

VAccine monitoring Collaboration for Europe

Articles of Association Draft March 21 2019.

Vaccine monitoring collaboration for Europe; Articles of association

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Section I. Legal status

1. Legal status, name and head office

1.1 The Association is governed by the provisions of Title III of the Belgian law of 27th June 1921 on non-profit organizations, international non-profit organizations and foundations and modified subsequently by the program law of December 31^{*}, 2004 regarding the articles 279 and 285 of the same law, as published in the Official Journal under the circular of June 2d., 2005.

1.2 The International Association is named: VAccine Monitoring Collaboration for EUrope or abbreviated such as VAC4EU.

1.3 Its domicile is located in Washington street 40, B-1050 Brussels for an unlimited period of time. It will be registered under the Bank Carrefour of Enterprise accordingly to the Belgian laws and obligations. By exemption to Article XX of the present Statutes, the office of VAC4EU can be transferred to any other address in Belgium following a corresponding decision of the Executive Board and in compliance with the linguistic legislation. The address change shall be published in the annexes of the Moniteur Belge and submitted to the registered file at the competent commercial court within a month from the date of the decision.

1.4 The official language within the VAC4EU is English. Official documents will be either translate into French or Dutch according to the principle of submission of an International Association status in a Belgian legal language

2. Duration

VAC4EU is incorporated for an indefinite duration. The Association shall be granted legal personality at the date of the Royal Decree recognizing the incorporation, in conformity of the Article 50 paragraph 1 of the law of June 27th. 1921.

3. Objectives and Activities

3.1 The overall objective of **VAC4EU** is to enable coordinate and accelerate the generation of best actionable evidence and expertise on vaccine coverage, benefits and risks.

The specific objectives will include but are not limited to:

- Create and implement a European partnership that can respond rapidly and reliably to relevant questions around post licensure vaccine coverage, benefits and risks by generating robust and trustworthy evidence. This will be achieved by supporting and maintaining a study network of experts and health data access providers, which can conduct vaccine coverage, benefit and risk studies collaboratively according to VAC4EU best practice.
- Stimulate scientific discussions and implement continuous methodological developments to support reliable and rapid generation of evidence on vaccines in Europe through the VAC4EU open community.

- Train and provide rapid access to a unique vaccine expert community and study network in Europe;
- Build synergy and consensus between stakeholders (regulators, public health, researchers, patient/citizen organizations, healthcare providers, vaccine manufacturers).
- Define and support the adoption of best practices in study conduct governance, including ethics, privacy protection, relating to the capture, sharing and trustworthy generation of evidence of health data Ensuring sustainability of VAC4EU.

3.2 Activities

The VAC4EU Secretariat will conduct the following activities

- Administer and promote VAC4EU in the broadest sense possible to the outside world
- Support the work and management of the VAC4EU Executive Board, the study network, the general assembly, the organizational independent advisory committees/board (e.g. community, strategic advisory board, audit committee)
- Advocate about the importance of transparent and easy to use evidence on vaccine coverage, benefits and risks
- Identify and characterize data sources that may be willing to participate in the VAC4EU study network
- Organize updates of database characterization amongst members
- Maintain, update and provide access to the VAC4EU website, data sharing platform, tools and templates for its members
- Organize development of new and ongoing activities
- Research & business development activities towards different funding agencies
- Operate as first contact point and matchmaking for study requests
- Organize meetings for the community, executive board and study network
- Develop and adminster training
- Organize meetings (virtual and physical)

The VAC4EU study network will conduct at least the following activities

- Maintain a repository of members and capacity
- Provide information on datasources (meta-data and database characterization)
- Conduct vaccine coverage, benefit, risk and benefit/risk studies and monitoring according to VAC4EU endorsed best practice and procedures
- Provide the community with practical methodological questions
- Propose, evaluate and implement procedures for generating timely and robust evidence on vaccine coverage, benefits and risks

3.3 VAC4EU shall carry out acts and take steps and commit to all activities that are deemed appropriate or useful in view of achieving its objectives.

3.4 VAC4EU is a non-profit-making organization.

3.5 Any application to the Belgian authorities for an alteration or expansion of objectives and activities of VAC4EU shall require the formal approval of the General Assembly.

