

DEVELOPING COUNTRIES VACCINE MANUFACTURERS NETWORK INTERNATIONAL (DCVMN)

STATUTES

Amending and restating any previous statutes of DCVMN

Submitted by the Board on September 16, 2024 and
approved by the Members of DCVMN on October 16, 2024



SECTION I - LEGAL FORM, NAME, SEAT AND DURATION

Article 1

Name

- 1.1 DEVELOPING COUNTRIES VACCINE MANUFACTURERS NETWORK INTERNATIONAL ("DCVMN" or the "Association") is a non-profit association, within the meaning of Articles 60 and following of the Swiss Civil Code.

Article 2

Seat

- 2.1 The registered office of the Association is in the Canton of Vaud, Switzerland.

Article 3

Duration

- 3.1 The Association is created for an unlimited period of time.

SECTION II: PURPOSES AND MEANS

Article 4

Purposes

- 4.1 DCVMN is a non-profit association.
- 4.2 The purposes of the Association are (paragraphs (a) to (s) together, the "**Purposes**"):
- a) to form a voluntary public health driven alliance of vaccine manufacturers from developing countries sharing common vision and mission;
 - b) to combat infectious diseases, especially those of the developing world, by strengthening the capacity of vaccine and vaccine-related product manufacturers, and potentially other health technology producers, in developing countries, to produce and deliver quality vaccines and other health technologies effectively in the long-term for national immunization programs in a sustainable manner;
 - c) to strive for an international recognition such that developing country vaccine manufacturers have an essential role in assuring the sustainability of quality vaccines supply for national immunization programs;
 - d) to encourage focus and investment on research, technology innovation and development efforts to meet vaccine needs of developing countries;
 - e) to foster the development of Members of the Association to attain and maintain the status of WHO prequalification;



- f) to promote a consistent and sustainable supply of quality vaccines at a sustainable price to developing countries and members of the Association;
- g) to improve the access of such manufacturers to technologies necessary to improve the quality of vaccines, vaccine-related products, and other health technologies currently being produced and to prepare for the transfer and production of newly developed health technologies;
- h) to encourage and support sustainable public-private partnerships;
- i) to strive for global governance strategies oriented to economic incentives to vaccine manufacturers, ensuring their survival in the market;
- j) to promote innovative models of ownership and sharing of intellectual property related to health improvement;
- k) to facilitate technical assistance to developing countries manufacturers in all aspects of production and distribution of vaccines, vaccine-related product, and other health related technologies;
- l) to facilitate the exchange of ideas and experience among developing countries health technology developers and producers and their counterparts in the developed world;
- m) to promote the participation of developing country vaccine and other health technology manufacturers in international strategic planning and decision making;
- n) to scale global immunization awareness and education;
- o) to encourage continuing research and development efforts of Members to meet the emerging vaccine needs in the developing countries;
- p) to encourage the compliance of Members of the Association with the requirements of the National Regulatory Authority (as defined by the World Health Organization, the "NRA") of the concerned country;
- q) to foster collaboration and communication amongst Members of the Association and actively participate in the international vaccine community to accomplish the Association specified goals;
- r) to highlight the progress and contribution of the Members to the Association's stakeholder community; and
- s) to encourage the development of vaccines against emerging pathogens for routine immunization and potential pandemic use.

Article 5

Means

- 5.1 The Association may engage in all activities and take all necessary or appropriate measures to carry out the Purposes according to these Statutes, in particular by:
 - a) building capabilities and strengthening capacity of vaccine manufacturers to produce and deliver quality vaccines across the long-term;



- b) keeping the Association's stakeholders informed of the needs of the domestic vaccine manufacturer in order to maintain the vaccine supply chain to UNICEF and PAHO, etc.;
- c) establishing systematic and proactive dialogue with international bodies to shape the thinking on high priority developing countries vaccine manufacturers issues;
- d) engaging members on priority issues shaping the broader landscape;
- e) organising information programs and professional training on technical improvements in the field of vaccine manufacturing;
- f) fostering research in vaccine development, production and distribution; and
- g) informing the public and the Association's stakeholders on various topics in view of creating healthy markets.

