Pharmaceutical services in immunization: Contributions, experiences, and implementation in the Americas region

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DECLARATION OF CONFLICT OF INTEREST

The authors and editors of this document declare that they have no actual, potential, or apparent conflicts of interest related to this publication.

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Foreword

The contributions of vaccinations to public health have an indisputable health, social, and economic dimension. According to the World Health Organization (WHO), vaccination is second in importance only to drinking water. Vaccines, or rather vaccinations, are therefore of unparalleled importance for the sustainability and efficiency of health systems, as well as for the well-being of communities and the prosperity of all countries.

However, we note that vaccination rates against several diseases remain below those recommended by the WHO and other international agencies. While it is true that most countries have established successful and efficient childhood vaccination programs, there is still some way to go not only to achieve high rates of herd immunity against several diseases, but also to achieve equity in access to vaccinations throughout life.

As a result of global population aging, susceptibility to vaccine-preventable diseases is increasing, as are the potential complications associated with them. Diseases such as COVID-19, influenza, pneumococcal disease, herpes zoster, and pertussis are major causes of morbidity and mortality in the elderly, where the importance of vaccination is often underestimated. It is therefore of utmost importance to increase attention to vaccinations throughout the life course and to ensure access to vaccines that are relevant for each age group.

At the end of 2020, the WHO published the Immunization Agenda 2030 (IA2030). This document outlines the axes for a global immunization strategy for the next ten years, and it has as its cardinal principle equity of access to vaccines, reflected in the subtitle (and vision) of this document: “A global strategy to leave no one behind.” It recommends that all Member States take steps to ensure that every person has access to the vaccines needed to maintain the highest attainable standards of health and well-being. It also proposes that vaccination should be considered a fundamental right of all people.

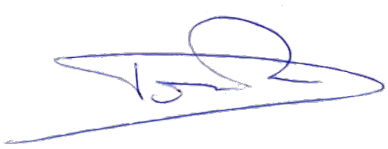
Expanding vaccination coverage rates and leaving no one behind means enabling and diversifying access to vaccination services by utilizing and optimizing existing resources through the efforts of all health professions.

In full harmony with these principles, the International Pharmaceutical Federation (FIP) has been promoting, for years, a greater role for the pharmacy profession in vaccination strategies. Pharmacists play an essential role in raising awareness and acceptance of vaccines and in providing a convenient access to vaccination services. Indeed, because of their accessibility and distribution, community pharmacies and pharmacists are ideally places to offer these services. With their expertise and knowledge of diseases and vaccines, pharmacists also play an important role as educators of the population; they are well placed to address vaccine-related concerns and reluctance and to provide evidence-based advice to the public. In addition, by contributing to higher vaccination rates, pharmacists will also be contributing to the reduction of antimicrobial resistance, among other public health goals related to immunization.

However, while pharmacists in several countries have full authority to prescribe and administer vaccines, many other countries have present barriers to the full use of pharmacists in the provision of vaccination services; these range from regulatory barriers and limited acceptance by other health

professions to the lack of adequate financing models for vaccines and vaccination services provided by pharmacies to ensure sustainability and equitable access to vaccinations services.

The Pharmaceutical Forum of the Americas (FFA) has, for many years, played a leading role in the development of the profession in the region by promoting integrated professional services in primary health care. Through its network, activities, and publications, the FFA represents an excellent platform for sharing innovations and strategies to make the profession increasingly relevant and valuable to health teams and health systems. With this new publication, FFA takes a new step forward to encourage pharmacists in the region to accept, claim, and adopt a greater role in the promotion of vaccination. FIP congratulates the FFA and pledges to continue working together to achieve this goal.



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Summary

Immunization has contributed enormously to global public health. The pharmacist is a professional involved in different stages of the immunization chain and is prominent the provision of pharmaceutical services. This technical report is based on a literature review of primary and secondary sources, including documents from international organizations, such as the International Pharmaceutical Federation, the World Health Organization, and the Pan American Health Organization. In addition, pharmacy professionals in the Latin American region were contacted with the aim of completing a data collection instrument designed for the purpose of systematizing the experiences of each of their countries regarding the participation of pharmacists in issues related to vaccines. This document is structured as follows:

- **Chapter I. Introductory framework.** Relevant basic concepts are described, including the benefits, impact, and barriers of immunization in general and vaccination in particular.
- **Chapter II. Successful experiences of pharmacists as immunizers at a global level.** Examples are given of successful experiences or aspects related to the subject and documented in the literature.
- **Chapter III. Successful experiences of pharmacists in Latin America in the field of vaccines.** The experiences of different Latin American countries in the field of vaccines are presented, highlighting aspects of success, according to information provided by the pharmacy professionals consulted and cases documented in the literature.
- **Chapter IV. Management of pharmaceutical services in the immunization chain.** The aim is to show the areas of application of immunization in the pharmacist's work and to provide useful tools for the implementation of pharmaceutical immunization services.

In conclusion, the experiences and successes related to the participation of pharmacists in vaccination and pharmaceutical services in immunization in Latin America are heterogeneous and vary depending on the situation in each country. In addition, the need to generate more evidence on this topic was noted. This technical document is intended to be a tool for the implementation of pharmaceutical services for immunization in the region.

Keywords. Immunization, Latin America, pharmacist, pharmaceutical services in immunization.

Limitations

Among the main limitations related to the elaboration of this technical document, the following are considered relevant: a response was obtained from 45% of the professionals contacted and, in some cases, the information provided was scarce. Furthermore, the literature review did not find any further data that could complement the information related to successful experiences of pharmacist´s participation in vaccinations and/or pharmaceutical services in immunization.

CHAPTER I
INTRODUCTORY FRAMEWORK

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1. BASIC CONCEPTS

For the purposes of this paper, a number of basic concepts are defined that are important for the understanding of the subject:

The **immune system** incorporates a complex interplay of mechanisms whose purpose is to identify "foreign or alien" substances, known as antigens, in order to protect the body, either through the production of antibodies or immunoglobulins, or through cell-mediated immune responses that facilitate the elimination of these substances (1).

Immunization is the process by which a person or animal is protected against a disease (2).

The various immune mechanisms that humans possess to protect against infection and disease can be actively acquired or passively generated, as described below (1):

- **Active immunity** against an infectious agent requires a prior stimulus that may be triggered by clinical or subclinical infection or by an antigen that the body recognizes as foreign. This elicits an immune response and generates specific protection against that agent. Vaccines are a form of actively acquired immunization (1, 2).

- **Passive immunity** protects the newborn when antibodies are transferred by the mother via the placenta or through ingestion of substances present in colostrum or breast milk. It is also acquired by administering human immunoglobulins, prophylactically or therapeutically, to prevent or mitigate the consequences of infections caused by specific agents (1, 2).

Based on the above concepts, the term **immunobiological** incorporates the following types of products, which exert an effect on the immune system by eliciting protective responses against specific agents in the body (1):

- **Toxoids:** These are modified toxins of bacterial origin that have lost their ability to cause disease but retain their antigenic power (i.e., they generate a protective immune response in the body) (1-3).

- **Immunoglobulins** (Ig)**:** These are macromolecules generated by the immune system in response to the presence of an antigen (1, 2). They are obtained by fractionation of large quantities of a sterile solution of human antibodies and are used as maintenance therapy for some immunodeficiencies or for passive immunization following exposure to disease. An antitoxin is a solution of antibodies obtained from the serum of animals immunized with specific toxins and is used for passive immunization or for treatment. Specific (hyperimmune) immunoglobulin is a special preparation of Ig obtained from plasma from donors pre-selected as having high levels of antibodies against specific diseases (e.g., immunoglobulins against hepatitis B, varicella zoster, rabies, or tetanus). They are used in special circumstances for passive immunization (1).

- **Vaccines:** These are suspensions of live, inactivated, or killed microorganisms, fractions thereof, or protein particles. When administered, they induce an immune response that prevents the disease against which they are directed (1, 2).

Vaccines, like other medicines, go through very rigorous development processes and evaluations for safety and efficacy. They are initially studied in animals and then tested in human clinical trials before being licensed for mass application in the population (1).

Vaccines are classified as (1):

- **Live attenuated** vaccines**:** These are vaccines that result from the modification of a live virus or bacterium that has been weakened by a technological laboratory process. These vaccines are more labile when exposed to temperature changes (1,2). Being live, they interfere with circulating antibodies; therefore, to be effective, they must replicate in the body and provoke an immune response similar to the natural infection but without producing clinical manifestations. Attenuated vaccines can be (1):

    - **Bacterial:** such as the vaccine that protects against tuberculosis (BCG) (1)
    - **Viral:** such as the measles, mumps, rubella (MMR) vaccine, the oral polio vaccine (Sabin), or the varicella (chickenpox) vaccine (1)

- **Whole-cell or fractionated inactivated vaccines:** These are produced by growth of the disease-causing bacteria or virus in a culture medium, followed by inactivation by heat or chemicals (1,2). When inactivated, the agent dies and cannot replicate, so it cannot cause disease and if not affected by the presence of circulating antibodies. Inactivated vaccines can be derived from (1):

    - **Whole cells**, whether of viral origin, such as hepatitis A vaccine, inactivated polio vaccine, trivalent influenza vaccine, and rabies vaccine, or of bacterial origin, such as whole-cell pertussis vaccine (1).
    - **Fractionation,** where the infectious agent is treated to purify only one of its components; these vaccines are subdivided into two types (1):

        - **Protein-based**: These include toxoids prepared from toxins obtained from bacterial cultures that are chemically or thermally modified (e.g., tetanus toxoid and diphtheria toxoid) and subunits developed from virus or bacterial fractions, such as the hepatitis B vaccine that is made from the surface antigen of the virus or the acellular pertussis vaccine (1).
        - **Polysaccharide-based**: These are composed of pure polysaccharides from the bacterial cell wall (e.g., the 23-valent pneumococcal vaccine or the meningococcal vaccine), or they may be conjugate vaccines if the polysaccharide is chemically linked to a protein (e.g., the 7- or 13-valent pneumococcal vaccine and the *Haemophilus influenzae* type b vaccine) (1).

Vaccines are composed of (1):

- **Suspension liquid:** These can be as simple as distilled water or saline or as complex as the biological medium in which the immunobiological product was produced (1,4).
- **Preservatives, stabilizers, and antibiotics**: These components are used to inhibit or prevent bacterial growth in viral cultures or in the final product or to stabilize the antigen (1,4). These are substances such as thimerosal and/or specific antibiotics (e.g., neomycin in the MMR vaccine) (1).

- **Adjuvants:** Some vaccines with killed micro-organisms and fractions also contain added aluminum, alum, or calcium compounds to increase the immune response. This in immune response occurs because the adjuvant slows the absorption of the antigen, thereby exposing it to the immune system for a longer time (1).

Definitions of immunization chain, pharmaceutical immunization service, and pharmaceutical care

For the purposes of this document, the following definitions of concepts discussed in later chapters are presented:

- **Immunization chain:** This refers to the sequence of interrelated processes from the conception and development of immunization products to their use by users and patients (5-8).

- **Pharmaceutical immunization service:** This refers to the set of actions in the health system developed or coordinated by the pharmacist to ensure comprehensive, continuous, and timely care of immunization needs against vaccine-preventable diseases, both at the individual and collective level. The objective is to achieve concrete results in public health, with a view to improving the quality of life of users (9).

- **Pharmaceutical care in immunization services:** This is the set of activities carried out by the pharmacy professional in order to achieve access, care, and follow-up for users of their services for vaccine-preventable diseases (9, 10).

2. BENEFITS AND IMPACT OF IMMUNIZATION

Immunization, in particular vaccination, has contributed to and had a considerable impact on global health (11). It is one of the most effective measures in public health because the generation of an immune response reduces the possibility of contagion; therefore, it is capable of preventing and even eliminating diseases. In addition, immunization is a high-impact strategy because it causes a population protection effect called “herd immunity,” which reduces the likelihood of infection even in susceptible individuals who reside in communities that have a high level of immunity (1).

The impact of immunization, in terms of reducing disease incidence and mortality in the population, depends critically on the existence of an effective and safe vaccine and an immunization program that ensures that high vaccination coverage is achieved and maintained in the population groups in which the transfer of infection is sustained (12).

The main benefits of introducing immunization programs are (13):

2.1. Disease eradication and control (13).
2.2. Herd immunity (13).
2.3. Prevention of related diseases and cancer (13).
2.4. Reduction of antimicrobial resistance (13).
2.5. Positive impact on social systems (13).

2.1. Disease eradication and control.

Unlike many other public health interventions, vaccines help people stay healthy, thereby helping to remove a major obstacle to human development. Moreover, they benefit not only individuals, but also communities and even entire populations (14). For example, vaccines have eradicated smallpox and reduced the number of polio cases by 99% (13).

Vaccines have also reduced associated morbidity and increased quality of life. This is especially relevant in chronic patients, who are more susceptible to developing complications from their disease (13).

In addition, for most vaccines, the impact on communities and populations is more rapid compared to other health interventions. In this regard, vaccines are estimated to have prevented more than 100 million cases of immunization-preventable diseases, such as polio, measles, rubella, mumps, hepatitis A, diphtheria, and pertussis, since 1924 (15).

Similarly, between 2000 and 2007, for example, the global measles mortality was reduced by 74% (from 750,000 to 197,000 cases). New vaccines against pneumococcal disease and rotavirus are now expected to have a rapid impact, within three to five years, in reducing the high burden of disease, disability (due to pneumococcal disease), and under-five mortality (14).

2.2. Herd immunity.

Vaccines offer protection not only to the vaccinated individual, but also to the rest of the community (1,13).

2.3. Prevention of related diseases and cancer.

Vaccines have been shown to offer protection not only against the target disease, but also against related diseases. For example, the influenza vaccine confers protection against otitis, the measles vaccine against dysentery or pneumonia, and, as is well known, the human papillomavirus (HPV) vaccine protects against various types of cancer (13).

2.4. Reduction of antimicrobial resistance.

Vaccination is a preventive strategy; therefore, it prevents infection and the corresponding use of antibiotics. This can aid in preventing the emergence of drug resistance; for example, vaccination against influenza can reduce antibiotic use by up to 64% (13).

2.5. Positive impact on social systems.

Vaccines reduce the costs of vaccine-preventable diseases, including indirect costs due to lost productivity, work incapacity, school absence, lost tax revenues, and improved social cohesion (13).

According to World Health Organization (WHO) data, immunization, even with the most expensive vaccines, remains a cost-effective investment (14). In addition, it promotes economic growth and other savings for society (the prevented mortality and morbidity translate into long-term cost savings and potential economic growth), prevents cancer and related diseases, and decreases the severity of infections and progression to chronic stages, among other benefits (16).

3. GLOBAL VACCINATION COVERAGE

Vaccination rates and coverage are the main indicators of the successful implementation of vaccination programs. Conversely, low numbers can be a public health problem (13).

According to the WHO, global vaccine coverage—the proportion of children worldwide who receive the recommended vaccines—has remained unchanged in recent years (17) (**Table 1**).

Table 1. Status of vaccination coverage of vaccine-preventable diseases

Vaccine-preventable disease	Global vaccination coverage status
Diphtheria, tetanus, and pertussis (DTP)	Diphtheria is an acute bacterial disease that can lead to airway obstruction; pertussis is an acute respiratory tract disease caused by *Bordetella pertussis*, with consequences such as pneumonia and neurological complications (17). In 2019, 14 million infants did not receive an initial dose of DTP vaccine, pointing to lack of access to immunization and other health services, and another 5.7 million were only partially vaccinated. Of these 19.7 million children, more than 60 per cent live in 10 countries: Angola, Brazil, Democratic Republic of Congo, Ethiopia, India, Indonesia, Mexico, Nigeria, Pakistan, and the Philippines (17).
Haemophilus influenzae type b (Hib)	*Haemophilus influenzae* type b (Hib) infection causes meningitis and pneumonia. By the end of 2019, the Hib vaccine had been introduced in 192 countries. Global coverage with three doses of Hib vaccine is estimated at 72%, although large disparities exist between regions. In the South-East Asia Region, coverage is 89%, while in the Western Pacific Region, it is only 24% (17).
Hepatitis B	Hepatitis B is a viral infection affecting the liver (17). By the end of 2019, hepatitis B vaccination of infants had been introduced nationwide in 189 countries. Global coverage with three doses of hepatitis B vaccine is estimated at 85%. In addition, 109 countries have introduced newborn vaccinations, with one dose in the first 24 hours of life. Global coverage is 43% and is as high as 84% in the Western Pacific Region. By contrast, in the African Region, it is estimated at only 6% (17).
Human papillomavirus (HPV)	Human papillomavirus (HPV) is the most common viral infection of the reproductive tract and can cause cervical and other cancers, as well as genital warts in both men and women (17). By the end of 2019, the HPV vaccine had been introduced in 106 countries; in three of them, only in parts of the territory. This was the largest year of increase (+15%) since the HPV vaccine reached the market in 2006. However, as many countries have not yet introduced the HPV vaccine and because vaccine coverage is suboptimal in many other countries, global coverage of the final HPV dose is estimated at 15% (17). In 2019, 33 countries also started vaccinating boys against HPV (17).

