codeem
comité de déontovigilance

CONFERENCE VETTING SYSTEM BY CODEEM
PRINCIPLES AND PRACTICE

Adopted on 9 December 2021 following consideration and adoption by the Professional Ethics and Conduct Committee

1. PROFESSIONAL CONDUCT AND EVENT ASSESSMENT

1.1 General background

The European Federation of Pharmaceutical Industries and Associations (**EFPIA**) has a long history of issuing codes of good practice focusing in most cases on relationships between its members and healthcare professionals.

Leem, an EFPIA member, has introduced its own code of professional conduct - the Leem Professional Ethics Provisions (**DDP**), and has its own professional practice and ethics committee known as the Codeem, which is responsible for implementing and monitoring the proper application of the DDP.

The overall objective of the DDP is to implement series of rules for good professional practice to complement the legal and regulatory obligations of pharmaceutical companies across a broad range of fields, with particular emphasis on the promotion of pharmaceutical products and the relationships between pharmaceutical companies and healthcare professionals.

In 2011, to ensure proper implementation of its code, EFPIA introduced the e4ethics platform to review the compliance of pharmaceutical industry Third-Party Organised Educational Events (TPOEs) with the provisions of the EFPIA Code of Practice. Managed by EFPIA until 31 December 2020, hosting and management of the e4ethics platform has been shared with EthicalMedTech (the compliance portal of MedTech Europe, the European trade association for the medical technology industries).

Both the EFPIA Code and the MedTech Code make clear that companies may provide financial support only for those events that comply fully with the professional ethics and conduct requirements they set out.

Similarly, pharmaceutical companies may invite only the healthcare professionals and representatives (or members) of patient and healthcare organisations (hospitals, scientific and medical bodies, learned societies, foundations, universities, etc.) hereinafter referred to as the **Beneficiaries** to events that fulfil these requirements.

The purpose of the platform is to assess the degree to which international events are compatible with the provisions set out in the Code in order to ensure compliance with the Code in terms of consistency and harmonisation in the interests of all stakeholders.

The e4ethics assessment may be requested only for those international events that meet certain criteria: events with more than 500 attendees from at least 5 countries in which the EFPIA Code applies.

In accordance with the EFPIA Code, the DDP sets out the conditions governing professional and scientific events that may receive support from Leem member companies, or to which they may invite Beneficiaries.

Adopting the same approach as e4ethics, Leem and the Codeem have decided to take the opportunity presented by revision of the Leem articles of association to introduce a similar mechanism for scientific and professional events hosted in France or abroad which do not meet the conditions for e4ethics assessment.

The voluntary mechanism introduced by Leem to assess events therefore serves the same purpose, and is complementary to, but not binding upon, the e4ethics mechanism.

Article 11-1 of the Leem articles of association incorporates this new competence delegated to the Codeem[1], and the Codeem internal regulations make clear that the assessment conditions and practices are adopted by the Codeem subject to consideration and adoption by the Professional Ethics and Conduct Committee.

The Professional Ethics and Conduct Committee adopted this change on 9 December 2021.

1.2 The principles of assessment

- The overall purpose of assessment is to promote compliance with the ethical principles set out in the DDP governing (i) support for events organised by third parties and (ii) the invitation of Beneficiaries to such events. It is also intended to assist and support companies and event organisers in assessing their own DDP compatibility.
- Codeem does not monitor events proactively, but rather responds to applications for assessment.
- Assessments are conducted by the Codeem solely on the basis of documents and information provided by the applicant, which remains responsible for updating them, if necessary. The Codeem also considers information provided by event organisers, which are always consulted as part of the assessment process before publication of the Codeem assessment.
- The general structure of the event agenda and sessions are reviewed, but the assessment does not express a view about the value of the scientific content offered by the event.
- Where the application for assessment comes from a pharmaceutical company, a consultation procedure is implemented to allow the event organiser(s) to provide their input.
- Completed assessments are published by Codeem on its web page at https://www.leem.org/codeem and are therefore publicly available for any interested party to read.
- Assessments are conducted without prejudice to any other appraisals of events made as a result of inspections conducted by the appropriate authorities within the framework governing implementation of the benefits inspection system provided for under the terms of Articles L.1453-3 and subsequent of the French Public Health Code. The cost of hospitality or donations falling within the scope of these articles must in all cases be declared to, or authorised by, the appropriate authorities, depending on the amounts involved.

