




MINISTRY OF FOREIGN & DIASPORA AFFAIRS

PARLIAMENTARY MEMORANDUM

ON

KENYA'S ACCESSION TO THE

AGREEMENT ESTABLISHING THE INTERNATIONAL VACCINES INSTITUTE

 THE NATIONAL ASSEMBLY	
DATE: 23 AUG 2023	
WEDNESDAY	
TABLED BY:	Hon. Naomi Wago, MP Deputy majority whip
CLERK AT THE TABLE:	Miriam Mudo

ACCESSION OF THE AGREEMENT ESTABLISHING THE INTERNATIONAL VACCINES INSTITUTE (IVI)

1.0 OBJECTIVE OF THE MEMORANDUM

- 1.1. The objective of this Memorandum is to seek the National Assembly's approval for Kenya's accession to the Agreement Establishing The International Vaccines Institute (herein referred to as the 'IVI'); and
- 1.2. The ratification process was approved by Cabinet during its meeting held on 6th December, 2022.

2.0 BACKGROUND

- 2.1. IVI is a nonprofit International Organization established on 12th May 1997 as an initiative of the United Nations Development Programme (UNDP). It is an organization dedicated to vaccines and vaccination for global health. Its mission is to discover, develop and deliver safe, effective and affordable vaccines for global public health.
- 2.2. IVI is headquartered in Seoul and hosted by the Republic of Korea with thirty nine (39) member countries and the World Health Organization (WHO) on its treaty.
- 2.3. IVI focuses on vaccines against infectious diseases affecting the World's most impoverished populations. It aims to make vaccines available and accessible to vulnerable populations in developing countries.
- 2.4. Kenya submitted a letter to IVI requesting the Board of Trustees' approval to become a party to the IVI Establishment Agreement on 24th November 2022 as per Article VI of the Establishment Agreement.

3.0 OBJECT AND SUBJECT MATTER OF THE IVI AGREEMENT

- 3.1. IVI's approach is based on three (3) components:
 - i. **Research:** vaccine research and development, transnational and field research.

- ii. **Partnerships:** product development partnerships, international research, consortia and networks; and
 - iii. **Capacity-building:** training, technical assistance and technology transfers.
- 3.2. The Kenyan Government has emphasized the need for technology transfer in pre-clinical, clinical development, regulatory review, approval, manufacturing, and quality control that is needed for the Country to establish itself in vaccine manufacture for both vaccines against Covid-19 as well as other types of vaccines.
- 3.3. The mandate of IVI is to promote the development and delivery of vaccines and facilitate knowledge transfer for low and middle-income countries (LMICs) to help advance global health.
- 3.4. The Ministry of Health, Kenya, the Republic of Korea, and IVI have jointly agreed to support the development, manufacturing and delivery of these vaccines to countries in need; facilitate joint research in vaccines, and biopharmaceuticals between business, universities, and laboratories in Korea; and provide training and education of global vaccine (and bio) workforce to enhance LMICs' vaccine production capacity.
- 3.5. As a Member State of IVI, Kenya would therefore, benefit from technical and hand-on training to develop skillsets across vaccine development and production processes, biopharmaceutical manufacturing, biosafety, and good manufacturing practice requirements.

4.0 OBLIGATIONS IMPOSED BY THE CONVENTION

- 4.1. The IVI Establishment Agreement does not expressly stipulate obligations for member states. However, by signing and ratifying the IVI Establishment Agreement, Kenya will be required to:
- a) Publicly affirm the appreciation of IVI efforts to a shared vision of a world free of infectious diseases;
 - b) Lend a supportive voice to IVI initiatives when called upon;
 - c) Attend meetings on IVI and where required, exchange information and discuss collaborative opportunities; and
 - d) Grant privileges and immunities to the members of the Board of Trustees, Directors, Staff of the Institute, and experts performing missions for the Institute.

5.0 PROBLEM STATEMENT

- 5.1. The COVID-19 pandemic was followed by an unprecedented global economic shutdown that exposed vulnerabilities in the global production strategies, supply chains of firms and increased vaccine nationalism that limited access to life-saving commodities especially for Low-income and most Middle-income countries predominantly situated in the Global South. Temporary trade restrictions and shortages of pharmaceuticals, critical medical supplies, and other products highlighted the weakness of dependability on imports for critical global health supplies including vaccines.
- 5.2. Kenya currently imports over 70% of her finished pharmaceutical commodity requirements and 100% of raw materials thereby consuming a significant portion of the Government's and private sector health expenditure. Further, Kenya and Africa as a whole, imports over 98% of its vaccine requirements in order to provide immunization services that is one of the most cost-effective public health interventions.
- 5.3. Drawing from lessons learnt from the COVID-19 pandemic, the Government of Kenya has initiated processes for establishing local manufacturing capabilities to improve self-reliance in vaccine supply. Cognizant of the complexity of realizing of local production of vaccines, emphasis on the need for establishing strategic partnerships for technology transfer in pre-clinical, clinical development, regulatory review, approval, manufacturing, and quality control has been placed to ensure building of capacity.
- 5.4. Establishing local production capacity for human vaccines will support sustainability of public healthcare programmes, promote self-reliance; contribute to national and regional economic growth; position Kenya as a bio-technology manufacturing hub for the region and continent; and enhance national health security while strengthening pandemic preparedness and planning interventions.
- 5.5. It will also be a positive step in the country's attainment of Universal Health Coverage, as enshrined in the Kenyan Constitution. Kenya's membership to IVI will therefore be valuable in Kenya's efforts towards building the necessary technical capacity in this endeavor.

6.0 BENEFITS OF KENYA'S MEMBERSHIP TO IVI

- 6.1. Upon acceding to the IVI Establishment Agreement, Kenya will accrue the following benefits:
 - (i) Training and technical assistance in the production technology and research of vaccines;
 - (ii) Gain from laboratory and field-based research and development;

- (iii) Support for clinical trials and field evaluations of new vaccines, as well as the introduction of new and improved vaccines; and
- (iv) Collaboration with vaccine manufacturers and other relevant bodies in vaccine research and development.

7.0 JUSTIFICATION FOR ACCESSION

- i. The proposed membership has been necessitated by Kenya's ongoing plans to establish local production of vaccines, cushion the country from potential escalating costs of immunization, work towards vaccine self-reliance and strengthen epidemic preparedness.
- ii. Vaccine manufacturing is a resource-intensive endeavor requiring specialized skills in vaccine discovery, development, testing, clinical trials, roll-out, market access, distribution and post-market surveillance.
- iii. As the country looks to start with fill/finish operations and subsequent backward integration, there is a need for technology and knowledge transfer in all the aforementioned areas for adequate capacity for end-to-end vaccines and biologics production.
- iv. Kenya's membership in IVI will assist the country in establishing itself as a biotechnology industrial center. As an IVI member, Kenya will benefit from technical and hands-on training to build skills in vaccine development and production processes, biopharmaceutical manufacturing, biosafety, and good manufacturing practice requirements.

8.0 CONSTITUTIONAL AND LEGISLATIVE IMPLICATIONS

- 8.1. The IVI Establishment Agreement is consistent with the Constitution of Kenya 2010 and promotes constitutional values and objectives; it does not allude to an amendment of the Constitution.
- 8.2. Upon accession, Kenya may need to engage and collaborate with different stakeholders including the private sector for the operationalization of local vaccine manufacture including pre-clinical and clinical research, manufacturing, quality assurance and regulation.

9.0 MINISTERIAL RESPONSIBILITY

- 9.1. The Ministry that will be responsible for the implementation and any activity regarding the IVI Agreement is the Ministry of Health.

