ANMAT â?? Carlos Chiale, National Administrator â?? Argentina

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Carlos Chiale, National Administrator of ANMAT, discusses the agencyâ??s latest strategy implementation and its pioneering work in the area of fighting drug falsification.

Could you provide a historical overview of ANMAT, its main achievements and current activities today?

Since its creation in 1992, ANMAT has performed activities intended for the regulation, monitoring and control of health products and, has consolidated and positioned itself as a national and international reference authority since its inception.

In 2003 the National Institute of Drugs was given the National Quality Award by the Secretariat of Public Management. Since 2008, it has been a full member of the Pharmaceutical Inspection Cooperation Scheme PIC/S, whose objective is to lead Good Manufacturing Practice development and implementation.

The ANMAT Observatory was established to improve interaction with non-government organizations and broaden the knowledge about particular topics across all sectors. This program procured closer proximity to the community, which is the final user of the products within ANMAT sphere of action. In terms of internal management, through the â??Going Paperless Programâ?•, digital signature and e-payment tools were implemented, thereby fulfilling the national e-government policy. This means that regulated sector players can carry out various procedures via electronic means and avoid geographical limitations otherwise posed by in-person procedures, which has streamlined procedures flow and timelines.

In 2009, ANMAT became the first agency ever to be certified by the Pan American Health Organization (PAHO) as a Regional Reference National Regulatory Authority for drugs. At present, other regulatory authorities have also been certified, such as ANVISA (Brazil), CECMED (Cuba),

INVIMA (Colombia), COFEPRIS (Mexico), FDA and Health Canada.

ANMAT has recently changed its structure towards a new regulatory science-based paradigm. Could you please expand on your new road map?

There are two axes on which our work is based. One is the Regulatory Science paradigm: the use of the best scientific evidence available in every decision and which results from the convergence of professionals, academicians, regulators and society. The other is the concept of Health Vigilance: the set of actions intended to prevent, reduce or eliminate health risks by means of an integral, cross-cutting and integrative system.

In July 2010, the ANMAT Federal Plan was set in motion to strengthen regulatory, monitoring and vigilance capacities at the national and provincial level. Thereby, the federal outreach was consolidated and a more fluent interaction with all provinces was obtained. Within this framework, we will:

â?? Strengthen ANMAT role as a high health vigilance agency, based on the new paradigm.

â?? Optimize the tools to ensure the safety, efficacy and quality of products for users.

â?? Improve evaluation processes for a safe access to new products and technologies.

â?? Accompany technological innovation processes and serve as a channel for them.

ANMAT is a member of the Executive Committee of the Regulatory Science Coalition, an initiative by top agencies worldwide for advancing international associations and collaborations that facilitate and promote the development of regulatory science. To facilitate training, scientific training and information exchange in the regulatory science field, we have focused on research development, the setting of better practices for data interpretation and understanding in terms of technological innovation, and facilitating the process of translating scientific innovation models into regulatory applications.

Argentina was chosen to lead the group of action of WHO against the falsification of drugs called SSFFC (*Member* State Mechanism on substandard/spurious/falsely-labeled/falsified/counterfeit medical products). What responsibility does this represent for you and what is your strategy to implement this action?

The falsification of medicines is a public health problem that must be monitored by national and global systems. Buenos Aires hosted the first WHO World Meeting on medicines falsification. Thanks to a joint collaboration between ANMAT, the Ministry of Health and the Ministry of Foreign Affairs, Argentina presides over the *Group* on *SSFFC* medical products this year. Since 1997, ANMAT has created different tools to improve its capacities against medicines falsification. Finally, upon the approval of the new organizational structure, the Office of Vigilance of Health Products was created to serve the purpose of strengthening market monitoring and vigilance, which allowed us to continue applying the same work methodology.

The current National Drug Traceability System is an important step to combat falsified products. It consists of the individual and unique identification of each unit of medicinal product marketed. The system traces units throughout the whole distribution chain in order to ensure the control of medicine and contribute to eradicating the flow of illegitimate ones. Over 240 million transactions have already been performed on this system and over 12,700 agents have used it.Argentina leads medicines traceability in the region and it has introduced the topic in WHO, PAHO and UNASUR. Also, Argentina is presently collaborating with Colombia and Ecuador to implement their traceability

systems. Argentina hosted the first reference authorities forum on drug traceability in 2013, in which authorities from the US, Turkey, the United Kingdom and the European Union took part. ArgentinaÂ´s efforts to prevent and control illegitimate medical products have been praised by former US Secretary of Health and Human Services Kathleen Sebelius at a meeting she held with our Minister of Health, Juan Luis Manzur, in Geneva. The WHO Mechanism that Argentina will preside over until next year focuses on international collaboration for addressing and analyzing the issue of medicines falsification. Its objectives include the identification of needs and hindrances; recommendations on policies; the creation of instruments in terms of prevention, detection and control of medicines without the due assurance of safety, quality and efficacy. Therefore, the setting by this WHO Mechanism of a clear mandate, whereby a public health perspective is taken and the safety and health of patients are placed above any commercial interest, has high importance. By consolidating a global strategy, operational and regulatory capacities can be improved while communication among countries can be strengthened for the combat against the falsification of medical products, with a focus on public health protection.

