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Argentina

Submission and Registration process in Argentina

26May 2022

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IPRAT – Managing Partner

Agenda

- Opportunities in the LATAM Region
- Argentina general overview
- Registration process in Argentina Medicinal Products
  - Regulatory overview
  - Requirements for product registration
  - Key Elements to Register in Argentina
- Take away messages

OPPORTUNITIES IN THE REGION

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Top 20 Global Markets over the forecast period

Based on Const. US$'bn
Growth vs PY %

GEM Markets

Rank	2021		2023		2025	
1	USA	+6.6%	USA	+3.3%	USA	+3.0%
2	China	+7.2%	China	+3.7%	China	+4.2%
3	Japan	-0.2%	Japan	+0.1%	Japan	+0.5%
4	Germany	+6.3%	Germany	+5.5%	Germany	+4.3%
5	France	+5.3%	France	+2.9%	France	+2.5%
6	UK	+5.9%	UK	+4.8%	UK	+4.6%
7	Italy	+2.3%	Italy	+3.6%	Brazil	+7.8%
8	Brazil	+13.4%	Brazil	+9.1%	Italy	+3.3%
9	Spain	+6.5%	Spain	+2.4%	India	+8.7%
10	Canada	+3.9%	India	+9.0%	Spain	+2.9%
11	India	+15.5%	Canada	+4.4%	Canada	+4.2%
12	Russia	+10.3%	Russia	+9.1%	Argentina	+26.5%
13	South Korea	+4.2%	South Korea	+5.0%	Russia	+7.8%
14	Australia	+2.6%	Argentina	+32.1%	South Korea	+4.8%
15	Mexico	+8.0%	Australia	+3.1%	Mexico	+6.4%
16	Poland	+3.5%	Mexico	+6.8%	Australia	+2.8%
17	Saudi Arabia	+5.6%	Turkey	+17.3%	Turkey	+7.5%
18	Belgium	+7.0%	Poland	+4.4%	Poland	+3.1%
19	Argentina	+66.3%	Saudi Arabia	+5.1%	Saudi Arabia	+4.2%
20	Turkey	+19.2%	Belgium	+3.5%	Belgium	+3.6%

Source: IQVIA MARKET PROGNOSIS 2021-2025 (Sep'21 edition) (Global 49 Countries)

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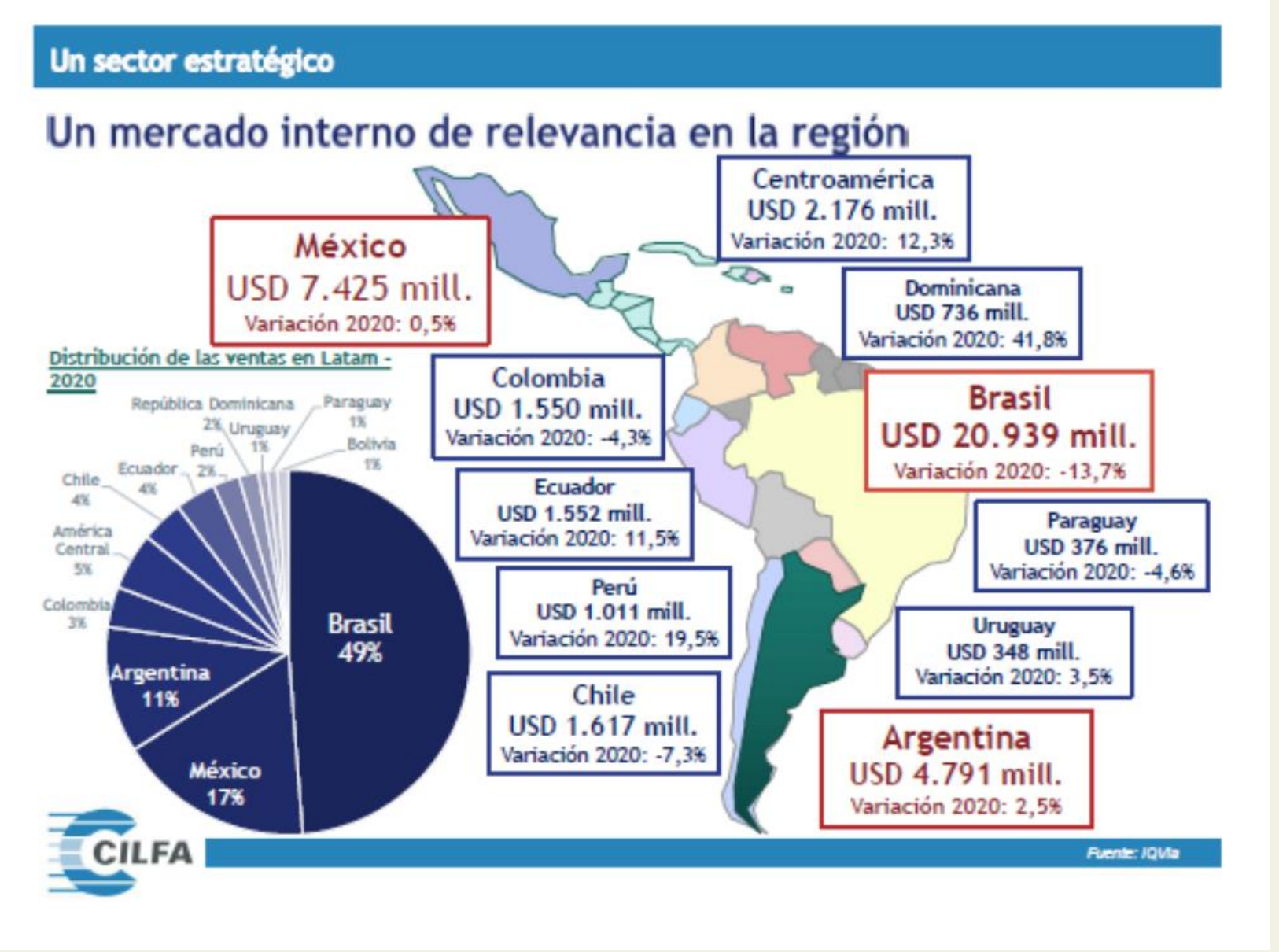
Latam Region Internal Market Distribution in sales 2022

