

UNOFFICIAL TRANSLATION

Bulletin No. 027 of 2023

Towards a Latin American agency to regulate medicines

*Through Ministry of Health, the Colombian government is promoting the creation of a regional agency to regulate medicines.*

Bogotá D.C., 6 February 2023 - With the articulated leadership of the Ministry of Health and Social Protection and the National Institute for the Surveillance of Medicines and Food – (INVIMA), the Colombian government has decided to promote, launch and lead the creation of the Latin American Medicines Regulatory Agency.

The initiative, similar to the European Medicines Agency (EMA), created in 1995 and the African Medicines Agency (currently in formation), aims to carry out the regulation of medicines, as well as being an independent agency, based on health criteria that respond to the socio-economic, industrial and sanitary level of the region, industrial and sanitary level of the region.

This profile will enable it to set norms and standards that guarantee the quality, safety and efficacy of medicinal products based on strictly defined requirements.

Similarly, the region is expected to have the capacity to harmonise the requirements for the market; to facilitate the development of a regional pharmaceutical industry and a regional market for medicines, vaccines and medical devices.

The initiative is framed by the need to harmonise sanitary standards for medicines and other consumer products subject to sanitary surveillance, so that, in addition to facilitating national and international trade in medicines and other consumer products, as well as to ensure access to and the proper use of medicines, vaccines and products for human consumption subject to health surveillance.

It should be recalled that since 1946 the WHO, through article 2 of its constitution, has provided for the mission to "develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products".

Harmonisation efforts have traditionally been led by the developed countries, but there has been growing concern in developing countries that regulations and standards do not necessarily driven by considerations related to the protection of human health and may pose barriers to competition, widening the scientific and technical competition, increasing the scientific and technological gap.

In this context, the integration of efforts also means that the South Centre has been asked to accompany and advice in the creation of this Latin American Agency.

INVIMA, on behalf of the health sector, has entered into a Framework Agreement of cooperation with the South Centre, and under the coordination of the Ministry of Health, will this year initiate actions to propose the creation of a Latin American regulatory agency in the region.