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Sharing regulatory data as tools for strengthening health systems in the Region of the Americas

Varley Dias Sousa,[1] *Pedro I. Ramalho,*[2] *and Dâmaris Silveira*[1]

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ABSTRACT *Regulatory transparency is an imperative characteristic of a reliable National Regulatory Authority. In the region of the Americas, the process of building an open government is still fragile and fragmented across various Health Regulatory Agencies (HRAs) and Regional Reference Authorities (RRAs). This study assessed the transparency status of RRAs, focusing on various medicine life-cycle documents (the Medicine Dossier, Clinical Trial Report, and Inspection Report) as tools for strengthening health systems. Based on a narrative (non-systematic) review of RRA regulatory transparency, transparency status was classified as one of two types: public disclosure of information (intra-agency data) and data- and work-sharing (inter-agency data). The risks/benefits of public disclosure of medicine-related information were assessed, taking into account 1) the involvement and roles of multiple stakeholders (health care professionals, regulators, industry, community, and academics) and 2) the protection of commercial and personal confidential data. Inter-agency data- and work-sharing was evaluated in the context of harmonization and cooperation projects that focus on regulatory convergence. Technical and practical steps for establishing an openness directive for the pharmaceutical regulatory environment are proposed to improve and strengthen health systems in the Americas. Addressing these challenges requires leadership from entities such as the Pan American Health Organization to steer and support collaborative regional alliances that advance the development and establishment of a trustworthy regulatory environment and a sustainable public health system in the Americas, using international successful initiatives as reference and taking into account the domestic characteristics and experiences of each individual country.*

Key words Disclosure; access to information; confidentiality; technical cooperation; regional development; Americas.

As set out in Pan American Health Organization (PAHO) resolution CD50/20 ("Strengthening the national regulatory authorities of drugs and biologicals"), compliance with principles of transparency and accountability by National Regulatory Authorities (NRAs) is essential for the protection and promotion of public health in the Americas (1). The resolution also recommends that Regional Reference Authorities (RRAs) (2), whose quality parameters are recognized by the World Health Organization (WHO), share information about their procedures for approving drugs and biologicals with other authorities to improve the latter group's capacity to make similar decisions about their own products.

Regulatory activities are becoming particularly onerous and complex as a result of new technologies and the globalization of pharmaceutical activities. Therefore, regulators should strive for greater access to and transparency and harmonization of existing medicine assessment information to avoid duplication of regulatory efforts. Dialog and multilateral initiatives should be established among regulators to increase cooperation, convergence, harmonization,

[1] Department of Pharmaceutical Sciences, Universidade de Brasília, Brasília, DF, Brazil. Send correspondence to: Varley Dias Sousa, varley.sousa@yahoo.com.br

[2] Agência Nacional de Vigilância Sanitária, Brasília, DF, Brazil.

and transparency, which will in turn build trust (3, 4).

The establishment of public policies to ensure information access has increased exponentially in the last decade, particularly in the Americas, where more than 20 countries have adopted Access to Information Laws (5, 6). Sharing data of a regulatory nature must be done expeditiously because of the legal, technical, and ethical aspects as well as the various rights, shielded by different legislative frameworks, that must be considered (intellectual and industrial property, patent, confidential commercial) along with privacy of research subjects; rules of engagement, and for e-submissions; and limits of access and disclosure (7, 8).

Access to data and information related to pharmaceutical products, particularly clinical trials, has raised a great debate worldwide (9, 10). The call for transparency is increasing quickly and appears to be an unavoidable requirement for regulators (10, 11). Special approaches to disclosure of regulatory data have emerged, but in a nonsystematic way. Therefore, institutional policies for regulatory transparency need to be consolidated and harmonized by key global regulators. In the field of health regulation, open access to regulatory data has been highlighted by the U.S. Food and Drug Administration (FDA) (12–14), the European Union (EU) European Medicines Agency (EMA) (15), and Health Canada (16), among numerous other entities.

Sharing data is a key good governance practice in health systems and is one of the main ways to strengthen regulatory transparency (17). There are two main types of data-sharing: external (when the information is disclosed to the community by the NRAs), and internal (when the data flow is "inter-agency" only and thus restricted to other regulatory agencies).

WHO has developed various projects designed to share information about medicine supply chains, such as the Medicines Transparency Alliance (MeTA). MeTA works with government, industry, and civil society to increase access to medicines by promoting greater transparency and accountability in the country's pharmaceutical sector (18).