Vaccine-preventable disease	Global vaccination coverage status
Measles	Measles is a highly contagious disease, caused by a virus that usually causes high fever and rash, and can lead to blindness, encephalitis, and death (17). By the end of 2018, 86% of children had received a dose of measles vaccine by the age of 2 years. Moreover, 171 countries had included a second dose as part of routine immunization, and 69% of children received two doses, in accordance with their country's immunization schedule (17). By contrast, by the end of 2019, 85% of children had received a dose of vaccine against this disease by the age of 2 years. Moreover, 178 countries had included a second dose as part of routine immunization, and 71% of children had received two doses, in accordance with their country's immunization schedule (17).
Meningitis A	Meningitis A is an infectious disease that can cause severe brain damage and is often fatal (17). Prior to the introduction of MenAfriVac in 2010—a vaccine developed in collaboration with the Serum Institute of India, through the WHO Meningitis Vaccines Project and the Program for Appropriate Technology in Health (PATH)—meningitis due to serogroup A accounted for 80–85% of reported meningitis epidemics in the African meningitis belt. In 2012, MenAfriVac was the first vaccine to be approved for use without a cold chain during campaigns (up to four days without refrigeration and at temperatures up to 40°C). By the end of 2019, nearly 350 million people in 24 of the 26 countries in the meningitis belt had received the MenAfriVac vaccine in different campaigns. In order to sustain the highly positive impact of these campaigns, Ghana and Sudan were the first two countries to integrate MenAfriVac into their routine vaccination program in 2016. They were followed by Burkina Faso, Central African Republic, Chad, Mali, Niger, and the Central African Republic in 2017; Côte d'Ivoire in 2018; and Gambia and Nigeria in 2019 (17).
Mumps	Mumps is a highly contagious viral disease that causes painful swelling on the sides of the face and under the ears (the parotid glands), fever, headache, and muscle aches. It can lead to viral meningitis (17). By the end of 2019, the mumps vaccine had been introduced nationwide in 122 countries (17).
Pneumococcal diseases	Diseases caused by pneumococci include pneumonia, meningitis, and febrile bacteremia, as well as otitis media, sinusitis, and bronchitis (17). By the end of 2019, the pneumococcal vaccine had been introduced in 149 countries (in three of them, it had been introduced in parts of the territory), and global coverage of the third dose was estimated at 48% (17).
Poliomyelitis	Poliomyelitis is a highly infectious viral disease that can cause irreversible paralysis (17). In 2019, 86% of infants worldwide received three doses of polio vaccine. In 2019, the percentage of infants who had received the first dose of inactivated polio vaccine (IPV) in countries still using oral polio vaccine (OPV) was estimated at 82% (17). Polio, the target of global eradication efforts, has been eliminated in all countries except Afghanistan and Pakistan. Until poliovirus transmission is interrupted in these two territories, all others remain at risk of importing the virus, especially vulnerable countries with weak public health and immunization services and with trade links where the disease is endemic or receiving travelers (17).

Vaccine-preventable disease	Global vaccination coverage status
Rotavirus	Rotaviruses are the most common cause of severe diarrheal disease among children worldwide (17). By the end of 2019, the rotavirus vaccine had been introduced in 108 countries; in three of them, only in parts of the territory. The estimated global coverage was 39% (17).
Rubella	Rubella is a generally mild viral disease in infants. Infection in early pregnancy can also result in stillbirth or congenital rubella syndrome, which in turn can cause damage to the brain, heart, eyes, and ears (17). By the end of 2019, the rubella vaccine had been introduced nationally in 173 countries, and global coverage was estimated at 71% (17).
Tetanus	Tetanus is a disease caused by a bacterium that grows in the absence of oxygen (e.g., in dirty wounds or in the umbilical cord if it is not kept clean) (17). *Clostridium tetani* spores are present in the environment, regardless of geographical location. The bacterium produces a toxin capable of causing serious complications and even death. Maternal and neonatal tetanus remains a public health problem in 12 countries, mainly in Africa and Asia (17).
Yellow fever	Yellow fever is a severe viral hemorrhagic disease transmitted by infected mosquitoes (17). As of 2019, the yellow fever vaccine had been introduced into routine infant immunization programs in 36 of the 40 countries and territories in Africa and the Americas where yellow fever is a threat. In these 40 countries and territories, coverage is estimated at 46% (17).

Source: *World Health Organization. [Internet]. Geneva: WHO; c2020 [cited 2020 Sep 14] . Vaccine coverage. Available at: https://www.who.int/es/news-room/fact-sheets/detail/immunization-coverage*

4. BARRIERS AND CHALLENGES TO IMMUNIZATION AT GLOBAL AND REGIONAL LEVELS

The high rate of childhood vaccination coverage in many countries indicates that immunization remains a widely accepted public health measure. However, national vaccination coverage levels do not reflect the variability within a country. In addition, unvaccinated individuals tend to cluster together, leading to increased transmission of vaccine-preventable diseases (18).

Despite high rates of childhood vaccination coverage in some countries, vaccine-preventable diseases are still endemic in different parts of the world. Several factors may be involved in their re-emergence and persistence: the rise of more virulent clones, international travel, compromised immunization coverage in developing countries or war zones, parents choosing not to vaccinate their children due to safety concerns, lack of good immunization programs for older people, incomplete vaccination schedules, waning immunity, imported cases, and suboptimal responses to vaccines in certain populations. These are among the reasons for the failure to reach the threshold of herd immunity needed to control diseases in some cases (15,19). **Table 2** shows the different barriers to immunization in childhood and adolescence (20):

Table 2. Barriers to immunization in childhood and adolescence

Barriers	Causes
Health system	• Costs (20). • Poor vaccine storage (20). • Reduction in vaccine supply and distribution (20). • Lack of a system to collect and consolidate the vaccination status of individuals (20). • Missed opportunities (due to lack of integration of health centers and misinformation through schools) (20).
Health professionals	• Lack of knowledge of the indications and contraindications for immunization (20). • Poor access to children's immunization records (20). • Missed visits, missed opportunities (20). • Poor communication with parents, caregivers, and adolescents (20).
Parents or carers	• Lack of knowledge of the real benefit of vaccines (20). • Fear of adverse events (20). • Problems in understanding the complex vaccination schedule (20). • Problems in accessing health services (20). • Economic problems (20).

Fuente: Modificado de Esposito S, Principi N, Cornaglia G. Barriers to the vaccination of children and adolescents and possible solutions. Clin Microbiol Infect. Mayo de 2014; 20:25-31.

Global immunization efforts reveal several barriers based on culture (e.g., religious beliefs) and geographic location. In developing countries, these include geographically isolated localities, limited access to health services, inadequate vaccine storage, and insufficient financial resources (21).

The US Centers for Disease Control and Prevention (CDC) notes that immunization programs serve as the entry point for primary health care in many developing countries and provide the only access for mothers and young children on a regular basis in many of these cases. However, immunization programs in these countries face many barriers to success, including shortages in and training of health workers and problems in managing vaccine supply. Each year, an estimated 21.8 million children are not vaccinated, leaving them vulnerable to disability and death from serious infectious diseases. If these vaccination programs do not reach this pediatric population, these children will probably not have access to other health services either (22).

The barriers present in developed countries are equally or even more alarming, as they include misinformation that leads many parents or caregivers to refuse vaccines for their children. Also troubling are mistaken beliefs that immunization-preventable diseases are no longer a problem or that the adverse effects of vaccines outweigh their benefits (20,21).

Parents or caregivers have an enormous influence on their children's immunization, so it is imperative that they rely on objective and timely information provided by health personnel (21).

That vaccine safety receives more public attention than vaccination effectiveness is understandable, but independent experts and the WHO have demonstrated the safety of vaccines relative to therapeutic medicines. Modern research has stimulated the development of less reactogenic products, such as acellular pertussis vaccines and cell culture-reduced rabies vaccines. Today,

vaccines have an excellent safety record, and most fears about vaccines have been shown to be fake news. Misplaced safety concerns in some countries have led to a drop in vaccination coverage and has contributed to the re-emergence of pertussis and measles (despite success in controlling them) (16).

Other barriers include economic costs, which limit access to vaccines (21). Along these lines, economic evaluations of vaccines differ between developed and developing countries, where immunization is more likely to be questioned on the basis of priority rather than value, as resources are scarce (19).

World Health Organization response

The WHO works with countries to improve global vaccine coverage, including through the initiatives adopted by the World Health Assembly in May 2012 (17):

- **Immunization Agenda 2030.** The 2030 Agenda for Immunization sets out an ambitious global vision and strategy for vaccines and immunization for the decade 2021–2030. It is the result of collaboration with countries and organizations around the world through thousands of contributions, and it will come into effect at the end of 2020, following its endorsement by the WHO World Health Assembly. This strategy builds on the lessons learned from the last decade and takes into account new and persistent challenges posed by infectious diseases (e.g., Ebola or COVID-19) (17).

- **Global strategy to accelerate the elimination of cervical cancer as a public health problem.** In 2020, the World Health Assembly adopted this strategy to accelerate the elimination of cervical cancer. This requires the introduction of the HPV vaccine in all countries, with a target of 90% coverage (17).

- **World Immunization Week.** World Immunization Week, celebrated at the end of April each year, aims to promote vaccination to protect people of all ages from disease (17).

The situation in Latin America and the Caribbean

Closer to our reality, the current vaccination coverage rates in Latin America and the Caribbean (LAC) are lower than the rates established in the region by the Pan American Health Organization. Identification of the factors that qualify as barriers to accessing vaccination services is crucial. These can be generalized into two main categories (23,24):

1. **Accessibility factors** (e.g., lack of vaccination infrastructure and services, availability of vaccines) (23, 24).

2. **Individual factors** (e.g., hesitancy about vaccination/vaccine acceptance) (23, 24).

With regard to vaccine **accessibility**, the implementation of vaccination policies in the LAC region faces several challenges that must be addressed to maintain successful immunization practices and resolve inequalities in vaccination coverage between and within countries. One of the main challenges is the lack of adequate financial support and common regulatory procedures between countries; the implementation of new policies could accelerate the entry of new vaccines into the region. This challenge is compounded by other non-financial challenges, such as the inefficient operational capacity of National Immunization Technical Advisory Groups (NITAGs) to facilitate the uptake of new vaccines and support evidence-based decision-making in the management of

national immunization programs. In addition, some LAC countries face challenges related to access to knowledge and to the training of health workers; specifically, accurate information on vaccines is lacking. Awareness of vaccine-preventable diseases in the population is also low, which can be attributed to the limited epidemiological surveillance systems in the region (23, 24).

Despite the barriers described above, regional efforts to improve adult vaccine coverage rates stand out and can serve as a basis for progress. For example, Mexico has employed a framework for diagnosing the root cause of vaccination gaps, known as the "5 As" (accessibility, access, awareness, acceptance, and activation). Mexico formed a comprehensive strategy for the 2014 Influenza Vaccination Campaign, with communication and health promotion on vaccination for social networks, crisis management, and community management. The result of this campaign was a 70% increase in timely immunization when comparing 2013 with 2014 (24).

Brazil has demonstrated progress since 2016, through the Brazilian Immunization Society, to implement a national immunization plan, a national committee on immunization practices, and a national system for monitoring vaccines. The associated costs are funded by the Brazilian government (24).

Instead, through the National Immunization Commission, Argentina has implemented a coverage program with the main strategy of mandatory vaccination for all health professionals starting a new job and periodically throughout employment. Chile used its annual influenza campaign as an opportunity to give people over 65 years of age the pneumococcal vaccine (24).

In 2016, consensus panel of experts in Colombia formulated guidelines for adolescent and adult immunization. In the same year, a brief entitled "Self-informed vaccination in the elderly: SABE Bogotá, Colombia study" was submitted to the Secretary of Health, along with a suggestion to continue a free pneumococcal and influenza vaccination program for adults aged 60 years and older. In addition, a vaccination card was introduced for older adults attending the outpatient unit of the Hospital Universitario San Ignacio in the capital city. Health professionals were also targeted by amending the geriatrics curriculum for medical students to include "Immunosenescence and Vaccination" (24).

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CHAPTER II
SUCCESFUL EXPERIENCIES OF PHARMACISTS AS A GLOBAL IMMUNIZER

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1. INTRODUCTION

The experiences included in this chapter refer to the following regions and countries at the global level:

- Asia-Pacific region: Australia, New Zealand, and the Philippines.
- European region: France, Switzerland, Portugal, and Ireland.
- Americas region: United States and Canada. The Latin American region will be examined in Chapter III.

When analyzing the information from each country on the processes that have enabled the pharmacist's role as an immunizer, the legislative component stands out. Changes in laws have helped to increase vaccination coverage and to offer a service closer to the people, with all the technical and scientific criteria required. In this sense, the great work carried out by pharmaceutical organizations to bring about changes and promote immunization services from community pharmacies is evident.

This chapter highlights the cases of the United States and Canada in the Region of the Americas with respect to the role of the pharmacist in the administration of vaccines. This region has served as an example for laying the foundations for pharmaceutical immunization services in other countries of the world and the region.

2. SUMMARY OF COUNTRY EXPERIENCES

The experiences are detailed below:

2.1 ASIA-PACIFIC REGION

2.1.1 AUSTRALIA

In Australia, the publication in late 2018 of the Provision of Vaccines by Pharmacists Regulations of the Poisons and Therapeutic Goods Act 1966 expanded the supply of vaccines that can be administered by pharmacists in community pharmacies in the state of New South Wales. This change came into effect in January 2019. Prior to this publication, only influenza vaccine was permitted. Now, community pharmacists can administer the combined measles, rubella, mumps (MMR) vaccine and tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccines in children under 16 years of age (1-3).

Pharmacists must meet four requirements to be able to administer all licensed vaccines in community pharmacies (2):

1. Pass a training program in the application of all licensed vaccines and be accredited as a certified vaccinator (2).
2. Have an up-to-date certificate on anaphylaxis performance (2).
3. Have a current first aid certificate (2).
4. Have an annually updated certificate in cardiopulmonary resuscitation (CPR) (2).

2.1.2 NEW ZEALAND

Since 2017, the New Zealand government has allowed pharmacists to provide influenza vaccines to patients over 65 years of age and to pregnant women, in addition to authorizing vaccination of adults under 65 years of age (2).

Achieving this provision required a nine-year period of joint activities and collaboration between pharmacy groups and decision-makers, including a pilot vaccination schedule in pharmacies in 2009 (2,4). In 2012, with the endorsement of the country's Ministry of Health, pharmacists were authorized as immunizers for the influenza vaccination campaign. This authorization is renewed every two years (5).

2.1.3 PHILIPPINES

In the Philippines, Republic Act 10918, known as the Pharmacy Act of 2016, empowers vaccination by pharmacists (1).

Professional pharmacy associations in the country have undertaken various activities to support immunization. In particular, the Pharmacists Association of the Philippines has formed a team called the Immunization Advocacy Group for training and development of guidelines for implementing immunization services in community pharmacies (2).

Under the Pharmacy Act of 2016, community pharmacies are required to maintain records of patient-requested medications and vaccines. Pharmacists are required to collect and store patient vaccination data, either electronically or manually, as part of proposed guidelines to the Food and Drug Administration (FDA), and the data must be kept confidential. Pharmacists are also required to report vaccination data annually to the Department of Health to reflect the pharmacists' contribution to the immunization program. A national health records system does not yet exist, although the e-health law has recently been passed. This development represents an opportunity to incorporate immunization data into the system (2). Currently, the Pharmacists Association of the Philippines is assisting in the preparation of implementing rules and regulations on the national electronic registry issue. Similarly, the Immunization Advocacy Group is working with the Professional Regulation Commission on the mechanism for professional certification on immunization (2).

2.2 EUROPEAN REGION

2.2.1 FRANCE

In France, with the entry into force of an amendment to law 2018-1203, influenza vaccination was authorized in accredited community pharmacies in all regions of the country from the beginning of 2019 (1,2). In 2020, the national implementation of pharmacist-led influenza vaccination services in community pharmacies was consolidated (2).

This achievement required the joint work of the pharmaceutical sector, with virtually no support from other health professionals, such as doctors and nurses. As a first product of this effort, a pilot project for influenza vaccination by pharmacists was authorized by law and ran for two years (2,6). During this period, it was possible to collect data and observe vaccination behavior in community pharmacies (2). The project resulted in 60% of the community pharmacists being able to vaccinate. In addition, service coverage in community pharmacies in the four pilot regions reached 76%. At the end of the pilot project, a total of 12,851 pharmacists vaccinated 902,699 patients against influenza (2).

Pharmacists participating in vaccination must be trained, either because they received their training during their undergraduate studies or because they received their training during the pilot scheme period. On the contrary, those who have not received training must obtain a certification after passing a six-hour theoretical-practical program that covers the pedagogical objectives defined by the French Chamber of Pharmacists and established by ministerial decree (7,8).

When distributing medicines, pharmacists are required to enter the information in a dispensing software program, as specified in article R. 5132-10 of the Public Health Code. In the specific case of vaccines, a decree is expected to be issued to record the date of administration and the batch number. The process carried out to solve this last step consists of transcribing the data indicated in the aforementioned article, together with the date of administration of the vaccine and its batch number, on a record, in ink, without correction fluid or overprinting (2,8).

2.2.2 PORTUGAL

Portuguese legislation allows for immunization in pharmacies, specifically for persons not covered by the National Vaccination Plan (2).

The actions of national pharmacy groups, such as the National Association of Pharmacies and the Portuguese Pharmaceutical Society, have been key in training and motivating pharmacists to offer immunization services in their pharmacies, based on the legislation issued. The National Pharmacy Association developed comprehensive training based on the American Pharmacists Association Certificate Training Program, which is recognized by the Portuguese Pharmaceutical Society, the registering body for practicing pharmacists (2).

National pharmaceutical organizations have developed other actions, in conjunction with the Portuguese Ministry of Health, to promote vaccination in the national public health system. In 2018, in order to increase vaccination in adults over 65 years of age and to improve access to the vaccine through the contribution of pharmacies, a pilot plan was carried out in 39 community pharmacies, together with the health centers of the national system, for influenza vaccination in the district of Lisbon. A comparison of the figures within the same period in the previous year showed an increase of 31.8% in vaccination coverage in that district (2).