SECTION III - MEMBERS

Article 6

Members

- 6.1 Public and private vaccine manufacturers active in developing countries, as well as public health and research institutions, may become members of DCVMN. Vaccine manufacturers shall be understood as entities that are active in manufacturing of drug substance ("DS") and/or in filling-in and finishing vaccines for human use (excluding entities acting solely as CMOs and CDMOs). Developing countries encompasses all the countries defined as developing economies in the annual report *World Economic Situation and Prospects* of the UN. Members of the International Federation of Pharmaceutical Manufacturers (IFPMA) are not eligible as members of DCVMN.
- 6.2 Membership in the Association shall be available to institutions interested in furthering the Purposes of the Association.
- 6.3 The Board may refuse an application for membership if the membership criteria are not met, or an applicant to membership does not enter into one of the categories of Members listed in Article 6.5.
- 6.4 Members of DCVMN admitted under former admission criteria may remain members of the Association. This does not give the right to new applicants to be admitted on the basis of the former admission criteria.
- 6.5 The Association comprises the following categories of members (together the "**Members**"):
 - a) "**Full Members**", which are Members with at least one vaccine pre-qualified by WHO for supply to UN Agencies located in countries with a fully functional NRA;
 - b) "**Prospective Full Members**", which are vaccine manufacturers having at least one locally produced vaccine by them in their own facility (i.e. facilities in which they have an ownership stake of 51% or more), fully licensed by the NRA however that do not fulfil the criteria to be Full Members;



- c) "**Resource Members**", which are governmental institutions, research institutes, UN agencies and NGOs. Resource members do not have the right to participate in the General Assembly or event;
 - d) "**Provisional Members**", which are private or public companies:
 - i. having DS and/or drug product ("**DP**") facilities intended for manufacture of vaccines that support local or global needs outside COVID-19 vaccines;
 - ii. conducting human clinical trials from DS or DP products pending NRA approval and where such products are manufactured in their own facilities (i.e. facilities in which they have an ownership stake of 51% or more) and meet local or global needs outside COVID-19 vaccines; and/or
 - iii. having been approved for grant under GAVI's African Vaccine Manufacturing Accelerator (AVMA) scheme.
- 6.6 The Board may propose to the General Assembly to create other categories of Members.
- 6.7 The General Assembly decides upon the admission and exclusion of Members. The General Assembly is not required to provide any reason to support the rejection of a membership application or the exclusion of a Member. Admission of Members may be pre-approved by the Board in accordance with the By-Laws.
- 6.8 The Board decides upon the exclusion of Members for the reasons listed in Article 7.2(b). The excluded Member shall have the right to challenge such decision by submitting an appeal to the General Assembly within 30 days after the notification of the decision.
- 6.9 The Board keeps a register of Members. Members must inform the Board of any address change. When a Member is a legal entity or an unincorporated partnership, a representative must be appointed to whom any notifications can be validly made. The identity of the representative shall be recorded in the register of Members.
- 6.10 No Member shall realize any gain or profit, either directly or indirectly by virtue of their membership in the Association and all profits or gains realized by the Association shall be used solely in the furtherance of the Purposes.

Article 7

Beginning, end and suspension of membership

- 7.1 Admission as a member bestows the rights and responsibilities provided for in these Statutes.
- 7.2 Membership and its associated rights and responsibilities cease:
- a) upon written resignation notified to the Board at least six months before the end of the financial year;
 - b) upon exclusion by the Board for just cause, which can be ordered in particular in the case of:
 - (i) non-payment of membership fees when due for more than one year;



- (ii) behaviour or activities which may damage the Association's reputation or jeopardize its ability to fulfil its Purposes.
 - c) upon exclusion by the General Assembly;
 - d) upon loss of legal personality, for legal entities; and
 - e) upon termination of the partnership agreement, for unincorporated partnerships.
- 7.3 If membership terminates during a financial year, the Association remains entitled to the full membership fees paid (or to be paid) for the relevant year. Members who have resigned or who have been excluded have no rights to any part of the Association's assets.
- 7.4 The membership, and all rights related thereto, is suspended in case of failure by a Member to pay the membership fees within 120 days after the due date until the payment has been received by DCVMN.

