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Pan American Network for Drug Regulatory Harmonization (PANDRH)

PANDRH Secretariat

Strategic Development Plan 2014-2020 of the Pan American Network for Drug Regulatory Harmonization (PANDRH)

Pan American Health Organization
World Health Organization
REGIONAL OFFICE FOR THE Americas

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1. Introduction and Context

1.1 Analysis of the situation in the Region of the Americas

According to the World Health Organization (WHO), public health refers to all organized measures designed to prevent disease, promote health, and prolong life among the population as a whole (*1*). In this regard, the three main public health functions are: i) assessing and monitoring the health of communities and populations in order to identify health issues and priorities; ii) formulating public policies designed to solve health issues and priorities identified at the local and national levels; and iii) ensuring that all populations have access to appropriate, effective, and affordable health care (*1*). The Pan American Health Organization (PAHO), in turn, has launched the "Public Health in the Americas Initiative," which aims at "defining and measuring the performance of the essential public health functions, as the basis for improving practice in public health and strengthening the leadership of the health authority at all levels of the State" (*2*).

Today, the world faces many challenges that make it difficult to respond to existing health demands, including such factors as globalization, a greater demand for health care services that fall outside of traditional health sector systems, diverse customs and lifestyles that have led to a significant shift in epidemiological transition, the emergence of innovative products with a high degree of technical and scientific content, and a lack of trained personnel with scientific knowledge (*3*–*5*).

Since the beginning of the last century, the countries in the Americas have made important advances in health. For example, the Region's infant mortality has plummeted from 167.4 per 1,000 live births to 15.2, life expectancy at birth has increased from 40.9 to 75.8 years, and the social determinants of health also have improved, such as a 36% increase in the rate of enrollment in primary school. Despite these and other major advances, however, several studies point out that health-related progress varies greatly from country to country in the Region (*6*–*8*), with clear health inequalities seen among countries and among minority groups within a single country. In response, the Region's countries have developed policies, strategies, and plans to improve equality and minimize social exclusion in health. The Pan American Health Organization (PAHO), in its effort to attain the Millennium Development Goals (MDGs) (*9*), also has maintained its commitment by working with the Region's countries and supporting their efforts to develop and implement the Health Agenda for the Americas, 2008–2017 (*10*) and public policies that promote the health and well-being of their populations.

The U.N. Millennium Declaration states that essential drugs should be accessible to anyone from a developing country who may need them (*11*). The number and variety of other medicinal products produced around the world—especially blood products, diagnostic tools, and vaccines—continue to increase. However, in many developing countries of the Americas, essential medicines and other public health supplies are not readily available or are not within the reach of the poorest sectors of the population. Insufficient funding and inadequate financial systems give rise to unequal access, and poorly developed delivery systems hinder the continuity of product supply and availability. Furthermore, access to quality products often cannot be guaranteed due to insufficient capacity to evaluate and regulate them, and as a result of their irrational use (*12*).

During the last 15 years, countries have made it a priority to develop their capacity to regulate medicines and other health technologies. The national regulatory authorities (NRAs) in the countries have played a key role in guaranteeing the quality of these products. Actions carried out by the NRAs include pre- and post-marketing safety assessments, effectiveness evaluations (and in some cases comparative effectiveness evaluations), the develop-

ment of national policies for technological innovation, and the implementation of strategies to promote competition in pharmaceutical markets. In addition to the health surveillance of medical products and patient safety, the NRAs play a key role in ensuring access to medicines and health technologies in the Region's countries, thereby contributing to the economic development in those countries that have a pharmaceutical industry.

Although the Region's countries have advanced in the development and implementation of pharmaceutical policies and in their capacity for health surveillance, much remains to be done in this regard. For example, in 2012, only 13 out of 28 countries had an officially approved pharmaceutical policy, and only 9 of them had an implementation plan (*13*). In addition, 18 out of 25 countries had a national regulatory authority with defined competencies for the basic regulatory functions of medicines (*13*). The lack of effective regulatory capacity makes it difficult for a country's health authority to implement policies for generic medicines or to ensure that new, complex, and costly health products are properly regulated.

Health regulation is regarded as one of public health's basic functions. Effective regulation of medicines promotes and protects the public's health by guaranteeing medicines quality, safety, and efficacy; promoting the adequate manufacture, storage, and distribution of medicines; facilitating the fight against substandard, spurious, falsely-labeled, falsified, or counterfeit (SSFFC) medical products; providing the necessary information to health professionals and patients so they can use medicines rationally; and ensuring that access to medicines is not hindered by inefficient regulatory frameworks (*14*). To this end, it is of utmost importance to establish (through a national system that promotes access to health care and that protects its citizens against health risks) effective NRAs with a clear mission, realistic goals, skilled and trained workers, sustainable financing, access to up-to-date technical literature, and the ability to adapt and respond to the ongoing and varying demands posed by the countries' challenges. In acknowledging the important role the NRAs play and the need to strengthen their regulatory capacity, PAHO continues to support and develop various mechanisms and tools to strengthen the NRAs' regulatory and oversight functions (*15*, *16)*. For example, the Region's countries, with PAHO's collaboration, initiated discussions in Oaxaca, Mexico, on exchange and mutual recognition mechanisms; this, in turn, has led to the evaluation and designation of regional reference NRAs.

Likewise, in 1999, the Governing Bodies of the Pan American Health Organization recommended that the Pan American Network for Drug Regulatory Harmonization (PANDRH) be established in response to the need for initiatives that promote drug regulatory harmonization in the Americas. PANDRH is an initiative of the Region's NRAs and PAHO that supports regulatory harmonization processes in the Americas, within the context of national and subregional health realities and policies, and while acknowledging existing imbalances.

PANDRH's mission is to promote drug regulatory harmonization, including such aspects as quality, safety, efficacy, and the rational use of pharmaceutical products, while strengthening the capabilities of the Region's NRAs, based on the population's right to have access to quality medicines consistent with advances in science and technology.

