



Welcoming remarks by INVIMA

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**Regulating biological products including biosimilars.
The Colombian experience**

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Invima - Instituto Nacional de Vigilancia de Medicamentos y Alimentos

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COLOMBIA



Universal coverage

“Colombia has a well-designed health system, with broadly effective policies and institutions that other countries could learn from and that deserves to be better known internationally”

OECD 2015

INVIMA



Established in 1995

Staff: 1.305

Annual budget: ~ USD 48 millones

State offices: 11

Border offices: 13

Laboratories: 7

Pharmaceutical trends

Pharmaceutical research is concentrating on specialty medicines.

Trends in oncology are also very promising, albeit worrying.

Drugs for *rare diseases* now account for about half of drugs approved.

The benefits from competition by generics are likely to be smaller in the future.

OECD, 2016

Resolution WHA 67.21

- Support NRAs particularly in developing countries, to strengthen their capacity in the area of the regulation of BPs, including (SBPs)
- Countries to implement regulatory frameworks for SBPs (WHO guidelines) that promote equitable access to quality, safe, effective and affordable medical products.
- Encourage and promote cooperation and exchange of information among MS in relation to BPs and SBPs whilst working towards regulatory convergence
- Strengthen regulatory functions, especially clinical evaluation and pharmacovigilance, including proactive collection of PV data.

Regulatory time frame

Decree 1782

18 Sep 2014

2010



2017

Decree preparation and drafting:
MOH - Invima

3 Jan 2010 – 24 Jan 2012

Debate and consultation (First round)

24 Jan 2012 - 13 Feb 2012

Debate and consultation (second round)

14 Feb 2012 - 23 May 2012

Debate and consultation (third round)

24 May 2012 - 21 Feb 2013

Debate and consultation (fourth round)

22 Feb 2013 - 25 Jun 2013

Debate and consultation (fifth round)

26 Jun 2013 - 25 Jun 2014

Inmunogenicity guideline

Sep 2014 - Mar 2017

Stability guideline

Sep 2014 - Aug 2016

GMP guideline

19 Sep 2014 - 17 Dec 2015



Thanks

 MINSALUD

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NUEVO PAÍS**
PAZ EQUIDAD EDUCACIÓN

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