

EUROPEAN PHARMACEUTICAL LAW ASSOCIATION (EPLA)

BY-LAWS

I – GENERAL

Article 1. LEGAL STRUCTURE - NAME – DURATION

1.1 The Association adopts the legal structure of international non-profit association governed by the provisions of the Law of 23 March 2019 (Belgian code of companies and associations).

1.2 The name of the Association shall be “**European Pharmaceutical Law Association**” (abbreviation “EPLA”), hereafter referred to as the “Association”.

1.3 The Association has been established for an indefinite duration and may be dissolved at any time.

1.4 The Association shall be governed by these By-Laws and by European and Belgian law.

Article 2. OFFICE

2.1 The office of the Association shall be in the region of Bruxelles-Capitale, Belgium.

II – AIM & ACTIVITIES

Article 3. AIM

3.1 The aim of the Association shall be to contribute in Europe:

- to a better knowledge of pharmaceutical law and related areas as a specific sector of general law.
- to the development of pharmaceutical law and related areas, including to its international harmonisation, with due regard to its specific and interdisciplinary character and to its particular role in the field of consumer protection and safeguarding public health.

Article 4. ACTIVITIES

4.1 For this purpose, the Association has the following activities:

- to create a network of experts in pharmaceutical law and policy, and their related areas of law, including medical device law, and to provide a focal point of expertise to its members
- to identify and debate legal questions raised by the developing nature of the pharmaceutical industry
- to encourage discussion between members through working groups
- to provide educational opportunities for members and others who are interested in pharmaceutical law and ethics
- to organise annual conferences on pharmaceutical law and related areas
- to draft and present position papers, statements and documents on points of pharmaceutical law
- to be a forum for the study and development of legal aspects of pharmaceutical law
- to organise workshops, meetings and similar events in Europe or on a wider international scale

- in order to promote the objectives of the association and to foster discussion on these topics
- to represent members in organisations, including in the Council of Europe.

4.2 The Association may co-operate within its means with any organisation or institution, national or international, public or private, established in Europe or in any region of the world, with similar aims on a non-profit basis.

III – Membership

Article 5. MEMBERS

5.1 The number of Members shall be unlimited, with the minimum being fixed at two Members.

5.2 The Association has Founding Members and Ordinary Members

5.3 Membership of the Association cannot be transferred or assigned.

Article 6. FOUNDING MEMBERS

6.1 Founding Members are automatically Ordinary Members and as such have the same rights and obligations as Ordinary Members. They are subject to the same procedures of resignation and expulsion.

Article 7. ORDINARY MEMBERS

7.1 Membership as an **Ordinary Member** (hereafter ‘Member’) in the Association shall be open to:

- **Individual members** who, by their professional activities or their publications, contribute to the development of pharmaceutical law in a legal or a non-legal field (such as lawyers, scientists, academics, employees of pharmaceutical companies)
- **Corporate members** such as academic institutions or other organisations with aims considered to be compatible with the aims of the Association.

Article 8. ADMISSION

8.1 All requests for membership shall be addressed in writing to the Secretary General. The letter of application for membership shall include a commitment to adhere to the present By-Laws and to fulfil the financial obligations imposed on the members, for the entire duration of their affiliation.

8.2 The Board of Directors shall review membership applications. Admission shall be subject to approval by the Board of Directors.

Article 9. RIGHTS AND OBLIGATIONS OF MEMBERS

9.1 Members are required to comply with these By-Laws and all decisions and internal rules of the Association.

9.2 Members are required to pay annual fees. The amount of the fees shall be determined by the General Assembly upon recommendation of the Board of Directors.

9.3 Members shall be informed regularly of the Association's activities and of the steps undertaken within the context of the representation of the common interests of the Association.

9.4 Members shall have the right to participate to General Assemblies and to express all the requests that fall under the competence of this body

Article 10. RESIGNATION AND EXCLUSION

10.1 Membership may be discontinued or revoked in the following cases:

- when a Member is dissolved or ceases to exist.
- by a letter of resignation submitted by the Member to the Secretary General of the Association, at least 3 months before the end of the financial year.
- by exclusion declared by the General Assembly upon recommendation from the Board of Directors for non-compliance with these By-Laws or any other internal rules of the Association. Prior to such decision by the General Assembly, the Member concerned shall be given an opportunity to explain its position before the General Assembly.
- by exclusion declared by the Board of Directors for non-payment of fees. The excluded member may appeal the decision of the Board of Directors in the next meeting of the General Assembly. All rights associated with membership (voting rights, right to attend meetings of the association and to participate in the activities of the association) are suspended for the duration of the appeal process.

