FRAMEWORK ACT ON VACCINATION FOR LATIN AMERICA

-Proposal prepared by the Latin American Parliament-

Prepared by the

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STATEMENT OF PURPOSE[1]

Vaccination has saved millions of human lives. As a measure of prevention of transmissible diseases, immunization has proved to be a highly efficient and cost-effective public policy, without mentioning its great economic and social value as regards its administration. Several achievements as regards immunization in Latin America, particularly the eradication of poliomyelitis and measles during the nineties, have confirmed this fact.

Vaccines are also a means to attain the Millennium Development Purposes internationally agreed, particularly in order to accelerate the achievement of Purpose Number 4 about "Reducing in two thirds, between 1990 and 2015, the mortality rate of children under five years".

Nowadays, however, within a context in which governments must fight to find additional resources in order to face new and urgent health needs, immunization actions are sometimes relegated to a second place, and it is necessary to make a solid defense of vaccination and to ensure the right to have access in our region to efficient and safe vaccines.

It is important to mention that for Latin America, notwithstanding the good results obtained in the past, there are still serious deficiencies among countries and in the interior of them and the difference in times for the introduction of new vaccines is increasingly evident; these deficiencies are produced by multiple reasons and reveal that present immunization policies and practices in the Latin American region are insufficient or obsolete to face the problems of the public health context, particularly in the field of diseases that may be prevented through vaccination.

Unfortunately, among vaccination disadvantages, it is usual to include regulatory barriers. The legal framework of Latin American countries is not homogeneous on this matter and on many occasions this fact not only hinders immunization practices but also contributes to delay the introduction of new biological products in the different countries.

It is important to take into account that the transmission of preventable diseases does not respect geographical barriers or political borders. If a country implements a policy directed to reduce the incidence of a preventable disease while a neighboring country doesn't, the result shall be that the populations of both countries shall take the same risk because the second one shall behave as a reservoir of the infectious agent. For all these reasons, it is essential to make the regional efforts necessary to efficiently face the new challenges of vaccination.

One of the strategies for efficiently fighting against immune-preventable diseases is to transform the legal frameworks of our countries so as to have an adequate legislation that eliminates regulatory barriers which impede the effective exercise of the right to vaccination.

As the Latin American Parliament is a regional agency created to promote Latin American integration, and directed to study, discuss and prepare policies aimed at the solution of the social problems of the Latin American society, this Parliament is the natural place to impulse this framework Act on vaccination for Latin America, which is designed to enhance the actions of legislators of each country of the region on this matter.

According to the above reasons, the Latin American Parliament, in the exercise of its powers, recommends the following:

[1] Los textos a partir de los cuales se construyó la parte sustantiva de esta Exposición de

FRAMEWORK ACT ON VACCINATION FOR LATIN AMERICA

CHAPTER I

General Provisions

Section 1. The purpose of this Act is to ensure the compulsory administration of the vaccines that are part of the National Vaccination Scheme, in the terms and conditions expressed by such Scheme, as well as those required in extraordinary situations, as a basic element for the full exercise of the Right to Health Protection.

The provisions of this Act are of public interest, preferential enforcement and compulsory compliance at health institutions of public, private and social sectors.

Section 2ª. Vaccines that, according to the provisions of this Act, are included in the National Vaccination Scheme, shall be furnished and administrated to the population in the terms and conditions established by the Scheme and in no case economic reasons or insufficient stock at public health services may be alleged.

Section 3ª. Every person shall be entitled to receive at the public health system the vaccines included in the National Vaccination Scheme free of charge and under the terms and conditions established by this Scheme.

Residents of the national territory shall be jointly responsible together with the Government for keeping updated their vaccine condition and shall give their consent to the administration of the corresponding biological products according to their age.

Those persons who exercise their paternal rights, guardianship, custody or that, in general terms, are responsible for minors and disabled, shall be forced to take all the necessary steps to make them receive the respective vaccines.

