Instituto de Salud Pública
Ministerio de Salud
Gobierno de Chile

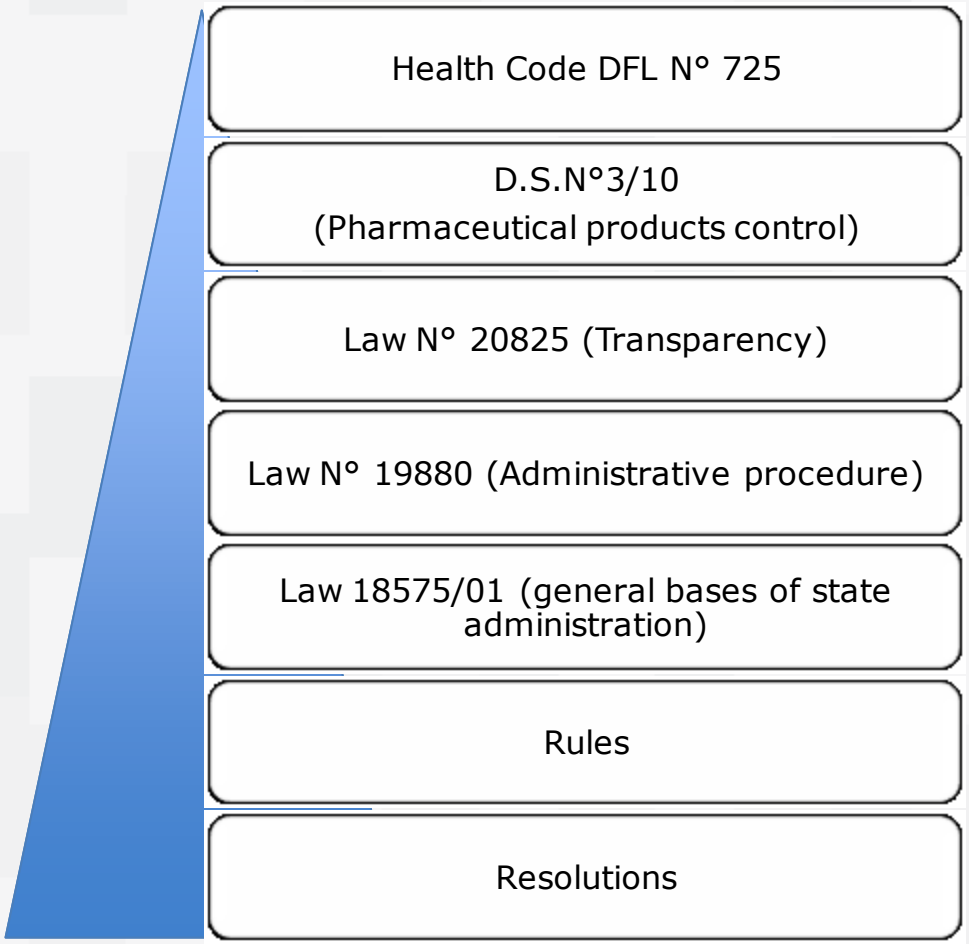
WHO/PAHO NRA IV

GBC 8:
Regulatory workshop

Regulatory framework for biological and biotechnological products

Pablo Díaz, PhD

Legal bases


Health Code DFL N° 725
D.S.N°3/10
(Pharmaceutical products control)
Law N° 20825 (Transparency)
Law N° 19880 (Administrative procedure)
Law 18575/01 (general bases of state administration)
Rules
Resolutions

DS 3/10

- All Biological products must be considered as new products and must submit the complete dossier to demonstrate quality, safety and efficacy. Complete package of information.

- Biosimilars must contain completed quality information, plus comparability vs reference product, safety and efficacy information based on quality comparability results.

- In the case of Biotechnological Products the norm indicate That, this products may present an abbreviated dossier of clinical and preclinical information, based on a biotechnological product approved with the complete dossier to demonstrate quality, safety and efficacy , and it also must point out the biotechnological reference products.

Marketing Authorization

- The **marketing authorization** is the inscription in a special role maintained by the Institute of Public Health of Chile, once the application has been submitted to an evaluation process to verify quality, safety and efficacy.

- The health registry establishes safety, quality and efficacy parameters.

