practice (i.e. its business address, place of incorporation or primary place of operation in Europe – "Principal Practice").

The objective of the EFPIA Disclosure Code is to require transparency of Transfers of Value to ensure that this information can easily be found by the searching patient or other interested stakeholder. The address where the HCP practices or HCO is located should be used as the reference when determining in which country the data should be disclosed.

Therefore, Transfers of Value that fall within the scope of the EFPIA HCP/HCO Disclosure Code should be disclosed in the country where the Recipient has their Principle Practice in Europe, whether the Transfer of Value occurs in or outside of that country.

Each Member Company will clarify in its Methodological Note how cross-border Transfers of Value are being disclosed.

Deviations and Variations

In principle, Member Associations are asked to transpose the Code in full and in a manner consistent with applicable laws and other applicable legal requirements. Member Associations are required to inform EFPIA of reasons why national disclosure requirements differ from those required under the EFPIA Code. Such differences shall be clearly and conspicuously so identified.

Unless there are strong legal mandatory requirements, it is expected that Member Associations will transpose the Code in full i.e. without deviations. In each country, Member Companies will be required to comply with the disclosure requirements applicable in that country.

With support of an independent consultant (ICE Ltd), EFPIA has conducted an in depth comparative analysis of all national codes versus the Code. Follow-up actions have been discussed and reviewed with the relevant Member Associations. The table below summarises the outstanding issues reported to the Board / Executive Committee.

DISCLOSURE CODE TRANSPOSITION STATUS – Actions Required

Latest update: 09 December 2014

Comment	Countries
TRANSPOSITION COMPLETED (21)	Austria, Belgium, Bulgaria, Croatia, Cyprus, Estonia, Germany, Greece, Hungary, Italy, Lithuania, Malta, Poland, Russia, Serbia, Slovenia, Spain, Sweden, Switzerland, Turkey, UK.
Outstanding issues with **CENTRAL PLATFORMS** (2) - being finalized	Ireland, Slovakia
Outstanding issues with **TEMPLATE** (3)	Ireland, Slovakia, Ukraine
DEFINITION OF HCP (2)	Czech Republic, Finland
LEGISLATION IN PLACE (8) – assessing how to close the gaps	Denmark, France, Latvia*, the Netherlands, Norway, Portugal, Romania*, Slovakia

Country	* Outstanding issues
Latvia	Legislation being past (no direct sponsorship to HCPs to attend Congress)
Romania	Legislations passed in February 2014, but outstanding implementation measures, making law inoperable – ARPIM's Code shall apply

Source: ICE Ltd

Member Associations are finalising/ fine-tuning transposition of the EFPIA Disclosure Code: variations and deviations have been identified, and follow-up actions are being completed with a view to ensuring consistency among countries, as appropriate. However, it has become clear that additional issues, clarifications, etc. will become apparent as companies move through implementation and these will be addressed as they come up – attempting to resolve all details (that are often company-specific) upfront will unduly delay/ increase complexity.

For good understanding:

- A VARIATION is a provision in a national code that is stricter than the provision in the Code – in such cases, the Code is transposed in full, but includes stricter standards (such as: an extended scope (for instance to include all OTC) or additional discloser categories).
- When, because of mandatory national regulations Member Associations cannot transpose the Code in full, the "gaps" are considered DEVIATIONS under Article 4.02 of the Code. EFPIA is preparing detailed reports for those countries where there are such DEVIATIONS, and will ensure they are kept to a minimum.

FREQUENTLY ASKED QUESTIONS
Submitted by the Membership
Questions follow the order of the Code Sections & Articles

PREAMBLE

Question Preamble - 1 (*Batch 1 Q.3 re-worded – previously List 1 Q 1)**:* **What efforts has EFPIA taken to ensure that transparency can be achieved without sacrificing the legitimate privacy interests of healthcare professionals?**
See also the "Point of Clarification & Definitions" on Privacy Law & Regulations", and questions 1 & 2 of the Section 3.02

Answer: When **transposing** the EFPIA Disclosure Code into national codes, each Member Association should obtain the necessary legal advice as to applicable laws and regulations in its country.

EFPIA has engaged (and will continue to engage) with scientific and medical societies at the European level with a view to ensuring full understanding of the industry's standards. Member Associations are expected to engage in similar discussions at the national level. In some countries, this has/may lead to co-creation of disclosure platforms with HCPs/HCOs *(see also section 2.04)*.

Question Preamble - 2 *(Batch 1 Q.1 – previously List 2 Q 29)***: Will there be a formal process for HCP or HCO enquiries? How long will companies have to respond to HCP or HCO requests to confirm or validate data?**

***Answer*:** It is strongly recommended that Member Companies' undertakings in their relationships with HCPs/HCOs are clearly set out in a written contract with the HCP/HCO. This recommendation is reflected in a footnote to Section 4.01 of the EFPIA Disclosure Code, as follows:

> *When making a Transfer of Value to an HCP/HCO, and in their written contracts with HCPs/HCOs, Member Companies are encouraged to include provisions relating to the recipients' consent to disclose Transfers of Value in accordance with the provisions of the EFPIA HCP/HCO Disclosure Code. In addition, companies are encouraged to renegotiate existing contracts at their earliest convenience to include such consent to disclosure.*

A Member Company should bear in mind the obligation under Section 3.01 to be able to demonstrate that its disclosures were accurate at the time they were made in the event of a complaint and be able to respond to requests to the relevant Recipient or the relevant authorities.

Question Preamble - 3 *(Batch 1 Q.2 - previously List 2 Q 31)***: Have any criteria or conditions been established for the types of events that would require Member Companies to restate or amend their disclosure reports? Where is the data expected to be amended: only in publicly viewable reports or also in the source systems / reporting databases**?

Answer: When a Member Company is aware of inaccuracies in its public disclosure, it must, as a matter of principle, correct that information. The company will decide if amendments to its source

systems or reporting databases are required. This may depend on the type and significance of the inaccuracy.

***Question Preamble - 4*: *(Batch 1 Q.61 – previously List 2 Q 30)* To ensure consistency among Member Companies, will EFPIA or EFPIA's Member Associations provide HCP and HCO master data lists (including unique identifiers, names, addresses, etc.)?**

Answer: No. EFPIA will not be developing a unique database of HCPs / HCOs.

Member Associations at the national level may develop such databases; however, Member Associations are under no obligation to do so. Member Associations may also recommend the use of the existing databases or otherwise provide additional clarification.

In any event, Member Companies have to ensure that each Recipient is identified in such a way that there is no doubt as to the identity of the HCP/HCO benefiting from the Transfer of Value. Therefore, it is expected that each Member Company will develop its own *unique identifiers*.

APPLICABILITY OF THE CODE

***Question Applicability - 1** (Batch 2 Q 32 – previously List 2 Q 32)**:** How should Member Companies involved in a co-promotion agreement disclose any Transfers of Value made under the agreement? Should disclosure align with the % split of cost-sharing set out in the agreement?*

Answer: Each Member Company involved in the co-promotion agreement will disclose their own Transfers of Value. The co-promotion agreement is not relevant in this case.