  In the event that the Codeem assessment conducted on the basis of this procedure reaches a different conclusion to that of the appropriate authorities on the basis of the legal criteria imposed by the benefits inspection system (Articles L.1453-3 and subsequent of the French Public Health Code), the assessment conducted by the appropriate authorities will prevail.

1.3 The significance of the assessment for companies and organisers

The Codeem assessment procedure is intended to help and support companies and event organisers in assessing their own compatibility with the DDP and the general conditions applying to event organisation.

It involves the Codeem in conducting DDP alignment assessments of events that companies, or organisers may organise and/or host themselves without reference to the Codeem.

It is therefore intended to facilitate this assessment for companies, at the same time as helping organisers to prepare and stage events that are fully compatible with the DDP.

The assessment is conducted only on application and is therefore not compulsory.

The outcome of the assessment is published so that all companies, organisers, and stakeholders can access its findings to facilitate a level playing field of interpretation for all stakeholders.

If, in the event of a complaint, for example, the Codeem were to give an opinion regarding practices related to an event it had previously assessed, that assessment would constitute one of the main elements of its decision, even where other circumstances may be relevant, given the context of the review.

[1] Article 11-1 of the Leem articles of association: *"assesses, at the request of pharmaceutical companies or stakeholders, the compatibility of professional and scientific events with the "Dispositions Déontologiques Professionnelles" (Leem Professional Ethics Provisions)"*

1.4 Experimental status

The assessment mechanism is implemented for an experimental period of one year from ....

At the end of this period, a review will be conducted to check that the procedure is working as intended.

Depending on the outcome of this review, the Codeem reserves the right to reconsider the assessment principles and practices described in this decision.

2. EVENT ASSESSMENT PRACTICES AND PROCEDURE

2.1. Scope

The assessment procedure applies to all professional, scientific and medical meetings, events, conferences and symposia organised by third parties with the aim of promoting scientific knowledge, medical progress or health service provision.

This definition therefore includes events initiated by organisations of healthcare professionals and patients, learned societies, conference and events companies, and public- or private-sector hospitals.

The assessment procedure applies to national, regional or local events held on French territory, including the French overseas departments, regions and territories when supported by companies based in France, or when such companies decide to invite Beneficiaries.

The procedure also applies to virtual/digital events, for which the Codeem will assess only the agenda of the event.

2.2. Submitting an event for assessment

Assessment applications may be submitted by:

- Leem member companies
- Event organisers
- Every stakeholder

The Codeem assesses only those events for which a formal application has been submitted.

2.3. The assessment application submission

The assessment application submission must include the following information:

- the agenda or draft agenda of the event **(see Criterion 1**),
- The following information, if not included in the agenda or draft agenda: date, location and venue **(see Criteria 2 and 3**),
- the accommodation or catering services to be provided by the organiser **(see Criterion 4**),
- the event registration costs, detailing the cost of the services to be provided **(see Criteria 4 and 5**)
- the schedule of partnership/support/sponsorship fees **(see Criterion 5**)
- the contact details of the organiser(s) (where the organiser is not the applicant)
- the event communication media to be distributed by the organiser **(see Criterion 6**)

At the time of application submission, the applicant may also inform the Codeem of any conditions relating to the organisation of the event which, in its opinion, requires the special attention of the Codeem.

The assessment application must be made using the form provided online by the Codeem. This form includes a list of the information requested. The applicant is requested to provide only the information listed by Codeem in this form.

The submission should be sent to the Permanent Secretary of the Codeem: cmarechal@codeem.org

2.4. Review process and deadlines

The assessment application must be submitted to the Permanent Secretary no later than **five (5) months prior to the date of the event**. Applications received after this cut-off time will not be considered.

The Permanent Secretary will acknowledge receipt of the file to the applicant. Once an applicant has received this acknowledgement of receipt, the event assessment application may no longer be withdrawn.

All interaction between the Codeem and the applicant in the context of this assessment remains confidential, subject to the exceptions listed below.

If the application has not been submitted by an organiser, the Permanent Secretary will, on receipt of the application, contact the organiser(s) to inform them of the (anonymised) application, and provide the latter with the information submitted in support of the application, giving them the opportunity to comment on the conditions governing the organisation of the event and their compatibility with the DDP or to provide any further information that may be relevant to the assessment process.

The organiser(s) will have eight (8) working days in which to submit any comments they may wish to make and/or provide additional information or documentation.

Where multiple organisers are involved, each will be asked to appoint a single point of contact for the Codeem in order to simplify interaction and coordinate any remarks they may wish to make.