Latin America Business



Source IMS, Cilfa report 2021

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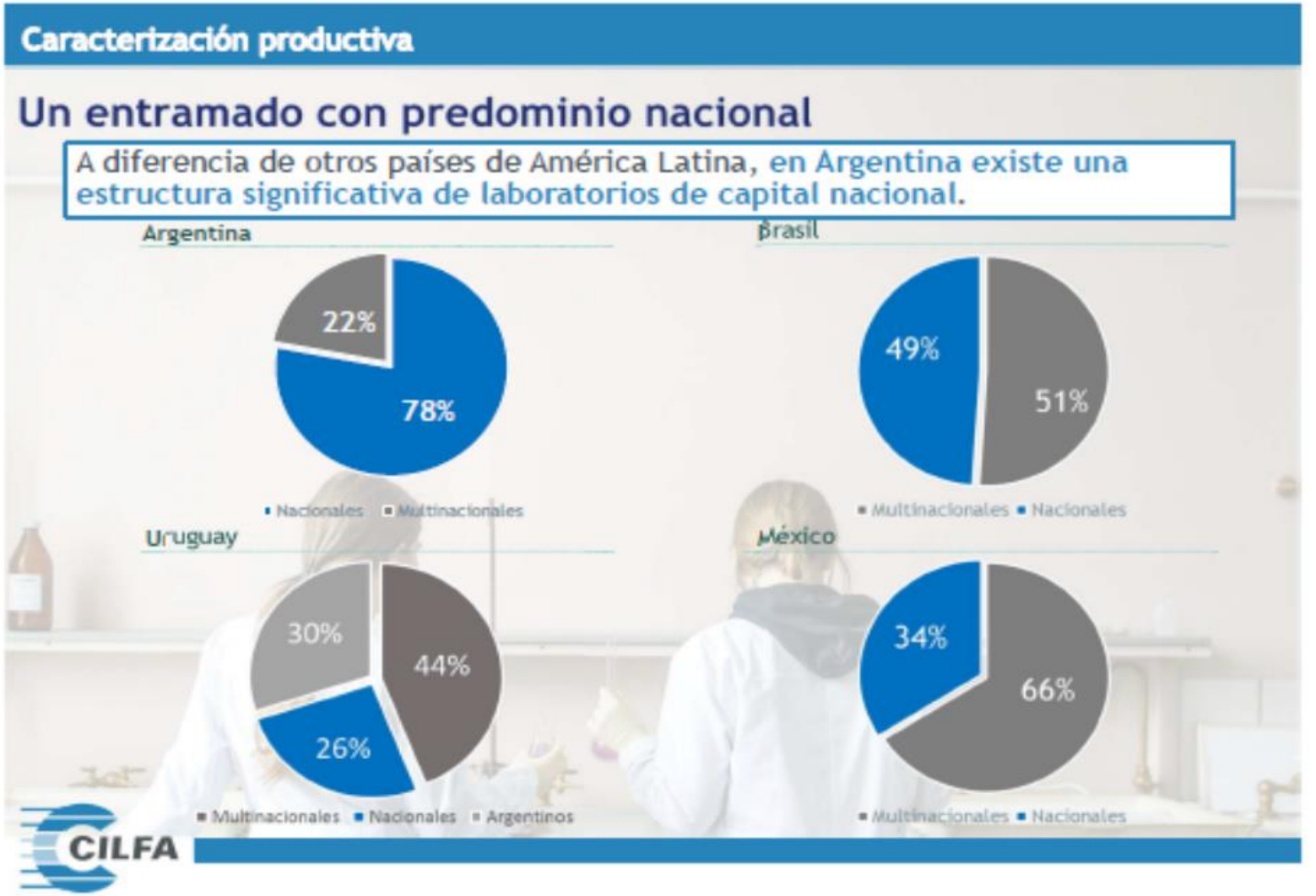
National Laboratories vs Multinational in Latam Distribution in sales 2022

Latin America Business



Source IMS, Cilfa report 2021

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ARGENTINE

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Argentina

Population	45.7 M	Spanish language, life expectation 78 years
Market size	4791 M	3rd of the South American region
Health care system	Mixed system	Public Social Security Private

Sources:
https://interactives.prb.org/2021-wpds/americas/#south-america
https://interactives.prb.org/2021-wpds/americas/#south-america

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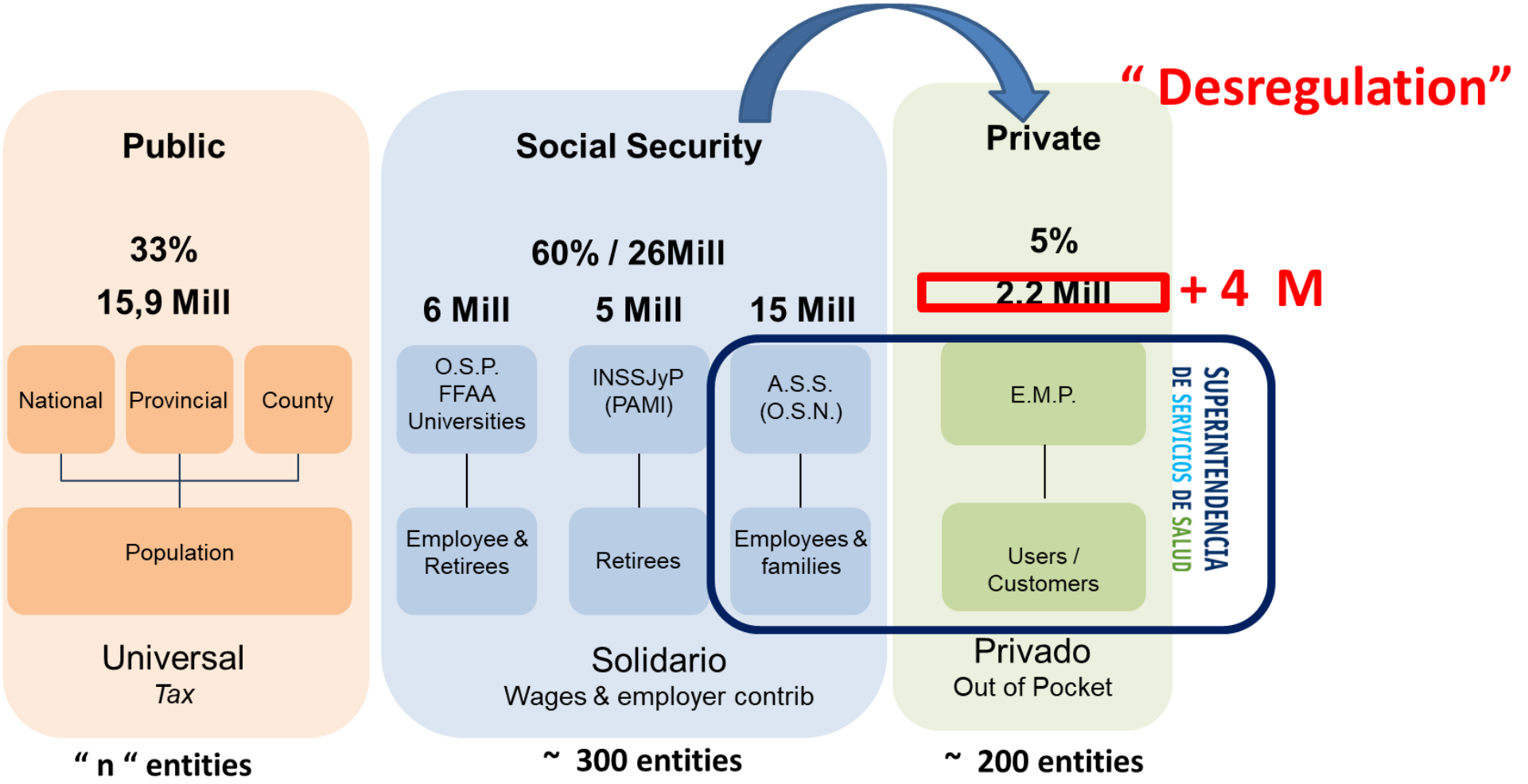
Health Care Map - Argentina