- Define a product: Name, formula, therapeutic indication or purpose of use.

- Establish those responsible: Owner, importer, manufacturer, distributor

- Determine the conditions of circulation in the country (labels, brochures, quality specifications, period of validity, storage, advertising or promotion)

Health code
DS. 3/10 - DS. 239/02 - DS.157/05

¿What is the health registry?

Quality

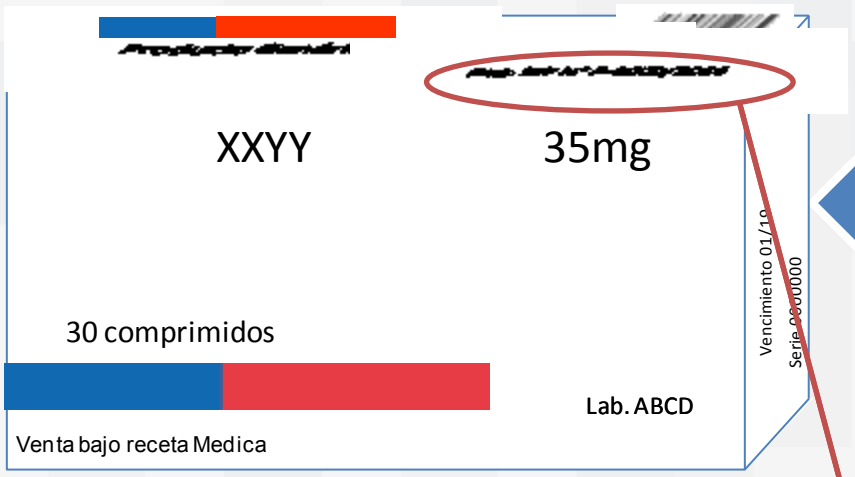
Safety

Efficacy

Evaluate

- **Evaluation process of:**
- Pharnaceutical information
- Non clinical
- Clinical

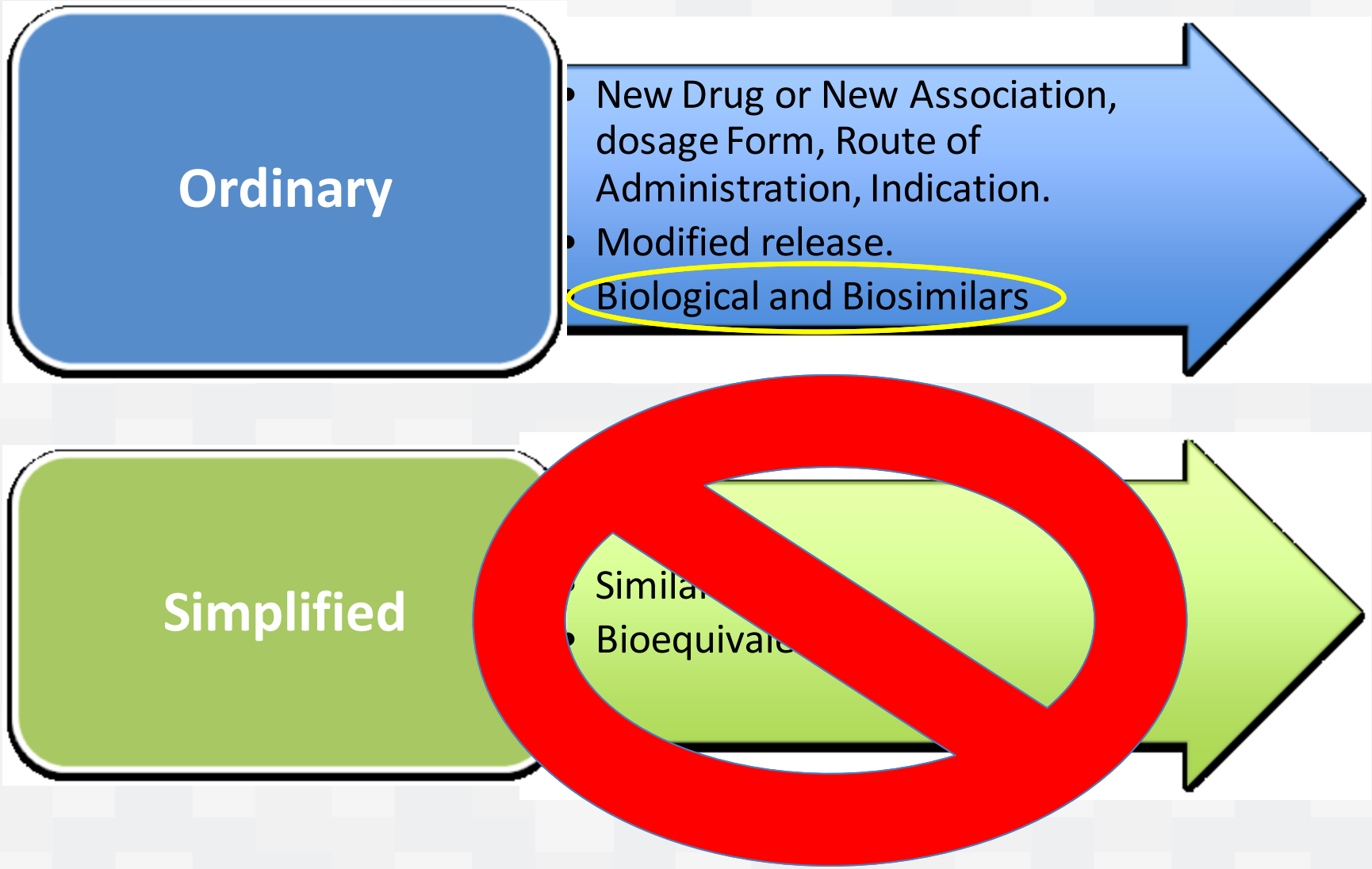
- **Inscription role with a correlative number given by the Institue of public health**



