GaBI Educational Workshops

30 April 2019, Hilton Bogotá, Colombia

3rd Colombian Educational Workshop on
REGULATORY ASSESSMENT OF BIOSIMILARS

Johanna Andrea García Cortes, MSc, Colombia

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

PPCI
Pro Pharma Communications International

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Biosimilar regulation in Colombia: one year later

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La salud es de todos

Minsalud

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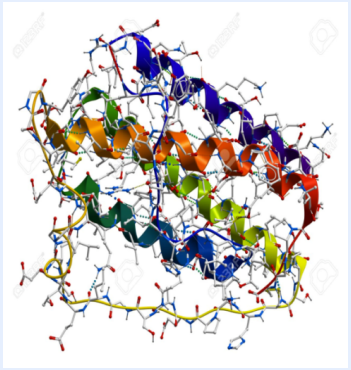

Biosimilar Regulation in Colombia – one year after its implementation

Johanna Andrea García Cortes, MSc
Biological Products Cordinator

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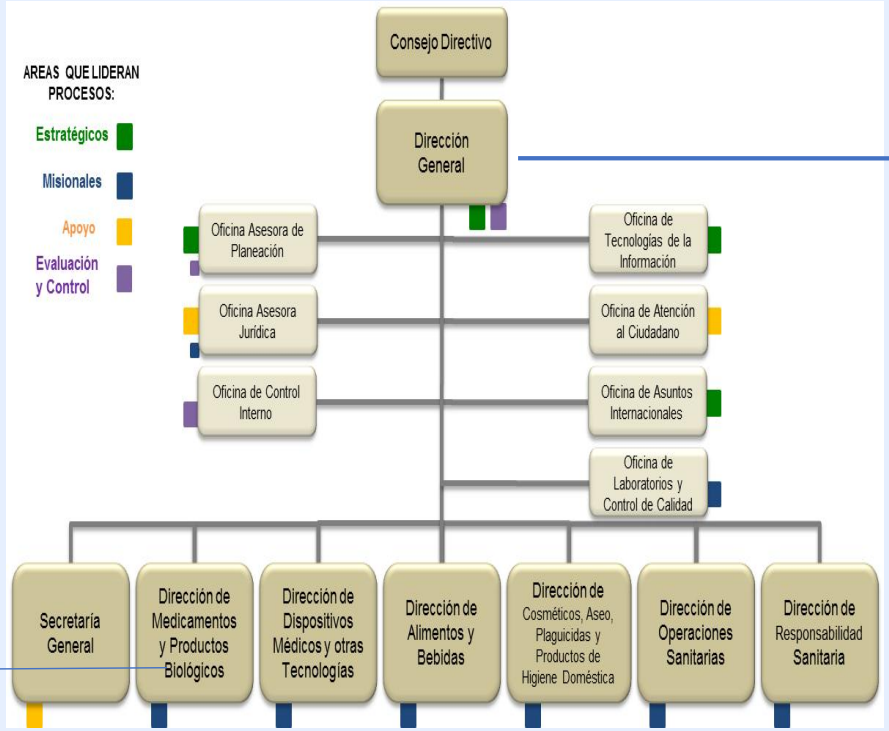
INSTITUTIONAL CHART



Dr Julio Cesar Aldana Bula

Dra Lucia Ayala Rodriguez

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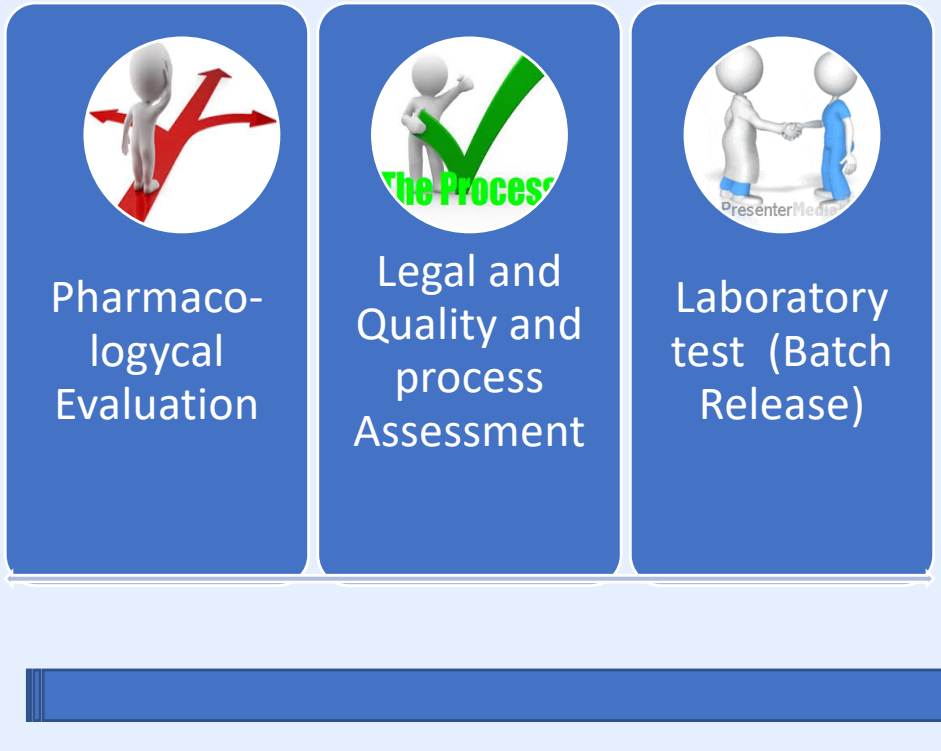
Before 1782 Decree