***Question Applicability - 2** (Batch 2 Q.2 – previously List 1 Q 3)**:** What should companies do if they believe that disclosure requirements may pertain to commercially sensitive or other information not suitable for being disclosed by Member Companies? Will EFPIA provide additional guidance with respect to such situations?*

Answer: The Methodology Note that each Member Company will add to its disclosures is designed to ensure it is clear how data has been managed such that companies do not have to publish what would be seen as commercially sensitive, in compliance with relevant laws and regulations.

The content of the Methodology Note is the exclusive responsibility of each Member Company, and EFPIA will not provide additional guidance.

***Question Applicability - 3** (Batch 1 Q.7 – previously List 1 Q 4)**:** Once a Member Association has transposed and adopted a local version of the Code, should Member Companies follow the national code (rather than the EFPIA Code) in each country in which they operate, even if a particular country has not transposed all of the EFPIA requirements?*

Answer: It is a condition of EFPIA membership that Member Associations adopt **all** EFPIA Codes **in full**, and that Member Companies comply with the national codes (even in those countries where they are not a direct member of the relevant Member Association). EFPIA has the right to exclude

any member – corporate or association – that does not meet its obligations under the EFPIA Codes or otherwise jeopardise achieving the goals pursued by EFPIA.

Where a Member Company operates in a jurisdiction where a Member Association has transposed the EFPIA Code into its national code by the relevant deadline but with a deviation agreed by EFPIA, such Member Company will be required to comply with the Member Association's Code.

Where a Member Company operates in a jurisdiction where a Member Association has **failed** to transpose the EFPIA Code into its national code by the relevant deadline, such Member Company will be required to comply with the EFPIA Code **directly** in the country concerned – i.e. the EFPIA Code would then have "direct effect" in such country *(see Applicability, § 6)*.

If a Member Company is not a member of the EFPIA Member Association in any given country in Europe, it agrees, as a consequence of its membership in EFPIA (either directly or through its relevant subsidiary), to be bound by that EFPIA Member Association's code *(see Applicability, § 7)*.

As a general rule, it is consider that where third parties represent or act on behalf of a Member Company, the respective obligations should be "transferred" to the third party. This will be reflected in the contractual arrangements, as appropriate.

ARTICLES

Article 1: Disclosure Obligation

Section 1.01: General Obligation

Question 1.01 - 1 *(Batch 1 Q.9 – previously List 1 Q 5)***: Does the reporting obligation apply to value/cost of Transfers of Value made by a Member Company, or should the disclosure focus on the income / benefit that the Transfer of Value constitutes for a HCP/HCO?**

Answer**:** The disclosure obligation pertains to Transfers of Value made by Member Companies, not to the resulting income / benefit to the HCP/HCO.

Question 1.01 - 2 *(Batch 2 Q.21 – previously List 2 Q 33)****:*** **When Transfers of Value are made through an intermediary, are Member Company required to disclose them on an individual basis? Will such disclosure require consents of the intermediary as well as of the HCP / HCO who is the ultimate beneficiary?**
See also questions 3 & 6 of Section 2.05

Answer: As a rule, Transfers of Value and payments should be disclosed on an individual basis, with aggregate disclosure being permitted as an exception.

Where an intermediary (third party) represents or acts on behalf of a Member Company, it must ensure that its respective obligations are fulfilled. It is recommended that the Member Company makes the necessary arrangements with the third parties, in a written contract, as to how its obligations under the EFPIA Codes will be fulfilled.

> For reference: The EFPIA HCP Code states: "*Member Companies shall also be responsible for the obligations imposed under any relevant Applicable Code even if they commission other parties (e.g., contracted sales forces, consultants, market research companies, advertising agencies) to design, implement or engage in activities covered by the Applicable Code on their*

behalves. In addition, Member Companies shall take reasonable steps to ensure that any other parties that they commission to design, implement or engage in activities covered by the Applicable Code but that do not act on behalf of the Member Company (e.g., joint ventures, licensees) comply with Applicable Codes."

Where the intermediary is a professional conference organiser (PCO), Member Company should declare the Transfers of Value in the appropriate category in the name of the sponsored HCO. This is because in such case, the Member Company provides the sponsorship through the PCO, but with the intention to sponsor the HCO.

Question 1.01 - 3 *(previously List 3 Q 55)***: How should Member Companies represented by (independent) distributors handle Transfers of Value through such distributors?**
See also questions 2 of Section 1.01

Answer: If this distributor is involved in the promotion of medicines on behalf of a Member Company in an EFPIA country, then its activities are reportable by the Member Company in that country. As such, the Member Company must ensure, via contracts or other means that the distributor complies with the relevant local code.

Section 1.02: Excluded Disclosures

Question 1.02 - 1 *(previously List 3 Q 48):* **Why are specific Transfers of Value exempted from the disclosure obligation?**

Answer: The disclosure categories are determined in Article 3 of the Code. They cover interactions between pharmaceutical companies and HCPs/HCOs, except those categories for which limitations are included in the HCP Code, i.e.: activities relating solely to OTCs; samples; meals and drinks (that are subject to specific prescriptions and to thresholds set in the national codes); and informational & educational materials and items of medical utility.

Question 1.02 - 2 *(Batch 2 Q.4 – previously List 1 Q 6):* **Where companies have Non-Medical, Over-the-Counter (OTC), Diagnostics and other Healthcare Divisions, what should they declare under the Code?**

Answer: The Code aims at disclosing monetary values attached to activities that are self-regulated by the EFPIA HCP Code, which governs activities relating to prescription-only medicines (POM).

The "legal status" (POM, OTC, etc.) of a medicine is defined in the pharmaceutical regulation, and may differ from one country to the other.

In principle, the Disclosure Code is linked to POM. The Code excludes Transfers of Value that:

- are solely related to over-the-counter medicines;
- are not listed in Article 3 of the Disclosure Code (e.g. informational or educational materials and items of medical utility; meals and drinks; medical samples);
- are part of ordinary course purchases and sales of medicinal products.

Transfers of Value relating to a group of products that includes a POM (e.g. combination products/diagnostics and medicinal products) should be reported in total following the disclosure requirements of the Code.

Member Companies should include additional clarification on how such situations have been managed, in their Methodological Note.

Question 1.02 - 3 *(Batch 2 Q 34 – previously List 2 Q 34)***: Section 1.02 of the Code states that Transfers of Value that are solely related to over-the-counter medicines (OTCs) are excluded from the disclosure obligations under the Code.**
Does that mean that any Transfers of Value to HCPs / HCOs related to OTCs that can also be prescribed need to be disclosed?

Answer**:** Transfers of Value that are solely related to over-the-counter medicines are excluded from reporting.

However, when a Member Company promotes an over-the-counter medicine with a prescriber, with the intention to generate prescription, then the Member Company should consider disclosing the Transfers of Value attached to this activity. Member Companies should include additional clarification on how such situations have been managed, in their Methodological Note.

