Know our history

ANMAT was created 30 years ago, to guard the health of the Argentine citizenry. Here, we tell you about how ANMAT expanded and consolidated itself as a regulatory agency of national and international reference.

Going through our timeline

History overview

The National Administration of Drugs, Food and Medical Devices (ANMAT) was **created on August 20th, 1992** under the former Ministry of Health and Social Action of the Nation.

Even though, its creation stemmed from the need of bringing order to the drug products registration and monitoring system nationwide, when its creation was decreed, its competences spanned all health products.

The main functions of this **scientific and technical agency** are established by Executive Decree 1490/1992 (link in Spanish: Decreto 1490/1992) and consist of controlling and monitoring drug products, diagnostic devices, medical technology materials and products, packaged food and material in contact with food, human hygiene products and cosmetics, and household sanitizing products. Accordingly, it also takes actions for the prevention and protection of public health.

Over time, in keeping with the emerging regulatory settings, the Ministry of Health of the Nation included new categories in the sphere of ANMAT functions, as is the case with disposable products and, more recently, cannabis-based plant products.

In its beginnings, this Administration had one single office on Defensa street. At present, it has five seats in the Autonomous City of Buenos Aires and five provincial delegations. The headquarters, located on 869 Mayo Avenue, embodies a historical value, as it used to be the venue of the "Home for the Employed Women", founded by Eva Perón in 1949. Recently, the Agency for State Property Administration allocated ANMAT a building situated on the corner of Riobamba street and Viamonte street, which will become a new seat.

Currently, this agency is made up of **over one thousand staff members, who enable the performance of its daily activities**. Various educational and specialization backgrounds call for interdisciplinary work, thereby, fostering diversity and plurality in the agency. And, likewise, trainings, scholarships and residencies continue to enrich the personal and professional level of its staff members.

Every task done at ANMAT leaves a trace on public health. This is the reason why, it has worked painstakingly over these years, to grow into a well-known health agency, with the recognition of the citizenry and various strategic players.

At the **national level**, ANMAT works, hand in hand, with representatives of the jurisdictional health authorities (link in Spanish: referentes de las autoridades sanitarias jurisdiccionales) to boost collaborative work in the federal arena and articulate actions for joint efforts on health products monitoring and control.

In the **international arena** (link in Spanish: **escenario internacional**), ANMAT reinforces the importance of regulatory convergence and harmonization. Currently, the agency is a Regional Reference National Regulatory Authority (PAHO/WHO) and is recognized as a high health vigilance agency at world level.

In line with strengthening the establishment of high regulatory standards and, as an ongoing improvement authority, ANMAT is actively involved in the following entities:

- WHO (World Health Organization)
- PAHO (Pan American Health Organization)

- MERCOSUR (Southern Cone Common Market)
- PIC/S (Pharmaceutical Inspection Cooperation Scheme)
- ICMRA (International Coalition of Medicines Regulatory Authorities)
- ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use)
- IMDRF (International Medical Device Regulators Forum)
- MDSAP (Medical Device Single Audit Program)
- FAO (Food and Agriculture Organization)
- CODEX ALIMENTARIUS
- ICCR (International Cooperation on Cosmetics Regulation)

For 30 years, ANMAT has promoted bilateral and multilateral dialogue and carried out cooperation and technical assistance programs among Agencies and Supranational Bodies. Furthermore, it took part in the design of consistent and intelligent regulatory strategies. Criteria harmonization and standardization allowed for the development of robust and flexible regulatory systems, which are capable of assertively providing responses to public needs.

Like any other sector in our country and the world, this National Administration faced the challenge of transforming itself, in the setting of the **global SARS-CoV-2 virus pandemic.** Therefore, it continued to reinforce its control and monitoring processes, by means of virtual and combined tools, and bolstered its decision-making communication in the emergency framework.

In line with the above, the use of various digital tools was boosted to simplify mechanisms and streamline regulatory procedures. Digitalization spurred key processes, such as the listing and registration of essential health products.

Streamlined decision-making was central for the country to have the health materials necessary in the sanitary emergency context, such as diagnostic reagents, vaccines,

disposable materials, masks, drug products and ventilators, among others. Over 13 clinical trials related to new vaccines were evaluated, as well as over 60 clinical trials concerning drug products, over 90 PCR diagnostic reagents for COVID-19 detection and over 60 rapid tests, which facilitated access to efficient diagnoses and concrete epidemiological data. Regulatory strategies were developed on the basis of control plans and public needs. It should be noted that the aforementioned decisions helped the health system prevent a shortage of critical inputs.

This Institution has been at the forefront of full innovation and digitalization processes, which enabled it to respond to the needs arising from the pandemic, without neglecting its daily tasks. In respect of medical devices, Gemha system (management of medical devices establishment modifications and licensing) was added to the already operative registration electronic systems intended for companies, such as Helena system (electronic registration of medical devices) and Bonita system (intended for medical devices import authorization applications).

Likewise, the Federal Information System for Food Control Management - SIFeGA (link in Spanish Sistema de Información Federal para la Gestión del Control de Alimentos (SIFeGA)), under the national Institute of Food, developed the System of Nutritional Seals and Warnings, as established in the Law for Healthy Eating Promotion. On the other hand, INAL´s National Laboratory of Reference (link in Spanish Laboratorio Nacional de Referencia) passed an evaluation based on international regulatory requirements that was conducted in 2020 by Organismo Argentino de Acreditación (Argentine Accreditation Body) and obtained a formal recognition of competence and impartiality, which contributes to ensure reliable, as well as technically valid and reproducible results.

In terms of direct **communication with the citizenry**, ANMAT shored up its direct access platforms to enhance reciprocal communication channels and respond to every query efficiently. The publication of updated information became essential and, consequently, weekly clarification documents on relevant topics were shared. Likewise, periodic updating of news on argentina.gob.ar/anmat and a stronger presence on the social media (Twitter, Instagram, LinkedIn) provided for an enlarged dissemination of official information.

The response to the **regulatory challenges** posed by the continuous transformation in different health-related fields is vital to accompany advances and emerging technologies, within the regulatory and control framework. This is why new emerging initiatives, proposals and developments, both in the personal and business areas, either public or private, find in this National Administration a place for containment, support and guidance to go along processes leading to new products intended for the population healthcare.

ANMAT was born 30 years ago to guard the health of the Argentine citizenry. It expanded and managed to consolidate itself as a regulatory agency of reference in the world. Based on its regulatory, monitoring and control role, ANMAT works every day for the health of the Argentine population.