SECTION IV - FINANCIAL MEANS

Article 8

Financial means

- 8.1 The Association derives its financial means from:
- a) membership fees;
 - b) donations;
 - c) legacies;
 - d) contributions in kind or financial contributions from Members;
 - e) private and public grants or contributions; and
 - f) any other resources authorized by law.
- 8.2 The membership fees may be set as annual fees or, if needed, one-off fees.
- 8.3 The Board proposes the amount of membership fees to the General Assembly, which may be set differently based on the membership categories. The Board may accept different payment methods for specific membership categories.
- 8.4 The fees proposed by the Board shall become mandatory for all Members once approved by the General Assembly.
- 8.5 The Association's resources shall be used toward the fulfilment of the Purposes.



Article 9
Financial year

9.1 The financial year shall begin on 1 January and end on 31 December of each year.

Article 10
Accounts and financial statements

10.1 The Association shall maintain accounts and establish financial statements in accordance with Title 32 of the Swiss Code of Obligations and in particular, in particular its Article 957 (2) (2).

SECTION V – CORPORATE BODIES

Article 11
Corporate bodies

11.1 The corporate bodies of the Association shall be the following:

- a) the General Assembly;
- b) the Board;
- c) the Secretariat; and
- d) the Auditor.

A. THE GENERAL ASSEMBLY

Article 12
Composition and Convocation

- 12.1 The General Assembly is the Association's supreme authority. It is composed of all Full Members, Prospective Full Members and Provisional Members of the Association (the "**GA Members**").
- 12.2 A General Assembly meeting shall be held at least once a year (the "**Annual General Meeting**"). The Annual General Meeting shall be validly convened if the Board has notified all GA Members at least fourteen (14) days before such meeting.
- 12.3 Meetings of the General Assembly may be held in person or by any electronic means, such as telephone conference or video conference or any other similar means of communication, as decided by the Board.
- 12.4 Extraordinary General Assembly meetings shall be held whenever deemed necessary by the Board, or whenever required or requested by written notice to the Chair of the Board by a fifth (1/5) of the GA Members (the "**Extraordinary General Meetings**"). Extraordinary General



Meetings shall be validly convened if the Board has notified all GA Members at least ten (10) days before such meeting.

Article 13

Proceedings

- 13.1 The General Assembly shall be considered quorate if at least a quarter (1/4) of the GA Members are present or represented. In the event that a quorum is not present within thirty minutes after the time called for the meeting, the meeting shall stand adjourned to a time and place determined by the Chair of the Board.
- 13.2 The Board shall set the means of legitimization of GA Members' representatives at the General Assembly. It may require that proxies be granted on the forms provided by the Association.
- 13.3 The General Assembly is chaired by the Chair of the Board. In the absence of the Chair, the General Assembly is presided by the Deputy-Chair of the Board. In both their absence, the GA Members present or represented shall appoint the Chair of the meeting.
- 13.4 The Chair of the General Assembly shall appoint the secretary of the General Assembly. He or she may also appoint one or more scrutineers.
- 13.5 For the avoidance of doubt, Members other than GA Members shall not have the right to participate in General Assembly meetings and shall not have the right to vote or request that any topic be added to the agenda. However, the Board may decide to invite any Member other than GA Members to take part to a General Assembly meeting as an observer, which may be subject to the payment of a fee.

Article 14

Powers

- 14.1 The powers of the General Assembly are as follows:
 - a) to elect and remove members of the Board;
 - b) to review and adopt the yearly financial statements;
 - c) to admit and exclude Members;
 - d) to approve the annual budget;
 - e) to discharge the members of the Board;
 - f) to supervise the activity of the Secretariat and other organs, which it may dismiss, stating the grounds therefore;
 - g) to appoint the Auditor;
 - h) to approve the membership fees proposed by the Board;
 - i) to amend these Statutes;



- j) to dissolve the Association;
- k) if needed, to elect one or more liquidators; and
- l) other Ad hoc item deemed necessary and approved by the Board.