Question 1.02 - 4 (Section 1.02): **Shall the investigational compounds and biological sample for a study have to be disclosed?**

Answer: As the medical samples are excluded from the disclosure obligations, the same principle should apply to investigationnal compounds and biological sample for study.
The investigationnal compounds and biological sample are subject to provisions under the Clinical Trials Directive, and their use will submitted to Clinical Trials approval processes.

Article 2: Form of Disclosure

Section 2.01: Annual Disclosure Cycle

Question 2.01 - 1 *(previously Batch 2/ List 2 Q35, and List 3 Q 71):* **How should expenses concerning congresses be disclosed when dates of expenses differ from a date when a congress takes place (e.g. advance payments, payments upon reservation to travel agencies and payments for air flights)?**

Answer: Member Companies are required to disclose Transfers of Value as and when they are made. They would therefore be expected to disclose Transfers of Value in a given year within 6 months after the end of the relevant reporting period. *Thus payments made in 2015 will have to be disclosed by 30 June 2016.*

It is expected that Member Companies will apply the relevant company accounting principles. However, the principles applied shall not allow Transfers of Value not to be disclosed, for instance by changing the principles from one year to the next.

Member Companies are expected to provide information on how their disclosures are managed in their Methodological Note, where they can also provide additional clarification on Transfers of Value recognition.

Section 2.02: Time of Disclosure

Question 2.02 - 1 *(Batch 1 Q.11 – previously List 2 Q 36)***: What are the obligations of a Member Company when a Recipient's consent is revoked? Is it sufficient to stop disclosing the relevant information on an individual basis going forward or are Member Companies required to amend / restate historical reports that have already been published? Are Member Companies required to remove all such information from all source systems, reporting databases, etc.?**

Answer**:** The relevant data privacy and other (local) laws will apply to such cases. Member Companies will need to assess the implications of such revocation on a case-by-case basis and are encouraged to seek independent legal advice.

However, depending on any (local) legal implications of revocation, companies must retain data relating to specific transactions and report such Transfers of Value on an aggregate basis, in line with applicable national law and regulations.

Section 2.04: Platform of Disclosure

Question 2.04 - 1 *(Batch 2 Q 37 – previously List 2 Q 37)**:*** **Methodological Note – where a central disclosure platform is in place, should the Member Companies be obliged to publish their Methodological Notes the same central platform or will it be sufficient if their Methodological Note are published on their own company website?**

Answer: It would be logical that the Methodological Notes can be accessed along the data they are supposed to clarify. How this is technically achieved will be decided at national level, as part of the "rules" applicable to the central platform.

Since the Methodological Notes are meant to explain how companies have constructed their data, it is obvious that companies take responsibility for the content of their methodological notes.

Section 2.05: Applicable National Code

Question 2.05 - 1 *(previously List 3 Q 66):* **Is the Member Company required to disclose in accordance to local regulations on one site, and in accordance with EFPIA recommendations on another site?**

Answer: Member Companies can make their disclosures either on a relevant website of the Member Company, or on a central platform. Member Companies will not be requested to duplicate disclosures. However, the information shall be accessible in the countries where the Recipients have their principal practice.

It may be helpful for Member Companies to make clear, on their own websites, where their disclosures can be accessed if they are not on the company's website where the Recipients have their principal practice (e.g. central platform, government website, the company's head offices website or another website of the company). Whatever the option the Member Companies all its Transfers of Value to a given Recipient shall be found in the same place.

Question 2.05 - 2 *(Batch 1 previously Q.56 – previously List 2 Q 38)**:*** **Should disclosures pursuant to the Code also be made in respect of secondary (that is, not the principal) practice or professional address?**

See also questions 2 of Section 1.01 & 6 of Section 2.05

***Answer*:** The Code requires disclosure in the country where the Recipient has its Principal Practice. All Transfers of Value to a given Recipient will be disclosed in the country where this Principal Practice is located.

As a principle, no disclosure would be required in the secondary (or other) country of practice of a given Recipient, unless this would significantly enhance transparency (for example, where the Principal Practice is in the country that is not within EFPIA's jurisdiction). Member Companies will provide additional clarification in their Methodology Notes if required.

Question 2.05 - 3 *(Batch 1 Q.15 – previously List 1 Q 8)**:*** **When a consultant is used in another country, where should this be disclosed?**

***Answer*:** Transfers of Value to a HCP / HCO whose practice, professional address or place of incorporation is in Europe, are required to be disclosed in the country where the **Recipient has its principal practice**, pursuant to the national code of the country where the Recipient's principle practice is located, whether the Transfers of Value occur in or outside that country.

The Code requires transparency of Transfers of Value based on the country of primary/principal practice, which will ensure that the searching patient or other interested stakeholder can easily find this information. The physical address where the HCP practices or HCO is located should be used as the reference when determining in which country the data should be disclosed.

Each Member Company will clarify in its Methodological Note how cross-border Transfers of Value are being disclosed.

Examples:

- A Member Company's US headquarters sponsoring a HCP whose practice is in Sweden for an activity in Germany will be required to disclose the Transfer of Value under the name of the Recipient HCP in Sweden (following the applicable laws, regulations and the national code in Sweden).
- An Italian Member Company sponsoring a HCO located in Italy to provide expertise to a hospital in Tunisia will be required to disclose the Transfer of Value in the name of the Recipient HCO in Italy (following the application of Italian laws, regulations and national codes in Italy).
- A Spanish Member Company sponsoring a US expert for participation in an advisory board in Argentina is not required to disclose that Transfer of Value under the EFPIA Code. However, disclosure may be required in other jurisdictions, including in the US under the "Sunshine Act".

Question 2.05 - 4 *(Batch 1 Q.14 – previously List 1 Q 7)**:*** **Which legal entities are required to make disclosures? Are disclosures by the parent company sufficient or are local affiliates required to make their own disclosures? Can affiliates of the same company in one country each disclose part of the Transfers of Value?**

***Answer*:** The EFPIA Code states that each Member Company will decide how to organise its disclosures, either at a central or local level, unless the national code fixes the platform of disclosure. However, disclosure should conform to the national code requirements and relevant disclosures should be publicly accessible in the country where **the Recipient has their practice.**

If a Member Company is not resident or does not have a subsidiary or an affiliate in the country where the Recipient has their principal practice, the Member Company should disclose such Transfer

of Value in a manner consistent with the national code of the country where the **Recipient has their practice**.

When a Member Company has separate organisations within the same country, it will decide on the most appropriate legal entity for such disclosures. All Transfers of Value to a given Recipient should be disclosed in "one place" – disclosure in the country where the Recipient has their practice must cover all Transfers of Value made to the same HCP/HCO, irrespective of where they occurred (i.e. whether in or outside of the country where the Recipient has its practice).

Regardless of the approach used (i.e. disclosure on the parent company's website or at an affiliate level), disclosures must be made in compliance with the national code applicable in the country where the Recipient has its practice, in line with applicable national laws and regulations.

In the event that several parts of the same Member Company generate payments in the same country to the same HCPs, these payments should be disclosed on the same website, and cannot be split, on the basis of a different part of the company engaging.

