

ITALY

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Italian national blood centre - CNS

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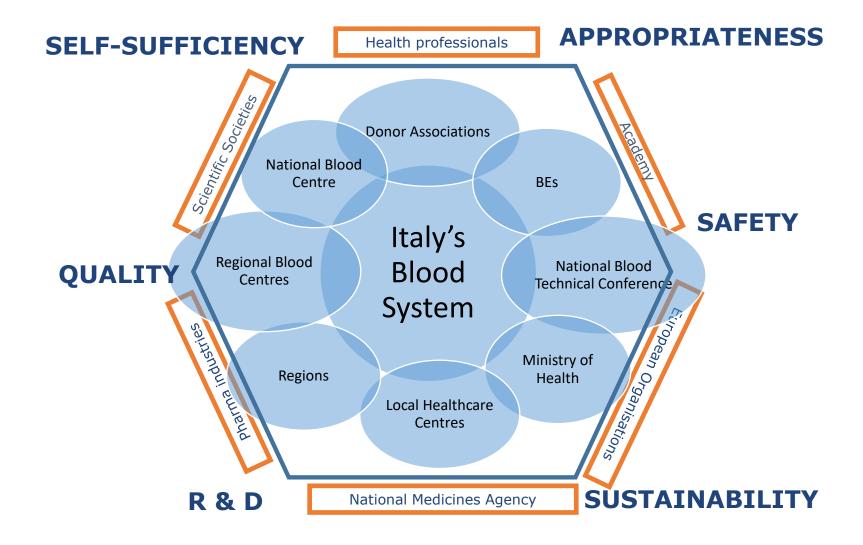
Agenda

- The Italian Blood System
- Preliminary gap analysis
- Roadmap toward the full application of the EU Regulation
- Conclusions





Italian Blood System: stakeholders and strategic goals







Italian Blood System: pursuant to the institutional Law (21 October 2005)

The **National Blood Centre** (Centro Nazionale Sangue – CNS) is the national competent authority for blood and blood components on behalf of the Ministry of Health. It is located at the National Institute of Health and it operates independently under the aegis of the Ministry of Health. It coordinates and controls the transfusion system from a technical-scientific point of view to ensure the achievement of specific goals:



- **1. regional and national self-sufficiency** in blood, blood components including plasma for fractionation
- **2. highest level of safety** in all processes from donating to transfusing blood and blood products
- **3. equity** in the provision of activities and products throughout the country in compliance with European legislation
- 4. continuous development of transfusion medicine
- 5. appropriateness of blood and PDMP usage promoting multidisciplinary activities aimed at avoiding unnecessary transfusions (Patient Blood Management)



Italian Blood System: pursuant to the institutional Law (21 October 2005)

Blood

Donors Associations

Regional

Blood

Centres

Regional Blood Centres:

In each of the 21 regions, a Regional Blood Centre is established by law. The regional Blood Centres coordinate the related local networks of Blood Establishments and Blood Collection Units, complying with national regulation and self-sufficiency, quality and safety plans.

Blood Establishments: in addition to perform blood and blood component collection, processing, testing, storage and distribution, most Blood Establishments also work as hospital blood banks.

Blood Donors Associations: there are four main blood donors organizations (AVIS, FIDAS, FRATRES, CRI) that are highly involved in the blood donor management. By law, they can run Blood Collection Units upon the release of specific regional authorization and accreditation, under the technical control of both Blood Establishments and Regional Blood Centres.





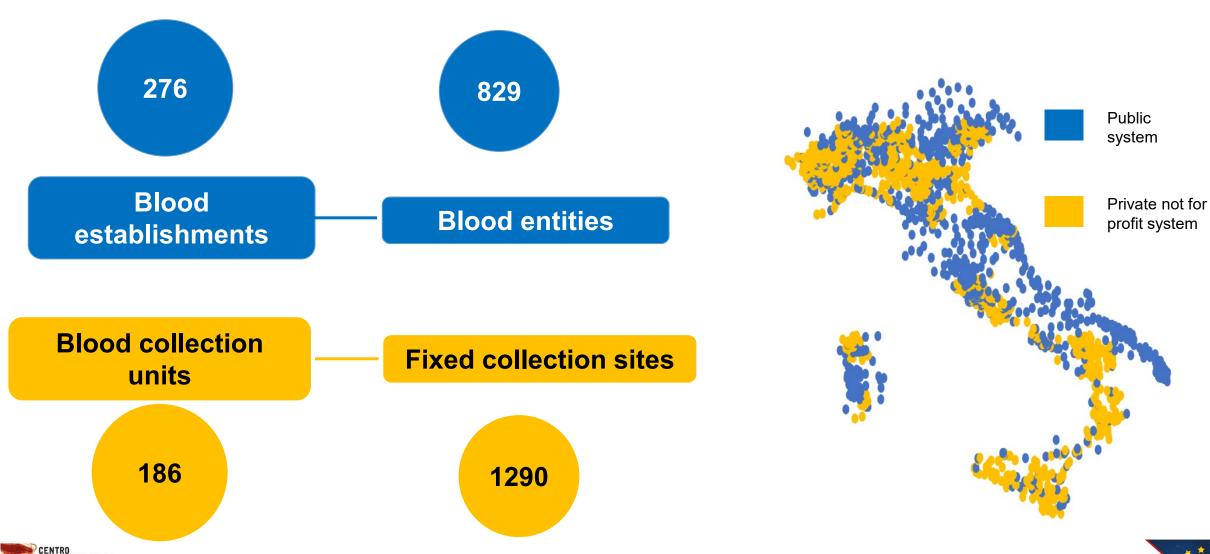






Blood Establishments

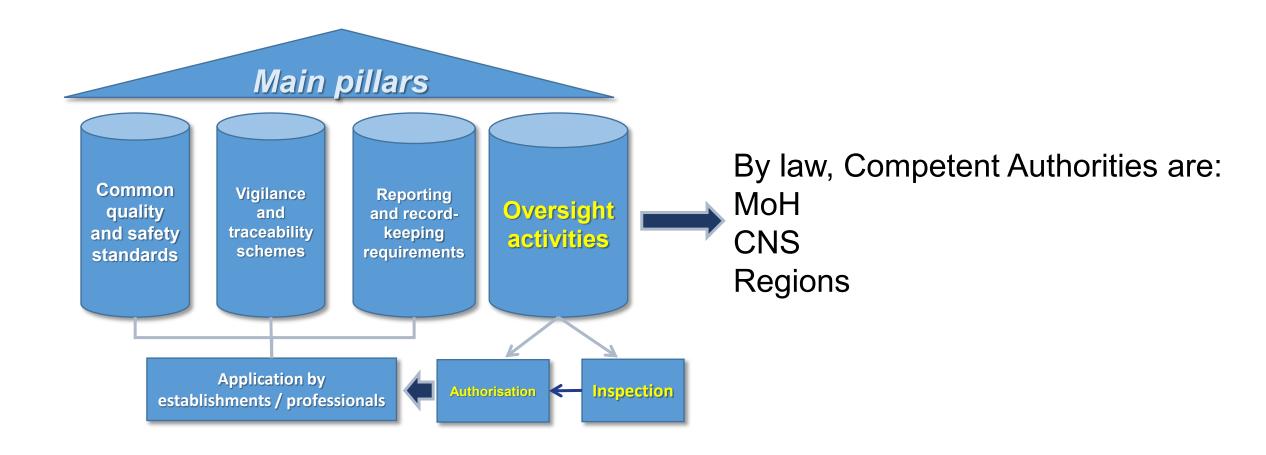
Italian Blood System: organizational overview





SoHO oversight system:

Italian Blood System: oversight system







Italian Blood System: oversight system

- Minimum requirements
- Additional requirements
- Inspection procedures

MoH / CNS / Regions

CNS

- Inspectors training and qualification
- Management of an official list of qualified inspectors (competence maintenance)
- Control measures (eventrelated inspections)

- Performance of inspections (every two years)
- Composition of inspection teams
- Systematic reporting to the MoH/CNS

