ANNEX E (binding)
EFPIA e4ethics rules and procedure

1. Background

Article 10 of the EFPIA Code defines the requirements applicable to pharmaceutical companies when organising events (professional, promotional, scientific, educational meetings, congresses, conferences) and/or providing hospitality during these events (paying for travel, meals, accommodation and genuine registration fees).

In 2011, EFPIA coordinated the monitoring of European third-party organised events (with more than 500 HCPs coming from 5 different countries in the scope of the EFPIA Code) by setting up an on-line platform to pre-assess events (named e4ethics).

Through e4ethics, EFPIA helps ensure a consistent implementation of the EFPIA Code provisions, enhances compliance with the Code and allows collaboration with our stakeholders (e.g. learned societies, congress organisers). While an EFPIA member company needed to take its individual decision to sponsor, participate or collaborate to an event, e4ethics provided an independent reference to inform such a decision.

2. e4ethics decisions binding and mandatory assessments

Based on a recommendation of the EFPIA Codes Committee (CodCom) and Ethics & Compliance Committee (E&CC), the EFPIA Board decided, in March 2020, to make the e4ethics platform binding, meaning that sponsoring, participation or collaboration in an event that has not been approved or has been qualified as non-compliant by e4ethics is considered as a potential breach to the EFPIA Code which could be enforced by the competent national Code authorities. **In summary, this means that e4ethics decisions are binding for EFPIA Member Companies and that Member Companies must verify that an e4ethics positive assessment is available.**

3. Collaboration with MedTech Europe

In 2012, MedTech Europe, the European Association for Medical Devices, set up the Conference Vetting System (CVS) as an independently managed system that checks the compliance of third-party educational events with MedTech Europe's Code of Ethical Business Practice and Mecomed's Code of Business Practice. The outcome of the assessment determines the appropriateness for MedTech Europe and Mecomed member companies to provide financial support to the events. The decisions rendered by the Compliance Officer are binding on MedTech Europe and Mecomed members. This means that these members cannot provide support to an event which is found to be non-compliant.

In March 2020, the EFPIA Board approved the collaboration with MedTech Europe in the field of congresses' assessments. Therefore, e4ethics assessments will be integrated in CVS even if the assessments will be directed to two different websites: e4ethics and CVS. Based on the EFPIA Board recommendation, a testing period of 6 months will be implemented and will start on 1st January 2021. During this testing period, the binding effect of decisions and the mandatory nature of assessments will be in force.

a. Key elements

Each platform keeps its identity and branding, meaning that each one would have its own page with relevant information, including specific user-friendly routing to the submission form, but both pages will be hosted on www.ethicalmedtech.eu. An e4ethics banner will be added on MedTech Europe website but decisions rendered by CVS Compliance Officers shall be posted on what will become the joint online calendar. Technical adjustment will have to be made within the CVS software to allow profile separation, while keeping a shared history of knowledge and an optimisation of service level.

Common back end[1]: In the back end, all assessment requests will be received by MedTech Europe Compliance Officers, which will become the Compliance Officers also for Pharma Events.

The scope of e4ethics will remain the same: European congresses, organised by a third party, with 5 different countries in the scope of the EFPIA Code and more than 500 HCPs. Virtual congresses are out-of-scope.

b. Alignment of criteria

The criteria applying to e4ethics will be aligned to those of CVS:

- The submission for events assessment must be done proactively and online by the EFPIA member companies or the congress organisers.
- The travel arrangements and meals & drinks threshold will no longer be part of the criteria assessed. Therefore, the EFPIA Member Associations will not be consulted.
- Submission in e4ethics will be mandatory**,** i.e. EFPIA Member Companies need to verify that an e4ethics positive assessment is available for the Event prior to being able to provide any kind of support, from the first day of the pilot phase. The submission for such assessment can be made by the Member Company or the Congress Organiser (HCO/PCO).
- Binding nature of all decisions rendered by e4ethics on the EFPIA members during and after the pilot phase, meaning that an Event assessed as non-compliant cannot receive any form of support from EFPIA members.
- Full MedTech Europe/EFPIA alignment on the approach and interpretation of the six assessment criteria[2], which means that there will not be a difference on how Pharma and MedTech Events will be assessed.

c. Important considerations

The following considerations are important:

- Decisions are rendered on the basis of the documents and information provided to the CVS Compliance Officer via the online submission form. The CVS Compliance Officer does not independently verify whether the information or documents are up to date.
- Decisions do not consider, nor supplant national and local laws, regulations or professional and company codes that may impose more stringent requirements upon members, HCPs, HCOs or PCOs.
- The schedule and relevance of scientific programme sessions of an Event are reviewed, but not their value or quality.
- The sole purpose of the vetting system is to assist corporate members in determining the appropriateness for member companies to provide support to an Event.