9.2. The Ministry of Foreign and Diaspora Affairs and the Office of the Attorney General and Department of Justice will coordinate the reporting process on State obligations pursuant to the Treaty Making and Ratification Act No 45 of 2012.

10.0 RESERVATIONS

10.1. The IVI Establishment Agreement does not provide for reservations.

11.0 RECOMMENDATION TO THE NATIONAL ASSEMBLY

- 11.1. In consideration of the aforementioned facts, the National Assembly is invited to:
1. Note the contents of the Parliamentary Memorandum;
 2. Consider and approve Kenya's accession to the Agreement Establishing IVI; and
 3. Direct the Cabinet Secretary of Foreign and Diaspora Affairs to prepare and deposit the instruments of accession to the relevant depository.

SIGNED.......... DATED.......... AUGUST, 2023

DR. ALFRED N. MUTUA, EGH
CABINET SECRETARY
MINISTRY OF FOREIGN & DIASPORA AFFAIRS



AGREEMENT ON THE ESTABLISHMENT
OF THE INTERNATIONAL VACCINE INSTITUTE
(as amended as of 15 December 2022)

WHEREAS the Children's Vaccine Initiative (hereinafter referred to as "the CVI") is a coalition of governments, multilateral and bilateral agencies, non-governmental organizations including foundations and associations, and industry dedicated to ensuring the availability of safe, effective and affordable vaccines, the development and introduction of improved and new vaccines and strengthening the capacity of developing countries in vaccine development, production and use in immunization programmes;

WHEREAS at the initiative of the United Nations Development Programme (hereinafter referred to as "UNDP"), the Republic of Korea has agreed to be the host country of a newly created institute to be named as the International Vaccine Institute (hereinafter referred to as "the Institute") dedicated to strengthening the capacity of developing countries in the field of vaccine technology and carrying out vaccine-related research and development;

WHEREAS the Parties to this Agreement consider the Institute as an instrument to contribute to achieving the goals of the CVI;

WHEREAS the Parties to this Agreement wish to create the Institute as an international organization with suitable governance, juridical personality, and appropriate international status, privileges and immunities and other conditions necessary to enable it to operate effectively towards the attainment of its objectives;

WHEREAS the Parties to this Agreement wish to establish the Institute as an integral part of the CVI policy framework, strategy and activities;

NOW, THEREFORE, the Parties signatory hereto agree as follows:

ARTICLE I
ESTABLISHMENT

There shall be established an independent international organization entitled the "International Vaccine Institute" which will operate in accordance with the Constitution appended hereto as its integral part.

ARTICLE II
RIGHTS, PRIVILEGES AND IMMUNITIES

1. The Government of the Republic of Korea grants the Institute the same rights, privileges and immunities as are customarily accorded to a similar type of international organization.
2. Privileges and immunities are granted to the Members of the Board of Trustees, the Director and staffs of the Institute as is stipulated in Article VIII, Article IX and Article XIII of the Constitution of the Institute hereto appended and to experts performing missions for the Institute.

ARTICLE III
DEPOSITARY

The Secretary-General of the United Nations shall be the Depositary of this Agreement.

ARTICLE IV
SIGNATURE

This Agreement shall be open for signature by all states and intergovernmental organizations at Headquarters of the United Nations, New York. It shall remain open for signature for a period of two years from 28 October 1996 unless such period is extended prior to its expiry by the Depositary at the request of the Board of Trustees of the Institute.

ARTICLE V
CONSENT TO BE BOUND

This Agreement shall be subject to ratification, acceptance or approval by the signatory states and intergovernmental organizations referred to in Article IV.

ARTICLE VI
ACCESSION

After the expiration of the period specified in Article IV, the present Agreement shall remain open for accession by any state or intergovernmental organization, contingent upon approval by the Board of Trustees of the Institute by simple majority.

ARTICLE VII
SETTLEMENT OF DISPUTES

1. The Parties shall attempt to settle any dispute as to the interpretation or application of this Agreement by negotiations or by any other mutually agreed method.
2. If the dispute is not settled in accordance with Paragraph 1, within a period of (90) days from the request by either Party to settle it, it shall, at the request of either Party, be referred to arbitration.
3. The arbitral tribunal shall be composed of three arbitrators. Each Party shall choose one arbitrator and the third, who shall be the chairperson of the tribunal, to be chosen jointly by the

Parties. If the tribunal is not constituted within (3) months of the request for arbitration, the appointment of the arbitrators not yet designated shall be made by the President of the International Court of Justice at the request of either Party.

4. In the event of a vacancy in the presidency of the International Court of Justice or of the inability of the President to exercise the functions of the presidency, or in the event that the President should be a national of the Party to the dispute, the appointment herein provided for may be made by the vice-president of the court or, failing him, by the senior judge.

5. Unless the parties decide otherwise, the tribunal shall determine its own procedure.

6. The tribunal shall apply the principles and rules of international law and its award shall be final and binding on both Parties.

ARTICLE VIII ENTRY INTO FORCE

1. This Agreement and the Constitution appended thereto shall come into force immediately after three instruments of ratification, acceptance, approval or accession have been deposited with the Secretary-General.

2. For each State or intergovernmental organization depositing an instrument of ratification, acceptance, approval or accession after the entry into force of this Agreement, this Agreement shall enter into force on the first day of the month after the date of deposit of the respective instrument.

ARTICLE IX DENUNCIATION

Any party to this Agreement may, by written instrument to the Depository, denounce this Agreement. Such denunciation of the consent to be bound shall become effective three months after the date on which such instrument is received.

ARTICLE X TERMINATION

This Agreement shall be terminated three months after the Institute is dissolved under the Article XXI of the Constitution.

ARTICLE XI AUTHENTIC TEXT

The authentic text of the present Agreement, including the Constitution appended thereto, shall be in the English language.

IN WITNESS WHEREOF, the undersigned representatives of states and intergovernmental organizations have signed this Agreement in a single original in the English language.

CONSTITUTION OF THE INTERNATIONAL VACCINE INSTITUTE

PREAMBLE

The International Vaccine Institute is founded on the belief that the health of children in developing countries can be dramatically improved by the development, introduction and use of new and improved vaccines and these vaccines should be developed through a dynamic interaction among science, public health, and business. The International Vaccine Institute will be a centre of the science for the public interest where this dynamic interaction can take place through research, training, technical assistance, service provision, and information dissemination.

ARTICLE I HEADQUARTERS' LOCATION

The Institute shall have its headquarters at Seoul, Republic of Korea as has been determined by an independent international site selection process initiated at the request of the UNDP, in accordance with the requirements for the exercise of the functions and fulfilment of the purposes of the Institute.

ARTICLE II STATUS

1. The Institute shall be an international research and development centre established at the initiative of UNDP, as part of its contribution to the CVI, which is an international movement of agencies, corporations, foundations and governments dedicated to ensuring the continued availability of effective and affordable vaccines, and the development and introduction of new and improved vaccines. The Institute shall operate as a non-profit autonomous organization, international in status and non-political in management, staffing and operations. The Institute shall be organized exclusively for scientific, developmental and educational purposes.

2. The Institute shall possess full juridical personality and enjoy such legal capacity as may be necessary for the exercise of its functions and the fulfilment of its purposes.

ARTICLE III SUBSIDIARY BODIES

The Institute may establish such centres, offices or laboratories, in locations within and outside the Republic of Korea as may be decided by the Board of Trustees (hereinafter referred to as the "Board") as being necessary for effective conduct of its programmes and the achievement of its objectives.

