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Regulatory convergence and harmonization: barriers to effective use and adoption of common standards

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ABSTRACT

Objective. *To evaluate 1) the level of use and adoption of eight Technical Documents (TDs) published by the Pan American Network for Drug Regulatory Harmonization (PANDRH) member states and 2) identify the hurdles that can prevent countries from successfully adopting a common standard.*

Methods. *An in-depth analysis of the incorporation of PANDRH Technical Document No. 1 ("TDNo1") recommendations in member states' national requirements was carried out.*

Results. *The results illustrate the role of PANDRH in promoting convergence/harmonization among its members.*

Conclusions. *The study results show that the rate of use of TDs varied greatly by product/area and country. Timing, TD content, and product/area, and, more importantly, national capacities, are critical determinants of the level of TD guideline adoption. While PANDRH TDs have proven instrumental for the harmonization/convergence of member states' national requirements, as shown by the level of convergence across a majority of the national requirements issued for vaccine licensing, several countries had yet to incorporate common standards due, in large part, to weak national regulatory capacities. Therefore, harmonization/convergence initiatives should include the strengthening of national regulatory capacities as part of their core strategy, which will, in turn, allow for the incorporation and deployment of common standards in all participating countries.*

Key words Regulations; pharmaceutical preparations; drug and narcotic control; vaccines; Americas.

Regulatory systems development and the dynamism of the health technologies markets will benefit from increased regulatory convergence and/or harmonization at the regional and global level. Regulatory convergence and/or harmonization can help countries develop efficient regulatory systems and thus contribute to product safety and a vibrant pharmaceutical market (1). There are now numerous international initiatives that focus on the harmonization of regulatory standards through the development, adoption, and implementation of technical guidelines and requirements distributed as Technical Documents (TDs). Notable examples include the International Council for (formerly the International Conference on) Harmonisation of Technical Requirements for Registration of Pharmaceuticals For Human Use (ICH) (2). Since its inception in 1990, ICH has developed regulatory guidelines (3) and other standards with the objective of harmonizing regulatory requirements in participating countries.

Spurred by globalization of pharmaceutical markets and regional and subregional economic integration mechanisms, a series of other harmonization initiatives have been created, including those pertaining to countries with transitional economies. The Asia-Pacific Economic Cooperation (APEC), Association of Southeast Asian Nations Pharmaceutical Product Working Group (ASEAN PPWG), and East African

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Community (EAC) are examples of groups that have adopted ICH guidelines and/or developed their own guidelines published as TDs (4).

In 1999, in response to the need for initiatives that promote regulatory harmonization in the Americas, Pan American Health Organization (PAHO) Governing Bodies recommended the establishment of the Pan American Network for Drug Regulatory Harmonization (PANDRH) (5–7). Like other harmonization initiatives, PANDRH has focused on the development of regulatory standards to achieve harmonized regulatory requirements. Although the TDs that PANDRH has developed over the past 16 years have made significant contributions to advancing the regulatory capacity in the Americas, adherence to and implementation of the above-mentioned standards has not been consistent across topics and countries. PANDRH working groups are established by its steering committee based on regional priorities. Once a working group reaches consensus on a specific TD, the document is put to the consideration of all PANDRH participating members during PANDRH Conferences, where the guidelines are discussed and formally adopted at the regional level.

While PAHO provides technical cooperation to support the implementation of the new guidelines by PANDRH participating members, it is up to each country to effectively adopt and deploy the recommendations at the national level by introducing changes in their regulatory frameworks and procedures. Exploring the level of adoption of harmonized technical guidelines and potential hurdles for their effective deployment at the national level by members of regulatory convergence initiatives can help guide future strategies for achieving harmonization and strengthening regulatory capacities.

Therefore, this study aimed to 1) measure the level of adoption of PANDRH TDs from 1999 to 2013 among participating countries and 2) identify the barriers that influenced their uptake. Moreover, it establishes the impact of PANDRH TD No. 1 ("TDNo1") in the countries, which offers an objective measure of the effective deployment of the TD in the national regulatory framework.