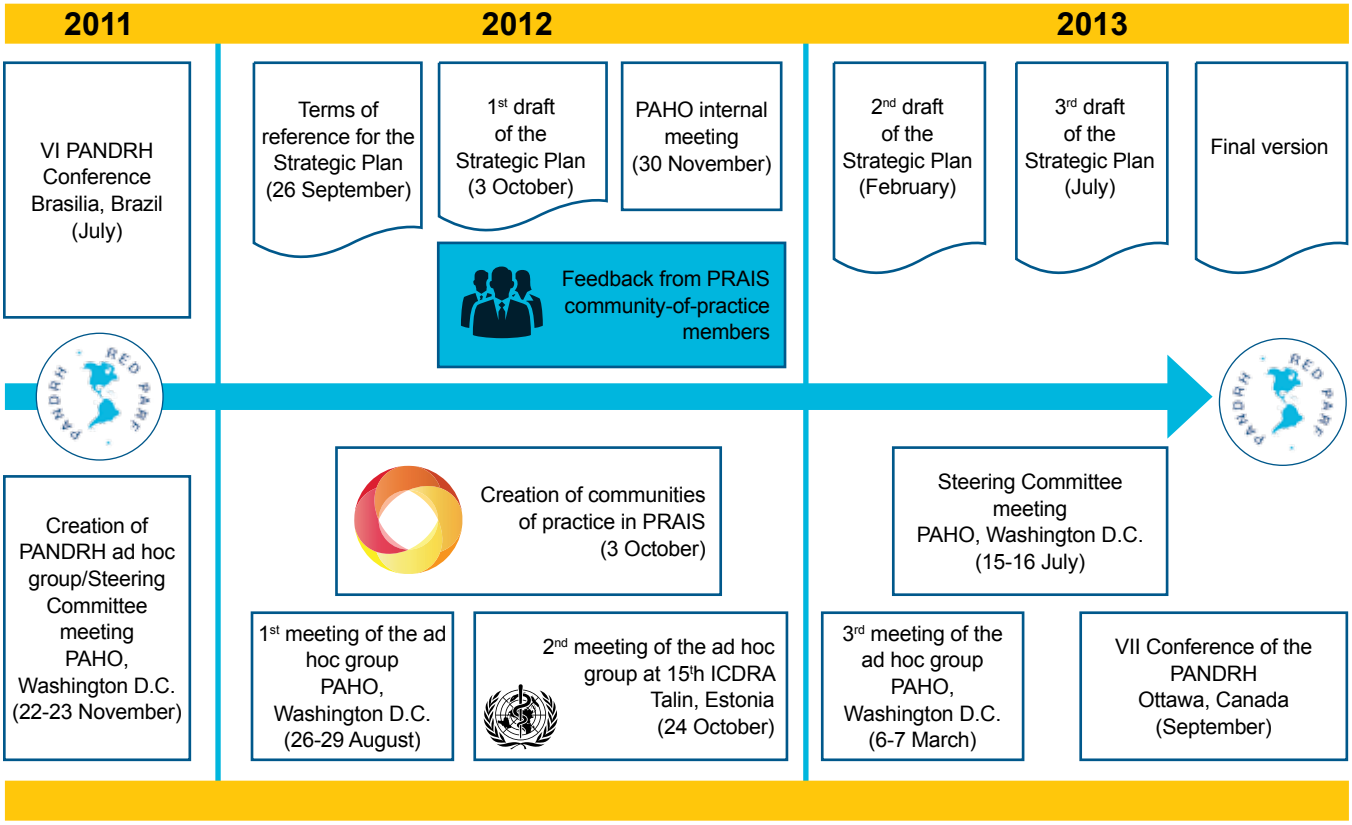
PANDRH's objectives include strengthening the NRAs in the Region's countries and promoting cooperation among them; preparing and approving technical documents on drug regulation; identifying mechanisms to support the implementation, monitoring, and evaluation of proposals adopted by NRAs; and promoting the establishment of reference NRAs (*17*–*19*).

PANDRH comprises the Pan American Conference on Drug Regulatory Harmonization; the Steering Committee; the technical working groups (for any areas defined as priorities by the Conference and the Secretariat); the Pan American Health Organization, which acts as the network's Secretariat (*20, 21*). Thirteen working groups (WGs) have been established since the creation of the Network, and they are responsible for developing harmonized proposals on subjects of priority and interest in the area of pharmaceutical regulation. To date, PANDRH has held seven conferences on drug regulatory harmonization. The first of these, held in Washington, D.C., in 1997, led to the establishment of PANDRH.

In light of the needs of the countries of the Americas and the future challenges that PANDRH will likely face, during the Network's sixth conference, held in Brazil in 2011, and at subsequent meetings of PANDRH's Steering Committee, the Region's NRAs requested that the Secretariat (PAHO) coordinate the preparation of a strategic development plan to tackle the unfinished agenda and new challenges (*22*). It was suggested that this plan be developed by an ad hoc group made up of NRA representatives and observer members, and that it be based on the following components: i) the global situation; ii) regulatory challenges; iii) the countries' pharmaceutical profile; iv) the results of the evaluations of the NRAs; v) lessons learned from the work carried out to date by PANDRH; and vi) the degree of implementation of the technical documents produced. It also was proposed that the plan should review PANDRH's impact on the NRAs in the Region, set the Network's priorities for 2014–2020, review the Network's current bylaws, propose more efficient communication and decision-making mechanisms for the Network, and suggest a sustainable mechanism to strengthen regulatory training in the region.

PANDRH's 2014–2020 Strategic Development Plan, presented here, was developed in response to the request of the PANDRH Steering Committee and the NRAs. This plan was presented and endorsed during the VII PANDRH Conference held in Ottawa, Canada, in September 2013, and includes the recommendations and conclusions that emerged during that Conference. The Plan mainly aims at promoting and supporting regulatory convergence and medicines harmonization processes in the Region, as well as at strengthening national and regional health surveillance systems for medicines and other health technologies. This includes developing the national regulatory capacity of PAHO Member States in accordance with the commitment made by the Ministers of Health of the countries of the Americas at PAHO's 50th Directing Council in 2010 (*16*). Figure 1 depicts the timeline for the plan's development.

Figure 1. Timeline for the development of PANDRH Strategic Development Plan



1.2 Lessons Learned

Since its creation, the Pan American Network for Drug Regulatory Harmonization (PANDRH) has functioned as a regional forum where countries can discuss medicines regulation issues of mutual interest. The Network's technical working groups have promoted a constructive dialogue among all sectors who work in developing PANDRH's technical documents. The participation of technical experts representing the industry has contributed to this constructive dialogue and to the technical quality of guidelines and other proposals. The working groups have produced multiple guidelines in their areas of interest aimed at strengthening the countries' regulatory capacity through: 1) the development of human resources; 2) the generation and sharing of knowledge about drug regulation, in support of criteria development and decision-making; 3) the sharing of experiences between the NRAs and other PANDRH members; and 4) the implementation and adoption of PANDRH's technical standards at the national level (*23*). Although not all countries participate directly in the development of PANDRH's technical documents, all do participate in the decision to adopt these documents. As the drug regulatory authorities participate in the processes of developing and adopting the Network's documents, they also strengthen their own national regulatory capacity.

Table 1 lists the technical documents that PANDHR has developed.