In the Americas, a cooperative initiative known as PRAIS (Regional Platform on Access and Innovation for Health Technologies), supported by PAHO/WHO, the U.S. FDA, and Brazil's Ministry of Health, was developed to improve access to essential medicine and biological products and diagnostics in all PAHO member states (19).

The legislative and regulatory situation in the Americas appears to be relatively heterogeneous, creating the need for 1) a comparative review of the various transparency systems being used region-wide and 2) analysis of the implications for public health organizations and future steps.

Access-to-information initiatives are growing exponentially worldwide, steering the establishment of public policies related to regulation of transparency. For this reason, and because a substantial portion of transparency-related data has significant potential to interfere with commercial competitive processes, these public policies—both conservative and innovative—should be based on analysis of the regulatory impact on society, government, and the productive sector, including the risks and benefits inherent to the process.

To provide evidence to help guide these efforts, this study assessed the transparency status of RRAs in the Americas, focusing on various medicine life-cycle documents (the Medicine Dossier, Clinical Trial Report, and Inspection Report) as tools for strengthening health systems.

MATERIALS AND METHODS

The study consisted of a narrative (nonsystematic) review of the level of transparency of RRAs in the Americas, focusing on the medicine life-cycle documents considered critical to the transparency regulation process. Regulatory transparency was assessed by data type: nonpersonal, nonconfidential (information public disclosure) and personal/confidential (inter-agency data- and work-sharing).

The risks/benefits of information public disclosure were assessed, taking into account the involvement and roles of multiple stakeholders and the need to protect commercially and personally confidential data. Inter-agency data and work-sharing were assessed in the context of harmonization and cooperation projects that focus on regulatory convergence.

The data was obtained from RRA websites and relevant legislation. The five NRAs selected for comparison (Brazil's Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária*, ANVISA); Argentina's National Administration of Drugs, Food and Medical Technology (*Administración Nacional de Medicamentos, Alimentos y Tecnología Médica*, ANMAT); Cuba's State Control of Drugs and Medical Devices (*Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos*, CECMED) Colombia's National Institute of Food and Drug Surveillance (*Instituto Nacional de Vigilancia de Medicamentos y Alimentos*, INVIMA); and Mexico's Federal Commission for the Protection Against Health Risks (*Comisión Federal para la Protección contra Riesgos Sanitarios*, COFEPRIS)) are considered reference entities in the region by WHO (2).

RESULTS

Health regulatory transparency on RRAs

The type of pharmaceutical product documents that are shared and the way in which it is done are indicators of a country's level of transparency. In the Americas, the political situation varies across countries, resulting in different levels of transparency across the various RRAs.

In Mexico, the Federal Institute for Access to Public Information and Data Protection (*Instituto Nacional de Transparencia, Acceso a la Información y Protección de Datos Personales*, INAI) is responsible for addressing and supervising organizations' compliance with the Federal Law of Transparency and Access to Public Information (2002) and the Federal Law of Protection of Personal Data (2008). INAI is the first institution in the world with constitutional autonomy and is designed to ensure that the principles of confidence, lawfulness, independence, impartiality, and objectivity prevail in all decision-making (20). Access to information can be requested through a centralized system (Infomex®) and the response is overseen by the COFEPRIS Information Committee (21). COFEPRIS periodically publishes a list of registered pharmaceutical products as well as Summaries of Product Characteristics (SPCs) as part of its proactive approach to information release, known as "targeted transparency" (22).

In Colombia, INVIMA publishes a list of documents and services that can be accessed by citizens, but there is no clear channel for requesting further

TABLE 1. Transparency status of Regional Reference Authorities (RRAs),[a] U.S. Food and Drug Administration (FDA), and European Medicines Agency (EMA), Americas region, 2015

	EMA	FDA	COFEPRIS	CECMED	INVIMA	ANVISA	ANMAT
Unapproved assessment report publicly	X		X		X		
Summary of Product Characteristics (SPC)	X	X[b]	X	X			
Clinical trial register platform	X	X		X		X	X[b]
Approved medicine list	X	X	X	X	X		X
Institutional framework to steer data access requests and transparency issues	X	X	X			X	
Access to inspection/audit reports	X	X[b]					
Public access to clinical trial data	X[c]						

Source: Prepared by the authors based on search of agency institutional websites.