Fuente: Obras sociales en Argentina - O.Cetrangolo – A. Goldsmith - Juilo 2018

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Registration process in Argentina Medicinal Products

REGULATORY OVERVIEW

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Regulatory landscape & ANMAT Profile

- **ANMAT** (National Administration of Medicines, Food and Medical Technology) is a **decentralized body** of the National Public Administration of the Argentine Republic **created in 1992** and dependent on the Ministry of Health.
- **Scope:** drug products, medical devices, food supplements/food, cosmetics, biologics, odontological products, IVD and hygienic products
- **ANMAT** regulates and guarantees that **drugs, food and medical devices** processes of authorization, surveillance and inspection of these products
- In 2011 was nominated as *Regional Reference Regulatory agency for Medicines*" by **PAHO** (Organización Panamericana de la Salud, OPS), **Level IV**
- Approval assessment reports and the list of products under registration are not public information.
- ANMAT´s paper- based **registration system** was gradually changed **to electronic system** during the last years with important progress during pandemic but still with pending issues and processes to be reviewed.
- **Patents:** There is no data exclusivity, no linkage after approval in Argentina. Resolution (Nos. 118/2012, 546/2012 and 107/2012) with new guidelines for examining chemical-pharmaceutical patent applications severely restricts the patentability of several categories of inventions in the pharmaceutical field.
- High focus on Local Industry development and ecosystem protection which could impact on different standards

Regulatory landscape & ANMAT Profile

ANMAT continues to advance in the decision-making spaces of international regulation as:

- ANMAT is a **member of PIC/S**
- ANMAT is **member of MERCOSUR** HAs Group
- Affiliate **member of the Medical Device Single Audit Program** (MDSAP) as well as a full **member of the Executive Committee of the International Pharmaceutical Regulators Program** (IPRP)
- **"Observer member"** of the International Council for the Harmonization of Technical Requirements for Pharmaceutical Products for Human Use **(ICH**)
- Participant in different forums focused on the design of strategies to strengthen cooperation mechanisms and the implementation of communication tools that **collaborate in the certification process of PAHO Reference Authorities.**
- **Associate Member of the International Coalition of Medicines Regulatory Agencies** (ICMRA), a forum made up of regulatory authorities dedicated to providing strategic leadership to address the regulations and safety of human medicines.
- In addition, **ANMAT has signed an information exchange agreement with the European Medicines Agency (EMA)** of, in order to establish a framework **for collaboration and cooperation in relation to SARS-CoV2, COVID-19 and the products regulated by both health authorities**.
- On the other hand, it also has **participated in the meeting of National Regulatory Authorities of Regional Reference together with officials from the agencies of ANVISA (Brazil), Health Canada (Canada), ISP (Chile), INVIMA (Colombia), FDA (United States) and COFEPRIS (Mexico) and the Pan American Health Organization (PAHO / WHO**) with the **aim of sharing the experiences of the region in decision-making in the context of the COVID-19 pandemic**.

https://www.argentina.gob.ar/anmat

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Registration process in Argentina Medicinal Products

REQUIREMENTS FOR PRODUCT REGISTRATION

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1. Regulatory Overview

Argentina

Country	Medicine And Healthcare Products Regulatory Agency	Time to evaluate registration product	FDA / EMA Approval	Main requirements	Products Register Regulation
Argentina 	National Administration of Drugs, Food and Medical Technologies (ANMAT)	Depending on product classification 6~12~ 36 months (in case of Biologics, an inspection of the manuf. Plant will be carried out in all cases)	Not mandatory but nice to have to reduce registration timelines	Specific depending on product classification In general: CPP from Country of origin/reference GMP Mfg Site Technical dossier (Module 3 CTD) Non clinical, clinical summary Labelling, PIL	Decree 150/92 All product classification: innovative, branded generics Disp 7075/11 Regulation for biologic and biosimilar products since 2011/2012. Circ 11, 2019 (CTD) Comparability studies required with pre-clinical and clinical data. The extension of the data requested is evaluated on a case by case basis

CPP Certificate of Pharmaceutical Product
GMP Man Site: Good Manufacturing Practices of the Manufacturing Site
CTD Common Technical Document
PIL Patient Information Leaflet

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1. Regulatory Overview

Reference countries

Annex I

- ✓United States
- ✓United Kingdom
- ✓France
- ✓Spain
- ✓Italy
- ✓Denmark
- ✓Germany
- ✓Israel
- ✓Japan
- ✓Belgium
- ✓Netherlands
- ✓Switzerland
- ✓Sweden
- ✓Canada
- ✓Austria

UE is not recognised as such, but as individual countries

Annex II

- ✓Brazil
- ✓Cuba
- ✓Chile
- ✓Mexico
- ✓Australia
- ✓Finland
- ✓Luxembourg
- ✓New Zealand
- ✓Hungary
- ✓Ireland
- ✓China
- ✓Norway
- ✓India

Manufacturing site certification from ANMAT mandatory

1. Regulatory Overview

Argentina: basic requirements

To act as MAH and sell goods in Argentina is necessary:

- company responsible for placing a medicinal product and/or medical product on the Argentine market
- may be a local branch of the company or an Argentine partner.

