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Checklist of Key Principles for Ensuring Legislative, Regulatory, or Ministerial Authority to Implement COVID-19 Vaccine Related Indemnity and Compensation

Receipt of vaccines through the COVAX Facility requires proper legal authority for governments to enter into agreements with the COVAX Facility partners, including Gavi, the World Health Organization (WHO), and vaccine manufacturers. These agreements require countries receiving vaccines to indemnify manufacturers in the event that there is a serious side effect or reaction to a vaccine, a serious adverse event following immunization (SAEFI), with a COVID-19 vaccine and that one or more lawsuits is filed against a COVAX partner. For example, countries receiving vaccines manufactured by AstraZeneca through COVAX may be required to agree to similar language as that contained in the agreement between the EU and AstraZeneca:

> Each Participating Member State shall indemnify and hold harmless AstraZeneca, its Affiliates, subcontractors, licensors, and sub-licensees, and officers, directors, employees and other agents and representatives of each (collectively, the "Indemnified Persons") from and against any and all damages and liabilities, including settlements for which the Indemnifying party has given its consent pursuant to Section 14.2, and necessary legal costs relating to, resulting from or associated with claims for death, physical, mental, or emotional injury, illness, disability, or condition, fear of the foregoing, property loss or damage, and business interruption of the injured party or a Related Person of such injured person (together, "Losses") relating to or arising from the use or administration of the Vaccine shipped or allocated to its jurisdiction.[1]

Similarly, proper legal authorizations may be required to allow compensation to be paid to those suffering SAEFIs through a specialized program administered by the World Health Organization.

Therefore, countries choosing to receive vaccines through COVAX must be able to show that they may legally indemnify COVAX partners, including manufacturers, and they must be able to show that they comply with all of the requirements of WHO's compensation system, if they wish their citizens to have access to that means of compensation for SAEFI.

This checklist is intended to assist countries identify the legal authorizations that may be used to fulfill these requirements. These legal authorities may be found in the constitutional text, in legislation, in regulations that may be issued by a proper authority, or by decree of the executive or authorized ministry. The checklist is supported by, and may be cross-referenced with, the accompanying document, *Indemnity and Compensation - Precedential Laws, Regulations, and Executive Decrees*

[1] This language is provided in the accompanying document, *Indemnity and Compensation - Precedential Laws, Regulations, and Executive Decrees*

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These legal authorities may and frequently do exist within general laws. They may be found in laws related to public health and public health emergencies, laws relevant to the procurement of goods and services for the public, and laws specific to immunization. Some governments have adopted additional rules specific to COVID-19, although these may not be necessary to fulfill the conditions required for receipt of COVID-19 vaccines through the COVAX Facility.

The checklist below provides steps for legal review that may be taken to ensure that proper authority exists to enter into agreements with COVAX Facility partners, including Gavi, vaccine manufacturers, and WHO. Relevant laws may be found in more than one of these general areas, and proper authority may be codified in more general laws like those authorizing the president or executive to act during an emergency. Laws identified should still be reviewed against the national constitution, which may impose limits on borrowing, public finance, or relinquishment of legal claims by individual citizens.

A. Public Health Legislation, Statutes, Regulations, Decrees, and Similar Enactments

1. Review national public health statutes and legislative enactments, where applicable, for broadly worded authority to enact measures through decrees by the executive including the minister of health. In some countries, these measures have included commitments to compensation for those suffering adverse events from immunizations and promises of indemnity to those properly registering medicines and vaccines during a public health emergency.[2]

2. Broadly worded authorizations may be phrased in various ways, for example: "The Minister shall have power, by statutory instrument, to make regulations generally for the carrying out of the purposes of this Act"; the "Minister of Health may by legislative instrument, make Regulations to provide for ... any matters necessary for the purposes of vaccination." and/or "The Ministry of Health . . . will act as supervisory authority in the selection of the [vaccine] product, the suppliers and the necessary conditions . . ." These types of authorizations have been used to enact provisions for compensation and indemnity.[3]

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[2] See *Indemnity and Compensation - Precedential Laws, Regulations, and Executive Decrees* document. For compensation, see DECREE of the PRESIDENT of the LAO PEOPLE'S DEMOCRATIC REPUBLIC On the Promulgation of the Immunization Law No. 211/PO. For indemnity, see New Zealand Public Finance Act (1989) Section 65ZD.