Section 4º. The public health system shall implement mechanisms to ensure the vaccination of the individuals included in the "captive population groups" of public institutions.

For the purposes of this Act, the term "captive population groups" means all individuals under the custody of Government institutions created for the care, training, or control or those ones sharing –both temporary and permanently- a specific geographical area, including -but not limited to- the following:

I. Children's care centers, children's homes, orphanages, nursery schools and kindergartens;

II. Schools, shelters, boarding schools, homes, juvenile detention centers and prisons;

III. factories, companies and public institutions

IV. refugee camps, and

V. Institutions for psychiatric patients, among others.

Those responsible for captive population groups shall provide all the necessary services and shall cooperate for the development of those activities related to vaccination and control of diseases preventable through vaccination.

Section 5°. Prior to the administration of the vaccine, individuals or their legal agents, shall receive information about the nature, purpose, benefits and possible risks of the corresponding vaccine.

Section 6°. An individual shall not receive a vaccine if:

I. he is affected by a condition contraindicated for that vaccine, according to the resolutions issued by the Advisory Committee on Vaccines, or

II. he submits a laboratory confirmation stating that he has immunity with respect to the disease prevented by the specific vaccine.

Section 7°. National, regional, provincial and municipal sanitary authorities shall –within their respective jurisdictions- develop permanent communication campaigns directed to inform the general population about the benefits of vaccines and the risks derived from the lack of a timely immunization.

CHAPTER II

Powers of the National Health Department (or its equivalent)

Section 8°. For the purposes of this Act, the National Health Department (or its equivalent) shall:

I. Define, in coordination with the Advisory Vaccination Committee , the criteria and procedures to achieve the control and eradication of diseases preventable through vaccination;

II. Establish, according to the provisions of this Act, the guidelines for the rendering of vaccination services, as well as the characteristics and rules governing the cold chain. For the purposes of this Act, the term "cold chain" means the logistical system formed by the staff, the equipment and the procedures used to store, transport and keep vaccines at adequate temperatures from their manufacturing up to their administration to the public;

III. Implement the National Vaccination Program;

IV. Coordinate the National System of Epidemiological Surveillance and the Operation of the Nominal Digital Information System. For the purposes of this Act, the term "Nominal Digital Information System" means the system that registers the name, age, address and vaccination actions adopted for the benefit of population.

V. Take the necessary steps to ensure the timely availability of vaccines and other vaccination inputs in adequate quantities throughout the national territory. For the purposes of this Act, the term "vaccination inputs" means disposable material resources used for the administration of biological products, including the latter, as well as cotton, alcohol, syringes and needles, among others;

VI. Annually assign, in coordination with the other competent agencies, the budgetary estimates for the efficient implementation of the National Vaccination Program, which shall be timely sent to the National Congress;

VII. Coordinate national, provincial, municipal or regional vaccination campaigns, both ordinary and extraordinary;

VIII. Provide assistance to provincial, municipal or regional authorities for the development of vaccination campaigns;

IX. Monitor vaccination activities throughout the national territory;

X. To assess –every six months- the results obtained through the implementation of the National Vaccination Program and the specific vaccination actions, and propose measures directed to enhance the effectiveness of successive activities;

XI. Define, in coordination with the Advisory Vaccination Committee, the technical rules for the administration, management and preservation of every biological product included in the National Vaccination Scheme. Supervise its compliance and sanction its lack of compliance;

XII. Spread ordinary and extraordinary national vaccination campaigns;

XIII. Quarterly report to the National Congress about the use of the financial resources authorized by it for the implementation of the National Vaccination Program, and

XIV. Comply with the other duties mentioned in this Act and other applicable legal provisions.

CHAPTER III

National Vaccination Scheme

Section 9º.

The National Vaccination Scheme shall include those vaccines determined by the Advisory Committee on Vaccines through its compulsory resolutions, as the adequate selection of biological products2 for the efficient control of immunopreventable diseases among the population.