- Consecutive Process
- The assesment was doing for three groups
- During this process don´t assess Risk Management Plan
- 27 Months

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With 1782 Decree

- Assessment At the same time
- The assessment for four groups
- Risk Management Plan is including in to the assessment
- From eight months to one year

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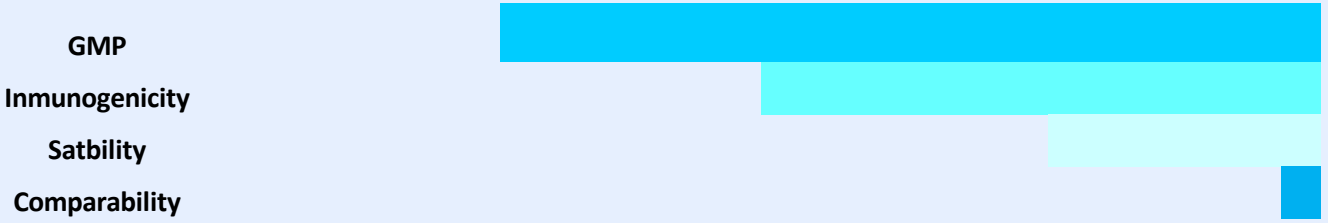
Regulatory History



NAME	LAW	IMPLEMENTATION
Good manufacturing practices to biological products	Decree 5402 2015	December 2016
Stability guideline for biological medicines	Decree 3690 de 2016.	August 2018
Guideline on the evaluation of immunogenicity of biological medicines	Decree 4490 del 2016	September 2017
Guideline on comparability of biological medicines	In process	

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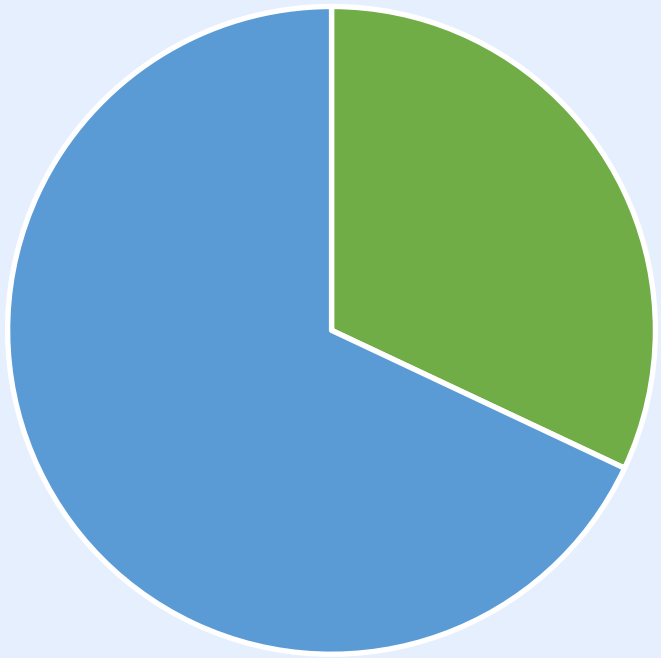
Number of Medicines submitted by 1782 Decree



- 141 Dossier assessed
- 45 Renewal (32%)
- 94 New Products (68%)

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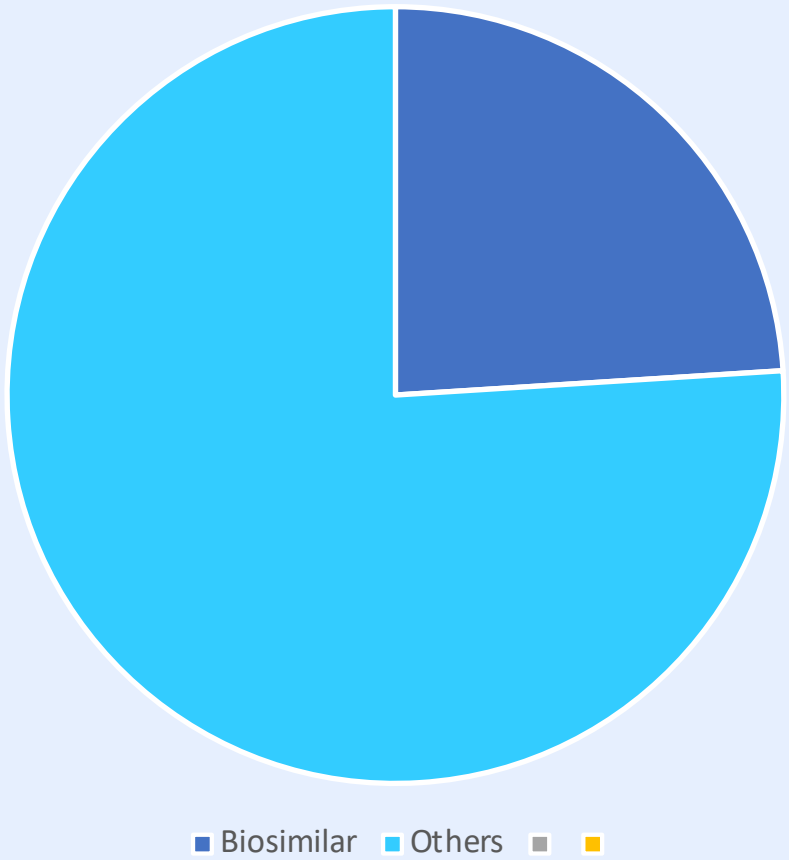
New Molecules submitted by 1782 Decree



- 94 New Product assessed
- 23 Biosimilar (24%)
- 71 Others (76%)

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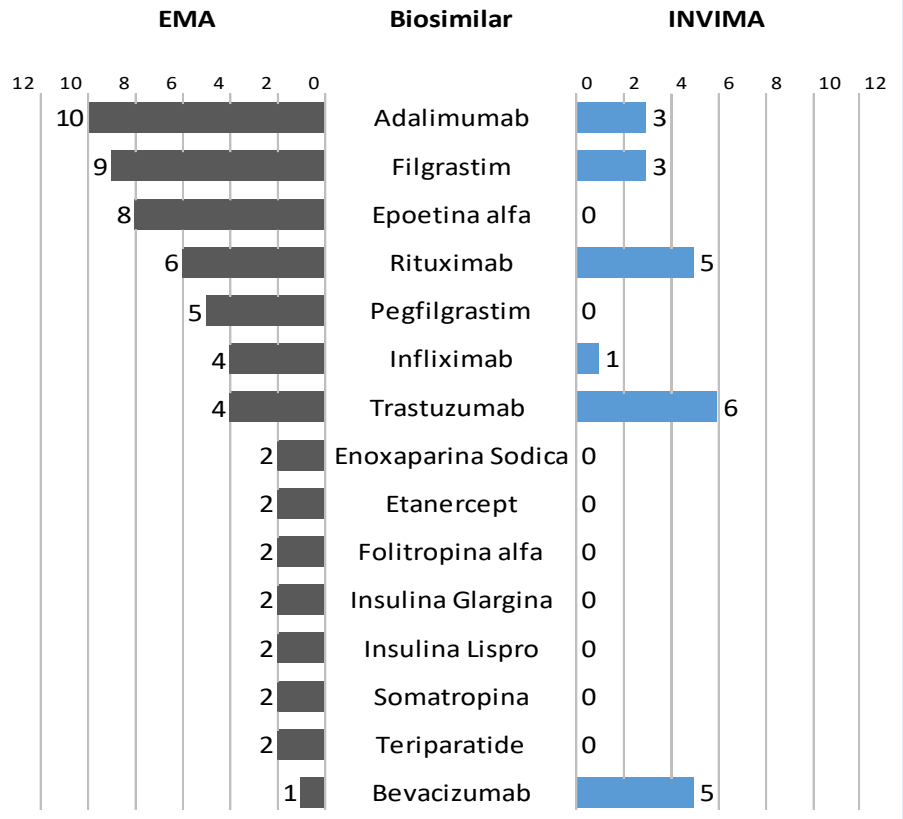
Comparison of the number of marketing authorization application studied by EMA vs Colombia



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Conclusion

- INVIMA as a regulator aims to create optimal condition for the competition, putting into the practice the 1782 Decree
- At the moment we have under review 23 Biosimilars
- Today only one trastuzumab finished all the process and have marketing authorization in Colombia
- With the implementation of 1782 Decree, all scientific and technical conditions are being ensured to biosimilar get in to the Colombian market with adequate quality, safety and efficacy standards, This will allow a relief to the Colombian health system promoting access to this type of molecules
- The next step is education to the health professionals in the use of Biosimilar Products with confidence

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Thank you

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