Pharmaceutical Requirements

Grupo Profesional SERTERE – Regulatory Consulting in Venezuela

Requirements for Imported Pharmaceutical Products in Venezuela

Below is a complete overview of regulatory requirements in Venezuela specifically for pharmaceutical products (imported medicines), including administrative documents, technical dossier content, and estimated approval timelines.

Authority:

Ministry of People's Power for Health (MPPS)

Autonomous Health Comptroller Service (SACS)

National Institute of Hygiene “Rafael Rangel” (INHRR)

1. Applicant Prerequisites (Importer)

- [ ] Commercial registration of the importing company
- [ ] Valid sanitary operating license
- [ ] Responsible licensed pharmacist
- [ ] Registration with SACS
- [ ] Legal representation agreement
- [ ] Marketing authorization from product owner

2. Administrative Documents

- [ ] Application form
- [ ] Apostilled Power of Attorney
- [ ] CPP or Free Sale Certificate
- [ ] GMP Certificate
- [ ] Importer sanitary license

- [ ] Fee payment proof
- [ ] Holder declaration
- [ ] Manufacturing agreement (if applicable)
- [ ] Trademark authorization

3. Technical Dossier (CTD)

3.1 Quality

- [ ] Full composition
- [ ] Manufacturing process
- [ ] Raw material controls
- [ ] Finished product specs
- [ ] Analytical methods
- [ ] Batch analysis
- [ ] Stability studies
- [ ] Process validation
- [ ] Container closure
- [ ] Shelf life

3.2 Non-Clinical

- [ ] Toxicology (if applicable)
- [ ] Pharmacology
- [ ] Safety data

3.3 Clinical

- [ ] Clinical studies
- [ ] Scientific literature
- [ ] Benefit-risk
- [ ] Pharmacovigilance

3.4 Labeling

- [ ] Label artwork
- [ ] Package insert
- [ ] Packaging info
- [ ] Storage conditions

4. Labeling Requirements

Primary/Secondary:

- [ ] Brand name
- [ ] INN
- [ ] Strength/form
- [ ] Composition
- [ ] Batch
- [ ] Expiry
- [ ] Storage
- [ ] Manufacturer
- [ ] Importer
- [ ] Registration number
- [ ] Net content
- [ ] Route
- [ ] Warnings
- [ ] Sale condition

Insert:

- [ ] Composition
- [ ] Indications
- [ ] Dosage
- [ ] Contraindications
- [ ] Warnings
- [ ] Interactions
- [ ] Adverse reactions
- [ ] Overdose
- [ ] Storage
- [ ] Manufacturer
- [ ] Revision date

5. Additional

- [ ] Samples
- [ ] Reference standards
- [ ] Translations
- [ ] Apostilles

6. Timeline

- Admin: 1 – 3 months
- Technical: 8 – 18 months
- Total: 12 – 24 months

7. Validity

- Typical validity: 5 years
- - Renewal requires updated dossier, GMP, pharmacovigilance