Section 10. The National Vaccination Scheme shall include for each biological product the following data:

I. Indications;

II. Kind of Administration;

III. Age or Risk Group aimed at;

IV. Scheme (Dose number), and

V. Dose.

Section 11. The National Vaccination Scheme shall be periodically assessed by the Advisory Vaccination Committee. Such Scheme shall be updated whenever the Committee issues a recommendation in any of the following senses:

I. To suppress a vaccine,

II. To eliminate or replace an included vaccine by another one that has proved to be safer or more effective, or

III. To incorporate new vaccines.

Section 12. The National Health Department (or its equivalent in the country) shall be in charge of the prompt publication in the official bulletin of the National Vaccination Scheme, as well as the updates recommended by the Advisory Vaccination Committee.

Section 13. The vaccines included in the National Vaccination Scheme shall be available for their administration during all the working days of the year at all the institutions of the public health system. Besides, specific campaigns may be made, including Vaccination Weeks or Days.

CHAPTER IV

Advisory Vaccination Committee[2]

Section 14. The Advisory Vaccination Committee is a permanent, autonomous and multidisciplinary consultation agency that defines, promotes and supports prevention, control, elimination and eradication actions at the national territory of the diseases that may be prevented through the administration of vaccines.

The Committee shall base its actions on scientific evidence, rationality and objectivity criteria.

Section 15. The Advisory Vaccination Committee shall have the following powers:

I. To propose the policies, strategies and measures it esteems necessary for the prevention, control, elimination and eradication of diseases that may be prevented through the administration of vaccines;

II. To assess:

   a. Any new vaccine with a Sanitary Record4 in the country;

   b. Any new vaccine with a high possibility of obtaining the Sanitary Record in the country in the short or medium term in order to accelerate the corresponding decision.

   c. Any new vaccine included in the National Vaccination Scheme from the point of view of the most recent scientific evidence.

III. To issue compulsory resolutions with respect to the vaccines included in the National Vaccination Scheme;

IV. To issue compulsory resolutions regarding the specific aspects of the administration of vaccines. These resolutions may refer to the principles applicable to the administration techniques, doses and intervals between doses, contraindications and precautions, reports of adverse effects and of events temporarily associated to vaccination, storage, management and registration of vaccines, as well as situations or populations that make necessary the modification of routine recommendations;

V. To propose adjustments to the National Vaccination Program as well as campaigns and any action related to the prevention, control, elimination and eradication of diseases that may be prevented through vaccination;

VI. To perform feasibility studies regarding the actions proposed by the National Vaccination Program;

VII. To assess the information systems and the performance indicators linked to vaccination actions;

VIII. To suggest modifications to the effective legal provisions related to the prevention, control, elimination and eradication of diseases that may be prevented through the administration of vaccines;

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[2] En algunos países de la región ya existen órganos similares bajo el nombre de Consejos o Comités Nacionales de Vacunación, los cuales deberían ajustarse a lo establecido en esta Ley, a efecto de dotarles, entre otros, de autonomía y permanencia.

IX. To issue its Operative Regulations, and

X. To comply with the other duties determined by this Act or the other applicable provisions.

Section 16. The Advisory Vaccination Committee may assess vaccines at the request of any of its members or of a third party not belonging to this agency.

The assessment shall include, among others, the following factors:

I. Disease impact;

II. Epidemiological information;

III. Vaccine effectiveness;

IV. Safety profile;

V. Cost-benefit and/or cost-effectiveness, and

VI. All other factors considered relevant to issue a solidly founded recommendation.

The Advisory Vaccination Committee shall be authorized to request –in writing- relevant information for its assessment to public and private agencies. Such agencies shall submit the available information within the reasonable term defined by the Committee in its request.

