Supplementary Information[1,2]

PAHO Indicators for the assessment of national regulatory systems

Organization and structure
5000. Pharmaceutical regulation is under the jurisdiction of the Ministry of Health and other organs (institutions, agencies, regulatory authorities) at the same or different levels of government.
5001. The responsibilities, functions, organization, powers, and structure of the organization(s) responsible for pharmaceutical and health-technology regulation are clearly defined in legal documents and supplementary documents, in particular as relates to the competencies and objectives associated with the pharmaceutical regulation that it/they control(s), such as categories of regulated products and regulatory functions.
5002. Legislation defines the institutions involved in the pharmaceutical regulatory system, their authority, functions, roles, responsibilities, and powers.
Legal basis
5003. Legislation defines the creation of the NRA, its mission, and its terms of reference, as well as its scope, functions, and responsibilities.
5004. The Regulatory Authority responsible for implementing and enforcing the regulations involved in developing them.
5005. During the process of developing legislation and regulations, there are mechanisms through which various sectors of civil society are involved, such as NGOs, health sector representatives, industry, consumers, patients, and other stakeholders.
5006. The legislation and regulations are publicly available for the stakeholders to whom they apply, and adequate means and channels of communication are available to make the legislation and regulations known.
5007. The legislation gives the NRA authority to bring in experts and create committees, and to define their functions and the situations in which they are to be brought in or created.
Administrative model
5008. The organizational structure of the NRA includes a governing board, executive staff, and administrative committee or organ responsible for creating and/or adopting the strategic development plan.
Institutional development
5009. The NRA has an institutional development plan that is implemented and up to date.
5010. The general objectives of the NRA are established and have been broken down into specific objectives, with timeframes for the different regulatory functions.
Quality management system
5011. The NRA has implemented a quality management system (QMS) for all regulatory processes.
5012. The quality management system is based on or recognizes reference standards (WHO, PIC/S, ISO, etc.).
5013. The documentation system needed to establish, implement, and maintain the QMS has been created (quality manual, records, policies, quality procedures, operational procedures).
Funding of the NRA
5014. The sources of funding for the NRA to carry out all its regulatory functions have been established.
5015. The rates, fees, charges, or costs that must be paid for the NRA's services are published. 0
5016. The NRA has the authority to collect funds and to use them internally.
Human resources management
5017. There is an organizational chart of the NRA's structure.

5018. The obligations, functions, and responsibilities of key staff are set forth in their job descriptions.
External committees and experts
5019. The NRA has an Advisory Committee (which may include in-house specialists and external experts) that is involved in the NRA's regulatory processes.
5020. There is a written policy/procedure for selecting and bringing in external experts, in which candidates are selected by a panel or jury whose final decision is made public.
5021. There is a general policy on potential conflicts of interest that applies to external experts brought in on an ad hoc basis as well as to members of the Advisory Committee.
5022. The NRA participates in a global network with recognized scientific associations and professional groups.
Transparency and confidentiality
5023. Legislation includes requirements to ensure confidentiality and transparency in the work of the NRA.
5024. There is a documented policy on public access to information, with defined exemptions/exceptions.
5025. Information on legislation, regulation, procedures, and guidelines is available to the public on websites and through other mechanisms that ensure that such information is satisfactorily available and up to date.
5026. Information on decisions is available to the public on a timely basis, and includes negative decisions on specific cases (when legislation so allows).
5027. The NRA holds meetings regularly with stakeholders and creates opportunities for consultation with the general public, such as days when it is open to the public.
Independence and impartiality
5028. There is a documented code of conduct for staff members involved in regulatory functions.
5029. There is an internal policy/established mechanism regarding potential conflicts of interest that applies to members of the staff and is updated with appropriate frequency.
5030. The NRA maintains independence from researchers, producers, distributors, and drug wholesalers.
Infrastructure
5031. The NRA's spaces, work environment, and room for filing documentation are adequate.
5032. The NRA has the appropriate equipment for conducting its regulatory functions.
Monitoring and control
5033. Regulatory functions and processes are monitored and reviewed regularly and systematically to identify problems, gaps, weaknesses, and inconsistencies within the NRA.
Information management system
5034. The NRA uses computer systems to manage data efficiently so that the information is collected, entered into a database, and put in reports where it can be consulted.
5035. The NRA has its own website, or has an agreement to use another institution's.

ISO=International Organization for Standardization; NGO=non-governmental organization; NRA=national regulatory authority; PAHO=Pan American Health Organization; PIC/S= Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme

References: 1. Dios MF. National regulatory system: organizational structure and legal basis, and the provisions for medicines regulation in the Americas. *PRAIS Bulletin* 2015;April(2),1.
2. Pan American Health Organization and World Health Organization. System for evaluation of the national regulatory authorities for medicines. Available at http://www.paho.org/hq/index.php?option=com_content&view=article&id=1615%3A2009-sistema-evaluacion-autoridades-reguladoras-nacionales-medicamentos&catid=1267%3Aquality-drug-regulation&Itemid=1179&lang=en Accessed May 24, 2018.