ARTICLE IV AIMS

The Institute shall carry out major scientific functions within the overall goals and framework of the CVI. Specifically, it will:

1. undertake and promote study, research, development and dissemination of knowledge in the vaccine-relevant sciences and directly related areas of public health, management sciences and technology to generate affordable and effective means to prevent death and disability arising from infectious diseases and, thereby, to improve the health status and general welfare of children and low-income people in developing and developed countries, especially in Asia; and
2. provide, in collaboration with relevant national and international institutions, facilities and training programmes aimed at strengthening expertise and capacity for developing and developed countries to conduct work in the areas of the Institute's interest and competence.

ARTICLE V GUIDING PRINCIPLES

1. The Institute will serve as an international resource centre devoted to developing specific areas of expertise and providing technical assistance for research and development of vaccines.
2. The Institute will complement its activities with those of other international and national institutions, public and private, that have similar aims. Its activities will, wherever appropriate, be planned and implemented in collaboration with such institutions. In particular, the Institute shall fully cooperate with the World Health Organization (hereinafter referred to as "WHO") in determining the technical and other aspects of its programme that relate to WHO's mandate.

ARTICLE VI FUNCTIONS

1. The Institute will have four programme areas:
 - (i) To provide training and technical assistance in the production technology and research of vaccines;
 - (ii) To conduct laboratory and field-based research and development;
 - (iii) To support and conduct clinical trials and field evaluations of new vaccines, and to facilitate and promote introduction of new and improved vaccines; and
 - (iv) To cooperate with vaccine manufacturers and national control authorities and other relevant bodies in developed and developing countries to promote vaccine research and development.

The Institute may identify other programme areas in accordance with its aims.

2. In fulfilling the aforementioned aims and responsibilities, in the spirit of its guiding principles, the Institute shall engage in a wide range of activities including:

- (i) holding meetings and arranging lectures, training courses, workshops, seminars, symposia and conferences;
- (ii) publishing and disseminating books, periodicals, reports and research and working papers;
- (iii) establishing and maintaining contact with individuals and other institutions with expertise in the vaccine-relevant fields through collaborative research seminars, exchange visits, sabbatical attachments and likewise;
- (iv) undertaking studies and other projects on behalf of or in collaboration with other institutions;
- (v) maintaining offices, field stations, laboratories, pilot plants, animal research facilities, information resources, scientific equipment and instruments, as may be necessary for its proper functioning; and
- (vi) taking such other actions as may further the aims and objectives of the Institute.

3. The Institute's programmes and plans shall be reviewed and approved by its Board taking into account the needs of developing and developed countries and the Institute's capabilities in meeting these needs.

ARTICLE VII CAPACITY

1. The Institute shall have the following capacity:

- (i) to receive, acquire or otherwise lawfully obtain from any governmental authority or from any corporation, company, association, person, firm, foundation or other entity whether international, regional or national, such charters, licenses rights, concessions or similar rights, and assistance - financial or otherwise - as are conducive to and necessary for the attainment of its aims;
- (ii) to receive, acquire or otherwise lawfully obtain from any governmental authority or from any corporation, company, association, person, firm, foundation or other entity, whether international, regional or national, by donation, grant, exchange, devise, bequest, purchase or lease, either absolutely or in trust, contributions consisting of such properties, real, personal, or mixed including funds and valuable effects or items, as may be useful or necessary to pursue the aims and activities of the Institute and to hold, operate, administer, use, sell, convey or dispose of the said properties;
- (iii) to enter into agreements and contracts;

- (iv) to employ persons according to its own regulations;
- (v) to institute, and defend in, legal proceedings; and
- (vi) to perform all acts and functions as may be found necessary, expedient, suitable or proper for the furtherance, accomplishment or attainment of and/or all of the purposes and activities herein stated, or which shall appear, at any time, as conducive to or necessary and useful for the aims and activities of the Institute.

2. No part of the earnings of the Institute shall inure to the benefit of, or be distributable to, its trustees, officers, or other private persons, except that the Institute shall be authorized and empowered to pay reasonable compensation for services rendered and to make payments and distributions in furtherance of the aims set forth in Article IV hereof.

ARTICLE VIII ORGANS

The organs of the Institute shall be:

- (i) The Board of Trustees; and
- (ii) The Director and staff.

ARTICLE IX COMPOSITION OF THE BOARD

1. The Board shall consist of not less than nine members, selected as follows:
 - (i) up to ten members-at-large elected by the Board. Regard shall be paid especially to proposed members' professional experience and qualifications, to appropriate geographical distribution, to agencies and countries which have concern for and provide substantial support to the Institute, or to countries where major facilities are located;
 - (ii) two members appointed by the host country, Republic of Korea;
 - (iii) one member appointed by WHO;
 - (iv) members appointed by the Board upon recommendation of governments of the Parties to this Agreement. The Board shall establish appropriate procedures for appointing members from the governments of the Parties to this Agreement;
 - (v) the Director of the Institute as a member ex-officio.

2. Members-at-large shall be appointed for terms of no more than three years as determined by the Board in advance of the appointment. In the case of vacancy of members-at-large by reason of their retirement, death, incapacity, or any other cause, the Board shall fill the vacancy in the same manner as the original appointment. A new member appointed to replace a member during the

latter's term, may be appointed for the remaining term of the member being replaced. He/she is eligible to serve two additional terms.

3. The members of the Board are eligible for reappointment to a second term, but shall not serve more than two successive terms, except that the member elected as a Chairperson, a Vice-Chairperson, a Secretary, or a Treasurer may have his/her term extended by the Board in order to coincide with his/her appointment as Chairperson, a Vice-Chairperson, a Secretary, or a Treasurer, as the case may be.

4. The members of the Board, other than the members serving ex-officio, the members appointed by the host country, Republic of Korea, and WHO, and the members elected upon recommendation of governments, shall serve in a personal capacity and are not considered, nor do they act, as official representatives of governments or organizations.

5. The term of office and the selection of the members appointed by the Government of the host country, Republic of Korea (hereinafter referred to as the "Government") will be determined by the Government.

6. The members of the Board elected upon recommendation of governments shall serve for a term of three years and be eligible for reelection.

ARTICLE X FUNCTIONS AND POWERS OF THE BOARD

1. The Board shall be responsible for all the affairs of the Institute. Its role, among other things, shall be to ensure that:

- (i) the Institute follows objectives, programmes and plans that are consistent with its aims and with the broad goals and objectives of the CVI; and
- (ii) the Institute is managed effectively by the Director in harmony with the agreed objectives, programmes and budgets, and in accordance with legal and regulatory requirements.

2. To this end, the Board shall:

- (i) define objectives, approve plans to meet the Institute's aims and monitor the achievement of these aims;
- (ii) specify policies to be followed by the Director in pursuing the specified objectives;
- (iii) ensure the Institute's cost-effectiveness, financial integrity, and accountability;
- (iv) approve the Institute's programme and budget;
- (v) appoint an external auditor and approve an annual audit plan;

- (vi) approve the Institute's broad organizational framework;
- (vii) approve personnel policies including scales of salaries and benefits;
- (viii) approve the Institute's fund raising and resource mobilization strategies, policies and programmes, and promote such fund raising and resource mobilization activities;
- (ix) maintain the composition of the Board with respect to expertise needed to discharge the full range of its responsibilities, monitor the performance of staff and evaluate the Institute's performance; and
- (x) perform all other acts that may be considered necessary, suitable and proper for the attainment of the aims of the Institute as set forth in Article IV hereof.

3. The Board may designate an Executive Committee of its members which shall have the power to act for the Board in the interim between Board meetings, and on matters which the Board delegates to it. All interim actions of the Executive Committee shall be reported to the full Board at its next meeting. The Board shall decide on the membership of the Executive Committee to be a subset of the Board. The Director and at least one ex-officio member of the host country, Republic of Korea, shall serve as members of the Executive Committee.