If the Advisory Vaccination Committee determines that it is not possible to obtain the information necessary for its assessment, because it does not exist or it is not available, the Committee itself shall propose the mechanisms necessary to generate such information and, for this purpose, it shall determine the responsible agencies, as well as the budget necessary to this end. Among these mechanisms, the Committee shall consider the extrapolation of regional figures to the national area, if possible.

Section 17. The Advisory Vaccination Committee shall have a maximum term of six months from the beginning of the corresponding assessment to issue its resolutions.

Exceptionally, and duly founded in objective reasons, the committee may extend the term mentioned in the previous paragraph for three additional months.

Section 18. The resolutions of the Advisory Vaccination Committee may include any of the following contents:

I. Founded proposal about the incorporation of a new vaccine to the National Vaccination Scheme, which shall include:

   a. Indications;

   b. Kind of Administration;

   c. Age or Risk group considered as aimed population and recommended initial coverage, if any;

   d. Scheme (Dose number);

   e. Dose;

   f. Contraindications;

   g. Secondary reactions;

h. Specific proposals for:

i. Surveillance of adverse effects, or

ii. Measurement of the vaccine introduction impact.

II. Founded proposal about the non incorporation of a new vaccine to the National Vaccination Scheme, in which case, a founded recommendation with respect to its administration or non administration in the private sector shall be included, and

III. Founded Proposal to eliminate or replace a vaccine included in the National Vaccination Scheme.

Section 19. The resolutions of the Advisory Vaccination Committee shall be:

I. Publicly spread, through the official bulletin and the web site of the Committee;

II. Analyzed and answered by the Health Department (or its equivalent in the country) in a maximum term of fifteen working days from the issuance of the recommendation. In case of submission of a proposal for the modification of issued resolutions, the Advisory Vaccination Committee shall have a maximum term of a month to analyze its convenience and consequently adjust such recommendation;

III. Used as reference by the Health Department (or its equivalent in the country) and other competent agencies both for the preparation of the respective yearly budgets, and the purchase of vaccination inputs;

IV. Used as reference by the National Congress for the purposes of the budgetary allocation and assignation of corresponding resources, and

V. Shared with the other Advisory Vaccination Committees of Latin America and with the Pan-American Health Organization, in order to consolidate a regional vaccination system.

Section 20. The Advisory Vaccination Committee shall be formed by the following permanent members, who shall be entitled to participate at the meetings with a right to speak and vote:

I. The Director of the National Vaccination Program of the National Health Department (or its equivalent in the country);

II. The Director of Epidemiology of the National Health Department (or its equivalent in the country);

III. The Director of the National Regulation Authority (or its equivalent in the country);

IV. The Director of the Public Health Institute (or its equivalent in the country);

V. A representative with decision-making capacity of the Treasury Department (or its equivalent in the country);

VI. A representative with decision-making capacity of the National Ombudsman (or its equivalent in the country);

VII. Representatives of the regional or provincial sanitary authorities of the country;

VIII. Representatives of academic and scientific organizations or institutions linked to vaccination;

IX. Representatives of civil society organizations related to the vaccination area, and

X. Experts in vaccination, infectology, immunology, economic assessment, epidemiology, health systems and other relevant disciplines.

Permanent members shall never exceed twenty in order to keep the executive operation of the agency and shall be re-elected every four years, according to the procedures established by the Operating Rules for such purpose.

The Committee shall be presided by one of the experts who shall be elected by the secret vote of the members of such agency. The President shall have a term of two years which may be extended only once for another two years.

The members of the Committee shall sign, prior to their incorporation, a declaration expressing that there is no conflict of interest. For the purposes of this Act, conflict of interest means the circumstances in which the objective judgment of a person related to a primary interest -which in this case would be the adoption of the best vaccination alternative for the benefit of population - is disproportionately influenced by a simultaneous secondary interest.

The members of the Committee shall hold their offices ad honorem; however, those who are not government officials may receive an economic compensation exclusively directed to reimburse labor costs and travel and living expenses that may derive from their participation at the Committee sessions.

