

ECUADOR



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



Ministerio
de **Salud Pública**



REGULATORY SYSTEM



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



REGULATORY INSTITUTION

National Health
Surveillance Agency

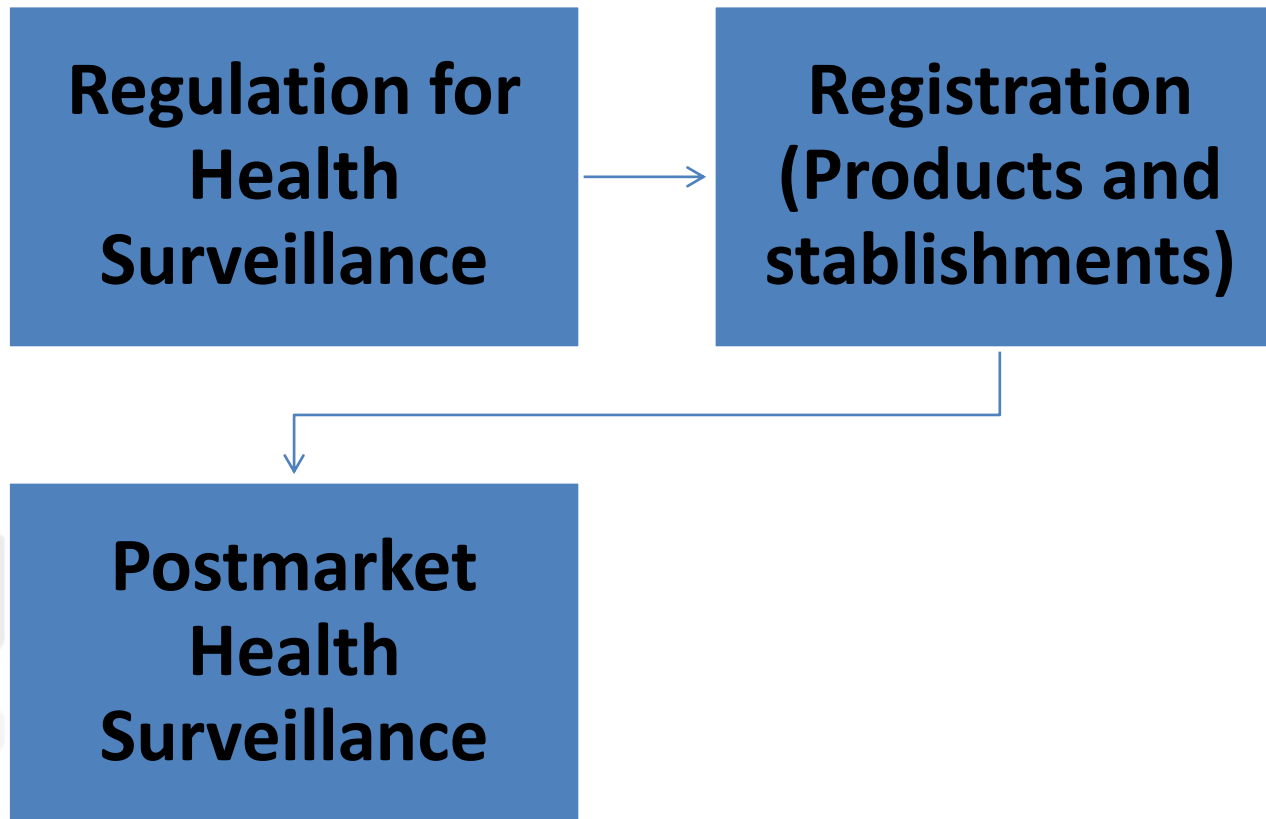


MISION

- Guarantee population's health through the regulation and control of human products, its quality, safety and efficacy, as well as hygienic sanitary conditions from establishments liable to control and surveillance sanitary.

VISION

- ARCSA will be consolidated as a national and international Regulatory Institution recognized by its reliability generated in population based in moral, technical capacity, efficient services, within 5 years.