4. Ethical conduct & Principles

4.1 Each Member of VAC4EU is committed to integrity and to respect the confidentiality of VAC4EU internal documents labelled as confidential.

4.2 Each Member shall maintain and enforce adherence to lawful business practice and shall act in good faith and transparently with respect to other Members.

4.3 VAC4EU and its Members shall operate in full compliance with all national And European laws.

Section II. Membership

5. Categories and conditions of membership

5.1 General provisions

Members of VAC4EU consist of "Organizations" (hereinafter named as "Member Organizations". A list of Member Organization will be maintained by the Secretariat. Members can be research organizations (governmental and non-governmental or private), public health institutes, and data access providers under the condition of being qualified and able to provide either access to relevant data and/or relevant expertise to the post-marketing monitoring of vaccines (exposure, coverage, risks, benefits).Publicly listed organizations and drug/vaccine manufacturers cannot be an organizational member of VAC4EU. Each Member will belong (based upon their own choice) to one of two groups (public health institute or public/private research organization).

5.2 Rights and obligations of Members

- 5.2.1 Members enjoy the following rights
 - a. Attending, also through a representative duly empowered by proxy, the meetings of the General Assembly;
 - b. Voting at the General Assembly
 - c. Calling for an extraordinary General Assembly;
 - d. Being excluded from Membership only after having been able to present in person their defense before the General Assembly;
 - e. Resigning from VAC4EU after having notified this decision to the Secretary-General of VAC4EU by registered letter to the registered office of VAC4EU;
 - f. Participate and lead in studies conducted by the VAC4EU study network.
 - g. Use of the VAC4EU platform, tools, best practice and procedures to conduct studies

with business development, contractual and procedural support from the Secretariat

- h. Receive and participate in training at reduced fees
- i. Having access to the detailed database characterization for population, exposures and events at reduced fees
- 5.2.2 Membership includes the following obligations, but is not limited to:
 - a. Acting in compliance with the VAC4EU articles, principles and bylaws
 - b. Notifying the Secretary-General of any changes regarding the status of Membership, in particular the Membership criteria as defined in this Article 5 and cooperating to investigations and inquiries from VAC4EU in this context.
 - c. Operating in accordance with the law of their country of origin.
 - d. Payment of the membership fees as established in the Bylaws.

6. Application for membership

6.1 Applications for Membership shall be addressed in writing to VAC4EU Secretary-General.

6.2 Every application for Membership implies complete adherence to the Statutes of VAC4EU, to all its rules and bylaws and to all decisions of its governing bodies and an undertaking to actively participate in activities.

6.3 The Secretary-General of VAC4EU shall be entitled to request additional information from an applicant.

6.4 Membership is granted by the General Assembly upon the proposal of the Executive Board

6.5 New Members may however be admitted provisionally by a resolution of the Executive Board. Such provisional admission shall be subject to formal confirmation at the following meeting of the General Assembly.

6.6 The General Assembly and the Executive Board have no obligation to disclose the reason why an application request has been rejected.

7. Termination of membership

7.1 Membership can be terminated by resignation, by exclusion of the Member and by the liquidation of the Member Organization

7.2 Resignation from membership must be notified to the Secretary-General by registered letter three months before the end of the financial year; otherwise the full financial contribution for the following financial year shall be due. During the notice period the rights and obligations attached to being a Member and the obligation to the financial contribution remains unchanged.

7.3 The Executive Board may terminate the Membership of any Member:

- In case of default of payment of the financial contribution;
- For contravention of the Statutes, the Bylaws, or a resolution of the General Assembly;

- For acting in a manner gravely injurious to the reputation of VAC4EU or the interests of the Members.

The Member whose exclusion has been requested shall be allowed to present its defence in person before the Executive Board and the General Assembly. The exclusion of a Member may be decided by a simple majority in the General Assembly.

7.4 Any Member, which ceases to possess the qualification required under Article 5, or terminates its membership (see article 7.4) shall cease to be a Member of VAC4EU.

7.5 The Member who sees its Membership terminated by resignation, exclusion or liquidation has no right whatsoever to the assets of VAC4EU or to the financial contribution and other contributions already paid. Any Member shall be deemed to have resigned if it has not paid its annual financial contribution in full and, after notice from the Secretary-General, remains in default of its obligations. If such resignation becomes effective during the first nine months of the financial year, VAC4EU shall be entitled to claim payment of the entire annual financial contribution. If the resignation becomes effective during the last quarter of the year, VAC4EU shall be entitled to claim payment of the at which the resignation becomes effective, and a sum equal to the financial contribution due for the following financial year.