4. Procedure applicable to e4ethics

a. Appeal

The assessments for e4ethics will follow the CVS process: the MedTech compliance panel will be in charge of the appeal procedure for the assessments. An appeal of the CVS Compliance Officer's assessment is possible. The body responsible for reviewing such appeals is the MedTech Europe Compliance Panel, given the value of having one single authority overseeing the decision processes respectively pertaining to MedTech and Pharma Events.

An appeal may be filed by the Member Company or the Congress Organiser (HCO/PCO) with the Compliance Panel provided that the following requirements are respected:

- Appeals must be filed within a deadline of 10 days for Pre-Clearance and Regular Submissions after the Compliance Officer's assessment decision has been published on the joint online calendar.
- A formal appeal needs to be addressed to the Chair of the Compliance Panel at cvs@ethicalmedtech.eu

[1] For the IT project, were underlined the importance to build-in data analytics tools as well as necessity to transfer historic data of e4ethics, to be used for later data analytics purposes.

[2] Event Programme - Geographic Location - Event Venue Facility – Hospitality - Event Registration Packages - Communication Support

The Compliance Panel will endeavour to respond to appeals within 72 hours of receipt.

b. Complaint related to an Event

In case of a complaint related to a European congress (and not related to an assessment), the EFPIA SOP is applicable (Annex D part A of the EFPIA Code). EFPIA will forward the complaint to the relevant national Code authority. The final decision of the national Code authority will be shared with the MedTech compliance panel for information.

"A. Complaints[3] received by EFPIA

Section 3 of the "Implementation & Procedural Rules" further provides that ***complaints received by EFPIA shall be processed as follows****:*

i. *EFPIA will forward any complaints it receives (without considering their admissibility or commenting upon them) to the relevant member association(s).*
ii. *EFPIA will send an acknowledgement of receipt to the complainant, indicating the relevant national association(s) to which the complaint has been sent for processing and decision.*
iii. *In addition, upon receipt by EFPIA of multiple external complaints (i.e. several complaints on the same or similar subjects lodged from outside the industry against several subsidiaries of a single company), EFPIA will communicate these complaints to the national association either of the parent company or of the EU subsidiary designated by the parent company.*

Procedural Steps

1 *When a complaint is received by EFPIA, the EFPIA Compliance Officer forwards it, within 10 working days, to the relevant Member Association(s) for action under the Member Association(s)'s procedure for dealing with complaints, and the complainant will be informed of which Member Association(s) are responsible for dealing with the complaint;*
2 *Simultaneously, the EFPIA Compliance Officer will inform, in writing, the responsible senior employee[4] of the company(ies) against which the complaint is made. If the complaint involves a number of countries, EFPIA will forward the complaint to the Member Association of the parent company and to the relevant company's subsidiary(ies);*
3 *The Member Association(s) must acknowledge receipt of the complaint from EFPIA within 30 days following EFPIA's communication;*
4 *The Member Association(s) should consider the complaint under its usual procedure, including timelines. During the adjudication period, EFPIA will not intervene, neither will it answer questions neither from the complainant nor from the Member Company(ies) involved in the case;*
5 *When the Member Association(s) has(ve) completed its(their) consideration of the matter, EFPIA must be so informed of the decision(s) made by the adjudication bodies, including, where appropriate, the sanction imposed. The Member Association(s) should provide updates to EFPIA as the matter proceeds no later than 6 months after it receipt of the complaint, and subsequently within each following quarter until a final decision is made on the compliant (within a reasonable timeframe);*
6 *A summary of decisions made on cases submitted to EFPIA will be published in EFPIA's Codes Activity Report – once the complaint has been concluded, the learnings might lead to further discussion by the Codes Committee including enhancing code consistent implementation, where relevant.*

Throughout the complaint procedure (from receipt of the complaint at EFPIA to decision of the competent adjudication bodies), EFPIA will not communicate with parties involved in the complaint within the limits of its involvement set out in the EFPIA Codes and following the procedural steps described in this SOP. In this context, communications within EFPIA will be limited to General Counsel and EFPIA Compliance Officer; the Director General will be involved to the extent justified by the complaint."

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3 EFPIA will consider as a complaint any concerns raised about an EFPIA Member Company for materials or activities related to EFPIA Codes' implementation and/or enforcement.

4 Each Member Company must appoint at least one senior employee who shall be responsible for supervising the company and its subsidiaries to ensure that the standards of the Applicable Code(s) are met. *See EFPIA Charter and Section 18.02 of the EFPIA HCP Code*