Requirements for pharmaceutical, cosmetic and medical device marketing

Marketing Authorization



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

Marketing Authorization Steps

1. GMP CERTIFICATION
2. OPERATION LICENSE
3. Upload to VUE the documents listed in the regulation
4. Marketing Authorization



Regulation



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

Drugs

Regulation	Reglamento Sustitutivo de Registro Sanitario para Medicamentos en General
Technical Reference	ICH Guidelines
	Pharmacopoeias
	WHO Publications

Biologics

Regulation	Reglamento para la obtención del Registro Sanitario, Control y Vigilancia de Medicamentos Biológicos para Uso y Consumo Humano
Technical Reference	ICH Guidelines
	Pharmacopoeias
	WHO Publications
	PANDRH

Cosmetics

Regulation:	
Decision 516	Cosmetics
Decision 706	Hygienic Products
Technical Reference	Cosing
	Normas INEN



Medical Devices

Regulation	Acuerdo Ministerial 205
Technical Reference	Global Harmonization Tack Force
	Universal Medical Device Nomenclature System
	ISO 13485
	ICH Guidelines



INSTITUTION'S ROLE IN PHARMA INDUSTRY



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



Arcsa's role in pharma industry:





PHARMACEUTICAL MARKET



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



MARKET

INDUSTRIES	NATIONAL LABORATORIES	
	GMP	OPERATION LICENSE
PHARMACEUTICAL INDUSTRY	43	43
BIOLOGICS INDUSTRY	0	0
MEDICAL DEVICES INDUSTRY	0	0
COSMETICS INDUSTRY	0	164





BUSINESS OPPORTUNITY



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



HOMOLOGATION

- REPUBLIC OF KOREA CAN HOMOLOGATE ITS MARKETING AUTHORIZATION WITH ECUADOR



DRUGS HOMOLOGATION PROCEDURE

1. Operation license (**Representative Office**)
2. Apply Drugs Homologation at VUE
3. Upload documentation at VUE

Ventanilla Única Electrónica (VUE)



<https://portal.aduana.gob.ec/>



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

DRUGS HOMOLOGATION

Documentation:

- CPF o CFS (GMP CERTIFICATION*)
- Registration Power of attorney from the owner of the product to the Representative Office in Ecuador
- Marketing Authorization (MFDS)
- Stability Study Zone IV other 6 months of shelf life, if product storage conditions are natural conditions.
- Draft label (Spanish language)
- Prospectus (Spanish language)
- Payment 2258,41\$

THECNICAL ANALYSIS

Stability Study Zone IV

- ICH Guidelines Q1A, Q1E
- Stability testing of active pharmaceutical ingredients and finished pharmaceutical products-WHO.
- Q6A & Pharmacopeias Specifications



Safety and efficacy Analysis

1.COMPARISON BETWEEN MARKETING
AUTHORIZATION AND THE APPLICATION

2.Draft label

3.Prospectus



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

BIOLOGICS HOMOLOGATION PROCEDURE

1. Operation license (**Representative Office**)
2. Apply Drugs Homologation at VUE
3. Upload documentation at VUE

Ventanilla Única Electrónica (VUE)



<https://portal.aduana.gob.ec/>



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

BIOLOGICS HOMOLOGATION

Documentation:

- CPF o CFS (GMP CERTIFICATION*)
- Registration Power of attorney from the owner of the product to the Representative Office in Ecuador
- Draft label (Spanish language)
- Marketing Authorization (MFDS)
- Stability Study Zone IV other 6 months of shelf life, if product storage conditions are natural conditions.
- Prospectus (Spanish language)
- Payment 2258,41\$

BIOLOGICS HOMOLOGATION

Specific Documentation:

- Blood Derivates
- Biothechnological
- Vaccines
- Biosimilars

These Documentation is Specified in “Reglamento para la obtención del Registro Sanitario, Control y Vigilancia de Medicamentos Biológicos para Uso y Consumo Humano”

Note: These Documentation is used for posmarket control



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

THECNICAL ANALYSIS

Stability Study Zone IV

- ICH Guidelines Q1A, Q5C
- Q6B & Pharmacopeias Specifications



Safety and efficacy Analysis

1.COMPARISON BETWEEN MARKETING
AUTHORIZATION AND THE APPLICATION

2.Draft label

3.Prospectus

We don't Analysis Specific Documentation, we
just see that the documentation is complete.

Objections

- 45 DAYS to amend Objections



Statistical Data

Approval Drugs for Homologation

EMA	85
ARGENTINA	179
BRASIL	41
CANADA	1
COLOMBIA	519
CUBA	5
USA	7
REINO UNIDO	4
FRANCIA	1
MEXICO	99
DRUGS APPROVED 2014	190
TOTAL	1131



