

Participation of different actors in the regulation of some health technologies: **Blood and blood products** : the regulatory plurality

Agência Nacional de Vigilância Sanitária- ANVISA
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Regulatory models for minimizing risks in blood and blood products

- Protect the health and safety of **blood donors**
- Assure the quality, safety, efficacy and availability of blood for transfusion and plasma for further manufacturing to make essential derivatives
- **Patient safety**

WHA45.17, WHA47.17, WHA52.19, WHA54.11, WHA59.24, WHA63.12, WHA65.19, WHA67

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Essential elements of regulatory blood in Brazil



To assure the affordability, quality and safety of blood

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A national blood system

MINISTRY OF HEALTH

- NATIONAL POLICY FOR BLOOD - PUBLIC HEALTH SYSTEM
- BLOOD SERVICES NETWORK NACIONAL COORDINATION
- PLASMA FRACTIONATION COORDINATION - HEMOBRÁS
- HAEMATOLOGICAL ASSISTANCE NACIONAL PROGRAM

Local Blood System

HEALTH AUTHORITY OF LOCAL (STATE)

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A national blood system in BRAZIL

BLOOD SERVICES NETWORKS

BLOOD ESTABLISHMENTS MANUFACTURERS (HEMOCENTROS)	338
BLOOD ESTABLISHMENTS COLLECTORS	145
BLOOD ESTABLISHMENTS LABORATORIAL CENTERS	8
TRANSFUSION SERVICES (storage, compatibility tests, transfusion)	1575
TOTAL	2066

150,000 liters plasma/year – plasma for fractionation
CONTRACT BRAZIL/FRANCE

In 2015
4.000.000 (blood collections)
7.598.872 (blood components)
3.500.000 (transfusions)

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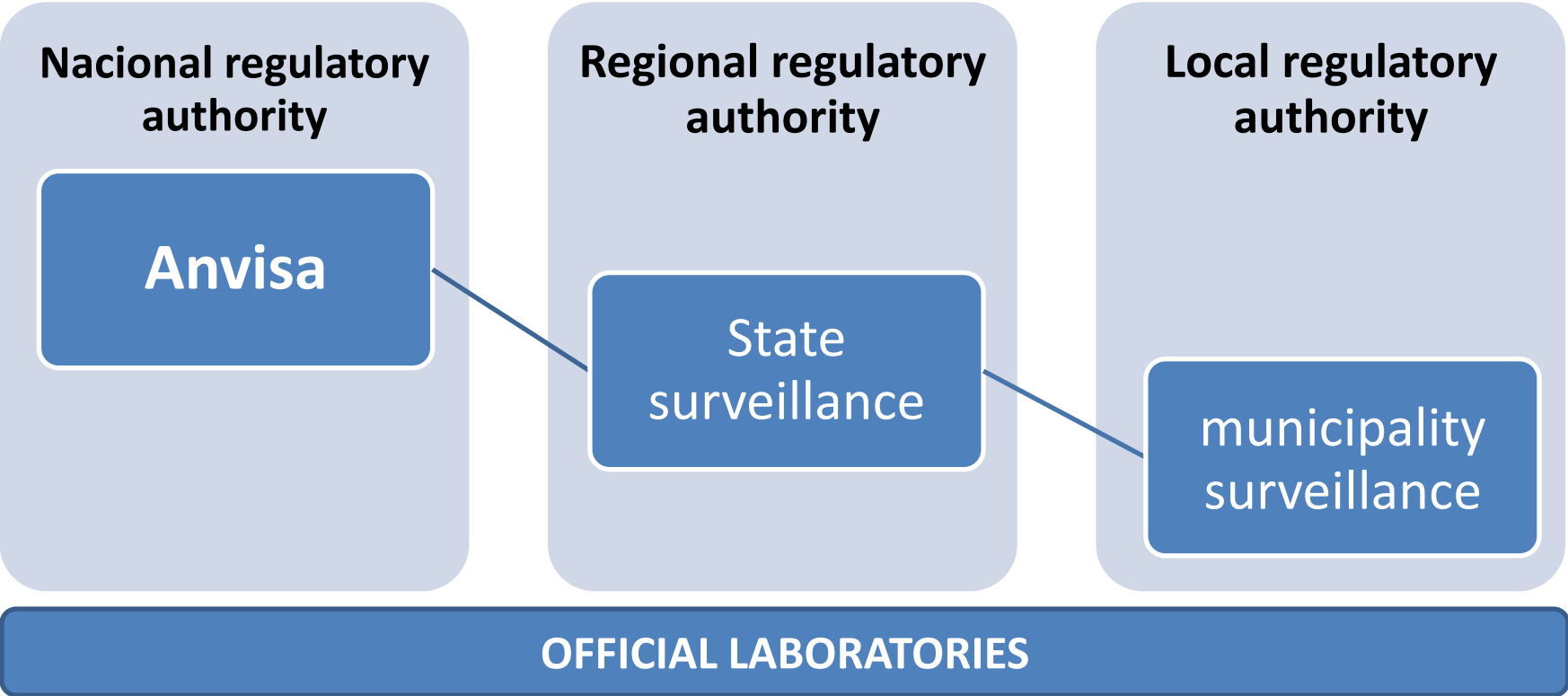
Legal framework

