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SJ 25/01/2019

Anvisa – Brazil's National Health Surveillance Agency

Disclaimer

My consideration are personal positions and It not represent the official position from Anvisa or Brazilian Government.

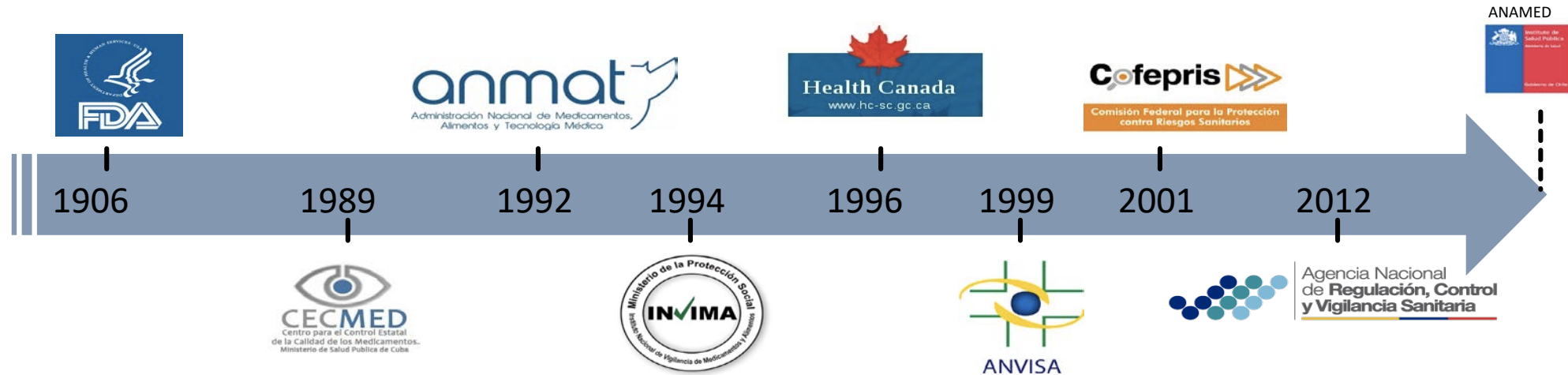
I don't have any relationship with Brazilian Government in the moment.



Medicines regulation in the Americas

- For the majority of the countries, medicines regulation is a contemporary issue.
- There are dedicated structures for regulation of medicines in practically all the countries of the region linked to the Ministry of Health.
- More and more countries have been understanding that the medicines regulatory system is a central component of the health system.
- The biggest pharmaceutical market are located in the more regulated countries.