Table 1. List of PANDRH technical documents

Document type	Technical group	Name of document
Technical Report No. 1	Vaccines	Harmonized requirements for the licensing of vaccines in the Americas and Guidelines for preparation of application
Technical Report No. 2	Good laboratory practices	Good practices for National Pharmaceutical Control Laboratories
Technical Report No. 3	Good laboratory practices	Good practices self-evaluation guide for National Pharmaceutical Control Laboratories
Technical Report No. 4	Good laboratory practices	Study of the Current Conditions of the Official Medicine Control Laboratories (OMCL) in Latin America and the Caribbean
Technical Report No. 5	Pharmacovigilance	Good Pharmacovigilance Practices for the Americas
Technical Report No. 6	Good laboratory practices	Document on Self-Evaluation of Good Laboratory Practices (GLP)
Technical Report No. 7	Biotechnology products	[Recommendations for the Evaluation of Similar Biotherapeutic Products (SBPs)] [Spanish and Portuguese versions]
Technical Report No. 8	Bioequivalence	Framework for Implementation of Equivalence Requirements for Pharmaceutical Products
Technical Report No. 9	Good laboratory practices	[WHO Good Practices for Quality Control Laboratories Pharmaceutical Products and Self-Assessment Document of Good Laboratory Practice (GLP)] [Portuguese version]
Technical Report No. 10	Registration of medicines	Requirements for the registration of medicines in the Americas
Documents approved or presented at the IV PANDRH Conference (2005)	Good manufacturing practices	Regional Guideline for GMP Inspection
	Good clinical practices	Good Clinical Practice: Document of the Americas
	Combat counterfeit medicines	Proposal for the executing unit to implement the actions to prevent and fight drug counterfeiting
	Combat counterfeit medicines	Indicators for the management and criteria for classification of counterfeit drugs
	Classification of medicines	Definition and criteria to apply to Over the Counter (OTC) drugs
	Combat counterfeit medicines	Proposal of national programs for prevention of drug counterfeiting and an action plan (roadmap)

Table 1. (continued)

Document type	Technical group	Name of document
Documents approved or presented at the V PANDRH Conference (2008)	Good clinical practices	Guide for conducting clinical studies in pediatric populations
	Good manufacturing practices	Decision tree for the implementation of the Guideline for good manufacturing practices inspection
	Good manufacturing practices	Good Manufacture Practices for Active Pharmaceutical Ingredient
	Good manufacturing practices	Code of Ethics for inspectors (Good Manufacture Practices)
Documents approved or presented at the VI PANDRH Conference (2011)	Combat counterfeit medicines	[Combating counterfeit drugs: Update of the Discussion of Tools and Generating Proposals reference document] [Spanish version]
	Combat counterfeit medicines	Model of focal points network to combat medicines counterfeiting- Updated document [Spanish version]
	Combat counterfeit medicines	[Guidelines to be considered by the Health Authorities in suspected Counterfeit Medical Products] [Spanish version]
	Registration of medicines	Proposal of Harmonized Requirements for Drug Registration in The Americas
	Good clinical practices	Considerations for the use of placebos
	Promotion of medicines	Ethical Criteria for Promoting, Advertising, and Publicizing Pharmaceuticals
	Good clinical practices	[Researcher manual] (Spanish version)

Training, an important component of PANDRH's work, also greatly benefits the national universities that participate in these activities, enabling them to update undergraduate, graduate, and continuing education programs in the respective areas. PANDRH also facilitates access to documents, evidence, and expert opinions on medicines regulation. The Network's training activities also create opportunities for professional development. For example, the NRAs benefit from the academic community's participation, in that the educational activities provide their professionals with opportunities for capacity building and training. PANDRH's working groups (WGs) also benefit from these educational opportunities, because the Network helps members of the WGs to participate in national and international events where WGs often hold their meetings, before or after PANDRH events. It should be noted, as established on PANDRH current statutes, that the WGs are coordinated by expert professionals representing a national regulatory authority, although exceptions to this rule can be made, if there is scientific justification to do so (*17*). This means that the NRAs lead and direct the work done by the WGs and, consequently, also lead the Network.

Since PANDRH's creation in 1999 the Region's regulatory environment has changed significantly. In recent years, for example, the countries have established numerous pathways and forums, both virtual and face-to-face, for exchanging ideas and having discussions. Through these forums, stakeholders can discuss issues related to the regulation of medicines and can share information and experiences within secure spaces. For example, in the area of medicines quality control, a network of Official Medicines Control Laboratories (OMCL) has been established; the official medicines control laboratories of 23 countries that are participating in this network all have the minimum equipment requirements recommended by WHO. Of these, eight are regional reference laboratories and four have been pre-qualified by WHO as reference laboratories for United Nations agencies (*24*). The more developed regulatory bodies share their knowledge and experience with less advanced bodies. In the Americas, there is a common interest at the national, regional, and global levels to promote and protect public health and to develop health surveillance capacities and competencies needed to ensure the quality, safety, and efficacy of medicines and other health-related technologies. The dissemination of state-of-the-art country regulations has supported the establishment of institutional, bilateral, and multilateral cooperation agreements aimed at strengthening and improving international trade.

Nevertheless, for the countries of the Americas, medicines regulatory harmonization represents a significant challenge and a long-term goal. In order to reach this goal, several conditions must be met. First, the countries must enter into agreements with one another, in order for the NRAs to adopt a common regulatory framework that ensures a comprehensive assessment of regulated products, and there must be trust in the regulatory processes carried out by other NRAs. In addition, processes must be simple and transparent, information must be available, and similar technical requirements should be consistent across all countries. The benefits of medicines regulatory harmonization processes have been documented, including easier access to medicines with a common quality standard across countries, and medicine registration processes facilitated by the pharmaceutical industry. There are many challenges to overcome in order to achieve effective pharmaceutical harmonization in the Americas, however, as well as major challenges facing PANDRH in its core mission.

In this matter, the first and foremost challenge the Region faces relates to regional integration. There are multiple integration mechanisms in the Americas, such as the Andean Community of Nations (CAN, for its Spanish acronym), the Bolivarian Alliance for the Peoples of Our America (ALBA, for its Spanish acronym), the Caribbean Community (CARICOM), the Central American Integration System (SICA, for its Spanish acronym), the North American Free Trade Agreement (NAFTA), the Southern Common Market (MERCOSUR, for its Spanish acronym), and the Union of South American Nations (UNASUR, for its Spanish acronym)(ALBA, CAN, CARICOM, MERCOSUR, NAFTA, SICA, UNASUR); some are geographically defined and some members participate in more than one. Each mechanism has a different strategic focus with regard to economic development policies, pharmaceutical policies, the integration of pharmaceutical markets, and the regulation of medicines and other health-related technologies, which limits the possibilities for drug regulatory harmonization throughout the Region at this time. Some countries in the Region also actively participate in global harmonization and convergence mechanisms involving countries outside the Americas. Some examples include the International Conference on Harmonization (ICH), the Asia-Pacific Economic Cooperation (APEC) forum, and the International Medical Device Regulators Forum (IMDRF). Considering the complexity of the medicines regulatory integration, convergence, and harmonization processes in the Americas, PANDRH's current governance model—conceived with a different regional context in mind—is not facilitating linkages between the multiple regional integration and convergence initiatives, nor guaranteeing that the countries are adequately represented in the discussions and decisions of the Network itself.