[a] COFEPRIS (Mexican Federal Commission for the Protection Against Health Risks); CECMED (State Control of Drugs and Medical Devices of Cuba); INVIMA (National Institute of Food and Drug Surveillance of Colombia); ANVISA (Brazilian Health Surveillance Agency); ANMAT (Argentine National Administration of Drugs, Food and Medical Technology).

[b] By request.

[c] Legally existent but not performed.

information. Public Assessment Reports (PARs) are available for approved, unapproved, and withdrawn products (23). CECMED (Cuba) shares SPCs, as well as lists of approved and canceled products, but the PARs that are used as the basis of the decision-making process are not available (24).

In Argentina, ANMAT publishes lists of approved products but only in an on-screen format (i.e., they are not available for download). PARs and SPCs are not accessible, but leaflets are available for some products (25).

ANVISA incorporates the essence of transparency in its regulatory systems and has changed its approach to the provision of data. The main guiding principle is that access is the rule and secrecy is the exception. Although it is ensured through a legal provision, access to a wide range of information remains on a by-request basis. Proactive disclosure is not ANVISA's current method, probably because of limitations in technology and human resources. Therefore, despite its well-structured legal framework for evaluation of data access requests, ANVISA still has not achieved a level of minimal proactive data release in the pharmaceutical field (26).

Both the EMA and the U.S. FDA have written standards for strength in regulatory transparency. Although the FDA established regulatory transparency initiatives before the EMA (27), the EMA has become the world reference on openness and disclosure approaches in the pharmaceutical arena (28, 29). These two agencies should support and serve as a model for less developed agencies in their efforts to reach minimum standards. Table 1 shows the transparency status of each agency based on relevant documentation and actions carried out thus far.

Public documents in Medicine Dossiers

SPCs are a component of the Medicine Dossiers (MDs) and are prepared by the Marketing Authorization Holder (MAH) and revised by the HRAs. SPCs contain all publicly available technical data for a product and are used as the main information source on product safety and efficacy by health care professionals. The information contained in SPCs should be evidence-based, patient-oriented, concise, readable, and actionable and should list the risks and benefits of each medicine product to help ensure to its rational use (30).

The PARs are the basis for the agency's decision-making. They describe the flow of data used in the analyses and explain the procedure(s) used in assessing the risks and benefits of each product. The PARs also include relevant technical information that is particularly useful to academics and industry in helping them understand the agency's way of thinking, the complete requirements for product approval prior to submission of applications, and the rationale that was used in a product approval, which might be relevant to or used to supplement other agencies' decisions about the same or similar products. PARs are written in a technical style, so use of PAR summaries, which are written in public-friendly language, will be helpful to laypersons.

Another document that is sometimes included in an MD and is available for public scrutiny is the Risk Management Plan (RMP). An RMP provides details about the safety profile of a product and is thus usually most important for new products, which are never distributed on a large scale. The RMP proposes ways to manage, prevent, or minimize potential product risks. Like the PAR summary, an RMP summary could be useful for determining an agency's communication approach.

While the components of the MDs differ in terms of content, style, and formats, they complement each other, and taken collectively provide patients and health care professionals with sufficient data to be well informed about the medicines they are using or prescribing. Additional documents and their characteristics are shown in Table 2.

Public documents in Clinical Trial Reports

A clinical trial report (CTR) is an important part of an MD for new products and usually includes evidence about safety and efficacy. Occasionally, generic MDs require completion of a clinical trial comparing a reference product and a test product (the "bioequivalence" trial), which mainly demonstrates efficacy.

In accordance with Good Clinical Practices (GCPs), the trials should be registered on a public platform, and the results (positive or negative) published once the trial has been completed, but in practice this may not be the case.

Making CTRs open to public scrutiny, with broad public access, tends to strengthen the HRA's image in the community as an indicator of its confidence in the products it approves and the trustworthiness of the agency's work. Open access to CTR raw

TABLE 2. Characteristics of public documents included in a Medicine Dossier, Americas region, 2015