MATERIALS AND METHODS

TD selection

Eight of the 23 TDs published by PANDRH were selected for the study (8–15). The inclusion criteria were: 1) document is relevant to essential regulatory functions, 2) document was developed by PANDRH working groups and related to the PANDRH mission and objectives, and 3) document has been adopted at a PANDRH Conference. Exclusion criteria were 1) document is not published on the PANDRH website, 2) document is still in process, or 3) document has not been adopted at a PANDRH Conference.

Surveys and data

To assess use and adoption, a set of eight surveys—one for each TD covered in the study—and a study participant consent form were sent by email to national regulatory authority (NRA) technical officers from 22 PANDRH member states. To assess the hurdles faced by countries to adopt a TD, 10 countries received a semi-structured survey. These countries were selected to ensure representation of all the subregions and different levels of regulatory capacity. For this stage of the research, the Delphi method was used to determine consensus among responders. Data used to assess TD use and adoption were scored based on "Yes"/"No" answers. The results were also classified according to different levels of adoption ("uses a TD and adopts it in full or partially" versus "might not use the TD"). The data for evaluating hurdles were grouped by the level of consensus among responders. All surveys were previously validated in one country from each of the subregions (Mercado Común del Sur (MERCOSUR); Caribbean Community (CARICOM); Central America Integration System (SICA); North American Free Trade Agreement (NAFTA); and Andean Group).

To measure the impact of TDNo1 (8), the PANDRH Vaccine Working Group (VWG) distributed an 11-question survey to regulatory professionals responsible for the evaluation of biological medicines licensing applications within the NRAs. A total of 17 countries were surveyed (Argentina, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Panama, Dominican Republic, Trinidad and Tobago, and Venezuela). For the 12 surveyed countries that reported having specific vaccine licensing requirements (all of the above except Chile, Honduras, Dominican Republic, Panama, and Trinidad and Tobago), plus Nicaragua, Peru, and the United States, the research team sought to identify the legal regulatory framework supporting vaccine licensing. Ministry of Health and NRA websites were searched for relevant laws, decrees, resolutions, and other legal documents. All relevant material was then searched using the following search terms: "biologics," "vaccine," "registration," "licensing," and "regulations. We also searched for the forms and procedures used for vaccine licensing. The research team was thus able to cross-check and verify the survey responses with the actual regulations and requirements used in the country (16–37).

RESULTS

Level of adoption of PANDRH TDs

PANDRH has developed and adopted 23 TDs. Their adoption by member states at the national level is understood as the development or revision of local regulations to reflect the recommendations established in a specific TD. The level of coherence between the national regulations and TD recommendations may vary, resulting in a partial or full level of adoption. To measure the success of PANDRH TDs in influencing national regulatory processes and thus contribute toward harmonization/convergence in the Americas, our study aimed at measuring the rate of use of eight predefined TDs by regulatory authorities in the Americas to develop national requirements.

NRA representatives from 27 countries in the Americas received a set of eight semi-structured surveys, each one tailored to a specific TD. Twenty-two countries completed a variable number of surveys from the set, representing an 81% participation rate. The five countries that did not submit any completed surveys were considered nonparticipants and eliminated from the analysis. The level of response varied from 68% (15 of the 22 countries) for both Good Clinical Practices (GCP) (15) and Good Laboratory Practices (GLP) (12) to 86% (19 of the 22 countries) for the Equivalence requirements for pharmaceutical products (BE) (11), Good Pharmacovigilance Practices (GPV) (5), and Requirements for Vaccine Licensing (8). Eleven of the 22 countries responded to all eight surveys while the remaining 11 countries responded to a variable number of surveys ranging from 1 to 7.