Reg. ISP N° F-0000/2016
B-

5 years validity

Health registry alternatives



Guidelines

Quality

- Standard N°129: "Guide For the preparation and presentation of stability studies in Chile and its annex"
- Standard N°131: "Roster of allowed colorants in cosmetic pharmaceutical products"
- Specifications guidelines for finished products (R.E.N°12166/04)
- Guide to Conducting Validation of Test Methods (R.E. 201/15)

Safety and Efficacy

- Standard N°131: "Defines the criteria to establish Therapeutic Equivalence"
- Standard N°136: "It determines active principles contained in pharmaceutical products that must demonstrate their therapeutic equivalence"
- Standard N°170: «Sanitary Registration of Biotechnological Products derived from Recombinant DNA"
- Guide for requesting a Vaccine Health Record(R.E.N°4115/13)
- Instructions published on the Institute of Public Health Web Page (Labels, Brochures, etc.)

Standard 170

Sanitary Registration of Biotechnological Products derived from Recombinant DNA

- General requirements of security and efficacy
- This standard is based on the guide of biotherapeutical and biosimilars products of WHO of the year 2009
- International standards of quality, security and efficacy
- This standard does not apply to vaccines, hemoderivates and heparins

- Administratives
- Technical information (pharmacology, clinical monography, graphic requirement, professional booklet,pacient booklet)
- Quality requirements (such as process description)
- GMP, GLP
- Security and efficacy requirements
- Pharmacovigilance
- Risk management

Registry authorization process

Admisibility

Background completness

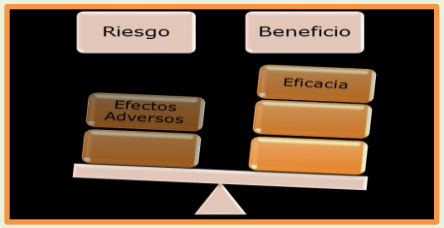
Resolve:
- Admissibe
- Non admissible
- Overruled

Background evaluation of Quality/Safety/Effectiveness

Technical reports:
- Analítycal and clinical
- Legal
- GMP
- Biopharmacy (if appropriate)
- Validation (if appropriate)
- External reports (if appropriate)

Registry commite (Experts)

Risk/Benefit profile analysis



Denial resolve

Authorization resolve

Registry number asignation

Annex

Labels

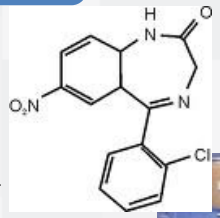
Patient information booklet

Finished product specification

Proffesional information booklet

Quality assessment

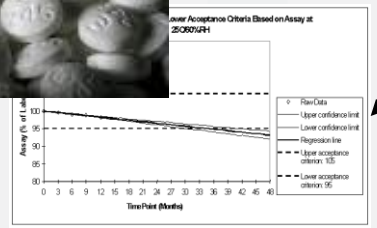
Composition



Analytical methodologies

Raw materials

Manufacturing



Quality Specs

Comparability studies (biosimilar)

Stability studies

INSTITUTO DE SALUD PÚBLICA DE CHILE

Safety and efficacy evaluation

R&D of Pharmaceutical product

Non-clinical information

Quality

Clinical information (Phase I, II, III)

Studies: accute and cronic toxicicty, teratogenicity

Commercialization

Pharmacovigilance (in case of imported products)

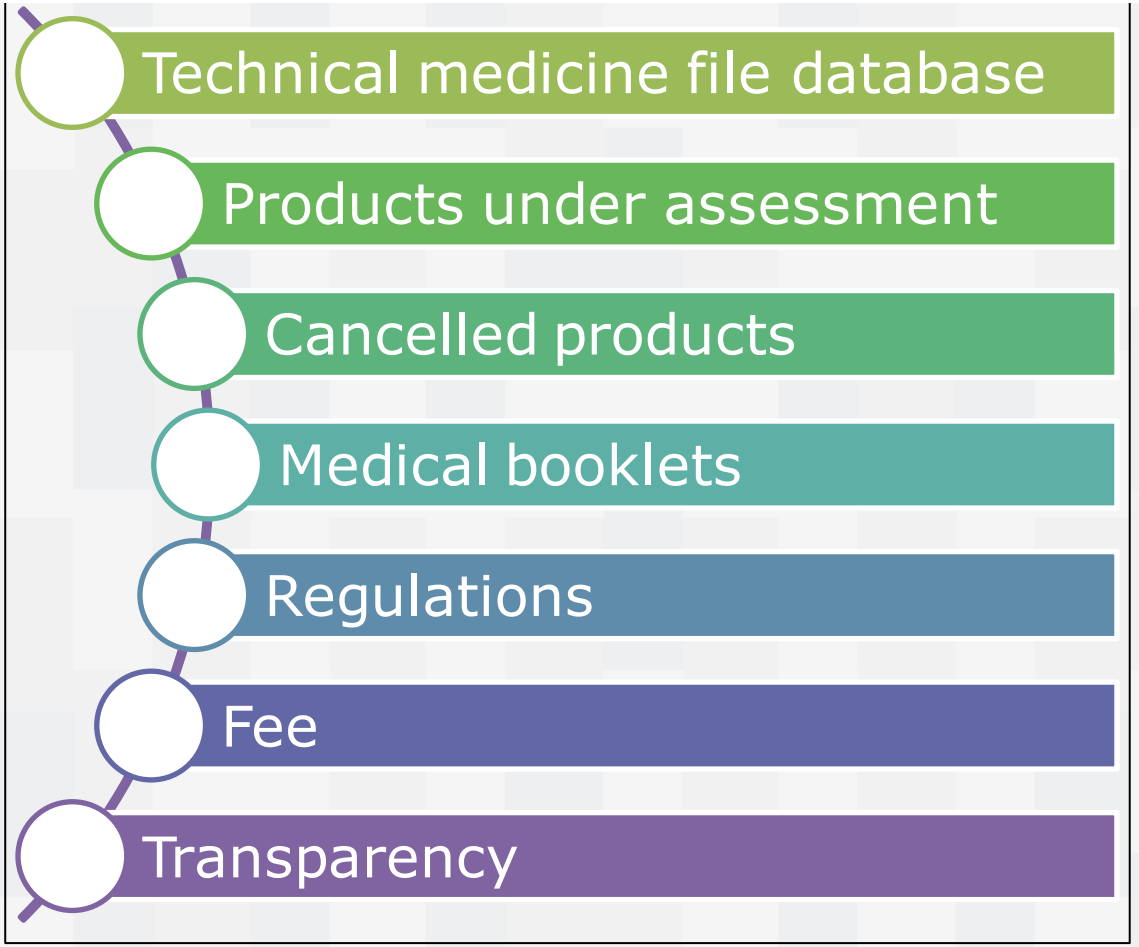
Therapeutic equivalence

Comparability studies (biosimilar, if appropiate)

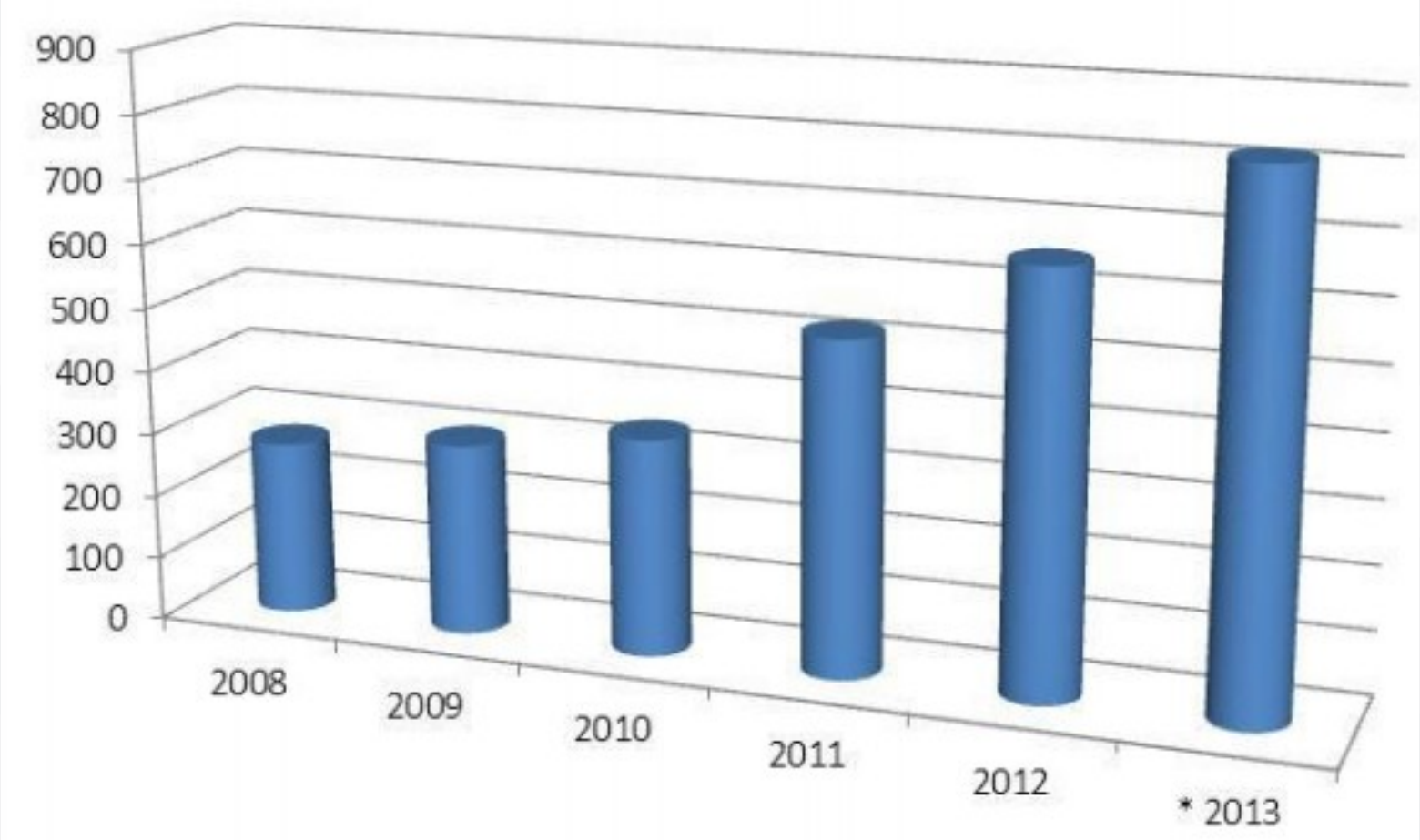
User information

Web page: www.ispch.cl

Electronic registry solicitude



Number of batches/year, imported biological products in Chile



Pharmaceutical products registry

Synthesis Biological Biotechnological