GaBI Educational Workshops

3rd Colombian Educational Workshop on
REGULATORY ASSESSMENT OF BIOSIMILARS

30 April 2019, Hilton Bogotá, Colombia

Aurelio Enrique Mejía Mejía, MSc, Colombia

- Director of Medicines and Health Technologies, Ministerio de Salud y de Protección Social Colombia

GaBi
GENERICS AND BIOSIMILARS INITIATIVE
Building trust in cost-effective treatments

PPCI
Pro Pharma Communications International

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Colombia's biological/biosimilar regulation: a year after its implementation

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Colombia's biological/biosimilar regulation: a year after its implementation

La salud es de todos

Minsalud

30 April 2019

Aurelio Mejia Mejia
Dirección de Medicamentos y tecnologías en Salud

Contents

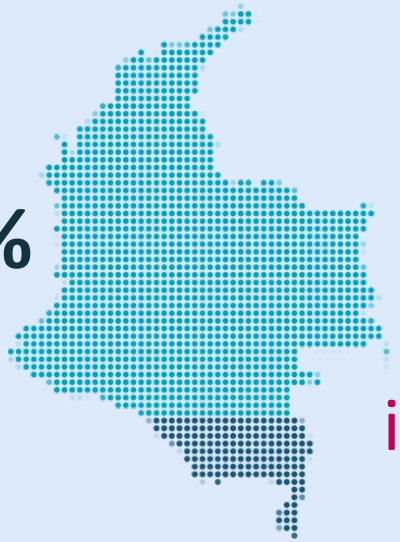
1. Context

Colombia is improving its healthcare system performance

Coverage

More people and technologies

23.7%
1993



94.6%
2019

From an explicit to an implicit benefits package

NEW
TECHNOLOGIES

Most for
Cancer
Arthritis

Source: Cifras del aseguramiento en salud con corte marzo de 2019. Available in: https://www.minsalud.gov.co/proteccionsocial/Paginas/cifras-aseguramiento-salud.aspx

Regulating the price of medicines AND devices

International Reference Pricing. The system regulates medicines with limited market competition regardless of whether they are included or excluded from the health benefits plan.

Increasing competition in the market

The government has passed legislation to increase competition in the market of biologic drugs by allowing **an abbreviated path for the marketing approval of biosimilars**. This legislation still needs to be implemented.

Health Technology Assessments

The government created the **Health Technology Assessment Institute-IETS** which at present has evaluated all the medicines recently included in basic healthcare plan.

ACCOMPLISHMENTS

The government has focused on the implementation of some of these strategies with special emphasis on the strategies targeting the supply of medicines.

NEED FOR A PARTICULAR REGULATION FOR BIOLOGICAL MEDICINES

Technics

Development of biotechnology

Updating of biologics medicines approval regulation.
Increasing applications for new or generic biological medicines (expiration of patents).

Legal

Reforms in the health system and public policies

Pharmaceutical policies

Sustainability

Biotechnology products are the fastest growing segment of the pharmaceutical market in Colombia

↑30%

Source: ABECÉ medicamentos biotecnológicos. Available in:
https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/abc-biomedicamentos.pdf

2. Decree 1782/2014

Guideline and procedure to pharmacological and pharmaceutical assessment

REPÚBLICA DE COLOMBIA

MINISTERIO DE SALUD Y PROTECCIÓN SOCIAL

DECRETO NÚMERO 1782 DE 2014

18 SEP 2014

Por el cual se establecen los requisitos y el procedimiento para las Evaluaciones Farmacológica y Farmacéutica de los medicamentos biológicos en el trámite del registro sanitario

EL PRESIDENTE DE LA REPÚBLICA DE COLOMBIA

Approval pathways

Full dossier. Required for new biotechnology

Evidence of efficacy and safety in animals and human

Comparability pathway. Required for biosimilars not sufficiently known.

It must be demonstrated that the product is highly similar to the reference medicine

Abbreviated comparability pathway. Required for widely known biosimilars

Must show similarity in quality attributes and PK / PD

Regardless of the pathway, all requests must include information on nine aspects:

1. Manufacturing process and production place
2. Expression system
3. Biological identity
4. Potency
5. Physicochemical Properties
6. Biological Activity
7. Purity
8. Immunogenicity
9. Risk management plan