Document	Characteristic	Target audience	Content
Summary of Product Characteristics (SPC)	• Technical document, evidence-based, patient-oriented • Risks and benefits • Prepared by Marketing Authorization Holder (MAH) and reviewed by agency	Health care professionals	• Name, qualitative and quantitative composition, and pharmaceutical form of medicinal product • Clinical and pharmaceutical specifications • Pharmacological properties • Marketing Authorization Holder (MAH) and number
Public Assessment Report (PAR)	• Explains how the agency assessed the benefits and risks of each medicine • Prepared by agency or (MAH) and reviewed by agency • Core set of regulatory documents	Regulators Academics Regulated sector	• Background information on the procedure • Scientific discussion (quality and clinical and nonclinical aspects, clinical efficacy, clinical safety, pharmacovigilance, user consultation) • Risk–benefit balance • Recommendations
PAR summary	• Written in user-friendly language that summarizes the information contained in the full PAR • Question-and-answer format • Prepared by agency • Nontechnical document	Laypersons	• Conditions of use (i.e., indication, contraindication, precautions, dosage, method of administration, handling, storage of the product, when to take it, what to do if the drug has been administered incorrectly, etc.)
Risk Management Plan (RMP)	• Provides details on medicine's safety profile and concerns • Explains the measures to be taken to prevent or minimize and manage the medicine's risks in patients • Prepared by (MAH) and reviewed by agency	Health care professionals	• A medicine's safety profile • How its risks will be prevented or minimized in patients • Plans for studies and other activities to gain more knowledge about the safety and efficacy of the medicine • Risk factors for developing side effects • Measuring the effectiveness of risk-minimization measures
RMP summary	• Written in user-friendly language that summarizes the information contained in the full RMP • Prepared by agency	Laypersons	• Overview of the epidemiology of the disease • Summary of the benefits and risks • Information currently missing • Planned studies

Source: Prepared by the authors based on European Medicines Agency pattern.

data might allow for external and independent reanalyses and meta- analyses, which can improve the quality of the health research and reveal risk relationships and product idiosyncrasies that did not emerge in the initial study.

Open access to patient-level clinical data can restore a society's confidence in a pharmaceutical sector's compliance with GCPs if it has been undermined by previous studies (e.g., exposes of the use of biased methodologies that resulted in the availability of ineffective or hazardous products). Despite some individual initiatives by pharmaceutical companies to proactively share CTRs for some products (31), the pharmaceutical sector has demonstrated resistance to open-data directives (32). As a pioneer of transparency regulation, in response to a European Parliament Directive, beginning in 2015, the EMA will proactively disclose CTRs, including raw (patient-level) data (33).

Actual implementation of transparency, however, is a learning process requiring broad collaboration and implementation of unequivocal legislation. It is expected that lawmakers, recognizing society's expectation for increasing transparency, will guide society toward the "sunlight" ("the best disinfectant") (34).

Since 2005, the International Committee of Medical Journals Editors has required every clinical trial included in published reports to be registered in a publicly accessible database (31). In response, big pharmaceutical companies, such as Roche and GlaxoSmithKline, have established platforms for publicizing clinical data (35–37).

Public documents in Inspection Reports

Compliance with GCPs is essential for a long product life cycle. Generally, this is ascertained through inspections or audits and documented in a certificate. Considering the large number of pharmaceutical companies, and the cost of in situ inspections, bilateral and regional agreements have been established to establish compliance.

As an example of Good Manufacturing Practice (GMP) cooperation initiatives, the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S) declared its approval of two international agreements between countries and pharmaceutical inspection authorities, which together provide for active and constructive cooperation in the field of GMP. Currently, 46 NRAs participate in the PIC/S, but only one (an HRA) from South America (ANMAT) (38).

Subsequently, in a pilot project on inspection of GCPs, the EMA and the U.S. FDA joined with regulatory authorities of a few member states of the EU and agreed to launch an initiative to collaborate on information-sharing and inspections of bioequivalence studies (39).

In the medical devices field, the U.S. FDA, ANVISA, the Australian Therapeutic Goods Administration (TGA), and Health Canada's Health Products and Food Branch (HPFB) seek to strengthen the existing mutual cooperation in the scientific and regulatory area of medical devices through the development of the Medical Device Single Audit Program (MDSAP) (40).

The European Community (EC) has shared reports through a platform designed exclusively for the European Economic Area (EEA): the EudraGMDP

database. The EudraGMDP database is the EC's database on manufacturing, import, and wholesale distribution authorizations and GMP and Good Distribution Practice certificates. A public version of the database allows public access to the information (other than commercial or personal confidential data). The public EudraGMDP displays a list of all certified companies. For those whose applications were rejected, the deficiencies are listed in a brief report, including non-conformance details only (41).