The Committee shall have a Technical Secretariat to enable said Committee to continue its work.

Section 21. The representatives of vaccine manufacturing companies may attend the sessions of the Vaccine Advisory Committee with the right to speak in the debates but without voting rights.

Section 22. The plenary sessions of the Vaccine Advisory Committee shall be public and shall be transmitted through its website.

However, the Committee may vote on the membership of the working groups by simple majority. Said working groups shall hold closed door sessions in order to facilitate the process of analysis and debate of specific subjects.

Section 23. The Vaccine Advisory Committee shall ordinarily meet at least once every six months.

The Committee shall hold extraordinary sessions when necessary or upon request of the Health Secretary or the Chairman of the Committee.

Section 24. The National Congress shall annually allocate financial resources of the budget of the National Health Department (or its equivalent in the country) to the Vaccine Advisory Committee, which shall administer said resources according to its needs.

Such resources shall be used for expenses incurred for:

I. The organization of analysis and debate sessions;

II. Technical support;

III. The operation of the Committee's website;

IV. The amounts paid to Committee members who are not government officials. These amounts are intended to reimburse travel and living expenses deriving from members' participation in the Committee sessions;

V. The maintenance of the Committee's Technical Secretariat, and

VI. The proper development of the Committee's general functions.

The National Health Department (or its equivalent in the country) shall provide the Committee with the convenient premises for holding its sessions and performing its daily functions.

Section 25. The Vaccine Advisory Committee shall send a biannual written report to the National Congress and the National Health Department (or its equivalent in the country).

Section 26. All aspects related to the operation and functioning of the Vaccine Advisory Committee not provided for herein, shall be defined in the Committee's Operational Rules.

CHAPTER V

Vaccination campaign and epidemiological information record

Section 27. The National Health Department (or its equivalent in the country) shall define the guidelines for establishing and operating the Nominal Digital Information System.

The System shall include precise, complete, updated and verifiable information about vaccination campaigns in the country.

Section 28. The health staff who administer the vaccines shall record the corresponding data in the nominal census, which shall be afterwards entered into the Nominal Digital Information System.

Likewise, health staff shall record the administration of the vaccine in the Vaccination Card[3] of the immunized individual, stamping the seal of the health institution and the corresponding signature.

Section 29. The Vaccination Card is a free, unique and non-transferable document which is used to keep record and control of the vaccines administered to an individual.

The Health Department (or its equivalent in the country), in consultation with the Vaccine Advisory Committee, shall determine the single format of the Card, which shall be used in all health institutions of the public, social and private sectors throughout the national territory.

Section 30. Should the health staff vaccinate an individual who has no Vaccination Card, they must provide one, fill in the user's general data and assign a number which shall be the same as that of the user's national identity card.

Likewise, health staff shall inform the user that he has to present the Card each time he is vaccinated, regardless of the place where he is inoculated.

The Card shall be kept by its bearer and, in the case of minors or disabled persons, it shall be kept by the persons who exercise parental rights, guardianship, or custody over them, or, in general, by those who are responsible for them.

Section 31. The Vaccination Card shall be considered fully valid by the institutions before which the vaccination has to be verified.

Evidence of vaccination shall be required by relevant authorities to the following persons or in the following cases:

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[3] It may also be called Vaccination Booklet or Vaccination Certificate, according to the custom or legal framework of each country.

I. To health staff;

II. At the time of entering elementary, secondary, tertiary or special -public or private- schools, as well as nurseries and kindergartens;

III. When epidemiological conditions so justify it, and

IV. In such other cases as health authorities may deem it necessary to verify compliance with vaccination requirements.

Section 32. Should the Vaccination Card be lost, a new one shall be provided with a transcription of previously administered vaccines. Said transcription shall be made exclusively by public health staff, based on the data found in the Nominal Digital Information System. Only in the case of the BCG vaccine shall the post-vaccination scar be considered as valid evidence.