8. Financial contribution

8.1 In order to pursue the Objectives and to carry out the activities of VAC4EU as described in Article 3 the Members will be required to pay an annual financial contribution, which is the Membership fee.

8.2 The amount of the Membership fee as well as the payment terms thereof are decided annually by the General Assembly upon proposal from the Executive Board. The detailed calculation methods are established in the Bylaws.

8.3 VAC4EU may receive grants, donations and testamentary provisions and any transfer not prohibited by law.

8.4 VAC4EU may charge for VAC4EU services with cost covering fees.

8.5 VAC4EU may receive overheads for services to contract studies by the study network

SECTION III: Organization of VAC4EU

9. Organizational structure

9.1 Management of VAC4EU is ensured by the following bodies:

The General Assembly (see Article 10) The Executive Board (see Article 11) The secretary General and Office (art 13 and 14) 9.2 VAC4EU may create advisory committees: Independent Scientific committees (study specific and open community), Financial Audit and Independent Stakeholder Advisory Boards and Working Groups within the -Objectives- of VAC4EU in various forms. They are established by the Executive Board but otherwise act independently. Further details are defined in the Bylaws.

10. General assembly

10.1 Composition

The General Assembly is composed of all Members

10.2 Organization of the General Assembly

10.2.1 The General Assembly of VAC4EU shall be convened by its President (see Article 15) or named substitute (see Article 10.5) and shall meet at least once a year at the place and on the date fixed by him or her after deliberation with the Executive Board. A convocation with an agenda, in the form of a letter or electronic mail, shall be sent at least four weeks before the date fixed for the meeting. The venue of the General Assembly shall be indicated in the convening notice and can be anywhere in the European countries.

Any General Meeting may consist in a virtual meeting or partially virtual meeting (physical participants and remote participants), if the notification to attend so provides (i.e. by teleconferencing system, by exchange of e-mail or any other method of remote communication).

Further details on the organization of the meetings of the General Assembly will be detailed in the Bylaws.

10.2.2 An extraordinary General Assembly shall be convened whenever the Executive Board judges it necessary or when at least one third of the Members inform both the President and the Secretary-General that they would like to organize an extraordinary General Assembly.

10.2.3 Each Member is represented at the General Assembly by one delegate with full powers. Members may delegate voting rights to another Member in writing, by electronic mail or any other electronic mean as mentioned in the bylaws

10.2.4 Voting in the General Assembly.

Two thirds of the members attending a meeting of the GA will constitute a quorum. For decision adoption, the majority (50% or more) need to be reached both within the public health member group and within the research group members.

10.3 Competence

10.3.1 The General Assembly is the ultimate decisional body of VAC4EU. The General Assembly approves the general policy of VAC4EU on the basis of proposals of the Executive Board and gives recommendations to the Executive Board for its application.

10.3.2 The General Assembly shall have exclusive competences which cannot be delegated on the following matters:

- Admitting and excluding Members;
- Amending the Statutes of VAC4EU subject to the specification in Article 3.5 and subject to modifications of the registered office;
- Electing and dismissing the members of the Executive Board;
- Appointing and dismissing the Auditor(s), if the association is obliged to appoint the latter, upon proposal of the Executive Board;
- Discharging the President, the members of the Executive Board and the Auditor(s), if any, from liability for the exercise of their mandate;
- Receiving and approving reports on the activities in the past year from the Executive Board;
- Approving the main policy lines to be followed by Executive Board on the basis of recommendations of the Executive Board;
- Approving proposals for resolutions and plans of activities proposed by the Executive Board;
- Approving the annual financial reports and the budget proposed by the Executive Board;
- Adopting internal rules for the calculation of the Members' financial contributions and the payment terms thereof, upon proposal of the Executive Board;
- The dissolution and liquidation of VAC4EU;
- VAC4EU membership of any other international body or its withdrawal from any such body.

