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ABC

Sanitary Registrations

OLARTEMOURE
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Introduction

The Regulatory Affairs practice at OlarteMoure has a top-tier multidisciplinary team made up of pharmaceutical chemists and attorneys with extensive experience in the pharmaceutical sector and in the regulatory framework applicable to life sciences products. This combination of technical and legal expertise enables an integrated approach to the challenges associated with regulatory compliance, product life cycle management, and engagement with health authorities.

Its extensive track record in the sector has enabled it to build a solid understanding of Sanitary Registration processes, quality control, labeling, manufacturing, importation, and marketing of different types of products subject to sanitary control, including medicines, medical devices, cosmetic products, dietary supplements, and other regulated products.

Building on this experience, the team designs and implements regulatory strategies tailored to the nature of the product, the complexity of the procedure, and the specific characteristics of the market, ensuring technical and legal support aligned with applicable national and international regulations.

What is a medicine?

It is a pharmaceutical preparation obtained from active ingredients, with or without auxiliary substances, presented in a dosage form that is used for the prevention, relief, diagnosis, treatment, cure, or rehabilitation of disease.

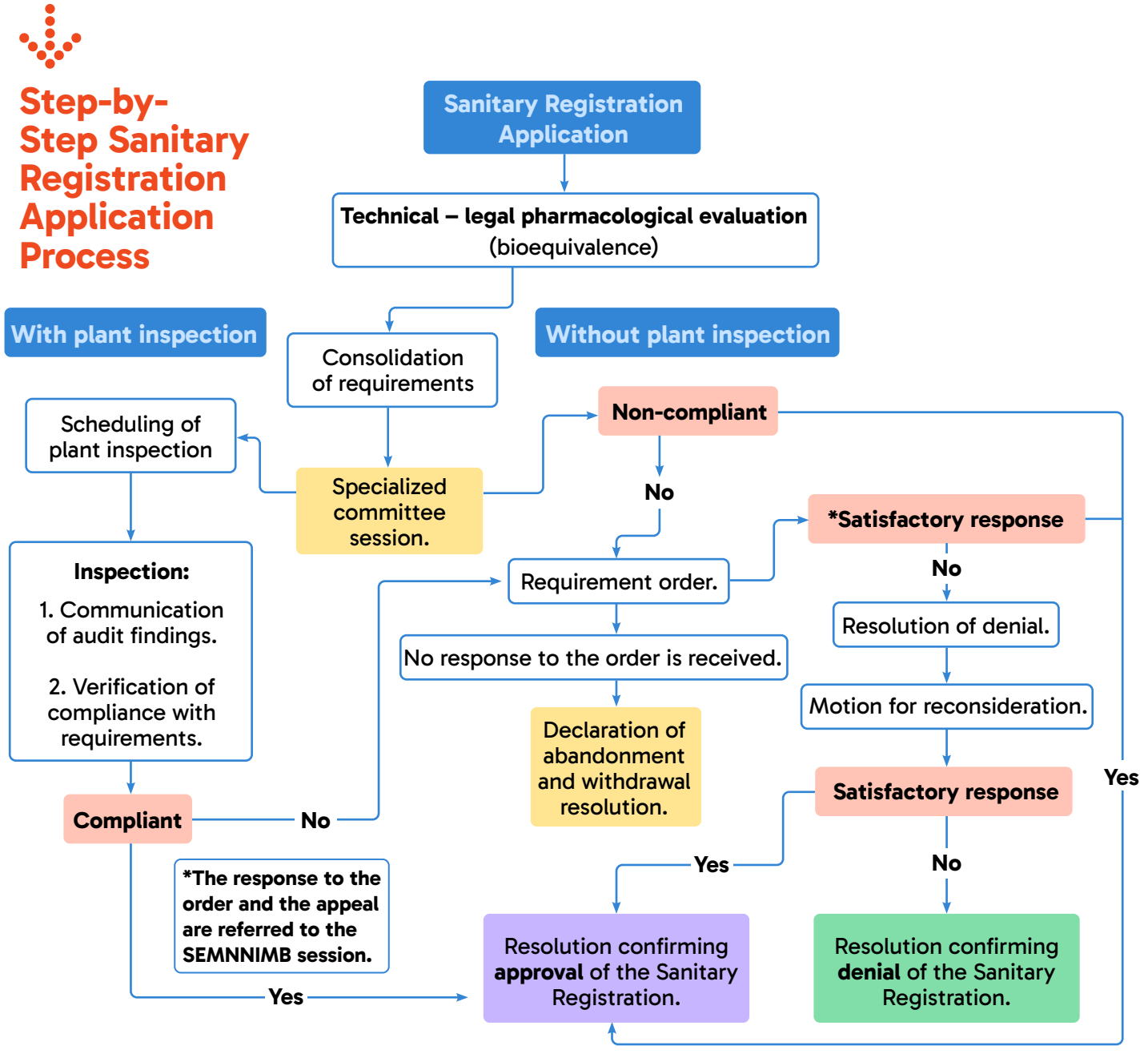
Types of medicines

- **Chemical synthesis (SQ):** these are products made through chemical processes, used to prevent, treat, diagnose, or relieve diseases.
- **Biologics:** derived from living organisms or parts of them. They include products such as vaccines, antibodies, hormones, and other biotechnology-derived products.
- **Homeopathic medicines:** produced using homeopathic techniques in accordance with recognized pharmacopoeias. They are intended to treat or prevent diseases in an individualized manner.