In the absence of data evidencing previously administered vaccines, the person shall be immunized according to the National Vaccination Scheme, taking into account said person's age.

Section 33. Health staff who treat or are aware of a disease which could have been prevented through vaccination, shall immediately give notice thereof to the Epidemiology Office of the National Health Department (or its equivalent in the country), as prescribed by said Office.

Section 34. All health facilities and staff of the public, social and private sectors must participate in epidemiological control measures of immunopreventable diseases. To such end, said staff must give the relevant notices in a systematic, timely and confidential manner, according to the International Classification of Diseases, and directly to the Epidemiology Office of the National Health Department (or its equivalent in the country), as prescribed by said Office.

Section 35. Health facilities and staff of the public, social and private sectors shall record and notify the presence of events temporarily associated with vaccination. Likewise, they shall conduct relevant case and field studies to make the diagnosis and establish the treatment, as well as relevant control measures.

To the effects of this Law, events temporarily associated with vaccination shall be the clinical manifestations occurred within thirty days after the administration of one or more vaccines and that are not provoked by a specific nosologic entity. The Vaccine Advisory Committee shall establish the biologics subject to a longer observation period.

Events temporarily associated with vaccination are classified as follows:

I. Mild events: they include local clinical manifestations occurring on the place where the vaccine was administered, and systemic manifestations that are treated on an outpatient basis and leave no after-effects;

II. Moderate events: they include clinical manifestations that, even if they require hospitalization, they represent no risk for the person's life or their after-effects do not affect the person's bodily functions, and

III. Serious events: they include clinical manifestations that put the person's life at risk or clinical manifestations whose after-effects have an impact on the person's bodily functions.

Notice of events temporarily associated with vaccination that are moderate or serious shall be given immediately, or as soon as their existence is ascertained, to the Epidemiology Office of the National Health Department (or its equivalent in the country), as prescribed by said entity.

CHAPTER VI

Extraordinary vaccination

Section 36. The National Health Department (or its equivalent in the country) shall order the extraordinary administration of vaccines in the following cases:

I. When a person has not been vaccinated according to the National Vaccination Scheme;

II. In case of outbreaks or epidemics;

III. When there is danger of entry of transmissible diseases into the national territory,

IV. In case of a natural disaster;

V. When there appears a new infectious agent or an infectious agent deemed controlled or eradicated re-appears, and

VI. Whenever so required, pursuant to applicable international provisions.

Extraordinary immunization measures shall be compulsory for all residents of the national territory.

CHAPTER VII

Professionalization of vaccination practices

Section 37. Vaccines may be administered by physicians, paramedics, nurses and, in general, by any qualified person who:

I. is competent to administer the vaccine, knows the indications and contraindications of the biologic and is able to recognize and treat any immediate reaction, and

II. has medicines and is able to administer them and to handle the necessary equipment to manage an emergency situation or a reaction to the vaccine.

Section 38. Public health staff must participate in vaccination campaigns, whenever national health authorities so require.

If institutional health staff is inadequate, additional staff may be exceptionally hired on a temporary basis. Said staff shall be subject to the relevant guidelines issued by the National Health Department (or its equivalent in the country).

Section 39. The National Health Department (or its equivalent in the country) shall establish the relevant standards and coordinate actions so that permanent training is provided to vaccination staff at different operational or administrative levels in, at least, the following areas:

I. Vaccine classification;

II. Vaccine administration;

III. Possible reactions to vaccines and treatment;

IV. Doses;

V. Cold chain or network;

VI. Epidemiological surveillance, and

VII. Such other areas as may be deemed necessary to ensure the systematic professionalization at all the instances involved in vaccination activities.

Section 40. Public, social and private health institutions within the country shall ensure the appropriate operation of the cold chain or network in all health units and administrative or distribution areas.

