



Ministerio
de **Salud Pública**

REGULATORY SYSTEM

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Ministry of Public Health of Ecuador

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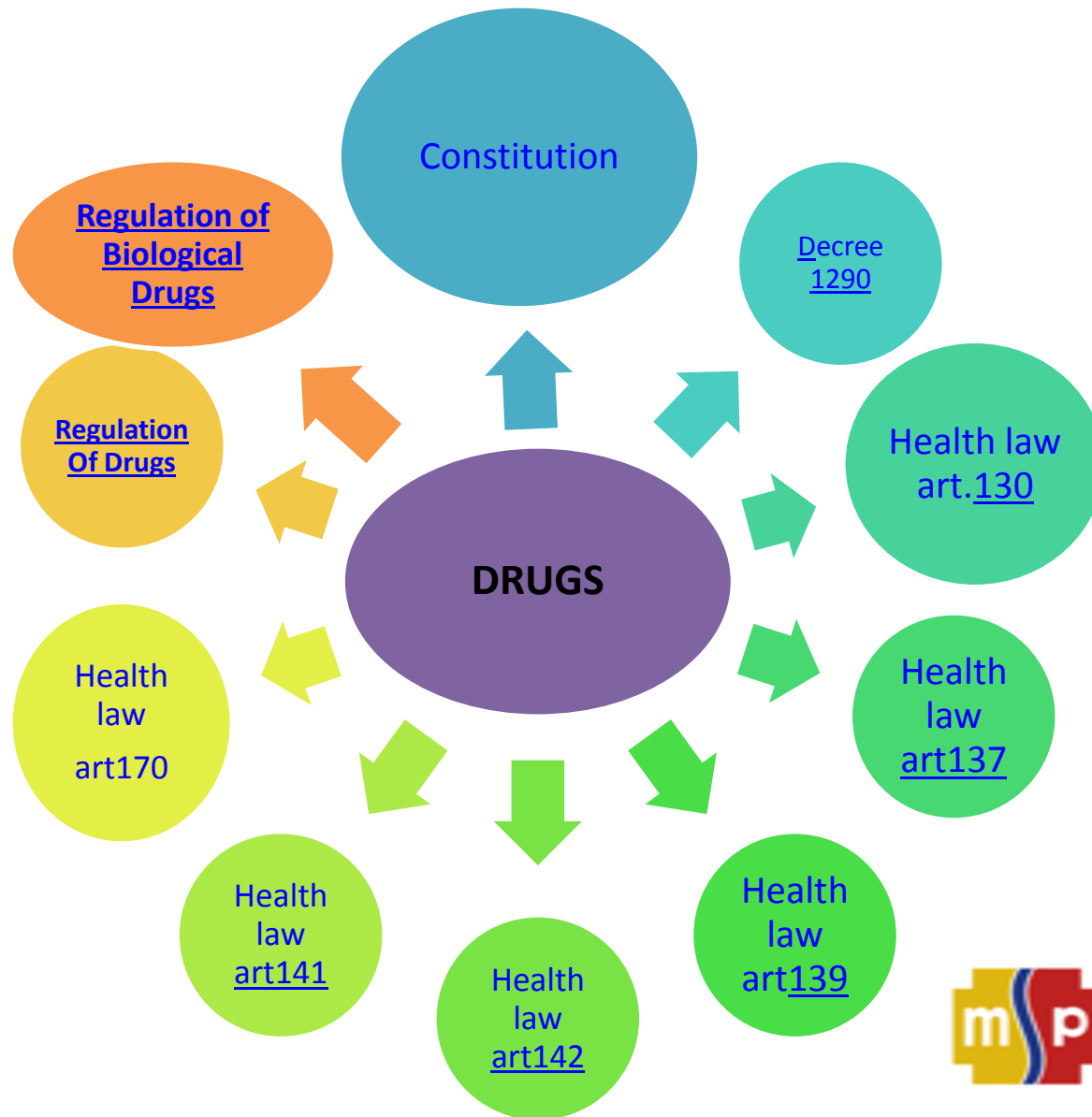
MISION

Exercise stewardship, regulation, planning, coordination, control and management of the Ecuadorian public health through governance and health surveillance and monitoring and ensuring the right to health through the provision of individual care, disease prevention, health promotion and equality, health governance, research and development of science and technology; articulation of the actors in the system, in order to guarantee the right to health

VISION

The Ministry of Public Health, will fully exercise the governance of the National Health System, a reference model in Latin America that prioritizes health promotion and disease prevention, with high levels of quality care, with warmth, ensuring comprehensive health population and universal access to a network of services, with the coordinated participation of public, private and community organizations.