Pharmacists involved in this process must comply with the certification issued by the Portuguese Pharmaceutical Society and have a pharmacy competency accreditation on vaccination and administration of injectable medicines; this includes knowledge in cardiopulmonary resuscitation and automated external defibrillation. The accreditation must be renewed every five years through an online course and by attending basic life support training (2).

2.2.3 SWITZERLAND

In Switzerland, the practice of pharmacy is regulated in each canton. In 2015, a change in legislation allowed immunization services by pharmacists in five of Switzerland's twenty-six cantons. Currently, there are 22 cantons where immunization is allowed directly at the pharmacy (i.e., pharmacists can vaccinate healthy adults over 16 years of age), although pregnant women and patients undergoing regular medical treatment must continue to be vaccinated by their doctor. In the canton of Tessin, pharmacists can vaccinate if they have a prescription for the vaccine. In the cantons of d'Appenzell Rhodes-Intérieures, d'Appenzell Rhodes-Extérieures, and Argovie, pharmacists have no legal basis to vaccinate (9-11). The vaccines offered and recommended are those that are part of the Swiss vaccination plan (9).

To involve pharmacists in immunization services, pharmaceutical organizations in the country have undertaken different actions to empower pharmacists to embrace their new role as immunizers. The Swiss Pharmacists Society encouraged actions, such as including pharmacists in the government's national immunization strategy and the development of high-quality educational programs for certification and immunization service materials, as well as data collection reports of vaccines administered, to support pharmacists in the promotion and delivery of immunization services. Consequently, this group has been actively involved from 2005 to the present in legislative changes associated with immunization in community pharmacies (2, 11).

As a prerequisite for permission to vaccinate, pharmacists must have completed additional specific training or have been empowered by vaccination specialists at the university. Certification consists of a theoretical and practical program covering aspects such as the government's national immunization plan, epidemiology, vaccine and disease theory, and electronic tools, as well as injection techniques and cardiovascular resuscitation courses (2).

Finally, recording of vaccination data in Switzerland is done in two ways, either through the vaccination registry (online tool) sponsored by the Ministry of Health or through the electronic vaccination registry, called Viavac (www.viavac.ch), the latter mostly promoted by the Swiss Society of Pharmacists (1,4). It is important to note that Switzerland has no national electronic health record (2).

Vaccinations against influenza, summer-summer meningoencephalitis (FSME), and hepatitis A and B are administered in pharmacies. During the last flu vaccination season, more than 35,000 people were vaccinated in pharmacies. In 2019, more than 40,500 vaccinations against FSME and about 790 vaccinations against hepatitis A and B were given (11).

An assessment reflecting the work of vaccinator pharmacists conducted in Switzerland was the pharmacy customer survey conducted in 2019, in which patients recognize the pharmacy as a place for vaccination (11).

2.2.4 IRELAND

Since 2011, Irish legislation has allowed pharmacists to dispense influenza vaccine without a prescription and to administer it to patients in the pharmacy (2). In addition, in 2015, legislation was amended to allow pharmacists to supply and administer two additional vaccines, pneumococcal polysaccharide and herpes zoster vaccines (12,13), as well as epinephrine for the treatment of anaphylaxis (12,14).

The initial change in legislation was generated by a number of causes, such as increasing vaccination, because, according to the European Commission, Ireland was not reaching 75% coverage against influenza in the elderly. The H1N1 pandemic also highlighted the lack of health professionals for immunization, as well as public demand for greater access to more health services by pharmacists (2).

To gain acceptance of pharmacy-based immunization services by different sectors, pharmacy organizations, such as the Irish Pharmaceutical Society, generated pharmacy advertising campaigns, media campaigns, and government support through the Department of Health and the National Immunization Bureau. To assist pharmacists in setting up these services, support materials were developed, such as the standard operating procedures for pharmacy immunization services (2).

To be permitted to vaccinate, pharmacists must attend a one-day classroom course that covers injection technique, anaphylaxis, and cardiopulmonary resuscitation (CPR). An online module on vaccination must be completed every year or every two years, depending on the type of module. Attestations in cardiopulmonary resuscitation are to be repeated every two years (2).

For the 2020/2021 influenza vaccination season, pharmacists will be able to supply and administer influenza vaccines to children aged 6 months and older. The legislation was also amended to allow the supply and administration of influenza nasal spray and suspension to children and adolescents from two years of age (12).

2.3 AMERICAS REGION

2.3.1 CANADA

In Canada, publicly funded immunization programs are a shared responsibility between federal, provincial, and territorial governments, including the purchase of vaccines (15,16). Provincial and territorial governments and local public health authorities are responsible for the planning and delivery of immunization programming (16).

The pharmacist's entry into the immunization arena has not been an easy process. Other health professionals and decision-makers have become more receptive to the pharmaceutical authority, which is the most accessible health care provider. Patients see the pharmacist up to ten times more frequently than they see their family doctor. The general population has also become more receptive (2).

The main aspects of success in the pharmacist's foray as an immunizer in Canada are summarized in the following points:

- A process to authorize pharmacist-administered vaccines has been underway for thirteen years. The first province to approve such authorization was Alberta in 2007. Today, nine of the ten provinces authorize the process. Only Quebec is missing (2).

- Injectables training is provided to students by all Schools of Pharmacy, as well as by colleges, associations, and other institutions. If not provided at a university school of pharmacy, courses must be approved by the Canadian Council on Continuing Pharmacy Education. Each jurisdiction has unique training and certification requirements for pharmacists to provide injections and immunizations. In addition, they must have a valid certification in first aid and cardiopulmonary resuscitation (CPR) from a recognized provider (2).

- Vaccine administration is a paid service in all provinces, ranging from CA$7 to CA$13 per service for publicly funded vaccines only, and in some provinces only for influenza vaccine (2).

- Pharmacy associations and leaders across Canada have communicated the importance and instilled the values of embracing expanded scopes of practice within the pharmacy profession. This has been a top-down and grassroots movement to embrace change in pharmacy practice and to improve patient care (2).

Pharmacists are well positioned to provide vaccine education, dispel myths, and encourage patients to get vaccinated. In a national survey (2018), 78% of Canadians said they would visit a pharmacist for influenza vaccination and 67% would visit a pharmacist for other vaccines (2).

Immunization registries exist in jurisdictions across Canada. Pharmacists are generally required to keep a documented patient history, assessment, signed consent form, and details of each vaccine administered, and to provide a written immunization record for each patient (2).

These professionals see vaccines as a way to increase customers in their pharmacies and to build better relationships with their patients, in addition to the ease of service delivery, as vaccines are administered quickly, require very little documentation compared to other services, and there is immediate patient satisfaction (2).

2.3.2 UNITED STATES

Pharmacists have made significant progress in the United States (US) over the past 24 years, increasing access to vaccines and protecting people from vaccine-preventable diseases (17).

Since 1996, the American Pharmacists Association (APhA) adopted a policy calling for pharmacists to assume at least one of three roles: educator, facilitator, or vaccine manager (immunizer) (2). This was seen as an indispensable professional strategy to increase immunization coverage in the population, as it was estimated that 250 million people visited a community pharmacy each week (18).

As of 2009, all 52 states in the country had legislation authorizing pharmacists to administer vaccines (19,20).

The main aspects of success in the pharmacist's foray as an immunizer are summarized below:

- APhA adopted guidelines for pharmacy-administered vaccines and 24 years ago developed a certified training program for pharmacists to prepare them, as informed and accessible human resources, to take active roles in the immunization community and to care for patients across the lifespan. Over the years, APhA has used a trainer preparation model, recognized as the gold standard by the US CDC for its capacity and content; a process and commitment to keep the program up to date and provide pharmacists with ongoing education on the latest immunization recommendations; and a specific training program for the provision of travel health services. By 2019, more than 340,000 pharmacists had been trained (2,17).

- With policy makers, the gap in vaccination rates was identified, and national targets were set under the current/traditional system. The role of pharmacists was demonstrated, and this led to a broadening of the scope of authority in the immunization activities of these professionals: more antigens were allowed for vaccination, along with a wider age range of patients who can be vaccinated (2).

- The public was educated about the importance of vaccines, the knowledge of pharmacists, and the appropriateness of immunization by pharmacists. Pharmacies used their marketing and advertising mechanisms to promote vaccines and the role of pharmacists (2).

The ultimate goal of the APhA in the USA is to obtain the authority for pharmacists to administer all vaccines recommended by the CDC's Advisory Committee on Immunization Practices throughout a person's lifetime (2). The pharmacist is an accessible professional, as an estimated 86% of the population lives within eight kilometers of a community pharmacy (21). The US vision is to make immunization information systems a portal for vaccine providers to report and access a patient's immunization history for forecasting their immunization needs (2).

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CHAPTER III
EXPERIENCES OF PHARMACISTS SUCCESSES IN VACCINATION AT THE LATIN AMERICAN LEVEL

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1. EXPERIENCES BY STAGE IN THE PROCESS OF USING VACCINES

The use of vaccines involves different activities in which the pharmacy professional may be involved. Initially, a research stage is necessary. This is followed by production, registration with regulatory authorities, and then marketing. Like other medicines, vaccines are stored, guarded, and distributed according to product-specific recommendations prior to administration.

After patients have been vaccinated, a follow-up phase is necessary, which involves assessing the response and reporting suspected adverse reactions and medication errors. The process of periodically reviewing vaccination schedules in each country is also key.

Finally, it cannot be overlooked that the knowledge generated in previous activities is shared through informative and educational activities aimed at the population in general and health professionals in particular.

In all these activities, pharmacists can be involved and contribute their perspective and experience.

2. METHODOLOGY

This chapter presents a record of the participation of pharmacy professionals in the stages described above in the Latin American region. The following methodology was used to collect the information:

1. The team used the following channels to contact professionals from the countries in the area:

    a. Direct contacts previously established by the authorities of the Pharmaceutical Forum of the Americas.
    b. Identification in the scientific literature of publications related to the topic of immunization services in the region, with subsequent contact with their authors.
    c. Email message sent by the Pharmaceutical Forum of the Americas to professional pharmaceutical organizations to identify leaders in the field of vaccination.

2. Contact with the referents was made through the institutional mail of the National Centre for Medicine Information (CIMED) of the Pharmaceutical Research Institute of the University of Costa Rica. In this email, people were informed of the objective of the activity and the reason why they were selected as a contact. In addition, a link was provided to the *Google Forms* platform, where they could access an instrument with 10 sections, each with 8 questions that guided them in the collection of the necessary data for each country. (**Annex**)

3. As a follow-up, a reminder was sent one week after the initial contact, and if no response was received, a reminder was sent to the referrer; this action was repeated as necessary.

4. In cases where no direct response was obtained from the professionals, a search was carried out for previously documented experiences in the literature.

3. OVERALL RESULTS

Pharmacy professionals from Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Puerto Rico, Uruguay, and Venezuela were contacted. In total, nine of these countries responded affirmatively by filling out the form. In the case of Brazil, despite not completing the form, we were able to identify examples of successful experiences in the area of vaccination in the literature. (**Table 3**).

Table 3. Actions developed in the countries of the region involving the pharmaceutical professional

Country	R&D	P	R	MV	S&C	D	Adm	Seg	Educ Prof	Educ Pac
Argentina	-	-	-	X	X	-	X	X	X	X
Brazil	X	X	X	X	X	X	X	X	X	X
Chile	X	X	X	X	X	X	X	X	X	X
Costa Rica	-	-	X	X	X	X	X	X	X	X
Cuba	X	X	X	-	X	X	-	-	X	-
El Salvador	-	-	X	X	X	X	-	X	-	-
Guatemala	-	-	X	X	X	X	-	-	X	X
Mexico	-	-	X	X	X	X	-	X	X	X
Peru	X	X	X	-	X	X	X	X	X	X
Venezuela	-	-	X	X	X	X	X	-	X	X

R&D: Vaccine research and development. **P:** Production of vaccines. **R:** Registration of vaccines with the regulatory authority for marketing. **MV:** Marketing of vaccines. **S&C:** Storage and custody of vaccines in the pharmacy. **D:** Distribution of vaccines. **Adm:** Administration of vaccines in the pharmacy. **Seg:** Follow-up (evaluation of patient response, reporting of suspected adverse reactions and medication errors, and review of vaccination schedules) in the pharmacy. **Educ Prof:** Education for health professionals. **Educ Pac:** Patient education. Corresponds to actions described in the literature.

***Source**: Own elaboration, based on the results obtained*

4. SUMMARY OF COUNTRY EXPERIENCES

The experiences involving pharmacists, compiled using the instrument designed for this purpose or by means of the literature review, are presented below. In addition, at the end of each case, the most relevant aspects in which the pharmacist played an important role are summarized. Note that, in some cases, the information provided did not allow us to detail specific interventions by the pharmacist; however, the analysis of all the cases allowed us to generate an overview of the various actions carried out in the area.

4.1 ARGENTINA

Information provided by:
Gisela Carignano

In Argentina, the national influenza vaccination campaign 2019, implemented by the National Institute of Social Services for Retired and Pensioners (PAMI), stands out. The aim of this vaccination strategy was to achieve coverage greater than or equal to 95% in people over 65 years of age, in order to reduce complications, hospitalizations, sequelae, and deaths caused by the influenza virus. This campaign was aimed at retirees and their dependents, pensioners, and veterans of the Malvinas War.

With the pharmacist in charge, this campaign was carried out free of charge in the pharmacies, where the vaccine doses were stored and kept in safekeeping. In the case of persons under 64 years of age, a medical prescription was additionally requested to justify the application.

In 2019 alone, this campaign allowed the administration of 874,859 doses from 38 Local Management Units. By 2020, there will be 6,600 participating pharmacies, where people who meet, the requirements can go to receive their vaccination.

Limitations of this experience include the delay in the provision of the vaccine and the need for equipment for its proper storage. During 2020, special protocols were also required to ensure social distancing measures within establishments in the wake of Covid-19. Additional information on this campaign can be identified on the website www.pami.org.ar.

Another campaign was carried out by the Provincial Ministry of Health through the Santa Fe province's social security system, the Instituto Autárquico Provincial de Obra Social (IAPOS). In this initiative, a flu vaccination campaign was carried out for members belonging to risk groups and IAPOS workers in the cities of Santa Fe and Rosario. In this activity, people were able to receive the vaccine free of charge at the pharmacy where they usually go. Among the positive points of this experience was the access of retired people to the vaccination. Likewise, similar to the PAMI experience, the pharmacist's participation in various activities of this campaign becomes an input to link the professional to the act of vaccination.

Note that, in the PAMI and IAPOS campaigns, a Vaccine and Immunization Suspected Attributed Event (VASI) reporting form was available. With this process, participating pharmacists became involved in ensuring the efficacy and safety of vaccines.

Additionally, with their participation in these activities, the community pharmacists are empowered in this area, and a need exists to increase training with formal proposals to increase knowledge on the subject of vaccination.

The workshop Public-Private Integration, Professional Pharmaceutical Services, developed by the Instituto de Formación en Gestión (IFG) of the Federación Farmacéutica Argentina (FEFARA), invites pharmacists to present their professional experiences in relation to the provision of Professional Pharmaceutical Services, with one of the topics to be considered being "Immunization". In order to increase the scope of this type of activity, cooperation between different institutions of the pharmaceutical guild is proposed, both at provincial and national levels, to achieve a greater dissemination and scope of the efforts.

ASPECTS OF SUCCESS
1. Participation in national vaccination campaigns. 2. Reporting of Events Suspected to be Attributed to Vaccines and Immunizations (ESAVIs) from pharmaceutical services provided to communities. 3. Continuous training and dissemination of experiences in immunization.

4.2 BRAZIL

Information provided by:
Joselia Quintao Pena Frade
Alessandra Russo de Freitas

In Brazil, at the vaccine research and development level, the Vaccine Technological Complex of the Institute of Immunobiological Technology (Biomanguinhos/Fiocruz), which supplies the essential vaccines of the Ministry of Health's basic immunization schedule, plays an important role. According to its website, *"the institute is basically dedicated to the production of vaccines for DTP and Hib, yellow fever,* Haemophilus influenzae *type B (Hib), meningitis A and C, poliomyelitis and MMR."* More information on the institute can be found at the following link: https://portal.fiocruz.br/es/vacunas.

Another notable strategy in Brazil is pharmacist-led immunization, which Russo da Freitas and Quintao Pena Frade refer to "in *addition to consolidating clinical practice and the establishment of pharmacies as health care centers, highlights the importance of pharmacists in Brazilian pharmacies and in the National Immunization Program"* (2). This is a remarkable achievement by the Brazilian pharmacy profession, as the main challenge was reportedly overcoming resistance from other health professionals, in particular medical and nursing staff. However, pharmacists in Brazil, for many years, have had the legal right and technical competence to provide and administer injectable drugs (contraceptives, vitamins, anti-inflammatory drugs, hormones, anticoagulants, insulin, etc.). This previous experience was important in the process of broadening the scope of pharmacists in providing immunization services.

However, a joint strategy was worked out with other political actors to achieve pharmacist-led immunization; this involved: a) advocacy on draft federal and state legislation; b) joint work with the parliamentary front on pharmaceutical care; c) advocacy among all organizations representing the profession, through a forum created to define strategies for the pharmacy profession; d) work with a consultancy firm on parliamentary affairs; e) creation of a working group dedicated to these issues and to the monitoring of bills related to the profession.

Meetings were also organized with the Ministry of Health and the president of the National Health Surveillance Agency (Anvisa) to demand health regulation reforms, and support was sought from organizations such as the Brazilian Society of Pharmacists and Community Pharmacies, the Brazilian Association of Pharmacies and Drugstores (Abrafarma), the Regional Pharmacy Councils and other organizations related to the profession and pharmacies.

