MedTech Europe AiSBL – Internal Rules

Adopted by the MedTech Europe Board of Directors on 4 July 2019

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Introduction

Purpose and Drawing up of the Internal Rules

The Internal Rules aim to clarify the Statutes of MedTech Europe ("the Statutes"), the registered office of which is located at Rue Joseph II 40, 1000 Brussels (Belgium) and whose purpose is set forth in Article 3 of the Statutes of MedTech Europe ("the Association").

The purpose of the Internal Rules is to supplement and/or explain certain provisions of the Statutes. These internal rules set out specific Association rules and policies pertaining to a variety of scenarios which require additional detail and specification¹. As provided for in the Statutes, "[w]ithin the limits allowed by the law, to detail and complete the provisions of these Statutes, the Board of Directors may adopt, amend and/or revoke internal rules, internal procedures, and/or any other kind of rules that fall within the scope of its powers?"). Furthermore, it is the Association's Board of Directors ("The Board") who is responsible for "the adoption, the amendment, and the revocation of the internal rules."

The Internal Rules are binding upon the Members of the Association⁴.

Board of Directors: Change of Role

The Association's General Assembly, organised in four electoral groups, appoints and revokes the Directors⁵. During a Director's tenure he/she may change roles, which requires an assessment of the new role to determine if it also meets the Director requirements as per Article 19.2 of the Statutes.

Changing Corporate Member Companies

Where a Director of Corporate Member “X” takes a new position at Corporate Member “Y,” that Director's mandate shall terminate as of right and with immediate effect⁶. While in his/her new role, the Director may meet the Statutes’ Director eligibility criteria, the corresponding Electoral Group elected the individual due to his/her role at Corporate Member “X,” and would not have necessarily done so at Corporate Member “Y.” Moreover, a Member cannot have more than one Director on the Board and it may be that Corporate Member “Y” is already represented in the Board. As a result, the individual’s directorship does not and cannot automatically transfer.

¹ These MedTech Europe Internal Rules are not exhaustive and will be reviewed and revised as necessary.
² Statutes Art. 44
³ Statutes Art. 20(b)
⁴ “By accepting the membership of the Association, each Member also commits itself to acting in compliance with these Statutes and the internal rules, if any…." (Statutes Art. 10, emphasis added)
⁵ Statutes Art. 13, 19.4 & 19.5.
⁶ See Statutes Art. 19.6
Changing Roles within same Corporate Member

Where a Director of a Corporate Member moves into a new role or position within the same Corporate Member, his/her directorship may continue, if, and only if, the individual’s new role meets the Director eligibility criteria7.

Members

New Members: Wash-Out Period

Any medical technology, device, or in vitro diagnostic company, as well as any medical device or in vitro diagnostic National Association meeting the Statutes requirements may become a Member of the Association8. All Members are responsible for compliance with the Statutes and its requirements, including but not limited to, compliance with the MedTech Europe Code of Ethical Business Practice (“the Code”). At the time a new applicant becomes a Member, it must begin to take all the necessary steps required to meet these obligations.

However, the Association recognizes the complexities involved and the time needed to make changes associated with these new obligations. For example, an applicant may have previously committed to participate in or support a Congress or Third-Party Educational Event that has not been approved by the Conference Vetting System (“CVS”), but that takes place two months after they have become Members. It would be unreasonable, and could deter interest in membership, to require the new Member to back out of those obligations. As a result, Corporate Members have one (1) year from the date of Membership approval by the Board of Directors to fully comply with the Code. Please note, this one-year time frame does not include an exemption from the Code’s ban on direct sponsorship. From the moment an applicant becomes a Member, direct sponsorship of HCPs is prohibited.

National Association Members will have one (1) year from the date of membership approval to transpose the Code, as per Article 2.2. of the Procedural Framework of the Code.