10.2 A Member which ceases to be part of the Association for one of the reasons set out in Article 10.1 shall have no right to the Association fund; it must still pay the fees of the current financial year.

IV – BOARD OF DIRECTORS

Article 11. POWERS OF THE BOARD OF DIRECTORS

11.1 Unless otherwise provided, the Board of Directors shall have full powers to perform all acts that are not reserved for the General Assembly. The Board of Directors shall have, among others, the following powers:

- to decide on the time and place of meetings of the General Assembly;
- to make proposals to change membership fees, with the final decision needing to be taken by the General Assembly
- to adopt the annual budget and the annual accounts, which will be submitted for approval by the General Assembly;
- to exclude a Member by a majority vote within the limits of Article 10;
- to delegate certain specific and limited powers and/or daily management to one or more persons and to decide whether they are remunerated or not.

Article 12. COMPOSITION OF THE BOARD OF DIRECTORS

12.1 The function of Director of the Board shall be open to Members, who will exert a non-remunerated mandate.

12.2 The Board of Directors shall be composed of not less than three (3) and not more than 6 (six) directors. The following officers shall be appointed by the Board of Directors from among its members:

- **President**

The President shall be responsible for implementing the decisions of the Board of Directors.

- **Vice-President**

In case of absence, unavailability or at the request of the President, the Vice-President shall act as Chairman.

- **Treasurer**

The Treasurer shall be responsible for drafting the budget and preparing the accounts of the Association. He/she submits the budget and accounts of the Association for approval by the General Assembly. He/she shall give reports on the budget and accounts in the annual meeting of the General Assembly.

12.3 Directors are elected for a mandate of two (2) years, renewable at the General Assembly meeting. They exert their role collectively.

12.4 The positions of President and Vice-President cannot be held more than six (6) consecutive years.

12.5 Should a Director resign during the course of their mandate, the Secretary General will send an invitation for nominations to replace the Director, in line with Art. 12.6.

12.6 Before each election of directors, the Secretary General will invite the Members to submit their nomination for the position of director not less than eight (8) weeks prior to the election. No later than four (4) weeks before the date of the election, the Secretary General shall circulate to all Members the names of the director candidates.

12.7 Each Member can only be represented by one representative on the Board of Directors. Members shall therefore ensure that their designated representatives express the desire and intent to represent them on the Board of Directors.

Article 13. MEETINGS OF THE BOARD OF DIRECTORS

13.1 The Board of Directors shall meet no less than once per year, at the request of the President, and as often as decided by the President.

13.2 A notice must be sent within a reasonable time before the meeting, except in emergencies. In emergencies, the nature and reasons of the emergency must be mentioned in the notice. Notices are valid if issued by post or email or any other means of communication specified in Article 1.5 of the Belgian Civil Code. The notice must contain the agenda of the meeting.

13.3 The Board of Directors shall meet in the location indicated in the notice. If the notice specifies the modes of participation, meetings may also be held using any means of telecommunication that permits a joint debate, such as telephone or videoconferencing.

13.4 Meetings of the Board of Directors are valid when attended by at least three (3) directors.

13.5 In case of inability to attend, the President delegates his/her powers to the Vice-President.

13.6 The President may invite persons from outside the Board of Directors at his/her own initiative or at the request of a director, provided no objection is expressed by the other directors.

13.7 Draft minutes of the Board of Directors shall be prepared by the Secretary General in coordination with the Chairman and distributed for information to the Board of Directors and to the General Assembly. Once approved by the members of the Board of Directors present or represented at the

meeting in the next Board meeting, the minutes shall be signed by the Chairman, sent to all members of the Board and kept at the Association's office.

Article 14. DECISION-MAKING PROCEDURE IN THE BOARD OF DIRECTORS

14.1 Decisions shall be taken by simple majority of the directors present or represented at the meeting.

14.2 Each director may cast one vote. Any director who is unable to attend a meeting of the Board of Directors may be represented by another director.

14.3 Resolutions of the Board of Directors may be approved by the unanimous written consent of all directors. At the request of one or more directors, the Chairman may distribute to all directors a document containing the resolutions proposed by post, fax, email, or any other means of communication specified in Article 1.5 of the Belgian Civil Code. This document must be returned signed and dated to the office of the Association within ten (10) calendar days of receipt thereof. Written resolutions are deemed to have been adopted as of the date of the last signature.