Although some survey results of PANDRH indicate that some professionals within NRAs are aware about the Network's activities, other results suggest that this information does not come from representatives of PANDRH's Steering Committee, but from PANDRH's website and the Network's listserv. Moreover, the countries are not sufficiently clear as to who represents them on the Steering Committee, since there are no established communication mechanisms between countries within a single integration mechanism or economic bloc. Specifically, evidence shows that information and communication do not flow efficiently or in a timely fashion through the channels established in accordance with PANDRH statutes.

The adoption, adaptation, and implementation of PANDRH-issued technical documents is a matter that is yet to be resolved. The Secretariat has conducted a qualitative and quantitative study designed to measure the impact of the adoption or implementation of eight technical documents produced by PANDRH. For the adoption phase of the study, results are based on responses from 22 countries. Results indicate that some 61% of the technical documents produced by PANDRH have been used for the development of NRA regulations—34% have been fully adopted and 27% have been partially adopted. Of the remaining 39%, 57% of the surveyed countries responded that PANDRH technical norms were not adopted due to the fact that countries previously implemented other regulations, and/or regulations were adopted on other harmonization initiatives. However, although countries have faced various challenges in the implementation of some documents, it should be noted that the partial adoption of documents in several countries shows that PANDRH technical documents have played a key role in building capacity in

the Region's countries and are important references in the preparation of national standards and in the training of human resources at the national regulatory authorities.

Table 2 summarizes the extent to which selected technical documents have been adopted by NRAs in the Americas. The last column of the table shows the reasons why the countries had not adopted the documents.

Table 2. Results of a study on the adoption and implementation of PANDRH technical documents

Technical Report	No. of countries that fully adopted (%)	No. of countries that partially adopted (%)	No. of countries that did not adopt (%)	Reasons for non-adoption
Regional Guideline for Good Manufacturing Practice (GMP) Inspection (based on results from 18 countries)	11 (61%)	1 (6 %)	6 (33%)	In all cases, other harmonization initiatives were considered.
Framework for implementation of equivalence requirements for pharmaceutical products (based on results from 19 countries)	4 (21%)	3 (16%)	12 (63%)	In 42% of the cases the NRAs based their regulations on other harmonization initiatives and/or they already had a regulation in place. In the remaining 58% of the cases, the NRAs did not currently have specific regulations.
Document on Self-Evaluation of Good Laboratory Practices (GLP)[a] (based on results from 15 countries)	13 (87%)	0.0	2 (13%)	In 50% of the cases the NRAs based their regulations on other harmonization initiatives. In the remaining 50% of the cases, NRAs did not currently have specific regulations.
Guidelines to be considered by the health authorities in suspected counterfeit medical products [Spanish version only] (based on results from 18 countries)	4 (22%)	5 (28%)	9 (50%)	In 78% of the cases the NRAs based their regulations on other harmonization initiatives or they already had a in place. In the remaining 22% of the cases, the NRAs do not currently have specific regulations.
Good Clinical Practice: Document of the Americas (based on results from 15 countries)	7 (46%)	4 (27%)	4 (27%)	In 50% of the cases the NRAs based their regulations on other harmonization initiatives. In the remaining 50% of the cases, NRAs did not currently have specific regulations.
Good Pharmacovigilance Practices for the Americas (based on results from 19 countries)	3 (16%)	12 (63%)	4 (21%)	In all cases, other harmonization initiatives were considered.
Harmonized requirements for the licensing of vaccines in the Americas (based on results from 19 countries)	4 (21%)	7 (37%)	8 (42%)	In 33% of the cases the NRAs based their regulations on other harmonization initiatives, 11% of the cases already had a regulation in place, 11% did not offer an explanation, and the remaining 45% did not currently have specific regulations.
[Recommendations for the Evaluation of Similar Biotherapeutics Products (SBPs)] (Spanish and Portuguese versions only) (based on results from 18 countries)	2 (11%)	6 (33%)	10 (56%)	In 20% of the cases the NRAs based their regulations on other harmonization initiatives or they already had a regulation in place. In the remaining 80% of the cases, they did not currently have specific regulations.
TOTAL	**48 (34%)**	**38 (27%)**	**55 (39%)**	

[a] Unlike the other technical reports, the document on Self-Evaluation of Good Laboratory Practices (GLP) is a self-assessment of the Official Laboratory for Control of Medicines (LOCM) for the World Health Organization (WHO) prequalification. This self-evaluation is accompanied by a training course.

The study's second phase sought to identify obstacles, critical issues, needs, and strategies in the implementation of PANDRH's technical guidelines. These results suggest that there is a need to strengthen human resources and establish ways to pursue ongoing skills training.

Although PANDRH has produced many technical documents, there are no clearly defined criteria for preparing PANDRH's technical standards. And even though the development of the Network's technical standards has led to demands for training in the countries, countries have lacked the basic regulatory functions needed to ensure effective implementation of the harmonized standards.

In addition, while technical training has been offered through the activities of PANDRH and its working groups, requests for training on different regulatory functions are still constantly received from the NRAs. There is a great need for training, both for the most advanced NRAs and for those still under development. In order to serve the Region's needs, a paradigm shift is required, with deeper consideration of the competencies required for each regulatory function and for the overall operation of NRAs in the national and regional context. A sustainable response is necessary, so that the regulatory authorities can perform their regulatory, oversight, and control functions, applying regulatory science to guide decision making, and good regulatory practices to ensure the quality of processes, functions, and decisions. The NRAs in the Americas need to have a team of skilled professionals, backed by universities and reference centers, that should assume their roles in regulatory research and in the training and specialization of regulatory experts.

The current environment of global health, international trade, and the post-2015 development agenda requires that countries of the Region face the challenge of moving toward universal health coverage, including ensuring access to high-quality, safe, and effective medicines and health-related technologies. This implies a renewal of international cooperation to develop national, regional, and global health surveillance systems for medicines and technologies under the coordination and leadership of the NRAs. The political, technical, and financial commitment of Member States also is required, in order for the countries to work together toward the common goal of strengthening regulatory capacity and, through collaborative processes, toward regulatory convergence. If drug regulatory harmonization is a long-term goal, the countries of the Americas can seek convergence in their processes, functions, and regulatory results. PANDRH will respond to this new regional context through the implementation of the 2014–2020 Strategic Plan aimed at:

- strengthening PANDRH's governance in order to support regulatory convergence processes, taking into account regional integration efforts and the need to ensure that countries are represented in the development of health regulation systems;
- establishing priorities, mechanisms, and strategies for the preparation of technical standards based on national needs and the development of regulatory systems;
- strengthening regional capacity in regulatory science and good regulatory practices by supporting sustainable professional development; and
- facilitating the exchange of information and experiences between the NRAs in the Network and other NRAs outside the Region, in order to contribute to worldwide regulatory convergence.