One of ANMATâ??s priorities is building convergence at a federal level. How do you ensure best practices are established throughout Argentina?

Some situations could be changed regarding lines of action to work jointly with our health jurisdictions. For example, the lack of formal articulation among the various monitoring and vigilance stages over the products within ANMAT sphere of competence; the absence of harmonized and converging regulations; insufficient post-marketing monitoring and vigilance processes as well as a lack of fluent exchange and intra and inter-institutional communication channels between ANMAT and them. As our country has a federal structure, a consensus built through adhesion and jurisdictional agreements by all stakeholders is essential. Therefore, it is necessary to take into consideration regional and/or provincial distinctive features, Nation-Province relations, the setting of objectives and the search for common tactics which facilitate the response processes and the consolidation of these strategies.

ANMAT Federal Plan objectives include making up an integrative network between the Nation and the provinces which strengthens cooperation actions on the tasks related to regulation, monitoring and vigilance of drugs, food and medical devices â?? for which purpose a reference person is designated in each jurisdiction; developing streamlined and reliable connectivity mechanisms among the various jurisdictions; articulating the activities of each of them according to regulations, which enables monitoring efficiency optimization; to work for the harmonization of monitoring instruments in the various jurisdictions; promoting information exchange among them by developing suitable systems; updating human capital training by means of transfer and exchange programs; and gradually introducing other products within the sphere of competence of ANMAT and the areas concerned, as well as topics related to their activity.

In July 2010, the creation of ANMAT Federal Plan was announced. Based on the joint work by ANMAT and provincial technical teams, the areas to work on were identified as well as the possible strategies to reach the goals set, which led to the creation of the Federal Programs of Drug Control, Food Control and Medical Devices Control. Responsible officials of this plan gather at least once annually with every health jurisdiction-referent person to monitor the Plan and current work, and decide on next steps. A streamlined and reliable mechanism has been achieved for the strengthening of information exchange and permanent outreach to jurisdiction reference persons to foster their designation and participation. Likewise, active work on human capital training by means of exchange and transfer programs like FOPEVISA Federal has been also implemented.

Argentina is considered one of the most advanced regulatory legislations in Latin America. How actively has ANMAT shared practices in the region?

Within the framework of FO.AR (Argentine South-South and triangular Cooperation Fund), ANMAT worked for the â??Strengthening of the Quality Control of Drugs at CARICOM (Caribbean Community) Laboratoriesâ?• project. Firstly, professionals from our Agency travelled to the region to provide training. Secondly, CARICOM professionals came to Argentina to be trained on Good Laboratory Practice at ANMAT laboratories. Lastly, our professionals returned to their region to strengthen the training previously provided. The challenges posed by the projects included contributing to the strengthening of drug control laboratories of the countries involved by means of developing new tools, reinforcing their capacities with a view to ensuring the safety and efficacy of the products under their control, as well as strengthening the area of physic-chemical controls in the laboratories of the countries involved, in terms of drug quality control techniques, mainly, AntiTB, anti-malaria and HIV/AIDS drugs.

At present, we continue working with and accompanying CARICOM countries.

What has ANMAT learned via collaboration with other regulatory agencies such as FDA or Health Canada?

Argentina was the first of the five countries to be designated as a Reference National Regulatory Authority for drugs. The goals of the group work include: participating in quality assurance processes, safety and efficacy of products acquired by PAHO on behalf of countries; collaborating, as reference bodies, in the implementation and follow-up of the recommendations approved by the Pan American Conference on Drug Regulatory Harmonization (PANDHR); supporting PAHO on the activities intended for the strengthening of other national regulatory authorities in the region, so that they also can be designated as regional reference regulatory authorities; exchanging public information through their websites and, pursuant to national legislations in effect, on the products approved by regional reference authorities. This provides authorities who have fewer capacities with tools to make decisions on their own products, given the fact that the products registered and marketed in the countries whose regulatory authorities are regional reference regulatory authorities can be considered compliant with WHO recommended quality standards. Actions resulting from joint work and the regulatory challenges sharing by the National Regulatory Authorities add value to agencies themselves and related stakeholders, to the region and, contribute globally. This joint work strengthens agencies interaction and even favors the growth of each of them. Learning provided by this interaction is omni-directional. We find this situation beneficial for the population being the user of the products registered at and monitored by the agencies. Therefore, setting a road of convergence, cooperation and exchange emerges as a pressing need.

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