4. The Board may establish such other subsidiary Committees as it deems necessary for the performance of its functions.

ARTICLE XI PROCEDURES OF THE BOARD

1. The Board shall elect one member except the Director as Chairperson. The normal term of the Chairperson shall be three years. The Board may re-elect its Chairperson for a second term.
2. The Board shall also elect a Vice-Chairperson, a Secretary and a Treasurer. The normal terms of these officers shall be three years. They are eligible for re-election.
3. The Board shall meet at least once annually.
4. The Board shall adopt its own rules of procedure.
5. The majority of the members shall constitute a quorum for Board meetings.
6. Staggered terms may be applied to the members who hold Board officer positions to exceed their normal terms as officers under a circumstance where more than two officers are exiting the Board in the same year. The Board may determine the staggered terms before or on the expiration of the normal terms of the officers. Notwithstanding Paragraph 2 of Article IX, the officers' terms as members of the Board may be extended to the expiration of the staggered terms. However, the staggered terms shall not exceed three years.

**ARTICLE XII
VOTING BY THE BOARD**

Normally, the Board shall operate by consensus. However, if the Chairperson determines the need for a vote, the following shall apply:

- (i) each member of the Board has one vote; and
- (ii) decisions of the Board shall be made by a majority of the members present except as specified otherwise in this Constitution.

**ARTICLE XIII
APPOINTMENT OF THE DIRECTOR**

The Board shall appoint the Director, and determine his/her terms of office and any cause for termination by a two-thirds majority of members present and voting.

**ARTICLE XIV
FUNCTIONS AND POWERS OF THE DIRECTOR**

1. The Director shall be responsible to the Board for the operation and management of the Institute and for ensuring that its programmes and objectives are properly developed and carried out. The Director shall take the lead in fund raising and resources mobilization for the Institute. He/she is the chief executive officer of the Institute.

2. The Director shall implement the policies determined by the Board, follow the guidelines laid down by the Board for the functioning of the Institute and carry out the directions of the Board. Specifically, the Director, in consultation with the Board, shall:

- (i) develop a strategic plan for the operation of the Institute for Board consideration and approval, and keep this plan under continuing review;
- (ii) develop programmes and budgets, and prepare the Institute's annual report;
- (iii) supervise the planning and direction of the Institute's research, developmental and educational activities to ensure effective implementation;
- (iv) recruit and manage highly qualified staff;
- (v) keep and have available the strategic plan, programmes and budgets for review by the Board on a regular basis;
- (vi) keep the Chairperson of the Board advised on matters of consequence that relate to the Institute; and
- (vii) perform such other functions as are delegated to him/her by the Board.

3. The Director shall be the legal representative of the Institute. He/she shall sign all deeds, contracts, agreements, treaties and other legal documents which are necessary to ensure the normal operation of the Institute. The Board may determine the extent to which these powers may be delegated by the Director. Contracts, agreements and treaties which affect the governance, objectives, location, expansions or dissolution of the Institute, or major issues concerning the relationship to the host country shall be subject to approval by the Board.

ARTICLE XV STAFFING

1. The staff shall be appointed by the Director in accordance with staff regulations to be approved by the Board.
2. The paramount consideration in the employment of staff and in the determination of the conditions of service shall be the necessity of securing the highest standards of quality, integrity, efficiency, and competence.
3. Salary scales, insurance, pension schemes and other terms of employment shall be laid down in staff regulations, and shall in principle be internationally competitive and comparable with those of the United Nations and affiliated institutions and other relevant international organizations.

ARTICLE XVI FINANCING

1. The budget of the Institute shall be funded by member states, international organizations and other public or private agencies and institutions, including members of the CVI, who wish to make financial and other voluntary contributions to it. The Institute may receive contributions from other sources. It may also receive contributions and gifts towards the establishment of an endowment programme.
2. The financial operations of the Institute shall be governed by financial regulations to be adopted by the Board.
3. The budget of the Institute is approved annually by the Board.
4. An annual audit of the operations of the Institute shall be conducted by an independent international accounting firm appointed by the Board upon recommendation of the Director. The results of such audits shall be made available by the Director to the Board for its consideration. Following the approval by the Board, the audit report shall be circulated to parties contributing to the Institute.

ARTICLE XVII PRIVILEGES AND IMMUNITIES

1. The Institute shall conclude with the Government a Headquarters Agreement relating to the facilities, privileges and immunities which the Institute, the members of the Board of Trustees, the

Director and staff of the Institute, and the experts performing missions on behalf of the Institute, will receive while in Korea for the purpose of exercising official duties.

2. The Institute may conclude with other states an agreement relating to the facilities, privileges and immunities which the Institute, the members of its Board of Trustees, the Director and staff of the Institute, and the experts performing missions on behalf of the Institute, will receive while in their territories for the purpose of exercising official duties.

3. The privileges and immunities are granted in the interest of the Institute and not for personal benefit. The Board of Trustees shall have the right to waive the privileges and immunities.

ARTICLE XVIII RELATIONSHIP WITH OTHER ORGANIZATIONS

In order to achieve its objectives in the most efficient way, the Institute may enter into agreements for cooperation with relevant national, regional or international organizations, foundations and associations, both public and private.

ARTICLE XIX DISPUTES RESOLUTION

The Institute shall make provisions for appropriate modes of settlement including arbitration of disputes between the Institute and its staff or among its staff.

ARTICLE XX AMENDMENTS

1. This constitution may be amended by the Board by a two-thirds majority of all voting members, provided notice of such a proposed amendment together with its full text shall have been mailed to all members of the Board at least four weeks in advance of the meeting, or such notice is waived by all members of the Board.

2. Such an amendment shall take effect immediately after having been adopted by the voting members under the procedure outlined in paragraph 1.

ARTICLE XXI DISSOLUTION

1. The Institute may be dissolved by a three-fourths majority of all voting members of the Board, if it is determined that the purposes of the Institute have been achieved to a satisfactory degree or if it is determined that the Institute will no longer be able to function effectively.

2. In the case of dissolution, any land, physical plant and other assets situated in the host country and other countries, and made available to the Institute by the Government, and permanent fixed capital improvements thereon shall revert to the Government. The other assets of the Institute shall be transferred to such countries for use for similar purposes or distributed to institutions having

purposes similar to those of the Institute in the respective countries after agreement between the governments of those countries and the Board in consultation with the Government.

CONSTITUTIONAL AMENDMENTS

AMENDMENT I

To carry out its FUNCTIONS, the Institute may prepare test vaccine lots for the purposes of evaluation and clinical testing. However, in accord with its STATUS as a scientific, developmental and education institution, the Institute shall not produce vaccines for sale under a product license or for other commercial sale.

AMENDMENT II INDEMNITY AND LIABILITY

The Board, officers, and employees, including consultants, of the Institute shall be indemnified by the Institute against all losses and expenses incurred by them in relation to the discharge of their duties, except such as have been caused by their willful act of default.

AMENDMENT III

The term of office and the selection of the members of the Board of Trustees appointed by WHO will be determined by WHO.





MINISTRY OF FOREIGN & DIASPORA AFFAIRS

PARLIAMENTARY MEMORANDUM

ON THE

**ACCESSION TO THE AGREEMENT ESTABLISHING THE
INTERNATIONAL VACCINE INSTITUTION (IVI)**

**PARLIAMENTARY MEMORANDUM ON KENYA'S ACCESSION TO
THE AGREEMENT ESTABLISHING THE INTERNATIONAL
VACCINE INSTITUTION (IVI)**

1.0 INTRODUCTION

- 1.1 The objective of this Parliamentary Memorandum is to apprise the National Assembly of and seek approval for Kenya's accession to the agreement establishing the International Vaccine Institution (herein referred to as the 'IVI') Establishment Agreement and to join as a 'Member State'.
- 1.2 The accession process was approved by Cabinet during its meeting held on **6th December 2022**.