Depending of the processes to be carried out in Argentina, the structural requirements of ANMAT vary from a Finished Product Warehouse and QC area to a whole manufacturing plant.

These requirements are based on regional directives (for all MERCOSUR members), which are based on cGMP (Current Good Manufacturing Practices)

1. Regulatory Overview

Argentina: basic requirements

Commercialization of pharmaceutical product in Argentina is subject to previous approval from ANMAT
Products authorized to be commercialized will be incorporated in the “Registro de Especialidades Medicinales” (REM) in the Ministry of Health.

Only laboratories with legal authorization issued by ANMAT (facilities, GMP certification, Qualified person, etc) can register and import products (pharmaceutical and medical)

The minimum requirements for a laboratory to register medicinal products are:
-Quality control lab with capabilities to analyze imported products
-Warehouse or Logistic Supplier Partner contract

While there is no specification of this in the legislation, usually areas as weighing room or secondary packaging area might be required.

Products may be manufactured in their own facilities or by a third party

For Imported Products, these minimum requirements must be adapted according to the Drug Substance, Product classification, selling volume, etc.

1. Regulatory Overview

Argentina: basic requirements

Drug Products (excluding Biological products)
Some definitions

Similar pharmaceutical product: same API or active molecular structure, same strength, same or similar dosage form, same administration route, same indication, same posology (different shape, size, excipients, shelf life, packaging material)

Evidence: Demonstrate the product is approved and commercialized

- ✓Certificate of Pharmaceutical Product from the Reference country/Country of Origin
- ✓Packaging material including batch number and expiry date
- ✓Copy of Vademecum

Bioequivalence: for some molecules (CNS, HIV, narrow therapeutic window)

First Batch Approval prior to commercialization: analytical transfer from Manufacturer, materials exchange and submission of results.

1. Regulatory Overview

Registration Alternatives in Argentina – Requirements

Framework	ManS certification	Evidence	CMC	Clinical
3º_Local	Local site	Similar in Argentina or Annex I	Manufacturing Analytical Stability In vitro equivalence	Proposed local Leaflet
3º_Annex II	Certified by ANMAT	Similar in Argentina and in CoO	Manufacturing Analytical Stability In vitro equivalence	Proposed local Leaflet
4º_Imported	Not required	CPP including GMP statement, shelf life, Mfg Site Packaging material	Not required (just Analytical Methods for local transfer)	Proposed local Leaflet
5º_Local	Local site	Not applicable	Manufacturing Analytical Stability	Preclinical, Clinical Proposed local Leaflet
5º_Imported	Certified by ANMAT	Not applicable	Manufacturing Analytical Stability	Preclinical, Clinical Proposed local Leaflet

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1. Regulatory Overview

Registration Alternatives in Argentina – Requirements

Framework	ManS certification	Evidence	CMC	Clinical
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3º_Annex II	Certified by ANMAT	Similar in Argentina and in CoO	Manufacturing Analytical Stability In vitro equivalence	Proposed local Leaflet
4º_Imported	Not required	CPP including GMP statement, shelf life, Mfg Site Packaging material	Not required (just Analytical Methods for local transfer)	Proposed local Leaflet
5º_Local	Local site	Not applicable	Manufacturing Analytical Stability	Preclinical, Clinical Proposed local Leaflet
5º_Imported	Certified by ANMAT	Not applicable	Manufacturing Analytical Stability	Preclinical, Clinical Proposed local Leaflet

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1. Regulatory Overview

Registration alternatives in Argentina – New products and Line extensions

Framework	Manufacturing	Origin	Evidence	Est. Timeline for approval
3º	Local	Argentina	Similar in Annex I or Argentina	8-12 months
3º	Imported	Annex II	Similar in Argentina and the same in manufacturing country	Depending on ManS certification
4º	Imported	Any country	Same in Annex I	6-10 months
5º	Local	Argentina	No similar neither in Argentina nor in Annex I	At least 12-18 months
5º	Imported	Any country	No similar in Argentina nor Annex I	Depending on ManS certification
5º	Imported	No Annex I & II	Similar in Argentina but not in Annex I	Depending on ManS certification

