Toolkit for the Establishment of a Medical Products Regulatory System in Small States

VOLUME 6

Communication and Outreach

In partnership with Canada

PAHO Pan American Health Organization

World Health Organization Americas Region

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Abbreviations and Acronyms

APEC	Asia-Pacific Economic Cooperation
ASEAN	Association of Southeast Asian Nations
CRS	Caribbean Regulatory System
EAC	East African Community
GCC-DR	Gulf Central Committee for Drug Registration
ICH	International Council on Harmonization
MoH	Ministry of Health
MoU	Memorandum of Understanding
NRA	National Regulatory Authority
PAHO	Pan American Health Organization
PANDRH	Pan American Network for Drug Regulatory Harmonization
PIC/S	Pharmaceutical Inspection Cooperation/Scheme
SADC	Southern African Development Community
WHO	World Health Organization

Introduction and Background

Communication and stakeholder and public engagement should be a priority for all National Regulatory Authorities (NRAs). Ongoing interactions with the health care sector, patients, and the public facilitates compliance with laws and regulations, provides information to allow informed use of products, and can serve to inspire public confidence in the NRA, particularly during time of public health emergencies.

The NRA's and Ministry of Health's (MoH) website can be a valuable tool in communication and may be the first-place members of the public will go to seek information about medical products. NRAs and MoH should put resources into upgrading their websites, so that information about the regulation of medical products is easily available to the public, health care practitioners, drug manufacturers, importers, and other NRAs. NRAs should establish, publish, and maintain a public list of registered medicines and their authorized suppliers, and develop an inventory of labels accompanying authorized products.

However, communication and outreach go beyond local communication.

Collaboration amongst NRAs is an essential activity, which serves to avoid the duplication of work, broaden available expertise, maximize scarce resources to serve more critical areas, identify safety concerns rapidly and ultimately improve patients access to new and affordable medical products. NRAs, including those from small states, should enhance international collaboration and networking activities and monitor developments in medical products internationally.

Developing Stakeholder and Public Engagement Plans

A well-developed stakeholder and public engagement plan can serve to:

- Facilitate the participation of patients and consumers in regulatory activities all along the lifecycle of medicines, by capturing patients' perspectives on issues such as disease burden, unmet needs, and meaningful outcomes of treatment
- Obtain information on the current use of medicines and patient experiences.
- Ensure that patients, consumers, and industry are consulted and, where appropriate, involved in the development of policies
- Enhance public understanding of the mandate and role of the NRA
- Communicate new safety issues rapidly and combat misinformation.

In some jurisdictions, the need to an NRA to engage stakeholders is enshrined in legislation. In others, it is part of an overall government commitment or policy. Regardless, a stakeholder engagement framework and strategy are an essential regulatory tool.

What's in a Communication and Stakeholder Engagement Plan?

A communication and stakeholder engagement plan may involve the following:

- Creating a communications team to address and combat miscommunication.
- Proactive transparency.
- Issuing advisories and engaging with the media.
- Releasing weekly updates and reports, i.e., data on adverse events.
- Creating dedicated webpage sections for certain topics, e.g.
- Public health emergencies and pandemic preparedness Creating a frequently asked questions page to answer large volumes of enquiries on similar topics.
- Encouraging more frequent and proactive release of information.
- Providing clear, consistent, independent, and impartial messaging.
- Creating telephone lines.
- Holding information sessions for members of the public.

Developing websites

When people seek information about medical products, they are instinctively directed towards the state MoH. The website for an MoH should serve as a single window into information about medical products. Putting in place a regulatory system webpage can be done very simply and inexpensively as an addition to the existing webpage. A regulatory website can improve transparency and accountability and inspire public confidence, through publishing a list of approved products and licensed importers, as well as recent regulatory decisions/enforcement actions, among others.

Ideally, a separate page on medical products should be set up and link directly to any other government information and sites with information about medical products.

An NRA website should contain or link directly to, at minimum:

- A list or searchable database of authorized medicines.
- National medical products legislation
- A list or searchable database of licensed manufacturers (if any), importers and distributors and the activities they are licensed to perform
- Communication about how medical products are regulated in the state, including how the NRA works to ensure safety and effectiveness.
- Information about how the NRA is organized and the functions performed by different units.
- Access to Adverse Drug Reaction (ADR) and other relevant forms.