2.0 BACKGROUND

- 2.1 IVI is a nonprofit International Organization established in 1997 as an initiative of the United Nations Development Programme (UNDP). It is an organization dedicated to vaccines and vaccination for global health. Its mission is to discover, develop and deliver safe, effective and affordable vaccines for global public health.
- 2.2 IVI is headquartered in Seoul and hosted by the Republic of Korea with 39 member countries and the World Health Organization (WHO) on its treaty.
- 2.3 IVI focuses on vaccines against infectious diseases affecting the World's most impoverished populations. It aims to make vaccines available and accessible to vulnerable populations in developing countries.
- 2.4 Kenya submitted a letter to IVI requesting the Board of Trustees' approval to become a party to the IVI Establishment Agreement as of 24th November 2022 as per Article vi of the IVI Establishment Agreement.

3.0 OBJECT AND SUBJECT MATTER

3.1. IVI's approach is based on three components:

- i. **Research:** vaccine research and development, translational and field research;
- ii. **Partnerships:** product development partnerships, international research, consortia and networks; and
- iii. **Capacity-building:** training, technical assistance, and technology transfers.

3.2 The Kenya Government has emphasized the need for technology transfer in pre-clinical, clinical development, regulatory review, approval, manufacturing, and quality control that is needed for the country to establish itself in vaccine manufacture for both vaccines against COVID-19 as well as other types of vaccines.

3.3 The mandate of IVI is to promote the development and delivery of vaccines and facilitate knowledge transfer for low- and middle-income countries (LMICs), to help advance global health.

3.4 The Ministry of Health, Kenya, the Republic of Korea, and IVI have jointly agreed to support the development, manufacturing, and delivery of these vaccines to countries in need; facilitate joint research in vaccines, and biopharmaceuticals between businesses, universities, and laboratories in Korea; and provide training and education of global vaccine (and bio) workforce to enhance LMICs' vaccine production capacity.

3.5 As a member state of IVI, Kenya would therefore benefit from technical and hands-on training to develop skillsets across vaccine development and production processes, biopharmaceutical manufacturing, biosafety, and good manufacturing practice requirements.

4 OBLIGATIONS IMPOSED BY THE IVI AGREEMENT

4.1 The IVI Agreement does not expressly stipulate obligations for member states. However, by signing and ratifying the IVI Agreement, Kenya will be required to:

- i) Publicly affirm the appreciation of IVI efforts to a shared vision of a world free of infectious diseases;
- ii) Lend a supportive voice to IVI initiatives when called upon;
- iii) Attend meetings on IVI and where required, exchange information and discuss collaborative opportunities; and
- iv) Grant privileges and immunities to the members of the Board of Trustees, Directors, Staff of the Institute, and experts performing missions for the Institute as are the same rights, privileges and immunities as are customarily accorded to a similar type of international organization.

5 PROBLEM STATEMENT

5.1 The COVID-19 pandemic was followed by an unprecedented global economic shutdown that exposed vulnerabilities in the global production strategies, supply chains of firms and increased vaccine nationalism that limited access to life-saving commodities especially for Low-income and most Middle-income countries predominantly situated in the Global South. Temporary trade restrictions and shortages of pharmaceuticals, critical medical supplies, and other products highlighted the weaknesses of dependability on imports for critical global health supplies including vaccines.

5.2 Kenya currently imports over 70% of her finished pharmaceutical commodity requirements and 100% of raw materials thereby consuming a significant portion of the Government's and private sector healthcare expenditure. Further, Kenya and Africa as a whole, imports

over 98% of its vaccine requirements in order to provide immunization services that is one of the most cost-effective public health interventions.

- 5.3 Drawing from lessons learnt from the COVID-19 pandemic, the Government of Kenya has initiated processes for establishing local manufacturing capabilities to improve self-reliance in vaccine supply. Cognizant of the complexity of realizing local production of vaccines, emphasis on the need for establishing strategic partnerships for technology transfer in pre-clinical, clinical development, regulatory review, approval, manufacturing, and quality control has been placed to ensure building of capacity.
- 5.4 Establishing local production capacity for human vaccines will support sustainability of public healthcare programmes, promote self-reliance; contribute to national and regional economic growth; position Kenya as a bio-technology manufacturing hub for the region and continent; and enhance national health security while strengthening pandemic preparedness and planning interventions.
- 5.5 It will also be a positive step in the country's attainment of Universal Health Coverage, as enshrined in the Kenyan constitution. Kenya's membership to IVI will therefore be valuable in Kenya's efforts towards building the necessary technical capacity in this endeavor.

6 JUSTIFICATION

- 6.1 The proposed membership has been necessitated by Kenya's ongoing plans to establish local capability for production of vaccines, cushion the country from potential escalating costs of immunization, work towards vaccine self-reliance and strengthen epidemic preparedness;

- 6.2 Vaccine manufacturing is a resource-intensive endeavor requiring specialized skills in vaccine discovery, development, testing, clinical trials, roll-out, market access, distribution and post-market surveillance;
- 6.3 As the country looks to begin local manufacturing with fill/finish operations and subsequent backward integration, there is a need for technology and knowledge transfer in all the aforementioned areas for adequate capacity for end-to-end vaccines and biologics production; and
- 6.4 Kenya's membership to IVI will help set the country on the path of establishing ourselves as a biotechnology manufacturing hub. As a member state of IVI, Kenya would therefore benefit from technical and hands-on training to develop skillsets across vaccine development and production processes, biopharmaceutical manufacturing, biosafety, and good manufacturing practice requirements.

7 CONSTITUTIONAL AND LEGISLATIVE IMPLICATIONS

- 7.1 The IVI Agreement is consistent with the Constitution of Kenya and promotes constitutional values and objectives, it does not allude to an amendment of the Constitution.
- 7.2 Upon accession, Kenya may need to engage and collaborate with different stakeholders including the private sector for the operationalization of local vaccine manufacture including pre-clinical and clinical research, manufacturing, quality assurance and regulation.

8 MINISTERIAL RESPONSIBILITY

- 8.1 The Ministry that will be responsible for the implementation and any activity in regard to the Convention is the Ministry of Health.
- 8.2 The Office of the Attorney General and Department of Justice and the Ministry of Foreign & Diaspora Affairs will coordinate the reporting

process on State obligations pursuant to the Treaty Making and Ratification Act No 45 of 2012.

9 FINANCIAL IMPLICATIONS

9.1 Kenya's accession to the IVI will not occasion any additional public expenditure if Kenya joins as a non-funding state. However, Article XVI of the Agreement provides for voluntary contributions of financial contributions by Members.

9.2 Any financial requirements during implementation will be catered for during the normal budgetary estimates of the relevant Ministries, Departments and Agencies.

10 RESERVATION

The IVI Establishment Agreement does not expressly provide for reservations.

11 RECOMMENDATIONS TO THE NATIONAL ASSEMBLY

In consideration of the aforementioned facts, the National Assembly is invited to:

1. Note the contents of the Parliamentary memorandum;
2. Consider and approve Kenya's accession to the Agreement Establishing the IVI, and
3. Direct the Cabinet Secretary of Foreign and Diaspora Affairs to prepare and deposit the Instruments of Ratification and accession to the relevant depository at the United Nations Office, as per the provisions of the Agreement.