Figure 1 depicts the rate of use of each PANDRH TD reported by PANDRH member states. The rate of use indicates the proportion of countries that used a specific TD to develop national requirements. The results showed that the rate of use varied by TD. The GPV TD was used by 68% of the participating countries (PCs) whereas the BE TD was used by only 32%. For all eight TDs, a sizeable number of countries either reported not using the TD at the national level or did not answer the survey. Countries stated variable reasons for not using a TD at the national level. While a number of countries based their current regulations on other harmonization initiatives, such as ICH, or adopted regulations prior to the development of the PANDRH TDs, others cited not having specific written requirements for the area covered by the TD as the basis for not having used it. For example, the GPV TD was used by 15 countries; three (13.64% of the PCs) reported adopting all requirements included in the document while the remaining 12 (54%) indicated they had selectively incorporated some of the requirements. The GPV TD was not used by four countries (18.18% of the PCs). Three of the latter indicated that they based their national regulations on guidance provided by other harmonization initiatives, such as ICH E2E ("Pharmacovigilance Planning") (38). The remaining country reported that its national requirements were developed in 1999 and 2000, before the GPV TD was published.

Similarly, seven of 22 countries reported using the BE TD; four of them reported adopting all requirements in the TD (18.18% of the PCs) while the remaining three said they selectively incorporated some of the requirements (13.64%). The BE TD was not used by 12 countries (54.54%). Four of the latter group indicated that they based their national regulations on guidance provided by other harmonization initiatives or had regulations in place before the PANDRH TD was published. Seven countries reported not having national regulatory requirements for BE and thus were not able to use and adopt the TD. The remaining country did not state the reason for not using the TD.

These data show that the rate of use of specific TDs varies across countries and subregions. Having a previous regulation in place seems to be a common factor preventing the use of the guideline. Furthermore, the adoption of a TD by a PANDRH Conference was not always followed by the development and adoption of the corresponding regulation at the national level.

Hurdles for the use and adoption of TDs

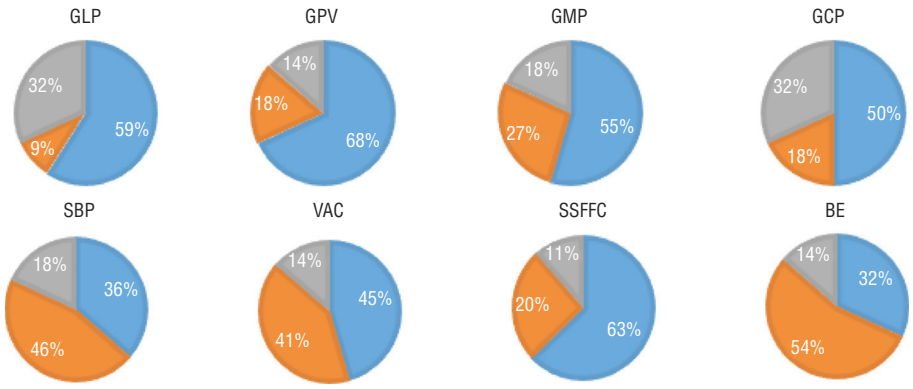
In addition to benchmarking use rates for each of the eight TDs, the study aimed to identify the factors that influenced the adoption of the TD at the national level using a Delphi-based qualitative survey. Ten countries—two per economic integration mechanism—were invited to identify the obstacles they faced when using the TD as well as the particular needs of the NRA to move forward with the adoption. The sample represented NRAs of diverse capacities, from countries with budding regulatory systems to those with well-established regulatory authorities. This sample also included countries that reported full, partial, and/or lack of adoption of specific TDs.

Table 1 summarizes the most relevant findings. Lack of adequate human resources was reported as the most pressing issue by the NRAs. Non-adoption or partial adoption of the TD requirements was attributed to deficiencies in the number, specialization, and overall competencies of the human resources. The content of the TD per se was also identified as a barrier to the adoption of the standards. Country representatives reported that a number of TDs lacked practical and detailed guidelines to facilitate their adoption.

Another factor weighed in the adoption of the guidelines was the degree of development of a quality management system (QMS). When a TD required ability to trace a process along the product's life cycle, many NRAs reported not having the QMS to perform this task. Lack of necessary infrastructure, including appropriate information systems, was also identified as a barrier to adopting part or all of the TD. Similarly, some TDs' lack of an appropriate information system to support reporting, traceability, and other data management requirements was identified as one of the reasons for the varied degree of adoption.