All this strategy paid off, as it achieved the following:

1. The Brazilian Federal Council of Pharmacy coordinated the creation of the National Advocacy Forum for the Recognition of the Value of the Pharmacy Profession, a political movement that acted with the approval of Law 13021/2014, which recognized Brazilian pharmacies as

healthcare centers, allowing the administration of vaccines in pharmacies.

2. Anvisa participated in the political and technical work to ensure the implementation of the new health regulation regarding immunization services in pharmacies, so that the pharmacist could be professionally responsible for those services. As a result, Resolution 197/2017 was published.
3. The specific working group, composed of pharmacists experienced in immunization, drafted the contents of the professional resolution defining the requirements necessary for the pharmacist to work with vaccines (Resolution CFF 654/2018). The professional regulations were based on the standards and requirements defined in the government's National Immunization Program documents.
4. The Brazilian Immunization Society welcomed pharmacists as potential professionals to join the association, which historically had only included doctors and nurses.
5. The population was made aware of the pharmacist's role in immunization through media publicity. Brochures produced by the Regional Pharmacy Councils were made available to promote the immunization offered by pharmacists. In addition, private pharmacies also undertook their own marketing strategies to implement immunization services.

It is worth noting that a pilot project is currently underway, post-implementation, which will assess whether immunizing pharmacists and the supply of immunization services have influenced vaccination coverage in the country.

In terms of education activities for patients and health professionals, the Vaccine Technological Complex of the Institute of Immunobiological Technology (Biomanguinhos/Fiocruz) has audiovisual material available on vaccines and vaccine-preventable diseases, such as yellow fever. This material can be consulted at the following links:
Fiocruz Youtube (https://www.youtube.com/user/fundacaooswaldocruz)
Canal Saude (https://www.canalsaude.fiocruz.br/buscaVideos?termo=vacinas).

For their part, as mentioned above, Regional Pharmacy Councils and private pharmacies have designed strategies and materials to promote immunization services by pharmacists.

However, even with these great achievements, other challenges are still reported by Brazilian colleagues involving: a) increasing the number of pharmacists licensed to provide immunization services; b) increasing the number of courses that provide training in basic life support, which will have an impact on the education of immunizing pharmacists. This also highlights the opportunity for pharmacists and pharmacies to educate patients on the importance of immunization, based on data from the Brazilian Ministry of Health that shows a decrease in immunization coverage rates among adults and the elderly.

ASPECTS OF SUCCESS
1. Production of vaccines from the basic immunization schedule of the Brazilian Ministry of Health. 2. Legal protection of pharmacists for the provision of immunization services, thanks to their experience in previous years, of providing injectable drugs (contraceptives, vitamins, anti-inflammatory drugs, hormones, anticoagulants, insulin, etc.). 3. Positioning the pharmacist as an immunizer and provider of pharmaceutical immunization services from the community pharmacy. 4. Work of different political actors for the drafting of public policies related to immunization services by pharmacists.

4.3 CHILE

Information provided by:
José Vicente González Aranmundiz
María Alejandra Rodríguez Galán
Adiela Saldaña

In Chile, at the level of vaccine research and development, the presentation in 2017 of the first Phase I study for the vaccine against respiratory syncytial virus, developed by a team of Chilean scientists, stands out. It was successfully conducted at the Pontificia Universidad Católica. A pharmaceutical chemist was in charge of ensuring the vaccine storage conditions and compliance with the protocol for this phase. However, in general, pharmacist involvement in applied research is low.

During the 1950s, 1960s, and 1970s, vaccines such as rabies vaccines were produced at the Instituto Bacteriológico de Chile, with the participation of pharmaceutical chemists.

In relation to the sanitary registration of vaccines, as part of the Regulatory Authority's team, pharmaceutical chemists are present in the evaluation of clinical studies and, in particular, have participated in the Phase I study of the vaccine against respiratory syncytial virus and the vaccine against 9 valent and t4 valent human papillomavirus (HPV), among others. Pharmacists from the Pharmacovigilance Section also participate in the registration process, where they must evaluate the safety information provided by the laboratory wishing to register a product and determine whether the risk-benefit ratio is favorable.

On the positive side, pharmacists provide relevant information related to vaccine safety and thoroughly assess the safety requirements for authorizing the registration of a new vaccine. On the other hand, the time and the number of staff available are not favorable.

On the subject of storage, custody, distribution, and administration of vaccines according to the specific recommendations, talks are conducted as necessary to encourage these aspects, especially the importance of the pharmacist's criteria in the custody of the cold chain. The contribution of pharmacists in pharmacies who manage the control of the cold chain, both in the storage and transport of these products, is highlighted.

With regard to the administration of vaccines, in pharmacy offices emphasize the application of the influenza vaccine. However, a point for improvement involves the lack of staff and the time required for pharmaceutical care actions. A need also exists to raise awareness of the impact of vaccination in pharmacies, using the United States as an example.

At the follow-up stage, Chile has had the Vaccine Pharmacovigilance in place since 2012, a system implemented by a team of pharmacists at the National Regulatory Authority. This program has been strengthened over the years, becoming a benchmark for countries in Latin America and the Caribbean, according to Dr Saldaña. This program has involved pharmacists, thanks to the implementation of national guidelines, the establishment of an expert committee, and the improvement of the website with information for professionals and patients, as well as the integration of one of the pharmacists in the strategic priority group of the *Global Vaccine Safety Initiative,* led by the World Health Organization.

Some of the Chilean contributions and work can be consulted in the following links:

- National experience in applying the minimum data elements for vaccine safety. An experience from Chile. En Global Vaccine Safety Initiative. 2018. Available at: https://apps.who.int/iris/bitstream/handle/10665/280125/WHO-MVP-EMP-SAV-2019.01-eng.pdf

- Development of a first experience of active pharmacovigilance. Available at: https://www.sciencedirect.com/science/article/pii/S0264410X17306205
- Incorporation of the Vaccine Pharmacovigilance web page on the International Vaccine Safety Net site, work carried out by a Pharmaceutical Chemistry undergraduate student and her tutor. Available at: http://www.ispch.cl/noticia/28317, https://www.vaccinesafetynet.org/vsn/network/public-health-institute-chile-ispvaccinepharmacovigilance; http://www.ispch.cl/anamed_/fármaco surveillance/vaccines
- Vaccine Drug Surveillance Bulletins. Available at: http://www.ispch.cl/newsfarmacovacunas/03/; http://www.ispch.cl/anamed_/fármaco surveillance/nram/pharmaceutical surveillance_vaccines/bulletins

As part of the positive aspects of pharmacists in these initiatives, they highlight the scientific rigor to evaluate clinical cases and the application of pharmacovigilance methodologies, as well as the ability to work as a team, both with doctors and nurses, in the development of a comprehensive surveillance system.

The education of patients and health professionals is an important stage in the use of vaccines, and Chilean pharmacists, prior to 2014 and especially after this year, help in the training of health professionals, in conjunction with the Chilean Ministry of Health (MINSAL), on the subject of vaccines. They highlight the intervention made to manage the myths surrounding the use of thimerosal in these drugs. In patient education, they highlight the initiative of a pharmacy student and a pharmacist, who generated educational material on the benefits and safety of vaccines, after three meetings with members of the community. These documents were subsequently approved by PAHO/WHO and can be consulted at the following link: http://www.ispch.cl/sites/default/Ales/Boletin01-%20beneAcio%20y%20Seguridad%2006032017A.pdf

All this helps to bring the pharmacist closer to the needs of the population and to stimulate the ability to communicate scientific content using language that is understandable to the general public.

ASPECTS OF SUCCESS
1. The creation of the Vaccine Pharmacovigilance Program, a system implemented by a team of pharmacists in the National Regulatory Authority. Work on this initiative has resulted in a member of the team being part of the strategic priority group of the *Global Vaccine Safety Initiative* led by the World Health Organization.

4.4 COSTA RICA

Information provided by:
Cristina Fernández Barrantes
Alejandra Fernández Jiménez
Nuria Montero Chinchilla
Alfonso Pereira Céspedes
Milania Rocha Palma
Eduardo Valverde Escobar

In Costa Rica, at the research level, clinical trials with vaccines conducted by the Institute of Pediatric Care are reported, where the pharmacist's functions were the storage, custody, and dispensing of the vaccines used. Among the vaccines investigated were diphtheria, tetanus, and pertussis (DTaP), polio (IPV), hepatitis B, *Haemophilus* b conjugate vaccine (PRP-T), influenza vaccine, pneumococcal conjugate vaccine, and meningococcal vaccine.

Two events to highlight in the area of vaccine research in Costa Rica are the country's participation in the testing of the experimental Zika vaccine and the incorporation of the human papillomavirus (HPV) vaccine into the basic immunization schedule.

Regarding the former, Costa Rica is part of the research project known as VRC 705, led by the National Institute of Allergy and Infectious Diseases (NIAID). Its aim is to enroll at least 2,490 healthy participants in areas of confirmed or potential Zika infection and includes Houston, Miami, San Juan, Puerto Rico, Brazil, Peru, Costa Rica, Panama, and Mexico. Further details of the study can be found at the following link: https://www.niaid.nih.gov/news-events/phase-2-zika-vaccine-trial-begins-us-central-and-south-america.

For the second event, with support from PAHO/WHO, the country marks a milestone in cervical cancer prevention and joins the 70 nations that give the vaccine to 10-year-old girls to protect them as adults. The Costa Rican Agency for Biomedical Research (ACIB), in collaboration with the US National Cancer Institute (NCI), conducted research studies to understand the causes and new ways to prevent cervical cancer, human papillomavirus (HPV) infection, and the development of cervical cancer in the initial trials before incorporating the vaccine into the basic schedule. More information on current ACIB projects can be found at the following link:
http://www.proyectoguanacaste.com/ACIB/category/estudios-actuales/

At the level of vaccine development and production, no experience is reported, as these activities are not currently carried out in the country.

With their registration with regulatory authorities and the marketing of vaccines, pharmacists in Costa Rica are involved in both stages. In relation to marketing, a successful experience can be mentioned: the vaccination campaigns in companies, where the doctors who work in them were visited and later, with the pharmacists, these campaigns were coordinated. The pharmacist's participation in issues such as knowledge of the disease, as well as the ability to motivate people to comply with vaccination schedules, are positive points. However, a limiting factor in some cases was the lack of knowledge of the reality of the communities.

With regard to the storage, custody, and distribution of vaccines according to the specific recommendations, the pharmacist contributes to the maintenance of the cold chain, with the use of devices for vaccine control and handling, as well as monitoring the process and reporting anomalies, if they occur. Costa Rica has a Manual of Standards for the Qualification of Pharmacies, which includes specifications for the storage, custody, and assurance of the cold chain for vaccines. A National Vaccination Standard, in addition to specifications for the vaccines in the country's vaccination schedule, includes guidelines for their handling and storage, as well as post-administration follow-up.

Still on the subject of vaccine storage, custody, and distribution, the Costa Rican Social Security (CCSS) has an Expanded Program of Immunization (PAI), which has a solid structure and involves the pharmacist. One of its tasks related to the storage and custody of vaccines is the guarantee of the cold chain. However, other actions of equal relevance are the hosting of regional workshops to identify and define the needs of each of the vaccines in the national schedule. In all regions, an interdisciplinary team manages the EPI, with great integration and participation of pharmacists in all cases. The results of the regional workshops are consolidated at the national level, where a pharmacist dedicated to vaccines works. This programming is the basis for setting up vaccine procurement processes or requests to the Pan American Health Organization (PAHO) for vaccines purchased through that channel. The centrally located pharmacist participates in not only in the ordering process, but also in the acquisition, distribution logistics, consumption control, investigation

of adverse event reports attributable to vaccination, as well as preparing and reviewing technical documents, including the National Vaccine Standard.

Positive points mentioned about the incorporation of the pharmacist in the EPI include the interdisciplinary work and the assurance that the vaccines reach the patient in a timely and safe manner. However, a limitation is identified related to the time and capacity to travel from the pharmacy to work with the interdisciplinary teams.

On the issue of vaccine administration, most private community pharmacies provide the application service, which is carried out by the pharmacist in charge. At the follow-up stage, Costa Rica has, as mentioned above, established the National Vaccination Standard, which includes the Surveillance of Events Suspected to be Attributable to Vaccination and Immunization (ESAVIs). In addition, the Costa Rican Ministry of Health has designed the Nominal System of Vaccination (SINOVAC), created for the purpose of collecting, integrating, and analyzing vaccine-related information in a timely manner. These documents and programs can be consulted at the following links:

- National Vaccination Standard. Available at:
https://www.ministeriodesalud.go.cr/index.php/vigilancia-de-la-salud/normas-protocolos-y-guias/vacunas-2/2302-norma-nacional-de-vacunacion-2013/file
- Manual of use of the Nominal System of Vaccination (SINOVAC). Available at:
https://www.ministeriodesalud.go.cr/index.php/acceso-a-sistemas-de-informacion

According to Dr Roberto Arroba, National Immunization Coordinator and Technical Secretary of the National Vaccination and Epidemiology Commission of the Costa Rican Ministry of Health, SINOVAC was implemented in 2017, with training for the country's community pharmacists and nurses who administer vaccines in private centers, with the support of the country's Directorate of the Governing Areas of Health. In the same year, community pharmacies and private clinics started reporting vaccinations as a mandatory activity.

Data from the report show that approximately 98% of the reported sites are community pharmacies, where the pharmacist markets, dispenses, administers, and notifies the vaccination. For 2017, SINOVAC reported 11,040 vaccinations; in 2018, a total of 42,087, and in 2019, a total of 76,520. These vaccination data, in addition to reports from community pharmacies, include those from private hospitals where the service is provided. In these establishments, the nursing staff administer and report vaccinations, but the pharmacists are responsible for the storage, custody, and distribution of the vaccines.

The Ministry of Health has now started to cross-check the information provided by vaccine distributors sales to private pharmacies and the amount of vaccine administration reported per month in SINOVAC by each pharmacy.

The vaccine with the highest number of registrations in SINOVAC is the influenza vaccine, with 5,516 applications in 2017, 15,076 in 2018, and 35,385 in 2019. In second place is the human papillomavirus vaccine, which in 2019 alone is reported to have been administered 8,715 times, followed by the yellow fever vaccine with 8,617 administrations. Other vaccines administered in 2019 in descending order of quantity are Tdap (5,322 applications), hepatitis B (3,195 administrations), measles, mumps, rubella (MMR; 2,915 administrations), hepatitis A (2,156 applications), BCG (958 applications), tetanus toxoid (1,536 applications), varicella (1,260 applications), meningococcal (1,131 administrations), and 13 valent pneumococcal (1,111 administrations), among others.

Although SINOVAC currently has limitations for the full traceability of all vaccines administered at the private level due to underreporting, the contribution of pharmacists in the reporting of

vaccination at this level has been fundamental. SINOVAC has great strengths, such as: a) having real-time online information on vaccines administered and reported at the private level since 2017; b) having a nominal register of vaccines administered; and c) being able to issue vaccination certificates to individuals.

Finally, regarding the education of patients and health professionals in Costa Rica, the Ministry of Health has designed educational material for the general population, in relation to the vaccines of the basic scheme and in adults. These can be consulted at the following link: https://www.ministeriodesalud.go.cr/index.php/material-educativo/vacunas-3. The CCSS has also developed informative material and vaccination campaigns for the Costa Rican population to complete their vaccination schedule, and pharmacists have participated in the development of these campaigns.

The National Medicines Information Center (CIMED), part of the Pharmaceutical Research Institute (INIFAR) attached to the Faculty of Pharmacy of the University of Costa Rica, has collaborated in the area of patient and health professional education with actions such as the design and development of information resources, resolution of consultations via telephone or in person, and training of health professionals through the Professional Update System (SAP), which ran from 2001 to 2010. As part of the SAP, in 2002, pharmacists enrolled in the program were trained in vaccine-preventable infectious diseases.

ASPECTS OF SUCCESS
1. The existence in the country of the Nominal System of Vaccination (SINOVAC), in which pharmacists participate and work together with nurses, as well as the Surveillance of Events Suspected to be Attributable to Vaccination and Immunization (ESAVIs).
2. The existence in the Costa Rican social security system, specifically in the Costa Rican Social Security Fund, of the Expanded Program of Immunizations (PAI), a solid structure that involves the pharmacist.
3. Costa Rica's participation in international multi-center research related to vaccines, more specifically the Zika and human papillomavirus (HPV) vaccines.
4. Vaccine delivery in community pharmacies by pharmacists.

4.5 CUBA

Information provided by:
Anai García Fariñas

In the case of Cuba, an outstanding guide to research and development processes can be identified. Concepción Campa, a graduate in Pharmaceutical Sciences, led the creation and development of the Cuban vaccine against meningococcus b (Vamengo BC). This process managed to convey an integrated perspective of the work of the pharmacy professional, from the development of pharmacological, pre-clinical, and clinical studies to clinical application.

Further details on 20 years of experience in the formulation of this vaccine can be found in the scientific literature (https://www.medigraphic.com/pdfs/medicreview/mrw-2007/mrw071f.pdf).

One of the limitations of participating in research development is the need to broaden the health team's recognition of the potential that pharmacists have in this area. Similarly, the possibility of working at the Institute is limited.

When considering the registration process for the Cuban vaccine against meningococcus b, it should be emphasized that the Finlay Vaccine Institute's pharmaceutical product registration team is

mainly made up of pharmacy graduates, who have successfully registered all the vaccines produced by the institution. As a result, preparing the registration dossier and a fluid communication with the regulatory authority is possible, based on the knowledge of the process of obtaining the medicine. The challenge of this work is to keep up to date with regulatory issues and to maintain the motivation of professionals to work on registration-related issues.