10.4 Quorum and Adoption of Resolutions

10.4.1 A General Assembly is always competent to pass resolutions.

10.4.2 The General Assembly shall strive to adopt its resolutions by consensus. If a vote proves necessary, the resolution shall be adopted if it receives a:

- Majority of votes (as specified in Article 10.2.4) of the Members present or represented in the case of regular resolutions both among the public health member group as well as the research institutions member group ;
- Two-third majority of votes (as specified in Article 10.2.4) of the Members present or represented in the case of an amendment of the Statutes (according to Article 10.3.2 (b) or dissolution and liquidation resolutions (according to Article 10.3.2 (k)).

Resolutions adopted are binding for all Members of VAC4EU.

10.4.3 The General Assembly resolves only on the points in the agenda.

10.5 Chairperson of the General Assembly

At all meetings of the General Assembly, the President (see Article 15) acts as a chairperson. In his absence the meeting is chaired by the Vice-Presidents or, in case they are unavailable, by the eldest member of the Executive Board.

10.6 Minutes

10.6.1 The minutes of the General Assembly are established by the Secretary-General and are signed by the Chairperson and one Member participating at the meeting and shall be circulated to all Members within one month.

10.6.2 The minutes shall be electronically archived and shall be accessible to all Members through the Website of VAC4EU.

10.7 Consent in lieu of a Meeting

Any resolution of the General Assembly may be adopted without holding a meeting by means of a written consent of Members. The form of the written consent in lieu of a meeting is detailed in the Bylaws.

11. Executive Board

11.1 Composition and designation

11.1.1 VAC4EU is managed by the Executive Board whose members are individuals of Members and are elected by the General Assembly. The number of Directors shall be higher than three and not higher than nine and have representatives from both the public health members and the research institutes members.

If the total number of Directors, due to resignation, death or dismissal by the General Assembly, falls under the minimum of three members, the remaining members shall call a General Assembly in order to secure the requested appointment(s).

11.1.2 The General Assembly shall elect directly the following candidates which will be proposed by the Executive Board

A Chairperson of the Executive Board and of the General Assembly, who will be called the 'VAC4EU President'; One Vice-President of VAC4EU; A Treasurer of VAC4EU.

All candidates for the Executive Board should make their full curriculum vitae plus declaration of interest available to VAC4EU members prior to the elections.

11.1.3 The Executive Board is elected by the General Assembly for a renewable period of three years. The Directors shall continue to act until re-election or until new Directors take office. When, in the course of his or her mandate, a Director ceases the functions occupied within his or her company or Institute, which were deemed a requirement at the time of election, a member of the Executive Board shall be deemed to have resigned from his or her function on the Executive Board. Subject to the conditions specified in the present Article 11, further details on the Executive Board are specified in the Bylaws.

11.1.4 Except by lawful resignation resulting from the application of the Statutes, the resignation of a Director must be notified by registered letter with acknowledgement of receipt to the President. The resignation is deemed to be effective at the date of the registered receipt. The dismissal of a Director in case of serious offence shall be decided by the General Assembly.

11.2 Competence

11.2.1 The Executive Board follows the resolutions, instructions and recommendations adopted by the General Assembly.

11.2.2 The Executive Board implements the policies and the plans of activities adopted by the General Assembly.

11.2.3 The Executive Board shall have exclusive competence (without possibility of delegation) on the following matters:

- Preparing the consolidated annual plan of activities and the long term strategic vision of VAC4EU for approval by the General Assembly, on the basis of input from the Members ad Independent Strategic Advisory Board
- Setting up and dissolving the VAC4EU study network, multi-stakeholder Advisory Boards, Committees and Topic Groups to assist VAC4EU in fulfilment of its objectives (membership of such boards may not be limited to members of VAC4EU) and determining requirements and funding for the establishment of such groups.
- Drafting, approving and amending Bylaws;
- Employing and dismissing the Secretary-General of VAC4EU (see Article 14);
- Appointing an organization to run VAC4EU Office (see Article 13);
- Proposing the agenda of the General Assembly;
- Proposing internal rules determining the calculation of the Members' financial contributions to the General Assembly;
- Providing recommendations to the General Assembly on applications for Membership or exclusion of Members;
- Inviting advisers to meetings of the Executive Board, as stipulated in Article 11.1.3;
- Having the power of ordinary management, including the right to perform all administrative acts and other necessary arrangements including legal proceedings;
- Being in charge of the financial management, preparing of budgets, including subscriptions for approval of the General Assembly, budgets and the control of expenditure;
- Proposing amendments to the Statutes of VAC4EU in accordance with Article 17;
- Representing VAC4EU at external events, promoting VAC4EU's visibility, public relation work and identity.
- Approving standards & procedures for conducting studies under the VAC4EU label
- Temporarily replacement of a missing Director in accordance with Article 11.1.1.