SIGNED.....DATED..... JULY 2023

**DR. ALFRED N. MUTUA, E.G.H.
CABINET SECRETARY
MINISTRY OF FOREIGN & DIASPORA AFFAIRS**

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SIGNED..........DATED.....31st.....JULY 2023

**MS. NAKHUMICHA S. WAFULA
CABINET SECRETARY
MINISTRY OF HEALTH**

SIGNED.....DATED.....JULY 2023

**PROF. NJUGUNA NDUNGU, CBS
CABINET SECRETARY
NATIONAL TREASURY**

SIGNED.....DATED.....JULY 2023

**HON. JUSTIN MUTURI, EGH
ATTORNEY GENERAL**

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29/12/22



EXECUTIVE OFFICE OF THE PRESIDENT
CABINET OFFICE

Telegraphic Address
Telephone: +254-20-22275621/2/3
When replying please quote

STATE HOUSE
P.O. Box 40530-00100
Nairobi, Kenya

CAB/GEN.3/1/1 VOL.XIX/(62)

6th December, 2022

Ref. No.
and date

Eng. Peter K. Tum, CBS
Principal Secretary
State Department of Medical Services
Ministry of Health
NAIROBI



Dr. Josephine M. - Wahogo, (PhD)
Principal Secretary
State Department for Health Standards & Professional Management
Ministry of Health
NAIROBI

Dr. Chris K. Kiptoo, (PhD), CBS
Principal Secretary
The National Treasury
The National Treasury & Economic Planning
NAIROBI

Mr. James B. Muhati
Principal Secretary
State Department for Economic Planning
The National Treasury & Economic Planning
NAIROBI

Dr. Korir A. Sing'oei, PhD
Principal Secretary
State Department for Foreign Affairs
Ministry of Foreign & Diaspora Affairs
NAIROBI

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Ms. Roseline K. Njogu
Principal Secretary
State Department for Diaspora Affairs
Ministry of Foreign & Diaspora Affairs
NAIROBI

Mr. Kennedy N. Ogeto, CBS
Solicitor General
State Law Office
NAIROBI

Dear

**KENYA ACCESSION TO THE AGREEMENT ESTABLISHING THE
INTERNATIONAL VACCINES INSTITUTE**

I refer to the **4th (Fourth) Cabinet meeting - 2022** held on **6th December, 2022** during which the Cabinet Secretary for Health presented a Cabinet Memorandum **CAB(22)121**.

The Memorandum sought to apprise Cabinet on the proposed Kenya's membership to the International Vaccines Institute (IVI); and Cabinet approval for Kenya to be a member.

I wish to inform you that Cabinet **considered** the Memorandum and:

- I. **Noted** the contents of the Memorandum;
- II. **Noted** that the International Vaccine Institute is a Treaty based non-profit International Organization established in 1997 as an initiative of the United Nations Development Programme (UNDP) to develop and deliver safe effective and affordable vaccines across the world especially among the most impoverished nations;
- III. **Noted** that upon acceding to the IVI Establishment Agreement Kenya will benefit through; Training and technical assistance in the production technology and research in vaccines; Gain capacity from laboratory and field evaluation of new vaccines; and collaborations with vaccine manufacturers and other relevant bodies in vaccine research and development;
- IV. **Noted** that the proposed membership has been necessitated by Kenya's on-going plans to establish local production of vaccines to cushion the country from the escalating cost of immunization;

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- V. **Noted** that Kenya's accession to the IVI will not occasion any additional public expenditure if Kenya joins as a non-funding state. However, Article XVI of the Agreement provides for voluntary contributions from member states;
- VI. **Approved** Kenya to join the International Vaccines Institute (IVI) and accede to the Establishment Agreement;
- VII. **Directed** the Cabinet Secretary for Health; the Cabinet Secretary for Foreign & Diaspora Affairs; and the Attorney-General to initiate the process for membership to the IVI;
- VIII. **Directed** the Cabinet Secretary for Foreign and Diaspora Affairs to facilitate Kenya's accession to the IVI and deposit the instrument of accession with the relevant depository; and
- IX. **Directed** the Cabinet Secretary for Health to provide supervision and oversight to implementation after membership is granted.

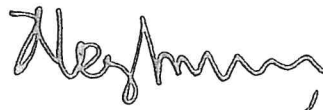
Please proceed and take necessary action as directed by **Cabinet**.

Yours

MERCY K WANJAU, MBS
SECRETARY TO THE CABINET

Copy to:

Ms. Susan N. Wafula
Cabinet Secretary
Ministry of Health
NAIROBI



Prof. Njuguna Ndung'u, CBS
Cabinet Secretary
The National Treasury & Economic Planning
NAIROBI

Hon. Alfred Mutua, EGH
Cabinet Secretary
Ministry of Foreign & Diaspora Affairs
NAIROBI

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International
Vaccine
Institute

Office of the Director General

December 16, 2022

Dr. Alfred N. Mutua, EGH
CABINET SECRETARY
The Government of the Republic of Kenya

Re: Accession of the Republic of Kenya to the International Vaccine Institute

Excellency,

In reference to your letter dated 24 November 2022, I have the honor to inform you that the Board of Trustees of the International Vaccine Institute, in its Resolution BOT-202212-02, unanimously approved the Republic of Kenya joining IVI as a state party to the IVI Establishment Agreement.

IVI looks forward to the completion of Kenya's internal ratification procedures and the deposit of an Instrument of Accession to the United Nations Treaty Section. We are ready to provide any additional assistance necessary to facilitate those processes.

Accept, Excellency, the renewed assurances of my highest consideration.

Sincerely,

A handwritten signature in cursive script that reads "Jerome H. Kim".

Jerome H. Kim, MD, FACP
Director General

KENYA - INTERNATIONAL VACCINE INSTITUTE ESTABLISHMENT AGREEMENT RATIFICATION PROCESS

AGENDA ITEM	ACTION	RESPONSIBLE PARTY	TIMELINES/STATUS
1. Request for approval as a member of the IVI	Submit to IVI headquarters	MFA	Done -24 th November 2022
2. Response from IVI welcoming Kenya to join IVI via ratifying the treaty	IVI response to Kenya	IVI -HQ	Done 16 th Dec 2022 via note verbale to MFA
3. Cabinet Memo on Kenya joining IVI	Drafting submission and approval of cabinet	MOH, MFA	Approval granted on February 2023
4. Parliamentary Memorandum	Drafting of the parliamentary memo	MoH + MFA- registrar of treaties	Done 5 th April 2023
	Technical inputs from MOH	MOH	Done 6 th June 2023
	Clarification on clause 4 sought due to diplomatic privileges on 9 th June 2023	MOH to review and offer guidance	Pending
	Concurrence on the Parliamentary memo from NT, AG and MFA <ul style="list-style-type: none"> To state we have been working on the parliamentary memorandum together. Letter to seek approval to submit the PM to Parliament 	DG office to draft the letters for signing by CS	5 th July 2023
	Attachment/ supporting documents to the parliamentary memo: <ol style="list-style-type: none"> IVI establishment agreement and constitution IVI approval of Kenya to be a member Cabinet memo and the cabinet approval Any other documents 	DG office to consolidate and submit	5 th July 2023

		Submission of the Parliamentary Memo to the Clerk, NA	MFA CS	12 th July 2023
5.	Public Participation	Biovax has carried out a stakeholder ecosystem mapping. Proposal to hold a breakfast meeting to engage on the IVI process. Country have minimum role as this is a policy function	Biovax	11 th July 2023
6.	Parliamentary memorandum: JOINT STATEMENT FOR PRESENTATION AT PARLIAMENT	Executive brief on why we want to join IVI to be prepared. To be co-written by MFA, AG and MOH Why is it late? Funding required now or in the future? Who are the stakeholders and were they engaged? PROPOSED TO BE SCHEDULED FOR 19 TH JULY 2023 PRIOR engagement to be done by biovax	Biovax to lead the process	Due on 12 th July 2023
7.	Parliamentary committee on health		CS HEALTH, DG HEALTH, Biovax	
8.	Ratification process	Depositing the instruments of ratification by end of July 2023 To be deposited in New York. 5 days	MFA – Treaty, Biovax, CS Health	28 th July 2023
9.	Host Country Agreement	IVI Board meeting to take place in October 2023 All UN bodies are under the 1978 UN agreement umbrella MFA, NT, Treasury, Immigration, KRA, MOH needed	To follow ratification	Oct 2023

		<p>IVI will seek the host country status dependent on how we lobby</p> <p>Week long meeting of negotiations: Outcome will be a cabinet memo</p> <p>Minimum process will be 90 days</p>		
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CAB NO.....