The storage, custody, and distribution of vaccines is supervised by professional pharmacists, but the administration of vaccines is not, as this is an activity that belongs to the nursing staff. Specifically, the storage and distribution is carried out by the only Cuban company for this purpose, the Empresa Comercializadora y Distribuidora de Medicamentos (EMCOMED), which is in charge of collaborating with the National Immunization Program. Most of the staff working there are pharmacists. In the polyclinics, where vaccines are administered, a pharmacist is in charge of storage, dispensing, and compliance with good distribution practices.

An example of teaching health professionals is the preparation of sites for the development of a clinical trial of the Cuban pneumococcal vaccine. For this, a pharmacist was in charge of seminars at selected sites, addressing topics such as the importance of the disease, product characteristics, handling, application, and the expected safety profile. In this way, adequate communication with the health team was generated, as well as a comprehensive understanding of the characteristics of the product and the research to be carried out, thereby guaranteeing compliance with international standards for the clinical analysis of vaccines.

Work toward the establishment of pharmaceutical care services in community pharmacies is also proposed, as well as efforts to obtain greater recognition by public health authorities of the importance and potential benefits of actions such as monitoring treatment response and reporting adverse reactions and medication errors. These go hand in hand with greater involvement of the pharmacist in patient education. However, as vaccines are administered directly in health centers, provided free of charge by the national health system, the polyclinic pharmacist would have to be involved in planning patient education sessions at the vaccinator's office, but this activity is not foreseen as part of his or her current work.

ASPECTS OF SUCCESS
1. Leadership in the production of the Cuban meningococcal b vaccine.
2. Participation in the teaching of health professionals.

4.6 EL SALVADOR

Information provided by:
Antonieta M. Anaya von Beck

The pharmacist in El Salvador participates in activities for the proper importation and customs clearance of vaccines and related supplies, such as the syringes needed for the national vaccination program. The pharmacist also participates in the process of safeguarding the cold chain of these medicinal products.

Within the pharmacy services of the Instituto Salvadoreño de Seguro Social (ISSS), although pharmacists do not carry out pharmacotherapeutic follow-up of each patient who receives vaccines, they do report suspected adverse reactions associated with their administration to the Health Surveillance Department, where the pharmacist and the epidemiologist coordinate the review of

the reports received, in order to issue technical reports.

It should be noted that, as in other countries in the area, the application of vaccines is an activity carried out by maternal and child technologists or nurses duly trained by the ISSS vaccines and immunization program.

ASPECTS OF SUCCESS
1. Participation in the process of pharmacovigilance of vaccines from the ISSS.

4.7 GUATEMALA

Information provided by:
Claudia Lucrecia García Álvarez
Elly Letona

In Guatemala, the registration of vaccines is a task of pharmacy professionals. They are also involved in the marketing of these products through their work as distributors or during medical visits. In both cases, it is necessary to increase the participation of the medicines expert in order to take advantage of his or her vast knowledge in the field.

Primary care areas have pharmacists in charge of the storage and custody of vaccines. All hospitals recognize the important work of this professional in the proper storage of these products. Similarly, drugstores are under the direction of this professional. The knowledge of the special conditions for the handling of vaccines is highlighted. However, not all places require the presence of a pharmacist for vaccine custody, contrary to their distribution, which does require the direction of a pharmaceutical chemist.

In Guatemala, the administration of vaccines is not the responsibility of the pharmacy professional. However, the need for their involvement in all health services is emphasized. This includes greater involvement within the National Pharmacovigilance Program.

Patient and professional education is one of the aspects in which Guatemalan pharmacists are involved, collaborating with the Ministry of Health through training on the proper handling and storage of medicines, including vaccines. In the case of patient education, campaigns have been developed by hospitals, primary care centers, companies, and the Ministry of Public Health. In addition, the pharmaceutical care services provided to users include information on vaccination.

The promotion of the pharmacist's work and knowledge in the area of vaccination is a noteworthy aspect for increasing their participation in this area. This allows a greater contribution of the professional in the safe use of these products.

ASPECTS OF SUCCESS
1. Involvement in the marketing and storage elements of vaccines.
2. Training for patients and professionals from the Ministry of Health.

4.8 MEXICO

Information provided by:
Karla Estefanía Hernández Vera

In Mexico, pharmacists are involved in the process of obtaining health registration for vaccines. This allows the application of their knowledge and skills in health regulation and the assembly of technical data sheets for the vaccines to be registered. One of the limitations to this process is that it is not a task exclusively developed by pharmacists, and the processes by the authorities tend to be slow.

The storage and custody of vaccines, through the assurance of the cold chain and the rational use of vials, is an important task for pharmacists in Mexico. The aim is to ensure that these products are properly preserved within the established temperature ranges in order to reduce waste and deterioration. The poor infrastructure of hospitals and shortages of vaccines are limiting factors. Pharmacy professionals should become more involved in this field and offer their knowledge in this area. In Mexico, the administration of vaccines is the exclusive task of nurses.

Regarding the reporting of suspected adverse reactions, the Vaccine Regulatory Authority and the National Center for Child and Adolescent Health have established a process for the exchange of information, as the two agencies generate information related to the reporting of vaccine safety events. For this, pharmacy professionals were trained on the subject by the Pan American Health Organization.

The training and clinical profiles of pharmacists make them leaders in the area of pharmacovigilance, as they have the necessary knowledge to interact with professionals from the chemical and epidemiological fields, among others, as well as with national regulatory agencies.

ASPECTS OF SUCCESS
1. Securing the cold chain.
2. Strengthening the pharmacovigilance system for the reporting of ESAVIs.

4.9 PERU

Information provided by:
María Genoveva Vargas Huilcanina

The participation of pharmacists in the research, development, and production of vaccines in Peru involves several actions, including providing information on the safety and effectiveness of the vaccine against the human papilloma virus (HPV) and vaccine development by pharmacists from the National Health Institute in the Viral Vaccine and Bacterial Vaccine Laboratories. More information can be found at the following link: https://web.ins.gob.pe/es/productos-biologicos/areas-y-laboratorios.

In relation to registration with the regulatory authorities and the marketing of vaccines, pharmacists in Peru are involved in both stages. In terms of registration, this refers to the technical support provided for the preparation of vaccine dossiers. In terms of marketing, the process of supplying vaccines to cover national vaccination schedules is highlighted.

For the storage, custody, and distribution of vaccines according to specific recommendations, the pharmacist contributes to the maintenance of the cold chain, as in other countries in the region.

In the follow-up phase in Peru, the pharmacist's contribution to the National Pharmacovigilance Plan for HPV, through technical criteria, is noteworthy. The experience and evaluation of the pilot project for this vaccine can be consulted at the following link: http://bvs.minsa.gob.pe/local/MINSA/1454.pdf

Peru has had a National Immunization Program since 1972. In 2001, it was incorporated into the Integrated Child Health Care Program, and later, in 2004, the Peruvian Ministry of Health created the National Health Strategy for Immunizations. More information is available at the following link: http://www.minsa.gob.pe/portalweb/06prevencion/prevencion_2.asp?sub5=7

Education of patients and health professionals is an important step in the use of vaccines. In Peru, pharmacists are reported to have collaborated in national training on vaccine safety for professionals and to have provided information on vaccine safety to patients.

ASPECTS OF SUCCESS
1. Vaccine production by the National Institute of Health in the Viral Vaccine and Bacterial Vaccine Laboratories, where pharmacists are involved.

4.10 VENEZUELA

Information provided by:
Freddy Ceballos
Saul Pena

Venezuela has a National Vaccine Center attached to the National Institute of Hygiene Rafael Rangel, of the Ministry of Popular Power for Health. The Center is currently inactive but promises to be an important element in the production of vaccines, with the participation of pharmacy professionals.

In addition, the Medicines Act establishes a sanitary registration; it guarantees effective, safe, and quality products for distribution in the private and public markets. In the case of biological products, they are registered by pharmacists. This includes the control of storage and conservation aspects of vaccines.

Pharmacists in Venezuela participate in the administration of vaccines in the private sector, but with a low profile, as this process is mainly carried out through the Ministry of Popular Power for Health. The limitation to greater participation is related to a regulatory issue, as the pharmacist's presence is not included in the public sector, where the national vaccination plan is guaranteed.

Finally, within the education of health professionals, the Venezuelan Pharmaceutical Federation's conferences, in which national and international professionals participate annually, include aspects related to vaccination. This, together with the perception of trust in the professional and the integration of pharmaceutical care within training programs, has reinforced professional practice. Raising mothers' awareness of the importance of vaccinating children is indicated as an activity related to patient education.

Important points to be taken into account are the promotion of the leadership of pharmacy professionals, the strengthening of continuous training, and the integration of the pharmacist in the health team within public and private institutions, highlighting their general knowledge of vaccines.

ASPECTS OF SUCCESS
1. Participation in the procedure for the registration of vaccines.
2. Development of continuing education elements for pharmaceutical professionals.

5. GENERAL RECOMMENDATIONS FROM LATIN AMERICAN COUNTRIES

Among the recommendations made by the participating countries on the issue of vaccines for the Latin American region, the following elements stand out:

- University education
  - Incorporate or strengthen the subject of vaccines in the curricula. This includes incorporating professional practices in the development and production of vaccines, specialized techniques for handling biological products, and training for participation in follow-up programs to ensure the efficacy and safety of these products.
  - Similarly, development of skills is proposed for appropriate interaction with communities on health issues, prioritizing those related to vaccination.
  - Greater interaction/connection between universities and companies or entities producing vaccines.

- Continuing education for professionals
  - Involvement of professional associations in the training and dissemination of activities related to vaccines, in which pharmacists should play a key role. Training in the reporting and detection of Events Suspected to be Atributable to Vaccination and Immunization, as well as the development of informative material.

- Educational and information activities for users.
  - Constant involvement of pharmacists in health information and educational activities on immunizations, aimed at patients and the general public.

- Participation in public policy management teams
  - Strengthening and inclusion of pharmacists within interdisciplinary teams, especially those linked to social security, ministries of health, and the World Health Organization, among others.

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CHAPTER IV
MANAGEMENT OF PHARMACEUTICAL SERVICES IN THE IMMUNIZATION CHAIN

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1. INTRODUCTION

Based on the experiences found in the countries analyzed, the aim of this chapter is to show the areas of service of immunization in the work of pharmacists and to provide useful tools for pharmaceutical immunization services, from the different areas of their competence and according to their possibilities, in accordance with the profile of the position held. Actions applicable to the different areas of pharmacy, such as community pharmacy, primary care, hospital pharmacy, and sub-areas of the pharmaceutical industry, are presented, and the power of this professional as a responsible actor in public health and in the immunization chain is visualized.

The term "immunization chain" can be defined in an analogous way to the drug chain, considered as the sequence of steps described in the life of a medicine from its creation, development, and use. It includes the experimental and clinical development of the medicine, its registration, marketing, promotion, distribution, prescription, dispensing, and use. Therefore, the immunization chain could be said to refer to the sequence of interrelated processes from the conception and development of a vaccine to its use by users and patients.

Within the entire immunization chain, the pharmacist can play an active role, from the development of effective vaccines to reaching the widest possible population and promoting their best use at the individual level (1-7). The current chapter is structured to describe the links in the immunization chain and the actions that pharmacists can take within them, with a particular emphasis on those involved in pharmacy-based immunization services.

However, within the immunization chain, two broad groups of stages can be distinguished: one comprises the upstream activities necessary to carry out pharmaceutical immunization services, and the other comprises the activities of the immunization services themselves. The first group will be referred to as ***industrial development and marketing*** and this group deals with research and development, production, registration, and marketing of vaccines. The second group, which will be emphasized, is oriented toward the ***management of pharmaceutical immunization services and encompasses*** vaccine administration, monitoring, drug surveillance, and educational activities, as seen from a pharmaceutical care perspective. In addition, storage, custody, and distribution are considered as supporting activities of pharmaceutical immunization services; however, they are themselves links in the immunization chain and should also be implemented at the industrial and commercial level (in distributorships and laboratories, for example; i.e., they are also part of the first stage of the chain) (See figure 5 at the end of this chapter).

2. INDUSTRIAL DEVELOPMENT AND MARKETING

2.1 Vaccine research and development

The pharmacist is involved in the research and development process of new vaccines at all stages, from the identification of the need, through formulation and clinical trials. For example, in the case of the license for the rotavirus vaccine, rotavirus was identified as the leading cause of acute diarrhea and gastroenteritis in children under 3 years of age worldwide, so the development of the vaccine was sought for this sector of the population to reduce the risks associated with the pathology (8). Work also continues on the research and development of new vaccines, such as West Nile virus, Lyme disease, and hepatitis C vaccines for adults (9,10), as well as the most recent research for the development of vaccines against the SARS-CoV-2 virus (11), and the development of new routes of administration, such as intranasal, oral, and patch vaccines (1).

The Global Alliance for Vaccines and Immunization (GAVI) indicates that approximately two million children die each year from diseases preventable by existing vaccines and that several million more lives could be saved if effective vaccines against diseases such as HIV/AIDS and malaria were available—a research challenge (10,12). In addition, in general, a need exists to promote research on adult vaccines and the development of new strategies to achieve greater acceptance by adults (9).

Once the research and development process in industry is completed, the pharmacist is then involved in the entire vaccine supply chain, from licensing by national health authorities to supplying public and private health systems according to demand (1).

ROLES THAT PHARMACISTS CAN PLAY IN VACCINE RESEARCH AND DEVELOPMENT
1. Identify the presence of prevalent or incident diseases (8).
2. Lead research into new vaccines (8).
3. Participate in preclinical and clinical studies for the development of new vaccines (8).
4. Determine, based on technical criteria, the primary and secondary packaging of the vaccine (7).

2.2 Vaccine production

In the interest of broadening the accessibility and acceptability of vaccines, the pharmacist is constantly working to improve every aspect of the vaccine antigen-containing medicine. Even within the manufacturing process, the pharmacist considers efficiency, safety, economics, and regulatory aspects in determining the primary packaging of the vaccine, whether it is a single-dose or multi-dose vaccine (7).

The safety of the vaccine is certified from its development through preclinical and clinical trials. The manufacture of vaccines under good manufacturing practices, batch sampling, and verification of purity and potency are key to the safety of the final pharmaceutical product and are processes in which the pharmacist can and should participate (10).

FUNCTIONS THAT THE PHARMACIST CAN CARRY OUT IN VACCINE PRODUCTION
1. Implement management tools that increase the competitiveness and performance of vaccine production processes (10).
2. Develop tools for vaccine quality assessment (10).
3. Ensure compliance with good manufacturing practices in vaccine production (10).
4. Coordinate the supply of public and private health systems according to demand (10).

2.3 Registration of vaccines with the regulatory authority

Pharmacists, in the area of health registrations, participate in the preparation of reports and documents necessary to comply with import and marketing requirements that allow the distribution and/or sale of vaccines. Their contribution is essential throughout the process, as well as in the renewal of registration and, in general, in monitoring the effectiveness and safety of the product, as reflected in the periodic safety reports after marketing (10, 12).

2.4 Marketing of vaccines

Since vaccines target all populations, their clinical value is universal. In particular settings, their marketing can be targeted to different niches: hospital practice, primary care, outpatient care, and community pharmacies. In addition, information dissemination should involve professionals involved in the immunization chain, such as nurses, doctors, microbiologists, pharmacists, and, of course, users. In this sense, pharmaceutical visits and the organization of lectures and publicity

materials are valuable and should be thoroughly conducted to raise awareness of the application criteria and relevant safety aspects of the products, as well as to show their great public health benefit.

In particular, when it comes to immunization, the approach must always remember the value of preventing diseases and complications of other pathologies (10).

ROLES THAT THE PHARMACIST CAN PLAY IN THE REGISTRATION AND MARKETING OF VACCINES:
1. Analysis of the specific local technical regulation for the type of product to be patented; in this case, for the registration of vaccines (7,10).
2. Preparation, review, follow-up, and communication of the dossier for the registration of the vaccine with the corresponding regulatory authority (12).
3. Submission of the dossier to the regulatory authority (17).
4. Resolution of doubts or objections of the regulatory authority on the application, for the issuance of the registration certificate (7,10).
5. Communication with the Regulatory Affairs and/or Research and Development departments of the manufacturing laboratories on the progress and status of registration (7, 10).
6. Analysis, review, and monitoring of technical documentation for state control of the marketing of vaccines (10).
7. Follow-up of the certificate of marketing authorization/approval for vaccines (7).
8. Making post-registration changes required or requested by the regulatory authority (10).
9. Communication with quality, production, and pharmacovigilance departments regarding post-marketing alerts or defects of the vaccines involved (7,12).
10. Management, custody, and updating of relevant health records (10,12).

3. MANAGEMENT OF PHARMACEUTICAL IMMUNIZATION SERVICES

A pharmaceutical immunization service refers to the set of actions in the health system developed by the pharmacist or under his coordination, in order to ensure comprehensive, continuous, and timely care of immunization needs in vaccine-preventable diseases, at both the individual and collective level. The objective is to obtain concrete results in public health, with a view to improving the quality of life of users (13).

The delivery of immunization pharmaceutical services to users is a key point in their management, as it involves a direct pharmacist-user relationship. Thus, the activities of pharmaceutical care in immunization, vaccine administration, follow-up, pharmacovigilance, and identification of at-risk populations, as well as education of health professionals and users, among others, are strategic processes that play an essential role in these services (13). Support activities are those that are indirectly related to the user but contribute to their care and enable the delivery of the service, including storage, custody, and distribution (13). These support activities, as mentioned above, are also performed at the industrial development and marketing stage; however, as the emphasis is on the management of pharmaceutical immunization services, they will be adapted to the reality of pharmacies.