After the passage of one (1) year, all Members must fully comply with all obligations under the Statutes, Code, etc. Any infringement or violation will trigger the necessary Enforcement Mechanism and/or processes9.

Membership Costs – M&A Compensation fee

Each Member is responsible for paying annual membership fees10. However, in the event that a Member is acquired by another Member, through a merger, combines with another Member, or who transfers substantially all its assets to another Member, (hereinafter referred to as a “consolidation”), it must pay to the Association a

7 See Statutes Art. 19.2 for Director criteria
8 See Statutes Art. 4-6 for membership types and criteria
9 See Statutes Art. 8 and the Code Part 3: Procedural Framework
10 See Statutes Art. 5, 6 & 9
fee (hereinafter referred to as a “merger fee”). This merger fee shall be calculated using a percentage of the Active member’s dues payment during the year of the consolidation (the “dues payment”)\(^\text{11}\). The total merger fee may be paid either in full within 30 days of the effective date of the consolidation, or over a period of five years. The merger fee shall be calculated one of two ways and the consolidated entity shall have the choice between the two options:

(1) The consolidated entity may choose a one-time pay out equal to three hundred percent (300%) of the phaseout amount (i.e. the phase-out amount is the amount of the membership fee that the acquired company used to pay); or

(2) The consolidated entity may choose to pay the merger fee over a five-year period, declining payments shall be made according to the following schedule:

<table>
<thead>
<tr>
<th>Year Following</th>
<th>Merger fee based on the last fee paid by the target entity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consolidation:</td>
<td>(i.e. merged/acquired) the year of the consolidation:</td>
</tr>
<tr>
<td>Year 1</td>
<td>80% of dues payment</td>
</tr>
<tr>
<td>Year 2</td>
<td>70% of dues payment</td>
</tr>
<tr>
<td>Year 3</td>
<td>60% of dues payment</td>
</tr>
<tr>
<td>Year 4</td>
<td>50% of dues payment</td>
</tr>
<tr>
<td>Year 5</td>
<td>40% of dues payment</td>
</tr>
</tbody>
</table>

In subsequent years, the consolidated entity’s dues shall be calculated according to MedTech Europe’s dues schedule.

**Resignation**

A Member may resign from the Association at any time\(^\text{12}\). Upon the Chief Executive’s receipt of a Member’s resignation, that company will no longer be a Member of the Association. As a result, from that moment the Member will lose all associated membership rights (but shall remain liable for its obligations towards the Association, as provided by Article 8 of the Statutes) including but not limited to, the right to vote in the General Assembly and the right to submit nominations for election to the Board of Directors. However, the Chief Executive may at his/her discretion, and for a limited time which cannot be longer than the period covered by the Membership Fee, allow the Member to continue to receive certain benefits such as participation in the Association’s Working Groups (unless that Working Group has specifically requested otherwise), receipt of discounted prices for events, receipt of the Members Newsletter, etc.

For avoidance of doubt, the payment of the phase-out amount does not prevent the consolidated entity to pay as of year Y+1 a fee that depends on the consolidated turnover.

\(^{11}\) As decided by the AGM during its 30 Nov 2017 meeting

\(^{12}\) Statutes Art. 8
Miscellaneous

Privacy Notice

As part of its legal obligations under the General Data Protection Regulation EU 2016/679 (“GDPR”) as an international non-profit association constituted under Belgian law, these internal rules include and refer to the Association’s Member Privacy Notice (“Privacy Notice”). This Privacy Notice aims to give Members’ employees information on how their personal data (i.e. information that directly or indirectly identifies a Member employee) is processed by the Association. Members are responsible for informing their employees of the existence of this Privacy Notice, as updated from time to time (available on Sharepoint – link to the Notice here).

Amendment of the Internal Rules

The Internal Rules are adopted by the Board of Directors and may be amended and/or revoked by the same Board. Any new or amended Internal Rules shall be shared with Members (i.e. internal newsletter) and uploaded on the Association’s website.