Moreover, disclosures have to take into account local arrangements and this is particularly relevant if the Member Association requires disclosure by means of a central platform.

Question 2.05 - 5 *(Batch 2 Q.8 – previously List 1 Q 9):* **A US affiliate of a company that is an EFPIA direct member makes a Transfer of Value to a (Spanish) HCP. Is it understood that this Transfer of Value has to be captured according to the (Spanish) Code, and the (Spanish) affiliate, if any – not the US one – would be responsible for reporting the Transfer of Value? Which entity would be sanctioned?**

Answer: Disclosures shall be made pursuant to the national code of the country where the Recipient has its principal practice. Unless the platform for disclosure is fixed in the national code or imposed by national law, the Member Company will decide whether the disclosure will be made on the companies head office website or each affiliates website. But it must be possible for the public to easily find and access the disclosed information in the country where the Recipient has its principal practice.

In case the Member Company is found in breach of the applicable code, the Member Association of the country where the Recipient has its principal practice – in this instance Spain – would sanction the Spanish company as this is within their jurisdiction.

For example, in the UK it is a clearly established principle that the UK Company is responsible under the ABPI Code for the activities of overseas companies in the UK.

Question 2.05 - 6 *(Batch 1 Q.16 –previously List 1 Q 10):* **Are non-European companies – e.g. a US company – required to disclosure Transfers of value to HCPs/HCOs in Europe?**

Answer: Any company that is a corporate member of EFPIA is required to comply with the EFPIA Codes. The Code requires, for example, that Transfers of Value made by the US part of a Member Company to HCPs/HCOs with their practice in one of the 33 countries covered by EFPIA should be disclosed.

The EFPIA Code applies to all EFPIA members as defined under the section "Applicability of The Code", which covers:

- Corporate Member Companies;
- Members of EFPIA Specialised Groups: (i) European Bio-pharmaceutical Enterprises
- (EBE); and (ii) Vaccines Europe (VE); and

- Member Companies of Member Associations that are not directly members of EFPIA.

For EFPIA direct membership (i.e. corporate members), separate entities belonging to the same multinational company – which could be the parent company (e.g. the headquarters, the principle office, or the controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organization – are deemed to constitute a single company, and as such all these entities are required to comply with the EFPIA Codes.

Question 2.05 - 7** (previously List 3 Q 69)**: **Are payments made to a European-based HCO from outside Europe required to be disclosed? If so, which exchange rate should be used?**
See also questions 2 of Section 1.01 & 3 of Section 2.05

Answer: Yes, Transfers of Value to HCOs, even when made from outside Europe, will require disclosure in line with the national code of the country of incorporation in Europe. *The 33 countries covered by the Code are listed in the footnote on page 4 of the Code.*

Member Companies are expected to provide information on the treatment of currency aspects in their Methodological Note.

Section 2.07: Documentation and Retention of Records

***Question 2.07 - 1** (Batch 1 Q.20 – previously List 2 Q 39)*: **What qualifies as "relevant records" that Member Companies should maintain? Does this refer to all source system transactions, reporting databases, etc. relating to individual HCPs and HCOs? Does this also include hard copies of supporting documents, such as contracts, receipts, reports, etc.?**

Answer: The definition of "relevant records" depends on the nature of a Transfer of Value. In the event of a enquiry / inquiry / complaint, a Member Company should be able to demonstrate that its disclosures were accurate at the time they were made and has to be able to respond to requests of the relevant Recipient or authorities under Section 3.01 in line with applicable law and regulations, including data protection laws (including in regard of retention of information / documents).

The requirements of the Code are in addition to any other document retention obligations that a Member Company may have.

Article 3: Individual and aggregate Disclosure

Section 3.01: Individual Disclosure

***Question 3.01 - 1** (Batch 1 Q.33 – previously List 1 Q 11)*: **What does the phrase "clearly identifiable Recipient" mean?**

***Answer*:** Member Companies have to ensure that each Recipient is identified in such a way that there cannot be any doubt about the identity of the HCP/HCO receiving the Transfer of Value.

Question 3.01 - 2** (Batch 1 Q.24 – previously List 1 Q 13)**: **How should "related expenses" agreed to in a Fee for Service or Consultancy contract be treated?**

***Answer*:** As a general rule, "related expenses" agreed to in a "Fees for Service" or "Consultancy" contract should be disclosed in the relevant category – i.e. the amount of the fee will be shown separately from the related expenses agreed in the Fee for Service or the consultancy contract *(see Schedule 2 Model Template, page 13 of the Code)*.

Where a service agreement / consultancy agreement is in place, incidental expenses would be, for example, the travel and accommodation cost associated with the activity and as such do not constitute part of the Fees being paid to the contracted party. When such expenses are not material (e.g. of limited value), Member Companies may not have registered them separately from the Fees. If disaggregation of expenses registered in the companies' accounts is not appropriate or easily achievable, Member Companies should explain the treatment of the "related expenses" in their Methodology Notes.

***Question 3.01 - 3** (Batch 1 Q.25 – previously List 1 Q 14)*: **If services are performed in connection with a third-party congress, should the related expenses be disclosed under "Contribution to costs related to Events" or "Fees for Service and Consultancy"?**

***Answer*:** In this example, services are performed (either by a HCP/HCO): therefore these should be declared under the "Fee for Service" category.

***Question 3.01 - 4** (Batch 1 Q.26 – previously List 1 Q 15):* **How should the hire of booths or stand space be disclosed?**

***Answer*:** In general, the hire of booths or stand space are regulated by "Sponsorship Agreements" with HCOs or with Third Parties that manage an event.

When organised by Third Parties, the sponsorship would be considered an indirect Transfer of Value. Disclosure should be made in the country where the HCO is registered.

Member Companies are advised to include a provision relating to the consent to disclose in their "Sponsorship Agreements".

***Question 3.01 - 5** (Batch 1 Q.42 – previously List 1 Q 16)*: **What Transfers of Value should be reported under "Registration Fees" paid to HCOs?**

***Answer*:** The total amount of Registration Fees paid in a given year to a HCO should be disclosed on an individual basis (in the name of the HCO) under "Contribution to costs related to Events".

***Question 3.01 - 6** (Batch 1 Q.43 – previously List 1 Q 17)*: **What Transfers of Value should be reported under "Registration Fees" paid to a HCP?**

***Answer*:** The total amount of Registration Fees paid in a given year to a HCP who is the clearly identifiable Recipient should be disclosed on an individual basis (in his / her name) under "Contribution to costs related to Events".

***Question 3.01 - 7 (Section 3.01)** (Batch 1 Q.35 – previously List 2 Q 40)*: **How should indirect sponsorship of HCPs through HCOs be disclosed?**

***Answer*:** Indirect sponsorship of HCPs through HCOs should be disclosed under payment to HCOs as this is the Recipient of the Transfer of Value. Such disclosures would be disclosed under the

category "Contribution to Costs related to Events / Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an event".