3.1 Pharmaceutical care in immunization services

Pharmaceutical care comprises a series of activities carried out by the pharmacy professional in order to ensure that patients obtain the best possible outcomes from their pharmacological treatments. These include dispensing, pharmaceutical indication, pharmacotherapeutic monitoring, pharmacovigilance, and public health education (14). Therefore, pharmaceutical care in

immunization services is seen in this document as the set of activities conducted by the pharmacy professional to provide users with access, care, and follow-up of immunizations against vaccine-preventable diseases.

For example, consultations during handover or user education, either directly or as determined by the pharmacy professional when a clearer exposition is required, can be addressed by the expert, so that both counseling and resolution are part of the pharmaceutical care provided by immunization services.

The following is a step-by-step guide to the process of providing immunization services from pharmaceutical care (14-18) (**Figure 1**):

Figure 1. Steps for the delivery of immunization services from pharmaceutical care
***Source**: Own elaboration*

1. **Harvest**
   At this stage, information is collected to determine whether the indication is necessary. This can be obtained through an interview with the user. Another input is the vaccination card. Among the data to be requested are age, health conditions, occupation, lifestyles, and upcoming trips. Determining relevant aspects, such as medical and vaccination history, allergies, medications, and pregnancy status, is also necessary (14-18).

2. **Planning**
   During planning, the aim is to schedule activities to promote immunization services, as well as the development of protocols to be used in the dispensing of vaccines and the timely monitoring of adverse reactions (14-18).

3. **Execution**
   At this point, the previously planned activities are carried out, and work is also done on various aspects, such as patient or user education, vaccine administration, and documentation for follow-up (14-18).

4. **Evaluation**
   This refers both to the identification of precautions and contraindications for the vaccines

that the individual requires, as well as the assessment of the actions already planned and executed. The aim is to be in a process of continuous improvement, where increasingly robust results are obtained in the execution of the activities (14-18).

5. **Follow-up**
   Similarly, follow-up refers to monitoring the individual 15 minutes post-vaccination to rule out syncope or anaphylaxis, scheduling follow-up appointments for multi-dose vaccines, monitoring for adverse reactions, and anticipating the education needs for users and health professionals (14-18).

In this way, a whole plan of action in an immunization service can be carried out from pharmaceutical care, according to the professional's criteria and the needs of the population.

This is followed by particular activities within this action, such as the administration of vaccines.

3.2 Administration of vaccines

The professional practice of pharmacists has strengthened the administration of vaccines, among other services offered, due to their accessibility, trust, convenience, proximity, and rapid access. Pharmacists possess or can develop the competencies to implement appropriate administration; in fact, they have been highlighted as a fundamental tool for expanding vaccination coverage (2, 3,5 -7,9, 22-32).

In this sense, the pharmacist is trained to recommend (33) and administer vaccines, as well as to perform associated activities, such as managing and producing vaccination cards. Sometimes the pharmacist does not administer the vaccine, but is instead actively involved in the process by recruiting nurses for immunization at the pharmacy or by ensuring the supply of the product (23). This depends on the legislation or regulations in force in each country or state, province, department, or territory, which the pharmacist must know beforehand. In other cases, the pharmacist must be accredited in order to participate in the administration (23).

In the case of **vaccination in the community pharmacy**, minimum requirements must be met in order to administer this type of medication: a private space exclusively for the administration of injectables, adequately lit and at an appropriate temperature (18–25°C); a hand-washing area; and sufficient space to accommodate the user with a companion and in which the pharmacist can maneuver (34).

The steps for vaccination are shown below (10):

1. Wash hands with soap and water.
2. Check that the user is seated or in an optimal position.
3. Identify and expose the area to be vaccinated.
4. Clean the area with alcohol if administered intramuscularly (IM), subcutaneously (SC), or intradermally (ID), and allow to dry.
5. Support the user in case of nervousness.
6. Insert the needle (at 90° for IM, 45° for SC, or 10° for ID), with a smooth and firm movement.
7. Push the plunger to inject the contents of the syringe.
8. Remove the needle quickly.
9. Apply cotton wool or gauze to the injected area.
10. Wash hands with soap and water.

The vaccine should not be loaded into the syringe until immediately prior to administration and different vaccines should not be mixed in the same syringe, unless recommended by the regulatory body (10). In case of anaphylactic shock following administration of the vaccine in the pharmacy, the protocol is as follows (35-36):

1. Identify if the user presents with sudden onset of generalized urticaria, angioedema, flushing, or pruritus. These are some of the most common signs in pediatric and adult populations, although sometimes skin symptoms may be absent (35-36).
2. Remember, for signs of anaphylactic shock (rapid progression of symptoms, evidence of respiratory distress such as wheezing, dyspnea, increased respiration, persistent cough and cyanosis, signs of poor perfusion, abdominal pain, vomiting, dysrhythmia, hypotension, or collapse), epinephrine has no absolute contraindication (35).
3. Check the individual's airway status; if the individual is unconscious, the pharmacist should place the person in a lateral safety position to avoid the risk of choking due to vomiting, unless this causes breathing difficulties. Pregnant women should be placed on their left side to avoid oppression of the vena cava by the pregnant uterus. If the individual is conscious, the pharmacist should position the individual in the supine position, with the head in a lateral position (36).
4. Activate the emergency number alert system, for which the pharmacist can request help from a colleague, if accompanied (36).
5. For adults, administer epinephrine 0.3 to 0.5 mg intramuscularly (1 mg/mL presentation), preferably in the mid-thigh. For the pediatric population, epinephrine 0.01 mg/kg should be injected intramuscularly into the mid-thigh. For large children (> 50 kg), the maximum is 0.5 mg per dose. You can repeat the dose, in both cases, every 5 to 15 minutes as needed. A response should occur with three doses (35).
6. Ensure the transfer of the individual, with emergency personnel, to the appropriate health facility (36).
7. Document the time the event occurred and where it took place, the management performed, and the dose of epinephrine administered (35-36).
8. Subsequently, make an appropriate report of a suspected adverse reaction to the relevant vaccine (35-36).

After vaccine administration, the pharmacist should enter in writing the date of immunization, vaccine-related data (product brand, batch, route of administration), user's personal information (full name, ID number, age), and the pharmacist's code in the digital dossier or equivalent (7, 27, 37, 30, 38), according to the legislation in force in each country. For internal control, place of residence, date of birth, and informed consent could be documented (34).

The pharmacist should refer to primary care medical centers, depending on the idiosyncrasies of the patient, the immunocompromised, those with a history of allergic reaction, thrombotic disorders or those on anticoagulants (22). Again, pharmacists should be aware of their country's legislation to understand the legal and professional implications of administering vaccines in their facility (3, 7, 34).

Whatever the situation, any pharmaceutical facility that vaccinates should have personnel, equipment, and a protocol for response in case of anaphylaxis or other emergency (35, 34, 38). In this regard, relevant regulation is vital to provide legal certainty for vaccine injury in the absence of negligence (e.g., anaphylaxis, syncope, administration site damage, or Guillain-Barré syndrome) (39).

Patient safety requires legal control over the pharmacist's relationship with a professional association, accreditation to administer injectables, management of anaphylaxis, and first aid (34,38)—aspects that can be contemplated in university training.

Along the same lines, community pharmacy immunization services still face general challenges that need work, and these must be addressed, together with the support of other health professionals acting as promoters (24). These challenges are outlined below:

1. Lack of knowledge on the part of the user about the possibility of receiving vaccinations at the community pharmacy (2, 7, 24, 38, 40, 41).
2. Perception that vaccines are not important (24).
3. Distrust of the pharmacist's qualifications and the facility's suitability to administer vaccines (7, 24, 42).
4. Lack of health authority policies that define, regulate, and support the pharmacist's role in vaccination (2, 7, 30, 32, 43).
5. Cost-effectiveness of specific vaccines in the pharmacy inventory (1, 39, 44).
6. Dissatisfaction of other healthcare actors who see this pharmaceutical practice as an encroachment on their competences (2).
7. Restrictions on certain vaccines for use in pharmacies (1, 30, 45).
8. Lack of permission for pediatric vaccination by pharmacists (3, 22, 43).

FUNCTIONS THAT CAN BE PERFORMED BY THE PHARMACY PROFESSIONAL WHEN ADMINISTERING VACCINES

1. Establish written protocols for the vaccination process, taking consent from the individual and reporting vaccination on file or equivalent (34), according to local and national regulations to enforce the required formality.
2. Update and manage the vaccination card (22, 37).
3. Recommend vaccines according to patient or user characteristics (31, 38).
4. Administer vaccines (2, 3, 5, 7, 7, 9, 22, 24, 25, 26, 30, 31, 38, 37, 45-48).
5. Dispose of sharps and clinical waste appropriately, according to the legislation in force in the country (33-34).
6. Schedule follow-up appointments for multi-dose vaccinations (37).
7. Document date of immunization, product brand, batch, route of administration, user's personal details, and pharmacist's code in the dossier or equivalent (7, 37, 49).
8. Know and understand the legal and professional implications of administering vaccines from their establishment, according to the country's legislation (3, 7).
9. Refer to primary health care facilities individuals who, because of their particularities, should not be vaccinated in a community pharmacy (33, 37).
10. Establish a vaccine transport and distribution protocol (50).
11. Rotate inventory and ensure availability of vaccines (50–52).
12. Ensure compliance with the cold chain (50–52).
13. Keep proper records and control of temperature (53–54).

Within the vaccination process, the pharmacy professional can also provide important contributions and support to the user and other professionals in the immunization service, from the point of view of pharmaceutical care. In this context, the pharmacist should be properly trained in vaccination intervals, a key aspect in guaranteeing the safety and effectiveness of immunization products, as well as in identifying at-risk populations. Therefore, while it will not be feasible in all territories or work roles for pharmacists to apply the vaccine themselves, they have the possibility to get involved in their nearest immunization service to participate in pharmaceutical care activities, such as consultation on these and other aspects of the issue.

Vaccination intervals

In the background collection stage for administering vaccines, the pharmacist should conduct an interview with key questions to determine the suitability of vaccination and ask about particular aspects, such as contraindications, precautions, and interactions with medications and pathologies. Regarding the latter, interactions can occur between vaccines and immunization products with antibodies, such as immunoglobulins. Inactivated vaccines can be administered concomitantly with antibodies, whereas live vaccines require checking what has been administered first: if it was the vaccine, then a two-week wait is necessary before administering the antibody (10). Otherwise, the wait time will depend on the specific antibody, ranging from three to eleven months inclusive; however, at least a minimum of a three- month waiting period should be employed for administering another vaccine without affecting the immune response and thus its effectiveness (10). However, oral and intranasal vaccines can be administered together with immunoglobulins or blood products without problem (10, 19).

The simultaneous use of live and inactivated vaccines can be done concomitantly without risk of affecting antibody production or the occurrence of adverse effects. In fact, the simultaneous use of all vaccines for which a child is eligible, according to the vaccination schedule, increases the likelihood of compliance with the full schedule. As expected, when possible, the administration of combination vaccines is preferred to the simultaneous administration of monovalent vaccines (11,19-21-34).

However, if two live vaccines are not administered simultaneously, they should be given at least four weeks apart. Exceptions are the MMR and yellow fever vaccines, where studies have shown that if both are required and not available simultaneously, they can be administered less than 4 weeks apart without affecting the immune response. Oral vaccines are also an exception, as they can be administered at any time before or after another vaccine (10, 19) (see **Table 4**).

Table 4. Guidance for identifying intervals in vaccine administration

Type of vaccine	Minimum interval
Inactivated vaccine + live attenuated vaccine.	Simultaneous administration or any interval between doses.
Two inactivated vaccines.	Simultaneous administration or any interval between doses.
Two live attenuated parenteral vaccines.	4 weeks. *
Live vaccine + immunoglobulin or other blood products.	3 - 11 months, depending on the specific antibody.

Oral live attenuated vaccines may be administered at any time.
***Source**: Own elaboration*

Identification of at-risk populations

With simple and routine questions, the pharmacist can identify elderly people, children, pregnant women, immunocompromised people, people with chronic diseases, and even travelers and either refer them to the corresponding vaccination center or administer the vaccine (2, 7, 17, 25, 46, 49). This is also part of the pre-interview of the user by the pharmacy professional. In this regard, the American Pharmacists Association (APhA) establishes age, health conditions, occupation, lifestyle, and future travel as minimum necessary information to be collected by the pharmacist (2, 37).

The need for immunization may be lifestyle-related, such as in children under 8 years of age or over 50 years of age who are frequent visitors to hospitals, nursing homes, outpatient centers, or emergency rooms or in health professionals and other occupations who are in potential daily contact with communicable diseases (7, 40). The need may also increase due to risky medical diagnoses, such as diabetes, asthma, heart disease, obstructive pulmonary disease, cancer, cirrhosis, acquired immune deficiency virus, and other conditions. It also applies to conditions such as pregnancy, as well as certain medical procedures, such as heart or lung surgery, splenectomy, radiotherapy, immunosuppression, dialysis, and drug therapies. This is because these conditions increase the risk of preventable infections and suggest the need for immunization (6, 7).

In addition, at the population level, vaccination is recommended against some seasonal outbreak infections, such as influenza, and when visiting some established risk sites, such as some areas of South America with respect to yellow fever (6, 7). These are all possible rubrics for screening beneficiaries for immunization.

However, the identification of at-risk populations also extends to patients with contraindications or who are more likely to have adverse effects, as the risk-benefit ratio of immunization may be negative in these individuals. In these cases, the health status, medical and vaccination history, allergies, and pregnancy should be considered (7, 48).

Allergic reactions should be prevented by consulting the information provided by the manufacturer on the formulation of the vaccine, as all its components are mentioned, including potential allergens, such as the antigen, animal protein residues, antimicrobial agents, preservatives, and stabilizers (55). In addition, the pharmacist can avoid duplication in those who, during the interview, say that they have already received the vaccine or that it is recorded on their vaccination card (49).

In addition to the interview, the pharmacist uses vaccination schedules and information provided by the user to determine vaccine needs. Although some platforms are already in place, such as the Nominal Vaccination System (SINOVAC), among others, the challenge of universality in the implementation of this type of tool still persists in the Americas, where the registration of confidential information on the record of immunizations applied to each individual is allowed by the subscribing health centers (10,37).

3.3 Monitoring and pharmacovigilance

An important part of the administration of any product for human use is to have a system capable of detecting adverse events related to its use and to be able to use these data to build an increasingly better risk-benefit profile for each product. Vaccines, having certain associated risks, are not exempt from this need; therefore, pharmacovigilance becomes relevant. Consequently, pharmacovigilance is essential in the immunization chain, as it allows the pharmacist to identify rare adverse reactions not detected in previous studies, to census increases in known reactions, to identify risk factors predisposing to adverse effects, to determine whether any production batch is associated with an increased number of adverse effects, and to assess whether new adverse effects warrant reconsideration of existing immunization recommendations (10).

Pharmacists, having extensive experience in the reporting of adverse drug reactions, can take a leading role in the follow-up after the administration of vaccines. In this way, they offer support to the user and explain the protocol for the timely detection of such reactions, as well as measures to deal with them (7, 22, 39). In the event of a possible adverse reaction caused by vaccines, the pharmacist should report the reaction to the official pharmacovigilance body in their country (2, 7,

22, 47, 48, 50). In any of the above cases, the reporting of adverse events (however well-known and predictable they may be) is essential for monitoring the post-marketing behavior of these products and to direct actions to improve their use.

Note that suspected adverse reactions to vaccines have been technically described as Events Suspected to be Attributable to Vaccination and Immunization (ESAVIs) (54). An ESAVI is defined as a clinical condition related or unrelated to the administration of a vaccine (15).

The classification of ESAVIs is described below (15) (**Table 5**):

Table 5. Guidance for the classification of Events Suspected to be Attributable to Vaccination and Immunization (ESAVIs)

Type of ESAVI	Description
Vaccine-related events	These are those associated with the administration of the vaccine at normal doses and with the effect of immunization.
Coinciding events	These are the result of another cause or pathology temporally related to the immunization, but not directly associated with the vaccine.
Programmatic errors	These are associated with human error in vaccine preparation, handling, or administration.

***Source**: Own elaboration*

Follow-up appointments can also be set up to complete schedules or to reassess risk factors. Follow-up calls can also be made and scheduled to check for the occurrence or course of adverse events following immunization.

As already highlighted in the previous chapters, the pharmacist's role as an immunizer leads to very good health outcomes for the general population because of his or her experience and skills.

IN GENERAL, THE PHARMACY PROFESSIONAL INVOLVED IN THE ADMINISTRATION OF VACCINES CAN:

1. Implement a medicine storage, handling, and supply plan (33, 48).
2. Consider stability and regulatory requirements for drug substances in their possession (33, 48).
3. Participate in the identification of at-risk populations, selection of immunological therapy, and application of vaccines (48).
4. Identify and address target populations according to age, pathology, occupation, and potential or overt exposure (2, 7, 25, 35, 37, 46, 49).
5. Conduct vaccination campaigns from the pharmacy and through health fairs. For example, when dispensing other medicines, the pharmacist can provide information about the immunization service and/or recruit potential beneficiaries (50).
6. Establish written protocols for dealing with adverse effects (34).
7. Explain the protocol to the user in case of potential adverse effects of the vaccine (7, 22, 39).
8. Report suspected adverse reactions to the competent authority (2, 7, 22, 47, 50).
9. Assess the user 15 minutes post-vaccination to rule out syncope or anaphylaxis (35-37).
10. In cases of post-vaccination allergic reactions, stabilize the user and refer to a medical center (35, 37).