To such effect, institutions shall have equipment and trained staff for the storage, preservation, distribution, control and transport of biologics.

Likewise, they shall closely survey the following elements of the cold chain or network:

I. Refrigeration, including cold chambers, refrigerators and vacuum flasks;

II. Temperature record and control;

III. Transport, and

IV. Biologic record and control.

CHAPTER VIII

Sanitary control of vaccination supplies

Section 41. All vaccines used in the country shall comply with the requirements and controls set forth by the National Health Department (or its equivalent in the country), as well as those included herein and other applicable legal provisions.

Other vaccination supplies shall be also be subject to sanitary control, in order to preserve security in the administration of vaccines.

Section 42. The National Regulatory Authority shall be the entity in charge of assessing the quality, effectiveness and security of vaccines, by carrying out studies on, *inter alia*, their power, innocuousness and biological sterility. Said Authority shall be empowered to grant and revoke Sanitary Records.

To the effects of this Law, a Sanitary Record is the instrument whereby the National Regulatory Authority grants an authorization for the use, distribution and commercialization of vaccines within the country.

Section 43. In order to initiate a vaccine's recording process, the National Regulatory Authority shall request such information as may be necessary to prove that the vaccine has passed the investigation, development, production and quality control stages, as well as clinical studies confirming the required quality, security and effectiveness for human use.

The information to be requested by the National Regulatory Authority in order to grant the Sanitary Vaccine Record shall be the following:

I. Legal-administrative information of the requesting company;

II. Information about chemical, pharmaceutical and biological quality;

III. Pre-clinical information, and

IV. Clinical information.

During the assessment process, the National Regulatory Authority shall take into account the Recommendations of the World Health Organization concerning the production and control of the

vaccine involved, as well as Good Manufacturing Practices and the clinical and pre-clinical assessment guides issued by said Organization.

When the same vaccine has been previously authorized by the US Food and Drug Administration or the European Medicines Agency, the National Regulatory Authority shall submit said vaccine to a short recording process.

Section 44. The National Regulatory Authority shall establish mutual acknowledgment schemes with other countries as regards vaccines records, especially with other Latin American countries.

CHAPTER IX

Financial aspects

Section 45. Vaccination campaigns carried out by the public health system shall have the following funding sources:

I. The specific budget appropriations to be annually allocated by the National Congress for the vaccination campaigns provided for herein.

   At least one of said appropriations shall be exclusively assigned for the acquisition of vaccination supplies, including vaccines, another appropriation shall be assigned for improving the Cold Chain or Network and another one for the National Vaccination Program, which shall include the resources for the acquisition and/or maintenance of computing equipment, vehicles, and the payment of vaccinators' fees, etc. In order to determine the budget appropriation for vaccination supplies, the National Congress shall take the resolutions of the Vaccine Advisory Committee as a benchmark for calculating such appropriation.

   The National Congress shall ensure that the resources for vaccination campaigns are allocated in such a way that immunization coverage is not impaired because of financial reasons. Likewise, the Congress shall survey the efficient use of allocated resources;

II. Transfers to be made from Emergency or Disaster Funds to cover the cost of the extraordinary vaccination campaigns provided for herein;

III. Resources assigned to the implementation of the vaccination campaigns provided for herein, in the states or regions of the country;

IV. Resources assigned to the implementation of the vaccination campaigns provided for herein, in the health facilities of Social Security institutions;

V. ____%[4] of the resources obtained from the collection of indirect taxes on health-harming products;

VI. Resources obtained from the ____ [5] draws of the national lottery;

VII. Resources obtained from national and international donations, and

[4] The percentage has not been determined on purpose, since each country shall check whether it has taxes of this kind, and, if so, which is the appropriate percentage to be fixed.
[5] The number has not been determined on purpose, since each country shall analyze which would be the appropriate number of draws.

VIII. Such other kind of regular or exceptional income as may ensure the financial sustainability of vaccination campaigns.