[3] **Costa Rica**: "The National Law on Emergency Management and Risk Prevention, Law Number 8488 of 22 November, 2005, section 29, establishes that the Executive Branch, in the face of public calamities caused by acts of man or nature, whether unforeseeable or inevitable if foreseeable, and which cannot be controlled, managed, or subdued through the use of the ordinary authorities of the Public Administration, possesses the authorities to declare a national emergency in order to integrate and define the functions of all bodies and entities, whether public or private, in order to provide a solution, consistent with the scale of the disaster. Furthermore, section 31 of the aforementioned Law, establishes that a declaration shall allow for the exceptional measures for the state of necessity and urgency, as a function of its nature, and, accordingly, the Government is granted the capability to expeditiously obtain sufficient economic, material, and other resources in the aid of endangered people, property, with the duty of ultimately accounting for any and all actions as it may take"; **Ghana** Public Health Act (2012) Section 31: "The Minister legislative instrument, make Regulations to provide for . . . any other matters necessary for the purpose of vaccination."

3. "Indemnity" and "immunity" under the law have different meanings. When a country promises "indemnity", it means that it will reimburse a person, business, or other organization for certain costs. These costs may be comprehensive such as all costs associated with legal proceedings (legal defense fees and any potential judgments or settlements) or a partial indemnity specified by agreement. "Immunity" means that no legal proceedings may be commenced by a party against the person entitled to that legal "immunity". Laws may provide for either or both of these alternatives for government action. The Gavi agreement requires that a receiving country grant unlimited indemnity.

4. The process for indemnity should consider, for example, how a COVAX partner seeking indemnity should give notice when seeking indemnity and what information must be provided. For example, a manufacturer seeking indemnity when defending a lawsuit may need to notify a specific person or office within the ministry of health or the ministry of finance and include details such as the date and details of the legal claim, estimated legal costs, and currency in which indemnity must be paid.

5. Related to the process for indemnity payment specified above, countries should make clear that the official authority who signs or affirms the agreement with Gavi or COVAX Facility partners can show that she or he possesses the required legal authority, including consultations with other ministers, other law-makers, or the executive of the country.

6. If the statute or enactment provides broadly worded authority, there are numerous examples from regulations issued by ministries of health that may provide direction as to compensation and/or indemnity: Argentina, Colombia, Costa Rica, Lao DPR, Malaysia, Nepal, New Zealand, the Philippines, Singapore, the United Kingdom, and Vietnam.

7. Public health statutes may authorize government officials to designate certain parties like medical providers or others involved in vaccination campaigns as their official agents, thus affording them otherwise available immunities from legal liability when undertaking measures related to vaccination. For example, the Minister of Health may designate foreign health or aid workers from international non-government organizations as authorized to deliver immunizations to their population. The public health law may separately provide that those administering immunizations during emergencies may not be liable for any injury caused, whether from the vaccine itself, or from its administration. That person would then not be liable to answer for damages in a lawsuit. The same protection may be afforded to vaccine suppliers, distributors, and others.

8. Some countries have required that manufacturers registering vaccines with a national authority must submit a risk management or similar plan to identify and address serious adverse events following immunization (SAEFI). These requirements may be used as part of fulfilling conditions required by the COVAX Facility. Chile, for example, in its agreement with Pfizer, has required that manufacturer to submit a Risk Management plan with respect to pharmacovigilance. Such a risk management plan could include assurances as to quality and manufacturing processes by the manufacturer and, in turn, establish indemnity for claims that arise outside of those promises.[4]

9. The public health laws in some countries provide for authority pursuant to the import of medicines. For example, the Minister of Health may be empowered by a public health law to provide assurances or impose conditions pursuant to authority to import medicines and vaccines.

B. Public Procurement Legislation, Statutes, and Regulations

1. Many commitments and promises of indemnity to date have been authorized through the law of public procurement, including authority dedicated to the Minister of Finance. Those laws specify the authority of the national government to make a number of commitments to private parties from whom goods and services are purchased, including indemnity.

2. For some countries without an applicable public procurement law, countries' legislatures have passed specific legislation to authorize the Ministry of Health to enter into contracts that provide for indemnity.[5]

3. Those laws may also impose limits on what the governments may promise. New Zealand law, for example, allows the Minister of Finance to give promises of indemnity up to $10 million if s/he determines it is in the public interest to do so. However, for indemnities exceeding $10 million, the Minister must provide a statement detailing the reasons and details to the legislature. The Gavi agreement requires that a receiving country grant unlimited indemnity.

[4] "Pfizer Chile S.A. must implement the Risk Management Plan presented in the authorization request, and must update it with the information as necessary. Said updates must be submitted in a timely manner to the Pharmacovigilance Subdepartment of this institute, through the established channels."

[5] Argentina, Law on Vaccines Intended to Generate Acquired Immunity against Covid-19, Executive Decree 260/20, its amendment and administrative decision 1,721 / 20, authorizes the Ministry of Health to enter into such contracts. See *Indemnity and Compensation - Precedential Laws, Regulations, and Executive Decrees* document.