Timing and participation in other harmonization initiatives were also identified as reasons for not using a TD for developing national regulatory requirements. When countries participate in and/or follow other harmonization initiatives such as ICH, they report having used those guidelines in developing their regulatory requirements. Other countries may have established their national requirements before the PANDRH TD was published and thus used other guidelines as the basis for their requirements. On the other end of the spectrum, some countries reported not using the PANDRH TD simply because their country had yet to incorporate requirements for the regulatory process in question. Most of these countries reported weak capacity in some or all of the determinants described above.

FIGURE 1. Rate of use of PANDRH TDs,[a–c] Americas Region, 1999–2013



Source: compiled by the authors based on the study results.

[a] Pan American Network for Drug Regulatory Harmonization Technical Documents.

[b] GLP: TD on self-evaluation of good laboratory practices; GPV: TD on good pharmacovigilance practices for the Americas; GMP: TD on good manufacturing practices inspection; GCP: TD on good clinical practices for the Americas; SBP: TD on evaluation of similar biotherapeutic products; VAC: TD on harmonized requirements for licensing of vaccines in the Americas and guidelines for preparation of applications; SSFFC: TD for health authorities on suspected counterfeit medical products; BE: TD on framework for implementation of equivalence requirements for pharmaceutical products.

[c] Blue shading: survey participant reported country used the TD; orange shading: survey participant reported country did not use the TD; grey shading: survey participant did not respond to the question.

TABLE 1. Determinants and identified hurdles for use and adoption of PANDRH TDs[a] reported by member states, Americas Region, 2013

Determinant	Identified hurdle
Standards, guidelines, specifications, and procedures	Some TDs are considered too general and lacking in sufficient guidance (e.g., clarification of difficult topics, practical steps to break down complex processes, and support in the interpretation of the proposed requirements)
Good-quality management system	Traceability system is either absent or inefficient
Human and financial resources	• Shortage of human resources dedicated to a specific task • Lack of appropriate competencies for the human resources assigned to a task due to absence of continuing education programs in the NRA[b] and/or the regulated sector (industry) • Lack of specific technical competencies needed to address new or emergent regulatory challenges (e.g., regulation of SSFFC[c] products or complex products)
Infrastructure (including information systems)	• Lack of digital information system(s) for systematization and follow-up actions • Lack of automated systems for generating notifications and alerts • Lack of physical infrastructure for compliance with specific requirements, particularly GMP[d]
Other harmonization initiatives and/or timing of adoption of new regulation	A country may participate in and/or follow guidelines produced by other harmonization initiatives (e.g., ICH[e] and other guidelines adopted in certain countries for a specific regulatory process prior to the publication of the PANDRH TDs)

Source: compiled by the authors based on the study results.
[a] Pan American Network for Drug Regulatory Harmonization Technical Documents.
[b] NRA: national regulatory authority.
[c] SSFFC: Substandard, Spurious, Falsely labeled, Falsified and Counterfeit.
[d] GMP: Good Manufacturing Practice.
[e] International Council for (formerly the International Conference on) Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (2).

In summary, countries face a series of challenges when trying to use and adopt a TD. Timing, quality, and appropriateness of the guideline seem to influence the use and adoption rate. However, weak infrastructure and a shortage of human resources with the appropriate competencies were the most cited hurdles for the adoption of the PANDRH TDs.

Impact of PANDRH TDs on regulatory requirements: the TDNo1

The results described above indicate the rate of use and adoption of a number of PANDRH TDs as reported by participating countries. Measuring TD impact at the national level involves assessing their coherence with national requirements. Hence, an in-depth analysis of the incorporation of TDNo1 recommendations was conducted to illustrate the role of PANDRH in promoting convergence/harmonization across member states.

The strategy for the analysis was twofold. Through NRA representatives participating in the PANDRH VWG, NRA technical officers were surveyed. The survey was directed at the active members of the VWG and additional countries to ensure broad representation. In addition, to complement the survey the research team sought to identify the legal regulatory framework supporting vaccine licensing in the countries by identifying publically accessible documents from ministries of health and NRAs and reviewing the content, format, and structure of published national requirements.