Regional Competent Authorities



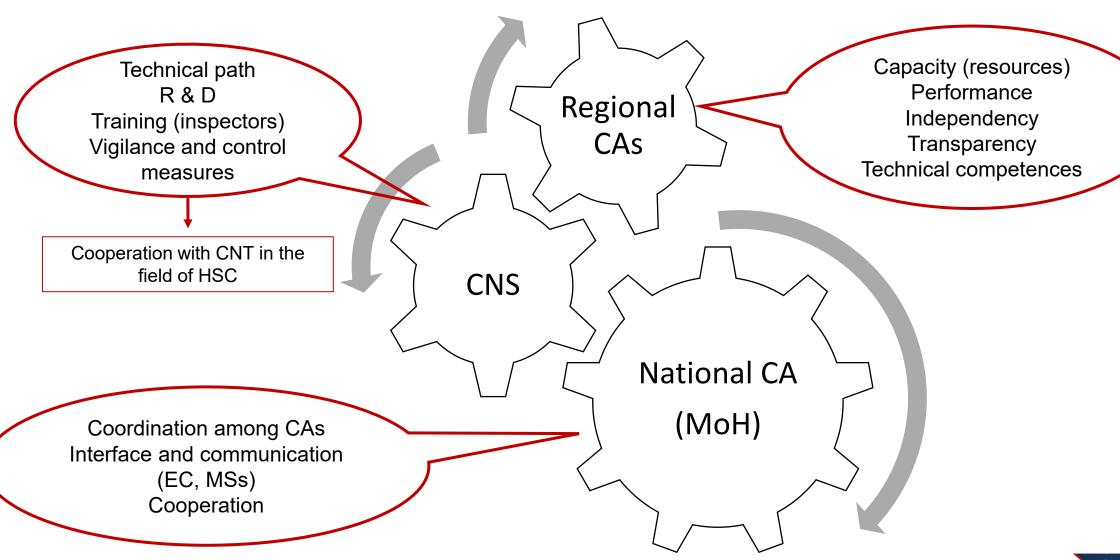
Preliminary GAP analysis

- CHAPTER II MEMBER STATES' SOHO COMPETENT AUTHORITIES
- CHAPTER III SOHO SUPERVISORY ACTIVITIES
- CHAPTER IV GENERAL OBLIGATIONS ON SOHO ENTITIES





Member States' SoHO Competent Authorities: who does what



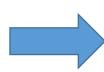


SOHO Supervisory activities: what extension?

SoHO entities registration: sharing of common criteria and approach

SoHo entities authorization: homogeneity of the inspection procedures

Preparation process authorization: building a common system, CNS role in the system



Management decisions to be taken in agreement between MoH, CNS, Regions



Roadmap toward the full application of the EU Regulation

Dedicated webpage centronazionalesangue.it/

Three inter-regional meetings with selected stakeholders

Information dissemination Knowledge dissemination Decision

Common understanding

Awareness

making Action plan definition





WORKSHOP

Il nuovo Regolamento europeo sulle SoHO:

l'impatto sul sistema trasfusionale



Three working groups

Group 1 (Regional Blood Centres, Blood donor associations)

Scope and functions of the EU Platform

Group 2 (Regional accreditation bodies)
Competent Authority obligations

Group 3 (Blood establishments)

New tasks for guaranteeing quality and safety of BC

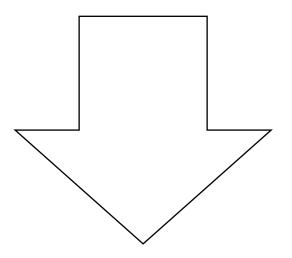


Main challenges: gap analysis

- Digital development and digital capacity in order to meet the EU Platform requests
- Development of a common risk-based approach for performing oversight activities in terms of inspection frequency and coverage
- Building a harmonized system for authorizing the new SoHO preparations
- Increasing awareness of professionals to be prepared for dealing not only with quality and safety but also efficacy of SoHO



Conclusions



A greatly decentralized system does not facilitate the implementation of common approach and solutions

A hospital-based system facilitates multidisciplinary approach and development of new knowledge and expertise