Transparency regulation for Inspection Reports (IRs) is not implemented by any RRA. The U.S. FDA and EMA have developed initiatives to disclose IRs on a regular basis. The EMA discloses a list of certificated companies and, in case of classifiable deficiencies, a part of the IR is publicized. The FDA has published a list of inspections performed and the respective outcome classifications (41). In addition, the FDA publishes Inspectional Observation Summaries and Citations per fiscal year describing the frequency of non-conformance findings during inspections (Form 483) (42). Requests for IRs on compliance with the FDA framework are complex and time consuming, so private companies provide the documents on a fee basis (43).

DISCUSSION

Transparency can be defined as the state's commitment to providing systematic information to citizens. This commitment should be reflected in the timely provision of responses to all citizens' questions about 1) the mechanisms and actions of the government, and the means of those actions, and 2) above all, why certain decisions are made versus the alternatives. One expected result of regulatory transparency and accountability is the reduction of information asymmetry and the recognition of NRAs as reliable and ethical. Regulators walk a narrow line between pressure for transparency and control of their actions at one end and the tendency to remain insular as a specialized bureaucracies on the other (44).

Regulatory transparency can comprise two different approaches, as shown in Figure 1.

Inter-agency data-sharing

The path of the pharmaceutical product, from its development through its availability to consumers, consists of many steps that are usually controlled by an HRA. Regulating a product's complete life cycle results in costs that some countries cannot afford; therefore, duplication of work must be avoided. Regulatory collaboration, as inter-agency work and data-sharing, can help strengthen the regulatory capacity of all partners by promoting sustainable exchange of technical knowledge.

Some collaborative projects were carried out to merge national/regional regulatory systems, strategically exploiting successful, novel initiatives to leverage collective HRA resources. The International Pharmaceutical Regulators Forum (IPRF) provides an environment for members to exchange information on issues of mutual concern and regulatory cooperation (45). Among others, IPRF (and WHO) members include the Pan American Network for Drug Regulatory Harmonization (PANDRH) and ANVISA. The last PANDRH Conference Report (2013) stated that "…at present, the cooperation, communication and exchange of information among regional NRAs are key elements for the effective functioning of regulatory agencies to guarantee medicines quality, safety, and efficacy" (46).

To streamline the regulatory environment, an alliance of regulators known as the International Coalition of Medicines Regulatory Authorities (ICMRA) was created. The ICMRA is one outcome of discussions at the International Conference of Drug Regulatory Authorities (ICDRA) about ways to strengthen collaboration and harmonization. For the same reasons, WHO has steered certain pilot programs such as the International Generic Drug Regulators Programme (IGDRP) to establish more permanent information and work-sharing arrangements as part of broader international efforts related to timely and effective regulation of generic products (47).

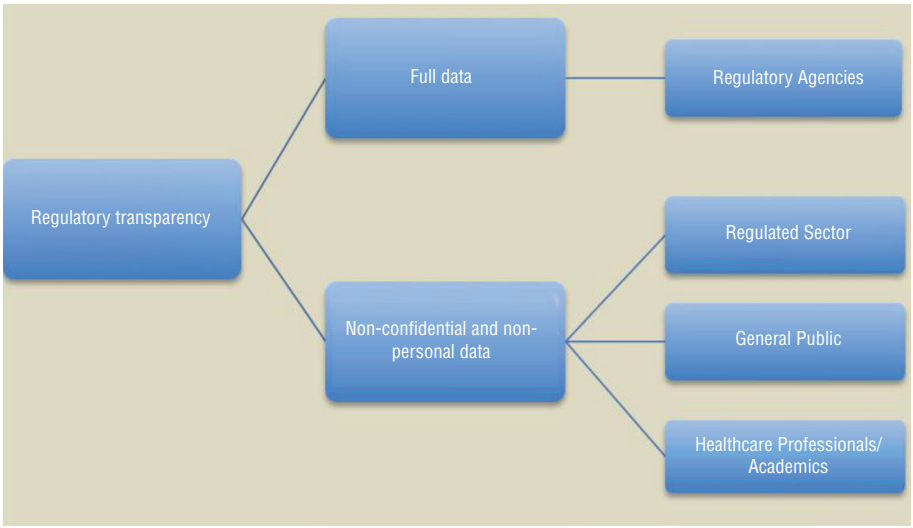
As noted above, other collaborative programs, such as the PIC/S and the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), have shown outstanding results in both cooperative work and data-sharing. Certain regulatory assessment and control activities (i.e., Medicines Reviews, Good Practices (GxP) certification, etc.) carried out by one HRA can be recognized by another HRA. However, outsourcing essential activities can be harmful to HRAs in the long term because of the risk that they will lose their assessment competence and become fragile, dependent entities.