For NRAs which exist as separate entities to the MoH, there should still be a direct link from the MoH website to the NRA website, clearly accessible to members of the public searching the MoH website for information on medical products.

Regional and International Collaboration

Collaboration amongst NRAs is an essential activity, which serves to avoid the duplication of work, broaden available expertise, maximize scarce resources to serve more critical areas, identify safety concerns rapidly and ultimately improve patients access to new and affordable medical products. There are many existing models of collaboration, some regional or sub-regional and others global. The growing awareness of the need for regulators to work together has led to the emergence of new models of cooperation. For example, the International Council on Harmonization (ICH), which initially had restricted membership, is now open to any NRA wishing to apply for membership and meeting membership qualification or observer status. In Africa, several regional communities and projects are in place to develop cooperation mechanisms amongst African states, such as the East African Community (EAC), the Southern African Development Community (SADC), the ZaZiBoNa project, which connects the regulatory systems of four participating countries (Zambia, Zimbabwe, Botswana, and Namibia) and the African Vaccine Regulatory Forum (AVAREF). The Association of Southeast Asian Nations (ASEAN), the Asia-Pacific Economic Cooperation (APEC) and the Gulf Central Committee for Drug Registration (GCC-DR) are among the regional initiatives in Asia working towards collaboration amongst regulators.

The Pan American Network for Drug Regulatory Harmonization (PANDRH)

Within the Americas, the Pan American Network for Drug Regulatory Harmonization (PANDRH) is a forum of NRAs with the aim to promote regulatory harmonization, the development of technical guidelines and regulatory capacity building.

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. 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 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.

Reference:
https://www.paho.org/sites/default/files/drug-harmonization-Strategic-Plan-PANDRH-04-20-2015.pdf

Increased collaboration through PANDRH and other networks on specific health issues and technologies, as well as participation in international harmonization and convergence mechanisms, can substantially boost regulatory capacity in the Region and facilitate adoption of WHO recommended standards and the exchange of information for regulatory decision-making.

Reference: CSP30/11. POLICY TO STRENGTHEN NATIONAL REGULATORY SYSTEMS FOR MEDICINES AND OTHER HEALTH TECHNOLOGIES.

Reliance is one of the most common uses of collaboration amongst NRAs, both in the registration and market authorization process and the inspection process, and it can be unilateral, bilateral (mutual) or multilateral. In a unilateral process, for example, when an NRA chooses to recognize the decisions of another NRA, no legal or formal arrangement is necessary. For bilateral arrangements, legally binding mutual recognition agreements can be established and may be necessary; however, they are complex and take a long time to set up, thus more informal Information-sharing initiatives are desirable.

The most common types of formal arrangements used by NRAs are the Memorandum of Understanding (MOU) and the Mutual Recognition Agreement. An MOU is a bilateral or multilateral agreement between NRAs or an NRA and another body such as a public health agency. It expresses a convergence goal between the parties, indicating the intention to undertake a particular activity, such as information sharing or work-sharing. It is a slightly more formal alternative to an oral or handshake agreement and is voluntary and typically nonbinding. An MRA is an international agreement where two or more countries agree to recognize each other's conformity assessments, decisions, or results. Many countries have MRAs with other countries regarding good manufacturing practices (GMP) for medical products, allowing for mutual recognition of inspections and certifications.

Small market states should look for information-sharing, collaborative platforms in which to participate, with a particular focus on sub-regional and regional initiatives under PAHO. Other international collaborations such as:

- the International Conference of Drugs Regulatory Authorities (ICDRA),
- the International Coalition of Medicines Regulatory Agencies (ICMRA),
- the Pharmaceutical Inspection Co-operation Scheme (PIC/S),
- the International Generic Drug Regulators Programme (IGDRP) and
- the International Pharmaceuticals Regulator Programme (IPRP),

are valuable sources of information, mentoring and guidance development and provide critical information on their websites.

A partnership or mentoring relationship with other states in the Americas, particularly those with strength in some of the essential functions is strongly mentioned. Partnerships with other states using the Caribbean Regulatory System (CRS) as part of its product registration, and with the CRS itself, as well as interactions with a well-established foreign regulator, will enhance the advancement of a national regulatory system by providing access to a greater pool of expertise and their lessons learned. Opportunities presented by PAHO, PANDRH and the CRS for training should be taken whenever possible.

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