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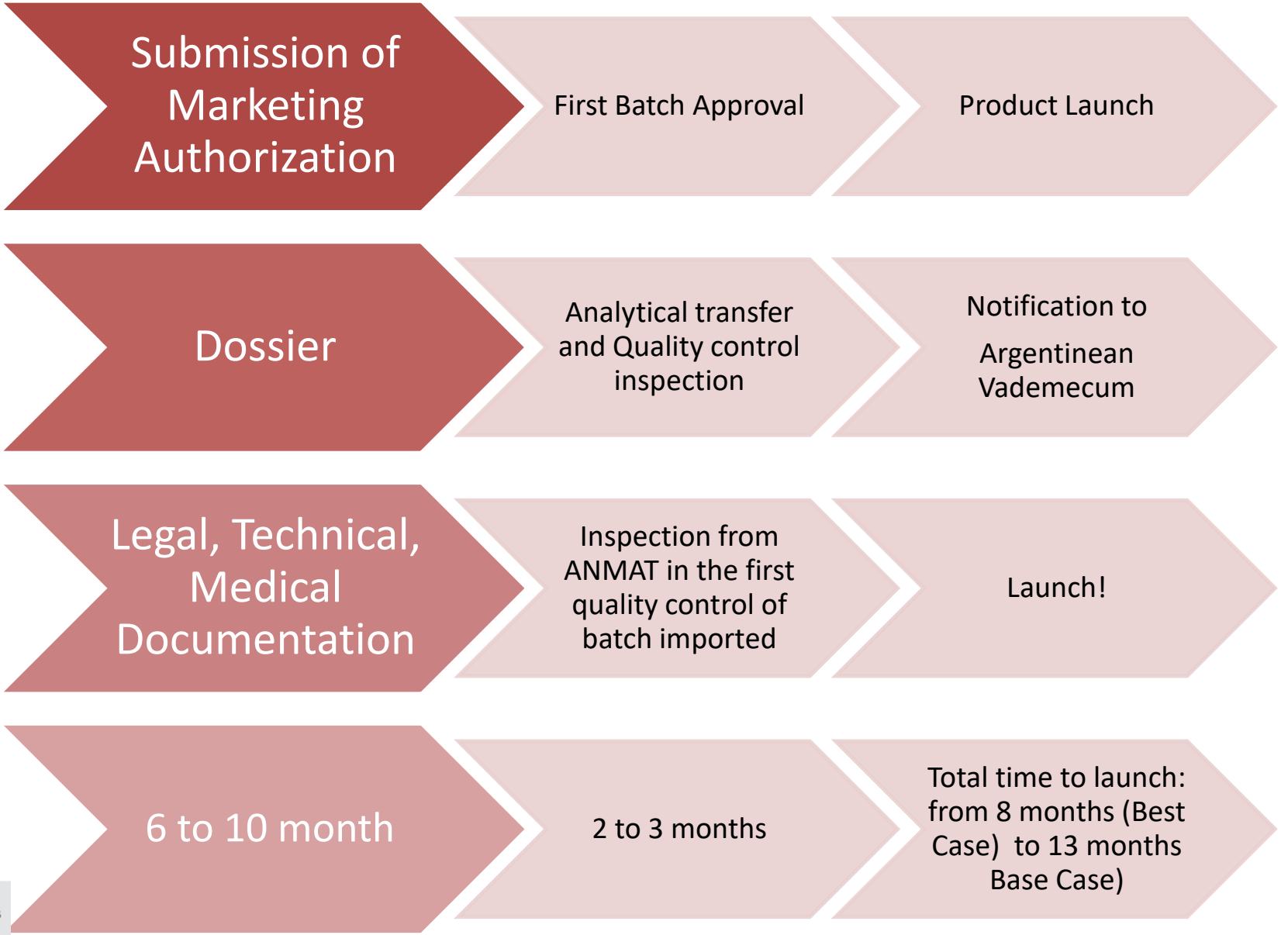
Full Registration process up to commercialization in Argentina: Art. 4th



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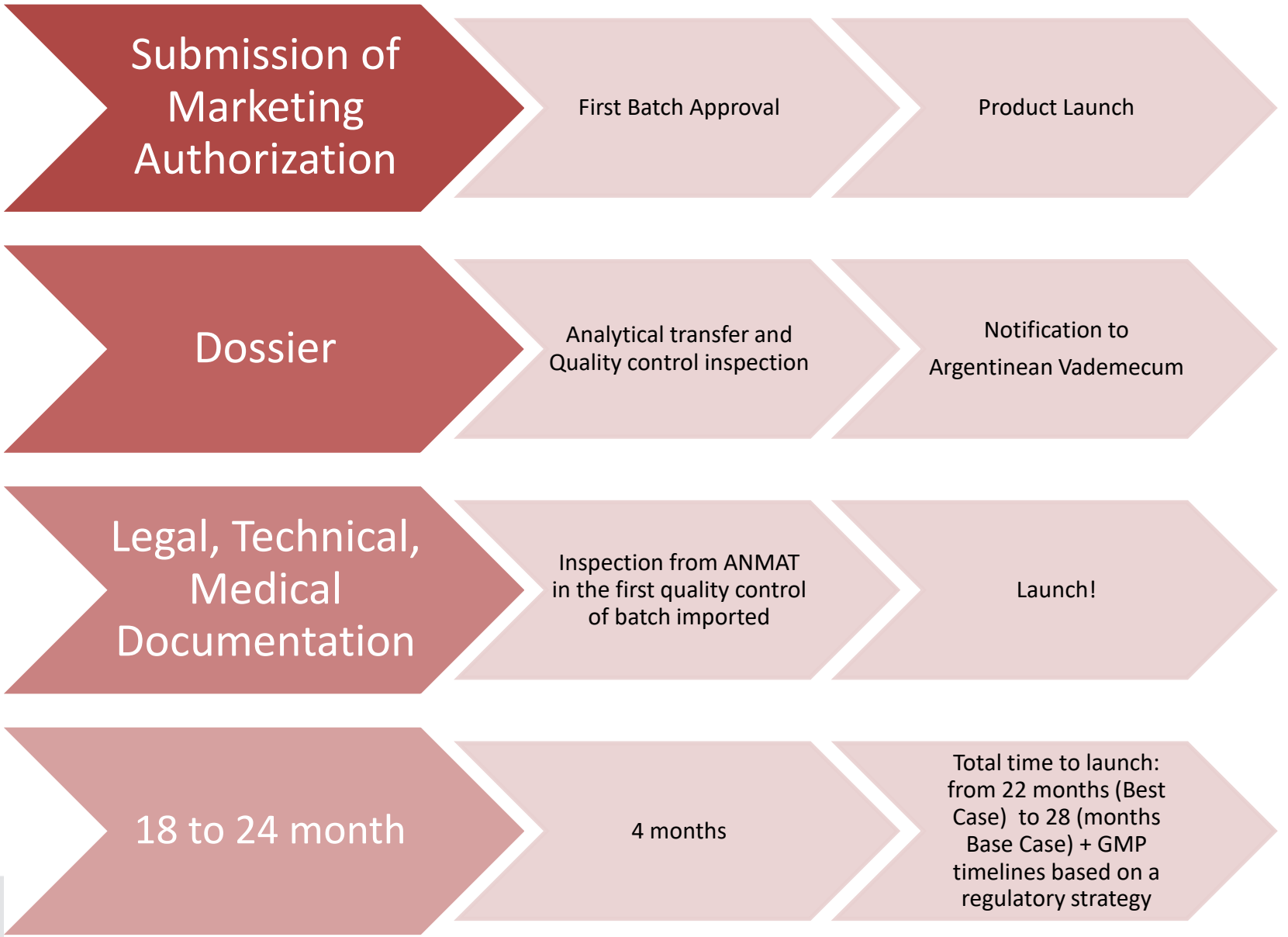
Full Registration process up to commercialization in Argentina: Art. 5th and Biologics

Pre requirement:

GMP Site certification

These timelines will affect the total project time.



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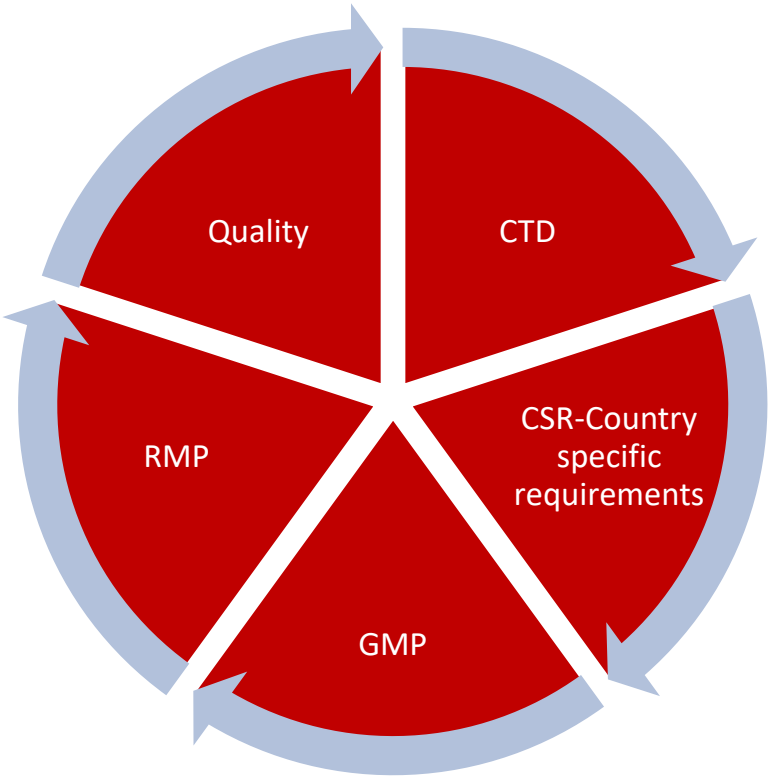
Registration requirements



- ANMAT Platform requires CTD dossier with customized organization. eCTD submission is not applicable.
- All Mod 3 documents must be submitted in Spanish and legal documents must be duly legalized or apostilled. Only Module 4/5 components could be accepted in English. High quality of translations is key.
- Applicable to no Annex I and no Annex II countries, like Korea

Registration and labelling deep-dive (1/2)

Argentina

General Procedures

General Requirements

- Commercialization of pharmaceutical products in Argentina is subject to previous approval from ANMAT
- Products authorized to be commercialized will be incorporated in the "Registro de Especialidades Medicinales" (REM) in the Ministry of Health
- Only laboratories with legal authorization (facilities, GMP certification, Qualified person, etc) can register products
- The minimum requirements for a laboratory to register products are:
  - To have a quality control laboratory / capabilities to analyze products to import and storage area
  - Warehouse or Logistic Supplier Partner contract
  - While there is no specification of this in the legislation, it must have areas to weighing room or packaging area
  - Products may be manufactured in their own establishments or by a third party
- Registration time for products already registered in Annex I countries (see below) can take between 6 to 9 months while for the rest, it can take from 12 up to 3 years
- Marketing authorization is valid for 5 years and renewals process is mandatory

Classification of country of origin

- The decree 150/92 which was later modified by the disposition 177/93 establishes a classification of countries depending on their sanitary condition
- Countries are classified as:
  - Annex I (or high sanitary vigilance countries)
    - United States
    - Canada
    - Japan
    - Austria
    - Belgium
    - Sweden
    - Germany
    - Denmark
    - France
    - Spain
    - Israel
    - United Kingdom
    - Italy
    - Netherlands
    - Switzerland
  - Annex II
    - Australia
    - Brazil
    - Finland
    - China
    - Norway
    - Mexico
    - Cuba
    - Hungary
    - Luxemburg
    - New Zealand
    - Chile
    - Ireland
    - India
  - Rest of the countries not mentioned in either Annex I or Annex II

Registration and labelling deep-dive (2/2)

Registration routes by type of products

Argentina

General products New Chemical Entities, Branded Generics	1	Art 3 • Products that will be manufactured in Argentina or that will be imported from countries included in Annex II that are similar to others already included in the REM • Products that will be manufactured in Argentina that are authorized for public consumption in at least one of the countries included in Annex I, even when this was a new product for the registry
	2	Art 4 • Products that are imported, authorized for consumption in at least one of the countries included in Annex I

	3	Art 5
		• Products that are an association or an innovation for containing a new drug in its composition or application or for offering an advantage in terms of therapeutic action or administration form
		  • Completely or partially locally manufactured products for which there are no
		  • Similar products registered and commercialized products
		  • Similar products authorized for public consumption in any country of Annex I
		  • Imported products not authorized for its consumptions in any of the countries of Annex I
		  • Not elaborated in any country in Annex II and with no similar product/s registered in Argentina
		  • No similar products in Argentina

Biologic & Biosimilar products	4	• Products that should be registered following this procedure are: hemoderivatives, products obtained from recombinant DNA, Monoclonal Anti Bodies; Biologic products obtained from biologic fluids or tissues of animal origin and other biological products; All Biosimilar products

New Chemical Entities/Innovative

Argentina

Marketing authorization process

Requirements for Marketing Authorization	Following Decree 150/92 and modifications the requirements are: • Registration form according to the product category, including registration fee payment documentation • General information of the product: Name, active ingredient, dosage form, pharmacological classification, sale condition, etc • Technical information dossier (module 3 from CTD, partial): control method, shelf life, manufacturing procedure following current GMP, bioavailability data. The content depends on product classification. • Labelling: packaging texts, patient information leaflet, prescription information (PI, PIL and Label) • CPP, if applicable • GMP certificate issued by HA • A reduced dossier could be submitted in case of product already registered in Annex I counties (art 4 D. 150/92)
Registration Process and Timeline	• Submission before ANMAT and different internal departments until final approval. Each department could request additional documentation by a deficiency letter. Art 4 registrations (annex I) could take from 6 to 10 months, while for the rest, it can take up to 3 years • After product is registered and to be allowed to commercialized the product in Argentina, the holder must submit the First batch Authorization (Disp. 5743/09) . Information of first batch importation/production and manufacturing/testing date, manufacturing procedure, quality control final tests and specifications are part of the dossier. The HA inspectors can decide whether to participate or not in the process, in the holder facilities (QC Lab). Finish Analytical transfer protocol is required, and authorization is then granted. This activity might take 2 to 3 months • After analytical information is presented to HA, ANMAT/INAME will approved the commercialization. Product will the included in HA vademecum and in traceability system if apply • Each subsequent batch imported or produced needs to be analyzed locally before local release

CPP	Certificate of Pharmaceutical Product
GMP	Man Site: Good Manufacturing Practices of the Manufacturing Site
CTD	Common Technical Document
PIL	Patient Information Leaflet

Generics and Branded Generics

Marketing authorization process

Argentina

Requirements for Marketing Authorization	• As there is no Generics regulation in place. Generics and Brand generics do not have additional requirements to get approval. • Submission should follow same regulation than NCE (Decree 150/92) but also fulfill Bioequivalence regulatrion. Bioequivalence Disp. 3185/99 • The extra requirement is to define if Bioequivalence studies are mandatory. Disp. 3185/99 was the basis to define the inclusion of this requirement and several resolutions gives details on the drug positive list, dosage forms, exceptions and deadlines for BE protocol submission and trial finalization. The holder of a MA with a listed API, should present studies of bioequivalence/bioavailability to maintain the MA active and commercialized. Should be compared to HA defined reference products (innovator if available, first registered in the country). The requirement also applies for all new registrations
Registration Process and Timeline	• Same as NCE registration

NCE	New Chemical Entity
API	Active Pharmaceutical Ingredient
MA	Marketing Authorization
HA	Health Authority

Biologic & Biosimilar products

Marketing authorization process

Argentina

Requirements for Marketing Authorization

Requirements for the registration of biological products (Regulation 7075/2011)

- Scope: hemoderivative products, products obtained by recombinant DNA, Monoclonal antibodies, biological medicines obtained from biological fluids or tissues of animal origin and other biologics
- Prerequirements: GMP certification of the manufacturing site of the API and biological product. Site Inspection by ANMAT is required in all countries, with ANMAT decision on exceptions
- Dossier including CTD data and summary of module 3, 4 and 5
- Module 3: information on Active pharmaceutical ingredients, intermediate products and finished products, manufacturing and quality
- Module 4 and 5: summary of the information
- Labelling: PI, PIL and Label
- The following products are excluded: Vaccines (Regulation 705/05), drug specialties (REM-Registry of Drug Specialties) of advanced therapies produced at a center under the authorization of the sanitary authorities and used in the same center, allergenic vaccines, blood, plasma and blood cells and its components

Biosimilar biological products (Regulation 7729/2011)

- Biocomparability studies
- It establishes specific requirements for recombinant APIs: Structure information, molecular description, of the primary, secondary, tertiary and quaternary sequence and site of glycosylation if pertinent. Among others, it requires relevant specifications to obtain macromolecule recombinant such as impurities related to the product or to the process and immunochemical identity
- It requires information inherent to the recombinant process: about master and working cell banks, determination of the genic sequence and cloning process among other requirements inherent to the process

For biologic obtained from recombinant DNA and Monoclonal Anti Bodies should present additionally to 7075/11, the requested information in Disp 3397/12 chapter I (DNA) and chapter I & II (monoclonal)

Registration Process and Timeline

- The dossier according to the requirements and corresponding fee should be submitted
- It will be review technically mainly by the Biologic Department in ANMAT, also in the usual relevant departments of the administrative process
- Approval timeline is not consistent, might be from 12 months up to 2 years

Lifecycle
Post approval changes

- Renewal, administrative submission every 5 years for synthetics products, variable dossier for biological products
- Minor Variations, notification (2 to 3 months, positive silence)
- Major Variations, approval prior implementation (diverse timelines and requirements)
- Labelling, approval prior implementation (usually 6 months for approval, clinical supportive data)
- Urgent Safety Restrictions, notification

Authority Fees

• New product Art 4	~ US 370
• New product Art 5	~ US 820
• New product Biologic	~ US 1250
• 1st Batch ~(205000)	~ US 1700
• RMP ~ (18000)	~ US 150
• Inspection GMP abroad	~ US 6600
	+ air tickets and per diem

Note: these figures are estimations based on actual List from ANMAT fees (which is updated due to inflation rate, several times in the year) and actual currency exchange rate. To be finetune at the time of application.

Registration process in Argentina Medicinal Products

KEY ELEMENTS TO REGISTER IN ARGENTINA

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Basic concepts

- Marketing Authorization Holder (MAH): pharmaceutical company that will hold the Marketing Authorization (MA), duties and responsibilities, independently of its location. The mother company from other territory may act as MAH in Argentina with a Local Representative (L-Rep) acting on its behalf. It can be a Manufacturing company or a Business company. All of them shall be related in corresponding agreements (representation, manufacturer, distribution, etc)

  Example:

  - The MAH of CPP of the reference country is usually the MAH appointed with the contracts
  - In case of license agreement, the appointed Licensee may act as MAH

- Local Representative company (L-Rep): Argentinean company, legally established in the country and duly authorized by ANMAT to import, control, release and sell pharmaceutical products

The L-Rep is local responsible and the QP and Legal representative are the liable persons for its action

The L-Rep might be:

- Local Affiliate of Mother company
- Hosting company- only regulatory purpose
- Local Company (distribution agreement)

Local ANMAT requirements for selling pharmaceutical products

Marketing Authorization Holder: Mother company
Local Rep by Hosting or Local business partner

2 steps approach:

- First step: a Hosting contract for regulatory purpose only, as Local Rep for the Mother company
- Second step: Business partner (medium or long term), after Contract, change in Local Rep for commercialization

This approach gives freedom to negotiate commercial contract with Local business partner while product is being registered in Argentina

QC, QP, QA, RA

Importation

Warehouse

Q system according to requirements, both Hosting and Business partner

- ANMAT inspection and approval
  The company will be authorized to import after registration process

- Warehouse service can be outsourced

Product registration

Registration via Art 4th

6 to 10 months for approval

Art 5th and Biological-Biosimilar

18 to 24 months for approval

First Batch Approval 2 to 4 months

Start up scenarios

Regulatory Hosting

- Mother company is MA holder
- Locally represented by a Hosting (pharmaceutical company acting before ANMAT) until MA is granted.
- **This strategy allows the company to keep full track of regulatory process, not opening the information, and use the 8 to 10 months of the registration process to close negotiations with the local Representative (commercial contract)**