3.4 Education of health professionals

By being in contact with other health professionals, pharmacists in clinics, health facilities, hospitals, community pharmacies, and regulatory bodies have the potential to disseminate information

of all kinds regarding vaccination (22, 50, 52). Therefore, they can contribute to the promotion of vaccination from the pharmacy by contacting users directly and by giving talks or updating meetings with members of the health care team. In this sense, a relevant point is the work carried out by pharmacists dedicated to the exclusive education on the subject of vaccines in the medical visit (22, 50, 52, 55, 58-61).

Another promotional tool in this area is the structure and implementation of courses and training on immunization for health professionals, as well as facilitating access to related scientific material. Promoting research and innovation, both locally and globally, as well as disseminating the results, are also competencies of the pharmacist in these services. In particular, the research and innovation in Latin America is a challenge to be addressed, as, unfortunately, it does not seem to have sufficient reach (12).

3.5 Service user education

In close coordination with the individual and his or her physician, the pharmacist can establish a vaccination plan that meets the individual's needs. The development and recommendation of this type of plan influences the decision whether to undergo immunization; therefore, a strong, clear, evidence-based recommendation by the pharmacist is a cornerstone of user guidance (37,55, 58-61).

Prior to vaccination, the pharmacist should provide relevant information on the storage, mechanism of action, possible adverse reactions, importance of immunization, and vaccination schedules (2, 7, 22, 37-38). This information should be supported by guidelines and studies that provide reassurance to the user (37) and should be shared in accessible language (38).

Similarly, pharmacists promote public health strategies by informing the general population about the importance and benefits of vaccination, the risk of infectious diseases and by demystifying the adverse effects and the anti-vaccine trend. In short, by providing confidence in vaccines (2, 5, 7, 22, 37, 56).

In addition, the pharmacist provides up-to-date scientific and evidence-based professional recommendations (49) that are useful in responding to the concerns of parents and the general public about undesirable effects of vaccines, which constitute a serious problem of misinformation on this topic (33). Communication strategies can include personal letters, telephone calls, posters, printed material, and stickers to accompany medicines, both those dispensed and those requiring vaccination (7, 26-27), without neglecting the direct oral communication of the consultation and pharmacist-user interaction (8). With cybernetic evolution, the pharmacist may even have the potential to reach new populations through media-based interventions, such as text messaging and electronic medical record software (28).

The importance of pharmacists and the strategic role of community pharmacies in organizing vaccination campaigns and raising awareness has also been mentioned. This involves knowledge and involvement of the professional in national public health policies, as well as the ability to discern the associated logistics (e.g., whether a vaccination is seasonal or pandemic) (11, 29).

However, the challenges in vaccine information go beyond teaching only the individual; scientific-technological knowledge must also be disseminated publicly, internationally, and constantly with other health science professionals to promote interdisciplinary cooperation and achieve the public health interests of Latin American countries and the world (7, 12).

FUNCTIONS THAT THE PHARMACY PROFESSIONAL CAN PERFORM WHEN WORKING TO EDUCATE USERS AND OTHER HEALTH PROFESSIONALS

1. Raise awareness among the elderly, children, pregnant women, immunocompromised, chronically ill, and travelers about the importance of vaccination and the benefits it would bring them (2, 7, 17, 22, 25-26, 37, 46, 49, 55, 58-61).
2. Refer users to the respective health centers when they require specialized care (2, 7, 17, 22, 25-26, 37, 46, 49).
3. Avoid duplication of doses in already vaccinated individuals (37, 49).
4. Provide relevant information on the storage, mechanism of action, possible adverse reactions, importance of immunization, and vaccination schedule in individuals (2, 7, 22).
5. Develop personal letters, posters, printed material, or stickers to accompany medicines dispensed that suggest a need for vaccination (7, 26).
6. Promote public health strategies for the general population, inform about the importance and benefits of vaccination and the risk of infectious diseases (2, 5, 7, 17, 55, 58-61).
7. Demystify misconceptions about adverse effects and the anti-vaccine movement (2, 17, 55, 58-61).
8. Conduct refresher talks or meetings and training for members of the health team (22, 50, 52, 55, 58-61).
9. Provide scientific material and/or results of innovation and research in vaccines.

4. SUPPORT ACTIVITIES IN PHARMACEUTICAL IMMUNIZATION SERVICES.

4.1 Storage and custody of vaccines in the pharmacy

Regarding vaccine custody and storage, it is recommended that a designated person in the pharmacy establishment implement the protocols (present in local or national guidelines) in collaboration with a deputy. Similarly, all pharmacy staff should be trained to maintain the cold chain and identify present or potential errors (10, 12, 50-51).

Note that the cold chain concept refers to the temperature-controlled supply system, including equipment and procedures used in the transport, storage, and handling of vaccines, from production to application (10-12, 50-52). The cold chain is established in the range of 2 to 8 °C; vaccines may be damaged above or below this temperature range. However, warming to 12°C for 15 minutes or less is acceptable (10-12, 50-52).

Protocols must clearly indicate the person who is to be notified of cold chain failures, refrigerator damage, or electrical shorts, and who will provide a documented and tested back-up storage option (10,57-60).

The responsible pharmacist should check the status of all vaccines entering his or her facility, ensure their cold chain at all times, as well as their proper storage, rotate inventory to remove vaccines with near expiry dates first, and never dispense expired vaccines (10, 33, 57-60).

As discussed above, the pharmacist is empowered to dispense the vaccine to the user, along with related education or information (22). In addition, depending on the regulations in each country, the pharmacist administers the vaccine (for example, in community pharmacies), while in other countries, where pharmacists are not empowered to administer the vaccine, they can serve as the point of liaison between the distributor and the immunizer, whether that be a physician or other health professional (55, 59-61).

Protocols for proper vaccine handling should include standard procedures for the entire supply chain, from instructions for ordering and receiving new vaccines to inventory rotation and proper storage (10, 50-52). The pharmacist forecasts vaccine requirements, monitors stocks, updates on proper vaccine handling, and establishes storage and safekeeping protocols (50).

In terms of storage, vaccines should be kept in an appropriate refrigerator specifically designated for vaccines and immunoglobulins. The temperature should be checked at least twice a day, by means of a properly functioning temperature measurement system. Internal audits of vaccine storage are recommended at least once a year. In addition, the placement of the vaccine refrigerator should meet the following requirements (10, 50, 52, 53, 54, 56, 60):

- It should be kept out of direct sunlight.
- It must be connected directly to the wall socket or power plant, never to a power strip.
- It must have appropriate ventilation to the sides and rear, as recommended by the manufacturer.
- The area in which it will be located must be secure, with access restricted to authorized personnel.
- It must not rest against external walls, which could heat up or cool down due to climatic changes.
- If the room temperature fluctuates, a thermal insulation system should be installed.
- It must have an alarm system in case of temperature deviations.
- In case of constant power cuts, an emergency generator should be available.
- It must have "do not switch off or disconnect" signage on the plug or electrical safety systems.
- Avoid opening the refrigerator without knowing in advance which vaccine is needed and where it is located, to avoid internal heating.
- Water bottles or cold packs should be available, as they help to keep the internal temperature down in case of fluctuations due to door opening and in the event of a power failure.
- Small refrigerators, with a single door fridge/freezer combination, should be avoided, as they are inappropriate.
- The refrigerator should be used exclusively for vaccine storage, both to avoid contamination by other medicines and because of temperature changes due to frequent opening and closing of the door.
- If other biologicals are to be stored in the refrigerator, they should be placed underneath the vaccines to avoid contaminating them.
- Food and beverages should never be stored in the vaccine refrigerator.
- Diluents should be stored according to the manufacturer's specific instructions.

The following is the arrangement of vaccines in refrigerators as proposed by the Pan American Health Organization (PAHO) (**Figure 2**):

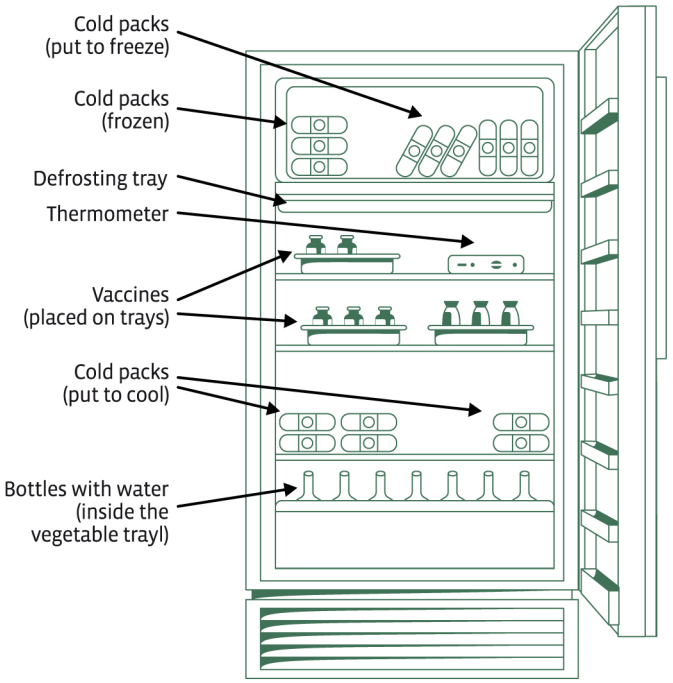

Figure 2. Organization of vaccines and other supplies in the refrigerator

***Source**: Module III. Cold Chain. Management course for the effective management of the Expanded Program on Immunization (EPI) by the Immunization Unit for Family and Community Health, copyright 2006 PAHO. Reprinted with permission of the Pan American Health Organization. Available at: http://www.paho.org/immunization/toolkit/resources/paho-publication/training-materials/modulo3.pdf?ua=1*

Due to the importance of maintaining the cold chain for the stability of vaccines, an action plan should be drawn up in the event of a power failure. The following is a guide to the steps to be taken in case of interruption of the cold chain for this reason (50,59).

1. A cooler should be available to ensure that the temperature of the vaccines is maintained (50, 59).
2. Isolate vaccines in cooler and label "do not use" to maintain temperature (50,59).
3. Contact technicians to repair the defect in case of failure (50).
4. Contact the manufacturer or a health authority for verification of special requirements (50).
5. Do not rule out vaccines unless the authority deems it necessary (50, 59).
6. Verify the correctness of the cause of the interruption (50).

FUNCTIONS TO BE PERFORMED WHEN THE PHARMACY PROFESSIONAL IS RESPONSIBLE FOR THE STORAGE AND SAFEKEEPING OF VACCINES
1. Inventory control and procurement of new vaccines as needed by the facility (7, 33).
2. Maintain and constantly check the cold chain (7, 50,57-60).
3. Have a protocol in case of interruption of the cold chain (7, 50, 57-60).
4. Verification of compliance with vaccine storage refrigerator specifications (10, 51).
5. Ensure proper storage of vaccines (7, 33, 57-60).
6. Designate staff responsible and deputy for vaccine storage controls (51, 52).
7. Establish a protocol for the procurement and safekeeping of vaccines (51, 52).
8. Dispense the vaccine with appropriate user education (50).
9. Ensure correct control and recording of temperatures (57-60).

4.2 Distribution of vaccines

During the transport and distribution of vaccines, the cold chain and other conditions needed to ensure stability must be maintained through the use of portable refrigerators, cool boxes, and cold gel packs (50, 51). The type of vaccine, volume, ambient temperature, and maximum travel time during transport are also important considerations (50). In this regard, pharmacists working in industry, distributors, and health centers are involved.

In the case of the pharmacist-distributor, he/she should keep strict control over the expiry dates, refrigerator layout, number of doses, and batches. The pharmacist regent of the health center, when receiving the vaccines, should document the type of vaccine, number of doses, condition of the packaging material, verification of the cold chain, batch, expiry date, origin, and type of packaging (50). Similarly, the industrial pharmacist must ensure that vaccines leave the production plant in optimal cold chain conditions.

The arrangement of vaccines in the pharmacy and refrigerator should consider thermal stability, accessibility, and shelf life (50). The pharmacist should perform daily temperature checks to ensure the cold chain (7, 22, 50) and ensure that quality standards are maintained in the proper storage of the vaccine. Similarly, the pharmacist should implement protocols for the supply of immunological medicines in high-demand health centers (7).

For these reasons, a series of activities to be carried out, according to the different stages of the vaccine distribution and custody protocol, are given below (**Table 6**) (10, 55, 58-61).

Table 6. Guide to activities to be carried out according to the protocol for the distribution and safekeeping of vaccines

Stages	Activities involved
Order of new vaccines	- The right amount at the right time. - Inventory should be conducted on a regular basis. - Include details on filling out, storing, submitting, and tracking new vaccine application forms.
Distribution	- Establish a designated person to receive vaccine orders. - Ensure strict control over the cold chain. - Transfer vaccines in their original packaging immediately to the pharmacy refrigerator. - Check the expiry date of vaccines. Keep expiring vaccines ahead of time in the refrigerator. - Document date, quantity, type, and batches of vaccines received. - Always include a contact person to report if the cold chain is broken.
Control of the cold chain	- Provide technical training on the use of the temperature control system: data storage in the computer, calibration dates, and data reading. - Have an emergency electrical system or, failing that, cool boxes to ensure that the temperature is maintained in the event of a power failure. - Monitor the refrigerator temperature twice a day, as well as the maximum and minimum temperatures. - Have a standard procedure ready in case of interruption of the cold chain, both during working hours and when the pharmacy is closed.
Equipment maintenance	- Provide training on how and when to change temperature sensor batteries. - Purchase a refrigerator service contact. - Provide instructions for the annual internal audit test of the chiller. - Provide instructions and records for cleaning the refrigerator.
Transport of vaccines	- Ensure correct packing of ice chests. - Ensure temperature control during transfer.

Source: *Own elaboration*

In addition, if it is necessary to **transport vaccines in coolers or thermoses**, it is necessary to know the following concepts and processes for their proper distribution.

Cold packs are special plastic containers that contain water or a colored eutectic mixture. Cold packs with frozen water are the best cooling medium for coolers and cold boxes. In general, a large number of these are necessary, as they should be sufficient to completely surround the coolers and cold boxes if they are used. The proper arrangement of cold packs in cold boxes will be discussed later (59).

Cold boxes or thermal boxes are containers with an insulating structure made of polystyrene or high-density polyurethane and are used to move vaccines from national to regional and local levels on extended journeys of 36 to 181 hours, depending on the specifications of the equipment and the environmental temperature of exposure (59).

In particular, cold packs with eutectic mixtures should not be used for the preparation of thermos flasks and thermo boxes, because when a water-filled cold pack starts the thawing process and there is liquid inside, there is no frost on the outer surface of the cold pack. This is not the case with the eutectic mixture pack, as it can be in a liquid state even below 0 °C and have frost outside the container. In other words, with eutectic mixtures, the only sign of permanence above 0°C is the melting of the frost, not the liquid state of the mixture (59). This is relevant because the established temperature for the cold chain is 2 to 8 °C, as discussed above.

Thermos flasks, by contrast, are smaller containers also made of polystyrene or polyurethane and are used for transport between all levels and for vaccination activities. Thermoses can maintain and preserve a temperature between 2 and 8 °C for 36 hours at an ambient temperature of 43 °C. Again, these characteristics depend on the equipment and the ambient temperature (e.g., the type of insulation, its thickness, the number of cold packs, and the incidence of radiation in the area where it is used) (59). Ideally, it is best to check the specifications of the individual equipment and the conditions in the transport area, as requirements are likely to be different between temperate and tropical areas (59).