Article 15. SECRETARIAT

15.1 The Secretary General shall be appointed by the Board of Directors.

15.2 The Secretary General shall be responsible for day-to-day management of the association. The Board can delegate to him/her tasks and authorities, including, for example, general administration, keeping the accounts, organising meetings, coordinating committees and working groups, representing the Association, facilitating and ensuring liaison between the Members, and ensuring the Association complies with legislation. This also includes keeping the register of Members, sending notices of meetings and drafting written documents such as the minutes of meetings. The Secretary General shall be present at meetings of the Association but shall not have voting rights. His/her presence shall be not taken into account in calculating the quorum.

Article 16. WORKING GROUPS

16.1 Working groups may be established by the Board of Directors to examine in detail specific matters of interest to the association. Such working groups shall recommend appropriate actions to the Board of Directors.

16.2 Working groups shall operate according to consensus, based on transparency of discussions, actions and reporting. Formal objections, provided they are expressed in a timely manner and by a duly mandated member representative, shall be taken into account by the Chairs of the working groups, who may defer matters of concern to the Board of Directors for decision, as appropriate.

V – DAY TO DAY MANAGEMENT

Article 17. DAY-TO-DAY MANAGEMENT

17.1 The Board of Directors may delegate the day-to-day management of the Association to one or more persons, who do not have to be members of the Board and who may act individually. The person entrusted with these powers of day-to-day management shall be called the "Secretary General".

17.2 The Board of Directors shall appoint the Delegate(s) charged with overseeing day-to-day management. It shall determine his/her/their mandate.

17.3 If the Delegate charged with day-to-day management shall be a member of the Board of Directors, his/her mandate as Delegate of day-to-day management shall end if his/her mandate as director is revoked.

VI – GENERAL ASSEMBLY

Article 18. POWERS OF THE GENERAL ASSEMBLY

18.1 The General Assembly shall be the supreme authority of the Association. It shall be responsible for determining the general policy of the Association and laying down the guidelines within which the Board of Directors shall operate.

18.2 The General Assembly shall have the following exclusive rights:

- to approve the budget and annual accounts of the Association;
- to appoint and dismiss Directors of the Board;
- to appoint and revoke an auditor;
- to decide whether to discharge directors and the auditor;
- to approve the fees proposed by the Board of Directors;
- to amend the By-Laws;
- to amend the criteria for membership of the Association;
- to take decisions regarding appeals by excluded Members;
- to decide whether to transfer the registered office of the Association;
- to decide whether to dissolve the Association.

Article 19. COMPOSITION OF THE GENERAL ASSEMBLY

19.1 The General Assembly shall be composed of all Members. All Members shall have voting rights.

Article 20. MEETINGS OF THE GENERAL ASSEMBLY

20.1 A meeting of the General Assembly shall be convened no less than once a year by the Board of Directors. In the annual meeting, the General Assembly shall vote, at a minimum, on the annual accounts from the previous financial year and the discharge to be given to directors and, where appropriate, the auditor, and the budget proposed for the current financial year. The General Assembly shall vote on the appointment/revocation of directors in its annual meeting.

20.2 Meetings shall take place at a time and place, including on-line, to be set by the Board. The Board may invite representatives of other organisations to attend the meetings of the General Assembly.

20.3 Notification of a meeting of the General Assembly must be issued by the Secretary at least four (4) weeks prior to the proposed meeting date. Notices are valid if issued by post, fax, email or any other means of communication specified in Article 1.5 of the Belgian Civil Code. The notice must contain the agenda of the meeting.

20.4 The agenda shall be determined by the Chairman of the Board. Members may add to the agenda any other item required provided that the majority of Members present at the meeting approve the

addition of such items to the agenda. The Secretary General shall transmit to the Members any changes in the agenda.

20.5 Except in exceptional cases as determined herein and in the law, the decisions taken by the General Assembly shall be adopted by a simple majority vote by the Members present or represented. Vote by proxy shall be authorised when the notice so provides. Each Member may cast one vote. Except as otherwise provided herein, no quorum shall be required for meetings of the General Assembly.

20.6 Decisions related to the approval of membership fees, the appeal of an excluded Member, amendments to the By-Laws, changes in the criteria for membership and any change in the location of the Association's office shall be taken by a two-thirds majority vote by the Members present or represented at the meeting of the General Assembly. Decisions related to changes in the aim and/or object of the Association or the dissolution of the Association (and those concerning any matters related to such dissolution) shall be taken by a two-thirds majority vote by the Ordinary Members present or represented at the meeting of the General Assembly.

20.7 For each of the decisions referred to in Article 20.6, a quorum of at least two-thirds of the Members present or represented at the meeting of the General Assembly must be reached. If this condition is not satisfied, a new meeting may be convened to deliberate and vote on all items placed on the agenda in the previous meeting, regardless of the number of Members present or represented.