2. Strategic Orientation

2.1 Purpose

In light of the request made by PANDRH's Steering Committee discussed in the previous section, this Strategic Plan for PANDRH aims to strengthen the capacity of National Regulatory Authorities (NRAs) in the Americas, so that they can fulfill their regulatory mandate efficiently, effectively, and transparently through greater cooperation efforts that lead towards regulatory convergence and harmonization.

This purpose is expressed through the development and implementation of the following four strategic objectives:

I. Promote the efficient governance of PANDRH and the active participation and cooperation of the NRAs towards regulatory convergence and harmonization.

II. Periodically define strategies and mechanisms for regulatory convergence and harmonization, and support their dissemination, adoption, and implementation by the regional NRAs.

III. Promote the strengthening of skills in Good Regulatory Practices and Regulatory Sciences.

IV. Promote the exchange of experiences and regulatory knowledge between NRAs within the Network and with NRAs outside PANDRH.

Each strategic objective section includes a justification for the plan of action, general lines of actions to reach the objective, expected results, and the next steps agreed upon during the VII PANDRH Conference.

2.2 Strategic Objectives

I. Promote the efficient governance of PANDRH and the active participation and cooperation of the NRAs towards regulatory convergence and harmonization

A. Justification and/or scope

The Region's rapid economic growth; the effects of globalization, with its impact on international trade; and the shift in the epidemiological profile in the Americas, whereby chronic, noncommunicable diseases are now the leading cause of morbidity and mortality, are key determinants in the growth of the pharmaceutical market in the Region. In recent years, an increase has been observed in the number of medical products that have become available in national pharmaceutical markets, with countries such as Argentina, Brazil, and Mexico having significantly increased their production capacity. Another major change observed has been the increase in the importation of products from other regions, especially from Asia. Considering that the national authorities are responsible for monitoring medical products for human consumption and in light of the challenges involved in the inspection, evaluation, and licensing of medicines, the globalization of the pharmaceutical markets presents new challenges for the NRAs in the Region's countries.

Considering that "drug regulatory processes are fundamental for guaranteeing the safety, efficacy, and quality of drugs," in 2000, the Region's Ministers of Health adopted Resolution CD42.11 ("Drug Regulatory Harmonization") during their 42nd Directing Council Meeting, which supported the creation of PANDRH (*19*). Given the high level of socioeconomic development that the Region has attained during the past 16 years, the increase in the NRAs installed capacity at the regional level, and a shift toward a new regional paradigm that involves multiple integration mechanisms with different levels of participation by the countries and with different political, economic and strategic directions, it has become necessary to refocus PANDRH's main mission towards the promotion of regional regulatory convergence. And while this is a good moment to define common medium- and long-term goals and objectives to guarantee the quality, safety, and efficacy of medicines and biologicals, there are multiple pathways to achieve these objectives and goals.

While the Region as a whole has advanced in terms of its capacity to regulate medicines and in the development of regulatory systems, disparities in the installed capacity and available resources from country to country require that different approaches be undertaken for developing regulatory systems. In this context, it is important to consider Resolution CD50.R9 ("Strengthening National Regulatory Authorities for Medicines and Biologicals"), adopted by the Directing Council in 2010, as the basis for developing PANDRH's strategic plan for promoting regulatory convergence between the NRAs and for creating and applying drug regulatory standards for the NRAs and other Network stakeholders. Regulatory convergence requires stepping up the cooperation between the countries and the NRAs for developing regulatory systems, sharing experiences and information on health regulatory processes, and designing training programs for the NRAs.

In recent years, the countries of the Region have placed a priority on the implementation of Resolution CD50.R9, "Strengthening National Regulatory Authorities for Medicines and Biologicals" (2010), the development of institutional development plans for NRAs, the evaluation of regulatory functions, and information sharing among NRAs. This process has contributed to increase trust, collaboration, and cooperation among NRAs in the Region. Information gathered by PAHO in preparation for the 15th International Conference of Drug Regulatory Authorities (ICDRA) in Estonia in 2012, showed an increase in the number of cooperation and confidentiality agreements subscribed by NRAs in recent years, especially after PAHO's Directing Council adopted the resolution.

Examples of the cooperation agreements entered into by the NRAs include:

- an agreement between the Brazilian Health Surveillance Agency (ANVISA, for its Portuguese acronym) and PAHO, designed to strengthen regional cooperation in Brazil and other countries in the Americas in health surveillance and regulation of medicines;
- a bilateral agreement between Colombia and the United States intended to galvanize and strengthen processes that support competitiveness and improvements in the country's health status, as well as the recognition of the National Institute for the Surveillance of Medicines and Food (INVIMA, for its Spanish acronym) as a regulatory agency in an international context;
- an agreement between Mexico's Federal Commission for the Protection against Sanitary Risk (COFEPRIS, for its Spanish acronym), Health Canada, and the United States Food and Drug Administration (FDA) on the regulation of medicines and medical devices; and
- an agreement between Argentina's National Administration for Medicines, Food, and Medical Technology (ANMAT, for its Spanish acronym), ANVISA, INVIMA, and Cuba's Center for the State Control of Medicines, Equipment, and Medical Devices (CECMED, for its Spanish acronym) for the exchange of information on market recalls, international inspections, and joint inspections.

Though small, these cooperation and recognition agreements represent significant steps towards regulatory convergence, through which the NRAs pledge to work together to strengthen national, regional, and global systems for health surveillance of medicines and other medical products. As a vehicle for cooperation among NRAs, PANDRH will facilitate the regulatory convergence process by promoting the development of national and regional regulatory systems based on a common methodology approved by PAHO's Governing Bodies. To this end, PANDRH will endeavor to build trust between the countries and the NRAs and to promote agreements on information sharing, collaboration, and cooperation that move the countries towards regulatory convergence. The proposed coordination with other regional entities is intended to reinforce efforts toward an ongoing improvement of the regulatory environment. Evidence shows that, while there have been significant improvements in the control functions of the Region's regulatory authorities, asymmetries persist, which will make it necessary to review regional strategies in order to bridge existing gaps, including the concepts set out in the Network's mission statement. PANDRH aims to contribute to global public health from a regulatory perspective and through a holistic approach, so that its activities facilitate and promote access to medicines and their rational use. Given that PANDRH's structure should facilitate a timely response to the regulatory requirements in the Region, the intention is to develop a structure that will better promote regulatory convergence, that is more agile and flexible, and that creates opportunities for all NRAs to participate NRAs.

Finally, PANDRH's governance will be responsive to the priorities established by the participating NRAs. PANDRH currently works on the pharmaceutical regulation of medicines produced by chemical synthesis and certain biologicals (vaccines and biotechnology products). It has been proposed that the scope of the Network be reviewed in light of the recommendations issued by the Steering Committee at the November 2011 meeting, so that it can address issues and priorities related to the development of health regulatory systems for medicines, biologicals, and medical devices in a way that more effectively meets the various needs and challenges that the countries currently face.

