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1. Statement of principles and purpose

EBMT is committed to compliance with Spanish and European legislation on advertising of medicinal products for human use and with applicable professional and industry codes of ethics and good practice. EBMT will establish and implement appropriate organisational measures to enable pharmaceutical companies, sponsors and other third-party exhibitors to conduct their participation in EBMT congresses held in Spain with as much respect as possible of the following principles, given the open floor plan of the congress venue:

- No advertising or promotion of prescription-only medicines to persons who are not healthcare professionals (HCPs).
- Scientific independence of the congress programme.

The purpose of this Protocol is to set out the organisational, control and operational measures needed to:

- a) Prevent any promotion of prescription-only medicines to non-HCPs.
- b) Implement appropriate identification and badge-based measures to allow the clear identification of non-HCPs within exhibition areas
- c) Define consistent rules for accreditation, badge design, and staff training for the EBMT 2026 Congress in Madrid and for any future EBMT congresses held in Spain.

2. Scope

This protocol applies to:

- The EBMT 2026 Congress in Madrid and any other EBMT congress or event held in Spain with participation of the pharmaceutical or medical technology industry.
- All EBMT personnel and staff from any other entity providing services in connection with the congress.
- All sponsoring and exhibiting companies and their representatives.
- All congress staff, hostesses/hosts, registration staff and security personnel.
- All attendees, including HCPs, non-HCPs, patients, patient advocates, trainees, association representatives, media and visitors.

3. Regulatory framework

This Protocol is based on and shall be interpreted in accordance with the applicable legal and self-regulatory framework in Spain, including, inter alia:

- Spanish Constitution.
- Royal Legislative Decree 1/2015, of 24 July, approving the consolidated text of the Law on guarantees and rational use of medicines and medical devices.
- Royal Decree 1416/1994, of 25 June, regulating advertising of medicinal products for human use.

- Applicable regulations of the Autonomous Community of Madrid on medicinal product advertising and promotional activities.
- EU legislation on medicinal products for human use and rules on advertising to healthcare professionals and to the general public.
- The Code of Practice of the Spanish Pharmaceutical Industry association (Farmaindustria) and other relevant sector codes.

Where this protocol is silent, it shall be interpreted consistently with the above framework and any future amendments or replacements.

4. Definitions

For the purposes of this protocol:

Healthcare Professional (HCP)

Any member of the medical, dental, pharmaceutical, nursing or podiatric profession, any other person legally considered as such under Spanish law, or any other person who, in exercising their profession, may perform or participate, directly or indirectly, in the prescription, purchase, supply, dispensation or administration of medicinal products for human use.

Non-HCP (non-prescriber)

Any attendee who does not qualify as an HCP. This includes, without limitation: data managers, administrative staff, students, patients, relatives, patient advocates, journalists, association staff, as well as nurses coming from countries where they are not recognised as HCPs for prescribing purposes.

Pharmaceutical / Medical Technology Industry

Companies that develop, manufacture, market or promote medicinal products for human use or medical devices, and their staff or representatives.

Commercial Exhibition Area

The physical area of the congress where stands or other structures of the industry are located and where medicinal products and medical devices may be promoted.

Industry Sessions

Sessions organised, sponsored or led by pharmaceutical companies or other commercial third parties, the content of which is determined by such third parties and for which EBMT does not exercise prior control over scientific or promotional content.

Non-promotional areas

Scientific session rooms, poster areas, general circulation and catering areas, patient and advocacy areas and any other zones accessible to non-HCPs, where promotion of prescription-only medicines is not permitted. Areas and sessions accessible to non-HCPs where promotion of prescription-only medicines is not permitted, including:

- Scientific sessions forming part of the EBMT scientific programme, excluding Industry Sessions;
- Poster areas;
- General circulation areas;
- Catering areas;

- Patient and advocacy areas; and
- Any other zones accessible to non-HCPs.

Promotion of medicinal products

Any form of information, canvassing or inducement designed to promote the prescription, supply, sale or consumption of medicinal products for human use.

5. Principles of conduct

1. No promotion to non-HCPs

Under no circumstances may prescription-only medicines be promoted, directly or indirectly, to non-HCPs.

2. Clear identification of promotional areas

Promotion and exhibition of prescription-only medicines shall be limited to clearly identified booths and activities within the Exhibition Area and supported by visual and badge-based identification measures.

3. Separation between scientific content and promotion

Scientific sessions must remain independent from commercial promotion. Only neutral corporate acknowledgement of sponsorship (company name and/or logo without product-related claims) will be allowed.