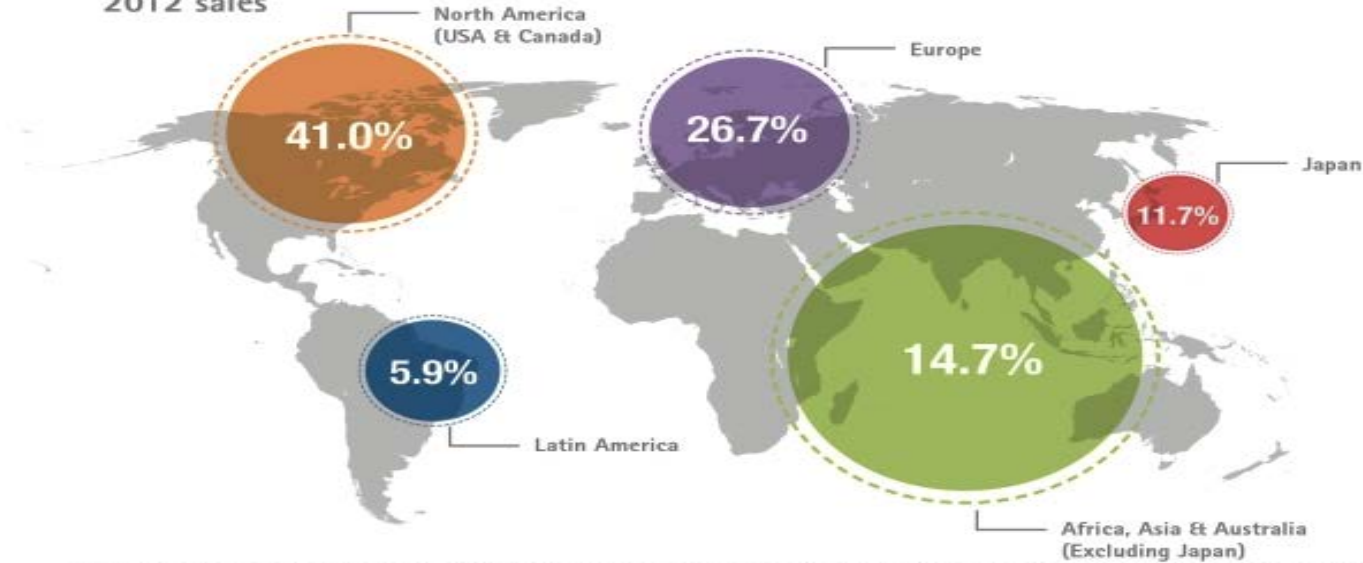
Regulatory Authorities in the region



In the last 30 years, national agencies have been created with reference to the US FDA

Breakdown of the World pharmaceutical market

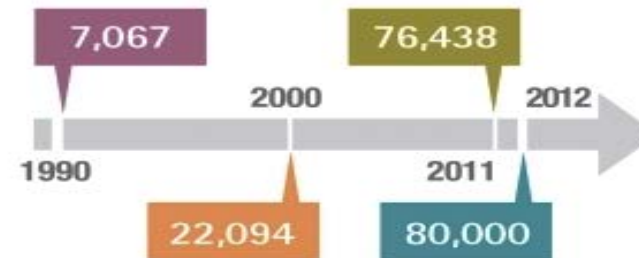
2012 sales



In 2012 Europe's pharmaceutical trade surplus was estimated at

€80 BILLION

European Pharmaceutical Industry Trade Balance



Ranking of Global Pharmaceutical Market

Source: IMS Health, Market Prognosis, September 2015

Appendix 1 - Global Country Rankings

Exhibit	2010	Index	Exhibit	2015	Index	Exhibit	2020	Index	
1	U.S.	100	1	U.S.	100	1	U.S.	100	
2	Japan	22	2 	China	27	2	China	30	
3 	China	19	3 	Japan	18	3	Japan	14	
4	Germany	11	4	Germany	10	4	Germany	9	
5 	France	10	5	France	8	5 	Brazil	8	
6	Italy	7	6 	U.K.	7	6	U.K.	6	
7	U.K.	6	7 	Brazil	6	7 	Italy	5	
8 	Spain	6	8 	Italy	6	8 	France	5	
9	Canada	6	9	Canada	5	9 	India	5	
10 	Brazil	5	10 	Spain	4	10 	Canada	4	

Anvisa



- First Regulatory Agency of the social area in Brazil -created by Law No. 9,782, of January 26, 1999;
- Governmental regulatory body with independency under special regime, liaison to the Ministry of Health;
- Coordinator of the National Health Surveillance System (SNVS);
- Performance goals agreed with the Ministry of Health and regulated under the Management Agreement;
- 83 Federal Posts of Health Surveillance in Brazil – border and import control.
- Staff: More than 3000 workers (400 MD and 100 PhD) linked with Federal Administration.

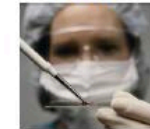
Responsibilities of Anvisa

Table 1 Areas regulated by ANVISA

- Blood and blood products
- Coordination of Brazilian Health Surveillance System
- Cosmetics
- Drugs
- Generic drugs
- Food
- Health services (e.g., hospitals)
- Drug Price regulations (part of a Committee)
- Medical devices
- Pharmacovigilance
- Ports, airports, and borders (health-related issues and products)
- REBLAS – Brazilian network of analytical laboratory
- Sanitizing products
- Tobacco
- Pesticides (also regulated by environmental agency IBAMA and by Ministry of Agriculture and Livestock)



Food



Health services



Post-marketing surveillance



Cosmetics



Drugs



Marketing control



Sanitizing Products



Medical Devices



Ports, airports and frontiers



Tobacco



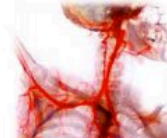
Laboratories



International



Toxicology (pesticides)