B. VII PANDRH Conference recommendations

In accordance with the recommendations issued at the VII PANDRH Conference, it has been proposed that the new governance structure should facilitate the participation of members, guaranteeing the representation of all sectors; must be dynamic and must respond efficiently to country needs; should integrate PANDRH's work with that of other international initiatives that promote harmonization and regulatory convergence; and should promote bilateral and subregional cooperation among member countries, taking advantage of existing international models based on bilateral or regional agreements.

Some of the proposed activities intended to help achieve this strategic objective involve the establishment of an ad hoc group that would develop a proposal for a new PANDRH governance model; the elaboration of a report of PANDRH technical working groups that includes an analysis of their current activity level, achieved results, and, when necessary, a proposal for the continuation of the group; and the use of the Regional Platform on Access and Innovation for Essential Public Health Functions (PRAIS, for its Spanish acronym) as tool to promote the flow of information and knowledge management.

C. Lines of action and expected results from Strategic Objective I

Table 3 describes the lines of action for achieving this strategic objective and the expected results.

Table 3. Expected results for Strategic Objective I

Lines of action	Expected results
Create a new organizational structure for PANDRH	Drafting of proposals for operational governance models.
	Adoption of by-laws for the new governance model.
	Definition of processes for drafting and adopting regulatory guidelines, rules for Working Groups, and expert committees (or other mechanisms).
Encourage bilateral and/or multilateral ties and agreements for collaboration and cooperation among NRAs	Development and/or definition of mechanisms and models for cooperation among NRAs. Links established with other collaborators and initiatives involved in regulatory convergence/harmonization (APEC, ICH, Alba, IMDRF among others).

II. Periodically define strategies and mechanisms for regulatory convergence and harmonization, and support their dissemination, adoption, and implementation by the regional NRAs

A. Justification and/or scope

The principles and elements of a health system based on primary health care are derived from three core values: the highest attainable level of health, equity, and solidarity (*25*). The premise for this concept rests on universal access and coverage, with health technologies (*26*) representing key inputs in the delivery of quality health care services, and scientific evidence playing a key role in deciding whether (or not) to employ those technologies. In this context, PANDRH's work and technical efforts must be guided by the role that medicines and technologies play in health promotion, disease prevention and treatment, and the need to develop health regulatory systems able to fulfill that role.

Although the technical guidelines and standards that PANDRH has developed over the past 16 years have significantly helped to improve the regulatory capacity in the countries of the Americas, there is still room to improve the Network's response in light of regional and national priorities, which should be determined on a regular basis. At the request of the ad hoc group charged with drafting this plan, in 2013, PANDRH's Secretariat conducted a survey to identify current and future challenges and priorities as the Region's countries develop their regulatory capacity. The survey identified three main aspects: 1) future national regulatory priorities and challenges for PANDRH's work plan, 2) offers for providing training and for strengthening the NRAs capabilities, and 3) cooperation mechanisms in the Region of the Americas. Of the participating countries, 76% responded to the survey, which identified the regulation of medical devices, biotechnology, and vaccines as areas that pose regulatory challenges and that, therefore, should be given priority for the future investment of resources in the Region (*27*). Similarly, the technical areas for combating counterfeit medicines, bioequivalence and/or bioavailability, control of importation and/or exportation, and the national laboratory of drug quality control were considered as the most relevant areas for human-resource investment and training. In short, survey results suggest that, in the future, PANDRH's development will face some important challenges, including:

- consolidating the Network's accomplishments;
- disseminating the standards that have been developed and supporting countries in their efforts to adopt and implement them;
- dealing with the Network's unfinished agenda for updating standards that support the development of the NRAs' critical functions; and

- and addressing new challenges in the regulation of medical and diagnostic devices and the latest high-complexity technologies, including biotechnological and genomic products.

The Network has proposed targeting its efforts on the Region's priority and cross-cutting regulatory areas, without detriment to the activities of existing working groups or of other groups that may be created in response to subregional needs. To that end, the proposal considers setting priorities in accordance with pre-established criteria and the semiannual review process. Priorities for action should take into consideration the development of basic regulatory functions, coupled with the NRA evaluation systems and international technical standards.

PANDRH's Working Groups should address priorities identified by the Network within a set time frame. Their mandate should include a review of the recommendations on regulatory convergence and harmonization that have been issued by other mechanisms, and their applicability in the countries of the Americas. For this work, they should also enlist the participation of the Region's NRAs and well-known experts in this area. The Working Groups should create better roadmaps for the dissemination, adoption, and implementation of PANDRH's technical standards, so that countries with different regulatory features and capabilities can determine the best possible pathway toward implementing the technical standards and for developing the corresponding regulatory capacity. The roadmaps for developing regulatory capability in the context of cooperation and collaboration agreements among countries should include joint action between countries and regional blocs.

In light of the above, PANDRH will intensify the dissemination of technical standards it has developed and adopted. It will also support the countries in the adoption of technical guidelines to strengthen existing regulatory functions and in the development of new technical standards that are responsive to new regulatory challenges in the Region. These efforts will be tied to the regional strategy set out in Resolution CD50.R9, "Strengthening National Regulatory Authorities for Medicines and Biologicals," which specifically aims to support countries in organizing their regulatory system, defining critical regulatory functions and processes, and developing quality management systems. All of these actions are intended to help countries establish effective regulatory systems that implement international pharmaceutical regulatory standards progressively and systematically and that contribute to regional regulatory convergence.

B. VII PANDRH Conference recommendations

According to the recommendations issued during the VII PANDRH Conference, the Network should adopt a systematic mechanism for setting priorities based on a periodic analysis of the NRAs' context and needs. This mechanism should include:

- data obtained through the assessment of regulatory functions and institutional development plans, as previously established in the Resolution CD50.R9 on the strengthening the capabilities of national regulatory authorities for medicines and biologicals;
- the NRAs' needs identified through periodic surveys that explore existing gaps;
- indicators to evaluate the efficiency of processes used for the adoption and implementation of technical documents adopted for the development of work plans; and
- the development and/or use of virtual tools to strengthen communication and socialization of work plans, technical documents, PANDRH products and other relevant information.

C. Lines of action and expected results from Strategic Objective II

Table 4 describes the lines of action for achieving this strategic objective and the expected results.

Table 4. Expected results for Strategic Objective II

Lines of action	Expected results
Respond to PANDRH's regulatory priorities, based on the findings of a situation analysis on needs and topics of interest	Establishment of a mechanism for setting priorities and for evaluation.
	A PANDRH-developed strategy for disseminating priorities and technical standards.
Form PANDRH working groups in response to the needs and priorities of the NRAs	Establishment of PANDRH working groups based on new regulatory priorities that support the adoption and implementation of PANDRH's technical documents, and for drafting and implementing roadmaps for developing the functions of the regulatory system.
Promote cooperation between NRAs in the development of regulatory systems	Established cooperation mechanisms developed with NRA participation to support the development of work plans for PANDRH's working groups.