The Permanent Secretary will review the application and may, at any time, request the applicant and/or organiser to submit any additional information required for the assessment.

The Permanent Secretary will prepare a draft assessment and forward it for validation to two (2) Professional Ethics and Conduct Committee members appointed for this purpose by the Committee.

The draft assessment will be sent to the applicant and/or organiser, either of which may submit any written remarks they may have within eight (8) working days.

The final assessment, validated by the two (2) members of the Codeem appointed for the purpose, is completed no later than two (2) months after receipt of the application, and no later than three (3) months in advance of the date scheduled for the event.

The outcome of the assessment will be provided to the applicant and/or organiser for information purposes prior to its publication in accordance with Article 2.5.

In the event that any of the details assessed change after final publication of the event assessment, the applicant must inform the Codeem accordingly to give the latter the opportunity of revising its assessment, should it see fit to do so.

In the event that the Codeem has assessed an event on the basis of information that later proves inaccurate, it reserves the right to make reference to such inaccuracy (or inaccuracies) on its web page and to remove the assessment from the web page.

2.5. Publication

The assessment process is transparent and is published on the Codeem web page at: https://www.leem.org/codeem

Event assessment applications are published on the Codeem website. They include:

- The date of application
- The name of the event
- The nature of the event
- The location of the event
- The country
- The event start and end dates
- The link to the event website (where applicable)

The final assessment is published no later than three (3) months before the date of the event in the form of a table identifying the event concerned, and listing the six (6) colour-coded assessment criteria:

- **Green**: DDP compatible
- **Blue**: information incomplete, criterion not assessed
- **Orange**: one or more areas are DDP non-compliant, with an explanation of the areas identified
- **Grey**: not applicable (applies only to assessments of virtual events)

Event organisers may make reference to the Codeem assessment on their agenda or website, subject to the following conditions:

- The only wording that may be used is 'Codeem-assessed event' or 'Codeem-registered event' to the exclusion of all other wording
- The wording must be accompanied by a direct link to the published Codeem assessment for the event concerned
- The wording must be presented unobtrusively, and should not take precedence over other professional and/or scientific information regarding the event
- The wording may be used only for the event assessed, and may not be reused for similar events for which the same organiser is responsible

3. THE ASSESSMENT CRITERIA

Assessments are made on the basis of 6 criteria:

- ✓ The scientific agenda
- ✓ The event location
- ✓ The event venue
- ✓ The hospitality provided
- ✓ The registration or partnership/support/sponsorship fees
- ✓ Communication

Communication

Criteria	Assessment factors (applied, but not limited to)
1. <u>Scientific agenda</u> Companies may only invite, and/or fund the attendance of, healthcare professionals or representatives of patient organisations to professional, medical or scientific events ***DDP Article 4.1***	✓ The agenda must make clear that the event has a genuine professional or scientific purpose ✓ Scientific sessions may not include any promotional content ✓ The detailed agenda must set out a clear timetable with no significant gaps between scientific sessions. For example, a minimum of 6 hours of such sessions in any given day, or 3 hours for any given half-day ✓ No activities with no direct relationship to the purpose of the event (social, leisure or sporting activities, or any other form of entertainment that does not qualify as a professional or scientific activity, etc.) may be offered during event sessions. Limited sections of the agenda devoted to subjects of a professional nature (leadership, management or communication skills) may be permitted, provided that they are very short and not under any circumstances funded by pharmaceutical companies ✓ Where the organiser offers a programme of social, leisure or sporting activities, or any other form of entertainment, such content may be provided only on the fringes of the event, and may under no circumstances form part of any scientific sessions. Where this is the case, this content must be promoted completely separately from the event, and paid for directly by those who wish to benefit from it