Blood, Cells, Tissues and Organs



Market regulation

Responsibilities of Anvisa

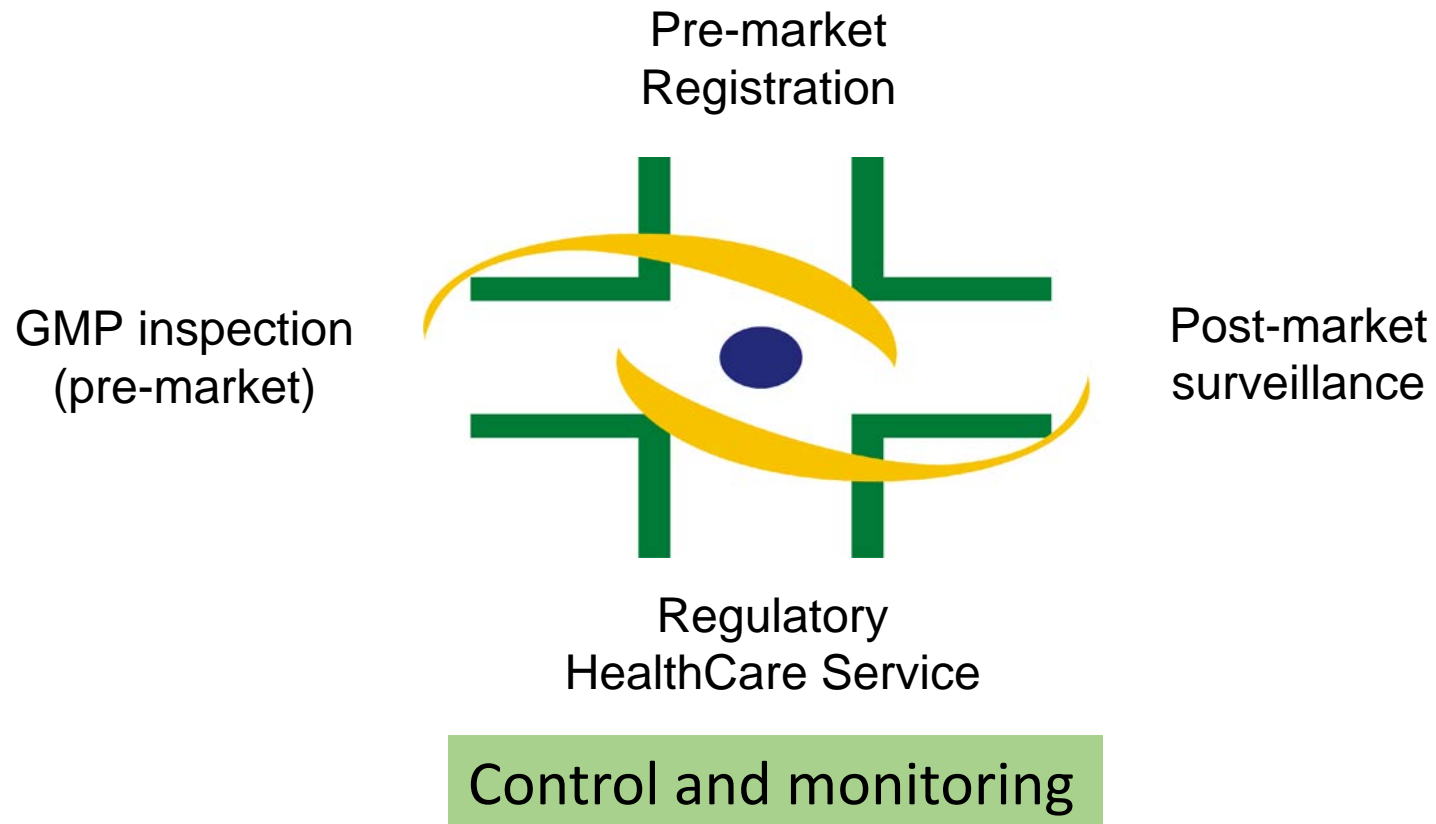
- Health products: 9,256 companies , and 1,774 producers
- 80.000 pharmacies
- 90 public health laboratories - LACEN
- 33,735 diagnostic imaging services
- 106,366 diagnostic imaging equipment (in use)
- 6,280 hospitals
- 4,166 haemotherapy services