20.8 In accordance with the Belgian Code of companies and associations:

- Any amendment to the By-Laws concerning the aim and/or object or activities performed to achieve such an aim and/or object must be approved by Royal Decree;
- Any amendment to the By-Laws concerning the powers and functioning of the General Assembly must be by notary deed; and
- Any amendment to the By-Laws concerning conditions for amending the By-Laws or the assignment of assets must be by notary deed.

20.9 Any Member may request to be represented by another Member at the meeting of the General Assembly. However, each Member present may only represent one (1) absent Member.

20.10 Each Member can also vote by letter or electronically using a form drafted by the Board of Directors, containing the following mentions: (i) identification of the Member, (ii) number of votes he is entitled to and (iii) for any decision that needs to be taken by the General Assembly according to its agenda, the notion "yes", "no" or "abstention"; the form must be sent to the Association and must reach the registered office at least one working day before the General Assembly.

20.11 The representatives must prove that they have the necessary powers by submitting a power of attorney to the Secretary General of the Association before the meeting for which they have received said power of attorney. Although more than one (1) representative of a Member may attend the meetings of the General Assembly, the Member shall only have one (1) vote.

20.12 Minutes of the meetings of the General Assembly shall be prepared and submitted for approval by all Members present or represented at the meeting of the General Assembly. They shall be definitively approved in the next General Assembly and kept at the registered office of the Association. The register remains at the disposal of the Members at the registered office of the Association.

Article 21. WRITTEN PROCEDURE

21.1 The General Assembly can also make a decision by written procedure.

21.2 In this case the Board shall prepare a note detailing the proposals that are subject to a decision by the General Assembly. For this purpose, upon request from the Board, the Secretary General shall submit to each Member the note detailing the proposed decisions, and a ballot paper.

21.3 At the initiative of at least twenty percent (20 %) of Members of the Association with voting rights and provided the request is made within a period of seven (7) calendar days from the date at which the note detailing the proposed decisions is submitted, a meeting of the General Assembly must be convened instead of the written procedure.

21.4 The ballot paper shall indicate the technical modalities for the vote, as well as the period during which the vote is open ("Voting Period"), which shall last at least fifteen (15) calendar days from the date at which the note detailing the proposed decisions is submitted to the Members. During the Voting Period, the Secretary General shall supervise the vote and shall count Members' votes. If formally requested by one or several Members before the end of the Voting Period, the votes shall be counted under the control of a bailiff.

21.5 Unless otherwise stated in the present By-Laws, no quorum applies in the written procedure. Within the limits of the applicable legal provisions, a decision made in the framework of the written procedure of the General Assembly shall be adopted by way of unanimous written decision.

21.6 The written procedure cannot be applied when the decision of the General Assembly shall concern the amendments of the By-Laws.

VII – REPRESENTATION OF THE ASSOCIATION

Article 22. REPRESENTATION

22.1 Without prejudice to the general power of representation of the Board of Directors as a whole, the Association shall be validly represented in court and before third parties by two members of the Board acting collectively.

22.2 For proceedings related to day-to-day management, the Association shall be also validly represented by one Delegate overseeing day-to-day management acting individually.

22.3 For proceedings related to its specific powers, the Association shall be also validly represented by special representatives appointed by the Board of Directors.

VIII. MISCELLANEOUS

Article 23. WORKING LANGUAGE

23.1 The official language of the Association shall be French. The working language of the Association shall be English.

Article 24. DISSOLUTION

24.1 In case of dissolution with liquidation of the Association, the General Assembly shall appoint one or more liquidators.

24.2 Net assets shall in such a case be dedicated to a non-profit purpose.

24.3 The foregoing shall be without prejudice to the Belgian code of companies and associations.

Article 25. FINANCIAL YEAR – AUDITOR

25.1 The financial year of the Association shall start on 1st January and end on 31st December of the same calendar year.

25.2 Any auditors appointed by the General Assembly shall have a mandate of three (3) years.

25.3 The external auditor shall review the balance sheet and statement of income and expenditure of the previous financial year before these documents are submitted for approval at the Annual General Meeting.

Article 26. CONFLICTS, DISPUTES AND LITIGATION

26.1 Any dispute or litigation concerning the interpretation of the above articles, or any dispute arising between a Member and the Association, must first be submitted to the Board of Directors, which will attempt to find an amicable solution before the matter shall be brought before the courts for a judicial decision.

26.2 In the event of legal action, the dispute shall be governed by Belgian law and fall under the exclusive jurisdiction of the courts of the judicial district in which the Association has its headquarters.

Article 27. GENERAL

27.1 Any points not covered herein shall be governed by the provisions of the Law of 23 March 2019 (Belgian code of companies and associations).