- ✓ Federal Constitution - CF 88
 - ✓ Federal Law of Blood
 - ✓ Federal Law of Public Health System (SUS)
 - ✓ Federal Law of Health Surveillance System
 - ✓ GMP for Blood Services (Anvisa)
 - ✓ Haemotherapeutic Technical Procedures (Healthy Ministry)
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- ❑ regulating blood components - define appropriate blood standards
 - ❑ assignment of a regulatory authority for supervising blood components

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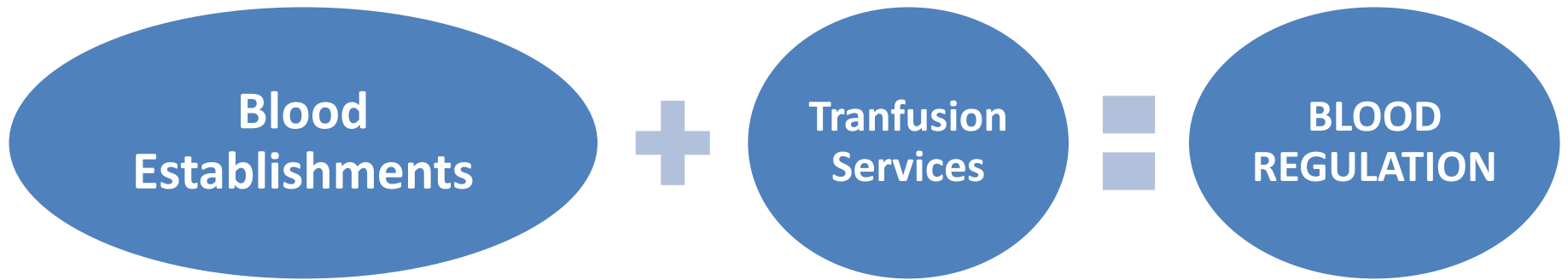
Regulatory authority system



SISTEMA NACIONAL DE VIGILÂNCIA SANITÁRIA

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PRODUCTS

1. Quality system
2. Donor selection criteria
3. Infectious disease marker testing strategy and immuno hematological qualification
4. Products Standards

SERVICES

1. Patient safety criteria
2. Quality system

Essential elements of regulatory blood in Brazil

Plasma Derivative Medicines

In Vitro Diagnostic Products

Medical Devices

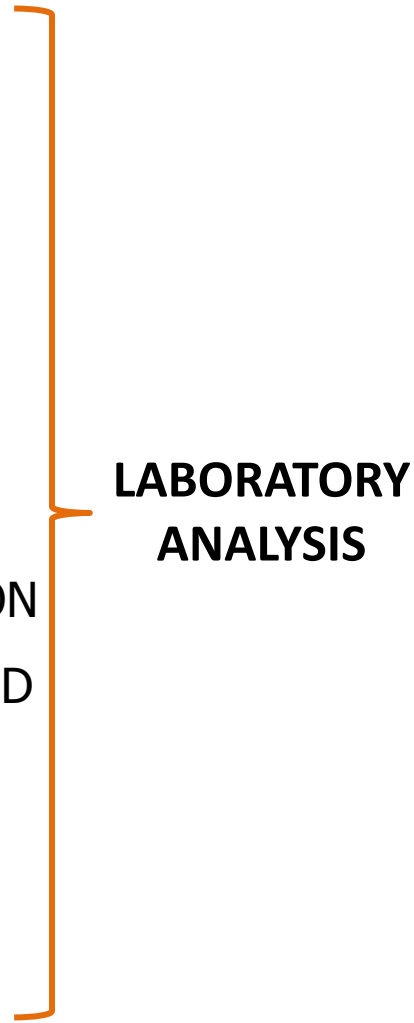


- ✓ LICENSING
- ✓ GMP INSPECTION
- ✓ REGISTERED (Marketing Authorization)
- ✓ PHARMACOVIGILANCE
- ✓ MEDICAL PRODUCTS VIGILANCE

Blood Establishments
Transfusion Services



- ❑ LICENSING/AUTHORIZATION
- ❑ NO REQUIRED REGISTERED BLOOD COMPONENTS
- ❑ GMP INSPECTION
- ❑ MONITORING RISK INDICATORS
- ❑ HEMOVIGILANCE



LABORATORY ANALYSIS



Thank you for your attention!
Muchas gracias!
Obrigado!

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