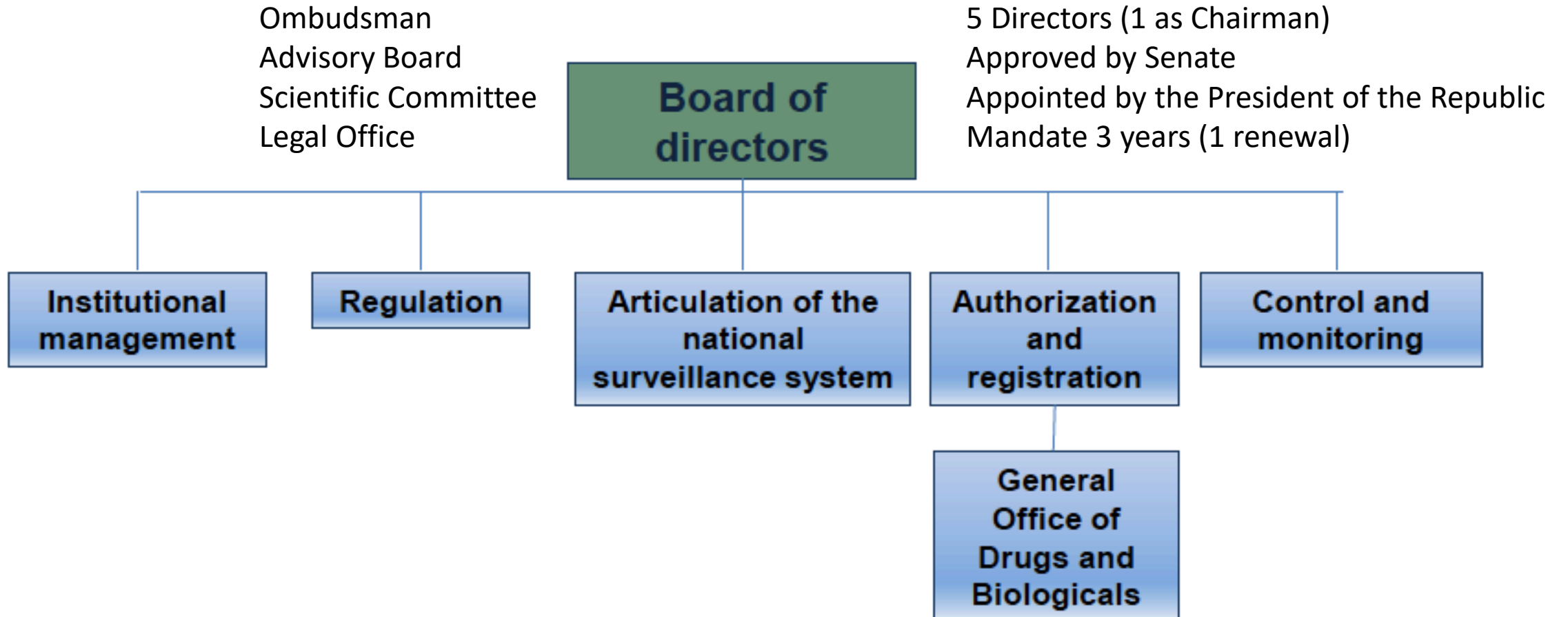
The Control System

Regulation

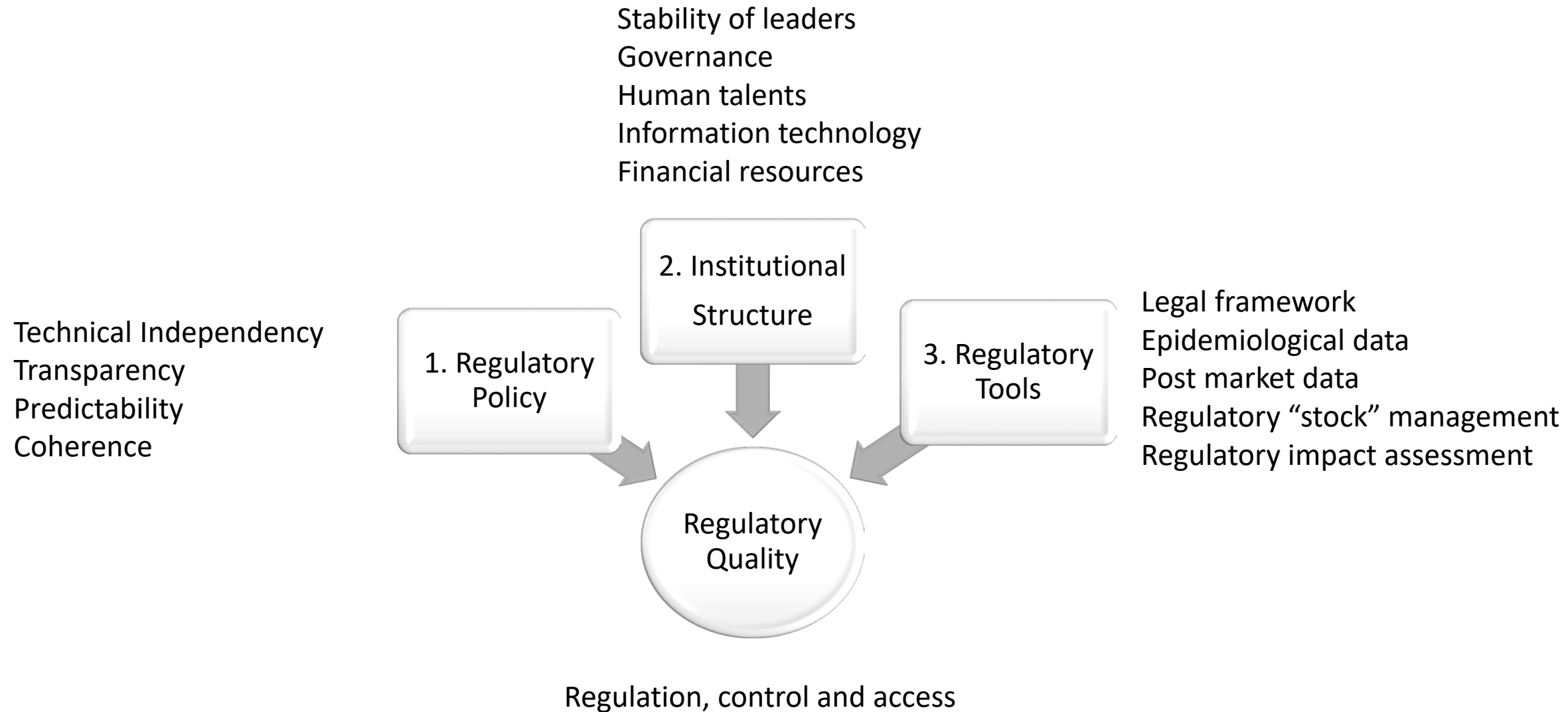
Articulation of the National Surveillance System



Organization by process (simplified view)



How to increase regulatory quality?



Challenges