- **Phytotherapeutic medicines:** preparations made from medicinal plants or their derivatives, used for therapeutic purposes. They do not contain isolated active ingredients.

General Requirements to Apply for Sanitary Registration

- Official application form submitted to INVIMA.
- Information on the registration holder and the manufacturer.
- Good Manufacturing Practices (GMP) Certificate of the manufacturer.
- Full product formula (active ingredients and excipients).
- Stability, efficacy, and safety studies.
- Information on the route of administration and dosage form.
- Indications, contraindications, warnings, and precautions.
- Estimated shelf life of the product.
- Marketing conditions.
- Bioequivalence or bioavailability studies, if applicable.
- Labeling, packaging, and labels.
- Payment of fees established by INVIMA depending on the product type.
- Pharmaceutical and pharmacological evaluations, depending on the type of medicine.
- Complete technical information: qualitative and quantitative formula, stability studies. list of excipients, dosage form, shelf life, among others.
- Labeling, labels, and packaging in accordance with current regulations.

Step-by-Step Sanitary Registration Application Process



General Requirements to Market Medicines

- **Valid Sanitary Registration:** every medicine must have a Sanitary Registration issued by INVIMA or the delegated authority, which authorizes its production, importation, exportation, and/or sale in the national territory.

- **Sanitary clearance or manufacturing certifications (GLP, GMP, GPP):** the establishment (laboratory, drugstore, pharmacy, or distributor) must be authorized by INVIMA through a license certifying compliance with Good Manufacturing Practices (GMP), storage, and distribution.

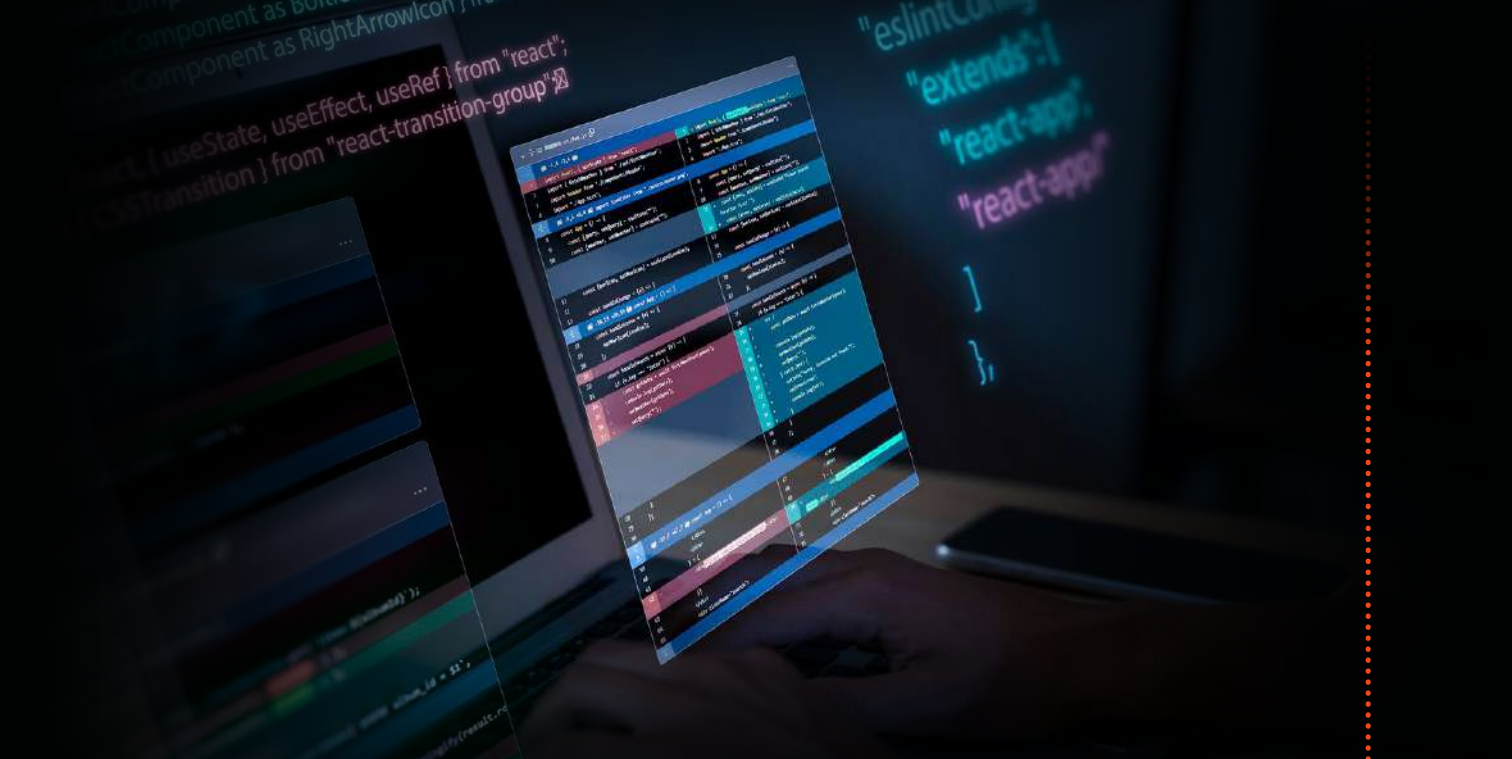
- **Authorized conditions of sale:** the medicine may only be marketed under the conditions approved in its Sanitary Registration:

  - Over-the-counter.
  - Prescription-only.
  - For hospital use only.
  - Under special control (when applicable).

- **Batch quality control certificate:** each batch that is marketed must have quality testing and approval issued by the manufacturer or an authorized laboratory.

- **Traceability:** distribution channels must allow the product to be traced from manufacturing through dispensing to the end user, ensuring integrity and safety.

- **Regulated advertising and promotion:** promotion of medicines is only permitted according to their category. For prescription medicines or medicines under special control, strict advertising rules directed to the medical community must be followed.



What is required for active ingredients (drug substances or APIs) and excipients?

- They must meet quality and safety standards.
- Their origin and characteristics must be documented and certified.
- They must comply with official pharmacopoeias (for example, USP – United States Pharmacopeia, BP – British Pharmacopoeia, EP – European Pharmacopoeia, etc.).
- They must be evaluated as an integral part of the quality control of the finished product.

Key Steps to Operate in the Pharmaceutical Market

Manufacture Medicines in Colombia

- Hold a Good Manufacturing Practices (GMP) certification issued by INVIMA.
- Have qualified personnel, suitable equipment, and validated facilities appropriate for the intended operations.
- Obtain the Sanitary Registration for each medicine intended to be manufactured.

Export Medicines from Colombia

- Hold a valid GMP certificate, which may be issued by INVIMA or the health authority of another country.
- Have qualified personnel, suitable equipment, and validated facilities appropriate for the intended operations.
- Obtain the Sanitary Registration for each medicine intended to be manufactured for exportation.

Import Medicines into Colombia

1. The manufacturing laboratory must be certified by a recognized health authority or by INVIMA.
2. Have all legal and technical documentation supporting the medicine.
3. In some cases, bioavailability and bioequivalence studies must be submitted.
4. Obtain the Sanitary Registration for each medicine intended to be imported.

Regulatory Framework

• **Law 9 of 1979 –** Whereby sanitary provisions for the protection of public health are regulated.

• **Law 100 of 1993 –** Social Security System for Health.

• **Decree 677 of 1995 –** Whereby the regime of registrations and licenses, quality control, and sanitary surveillance of medicines is partially regulated.

• **Decree 2266 of 2004 –** Whereby the regimes for Sanitary Registrations and sanitary surveillance and control of phytotherapeutic products are regulated.

• **Decree 3554 of 2004 –** Regulates the regime for homeopathic medicines for human use.

• **Decree 1782 of 2014 –** Whereby the regime for biological medicines in the Sanitary Registration procedure is established.

• **Resolution 1124 of 2016 –** Whereby criteria and requirements are established for bioavailability and bioequivalence studies for medicines.

• **Decree 334 of 2022 –** Regulation for the sanitary control of medicines.

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