11.2.4 The Executive Board shall meet according to rules defined in the Bylaws. The calling notice shall be notified by email.

11.2.5 Meetings of the Executive Board may be held virtually, without the members physically attending the meeting in the same place, by conference call or video conference or by any other relevant communication means, according to practical procedures defined in the Bylaws.

11.3 Resolutions of the Executive Board and Bylaws

11.3.1 The Executive Board shall strive to reach its decisions by consensus. If a vote proves necessary, resolutions and decisions of the Executive Board are adopted by the simple majority of the votes of the Directors present or represented. In the event of a tie, the President has a casting vote. The Executive Board can only act if at least 2/3 of the Directors are present or represented.

11.3.2 Minutes of the meeting of the Executive Board shall be distributed to all members of the Executive Board within two weeks. They shall be electronically archived and be accessible to all Members of VAC4EU.

11.3.3 Bylaws can be drafted and they shall be adopted by a two-thirds majority of members of the Executive Board present or represented. Changes to the Bylaws will be announced to all Members together with a list of differences with respect to the previously valid version

11.3.4 Any resolution of the Executive Board may be adopted without holding a meeting by means of a written consent of the Directors in accordance with the quorum set forth in Article 11.3.1. The form of the written consent in lieu of a meeting is detailed in the Bylaws.

12. Advisory Boards, committees and topic groups

12.1 Scientific and Strategic Advisory boards, Standing Committees and Topic Groups can be established to address specific matters of common interest within the 'Objectives' of VAC4EU under the authority of the Executive Board.

12.2 The Executive Board shall consider and approve mission statements and terms of reference issued for the Study network, Advisory boards, Standing Committees and Topic Groups.

12.3 The operational details of the functioning of these groups are further detailed in the Bylaws.

13. VAC4EU office

The VAC4EU Office operates under the authority of the Secretary-General (see Article 14) and executes the daily management of VAC4EU as described in the Bylaws.

14. VAC4EU Secretary-General

14.1 The Secretary-General of VAC4EU discharges his/her duties in accordance with the Statutes and the Bylaws.

14.2 Together with the President, the Secretary-General is representing VAC4EU to stakeholders and third parties outside VAC4EU.

14.3 The Secretary-General is responsible for the day-to-day management of VAC4EU. He/she shall, inter alia, prepare, coordinate and follow-up the meetings of the Executive Board and the General Assembly in coordination with the President of VAC4EU. The Secretary-General operates in accordance with the general guidelines he receives from the President of VAC4EU and under the supervision and authority of the Executive Board. These general guidelines are defined in the Bylaws.

14.4 The Secretary-General is proposed by the President and appointed and dismissed by the Executive Board.

14.5 The duties of the Secretary-General and the outline of the organization of VAC4EU Office are specified in the Bylaws.

15. VAC4EU president and vice-president

15.1 The General Assembly elects a President and a Vice-President for a renewable period of three years. The President is expected to be a highly respected member of the European Vaccine Research Community, proven by service to the IMI-ADVANCE project or VAC4EU, plus documented experience in management and coordination. No such obligations hold for the vice-president and treasurer. The President and Vice-Presidents shall continue to act until the new President and/or Vice-Presidents take office.

15.2 The President and the Vice-Presidents are respectively the President and Vice-Presidents of the General Assembly and the President and Vice-Presidents of the Executive Board.

15.3 The President is in charge of representing VAC4EU vis-à-vis political institutions and other stakeholders at high level and on important occasions and important matters. He will also provide new ideas and impetus for VAC4EU's work.

16. VAC4EU treasurer and auditors

16.1 The Treasurer is elected pursuant to Article 11.1.2 above and is responsible for:

- Controlling the annual budget of VAC4EU;
- Controlling the financial reports and maintaining VAC4EU accounts;
- Proposing the financial contribution, if necessary.