III. Promote the strengthening of skills in Good Regulatory Practices and Regulatory Sciences

A. Justification and/or scope

In order to perform their essential functions, the NRAs of developing countries must have qualified staff capable of professionally and skillfully applying good regulatory practices (GRP) and incorporating periodic regulatory-science advances into their activities. Some of the challenges currently facing NRAs include insufficient qualified staff with sound regulatory skills, and an ongoing need for training and incentives to retain professionals. These and other aspects are being addressed by regional initiatives that propose a regulatory curriculum to support the continuous development of NRA technical staff.

While there is no common definition for the GRPs, the following basic principles serve to guide them:

- decision making based on regulatory science;
- risk management;
- quality, transparency, and efficiency in regulatory processes;
- transparency and knowledge management;
- performance evaluation; and
- the participation of the regulatory authority and the sector being regulated.

The GRPs require that the NRA have a duly defined legal framework, that its mission be clearly articulated in public health laws and regulations, and that it be linked with the country's ministry of health. GRPs also include human resource development programs, trained professional technical staff working in facilities that foster high performance, mechanisms to ensure the quality of operational procedures, and access to know-how and appropriate technologies (*28*). Some country experiences have shown that regulatory capabilities develop in phases and over

a long time. In a given country, the pharmaceutical sector's level of development, the availability of trained human resources, the infrastructure, the size of the regulatory authority and its assigned functions, and available financing and resources are decisive factors in ensuring the application of GRPs.

In order to apply GRPs, regulatory science must inform decision making. Regulatory science—which is both multi- and interdisciplinary—focuses on the development of new instruments, standards, and processes for evaluating the safety, quality and efficacy of medicines and other technologies. Today, regulatory science is being applied in the regulation of all medical products, including those already established in the global market and emerging health technologies. Examples of innovative technologies include advanced therapies, medicinal products containing genetically modified cells for the treatment of inherited monogenic diseases, tissue engineering, artificial organs, molecular medicine, and nanoparticle or virus therapy (*29*–*32*). Innovative technologies require new and alternative methods specifically developed to cope with the quality control of new medications or medications that are still under development; the adaptation of clinical trials for innovative products; and new research methodologies and areas, together with pharmacoepidemiology to support regulatory decision making based on the risk-benefit ratio (*33*). Regulatory science must rely on scientific knowledge for developing regulatory pathways that foster the development of new products needed for public health. It also promotes technological innovation in countries and plays a key role in the development and implementation of innovative policies by the NRAs.

Skilled professionals are required for the application of GRPs in the development of the essential functions of health regulation and for using regulatory science to improve evidence-based regulatory processes and decision making. NRAs need to institute a human resources policy that includes the identification of skills that are consistent with their regulatory processes and functions, the selection of qualified professionals through transparent processes, and the development of incentives that facilitate individual professional development as well as the institutional development of the NRA.

As a forum for regulatory convergence among the NRAs in the Americas, PANDRH will support the development and application of GRPs in the Region, and will facilitate the generation and exchange of knowledge and the application of regulatory science by the NRAs. The Network will also make it a priority to develop professional staff needed to ensure the implementation of GRPs in the countries, the strengthening of regional capabilities in regulatory science, and the consolidation of health regulation processes and functions.

B. VII PANDRH Conference recommendations

Conference participants considered that, in order to strengthen basic and advanced regulatory functions, the Region must renew its efforts on human-resource development and increase the use of good regulatory practices based on advances in regulatory science. To that end, they proposed the development of a skill-based curriculum and a comprehensive development plan for staff and regulatory entities that reflects the Region's various realities and diversity. In order to do this the following requirements are needed:

- a diagnosis of each country's priorities and capabilities arrived at through evaluation processes;
- the development of a regulatory curriculum that addresses the necessary skills for small NRAs and for NRAs with broader functions, incorporating recommendations from WHO and other government leaders in regulatory science;
- training based on institutional development plans that consider gaps that arise during the NRA's evaluation process;

- a mapping of existing training opportunities, so that, based on the regional NRAs' strengths and experiences, existing resources can be used; and
- the monitoring of the implementation of the development plan to establish cost-effectiveness and sustainability of this investment.

C. Lines of action and expected results from strategic objective III

Table 5 describes the lines of action and expected results in order to achieve this strategic objective.

Table 5. Expected results for Strategic Objective III

Lines of action	Expected results
Promote the development and application of Good Regulatory Practices in the Americas	Development of technical standards for good regulatory practices in the Americas.
	Adoption of good regulatory practice standards by the Region's NRAs.
Promote the development and application of regulatory science in decision making processes	Development and dissemination of a position paper on regulatory sciences to support the strengthening of the NRAs and regional regulatory convergence.
	Participation of centers of excellence, universities, and PAHO's regulatory authorities of reference in the Network to strengthen regional and national capabilities in research and the application of regulatory sciences.
Strengthen the regulatory competencies of human resources and professionals in a sustainable way	Periodic review and update of PANDRH's training priorities.
	Development of PANDRH's professional training models on regulation of medicines and other health technologies based on the priorities. Development of a curriculum for regulatory professionals, made available to PANDRH's participating NRAs.

IV. Promote the exchange of experiences and regulatory knowledge between NRAs within the Network and with NRAs outside PANDRH

A. Justification and/or scope

The strengthening of the NRAs aims at improving access to quality health technologies and the overall strengthening of the health systems. Acknowledging that the exchange of information, knowledge, and experience among NRAs helps Member States to strengthen regulatory capacity, the Region's NRAs are searching for ways to effectively communicate with one another. NRAs also are seek to expedite the exchange of confidential information on regulatory decisions, which will enable them to better perform their essential regulatory functions. Their interest in communicating with one another and in having the mechanisms to do so, is critical for knowledge management. New technologies can be used to integrate information, generate databases, and share outputs that can be used to inform decision-making in other countries.

The Regional Platform on Access and Innovation for Health Technologies (PRAIS), launched in May 2012, brings together the main regional and international stakeholders in the health technologies sector (*40*, *35*). PRAIS is designed to facilitate networking, in order to promote cooperation and communication on issues related to health technologies from the public health perspective. One of PRAIS's main focuses is the quality, safety, and other aspects of health technologies regulation. The platform makes a wealth of resources available in support of regulatory activities:

- The Observatory systematizes the results of activities associated with NRA evaluations under resolution CD50.20.
- The Annotated Medicine Lists include information on essential and strategic medicines, as well as the medicines obtained through PAHO's Strategic Fund.
- PRAIS's public repository also systematizes regulations, national policies, and situation analyses related to health technologies.
- The communities-of-practice tool facilitates the interaction and collaboration among NRAs or with other subsectors in the health technologies field.

