



Ministerio de Salud
más y mejor salud para todos los peruanos



Medical Devices Regulatory System

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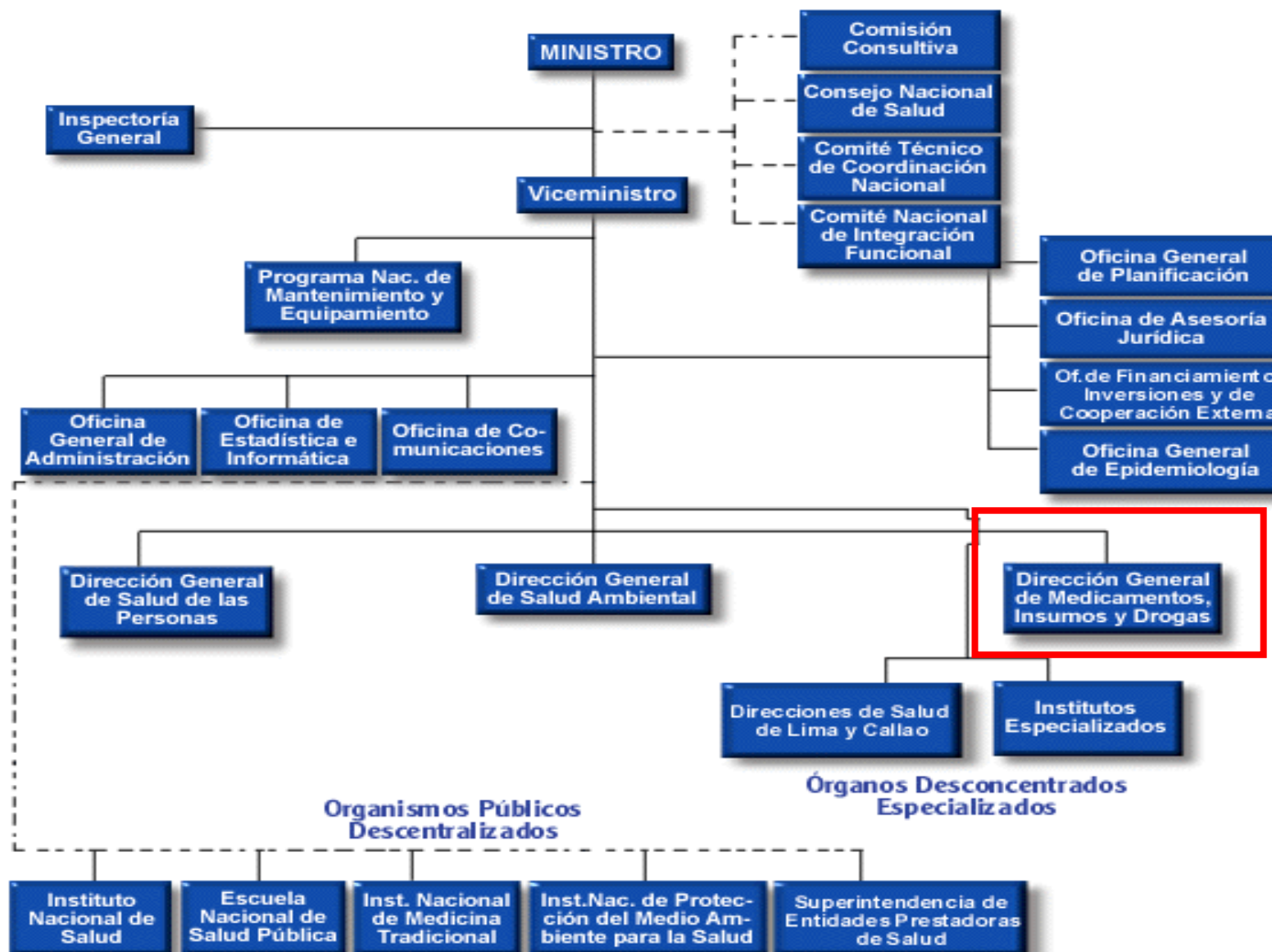
Dirección General de Medicamentos Insumos y Drogas

Ministerio de Salud

PERU

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Organigrama General del Ministerio de Salud (Oficinas Generales)





Medical Device Regulations

- ★ Jul 1997: Health General Law
 - Chapter III: Pharmaceutical products and natural therapeutic resources

- ★ Dec 1997: Regulation for Registration, Control and Sanitary Vigilance of Pharmaceutical Products and others.

- ★ Jul 2001: Modification of Regulation



Categories of Pharmaceutical Products and others

- ★ Pharmaceutical Products
- ★ Natural Therapeutic Products
- ★ Cosmetic Products
- ★ Sanitary and Domestic Cleaning Products
- ★ Material, Devices and Equipments for Medical or Chirurgic Use

Regulations Development

	Pre-market	On-market	Post-market
<i>Pharmaceutical</i>	+++	+++	+++
<i>Cosmetic</i>	+++	+++	++
<i>Sanitary and Domestic Cleaning</i>	+++	++	++
<i>Natural Therapeutic Products</i>	+	+	+
<i>Material, Devices or Equipment for Medical or Chirurgical Use</i>	+	+	+



Plan

★ Sensitization

- Health Authority and other regulators
- Industry (Importers)
- Public

★ Get Commitment

★ Team Work

- Internal
- External

★ New Regulation

- According to national and international objectives



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Thank you

Muchas Gracias