Question 3.01 - 8 *(Batch 1 Q.44 – previously List 1 Q 18)****:*** **What types of items should be reported under "Sponsorship Agreements" with HCOs or with Third Parties Appointed by a HCO to Manage an Event"?**

Answer**:** "Sponsorship Agreements" are formalised in contracts that describe the purpose of the sponsorship and the related Transfers of Value. If the contract includes "Registration fees" and "Travel and Accommodation", such Transfers of Value should be disclosed separately in the relevant categories in the name of the HCO.

Examples of activities that should as a minimum be covered under "Sponsorship Agreements":

- Rental of booths at an "Event";
- Advertisement space (in paper, electronic or other format);
- Satellite symposia at a congress;
- Sponsoring of speakers/faculty;
- If part of a package, drinks or meals provided by the organisers (included in the "Sponsorship Agreement");
- Courses provided by a HCO (where the Member Company does not select the individual HCPs participating).

Member Companies may provide additional clarification on the nature of the Transfers of Value included in this category in their Methodology Notes.

Question 3.01 - 9 *(Batch 1 Q.48 – previously List 1 Q 19)****:*** **What types of items should be reported under "Fees for Service and Consultancy" to a HCP/HCO, directly or through a third party?**

Answer**:** As good practice, Member Companies will formalise such collaboration in a contract describing the purpose of Transfers of Value.

Examples of Transfers of Value that could be covered under Fee for Service and Consultancy agreements:

- Speakers' fees;
- Speaker training;
- Medical writing;
- Data analysis;
- Development of education materials;
- General consulting / advising.

The payment received by the contracting entity – which may be a HCP, a legal entity owned by a HCP (which is then a HCO) or a HCO – will be disclosed as a Transfer of Value made to that entity.

Member Companies may provide additional clarification on the nature of the Transfers of Value in their Methodology Notes.

Question 3.01 - 10 *(Batch 1 Q.21 – previously List 2 Q 41)****:*** **When a Fee for Services is provided to a legal entity that is owned by a physician should this be disclosed as a Transfer of Value to an HCP or an HCO? Similarly, how should a payment to a clinic where a physician is employed be disclosed?**

***Answer*:** Disclosure is made on the Recipient's name. The Fee for Service paid to a legal entity owned by a physician should be disclosed under the name of the legal entity (considered an HCO under the Code), as this is the Recipient of the payment. Similarly, payments to a clinic, when disclosed on an individual basis, will be disclosed in the name of the clinic.

The Code requires that Member Companies will make individual disclosures in the name of the person / legal entity that receives the Transfer of Value (i.e. the Recipient).

***Question 3.01 - 11** (Batch 1 Q.28 – previously List 2 Q 42)*: **What should be disclosed under "Travel and Accommodation"?**

***Answer*:** All expenses related to "Travel and Accommodation", such as costs of flights, trains, car hire, tolls, parking fees, taxis and hotel accommodation should be disclosed.

The Code does not require disaggregating Transfers of Value to a group of HCPs. For instance, where mass group transport (e.g. a bus / coach) is organised for an event, the cost can be disclosed on an aggregate basis and does not need to be apportioned / allocated to each individual HCP having benefitted from the "Travel and Accommodation".

Each Member Company will clarify what it includes under the "Travel and Accommodation" category in its Methodology Note.

For the avoidance of doubt, under the EFPIA Code, "meals and drinks" do not need to be disclosed as such Transfers of Value are regulated by the new provisions in the EFPIA HCP Code. National laws and regulations may have additionnal obligations.

> For reference:
> The EFPIA HCP Code requires *"each Member Association to set a monetary threshold in its national code by 31 December 2013, failing which EFPIA will set such threshold. Where the monetary value of "meals and drinks" does not exceed the applicable threshold, these will not need to be disclosed. Where Member Companies would provide or offer "meals and drinks" exceeding the applicable threshold, they would not be compliant with the EFPIA HCP Code."*

***Question 3.01 - 12** (Batch 2 Q.14 – previously List 2 Q 43)*: **In market research studies the identity of the respondents is usually not known and such research is often performed through market research companies. However, Member Companies usually know how many HCPs will participate and how much they get paid. In such case, should Member Companies disclose related Transfers of Value in aggregate?**

***Answer*:** The Code does not require disclosure of the Transfers of Value made to market research companies when the identity of the HCPs/HCOs participating in the market research studies is not known.

As a rule, one of the basic tenets of market research is the right of the respondents to remain anonymous, which is also enshrined in market research definitions and relevant codes of conduct worldwide. However, where the Member Company knows the identity of the HCP/HCO participating in activities defined as market research the Member Company should disclose it in the "Fees for Service and Consultancy" category. In such exceptional cases, it is expected that the Member Company will secure the consent to disclosure through contract.

Question 3.01 - 13 *(Batch 2 Q.15 – previously List 2 Q 44)***: Should a Member Company disclose the costs relating to 'stand alone' half-day meetings dedicated to therapeutic education or general scientific meetings – where the Member Company would cover the cost for the facility, lunch and lecturers? If so, under which category will these costs be reported?**

Answer**:** "Stand alone" events are within the scope of the Code. Transfers of Value relating to such events will be disclosed in the relevant categories (as will be the case: "Events", "Fee for Service and Consultancy", R&D Transfers of Value).

Member Companies are not obliged to disclose any logistical costs e.g. hire of Member Companies facility associated with a stand-alone event. However, Transfers of Value to participants to such events must be disclosed. *For instance, Transfers of Value for non-investigators HCPs during an investigator meeting are disclosable.*

Question 3.01 - 14 *(previously List 3 Q 61)*: **How should Transfers of Value be disclosed when a vendor is organising an event, with sponsorship of a Member Company, on behalf of more than one HCO?**
See also questions 8 & 9 of Schedule 1

Answer: If the Member Company knows which Transfers of Value each HCO has received, it should report the Transfers to the relevant HCO.

Where it would not be possible to allocate the Transfers of Value to each HCO involved in the event, it would be reasonable to consider that the HCOs have similar levels of involvement. In such case, the Transfers of Value would be divided by the number of HCOs, which would each be reported as having received their equal share of the Transfers of Value.

Information on how this is managed should be considered in the Methodological Note.

Question 3.01 - 15 *(previously List 3 Q 54):* **How should Member Companies handle the more intangible Transfers of Value relating to medical publications support?**
See also question 3.01 - 16

Answer: Medical publications may include case studies, supplements, congress write ups, consensus reports, clinical management guidelines etc. Health industries' support to medical publications are submitted to law and regulations, or self-regulatory codes which the Member Companies have subscribed to.

Without prejudice to applicable regulations and codes, Member Companies' support to medial publications, either directly or indirectly, should be disclosed according to the Code.

For example, if a Member Company pays a Fee for Services to a HCP to write an article, then the Transfer of Value has to be disclosed in the Fees for Services category. If a Member Company gives other kind of (direct or indirect) support, then it has to explain the way of disclosure in its Methodological Note.