The networks created in the Platform enable the Region's NRAs to share experiences and knowledge, enhancing the quality of regulatory activities. Ongoing lessons from the achievements and challenges faced by the Network's members serves to improve the health surveillance functions. In the area of pharmacovigilance, for example, the lessons learned in regulating the quality, safety, and efficacy of medicines in one country may be useful to another country.

PANDRH will facilitate the generation and exchange of knowledge based on the priorities established by the Network itself, functioning as a catalyst for the sharing of information among members and promoting the effective and efficient use of resources. It also will foster agreements that facilitate information sharing among NRAs. And it may call on collaborating and knowledge-management centers to complement and expand the information resources required for decision-making and for the regulation of new and complex health-related technologies. Furthermore, PANDRH will actively support the establishment of secure and responsive channels for the exchange of confidential information—such as the mechanism that PAHO is developing for sharing inspection reports on good manufacturing practices (GMPs)—thus gaining in efficiency and making better use of resources by avoiding duplicate inspections of the same plant by several countries. The many tools available through information/communication technology present the Network with an extraordinary opportunity to enhance cooperation mechanisms between the countries. There is consensus that substantive progress can be made with fewer financial, logistical, and human resources.

B. VII PANDRH Conference recommendations

To date, the cooperation, communication, and information exchange among regional NRAs are key elements for the effective functioning of regulatory agencies to guarantee the quality, safety, and efficacy of medicines. To that end, the Conference recommended that the information exchange between PANDRH members and other lead entities in regulatory science be promoted, using tools that facilitate communication and knowledge management in support to the PANDRH Strategic Plan and the achievement of its strategic objectives. In light of this recommendation, it will be necessary to:

- foster the creation of bilateral and multilateral agreements that promote information exchange among NRAs;
- use virtual tools that streamline information exchange, including products that emerge from the regulatory processes;
- create and populate repositories with data from the NRAs standardized evaluations to establish benchmarks that make it possible to assess the regulatory agencies' strengths and establish the regional regulatory capacity profile; and

- use new communication technologies that make it possible to integrate information, create databases, and share products and results that can be used in decision making processes in other countries.

C. Lines of action and expected results from Strategic Objective IV

Table 6 describes the lines of action and expected results in order to achieve this strategic objective.

Table 6. Expected results for Strategic Objective IV

Lines of action	Expected results
Promote the exchange of knowledge and information required to efficiently carry out the essential regulatory functions	Regulatory documents and other sources of knowledge required to carry out regulatory functions developed by PRAIS Communities of Practice.
	Regulations and regulatory policies systematized and disseminated by PRAIS.
	Indicators on the regulatory situation and other key information data sets systematized and accessible through PRAIS.
Create mechanisms for the efficient and timely exchange of information	A secure channel for sharing reports on GMPs established and used by the NRAs
	Communication channels such as listservs, blogs, webinars, bulletins, etc., updated on an ongoing basis and available to meet the PANDRH's information needs

3. Next Steps

The recommendations presented at the VII Conference of the Pan American Network for Drug Regulatory Harmonization (PANDRH), held in Ottawa, Canada, in 2013, include the establishment of two working (ad hoc) groups (WGs) to revise PANDRH statutes and develop a proposal that leads to the restructure of PANDRH's governance, guaranteeing the Network's flexibility and functioning, and to develop a proposal of a regulatory curriculum based on the NRAs current needs and regional context, and a methodology for continuing education of NRA's personnel.

In addition, it was recommended that several activities be conducted, to be presented to the Network's Steering Committee, including:

- analyzing and publishing the results of the study on adoption, adaptation, and implementation of PANDRH technical reports;
- elaborating a proposal that allows for the establishment of a systematic mechanism for priority setting, based on a periodic analysis of PRAIS-Observatory data, surveys, and other relevant sources;
- issuing a report of PANDRH's WGs, detailing the group's functionality, current activity level, list of members, current working plan with obtained results and products, and, when necessary, a proposal for each group's continuity; and
- using PRAIS within PANDRH's new governance model as a tool to promote the effective information exchange and knowledge management in support of the new strategic development plan and its objectives.

In conclusion, the VII Conference of the Pan American Network for Drug Regulatory Harmonization approved the Strategic Development Plan presented here. The active participation during the Conference fostered dialogue among countries, institutions, and other sectors, thus providing the information necessary for the emergence of future activities that will contribute to the strengthening of PANDRH and the regulatory structure of the countries of the Region. This Strategic Development Plan has been reviewed and edited by PANDRH's Secretariat, which is also responsible for its publication. Each of the recommendations presented during the Conference will guide the future development of an operational plan and the implementation of this strategic plan (*36*).

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5. Annex: Definition of Terms

Biological product (biologics): substances obtained from living organisms, or their derivatives, used to prevent, treat, or diagnose diseases. They include viruses; therapeutic serums; toxins; antitoxins; vaccines; blood, blood components, or derived products; allergens, hormones, colony stimulating factors, cytokines, antibodies, etc.

Biotechnological products: medicines produced from animal cell substrates and microbial cultures. Constitute proteins obtained by the recombinant DNA technique expressed in animal tissues or in microbial life forms, including products obtained through the monoclonal antibody techniques. Most of these products are used in treating chronic conditions.

Cooperation agreement: an instrument governed by public international law and subscribed in writing between any department or decentralized organism of a state, municipal, or federal administration and one or more foreign governmental bodies or international organizations, covering issues pertaining to the programming, promotion, coordination, execution, measurement, evaluation, and monitoring of actions and cooperation programs for the transfer, receipt, and exchange of resources, goods, knowledge, and educational, cultural, technical, scientific, economic, or financial experiences.

Harmonization: represents the development and adoption of the same standards or requirements. Harmonization may also be applied to procedures and practices, so they are the same across economies. Harmonization represents an important means for achieving regulatory convergence over time, as does the adoption of common procedures and practices.

Health technologies: refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve quality of life. It also includes biological and biotechnological products, blood and its components, human cells and tissue, laboratory inputs, medical imaging, radiation therapy, medical equipment.

Medication: a pharmaceutical product used for the prevention, diagnosis and/or treatment of a disease or condition, or for modifying physiological systems for the benefit of the person to whom it is administered. This definition includes medicines of biological origin (biologics) and derived through chemical synthesis.

Pharmaceutical product: a product that contains one or more active ingredients and excipients, formulated in a pharmaceutical or dosage form.

Regulatory convergence: represents a voluntary process whereby regulatory requirements across economies become more uniform, or “aligned,” over time, as a result of the gradual adoption of internationally recognized technical guidance documents, standards, and scientific principles (harmonization), and common or similar practices and procedures. It does not represent the harmonization of laws and regulations, which is not necessary to allow for the alignment of technical requirements and for greater regulatory cooperation.

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