Article 15

Decisions

- 15.1 The General Assembly deliberates on the items included in the agenda. If all GA Members are present or represented at the meeting, the General Assembly may decide on points, which are not on the agenda.
- 15.2 Each GA Member has one vote at the General Assembly.
- 15.3 Unless otherwise provided for by these Statutes, decisions of the General Assembly shall be taken by a majority of the votes cast by the GA Members present or represented.
- 15.4 In case of deadlock, the Chair shall have the casting vote.
- 15.5 A GA Member shall not participate in a vote relating to the removal of its own representative at the Board.
- 15.6 Articles 29 and 31 provide specific rules for decisions pertaining to the dissolution of the Association or amendments of these Statutes. In addition, the following decisions require the approval of a two-third (2/3) majority of the GA Members present and represented at the General Assembly:
 - a) the removal of a member of the Board; and
 - b) the decisions on major policy issues.
- 15.7 Votes are taken by a show of hands, unless at least five (5) GA Members decide upon a secret ballot or another means of voting.
- 15.8 The decisions of the General Assembly are recorded in minutes, which are signed by the Chair and the secretary of the General Assembly.
- 15.9 The General Assembly may also take decisions by circular. Such decisions require a simple majority of all GA Members, subject to decisions pursuant to Article 15.6 that require a two-third (2/3) majority of the GA Members present and represented at the General Assembly. Electronic signatures through secure service providers (e.g. Adobe Sign or DocuSign) and scanned handwritten signatures shall be deemed equivalent to a handwritten signature.



B. THE BOARD

Article 16

Composition

- 16.1 The Board shall be composed of minimum five (5) and maximum seven (7) individuals. The Board is composed of the Chair, the Deputy-Chair and the other members of the Board.
- 16.2 Members of the Board shall be appointed as set forth in the By-Laws.
- 16.3 No representative of a Member shall be eligible for election to the Board, or to any other legal body of the Association, or be entitled to be present at or to take part in the proceedings of the meeting or any adjournment thereof nor to vote (and his or her signature shall not be required in case of a decision by circular) if, at the time, the membership fees of the Member it represents are in arrears.

Article 17

Powers

- 17.1 The Board is the executive decision-making body of the Association.
- 17.2 The Board has the power to handle and decide on all matters that do not fall within the remit of the General Assembly or the Auditor.
- 17.3 In particular, the Board has the following powers:
- a) to control the general policy, direction, operations and affairs of the Association and of the Secretariat;
 - b) to set the strategy and the main orientations of the Association;
 - c) the representation of the Association vis-à-vis third parties and authorization of the Chair to act in justice in the name of the Association;
 - d) to collect and establish the allocation of the funds and means of the Association;
 - e) to execute the necessary contracts for the furtherance of the Purposes (including lease and work contracts);
 - f) to appoint members of the Secretariat;
 - g) to prepare the General Assembly and implement its decisions;
 - h) to present the budget established by the Secretariat, annual accounts and annual report of the Association for approval by the General Assembly;
 - i) to propose the amount of the membership fees for the different categories of Members for approval by the General Assembly;



- j) to convene the General Assembly (including Annual General Meetings and Extraordinary General Meetings) and establish the agenda of such meeting;
- k) to suggest changes of the Statutes to the General Assembly; and
- l) to adopt and amend internal regulations such as by-laws (which have the purpose of specifying the principles set forth in these Statutes and to further detail some aspects of the functioning of the DCVMN) and a conflict of interest policy.

Article 18
Compensation

- 18.1 The Board's Members shall act voluntarily and be entitled only to the compensation of their effective costs and travelling expenses. For activities exceeding the usual scope of the Association, each member of the Board may receive an appropriate compensation.

Article 19
Organization

- 19.1 The Board is self-governed. A Chair and a Deputy-Chair are appointed as set forth in the By-laws. It shall appoint the members of the Secretariat (including the CEO) and a Treasurer (who may be a member of the Board).
- 19.2 The Board may delegate its competences for the day-to-day administration of the Association to the Secretariat in accordance with the By-laws. The Secretariat is headed by a CEO.
- 19.3 The Deputy-Chair shall assume the duties of the Chair in the event of the Chair's prolonged incapacity. If both the Chair and Deputy-Chair are unable to act, the remaining members of the Board shall appoint an ad hoc Chair.
- 19.4 The Board may delegate specific tasks to one or more of its members, or to one or more third parties.

Article 20
Meetings

- 20.1 The Board shall be convened by the Chair or by half of its members, as often as the interest of the Association so requires.
- 20.2 Any member of the Board may request that the Chair convenes a meeting, if the activities of the Association so require.
- 20.3 The meetings of the Board shall be held in person or by any electronic means, such as telephone conference or video conference or any other similar means of communication.
- 20.4 Provided that the meeting has been validly convened, the Board shall be quorate if more than 50% of the total number of its members are present.