Regulatory System



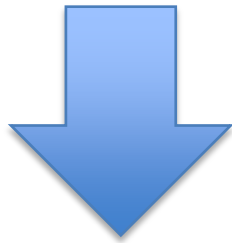
Number 7: "**Ensure availability and access to quality medicines are safe and efficient**, fair marketing and promoting domestic production and use of generic drugs that meet the epidemiological needs of the population. Access to medicines, public health interests prevail over economic and trade. "

Art. 1 / Art. 2
Decree 1290

Article 1 -. "**Creating the National Regulatory Agency, Health Surveillance and Control - ARCSEA** and the National Institute of Public Health Research - INSPI as legal entities of public law, administrative, economic and financial independence, under the Ministry of Public Health."



**National Department of Health
Surveillance**

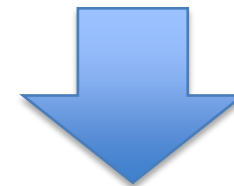


Developing legislation and
policy products for human use

**National Health
Agency - ARCSA**



Agencia Nacional
de **Regulación, Control
y Vigilancia Sanitaria**



Apply legislation for the control and
sanitary surveillance products for
human use



Health law
Art. 130

Article 130 -. "Establishment subject to health control for operation must have the permission granted by the national health authority. **The operating permit will be valid for one calendar year.** "



“Subject to sanitary registration processed foods, food additives, drugs in general, nutraceuticals, biological products, processed natural medicinal use, homeopathic medicines and dental products; medical devices and diagnostic reagents, hygienic products, pesticides for domestic and industrial use, manufactured in the country or abroad, for import, export, sale, supply, including those received in donation...”



"Regulatory approval will be valid for five years, counted from the date of grant. Any change in the condition in which the product was approved in the health record must be compulsorily reported to the national health authority through the ARCSA (exINHMT Izquieta Perez) will result in the procedure stipulated by the law and regulations "



"The National Health Authority through its competent organization shall carry out **periodic post-registration control of all products subject to approval** by taking samples for quality control and safety, either at the place of manufacture, storage, transportation, distribution or dispensing.. "

"Regulatory approval will be suspended or canceled by the National Health Authority through the ARCSA (exINHMT Izquieta Perez), at any time if it is found that the product or its manufacturer does not comply with the requirements and conditions of this Law and the regulations or when the product is likely to cause injury to health, and other sanctions provided for in this Law shall apply "

REGULATION OF DRUGS SYNTHESIS

Ministerial Agreement 586 of October 27, 2010, in force, with the following amendments:

1. Ministerial Agreement 710 of August 18, 2011, approval by homologation of drugs is included.
2. Ministerial Agreement 2883 of January 28, 2013, in force, with changing requirements and homologation procedure
3. Ministerial Agreement 4711 of February 11, 2014, in force, with changes in the scope of homologation: KOREA

REGULATION OF DRUGS SYNTHESIS

1. Sanitary Registration requirements for domestic and foreign medicines
2. Procedure for obtaining SR
3. Requirements for Approval
4. Modifications SR
5. Reinscription SR
6. Requirements for labels and leaflets
7. Post-registration control
8. Suspension or cancellation of sanitary registration

REGULATION OF BIOLOGICAL DRUGS

Ministerial Agreement 3344 of May 17, 2013, in force, contains the homologation, with the following amendment:

1. Ministerial Agreement 4711 of February 11, 2014, in force, with changes in the scope of homologation

HOMOLOGATION

It is the official recognition of Sanitary Registrations, approved by health authorities of the countries whose drug regulatory agencies have been ranked by the PAHO Regional Reference Authorities as well as those granted by countries high health surveillance:

BRAZIL
COLOMBIA
ARGENTINA
CUBA
MEXICO
UNITED STATES
CANADA
AUSTRALIA
JAPAN
MFDS REPUBLIC OF
KOREA
EMA

DRUGS SYNTHESIS

**BIOLOGICAL
DRUGS**

* For approval of biological drugs by homologation the countries should have specific regulations

REGULATION OF MEDICAL DEVICE

- Regulations for the sanitary registration medical device; reagents biochemical and diagnostic; and dental products. Acuerdo Ministerial 205, Registro Oficial 573 de 20-abr-2009



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Thank you