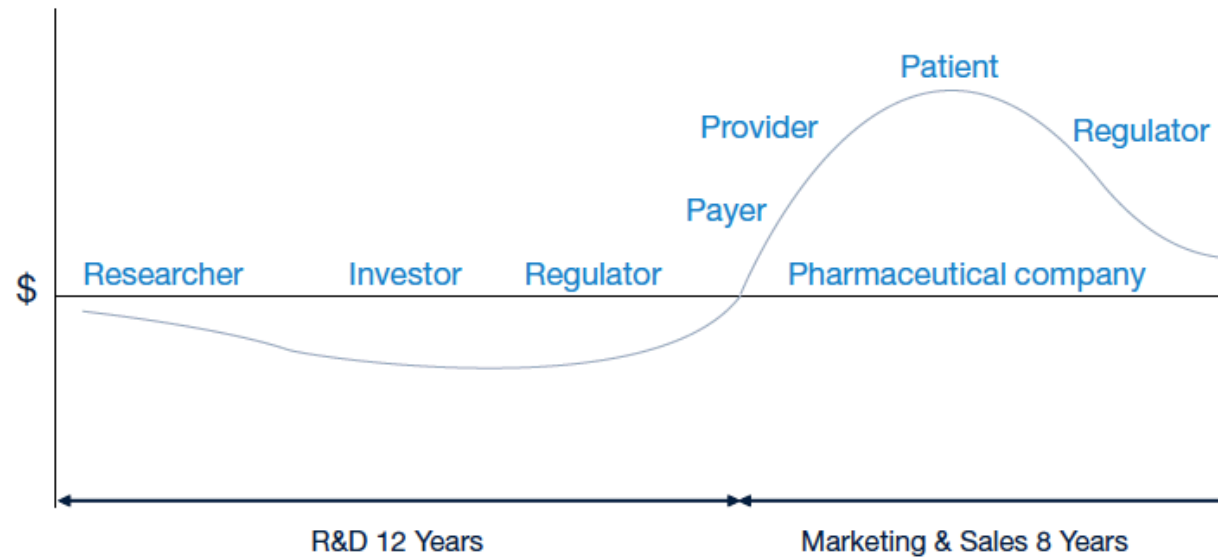
- The world is in constant and rapid change. The scenario changes every time.
- Social and demographic change
- Increased pressure on health protection
- Requirements for more rigorous control on the spending and efficient management of financial resources;



