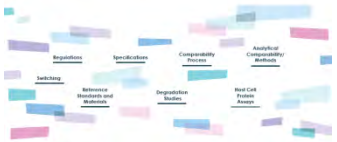


Welcoming remarks by INVIMA

Javier Humberto Guzmán Cruz

15 August 2017

Regulating biological products incluidng biosimilars. The Colombian experience

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

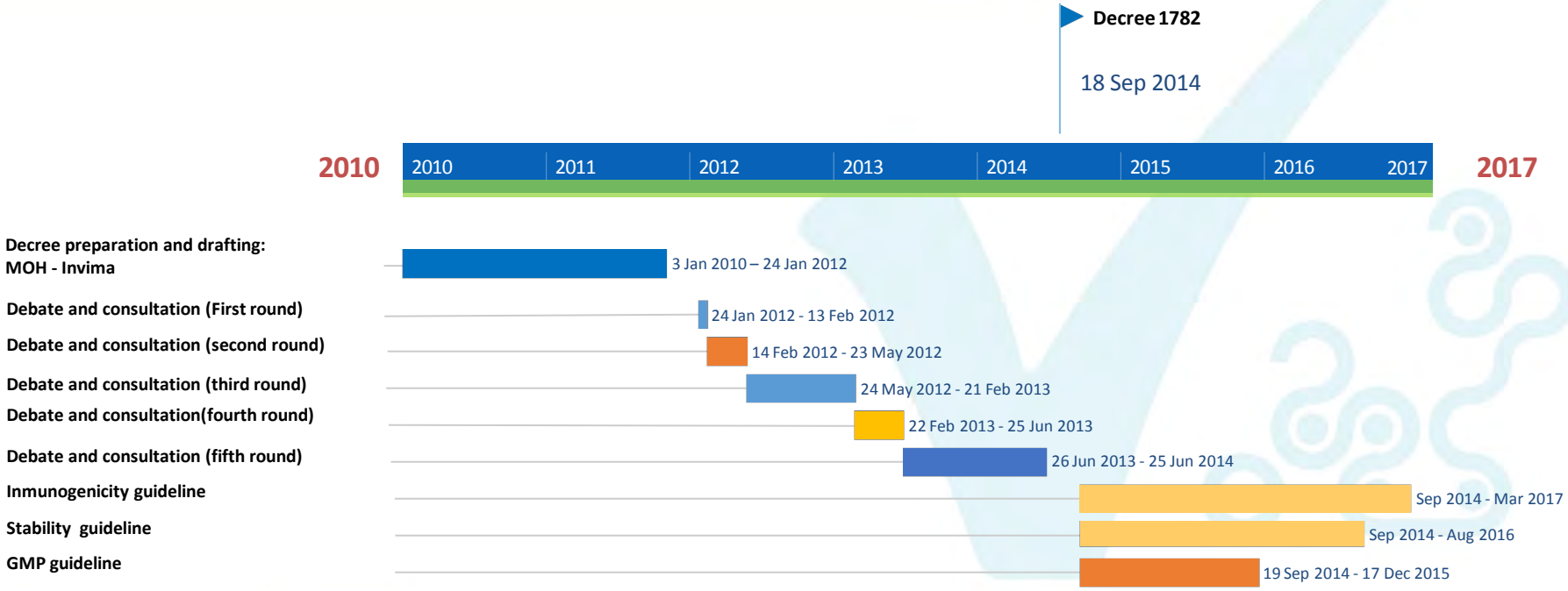
- Support NRAs particularly in developing countries, to strengthen their capacity in the area of the regulation of BPs, including (SBPs)

- 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



Thanks