2. <u>Event location</u> The location of the event must not constitute its main attraction and must be justified in terms of the conditions governing the organisation of the event and its size, and be compatible with the rigorous ethical requirements applying to professional or scientific events. ***DDP Article 4.1.2***	✓ The event location must be consistent with the size of the event, whether international, national, regional or local ✓ The choice of event location should be determined primarily by its accessibility for speakers and delegates in relation to the size of event. For example, international and national events should preferably be held in cities where the transport infrastructure facilitates access for delegates and speakers from many different locations. Local or regional events should be held in the corresponding regions or departments of France ✓ The event location should not be best known for its tourist facilities or leisure attractions ✓ The time of year also forms part of the assessment: Justifications given for holding winter events (between 20 December and 31 March) in well-known winter sports resorts, or summer events (between 15 June and 15 September) in coastal resorts or similar locations recognised as holiday destinations will be closely reviewed ✓ The hosting of events outside France in particular must be justified on the basis of the following considerations: • The majority of speakers/delegates come from different countries • Given the countries of origin of the speakers/delegates, it makes more sense logistically to host the event in another country • Given the geographical location of the relevant resources or expertise that form the main subject matter for the event, it makes more sense logistically to host the event in another country
3. <u>Event venue</u> The venue must be appropriate for the professional or scientific nature of the event. ***DDP Article 4.1.1***	✓ The venue must be compatible with the ethical requirements governing the organisation of any event addressing issues around health ✓ The event must take place in a venue appropriate to its purpose and must not be lavish/extravagant in nature ✓ The venue should be a scientific or business centre with conference rooms and facilities appropriate for the professional and scientific character of the event ✓ The venue should be easily accessible ✓ <u>Clarification</u>: such venues may be located in healthcare, research and/or educational institutions, conference centres, exhibition centres, community centres or conference and meeting rooms in hotels rated no higher than 4 stars ✓ <u>Clarification</u>: For example, the following venues should be avoided: resort hotels (defined as hotels that form part of a complex with leisure and sports facilities), cruise ships, golf clubs (attached to the hotel), centres whose main purpose is to provide wellness or thalassotherapy treatments, hotels in casinos or with private beaches, theme parks, water sports centres, abbeys, museums, wine estates, castles, famous monuments, concert halls or theatres and venues with Michelin-starred restaurants ✓ Exceptions may be made where to do so is justified by objective considerations, such as the absence of alternative solutions
4. <u>Hospitality provided</u> The hospitality provided must be of a reasonable standard and incidental to the main purpose of the event ***DDP Articles 4.1.3 to 4.1.8*** ***DDP Article 4.2***	✓ Hospitality includes accommodation, meals, snacks and event-related functions (such as a welcome or closing reception) for invited members only. Hospitality extended to include family members, guests (etc.) is not eligible and must be charged separately to the individuals concerned ✓ The hospitality provided should be neither ostentatious nor celebratory in nature

	✓ Under no circumstances may hospitality include the direct or indirect provision of entertainment, social activities or any activities that are not strictly professional in nature ✓ Multiple factors are included when assessing what may be considered reasonable: the significance of the event, the seniority of healthcare professionals invited, the type and level of services provided and paid for in full or in part (transport, hotels, catering, etc.) and the use of time within the event agenda, etc. are all included. The cost of meals must not exceed €60 (inc. taxes) per person, or the amount permitted under the local self-regulatory code (the 'host country' principle) where the event is hosted outside France ✓ No gifts may be offered to delegates ✓ Where ostentatious or celebratory activities are offered to delegates, they must: • Take place only on the sidelines of the main event; in other words at a separate time • Not form part of the official agenda • Not be funded directly or otherwise by pharmaceutical companies • Be offered at the normal standard price of the service(s) concerned and be paid for by delegates themselves at full cost
5. Registration or sponsorship fees ***DDP Article 4.1*** ***DDP Article 4.2.1***	✓ The registration fees must cover only attendance at the event, permitted activities and hospitality: transport, meals, accommodation and registration entitlements ✓ The registration fees offered to delegates and/or the financial sponsorship provided by companies may not under any circumstances include payment for recreational, tourism or non-professional expenses ✓ Clarification: Registration fees must not include the cost of learned society membership or a subscription to a journal related to the event or organiser ✓ The registration fees charged by the organiser must be detailed and/or justified in terms of the amount of services provided (overnight stays, transport, meals/snacks, etc.) ✓ In no event may registration or sponsorship fees cover, whether directly or indirectly, any of the costs relating to the attendance of any other person accompanying a delegate. Payment of such costs by pharmaceutical companies is prohibited. Anyone accompanying a delegate must pay for their own expenses at the full cost of the services provided, and a separate invoice must be issued for this purpose. ✓ The registration or hospitality fees may not cover costs incurred by students ✓ Where a social activities programme (including social, leisure, sports or other forms of entertainment) is offered to delegates by the organiser, it must be paid for directly by those wishing to take advantage of it, and invoiced separately
6. Communication ***DDP Article 4.1***	✓ Event communication media (brochures, website, etc.) must highlight the scientific nature of the event. They must not highlight its location or contain excessive or inappropriate references, images of tourism, entertainment, sporting events or any other non-professional or scientific activities. ✓ Where the organiser offers a social activities programme in conjunction with the event, it must be promoted separately from the event itself.