Challenges

- Increased complexity and volatility of technologies facing new and growing risk exposure situations.
- Lack of interest on “mature” products (old and new neglected diseases)

Figure 7: Seven stakeholders are involved in deciding whether a new product is innovative



Source: PricewaterhouseCoopers





Challenges

- Competitive environment for innovation (rare diseases, cell therapy, oncologic immunotherapy)
- Need for answers in reasonable and increasingly short time



Challenges

- Conclusion of the biosimilars cycle.

EMA 	FDA 	Health Canada 	Anvisa 
Individual countries in EU have adopted varying policies	US law allows FDA to designate a product as interchangeable. However, decisions about substitution by the pharmacy are governed by state laws	Health Canada doesn't declare interchangeability for biosimilars	Interchangeability is under discussion. Currently, Anvisa only considers interchangeability after the review of the clinical data obtained for this purpose

Challenges

- Economic growth and expansion of regulated markets;
- Globalization of production chains and needs for global protection.



Opportunities

- Pan American Health Organization (PAHO) has been a privileged space to discuss the role of medicines regulations and health in the Americas acting through two main initiatives:
 - Pan American Network for Drug Regulatory Harmonization (PANDRH)
 - System of evaluation of national regulatory authorities for medicines



Opportunities

Pan American Network for Drug Regulatory Harmonization



- PANDRH was officially recognized by the 42nd Directing Council of the in September 2000.
- PANDRH includes the drug regulatory authorities of all PAHO member states, representatives of the regional pharmaceutical industry associations, academia, consumer groups, professional associations and representatives from the five sub-regional trade integration groups within the Americas such as the ANDEAN COMMUNITY, CARICOM, CCMA, MERCOSUR and NAFTA.
- PANDRH's role includes technical guidelines, regulatory processes and the strengthening of national regulatory agencies through harmonization of processes and standards to improve drug quality and quality assurance

Opportunities

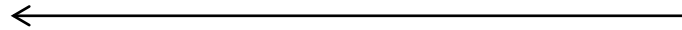
Regional Reference Authorities for medicines CD50.R9 (January, 2018)



2017



2015



2015



2012



2010



2010



2010



2009

Opportunities

- ICH (The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use)
- 10 Regulatory members
- 05 Industry members
- November 2016 - Anvisa became member
- Anvisa has promised to implement 05 guides until November 2021.
- Implemented
 - E2A: Clinical safety data management: definitions and standards for expedited reporting
- Under implementation:
 - E2B
 - E2D
 - M4
 - M1

Opportunities

- PIC/S (Pharmaceutical Inspection Co-operation Scheme – 54 countries)
- MDSAP (Medical device single audit program – 07 countries)

Table 1. Number of inspections per country and conclusions. Countries of which the number of inspections was fewer than five are grouped as “other.”

	Number of Inspections	Percentage	Satisfactory (%)	On Demand (%)	Unsatisfactory (%)
India	39	15.29%	25 (64.10%)	8 (20.51%)	6 (15.38%)
United States	37	14.51%	28 (75.68%)	5 (13.51%)	4 (10.81%)
France	23	9.02%	7 (30.43%)	10 (43.48%)	6 (26.09%)
Germany	22	8.63%	15 (68.18%)	7 (31.82%)	-
United Kingdom	13	5.10%	9 (69.23%)	3 (23.08%)	1 (7.69%)
Ireland	12	4.71%	7 (58.33%)	2 (16.67%)	3 (25%)
Italy	12	4.71%	10 (83.33%)	1 (8.33%)	1 (8.33%)
Switzerland	11	4.31%	7 (63.64%)	3 (27.27%)	1 (9.09%)
China	10	3.92%	5 (50%)	3 (30%)	2 (20%)
Spain	9	3.53%	6 (66.67%)	2 (22.22%)	1 (11.11%)
Austria	5	1.96%	4 (80%)	1 (20%)	-
Belgium	5	1.96%	3 (60%)	2 (40%)	-
Canada	5	1.96%	4 (80%)	1 (20%)	-
Denmark	5	1.96%	3 (60%)	1 (20%)	1 (20%)
Mexico	5	1.96%	3 (60%)	2 (40%)	-
Other	42	16.47%	24 (57.14%)	12 (28.57%)	6 (14.29%)
Total	255	100%	160 (62.75%)	63 (24.71%)	32 (12.55%)