16.2 The Auditors are either appointed/dismissed pursuant to Article 10.3.2 among Members, if necessary, appointed from the Belgium Institute of Auditors, l'Institut des Réviseurs d'Entreprises.

SECTION IV: OTHER CLAUSES

17. Representation

17.1 All acts binding VAC4EU as approved by the Executive Board, other than those of dayto- day business as described in the Bylaws are valid only if signed by one member of the Executive Board and the Secretary-General.

17.2 Any commitment, contract, investment, bank transfer or payment or any other obligation of VAC4EU that was not foreseen in the annual budget of VAC4EU will require the joint signature of the President or the Vice President and the Treasurer.

17.3 All legal proceedings, whether as plaintiff or as defendant, are conducted, in the name of VAC4EU, by the Executive Board represented by its President, or by its Vice-Presidents, by the Secretary-General or by any other person appointed for this purpose by the Executive Board

17.4 Details regarding the authorities with financial limits delegated to the Executive Board, the Secretary-General, the President and Vice-Presidents are constituted in the Bylaws.

18. Accounts, budget and cost

18.1 The financial year of VAC4EU starts on 1st January and ends on 31st December of each year.

18.2 During the start-up phase of VAC4EU the financial year will start at the registering date of VAC4EU and will end on 31st December 2020. Financial contributions are due pro rata temporis until 31st December 2019.

18.3 The Executive Board shall submit for approval by the Annual General Assembly accounts for the past financial year and a budget for the next year.

18.4 As long as nothing else is specified in the Bylaws, every Member, any of its representatives, any Director, the President and the Vice-President as well as the Treasurer shall bear all their own costs in connection with the performance of their activities for the benefit of VAC4EU while any costs and expenses sustained by the Secretary- General and VAC4EU Office in the performance of their duties will be borne by VAC4EU.

19. Changes to these statutes

19.1 Subject to the provisions of Article 10.4.2, on a proposal from the Executive Board, the General Assembly may vary the Statutes of VAC4EU.

19.2 The Executive Board must bring any proposals for the variation of the Statutes to the attention of the Members of VAC4EU at least four weeks prior to the date of the General Assembly that will resolve thereon.

19.3 Only modifications of the Statutes in accordance with article 50, §3 of the Law of 27th of June 1921 are subject to the approval of the Belgian Ministry of Justice . Such modifications will be published in the Annexes of the Moniteur Belge.

20. Dissolution

20.1 In case of dissolution of VAC4EU, the General Assembly establishes the method, designates the liquidators and determines their powers and fees.

20.2 The liquidators shall distribute the net assets of VAC4EU, if any, to a European non-profit organization with similar or closely related objectives to that of VAC4EU.

20.3 No Member of VAC4EU shall be held liable for any remaining debts and liabilities of VAC4EU after the dissolution procedure. The President and the Directors of VAC4EU are not liable if they have acted within their powers. Should the President and/or the Directors have exceeded their powers or neglected their obligations they may be held personally liable.

21. Bylaws

21.1 The Executive Board shall adopt the Bylaws, which implement and specify the provisions of these Statutes and also regulate the daily activities of VAC4EU.

20.2 In case of discrepancies between the Bylaws and these Statutes, the latter shall prevail.

22. Language

22.1 The official working language of VAC4EU is French, in compliance with the Belgian Linguistic legislation. An English and Dutch translation of all documents has always to be made.

22.2 The French version of these Statutes is the official version.

23. Applicable law

All questions not covered by these Statutes or by any regulations made for their application shall be settled in accordance with Belgian law.

24. Conflict of interest

START OF ACTIVITIES

The first financial year of VAC4EU will begin on the day of registration of the current statutes at the office of the commercial court and will close the 31st December 2020.

During the course of the period between the General Meeting constituting the VAC4EU association and the first Extraordinary General Meeting following the publication of the Royal Decree of recognition, the ADVANCE Coordination team will approve a list of members called « initial members »; the initial members will be Member Organizations and the founding members. The initial members of the association will be convened to the Extraordinary General Meeting that will be held following the publication of the Royal Decree of recognition of the association.

DULY ACKNOWLEDGE AND HENCE ACT

Completed and dated below at -, Belgium. And after a reading through these documents with time for discussion, the present representatives signed with us, the Notary.