Question 3.01 - 16 *(Batch 2 Q.13 – previously List 2 Q 45)*: **A HCP may ask companies to assume the translation costs into different languages of a piece he / she authored. A healthcare professional may also ask for financial support for editing or publishing such materials in a scientific journal.**

Are companies required to disclose the Transfers of Value associated to those collaboration?

***Answer*:** It is reminded that under the new Article 9 of the EFPIA HCP Code does not permit to provide support that offset routine business practices of the Recipient. If the cost referred to in the question constitute costs relating to routine business practice such support shall not be provided, and doing so would constitute a breach of the HCP Code.

The answer to the question will therefore depend on the specifics of the situation:

- If the request was associated with an activity where there was already a service agreement in place or there was a contractual relationship between the HCP and the company, then this support would, in principle, not be considered as off-setting costs relating to routine business practices of the HCP. In this case, this service should be included in the contract / agreement in place and disclosed accordingly, under "Fee for Service and Consultancy".
- If the request was not associated with any agreement or contractual relationship, then care should be taken to ensure, first and foremost, that the requirements of the HCP Code are complied with.

Question 3.01 - 17 *(Batch 1 Q.45 – previously List 2 Q 46)* **Indirect Payments (example): We have recently engaged a university to provide some services. We knew that the individual employee at the university who would be involved in the provision of those services was a specific doctor, but understand that none of the payment for those services will be provided to the doctor, who would simply be performing the work as part of his role and paid his normal salary.**
Is it consistent with EFPIA's interpretations to view this as a payment made to the HCO and not an indirect payment to the HCP in question?

Answer: Yes. In the example as described, the Recipient of the payment will be the HCO, and the payment should be disclosed as "Fee for Service and Consultancy" paid to an HCO

Question 3.01 - 18 *(previously List 3 Q 53):* **If an adverse event is cited within the context of a market research study, and the adverse event contains the HCP's contact details (in case of follow-up on the adverse event by the company's drug safety team or the regulator), is it required to disclose Transfers of Value to the respondent HCP taking part in the market research study?**

Answer: No, since at the point of deciding the Transfer of Value, the company would not know the HCPs participating in the market research study, but would only learn after an adverse event occurred.

If in a market research investigation a HCP mentions an adverse event related to a product of the company sponsoring the survey that has occurred in a specific patient or group of patients, the market research agency would have to pass a report onto the company's Drug Safety Department, even if the HCP has already reported the adverse event himself.

In order to comply with this pharmaco-vigilance obligation, market research agencies ask the HCPs if they are willing to renounce confidentiality only for the purpose of reporting the adverse event, in such a way that the sponsoring company is able to contact the HCP(s) if additional information is required. This would not be linked in any way to the responses given during the survey. As this is a necessary exception to comply with the pharmaco-vigilance legislation, the Transfers of Value would not need to be disclosed.

Question 3.01 - 19 *(previously List 3 Q 62)***: How should the Transfers of Value to HCPs / HCOs that participate in a Steering Committee supporting the organisation of an international event be disclosed?**

Answer: Unless the activity is within scope of the R&D Transfers of Value (in which case it will be part of the aggregate disclosure), the Transfers of Value are to be disclosed in the name of the Recipient HCP/HCO.

If the HCO is paid "in lump" for organising a meeting of experts the Transfers of Value attached will be disclosed in the name of the HCO organising the international event. However, if members of the Steering Committee receive direct compensation for their support, the Transfers of Value will be disclosed individually, in the name of the individual HCP / HCO, as will be the case.

Question 3.01 - 20 *(previously List 3 Q 60)*: **In which category should independent investigator trials (IIT) / investigator sponsored trials (IST) be disclosed?**

Answer: If the trials come within the definition of Research & Development Transfers of Value, then they should be disclosed in the R&D aggregate disclosure. **If not**, then the IIT / IST should be disclosed as a fee-for-service to the Recipient.

Question 3.01 - 21 *(previously List 3 Q 64):* **How should investigator meetings be disclosed when both HCOs/HCPs and non-HCOs/HCPs are present?**

Answer: Transfers of Value to investigator meetings are disclosable under the Code. The Member Company would be expected to disclose the total amount of the Transfer, since the EFPIA Code does not require Tranfers to be disaggregated.

Where the investigator meeting would fall under the definition of R&D Transfers of Value, it will be part of the aggregate disclosure under this category.

If it does not fall within that definition, the Transfers of Value will be disclosed in the relevant disclosure categories, in the name of Recipient HCOs/HCPs.

Question 3.01 – 22 *(previously List 3 Q 67)*: **When a Member Company organised an HCP information / education event, assisted by one or more agencies, payment to the agency(ies) may cover different kind of costs. Where participating HCPs are identifiable, are Member Companies required to establish a method for calculating "Registration Fees", and if so, which kind of costs would go into the calculation?**

Answer: If a Registration Fee is charged then it should be disclosed in the name of the Recipient.

If there is no Registration Fee then Member Companies are not obliged to disclose any logistical costs (e.g. hire, technical expenses) of Member Companies facility associated with a company-organised meeting. However, if the company pays travel and accommodation to the attendees or contracts a HCP as speaker, these costs must be disclosed under the each individual HCP.

When Member Company organise internal events and in application of the requirement for disclosure in the name of the Recipient, the Transfers of Value reported have to be described in its Methodological Note.

Question 3.01 - 23: **How should Member Companies disclosure a grant to an hospital/university department? An hospital/university department is it consider as a legal entity?**

Answer: The disclosure should be made in the name of the legal entity that is the Recipient of the Transfer of Value – this may be the hospital/university, but could also be the department.

A Grant must be disclosed in the name of the Recipient, whether hopsital/university or the (independent) department within the hospital/university and will describe the way they treat such cases in their Methodological Notes.

Question 3.01 - 24: **How should a Member Company disclose the charitable ~~unsolicited~~ product donations to HCOs?**

Answer: Humanitarian aid is material and logistic assistance to people in emergency need, and Member Companies could be solicited to provide medicines. When the charitable product donations are made in this context, the Member Companies have to disclose it in the Donations & Grants category.

Section 3.02: Aggregate Diclosure

Question 3.02 - 1 *(Batch 1 Q.23 – previously List 1 Q 20)****:*** **What must a Member Company do if it does not obtain a consent from a HCP (or a HCO, where applicable) for disclosure on an individual basis?**
See also "Points of Clarification" on "Privacy Law & Regulations", and question 2 of Section 3.02

Answer: Member Companies should make their best efforts to obtain the consents necessary to disclosure of Transfers of Value at the individual level, with aggregate disclosure being permitted in exceptional circumstances only.

Where Transfers of Value occur in the context of a contract, the contract provides an opportunity to obtain the HCP's /HCO's consent to the processing of his/her/its personal data for the purpose of meeting the Member Company's obligations under the Code. It is recommended that Member Companies (data controllers) create and retain evidence showing that such consent has been requested / obtained.