Before packaging vaccines for transport, consideration should be given to cold pack ambience (i.e., to abandon the temperature below 0°C and to aim for the required minimum of 2°C) (**Figure 3**):

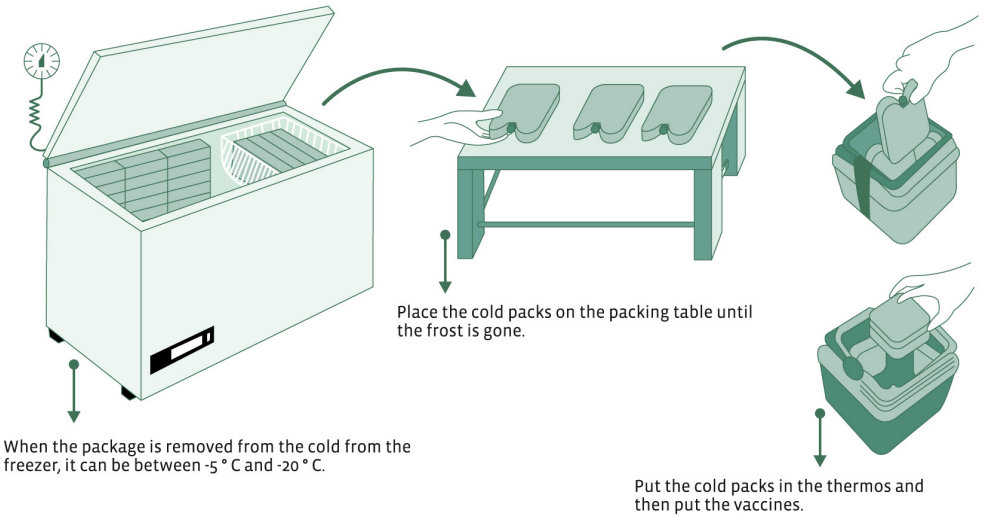

Figure 3. Setting up the cold packs prior to placement in the coolers or thermoses
***Source**: Module III. Cold Chain. Management course for the effective management of the Expanded Program on Immunization (EPI) by the Immunization Unit for Family and Community Health, copyright 2006 PAHO. Reprinted with permission of the Pan American Health Organization. Available at: http://www.paho.org/immunization/toolkit/resources/paho-publication/training-materials/modulo3.pdf?ua=1*

The following figure shows how to pack vaccines in ice chests or thermoses and the correct placement of the cold packs. With this arrangement, as long as there is water and ice in the cold pack, no heat will be transferred to the vaccines (59) (**Figure 4**):

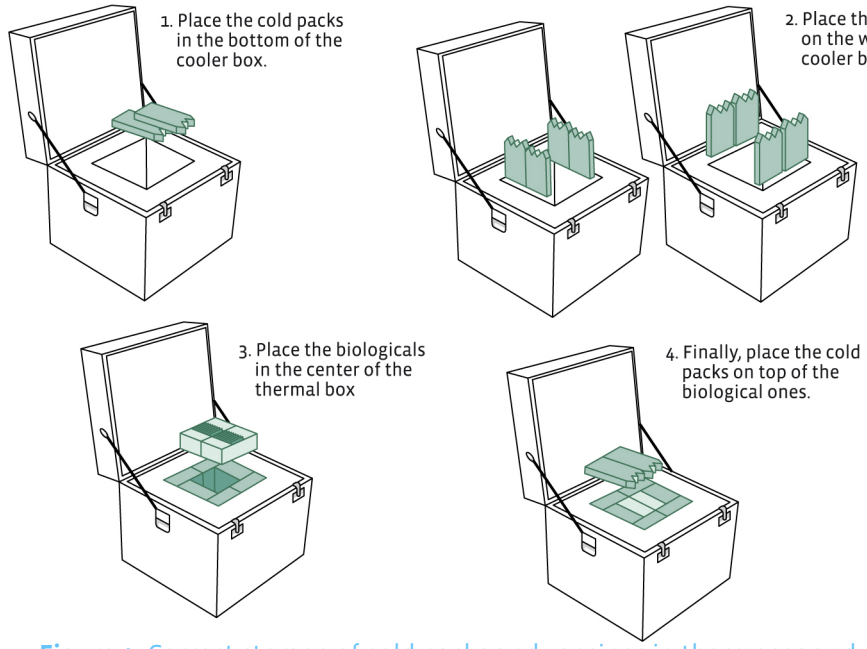

Figure 4. Correct storage of cold packs and vaccines in thermoses and coolers
***Source**: Module III. Cold Chain. Management course for the effective management of the Expanded Program on Immunization (EPI) by the Immunization Unit for Family and Community Health, copyright 2006 PAHO. Reprinted with permission of the Pan American Health Organization. Available at: http://www.paho.org/immunization/toolkit/resources/paho-publication/training-materials/modulo3.pdf?ua=1*

5. GRAPHICAL OVERVIEW OF THE IMMUNIZATION CHAIN

Finally, to conclude this chapter, the following is a summary of the entire immunization chain with the possible tasks to be performed by the pharmacist in each of the links (**Figure 5**):

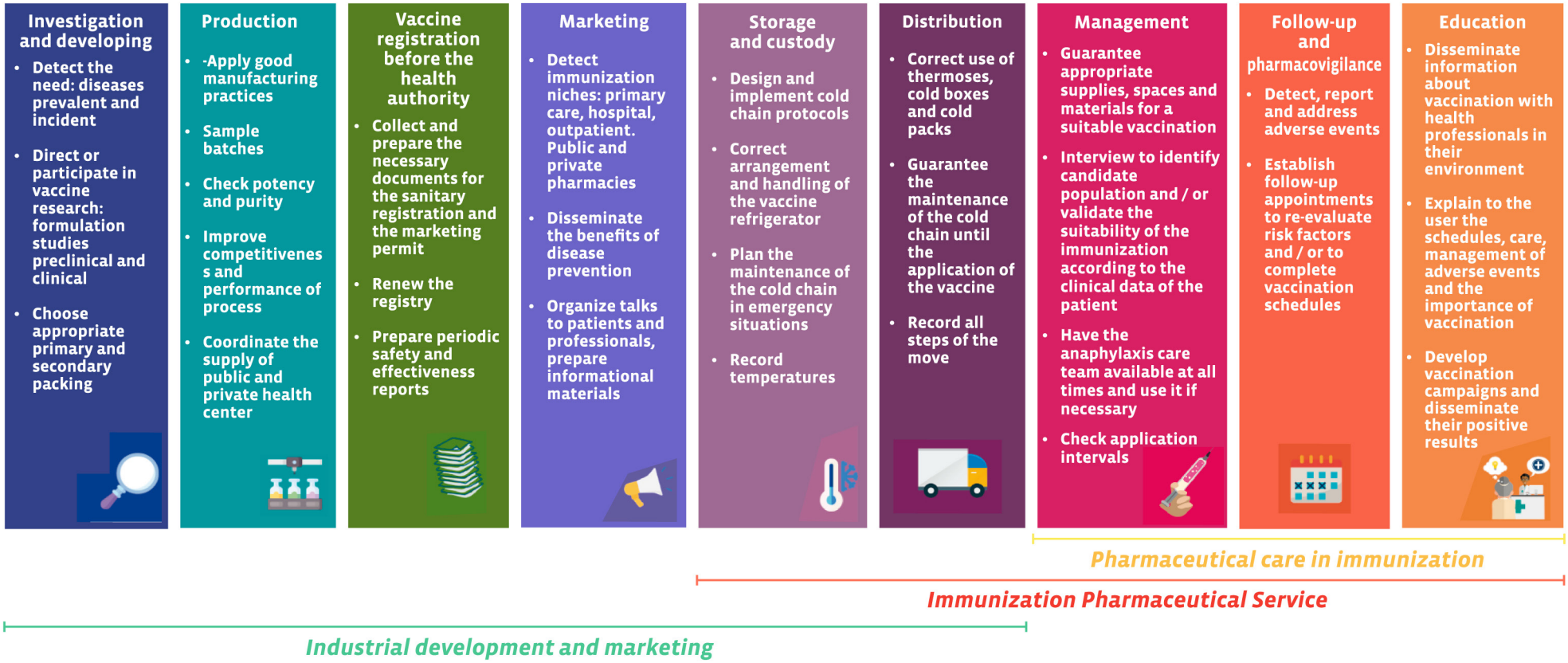

Figure 5. Roles of the pharmacy professional in the links of the immunization chain

Source: Own elaboration.
Icons taken from:
Becris. Calendar [Internet] [cited 3 August 2020]. Available at: https://www.flaticon.com/free-icon/event_3079026?term=calendar&page=1&position=40
Creative Commons 4.0 BY-NC. Vaccination [Internet] [cited 3 August 2020]. Available at: https://www.pngarts.com/explore/5469
Cuby Design. Delivery, shopping, transport, truck icon [Internet] [citado 3 agosto 2020]. Available at: https://www.iconfinder.com/icons/3387313/delivery_shopping_transport_truck_icon
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Freepik. Search [Internet] [cited 3 August 2020]. Available at: https://www.flaticon.com/free-icon/search_3037910?term=magnifying%20glass&page=1&position=27
Kyle Art War Agency. Paperwork [Internet]. 2017 [citado 2 Marzo 2020]. Available at: https://www.efilecabinet.com/hr-departments-conquer-industry-challenges-with-efilecabinet/paperwork/
Siwat V. Advertise, business, marketing, megaphone, seo, work icon. [Internet] [citado 3 agosto 2020]. Available at: https://www.iconfinder.com/icons/2377630/advertise_business_marketing_megaphone_seo_work_icon
Tiporiyaman. It Takes Patients - Patient Adherence Therapy Chronic Condition Symptom [Internet]. 2018. [citado 3 agosto 2020]. Available at: https://favpng.com/png_view/it-takes-patients-patient-adherence-therapy-chronic-condition-symptom-png/WV7Rrn

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ANNEX
DATA COLLECTION INSTRUMENT
SUCCESSFUL EXPERIENCES IN LATIN AMERICA AND THE CARIBBEAN IN THE AREA OF VACCINES

Prepared by:
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The Pharmaceutical Forum of the Americas, through the Medicines Information Center of the University of Costa Rica, seeks to identify successful experiences in Latin America and the Caribbean where the pharmacy professional has been involved.

Objective of the instrument: to identify successful experiences in the Americas where pharmacists have been involved.

1. VACCINE RESEARCH AND DEVELOPMENT

a. In your country, have pharmacists been involved in research and development groups for new vaccines?
   i. Yes - Go to 1.b.
   ii. No - Go to 1.h

b. In this process (new vaccine research and development groups), have you identified any successful experiences in which a pharmacy professional has been involved?
   i. Yes - Go to 1.c
   ii. No - Go to 1.h
   iii. Don't know - Go to 1.h

c. Describe briefly and concisely the purpose of the successful experience in which the pharmacy professional participated.

d. Briefly describe the successful experience in which the pharmacy professional participated.

e. Indicate two positive points to highlight from the pharmacist's participation in this successful experience.

f. Indicate the two main constraints to pharmacist involvement in this successful experience.

g. Please indicate your recommendations for the encouragement of pharmacy professional participation in similar experiences.

h. (Only if you answer no or don't know to 1.a or 2.b) Please indicate how you think pharmacists could be motivated to be part of research and development groups for new vaccines in your country. (Go to question 2)

2. VACCINE PRODUCTION

a. In your country, have pharmacists been involved in the vaccine production process?
   i. Yes - Go to 2.b.
   ii. No - Go to 2.h

b. In this process (Production of new vaccines), have you identified any successful experience in which a pharmacy professional has been involved?
   i. Yes - Go to 2.c
   ii. No - Go to 2.h
   iii. Don't know - Go to 2.h

c. Describe briefly and concisely the purpose of the successful experience in which the pharmacy professional participated.

d. Briefly describe the successful experience in which the pharmacy professional participated.

e. Indicate two positive points to highlight from the pharmacist's participation in this successful experience.

f. Indicate the two main constraints to pharmacist involvement in this successful experience.

g. Please indicate your recommendations for the encouragement of pharmacy professional participation in similar experiences.

h. (Only if you answer no or don't know to 2.a or 2.b) Please indicate how you think pharmacists could be encouraged to be part of the vaccine production process in your country. (Go to question 3)

3. VACCINE REGISTRY

a. In your country, have pharmacists been involved in the vaccine registration process?
   i. Yes - Go to 3.b.
   ii. No - Go to 3.h

b. In this process, have you identified any successful experiences in which a pharmacy professional has been involved?
   i. Yes - Go to 3.c
   ii. No - Go to 3.h
   iii. Don't know - Go to 3.h

c. Describe briefly and concisely the purpose of the successful experience in which the pharmacy professional participated.

d. Briefly describe the successful experience in which the pharmacy professional participated.

e. Indicate two positive points to highlight from the pharmacist's participation in this successful experience.

f. Indicate the two main constraints to pharmacist involvement in this successful experience.

g. Please indicate your recommendations for the encouragement of pharmacy professional participation in similar experiences.

h. (Only if you answer no or don't know to 3.a or 3.b) Please indicate how you think pharmacists could be motivated to be part of the vaccine registration process in your country. (Go to question 4)

4. MARKETING OF VACCINES

a. In your country, have pharmacists been involved in the vaccine marketing process?
   i. Yes - Go to 4.b.
   ii. No - Go to 4.h

b. In this process, have you identified any successful experiences in which a pharmacy professional has been involved?
   i. Yes - Go to 4.c
   ii. No - Go to 4.h
   iii. Don't know - Go to 4.h

c. Describe briefly and concisely the purpose of the successful experience in which the pharmacy professional participated.

d. Briefly describe the successful experience in which the pharmacy professional participated.

e. Indicate two positive points to highlight from the pharmacist's participation in this successful experience.

f. Indicate the two main constraints to pharmacist involvement in this successful experience.

g. Please indicate your recommendations for the encouragement of pharmacy professional participation in similar experiences.

h. (Only if you answer no or don't know to 4.a or 4.b) Please indicate how pharmacists could be motivated to be part of the vaccine marketing process in your country. (Go to question 5)

5. STORAGE AND SAFEKEEPING OF VACCINES

a. In your country, have pharmacists been involved in vaccine storage and safekeeping processes?
   i. Yes - Go to 5.b
   ii. No - Go to 5.h

b. In this process, have you identified any successful experiences in which a pharmacy professional has been involved?
   i. Yes - Go to 5.c
   ii. No - Go to 5.h
   iii. Don't know - Go to 5.h

c. Describe briefly and concisely the purpose of the successful experience in which the pharmacy professional participated.

d. Briefly describe the successful experience in which the pharmacy professional participated.

e. Indicate two positive points to highlight from the pharmacist's participation in this successful experience.

f. Indicate the two main constraints to pharmacist involvement in this successful experience.

g. Please indicate your recommendations for the encouragement of pharmacy professional participation in similar experiences.

h. (Only if you answer no or don't know to 5.a or 5.b) Please indicate how you think pharmacists could be encouraged to be part of the vaccine storage and custody process in your country. (Go to question 6)

6. VACCINE DISTRIBUTION

a. In your country, have pharmacists been involved in vaccine distribution processes?
   i. Yes - Go to 6.b
   ii. No - Go to 6.h

b. In this process, have you identified any successful experiences in which a pharmacy professional has been involved?
   i. Yes - Go to 6.c
   ii. No - Go to 6.h
   iii. Don't know - Go to 6.h

c. Describe briefly and concisely the purpose of the successful experience in which the pharmacy professional participated.

d. Briefly describe the successful experience in which the pharmacy professional participated.

e. Indicate two positive points to highlight from the pharmacist's participation in this successful experience.

f. Indicate the two main constraints to pharmacist involvement in this successful experience.

g. Please indicate your recommendations for the encouragement of pharmacy professional participation in similar experiences.

h. (Only if you answer no or don't know to 6.a or 6.b) Please indicate how you think pharmacists could be motivated to be part of the vaccine distribution process in your country. (Go to question 7)

7. VACCINE ADMINISTRATION

a. In your country, have pharmacists been involved in vaccine administration processes?
   i. Yes - Go to 7.b
   ii. No - Go to 7.h

b. In this process, have you identified any successful experiences in which a pharmacy professional has been involved?
   i. Yes - Go to 7.c
   ii. No - Go to 7.h
   iii. Don't know - Go to 7.h

c. Describe briefly and concisely the purpose of the successful experience in which the pharmacy professional participated.

d. Briefly describe the successful experience in which the pharmacy professional participated.

e. Indicate two positive points to highlight from the pharmacist's participation in this successful experience.

f. Indicate the two main constraints to pharmacist involvement in this successful experience.

g. Please indicate your recommendations for the encouragement of pharmacy professional participation in similar experiences.

h. (Only if you answer no or don't know to 7.a or 7.b) Please indicate how you think pharmacists could be motivated to be part of the vaccine administration process in your country. (Go to question 8)

8. MONITORING OF THE ADMINISTRATION

a. In your country, have pharmacists been involved in the process of monitoring the administration of vaccines to identify adverse reactions and/or monitoring vaccination schedules?
   i. Yes - Go to 8.b.
   ii. No - Go to 8.h

b. In this process, have you identified any successful experiences in which a pharmacy professional has been involved?
   i. Yes - Go to 8.c
   ii. No - Go to 8.h
   iii. Don't know - Go to 8.h

c. Describe briefly and concisely the purpose of the successful experience in which the pharmacy professional participated.

d. Briefly describe the successful experience in which the pharmacy professional participated.

e. Indicate two positive points to highlight from the pharmacist's participation in this successful experience.

f. Indicate the two main constraints to pharmacist involvement in this successful experience.

g. Please indicate your recommendations for the encouragement of pharmacy professional participation in similar experiences.

h. (Only if you answer no, or don't know, go to 8.a or 8.b) Please indicate how you think pharmacists could be encouraged to be part of the vaccine administration process for the identification of adverse reactions and/or the monitoring of vaccination schedules in your country. (Go to question 9)

9. EDUCATION FOR HEALTH PROFESSIONALS

a. In your country, have pharmacists been involved in education processes for health professionals on vaccines?
   i. Yes - Go to 9.b
   ii. No - Go to 9.h

b. In this process, have you identified any successful experiences in which a pharmacy professional has been involved?
   i. Yes - Go to 8.c
   ii. No - Go to 8.h
   iii. Don't know - Go to 8.h

c. Describe briefly and concisely the purpose of the successful experience in which the pharmacy professional participated.

d. Briefly describe the successful experience in which the pharmacy professional participated.

e. Indicate two positive points to highlight from the pharmacist's participation in this successful experience.

f. Indicate the two main constraints to pharmacist involvement in this successful experience.

g. Please indicate your recommendations for the encouragement of pharmacy professional participation in similar experiences.

h. (Only if you answer no or don't know to 9.a or 9.b) Please indicate how you think pharmacists could be motivated to be part of education processes for health professionals on vaccines in your country. (Go to question 10)

10. Patient education

a. Have pharmacists in your country been involved in patient education processes on vaccines?
   i. Yes - Go to 10.b
   ii. No - Go to 10.h

b. In this process, have you identified any successful experiences in which a pharmacy professional has been involved?
    i. Yes - Go to 10.c
    ii. No - Go to 10.h
    iii. Don't know - Go to 10.h

c. Describe briefly and concisely the purpose of the successful experience in which the pharmacy professional participated.

d. Briefly describe the successful experience in which the pharmacy professional participated.

e. Indicate two positive points to highlight from the pharmacist's participation in this successful experience.

f. Indicate the two main constraints to pharmacist involvement in this successful experience.

g. Please indicate your recommendations for the encouragement of pharmacy professional participation in similar experiences.

h. (Only if you answer no or don't know to 10.a or 10.b) Please indicate how you think pharmacists could be motivated to be part of patient education processes on vaccines in your country.

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