MINISTRY OF HEALTH

**CABINET MEMORANDUM ON KENYA ACCEDING TO THE AGREEMENT
ESTABLISHING THE INTERNATIONAL VACCINES INSTITUTE**

1. OBJECTIVE OF THE MEMORANDUM

The Objective of this Memorandum is:

- i. To apprise the Cabinet of the proposed membership to the International Vaccines Institute (IVI).
- ii. To seek the Cabinet's approval for Kenya to be a member of the International Vaccines Institute.

2. BACKGROUND OF THE SUBJECT MATTER

2.1 About IVI

The International Vaccine Institute (IVI) is a treaty based nonprofit International Organization established on 12th May 1997 as an initiative of the United Nations Development Programme (UNDP). It is among the few organizations in the world dedicated to vaccines and vaccination for global health.

- i) IVI is headquartered in Seoul, in the Republic of South Korea with 39 member states and the World Health Organization (WHO). The IVI mission is to discover, develop and deliver safe, effective, and affordable vaccines for global public health.
- ii) African member states to IVI are: Liberia which became a member state in September 2005 and Rwanda in March 2022. Senegal and Egypt became signatory states in October 1996 and April 1997 respectively.

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- iii) African states approved by the IVI Board of Trustees which have not yet deposited an Instrument of Accession with the United Nations include: Côte d'Ivoire, Madagascar, and Sudan.
- iv) IVI focuses on vaccines against infectious diseases affecting the world's most impoverished. They aim to make vaccines available and accessible for vulnerable populations in developing countries. Additionally, since we live in an increasingly globalized world where new and emerging infectious diseases can become global health threats, IVI also focuses on vaccines against infectious diseases of major global health concern.

2.2 Functions of IVI

As per the Establishment Agreement Article IV, the Institute shall carry out major research and development functions. Specifically, it will:

- i) undertake and promote the study, research, development, and dissemination of knowledge in the vaccine-relevant sciences and directly related areas of public health, management sciences, and technology to generate affordable and effective means to prevent death and disability arising from infectious diseases and, thereby, to improve the health status and general welfare of children and low-income people in developing and developed countries, especially in Asia; and
- ii) provide, in collaboration with relevant national and international institutions, facilities and training programs aimed at strengthening expertise and capacity for developing and developed countries to conduct work in the areas of the Institute's interest and competence.

2.3 The IVI approach spans the spectrum from discovery through development, to delivery and capacity building. Their focus is in:

- i) **Vaccine Discovery**

By designing and formulating new vaccines, optimizing production processes for industrial scale-up, and developing new technologies to support the clinical testing of vaccines in humans.



ii) **Vaccine Development**

By transferring technology to local manufacturers and forming partnerships with them to develop and commercialize vaccines – including sponsoring and supporting clinical trials, registration, WHO prequalification – for the public-sector market. IVI also leads and manages private-public partnerships, and pools resources and funding from different sectors to develop vaccines.

iii) **Vaccine Delivery**

To accelerate vaccine introduction by generating data on the need for vaccines (numbers of deaths and illnesses, high-risk populations, economic costs of disease) for governments and policymakers. Further, they implement vaccine delivery and effectiveness studies to see how well vaccines work in real-life situations and to measure programmatic feasibility, as well as conduct research on vaccine safety with a focus on special populations like pregnant women, refugees, and internally displaced people.

iv) **Capacity building**


The International Vaccines Institute ensures vaccine security and self-reliance in developing countries through technical assistance, technology transfer, training programs, and the annual Vaccinology Course.

2.4 The obligations of IVI member states

The IVI Establishment Agreement does not expressly stipulate obligations for member states.

However, by signing and ratifying the IVI Establishment Agreement, Kenya will be required to:

1. Publicly affirm the appreciation of IVI efforts to a shared vision of a world free of infectious diseases;

- 
2. Lend a supportive voice to IVI initiatives when called upon;
 3. Attend meetings on IVI and where required, exchange information and discuss collaborative opportunities; and
 4. Grant privileges and immunities to the members of the Board of Trustees, Directors, Staff of the Institute, and experts performing missions for the Institute.


However, states derive various benefits from their membership in IVI.

2.5 Benefits of Kenya's membership to IVI

Upon acceding to the IVI Establishment Agreement, Kenya will accrue the following benefits:

- i) Training and technical assistance in the production technology and research of vaccines.
- ii) Gain from laboratory and field-based research and development.
- iii) Support for clinical trials and field evaluations of new vaccines, as well as the introduction of new and improved vaccines.
- iv) Collaboration with vaccine manufacturers and other relevant bodies in vaccine research and development.

3.0 Justification and rationale for Kenya's proposed membership to IVI

- i) The proposed membership has been necessitated by Kenya's ongoing plans to establish local production of vaccines, cushion the country from potential escalating costs of immunization, work towards vaccine self-reliance and strengthen epidemic preparedness.
 - ii) Establishing vaccine manufacturing is costly and difficult: Large capital expenditure is required; technical capabilities and expertise in production, clinical trials, Quality Management Systems, and regulatory activities are all critical components of establishing vaccine manufacturing.
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- iii) As the country looks to start with fill/finish operations, there is a need for technology transfer in all the aforementioned areas for adequate capacity to move to full-scale vaccine production.
- iv) The country's membership in IVI will help set us on the path of establishing ourselves as a future research and pharmaceutical manufacturing hub.

4.0 CONSTITUTIONAL IMPLICATIONS

The IVI Establishment Agreement does not propose any amendments to the Constitution and is consistent with constitutional provisions in particular Article 43 (1) (a).

5.0 POLICY AND LEGAL CONSIDERATIONS

The Treaty Making and Ratification Act, 2012 (Rev 2018), requires that a country position paper and a Cabinet Memorandum be developed by the relevant state department for accession to be effected.

Upon accession, Kenya may need to engage and collaborate with different stakeholders including the private sector for operationalization of local vaccine manufacture including pre-clinical and clinical research, manufacturing, quality assurance and regulation.

6.0 REQUIREMENTS FOR ACCEDING TO THE IVI ESTABLISHMENT AGREEMENT

To become a party to the IVI Establishment Agreement, Kenya will be required to: Submit a letter to IVI requesting the Board of Trustees' approval to become a party to IVI Establishment Agreement.

1. Upon receiving approval from the IVI Board of Trustees, the interested state or entity must deposit an Instrument of Accession with the United Nations.

The instructions for depositing the instrument are as follows:

1. Prepare the instrument of accession per the UN standards.

2. Deliver the instrument by hand, mail, or fax to the Treaty Section of the United Nations, preferably including translation into English or French, where appropriate.

7.0 FINANCIAL IMPLICATIONS AND SUSTAINABILITY

Kenya's accession to the IVI will not occasion any additional public expenditure if Kenya joins as a non-funding state. However, Article xvi of the Agreement provides for voluntary contributions of financial contributions by Members.

8.0 MINISTERIAL RESPONSIBILITY

The implementation of the IVI activities will be done by the Ministry of Health.

9.0 IMPLICATIONS TO COUNTIES OF KENYA'S ACCESSION TO THE IVI ESTABLISHMENT AGREEMENT

The obligations under the IVI are concurrent functions of both the National and County governments according to the Fourth Schedule of the Constitution of Kenya, 2010.