The recognition process must include assessment of the technical context of the decision-making process. Sharing regulatory data means sharing knowledge and expertise and is essential for building trust and confidence in both the product recognition process and the HRA decision-making process, which strengthens the partnership and all of its members.

Public disclosure

One of the core issues of sharing data with the public is the need to prevent the

FIGURE 1. Regulatory transparency approaches by data type (nonconfidential / nonpersonal versus complete) and target audience, Americas region, 2015



Source: Prepared by the authors.

disclosure of commercially confidential data (information that could give commercial advantages to competitors in the marketplace) and personal data.

Two key steps that must be taken at this point are defining 1) exactly what qualifies as personal and commercially confidential data and 2) how to protect it.

The term "commercially confidential data" refers to information that requires research and intellectual effort to determine and for which disclosure may undermine economic interests or competitive positions of its owner. In the pharmaceutical field, industrial secrets, product flow, programs, patent specifics, quantitative formulae, techniques, methods, procedures, and know-how can be classified as commercially confidential data. General information is not considered commercially confidential. In all cases, the release of this type of data should be done after granting market authorization to avoid compromising the integrity of the decision-making process.

The term "personal data" refers to information related to an identified or "identifiable" natural person (the "data subject"); an "identifiable" person is one who can be identified, directly or indirectly, including or especially through reference to an identification number or to one or more factors specific to his/her physical, physiological, mental, economic, cultural, or social identity (48).

Documents that contain both confidential and nonconfidential information are often deidentifed/redacted, which can require a lot of time and other resources. One alternative to carrying out deidentification/redaction is dividing the MD into two parts: public and confidential. Use of this method improves transparency because it does not require deidentification/redaction of all documents, one by one.

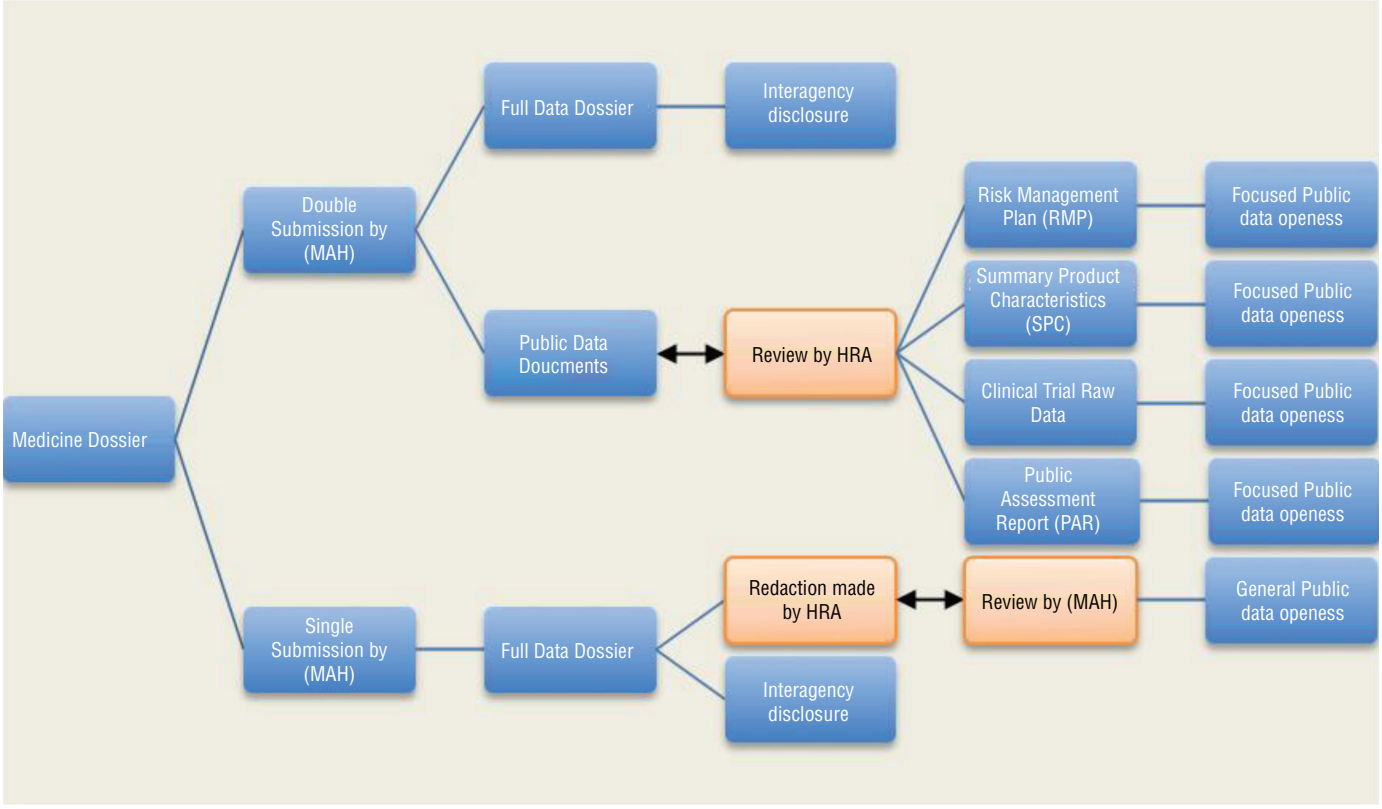
An additional advantage of two-part MDs is that the public information sections of the documents can be processed by the regulatory sector without the need for consultation with any agencies prior to their publication, thus saving time. External Committees can be formed at regulatory agencies to arbitrate any disagreements between industry and the HRAs. Figure 2 shows two different approaches to data processing by type of data (public versus confidential).