> The following footnote will be added to Section 4.01 of the EFPIA Code:
> "*When making a Transfer of Value to a HCP/HCO, and in their written contracts with HCPs/HCOs, Member Companies are encouraged to include provisions relating to the Recipients' consent to disclose Transfers of Value in accordance with the provisions of the Code. In addition, Member Companies are encouraged to renegotiate existing contracts at their earliest convenience to include such consent to disclose*."

Where Member Companies would be required by national laws and regulations to obtain the consent of the Recipient for individual disclosure and the Recipient does not consent to such disclosure following Member Companies repeated efforts, the relevant Transfer of Value may be disclosed on an aggregate basis. The Member Companies are also required to indicate the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed (respectively under the HCPs and HCOs disclosures). *See also the Template, page 13 of the Code*

Question 3.02 - 2 *(previously List 3 Q 50)**:*** **How should disclosure be managed where the Recipient gives partial consent? For example, where consent is given for the consultancy fees to be disclosed, but not associated payments for travel & accommodation, what would be the disclosure requirement?**
See also "Points of Clarification" on "Privacy Law & Regulations", and question 1 of Section 3.02

Answer: Member Companies are encouraged to include a consent notice in their contracts that would prevent, wherever possible, Recipients from "cherry picking" which Transfers of Value they consent to be disclosed.

If notwithstanding the Member Company's efforts a Recipient gives only partial consent to any aspect of disclosure (i.e. the Recipient does not allow for disclosure of all categories or of all Transfers), all Transfers of Value of the Member Company made to that Recipient should be declared in the aggregate disclosure (not in the individual disclosure category), subject to applicable laws.

Partial disclosure under the individual disclosure category would be misleading with respect to the nature and scale of the interaction between the Member Company and the Recipient, and would as such not fulfil the intent of the Code.

Information on how this is managed should be considered in the Methodological Note.

Question 3.02 - 3 *(Batch 1 Q.22 – previously List 1 Q 21)**:*** **What circumstances can constitute "legal reasons" preventing disclosure on an individual basis for purposes of Section 3.02?**

Answer: This can happen, for example where disclosures on an individual basis are not permitted by local personal data protection laws unless the Recipient's consent has been obtained.

The EU Data Protection Directive (Directive 95/46/EC) has been transposed into national legislation in all EU Member States. National requirements regarding the processing of personal data and obtaining the consent to disclosure from the data subject differ significantly from jurisdiction to jurisdicton.

Member Companies must comply with applicable personal data protection and other laws, which may impose certain limitations on their ability to make disclosures on an individual basis. A company (as a data controller) may have legitimate interest in disclosing data, for instance, to promote confidence in its relationship with HCPs. The data subject's interests must outweigh this legitimate interest. The legal basis is significantly strengthened when a data controller can show the required consent had been obtained.

Data privacy requirements must in each case be checked at the national level (i.e. the jurisdiction of the Recipient) by the Member Company prior to disclosure.

For good understanding, transposition of the EFPIA Code into Member Associations' codes is not prevented by unresolved consent issues. However, Member Associations are encouraged to support local operations with resolving consent issues, for instance through reaching out to HCPs/HCOs to promote the merits of transparency for all stakeholders and for the patients indeed.

Question 3.02 - 4**: Which amounts / percentages does the Member Company have to publicise in case of aggregate disclosure of Transfers of Value to non-consenting Recipients?**

Answer: The Member Company has to disclose:

- the aggregate amount attributable to Transfers of Value to Recipients that did not consent to individual disclosure;
- the number of Recipients included in the aggregate disclosure;
- the percentage of HCPs (respectively HCOs) that did not consent out of the total number HCPs (respectively HCOs).

Section 3.04: Research and Development Transfers of Value

Question 3.04 - 1 *(previously List 3 Q 52):* **Why shall Transfers of Value connected to R&D as defined in the Code be disclosed in aggregate?**

Answer: At the request of CCSG, this answer is submitted to legal counsel opinion.

Section 3.05: Methodology

Question 3.05 - 1 *(previously List 3 Q 70)**:*** **Is VAT associated with Transfers of Value to be excluded or included?**

Answer: Member Companies are expected to provide information on the treatment of VAT and other tax aspects in their Methodological Note.

Section 4.03: Disclosure Requirements Different from this Code

Question 4.03 - 1 *(Batch 1 Q.6 – previously List 1 Q 22)**:*** **Should the existing national codes be modified to cover the same scope of disclosures as the Code? When local law does not cover the same spectrum of disclosures as the Code, would disclosures pursuant to local law be deemed sufficient?**

Answer: Member Associations are asked to transpose the Code in full and in a manner consistent with applicable laws and other applicable legal requirements. Member Associations are required to inform EFPIA of reasons why national disclosure requirements differ from those required under the EFPIA Code. Such differences shall be clearly and conspicuously so identified.

Unless there are strong legal mandatory requirements, it is expected that Member Associations will transpose the Code in full i.e. without deviations. However, where national codes impose additional requirements in line with national laws and regulations, such variations from the EFPIA Code are admissible. This may be the case when national laws are in place. In each country, Member Companies will be required to comply with the disclosure requirements applicable in that country, whether imposed by law or by self-regulation.

Based on a detailed "gaps" analysis between legal requirements versus the EFPIA Code, efforts will be made to close these gaps with a view to ensuring consistent reporting around Europe.

Question 4.03 - 2 (Section 4.03) *(Batch 1 Q.5 reworded – previously List 1 Q 23)**:*** **Would disclosure in line with national requirements be considered sufficient if the national provisions do not require as many provisions as the Code?**

Answer: Yes, when the EFPIA Code provision is in conflict with applicable national law or regulation, in which case the deviation is allowed.

SCHEDULE 1 - DEFINITIONS

Question Definitions - 1 *(Batch 1 Q.54 – previously List 2 Q 47)*: **Is a clinical research organization (CRO) a HCO?**

Answer: A CRO is not a HCO. A clinical research organization (CRO) is an organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis. However, Member Companies may make Transfers of Value to HCPs / HCOs through CROs – such indirect payments are within the scope of the Code.

As a rule, each Member Company will decide on the inclusion of Transfers of Value to CROs into the different categories of disclosure.

If activities contracted to CROs fall within the scope of the definition of R&D Transfers of Value, they will be part of the aggregate disclosure under that category. Otherwise, they will be reported under the relevant category.

In their written contracts with CROs, Member Companies are encouraged to include provisions relating to the CROs' consent to disclose Transfers of Value that will ultimately benefit HCPs/HCOs in accordance with the provisions of the Code. In addition, companies are encouraged to renegotiate existing contracts at their earliest convenience to include such consent to disclosure.

In the Methodology Note, the Member Company are encouraged to provide additional clarification on the nature of the Transfers of Value included.

Question Definitions - 2 *(Batch 2 Q 24 – previously List 1 Q 24)*: **Does EFPIA plan to provide Member Companies with a list of all specialties and professional designations that fall into the definition of a "HCP"?**

Answer: No. The EFPIA HCP Code defines HCPs as 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, purchase, supply or administer a medicinal product. *See also the EFPIA HCP Code (Scope - § 4)*

The Member Associations have transposed the EFPIA HCP Code into their national codes. In principle, these codes will include the list of specialities and professional designations that fall into the definition of an HCP, also reflecting healthcare practice in the country – for instance, nurses can prescribe medicines in some countries but are not allowed to do so in other countries.