Commercial license to local Pharmaceutical company

- Mother company might be MAH or relay on Partner
- Company authorized by ANMAT as importer of medicinal products with all prerequisites
- Distribution or CoMarketing or CoPromotion agreement, according to business model

Affiliate

- Setting up an Argentinean subsidiary (model) legal and taxes
  - Authority Fees: Importer company certification ~ US 3600
- Minimum requirements: QC and Warehouse
- Different Business models to be evaluated

Start up scenarios

Regulatory Hosting

- Annual cost of Hosting fees (per product USD 9000 to 15000)
- Since importation, % (negotiation with hosting)
- Service costs: QA, RA, PV (monthly fee, depending on the product expenses and equipment, API, impurities, etc)

Commercial license to local Pharmaceutical company

- Different % depending on Distribution or CoMKG or CoPromotion agreement

Affiliate

- Investmente: usually non less than 1.5 to 2 Mio USD)
  - own full QC Physico-Chemical and Microbiology
  - Warehouse might be in logistic operator facilities
  - QP, QPV, RA, QC, QA functions

Start up scenarios

Regulatory Hosting

Pros

- Saving time to launch the products. This strategy allows the company to keep full track of regulatory process, not opening the information, and use the timeframe of the registration process to close negotiations with the local Representative (commercial contract)

Cons

- Change in Local Representative will be needed
- First batch approval recommended to be done by the new Rep

Commercial license to local Pharmaceutical company

Pros

- Only one step in the registration and contractual issues

Cons

- Full Commercial negotiation finalized to initiate regulatory activities

Affiliate

Pros

- Own company, resources and management of information and business

Cons

- High cost for start up
- Monthly Costs of structure

Registration process in Argentina Medicinal Products

TAKE AWAY MESSAGES

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TÜVRheinland CERTIFICADO
Sistema de Gestión ISO 9001:2015
www.tuv.com ID 9000004695

Key steps for Registering in Argentina

Define a local Representative

- Due Diligence
- Legal agreement
- Quality Agreement
- Access to local requirements: QC lab & warehouse through a local company

Products registration

- CTD/CSR and reference approval availability
- GMP status of manufacturers
- RMP and local Pharmacovigilance system in place
- Local equipment and facilities readiness /Method transfer planning

MAA APPROVAL

- License validity: 5 years
- Artworks development
- Local /Global Serialization implementation (Global trade importation number)

Operations activities

- Technical support for Method transfer/Local training
- Agreement of testing proposal
- Method transfer execution
- First batch importation
- First Batch inspection for local release

Effective Authorization of commercialization

- ANMAT Approval Notice
- Local batch release to the market
- Local Vademecum inclusion

Registration of Medicinal Product in AR

Steps

Launching imported Products

Pharma Company, Quality control lab and Warehouse duly authorized for product importation

anmat
Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

Prerequisite
- Mfg Site Certification (GMP)

First step:
- Registration of Product
- Risk Management plan

Second Step
- First Batch Approval to be done by the hosting or the final commercial partner

Launch AR

MARISA CARCIONE

Pharmacist UBA
Post-Graduation in Quality Assurance in the Pharmaceutical Industry UBA
MBA IAE
RAPS member

PROFESSIONAL EXPERIENCE

More than 25 years of experience in the pharmaceutical industry in Latin America.
Main responsibilities: leadership and management of Regulatory Affairs teams in multinational and regional companies, strategy development and operation of new registrations and post-marketing activities of drugs , medical products, cosmetics and dietary supplements in Latin America.

iprat

OCTOBER
2014 present

Managing Partner
IPRAT consulting company for Latin America

Main functions: Business development, Regional Regulatory Strategy definition for new products, clinical trials authorization, distributors identification and evaluation, product registration and life cycle management maintenance, labelling.
Start-ups and alternatives of start of operations in the region, regulatory quality system and teams training.

Boehringer Ingelheim

BS.AS., OCTOBER
2006 -2014

Drug Regional Regulatory Affairs Manager for Latin America

In charge of 19 countries with a team of about 65 members.
Team leadership and training, talent management.

Responsibilities: Innovative drug registration strategy and product maintenance of the LATAM portfolio.
Clinical trials applications.
Regulatory Intelligence.

GERMANY, SEPTEMBER
2004 -2006

Drug Regulatory Affairs Manager for Regional Coordinating Centres

International activities: Clinical trial application submission in EU, Company Core Data sheet implementation and PSUR EU birthday harmonization initiative.
Responsible for Arabian Countries regional strategy, regional teams supports.

BS.AS., OCTOBER
2001 -2004

Drug Regulatory Affairs Manager for Argentina, Uruguay and Paraguay

BS.AS., OCTOBER
Before 2001

Analyst, Responsible for Regulatory Affairs in
Schering Plough
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Back up information

A few Key Elements to be considered

Local Representative

- Legal entity for filing, duly authorized
- Local affiliate or Local Rep to act supporting Mother company as MA holder
- QP for Q System implementation

Reference

- High sanitary vigilance agency approval for commercialization
- Technical information based on approval

Manufacturer

- GMP
- Certification from agencies as basis (European, FDA, JP, etc)

A few Key Elements to be considered

Dossier

- Dossier (partial from CTD), reduced
- Labelling
- RMP

Language

- Spanish

Legal Reg Docs

- CPP (apostilled)
- GMP (apostilled)
- POA (apostilled)

Basic Regulatory decision:

How to register a Small Molecule, OD designated, for a Rare disease, to be imported in Argentina, with CPP from EU (Ref Co) and Phase III finalized?

a. Registration under special conditions

Regulation
Disp.4622/2012, Circ. 3, 2018

Procedure for the registration of drug products in AR for the prevention, diagnosis and treatment of rare or serious diseases (listed in Annex 1)

Conditions: New API not registered in AR, Rare disease designation, Approved in reference country (EU, US) with RD designation, Phase III not available or finalized but particular characteristics in country of origin-reference.

b. Registration as usual pharmaceutical product

Decree 150/92, Art 4th

Product imported from Annex 1 country

Commercially available and with CPP from Annex 1 country

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