10.0 RECOMMENDATIONS TO THE CABINET

The Cabinet is invited to note the contents of this Memorandum and:-

1. Approve Kenya to become a member of IVI and accede to the Establishment Agreement;
2. Direct the Cabinet Secretary for Health, the Ministry of Foreign Affairs, and the Office of the Attorney General to initiate the process for membership to the International Vaccines Institute;
3. Direct the Cabinet Secretary for Foreign Affairs to facilitate Kenya's accession to the IVI and deposit the instrument of accession with the relevant depository; and
4. Direct the Cabinet Secretary for Health to provide supervision and oversight to the foregoing processes after membership is granted.

SECRET

Signed *[Signature]* Dated *16* November, 2022

MS. NAKHUMICHA S. WAFULA
CABINET SECRETARY
MINISTRY OF HEALTH

Signed *[Signature]* Dated *17/11/22* November, 2022

PROF. NJUGUNA NDUNG'U, CBS
CABINET SECRETARY
NATIONAL TREASURY

Signed *[Signature]* Dated *28th* November, 2022

DR. ALFRED MUTUA, EGH
CABINET SECRETARY
MINISTRY OF FOREIGN AFFAIRS

Signed *1st* Dated *December* November, 2022

HON. JUSTIN MUTURI, EGH
ATTORNEY-GENERAL

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DRAFT COUNTRY POSITION PAPER FOR KENYA'S PROPOSED MEMBERSHIP TO THE INTERNATIONAL VACCINES INSTITUTE (IVI)

1.0 BACKGROUND

Immunization is one of the most cost-effective public health interventions. The impact of immunization in reducing morbidity and mortality from disease is only second to the provision of clean water. The Kenya Expanded Programme on Immunization (KEPI) was established in 1980 with the main aim of providing immunization against six killer diseases of childhood (tuberculosis, diphtheria, pertussis, tetanus, measles, and polio). In the last decade, six new vaccines have been introduced into the routine immunization schedule with support from Gavi. In addition, Gavi supported Kenya to introduce the Covid-19 vaccine. Kenya is due to graduate from Gavi support in 2027.

Access to vaccination is also a key element in the progress towards Universal Health Coverage which is a means to realizing the right to health as enshrined in the Kenyan Constitution, and ambitions set out in Vision 2030 and the Kenya Health Policy 2014 – 2030, Sessional paper No 2 of 2017, Health Act 2017. Additionally, it is in line with Kenya's commitment to Sustainable Development Goals (SDGs). Vaccines are pharmaceuticals that are regulated through the provisions of Cap 244.

The Covid 19 pandemic was followed by an unprecedented global economic shutdown that exposed vulnerabilities in the global production strategies and supply chains of firms everywhere. Temporary trade restrictions and shortages of pharmaceuticals, critical medical supplies, and other products highlighted the weaknesses of dependability on imports for critical global health supplies including vaccines. For Kenya, the importation of health commodities also consumes a significant chunk of our health budget.

The decision by the Kenya government to address these issues by establishing local vaccine manufacturing is therefore timely. In addition to being a step towards self-sustainability in the supply of medical commodities, it is envisioned that the local production of human vaccines will support public healthcare programmes, national and regional economic growth, and national security as well as enhance the capacity to control disease outbreaks that may arise in the future. Drawing from lessons from the Covid-19 pandemic for self-reliance in vaccine supply, the Kenya government established the Kenya Biovax Institute which will start off as a fill-and-finish production plant, whereby vaccines from the main manufacturers will be put into vials before packaging them for distribution. Of note is that Kenya already produces livestock vaccines through the Kenya Veterinary Vaccines Production Institute (KEVEVAPI).

Kenya has been invited to accede to the Agreement establishing the International Vaccine Institute (IVI) headquartered in Seoul, in the Republic of South Korea.

2.0 THE CASE FOR KENYA'S PROPOSED MEMBERSHIP TO THE INTERNATIONAL VACCINE INSTITUTE (IVI)

2.1 Besides being a resource-intensive endeavor, vaccine manufacturing requires specialized skills in vaccine discovery, development, testing, and roll-out.

2.2 The Kenya government has emphasized the need for technology transfer in pre-clinical, clinical development, regulatory review, approval, manufacturing, and quality control that is needed for the country to establish itself in vaccine manufacture for both Covid and other types of vaccines.

2.3 The mandate of IVI headquartered in Seoul, Korea is to promote the development and delivery of vaccines and facilitate knowledge transfer for low- and middle-income countries (LMICs) to help advance global health.

2.4 The Ministry of Health and Welfare (MOHW), the Republic of Korea, and IVI have jointly agreed to support the development, manufacturing, and delivery of...

vaccines, and biopharmaceuticals between businesses, universities, and laboratories in Korea; and provide training and education of global vaccine (and bio) workforce to enhance LMICs' vaccine production capacity.

2.5 As a member state of IVI, Kenya would therefore benefit from technical and hands-on training to develop skillsets across vaccine development and production processes, biopharmaceutical manufacturing, biosafety, and good manufacturing practice requirements.

2.6 As a non-state funder, Kenya can take advantage of the following benefits available to state parties:

- Enhanced global health recognition by publicly affirming to the international community Kenya's appreciation of IVI's mission to free the world from infectious diseases.
- Information exchange with IVI on vaccines and potential collaborative opportunities.
- Participation in IVI diplomatic events to make statements on IVI's work and strategy, periodic forums, and regional workshops.

2.7 It is noted that non-funder African state parties such as Egypt and Senegal have benefitted from having their researchers attend the vaccinology course and have collaborated in vaccine efficacy studies.

2.8 Kenya can therefore accrue similar benefits as a non-funding state party to IVI.

3.0 POLICY AND LEGISLATIVE CONSIDERATIONS

The Treaty Making and Ratification Act, 2012 (Rev 2018), requires that a country position paper and a Cabinet Memorandum be developed by the relevant state department for accession to be effected. Joining the IVI is consistent with constitutional provisions, particularly Article 43 (1) (a).

Upon accession, Kenya may need to engage and collaborate with different stakeholders including the private sector for operationalization of local vaccine manufacture including pre-clinical and clinical research, manufacturing, quality assurance and regulation.

4.0 COSTS OF FORMULATING AND ADOPTING THE TREATY TO KENYA

4.1 Kenya will have no financial obligations for becoming an IVI non-funding member state.

4.2 However, state parties have the option to voluntarily contribute unrestricted core funding to IVI which in turn strives to provide a return on investment to its state funders through a variety of collaborative development opportunities.

4.3 IVI currently has 4 state funders, namely: South Korea, Sweden, India, and Finland. Their annual contribution ranges from USD 500,000 to USD 5 million. They accrue various benefits including assistance with global health programs, vaccine development, technology transfer of vaccines to local manufacturers, disease surveillance, clinical trials and economic studies, collaboration centers, and fellowship programs, and Covid 19 vaccine development.

5.0 RECOMMENDATIONS

5.1 Kenya should accede to IVI's Establishment Agreement as a non-funding state to access needed support that will place the country on the path to building the necessary capacity for fill and finish requirements and eventual fully fledged vaccine production.

5.2 In the future, Kenya may consider becoming an IVI state funder to derive additional benefits.

6.0 CONCLUSION

Establishing local production of vaccines within the country will help to circumvent the current challenges encountered in the importation of over 70% of the country's medical products, including vaccines and biologicals. It will also be a positive step in the country's attainment of Universal Health Coverage, as enshrined in the Kenyan constitution. Kenya's membership to IVI will therefore be valuable in our efforts towards building the necessary technical capacity in this endeavor.