Question Definitions - 3 *(Batch 1 Q.51 – previously List 1 Q 25)*: **How is a "Foundation" defined for the purposes of the "HCO" definition?**

Answer: A "Foundation" is one of the legal forms in which HCPs/HCOs may operate and organise relationships with Member Companies.

Member Companies will need to determine on a case-by-case basis whether a particular Foundation falls within the definition of a HCO under the Code, taking into account factors such as the foundation's characteristics, members, bylaws and purpose.

Where Member Companies engage, provide a Transfer of Value etc. to a Foundation, due diligence would be to ensure all such support, engagements and the like are appropriately documented in a writing (preferably a contract), that may also include a clause consenting the individual disclosure of the Transfer of Value.

Question Definitions - 4 *(Batch 1 Q.52 – previously List 1 Q 26)**:*** **Are research organisations (such as INSERM in France) considered HCOs for purposes of the Code?**

Answer: INSERM is a Medical Research Organisation and as such would be classified as a HCO.

As with any Transfer of Value, the purpose and intent of any payment made to INSERM, or similar organisations, should be considered to establish if such payments are in scope of the Code. If they are, they should then be disclosed under the appropriate category for a HCO.

Where Member Companies engage, provide a Transfer of Value to a research organisation, due diligence would be to ensure all such support, engagements and the like are appropriately documented in a writing (preferably a contract), that may also include a clause consenting the individual disclosure of the Transfer of Value.

Question Definitions - 5 *(Batch 1 Q.53 – previously List 1 Q 27)**:*** **Should Transfers of Value to universities or teaching institutions be disclosed under the Code?**

Answer: As a general matter, the Code does not provide for the disclosure of interactions between Member Companies and teaching institutions (such as support of or involvement in a management programme). However, where such support or involvement ultimately benefits a HCP, then such Transfer of Value should be disclosed under the Code identifying the Recipient, in this instance the teaching institution, of such Transfer of Value.

As such, Transfers of Value to a Faculty of Medicine at a university or to a University Hospital should be disclosed under the relevant category. Collaboration with such entities will be company-specific and each Member Company should organise its disclosures accordingly and provide additional information in its Methodology Note.

Where Member Companies engage, provide a Transfer of Value etc. to a university or a teaching institution, due diligence would be to ensure all such support, engagements and the like are appropriately documented in a writing (preferably a contract), that may also include a clause consenting the individual disclosure of the Transfer of Value.

Question Definitions - 6 *(Batch 2 Q.22 – previously List 1 Q 28)**:*** **Under the Code, would a self-incorporated HCP (where he/she is the only employee of the corporation) be considered a HCO?**

Answer: Yes. HCO is defined as "Any legal person (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations within the scope of the EFPIA PO Code) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services".

***Question Definitions - 7** (previously List 3 Q 57):* **Why do the retrospective non-interventional studies fall under the individual disclosure category?**

Answer: Following the definition of R&D Transfers of Value in Schedule 1 in the EFPIA Code approved in June 2013, retrospective non-interventional studies do not fall within the scope of the definition of R&D Transfers of Value. Only the non-interventional studies that are prospective in nature will be included in the aggregate disclosure of Research & Development Transfers of Value.

Transfers of Value relating to retrospective non-interventional studies, that shall comply with the provisions of Article 15 the EFPIA HCP Code, shall be disclosed under the name of the individual Recipient.

Comment: This interpretation has been confirmed at the General Assembly of 6 June 2014, following Board decision.

***Question Definitions - 8** (previously List 3 Q 56):* **How should Member Companies disclose Transfers of Value through contracted third parties, which may include e.g. Clinical Research Organisations (CROs), Professional Congress Organisers (PCOs), travel agencies?**

Answer: Member Companies would be expected to collect details from third parties to disclose following the disclosure requirements of the Code (category of disclosure, individual or aggregate). Individual disclosure, where applicable, should be under the name of the HCO on whose behalf the third party is operating.

The process followed to collect the information should be described in the Methodological Note.

***Question Definitions - 9** (previously List 3 Q 58):* **How should Member Companies disclose Transfers of Value attached to services provided by commercial entities (such as events providers, publishers or general suppliers) who may engage with HCPs on behalf of the Member Company to obtain HCP services?**
See also questions 2 of Applicability of the Code & 2 of Section 2.04

Answer: Services provided by commercial entities or materials prepared by internal staff do not, as such, constitute a Transfer of Value to on HCP/HCO. However, the Member Company's contract with the commercial entity expects that HCP/HCO services will be obtained, then related Transfers of Value should be disclosed in accordance with the Code.

***Question Definitions - 10** (previously List 3 Q 65):* **If a company sponsors an event / activity through a third party without indicating the particular HCPs by name who should be invited, should the indirect Transfers of Value be disclosed or are they only to be disclosed when a HCP receives the transfers at the instruction of the Member Company?**

Answer: If a company sponsors a third party event (e.g. a medical congress) and in return has the possibility for image promotion activities (e.g. a booth etc.), this must be disclosed under the category "Sponsorship" naming the Recipient (the HCO).

The same applies if the Recipient HCO uses some of the received sponsorship to invite HCPs or to hire HCPs as speakers for that congress.

However, if it is part of the sponsoring contract that the organization must use some of the sponsorship to invite a given list of HCPs to that congress, this should be split-up and disclosed individually under the name of each HCP.

Following the same principle, where a Member Company provides a third party organisation conducting market research on its behalf with a specified list of named HCPs to use for recruitment purposes, and the Member Company is made aware of which HCPs have agreed to participate in the market research, it would make sense that the Member Company discloses it in the "Fees for Services and Consultancy" category.

SCHEDULE 2 – STANDARDISED TEMPLATE

Question Template - 1 *(previously List 1 Q 12)**:*** **What is meant by the "unique identifier"?**

Answer: For the purpose of the disclosure in the Template, Member Associations are strongly recommended to provide guidance on the most appropriate "professional code" in their country that Member Companies should use as unique identifiers.

In the Model Template (see Schedule 2), it has been suggested that such *unique identifier* would include:

- the Full Name;
- for a HCP: the City of Principal Practice;
- for a HCO: the City where Registered;
- the Country of Principal Practice;
- the physical address of the Principal Practice; and
- (where applicable) the Unique Country Local Identifier (e.g. a professional code)

Whether such full details can be publically disclosed may depend on applicable personal data protection laws and regulations.

For sake of clarity, EFPIA will not develop unique identifiers for HCPs / HCOs in Europe.

Question Template - 2 *(previously List 3 Q 64)***: What text is the Member Company expected to put in the last section of the Template under "R&D – aggregate disclosure"?**

Answer: As is reflected in the Template, the Code requires Member Companies to disclose the total amount of R&D Transfers of Value to HCPs / HCOs per year (reporting period) in aggregate.