Section 46. The annual budget estimates of the National Health Department (or its equivalent in the country) must include estimates concerning the regular vaccination campaigns provided for herein, pursuant to the resolutions issued therefor by the Vaccine Advisory Committee.

Section 47. The acquisition, sale, national production and import of the vaccines included in the National Vaccination Scheme and those required for extraordinary vaccination campaigns, as well as the acquisition and maintenance of the necessary equipment and supplies for the cold chain or network, shall be exempted from the payment of taxes, contributions and duties.

CHAPTER X

Vaccine acquisition

Section 48. Vaccines included in the National Vaccination Scheme and those required for extraordinary vaccination campaigns shall be considered national security supplies[6] and, as such, they shall not be subject to the provisions regarding regular public acquisitions.

In this sense, exceptional conditions for the acquisition of the above mentioned vaccines may be established, provided said vaccines have passed the sanitary control of the National Regulatory Authority.

The exceptional conditions, if any, that may be established according to this section shall have at least one of the following goals:

I. To secure greater negotiation power with vaccine manufacturers;

II. To reduce administrative and transaction costs incurred in vaccine acquisition;

III. To address a situation that endangers the nation's public health;

IV. To allow the continued supply and administration of biologics, and

V. To facilitate the introduction of new vaccines into the National Vaccination Scheme.

Transparent processes shall be promoted in vaccine acquisitions. Said processes shall be subject to audits by relevant authorities.

CHAPTER XI

Assessment

Section 49. In order to effectively assess the activities provided for herein, the following indicators must be used:

I. Coverage measurement;

II. Epidemiological surveillance;

III. Burden of disease;

IV. Measurement of health condition;

V. Social protection in the health sector;

VI. National Health Accounts, and

[6] Each country shall decide whether or not vaccines are national security supplies.

VII. Technical capacity of human resources.

The National Health Department (or its equivalent in the country) shall issue guidelines related to the use of the above mentioned indicators. One of the goals of said guidelines shall be to ensure the reliability, validity, specificity and sensitivity of the above mentioned indicators.

Section 50. The above mentioned performance indicators shall also be used as a benchmark for the definition of public vaccination policies. Likewise, they shall serve as guarantees of the efficient use of the resources allocated by the National Congress to immunization activities.

CHAPTER XII

Innovation and development

Section 51. The National Health Department (or its equivalent in the country) shall foster the establishment of tax incentives, as well as other promotion mechanisms to encourage and boost the research and development of new vaccines, especially those aimed at treating diseases that are considered important in the public health sphere, both within the country and in the rest of Latin America.

Likewise, the State, through the Health Department and other institutions, shall encourage private sector cooperation and investment in scientific and technological innovation and development in the field of vaccines.

The above mentioned mechanisms and strategies shall contemplate the establishment of alliances with the private sector, in order to encourage vaccine manufacturing within the country.

CHAPTER XIII

Infringements

Section 52. The following actions shall be considered infringements to the provisions of this Law:

I. Hindering the vaccination activities provided for herein;
II. Failing to comply with the technical rules, guidelines and regulations issued pursuant to this Law;
III. Receiving payment for the administration of vaccines included in the National Vaccination Scheme of the public health system,
IV. Selling vaccines intended for vaccination campaigns conducted within the public health system, or obtaining a benefit for said vaccines;
V. Issuing forged Vaccination Cards o Cards with false vaccination records, and
VI. Such other actions as may imply non-observance of any of the provisions included herein.

The infringements provided for herein shall be administratively punished by the National Health Department (or its equivalent in the country), pursuant to applicable regulations, notwithstanding the relevant penalties arising from civil or criminal rules.

CHAPTER XIV

Final provisions

Section 53. All matters not explicitly referred herein for their development in other rules, shall be governed by the regulations or technical provisions issued by the Executive Power, which regulations or provisions shall not conflict with this Law.