Inspection Reports can be designed and processed using the same approach (e.g., the agency can issue two documents—a full report, for inter-agency exchange, and a public version without confidential information).

Perspectives

As noted above, different regulatory approaches and practices have been adopted in the countries of the Americas. The current challenge is to connect all these experiences and competencies to derive a harmonized and well-structured transparency policy. Regional agencies could carry out the steps described in Box 1 to achieve optimal transparency across their organizations.

FIGURE 2. Two different approaches to Medical Dossier submission by flow of data through Health Regulatory Agencies (HRAs) and Marketing Authorization Holder (MAH), Americas region, 2015



Source: Prepared by the authors.

Box 1. Recommendations for improving regulatory transparency, Americas region, 2015

- Intra-agency steps
  - Consider use of risk assessment to prioritize actions that can show better results in less time.
  - Establish harmonized:
    - Principles for redacting and deidentifying personal and commercially confidential data in regulatory dossiers and Inspection Reports (IRs).
    - Standards for electronic Medicine Dossiers (MDs) and clinical trial registries, establishing Common Technical Documents (CTDs) using a standard language (e.g., Medical Dictionary for Regulatory Activities, MedDRA).
    - Define criteria and develop ways to proactively publicize information on Health Regulatory Agency (HRA) websites, including smart search tools with a download option, and regular activities reports.
  - Define the minimum information that should be publicized.
  - Involve different stakeholders (e.g., academics, health care professionals, and regulatory sector) in policy debate.
  - Describe different types of data shared according to target audience (academics, health care professionals, regulatory sector, layperson).
  - Establish incentives for data compilation and summary analyses among layman target audience.
  - Recommend the establishment of a Data Access Committee at each agency as well as an External Committee to arbitrate data classification.
  - Adopt technology to allow for electronic submissions (e-submissions) by regulatory dossier and Clinical Trial Registry applicants.
  - Standardize the content and format of datasets to be publicized.
  - Perform Regulatory Impact Analysis (RIA) that considers the national regulatory environment and legal framework before implementing a transparency policy.
- Inter-agency steps
  - Recognize the authority of each HRA in addition to any cooperation or harmonization agreement related to data classification.
  - Establish an institutional and official discussion environment to ensure better understanding and consensus on regulatory transparency.
  - Recognize and strengthen supranational organizations such as the Pan American Health Organization (PAHO) along with the leadership of regional National Regulatory Authorities.
  - Support World Health Organization (WHO) transparency initiatives (e.g., the Regional Platform on Access and Innovation for Health Technologies (PRAIS) and the Medicines Transparency Alliance (MeTA)).
  - Improve the Americas regional platform (PRAIS) by adding an inter-agency platform channel for exchange of confidential documents such as IRs, technical reports, or clinical trial data.
  - Recognize innovative initiatives of individual HRAs.
  - Work on a secure IT platforms to maintain confidential datasets.