Approval pathways

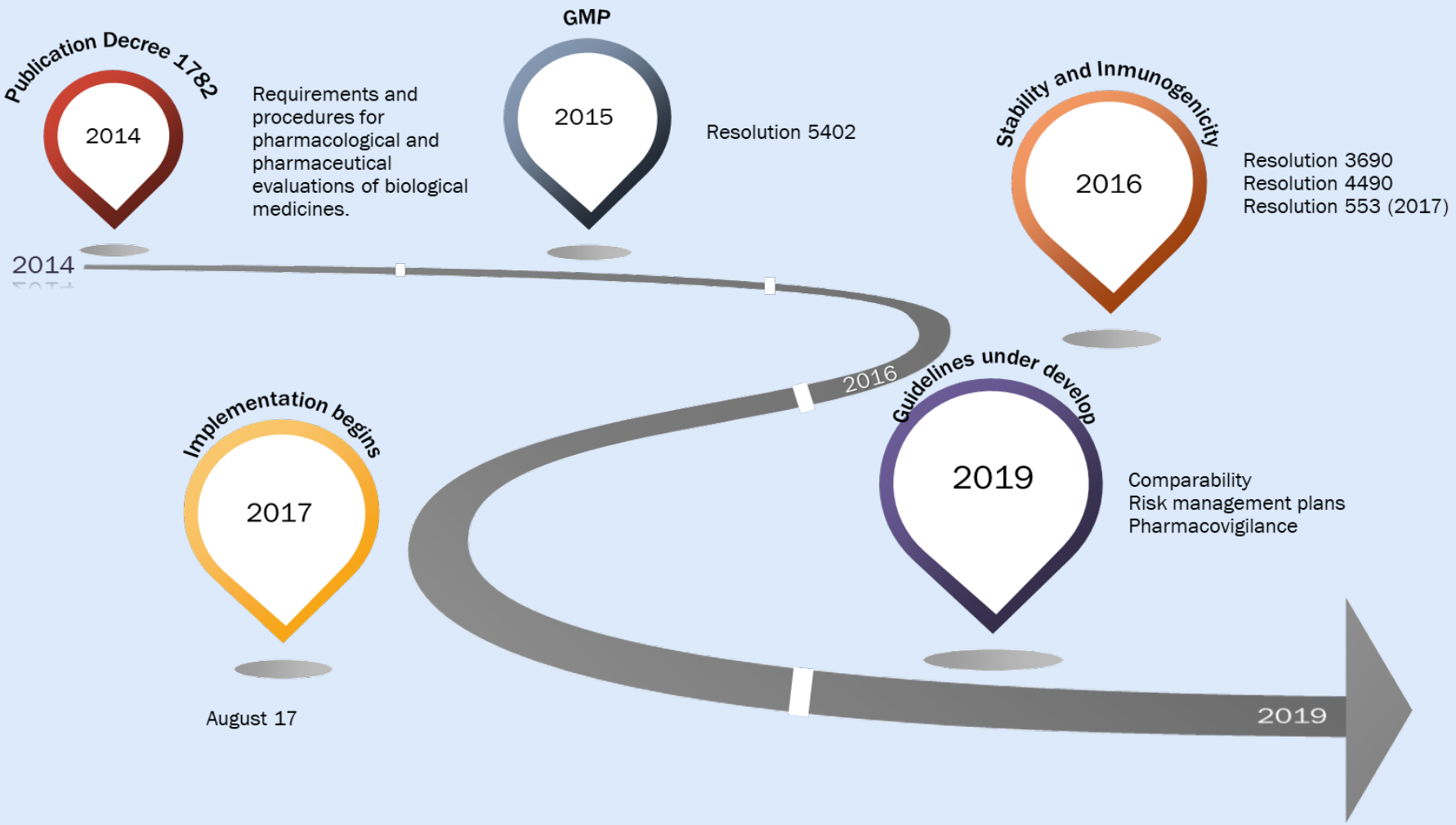
Pharmacological assessment:
Privative function of the Special Chamber of Drugs and Biological Products of Invima

- **Full dossier**
- **Comparability pathway**
- **Abbreviated comparability pathway**

=

- Quality
- Efficacy
- Safety

3. Implementation



Ministerio de Salud y Protección Social de Colombia

Top 10

Medicines with the biggest number in sales (2017)

4 MABs

8 Biological medicines

10% total sales of medicines

Medicamento	Principio activo
Humira - 50 mg / 0.8 ml - Solución o suspensión inyectable x 2 ✓	ADALIMUMAB
Avastin 100 mg - Solución o Suspensión Inyectable x 1 ✓	BEVACIZUMAB
Herceptin 440 mg - Polvo Reconstituir a Solución o Suspensión Inyectable x 1 ✓	TRASTUZUMAB
Mabthera 500 mg - Polvo Reconstituir a Solución o Suspensión Inyectable x 1 ✓	RITUXIMAB
Enbrel 50 mg - Polvo Reconstituir a Solución o Suspensión Inyectable x 4 ✓	ETANERCEPT
Zytiga - 250 mg - Tableta o cápsula x 120 ✗	ABIRATERONA
Lantus 300 U - Solución o Suspensión Inyectable x 1 ✓	INSULINA GLARGINA
CEREZYME - 400 UI - Polvo para reconstituir a Solución o suspensión inyectable x 1 ✓	IMIGLUCERASA
Meronem 1000 mg - Polvo Reconstituir a Solución o Suspensión Inyectable x 10 ✗	MEROPENEM
Forteo 600 Vial - Solución o Suspensión Inyectable x 1 ✓	TERIPARATIDE

Source: SISMED Bulletin 2018

Ministerio de Salud y Protección Social de Colombia

Decree 1782/2014

Begins its implementation

Previous Decree

3 / 8

Medicines with the biggest number in sales (2017)

- Etanercept
- Glargina
- teripartide

Source: SISMED

License application of biological medicines

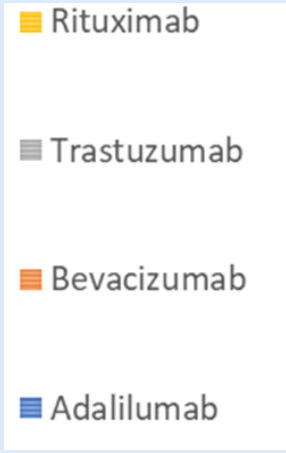
New and biosimilar vaccinates, blood derivatives, monoclonal antibodies, recombinant proteins

4 MABs

with the biggest number in sales (2017)

Could have biosimilars in the country soon.

Have biosimilars approval from other agencies (EMA-FDA).



2017

August

Impact

Implementation Decree 1782 de 2014

Therapeutic options

Competition

- Sustainability and the efficiency of the health system
- Improve the availability of biological medicines
- Increase of the number of patients who will be able to gain of the treatments, facilitating the access

THANK YOU

For your attention