4. Where special contracts for procurement are authorized, they also include terms such as allowing arbitration to resolve disputes, to designate which country's law may apply, and/or to designate a specific administrative authority to oversee the implementation of the procurement agreement. Countries should pay particular attention to the steps that must be taken in order to establish a legal claim and how an arbitration panel may be comprised. Colombia's law, for example, requires a decision by review committee on the existence of causal link between adverse event and administration of vaccine.

5. The foregoing authorizations have in some cases been limited to those vaccines procured by the national Ministry of Health. If private organizations or provincial governments endeavor to procure vaccines, they may not be protected by such laws, and further regulations may be necessary. For example, under Argentina's law, indemnity and dispute resolution provisions are limited to those contracts entered into by the Ministry of Health.

6. The language covering indemnity must be considered. Some countries have extended indemnity for all serious adverse events following immunization (SAEFI) except those attributable to malicious or willful misconduct. Others have also provided exceptions to indemnity when negligence on the part of the manufacturer is shown.

C. Immunization Legislation, Statutes, and Regulations

1. For countries with immunization-specific legislation, those laws may provide for the responsibility of the state for serious adverse events following immunization (SAEFI).

2. The legislation may provide that the national government is responsible for compensating adverse effects following immunization, and may not directly address indemnity.

3. Those laws provide for the establishment and/or role of a national immunization technical advisory group (NITAG), which advises the government on procurement, safety, monitoring, risk management and other conditions for providing access to vaccines and post-administration procedures.

4. Immunization specific laws may provide how immunization activities are funded and the wording of these laws may allow authorization of indemnity to vaccine-related parties as part of the procurement and distribution process.

5. Authorization for compensation or indemnity may be phrased in law as a right held by citizens, a duty owed by the government, or both. For example, "The State shall ensure that every [citizen] required to be immunised under this Act or any other related law, has access to vaccines."

6. The process for those suffering serious adverse events following immunization (SAEFI) should be specified, in addition to, or in emphasis of national programs for post-immunization monitoring and reporting.

D. Components of Compensation Systems

1. For countries that do not already possess compensation schemes for SAEFI, or do not plan to establish them, the World Health Organization has established a no-fault compensation system that will be administered subject to the acceptance of conditions by countries that choose to join it.

2. In order to make this system available to their citizens, countries must agree that their laws permit the payment facilitated by WHO as full and final settlement of any and all claims.

3. If their laws do not so currently provide, countries wishing to join the WHO system must determine which legal steps are necessary, for example a new law or decree, to establish the enforceability of the finality of a WHO-facilitated payment.

4. For countries that wish to establish their own compensation systems, the following factors are relevant:

5. The process for identifying and compensating those suffering serious adverse events following immunization (SAEFI) should be formed in partnership with the country's national immunization technical advisory group (NITAG). Many countries, as a condition of procurement and import, have required manufacturers to submit a plan of risk management to the NITAG and work closely with it.

6. Global surveillance systems should be used to regularly update information about SAEFI associated with COVID-19 vaccine administration and to allow affected individuals to make compensation claims on the basis of such surveillance data.

7. Those suffering SAEFI may be required to demonstrate a causal link between the vaccine and the relevant damages. In most countries with no-fault compensation systems, those suffering injuries associated with vaccine administration generally do not need to prove negligence, fault, or product defect.

8. The evidentiary standard for awarding compensation must be determined. Some countries do not require strict proof of causation, and instead rely on a more lenient standard that requires proof of injury proximate in time to vaccination.

9. Countries may make use of existing administrative and bureaucracies, like national social security funds or worker compensation systems, to receive, process, and administer vaccine injury claims.

10. These administrative bodies generally include representation from diverse stakeholders.

11. Within these administrative bodies, specific decision making panels may be comprised. Those panels may be composed of experts from law and medicine.

12. Submissions for compensation may be based upon intake forms.

13. Generally, submission of forms should not require payment or legal assistance.

14. Compensation systems may specify timelines for processing claims and rendering decisions. To date, these timelines range from 60 days after vaccine administration (Honduras) to 36 months after a 2-year window after a vaccine was authorized for a given market (World Health Organization/ESIS).

15. Compensation systems may allow victims to appeal decisions within the compensation system and finally through a court system (adequate legal remedies).

16. The level of compensation must be considered relative to the severity of the injury, access to care and its anticipated costs to the individual, and the purchasing power of the financial award in the country in which the adverse event occurred.

17. Systems may cover a reasonably broad class of damages, including death, injury, disability, pain and suffering, and other forms of economic and non-economic loss resulting from the injury.

18. The level of compensation offered by the system may be considered along with other governmental arrangements (e.g., social security programs).

19. Financing options may include per dose fees, set-asides from budget allocations to procurement, and contributions from manufacturers.

20. Systems may cover injuries resulting from Covid-19 vaccines as well as other classes of vaccines, but specific designation of COVID-19 vaccines may be required in order to fulfill conditions of receipt for vaccines procured through the COVAX Facility.