Source: Prepared by the authors.

Conclusions

Regulatory transparency has become a global challenge worldwide and it is important that HRAs in the Americas become involved in the debate. While these HRAs have different levels of regulatory transparency, even the RRAs are not exhibiting minimum competence levels with regard to data-sharing.

Despite the advances achieved in the region, only COFEPRIS demonstrates a well-structured system for disclosure of public information that allows for the participation of all stakeholders (academics, health care professionals, regulators, the regulatory sector, and community). Public MD documentation is not standardized across all RRAs, but at least PARs, RMPs, and SPCs have the potential to be implemented more quickly by simply changing the registration method to a split approach in which the documentation can be prepared by the AMH and reviewed by the HRAs. A fundamental requirement in public disclosure is the classification of personally and commercially confidential data and the development of systems to protect these two types of information, which is why the disclosure of CTRs and IRs may be considered a challenge in the medium term.

Cooperation and harmonization has become an international opportunity for the exchange of knowledge and experiences as well as regulation improvements. The aim of these efforts was to support HRAs in their commitment to implement scientific standards in drug registration, inspections, and pharmacovigilance. A key requirement for regional harmonization initiatives is the establishment of inter-agency data- and work-sharing, using a secure platform to streamline the process. In the Americas, PANDRH provides a useful environment for uniting HRAs in a PRAIS-wide cooperation and harmonization project.

Regulatory transparency policies are important for strengthening HRAs, reestablishing society confidence in agency work, and supporting convergence of policies and procedures across agencies. While various elements of regulatory transparency require different approaches to determining product risks and benefits, it is clear that developing and maintaining more openness will strengthen the public health environment. Regulatory transparency policies tend to reduce costs and workloads, avoiding duplication of efforts, and enabling HRAs with limited capacities and/or resources to regulate processes related to public health more efficiently, strengthening the public health system.

Conflicts of interest. None.

Disclaimer. Authors hold sole responsibility for the views expressed in the manuscript, which may not necessarily reflect the opinion or policy of the RPSP/PAJPH, the Pan American Health Organization (PAHO), or the Brazilian Health Surveillance Agency (ANVISA).

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El intercambio de datos sobre reglamentación para fortalecer los sistemas de salud en la Región de las Américas

RESUMEN

La transparencia normativa es una característica indispensable de las autoridades de registro sanitario fidedignas. En la Región de las Américas, el proceso de crear un gobierno transparente sigue siendo frágil y fragmentado en distintos organismos de reglamentación sanitaria (ORS) y organismos de referencia regionales (ORR). En el presente estudio se examinó la transparencia de los ORR mediante el escrutinio de diferentes documentos con datos relativos al ciclo vital de los medicamentos (el expediente farmacológico, el informe de los ensayos clínicos y el informe de las inspecciones) como instrumentos para fortalecer los sistemas de salud. Sobre la base de una revisión narrativa (es decir, no sistemática) de la transparencia reglamentaria en los ORR, la situación relativa a la transparencia se clasificó en dos tipos: la divulgación pública de información (datos intrainstitucionales) y el intercambio de datos y la colaboración (datos interinstitucionales). Se evaluaron los riesgos y beneficios de la divulgación pública de información sobre medicamentos teniendo en cuenta (1) la participación y las funciones de los distintos interesados directos (profesionales de la salud, el sector industrial, la comunidad y el sector académico) y (2) la protección de los datos comerciales y personales de carácter confidencial. El intercambio de datos y la colaboración entre agencias se evaluaron en el contexto de diversos proyectos de armonización y cooperación dirigidos a lograr la convergencia reglamentaria. Se propone la toma de medidas técnicas y prácticas para establecer una directiva en pro de la transparencia en el medio reglamentario farmacéutico a fin de mejorar y fortalecer los sistemas de salud en las Américas. Hacer frente a estas dificultades exige el liderazgo de entidades como la Organización Panamericana de la Salud en la dirección y el respaldo de alianzas de colaboración regionales que fomenten el desarrollo y establecimiento de un entorno reglamentario fidedigno y de un sistema de salud pública sostenible en las Américas, usando como punto de partida las iniciativas internacionales que hayan dado buenos resultados y teniendo en cuenta las características internas y las experiencias de cada país.

Palabras clave Revelación; acceso a la información; confidencialidad; cooperación técnica; desarrollo regional; Américas.