

# Immunization Financing Legislation and Regulation

## KEY POINTS

- \* Immunization advocates consider legislation to be a powerful tool in support of sustainable immunization financing because it provides a legal commitment to immunization and an operational framework for immunization services.
- \* Legislation can be effective only if it is enforced and implemented by the government.
- \* Immunization legislation frequently includes three types of legal provisions: operational, declarative, and financial.

TO MANY IMMUNIZATION advocates, immunization legislation is a potentially powerful tool in support of sustainable immunization financing. Legislative action can provide a legal commitment to public funding of immunization, which can help secure adequate financing and promote accountability and transparency. The Global Vaccine Action Plan 2011–2020 recommends ensuring “legislation or legal framework in all countries, including provision for a budget line for immunization, and for monitoring and reporting” to support the strategic objective that all countries commit to immunization as a priority. Legislation can also provide a legal framework for the operation of immunization programs, including how vaccines are added to the national immunization schedule and who has regulatory oversight.

Explicit legislation can also help clarify legal frameworks for the procurement of vaccines and injection supplies. Some countries in Latin America, for example, have legislation that explicitly provides for procurement through the Pan American Health Organization (PAHO) Revolving Fund. Other countries have procurement regulations that restrict payment in advance of delivery, making it difficult for ministries to procure vaccines and injection supplies through UNICEF Supply Division.

Immunization legislation varies across countries. Some countries have separate immunization laws; others legislate immunization through provisions within general health acts or public health laws. Countries have also taken different approaches to the legislation

of immunization financing. In Vietnam, the Law on Prevention and Control of Infectious Diseases guarantees “funds for the use of vaccines and medical bio-

products,” while Bolivia’s Law on Vaccines mandates that a specific share of earmarked funds for health go toward vaccines and associated syringes and operational costs. Some laws, such as Georgia’s Public Health Law, require the financing of vaccines in the national immunization schedule; others, such as Panama’s Law 48, enshrine access to vaccines in the national immunization schedule as a legal right for all citizens.

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Legislation is only as strong as its enforcement and implementation, however. The adoption of an immunization law is not in itself a guarantee of sustainable financing. It might be only a milestone on the road to sustainable immunization financing.

This brief examines legal provisions in immunization legislation enacted by various countries and discusses recent efforts by the Sabin Vaccine Institute and by PAHO and the Latin American Parliament to promote sustainable immunization financing through legislative action.

### COMMON PROVISIONS IN IMMUNIZATION LEGISLATION

Immunization legislation can include a variety of provisions. According to a 2013 study by Trumbo et al. that analyzed immunization legislation in 24 countries and three territories in the Latin America and Caribbean region, the most common provisions fall into three categories: declarative, operational, and financial.

Declarative provisions establish legal rights and duties relating to access to immunization. Some countries mandate universal access to immunization for all citizens; some adopt legislation recognizing immunization as a public good. Many countries establish clauses guaranteeing free and universal access to vaccines in the national immunization schedule. Legislation can also establish a legal duty to vaccinate and call for mandatory vaccination for adults and children (particularly in the context of school enrollment).

Operational provisions in immunization legislation provide a legal framework for public health authorities relating to

immunization. These provisions may establish regulatory oversight of immunization programs to ensure that vaccines are administered in accordance with legislative directive. They may require a legally chartered national immunization technical advisory group (NITAG). In countries with mandatory vaccination, operational provisions may set legal penalties for individuals who fail to comply.

Immunization legislation often includes an operational provision that governs the national immunization schedule. Such a provision usually defines the process by which vaccines are introduced and removed from the schedule, who is empowered to make the decision, what the decision-making criteria are, who has oversight over the decision-making process, and so on. These elements are critical for both routine vaccine delivery and the financial needs of national immunization programs.

Financial provisions establish the legal framework for immunization financing. They might establish explicit line items within the national budget for the procurement of vaccines and for other elements of the immunization program; identify the procurement mechanisms that must be used; and guarantee tax exemptions for the purchase and importation of immunization materials (including vaccines and cold chain equipment).

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Financial provisions might also establish the sources of immunization financing. Many countries have adopted legislation declaring that the government must pay for immunization, but immunization laws typically do not define the mechanism by which immunization should be financed.

### EFFORTS TO SUPPORT IMMUNIZATION LEGISLATION

The Sabin Vaccine Institute's Sustainable Immunization Financing (SIF) Program has supported efforts by immunization advocates and policymakers in 22 countries to develop or update immunization legislation. The program convenes national and subnational briefings for policymakers, parliamentarians, and other government officials and facilitates peer-to-peer exchanges, workshops, and meetings on achieving sustainable immunization financing. To date, the program has guided three countries in passing laws that mandate public funding for immunization.

The SIF Program recently worked with immunization advocates to push for Nepal's Immunization Act, which became law in 2016. The law outlines a fiscal framework for the country's immunization program, including financing provisions. As of August 2016, six other SIF countries had adopted immunization legislation.

In 2010, the Latin American Parliament, in conjunction with PAHO, developed a model vaccination law that could serve as a framework and template for revisions to existing legislation in Latin American countries or as the basis for new legislation. The law includes declarative, operative, and financial provisions that can be tailored to suit particular countries.

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### SOURCES AND FURTHER READING

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