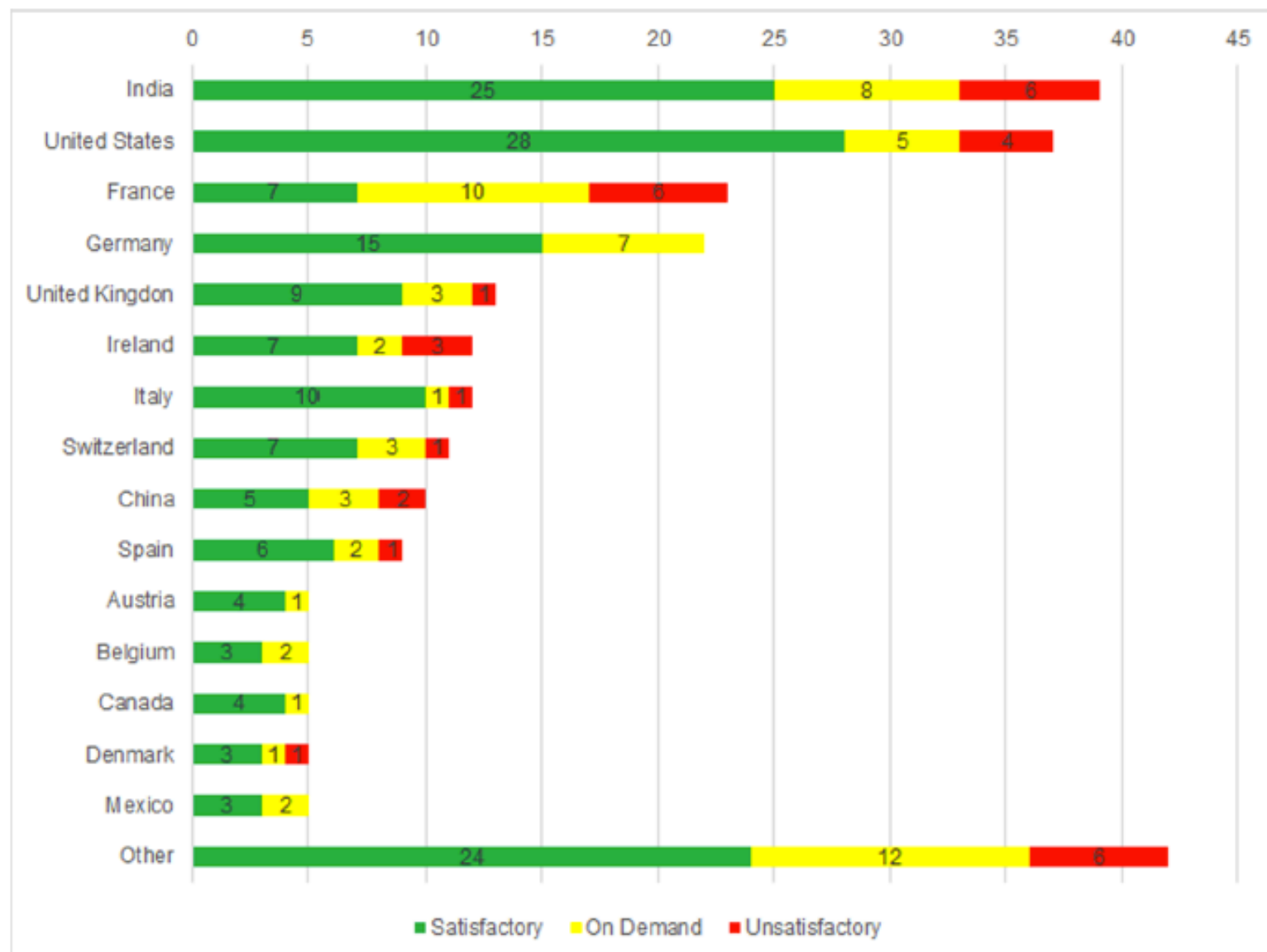


Fig 1. ANVISA inspections per country and the respective company classification.

Thank you!

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