4. Transparency and traceability

All compliance-related actions and decisions in the congress shall be documented and kept in the Congress Compliance Dossier described in this Protocol.

6. Organisation and responsibilities

EBMT Event Director

- Ultimately responsible for approval, implementation and review of this protocol.

Compliance Unit

- Advises on the interpretation of applicable legal, regulatory and industry code requirements
- Reviews and validates the Compliance and Control Plan for each congress.
- Supports the Congress Compliance Officer in the assessment and resolution of complex or escalated incidents and coordinates corrective measures, where required.

Congress President / Local Chair

- Ensures that the scientific programme and logistics comply with this Protocol.

PCO - Professional Congress Organiser

- Implements the operational measures defined by EBMT, including zoning, accreditation flows, signage and access routes, in coordination with the venue.

Congress Compliance Officer

- Defines and oversees the implementation of compliance measures under this Protocol. Acts as the primary point of contact for compliance-related matters during the congress.

Industry representatives

- Must comply with contractual obligations and this Protocol, train their own staff accordingly and correct any non-compliance immediately.

7. Accreditation process and HCP / non-HCP classification

1. Online registration form

The online registration form will include at least:

- Main professional role (drop-down list).
- Mandatory question that allow the participant to self-identify as HCP / non-HCP as per legislation of Spain.

2. Automatic classification

Based on the answers provided, the system will automatically classify the person as HCP or non-HCP and generate the corresponding badge type.

3. Pre-congress review of lists

Prior to the congress, the Compliance Unit will review the list of attendees classified as non-HCP (by country and role) to detect obvious inconsistencies and request clarifications where needed.

4. Confirmation Email

Prior to the congress, each participant receive a confirmation email with instructions to collect their badge.

Confirmation email to participants registered as non-HCPs will include information clause explaining that non-HCPs are to avoid areas with and participate in activities involving advertising or promotion of prescription-only medicines.

5. On-site changes

HCP / non-HCP status is determined based on self-declaration during registration. EBMT does not systematically verify the accuracy of such declarations.

If a participant identifies an error in their registration status, or if a clear and objective discrepancy is brought to the attention of the Congress Compliance Officer, the participant may be invited to update their registration record and, where appropriate, their badge category may be adjusted.

8. Venue zoning and access control

8.1 Zoning

The venue shall be divided at least into the following areas:

- a) **Exhibition Area (Promotional)** –
- b) **Scientific Areas** – plenary and parallel session rooms, poster areas.
- c) **Patient and Advocacy Areas** – dedicated patient and advocacy activities.
- d) **General Areas** – registration, corridors, etc.

Access to the Exhibition Area shall not be managed by EBMT staff. Instead participants will be furnished with distinctive badges identifying them as HCPs / non-HCPs (non-prescribers). This will be

supported by appropriate signage requesting them to avoid areas with promotion of prescription medication.

8.2 Badges and access coding

The badge is the primary tool for attendee identification. EBMT will use a standardised badge design, inspired by badges used at previous EBMT congresses, with specific adaptations for Madrid 2026 (see Annex V):

- First name and family name.
- Country.
- Main role.
- Visible distinction between "HCP / non-HCP"
- Background colour code according to access category.

Signage at the entrance of the Exhibition area and around it with a short summary of access rules, a request for non-HCP attendees to avoid the promotional areas and the contact details of the Congress Compliance Officer, will be placed.

8.3 Access process

1. Access to the exhibition areas will not be actively restricted or monitored for non-HCP (non-prescribing) attendees..
2. If a person with "non-HCP" marked badge is found in a booth with advertising or promoting prescription-only medicine:
 - Staff will request to see the badge.
 - Staff will explain the applicable rules and invite the person to leave the area.
 - The incident will be recorded in the incident log (Annex IV).
 - In case of refusal to leave, the matter will be escalated to the Congress Compliance Officer.

9. Obligations of the pharmaceutical industry

Sponsoring and exhibiting companies shall, through a specific contractual clause:

- Comply with Spanish law and applicable codes of practice on medicinal product advertising.
- Restrict all promotion of prescription-only medicines to the Commercial Exhibition Area.
- Train their own staff on the congress access rules and this Protocol.
- Immediately remove any material or activity that EBMT considers non-compliant.

In case of serious or repeated non-compliance by a pharmaceutical company or exhibitor, EBMT may take proportionate corrective measures, including requesting the removal of specific materials or staff, restricting specific activities, and escalating the matter to the relevant company and, where appropriate, to applicable industry bodies.