Based on the survey, the research team determined which countries reported using TDNo1 to develop national requirements and asked participants to assess the level of coherence (match) between their requirements and TDNo1 (Tables 2 and 3). Fifteen out of 19 countries reported having specific vaccine licensing requirements (Argentina, Bolivia, Brazil, Canada, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Mexico, Nicaragua, Peru, United States, and Venezuela) (Table 2). Nine of the 19 countries reported using TDNo1 for developing national requirements (Table 2). Colombia, Ecuador, Peru, and Venezuela reported full adoption of TDNo1, while Brazil, Costa Rica, Mexico, Nicaragua, and Uruguay reported partial adoption. At the time of the survey, some of these countries were in the process of developing their national requirements. This was the case for Ecuador, Colombia, and Uruguay. In 2013, Honduras, which still lacks specific vaccine requirements, reported using the TDNo1 as a reference document during the licensing process.

Based on survey responses, the research team checked publicly available documents to confirm which countries had developed specific requirements for vaccine licensing and to assess all national licensing requirements for their level of coherence with the TDNo1 guidelines (Table 3). The findings were grouped in three categories: "content" (information that must be submitted by the manufacturer); "format" (the numbering system—use of the protocol recommended by TDNo1, or lack thereof); and "structure" (number and type of data items included in each of the five modules of the Common Technical Document (CTD)). For nine countries differences between national requirements and TDNo1 guidelines involved only format and/or structure. Bolivia's national requirements preceded the 2008 PANDRH adoption of the TDNo1, whereas the requirements of the other three countries were developed afterward (Table 4).

In conclusion, the research team was able to objectively assess the impact of the TDNo1 in the countries that reported having specific licensing requirements for vaccines. The requirements in the majority of those countries had a high level of correspondence with the TDNo1 content, even when there were discrepancies in structure and/or formatting. Most of the countries that issued their requirements before 2008 (including Argentina, Canada, and Cuba) have requirements similar to those in the TDNo1 as they were active participants in the PANDRH VWG and their regulations were used as input, together with the ICH-CTD

TABLE 2. Impact of PANDRH TDNo1[a] on national requirements of member states: PANDRH VWG[b] participants and nonparticipants, Americas Region, 2013

Country	Participates in PANDRH VWG	Uses TDNo1 for development of local requirements	NRA[c] has specific requirements for licensing vaccines
Argentina	Yes	No	Yes
Bolivia	No	No	Yes
Brazil	Yes	Yes	Yes
Canada	Yes	No	Yes
Colombia	No	Yes	Yes
Costa Rica	No	Yes	Yes
Cuba	Yes	No	Yes
Dominican Republic	No	No	No
Ecuador	Yes	Yes	Yes
El Salvador	No	No	Yes
Guatemala	No	No	Yes
Honduras	No	No	No
Mexico	No	Yes	Yes
Nicaragua	No	Yes	Yes
Paraguay	No	No	No
Peru	No	Yes	Yes
Uruguay	No	Yes	No
United States	No	No	Yes
Venezuela	Yes	Yes	Yes

Source: compiled by the authors based on the study results.
[a] Pan American Network for Drug Regulatory Harmonization Technical Document No. 1 (*Harmonized requirements for the licensing of vaccines in the Americas and guidelines for the preparation of applications*).
[b] VWG: PANDRH Vaccine Working Group.
[c] NRA: national regulatory authority.

TABLE 3. Legal regulatory framework supporting vaccine licensing: level of coherence between national and PANDRH TDNo1[a] requirements, Americas Region, 2013

Country	Requirements for vaccine licensing	Capacity to manufacture human-use vaccines	Differences between national and TDNo1 requirements
Argentina	V[b]	Yes	F[c]
Bolivia	V	No	F, S,[d] C[e]
Brazil	V	Yes	F, S
Canada	V	Yes	F
Colombia	V	No	Harmonized
Costa Rica	V	No	F, S, C
Cuba	V	Yes	F
Ecuador	V	Yes	F
El Salvador	M[f]	No	N/A
Guatemala	V	No	F, S
Mexico	V	Yes	F, S
Nicaragua	B[g]	No	F, S, C
Peru	B[g]	No	F, S, C
United States	V	Yes	F
Venezuela	V	Yes	F

Source: compiled by the authors based on the study results.
[a] Pan American Network for Drug Regulatory Harmonization Technical Document No. 1 (*Harmonized requirements for the licensing of vaccines in the Americas and guidelines for the preparation of applications*).
[b] V: vaccines.
[c] F: format.
[d] S: structure.
[e] C: content.
[f] M: medicines.
[g] B: biologicals.

(39). Some of the countries studied still lack a specific requirement for vaccine licensing. El Salvador issued general requirements for vaccine licensing based on medicines requirements, and Nicaragua, Peru, and Uruguay issued general requirements for vaccine licensing based on biological products. In addition, Costa Rica reported the need to strengthen its capacities to facilitate the full adoption of TDNo1.

DISCUSSION

Measuring the impact of use and adoption of a harmonized guideline helps to 1) assess the success and effect of harmonization initiatives and 2) establish and review priority areas of work. Moreover, it can help improve strategies to increase the deployment of harmonized standards in participating countries. As shown by the variable level of use, issuing a TD is not an automatic guarantee for its national adoption and deployment. Ideally, countries should incorporate standardized requirements by changing the requirements of local norms, regulations, and policies. As this study shows, however, countries may use the document even before the formal adoption of a requirement to inform the review process or to request additional information ad hoc. The study has found several instances of countries that report "informal" use of a TD to oversee regulatory processes before formal adoption.

National regulatory capacities are a major determinant of the rate of use of a TD. If a country does not have the minimum capacities to perform a recommended regulatory function, it will not have the ability to adopt a TD in a timely and effective manner. Therefore, strengthening regulatory capacities is a precondition for the success of harmonization/convergence efforts. It is recommended that any harmonization/convergence initiative include in its mission the strengthening of national regulatory capacities, which will, in turn, allow for the incorporation and deployment of common standards. At the same time, issuing regulatory guidelines and standards that are appropriate for a specific context may help guide capacity building efforts for regional NRAs. TDs should inform how to progressively incorporate the

TABLE 4. Year of adoption of national vaccine licensing requirements Americas Region, 2000–2014[a]

Country	Year specific vaccine licensing requirements were implemented	
	Before TDNo1[b] adoption (prior to 2008)	After TDNo1 adoption (2008 and beyond)
Argentina	2005	–[c]
Bolivia	2003	–
Brazil	–	2010
Canada	2003	–
Colombia	–	2014
Costa Rica	–	2012
Cuba	2000	–
Ecuador	–	2013
Guatemala	–	2010
Mexico	–	2011
Nicaragua	–	2012
Peru	–	2011
United States	2003	–
Venezuela	–	2008

Source: compiled by the authors based on the study results.

[a] El Salvador is not included in this table because national vaccine licensing requirements are based on medicines requirements. In the case of Nicaragua, available information is included in this table because vaccine licensing requirements are based on biological products.

[b] Pan American Network for Drug Regulatory Harmonization Technical Document No. 1 (*Harmonized requirements for the licensing of vaccines in the Americas and guidelines for the preparation of applications*).

[c] Not applicable.

recommendations considering different levels of capacity. Furthermore, TDs should suggest alternative pathways that may include leveraging the results of well-established regulatory authorities and that may be more easily implemented in low-resource settings while actions are taken to strengthen NRA QMS and other critical capacities. In all cases, developing implementation guidelines similar to those in ICH's stepwise procedure (40) to support the deployment of the practices promoted in each TD may facilitate their effective adoption by countries.

Developing a TD is a very involved process and timing is critical to respond to regulatory challenges at any given time. Member states do not always wait for PANDRH to issue a TD to update their regulations. To make the publication of its guidelines more timely and efficient, and prevent multiple guidelines, PANDRH may choose to adopt and adapt existing guidelines rather than develop new ones. Adapting existing guidelines that have been developed in a transparent process, based on regulatory science and good regulatory practices, and that have harnessed a certain level of international consensus, may prove a more efficient strategy than developing new ones. Ensuring active and significant participation from PANDRH in the development of international standards may improve regional coordination and allow participating members to take advantage of existing guidelines and incorporate a regional perspective.

The analysis of TDNo1 adoption underscores some of these issues. The results indicate that a majority of countries with specific vaccine licensing requirements have achieved what we consider convergence in this area. Most regulations differ only in format and structure but are coherent in content. Therefore, convergence has been achieved not only by the specific adoption of TDNo1, but through the activities surrounding its development, such as the activities of the PANDRH VWG. A number of countries have adopted standards from other harmonization initiatives while others still lack a specific requirement for vaccines. Before adopting new requirements to perform this core regulatory function, the latter need to strengthen national regulatory capacities.

Nevertheless, since the publication of the situational analysis of the regulation for biologicals in the Americas up until 2008 (41), there has been significant progress in the number of countries that reported specific regulations for these products. Currently, at least 15 countries have specific requirements for the registration of vaccines, most of them convergent with TDNo1. Moreover, these countries have strengthened registration of medicines by incorporating differentiated requirements for pharmaceuticals and biological medicines.

Conclusions

Through dialogue, working groups, and the development of TDs, PANDRH has played an important and significant role in promoting harmonization/convergence. More efficient and effective strategies will help promote further harmonization and convergence among PANDRH member states. The VII Conference of the Pan American Network for Drug Regulatory Harmonization (CPANDRH) (Ottawa, Canada, 5–7 September 2013)[5] recognized this challenge when it adopted its Strategic Development Plan 2014–2020, which calls for 1) active participation of NRAs toward regulatory convergence and harmonization; 2) the integration of PANDRH work with other international initiatives; and 3) the identification of priorities, strategies, and mechanisms for regulatory convergence and harmonization in the Americas.

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Conflicts of interest. None.

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[5] http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=23917&Itemid=270&lang=en

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RESUMEN

La convergencia y la armonización regulatorias: barreras en el uso y la adopción eficaces de normas comunes

Objetivo. Evaluar (1) la medida en que se usan y se han adoptado ocho documentos técnicos (DT) publicados por los estados miembros de la Red Panamericana para la Armonización de la Reglamentación Farmacéutica (Red PARF) y (2) definir los obstáculos que pueden impedir que los países adopten una norma común.

Métodos. Se realizó un análisis minucioso de la incorporación de las recomendaciones contenidas en el Documento Técnico No. 1 ("DTNo1") de la Red Panamericana para la Armonización de la Reglamentación Farmacéutica en los requisitos nacionales de los estados miembros.

Resultados. Los resultados ilustran el papel que desempeña la Red Panamericana para la Armonización de la Reglamentación Farmacéutica en la promoción de la convergencia y armonización entre sus miembros.

Conclusiones. Los resultados del estudio indican que el uso de los DT varía enormemente según el producto o el área y el país. El momento, el contenido del DT, el producto o área y, lo que es más importante, la capacidad nacional son factores determinantes del grado de adopción de las directrices contenidas en los DT. Si bien los DT de la Red Panamericana para la Armonización de la Reglamentación Farmacéutica han sido decisivos en la armonización y convergencia de los requisitos nacionales de los estados miembros, como demuestra el grado de convergencia de la mayor parte de los requisitos nacionales emitidos para la concesión de licencias para vacunas, varios países no habían incorporado normas comunes todavía debido, en gran parte, a una capacidad de reglamentación nacional deficiente. Por lo tanto, las iniciativas en pro de la armonización y convergencia deben comprender el fortalecimiento de la capacidad de reglamentación nacional como parte de su estrategia central, lo cual permitirá, a su vez, que se incorporen y desplieguen normas comunes en todos los países participantes.

Palabras clave Reglamentos; preparaciones farmacéuticas; control de medicamentos y narcóticos; vacunas; Américas