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

Agência Nacional de Vigilância Sanitária- ANVISA
Brasil

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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
Essential elements of regulatory blood in Brazil

To assure the affordability, quality and safety of blood
Essential elements of regulatory blood in Brazil

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)
## BLOOD SERVICES NETWORKS

<table>
<thead>
<tr>
<th>Blood Services</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Establishments Manufacturers (Hemocentros)</td>
<td>338</td>
</tr>
<tr>
<td>Blood Establishments Collectors</td>
<td>145</td>
</tr>
<tr>
<td>Blood Establishments Laboratorial Centers</td>
<td>8</td>
</tr>
<tr>
<td>Transfusion Services (storage, compatibility tests, transfusion)</td>
<td>1575</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2066</strong></td>
</tr>
</tbody>
</table>

### In 2015

- **4.000.000** (blood collections)
- **7.598.872** (blood components)
- **3.500.000** (transfusions)

### 150,000 liters plasma/year – plasma for fractionation

**Contract Brazil/FRANCE**

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**Source:** Hemocad, 2014.
Essential elements of regulatory blood in Brazil

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)
- Haemotherapic Technical Procedures (Healthy Ministry)

- regulating blood components - define appropriate blood standards
- assignment of a regulatory authority for supervising blood components
Essential elements of regulatory blood in Brazil

Regulatory authority system

Nacional regulatory authority
Anvisa

Regional regulatory authority
State surveillance

Local regulatory authority
municipality surveillance

OFFICIAL LABORATORIES

SISTEMA NACIONAL DE VIGILÂNCIA SANITÁRIA
Essential elements of regulatory blood in Brazil

Blood Establishments + Tranfusion Services = BLOOD REGULATION

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
- Blood Establishments
- Transfusion Services

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

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

* POST-REGISTRATION
Thank you for your attention! Muchas gracias! Obrigado!

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