- 20.5 Decisions of the Board require the simple majority of the members of the Board present at that meeting. Each member shall have one vote. In the event of a tie, the Chair shall have the casting vote.
- 20.6 The decisions of the Board may also be taken by circular signed by a simple majority of the members of the Board, provided that (i) the decision proposal was submitted to all members of the Board and (ii) that no member of the Board has requested the proposal to be discussed at a meeting of the Board.
- 20.7 The Board shall adopt organisational regulations (including the By-Laws), which set out how the Board operates and in particular the voting procedures.
- 20.8 The Board' decisions are recorded in minutes, which are signed by the Chair and the minute-taker and shall be approved at the next meeting.
- 20.9 Electronic signatures through secure service providers (e.g. Adobe Sign or DocuSign) and scanned handwritten signatures shall be deemed equivalent to a handwritten signature.

Article 21

Resignation

- 21.1 The members of the Board may resign at any time by submitting a written declaration to the Chair specifying when the resignation shall take effect.

C. THE SECRETARIAT

Article 22

Competencies

- 22.1 The competencies of the Secretariat shall be provided for in the By-Laws and may be further specified by the Board.

Article 23

Organization

- 23.1 The Secretariat is headed by a Chief Executive Officer (the "CEO"). The Board may adopt specific organizational rules applicable to the Secretariat.



D. THE AUDITOR

Article 24

Appointment

- 24.1 The Auditor is elected for a term of office of one year, which ends when the financial statements for the financial year for which the Auditor is elected are approved.

Article 25

Competencies

- 25.1 The Auditor shall deliver a yearly written report. They communicate their observations, if any, to the Board and to the General Assembly.

SECTION VI – REPRESENTATION, SIGNATURE AND LIABILITY

Article 26

Representation

- 26.1 The Association shall be represented by the Chair of the Board or any other representative authorized by the Board.

Article 27

Signature

- 27.1 The By-Laws shall set forth the rules pertaining to signatures.

Article 28

Liability of the Members

- 28.1 The Association's financial obligations and liability shall be satisfied only from its assets.
- 28.2 Members of the Association shall not be personally liable and shall not owe any further supplementary payments for any commitment taken by the Association.

SECTION VII – DISSOLUTION-LIQUIDATION

Article 29

Dissolution

- 29.1 The dissolution of the Association shall be decided by the General Assembly, provided however that the Board may dissolve the Association if the number of Members falls below three (3) GA Members (whose membership fees have been paid) and a motion to dissolve the Association has been approved by circular by at least two (2) of those three (3) GA Members.



Article 30
Liquidation

- 30.1 In case of a dissolution, the General Assembly appoints a liquidator and gives him or her the necessary instruction to that effect.
- 30.2 In the event of liquidation of the Association, its remaining assets, after the payment of the debts, shall be entirely assignable to one or several public utility and tax exempt entities pursuing similar objectives to those of the Association. In no case shall the Association's assets be returned to the founders or Members or to any of their successors or assignees or be used in any way for their profit, be it in whole or in part.

SECTION VIII – MISCELLANEOUS

Article 31
Amendment of the Statutes

- 31.1 The Board or a group of ten (10) or more GA Members may propose amendments to the Statutes.
- 31.2 Such proposed amendments must be circulated in writing to the GA Members at least two (2) weeks in advance of a General Assembly meeting and discussed at that meeting.
- 31.3 In case at least two thirds (2/3) of the GA Members present or represented at that General Assembly meeting decide to amend the Statutes substantially as proposed, the Board must notify all GA Members of the resolution of the General Assembly pertaining to the amendment of the Statutes together with a paper summarizing the views expressed at such meeting.

Article 32
By-Laws

- 32.1 The provisions of the present Statutes are completed with By-Laws that detail certain provisions of these Statutes, with respect to the functioning of the Association.

Article 33
Governing Law

- 33.1 The Association is governed by Swiss law, and in particular Articles 60 et seq. of the Swiss Civil Code, which shall apply to any questions not covered by these Statutes.

* * *

Done in: *Bandung, Indonesia*

On: *22/10/2024*

In original copy/copies

Board Chair: *[Signature]*