10. Training of staff and security

EBMT will implement a training plan based on the “Staff and Security Training – Intervention Protocol” used in previous congresses, adapted to the Spanish legal environment and congress layout.

Training will include:

- A pre-congress training module (30 minutes) covering the legal framework, HCP / non-HCP definitions, zoning and practical examples shall be completed by EBMT staff and key operational leads.

For remaining hostess and security staff, this content may be delivered through a condensed face-to-face briefing on site, supported by written quick-reference materials.

EBMT shall ensure that last-minute replacements receive an appropriate short briefing before starting their duties.

- A face-to-face briefing (around 30 minutes) on the day before the exhibition opens, covering the venue map, badge types and standard intervention phrases, organised by EBMT or delegated to the Professional Congress Organiser (PCO) or another designated supplier under EBMT's supervision.
- Mandatory signature of the **Training Attendance Record** (Annex III). shall apply to the face-to-face briefing. Completion of the pre-congress training module shall be evidenced through digital records

No member of staff or security will be allowed to perform access-control duties unless they have completed the training or a face-to-face briefing

11. Incident management and reporting

1. Any member of staff or security who detects a potential breach of this Protocol shall promptly inform the Congress Compliance Officer and enter the incident in the log using the template in Annex IV.
2. The Congress Compliance Officer will assess the severity, coordinate the response and, where appropriate, inform the company involved.
3. After the congress, a **Congress Compliance Report** will be prepared, summarising incidents, root-cause analysis, corrective actions and lessons learned.

12. Congress Compliance Dossier

For each EBMT congress held in Spain, EBMT will maintain a **Congress Compliance Dossier**, which will include at least:

- This Protocol and the event-specific Compliance and Control Plan (Annex I).
- Venue zoning map, Mapping of the exhibition area identifying booth advertising or promoting prescription-only medicines and photographs of signage.
- Badge templates and colour legend (Annex V).
- Lists of attendees classified as HCP / non-HCP generated from the registration system.

- Training records (Annex III).
- Incident logs (Annex IV) and the final Congress Compliance Report.
- Copies of signed contractual compliance clauses with sponsoring and exhibiting companies.

13. Entry into force, review and filing

This Protocol enters into force on the date indicated in the header ("Effective Date") and shall apply from the EBMT 2026 Congress in Madrid.

The Compliance Unit will review this Protocol if there are relevant legal changes or lessons learned from congress experience that require updates.

Printed or PDF copies distributed for operational purposes are considered **uncontrolled copies**. The current controlled version is kept in the EBMT document management system.

ANNEXES

Annex I – Compliance and Control Plan (operational summary)

1. Identification and classification of attendees as HCP / non-HCP through registration.
2. Venue zoning, + Mapping of the exhibition area identifying booth advertising or promoting prescription-only medicines .
3. Design and production of badges in line with Annex V.
4. Training of staff and security (Annex II and III).
5. Implementation of access points and signage.
6. Use of the incident log (Annex IV).
7. Preparation of a final Congress Compliance Report and filing in the Congress Compliance Dossier.

Annex II – Minimum content of staff and security training (Intervention Protocol)

Training modules:

1. Introduction and objectives.
2. Overview of Spanish legal and ethical framework.
3. Definitions of HCP / non-HCP and usual roles at EBMT congresses.
4. Venue zoning, + Mapping of the exhibition area identifying booth advertising or promoting prescription-only medicines and map of the congress.
5. Badge types and how to read them quickly.
6. Step-by-step intervention procedure, including suggested wording:

“Good morning, may I please see your badge?”

Under Spanish regulations, only accredited healthcare professionals are allowed to access this commercial exhibition area of the pharmaceutical industry. I'm afraid I have to ask you to leave this area; I'll be happy to guide you to the general congress areas.”

7. Use of the incident log and escalation to the Congress Compliance Officer.

Annex III – Training attendance record template

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Annex IV – Incident log template

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Annex V – Badge design specifications and attendee coding

Inspired by the badge design used to manage in-person non-HCP attendees at previous EBMT congresses.

Mandatory elements (front):

- EBMT logo + “EBMT 52nd Annual Meeting – Madrid 2026”.
- First name and family name.
- Country.
- Main role.
- Visible distinction between "HCP / non-HCP
- Lower band showing category (FACULTY, MEMBER, INDUSTRY, NETWORKING EVENT, etc.).

Sample Badges HCPs:



Sample Badges No-HCPs:

