

# ITALY

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*Italian national blood centre - CNS*

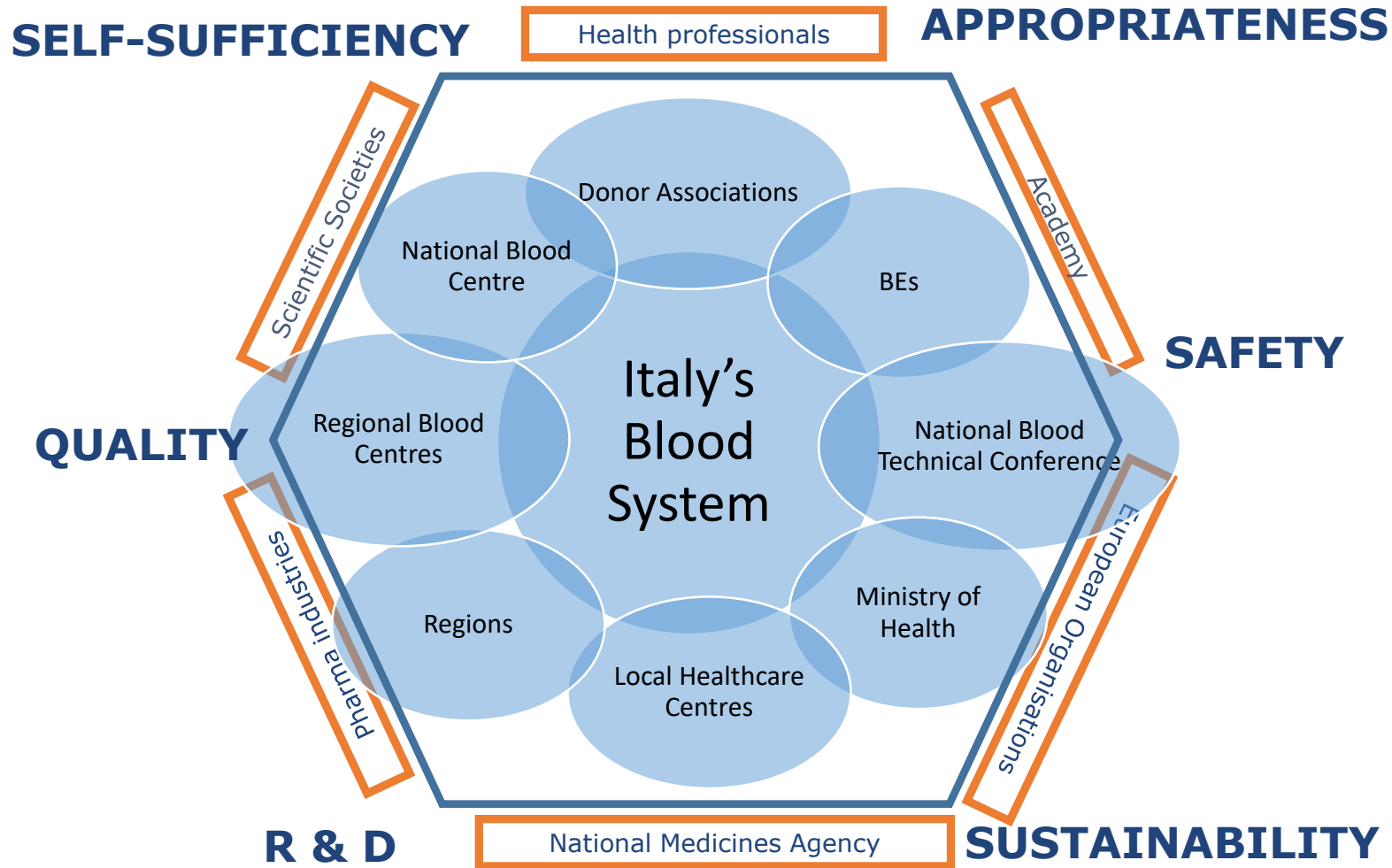
*Rome, April 8<sup>th</sup> 2025*

# 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)

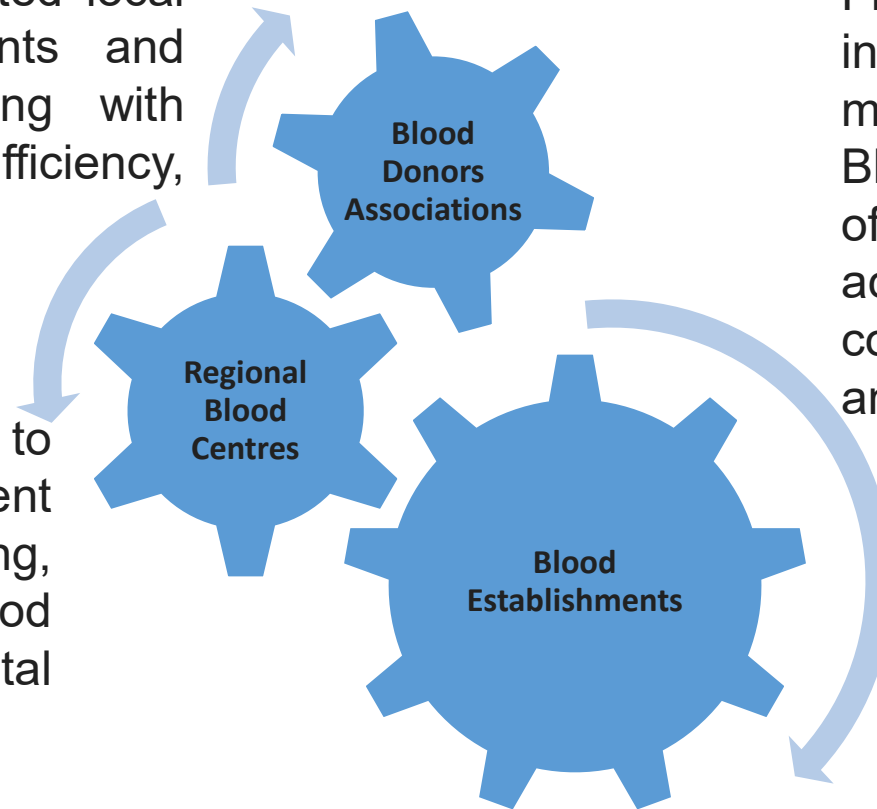


# Italian Blood System: pursuant to the institutional Law (21 October 2005)

## 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.

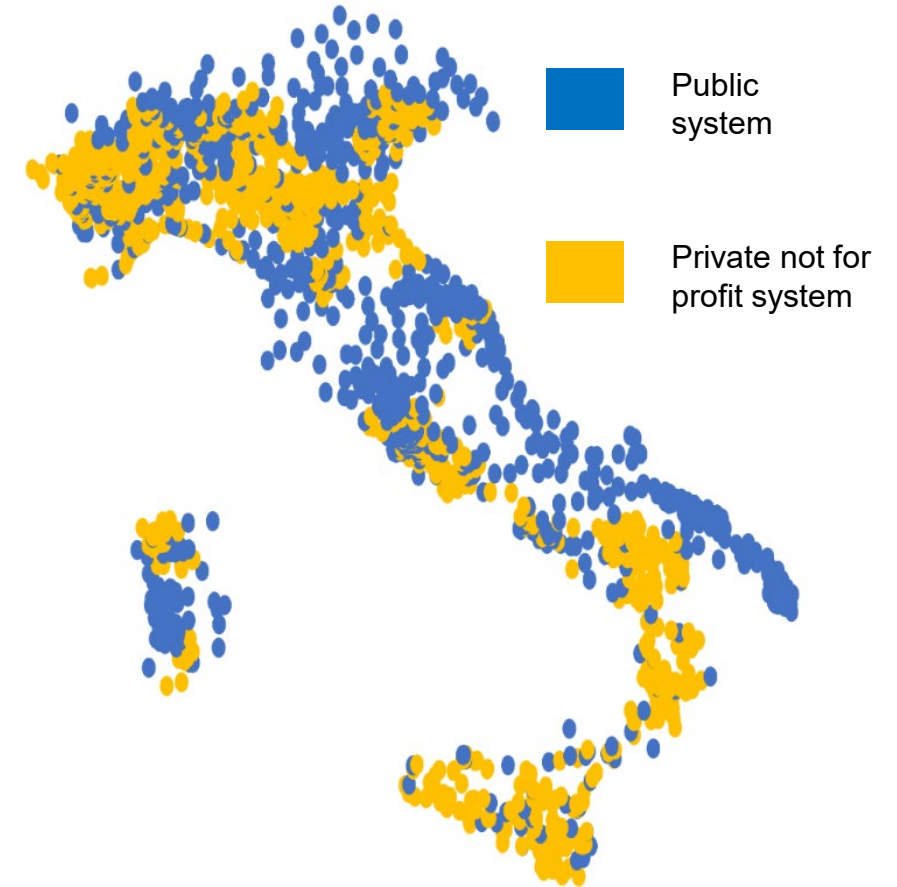
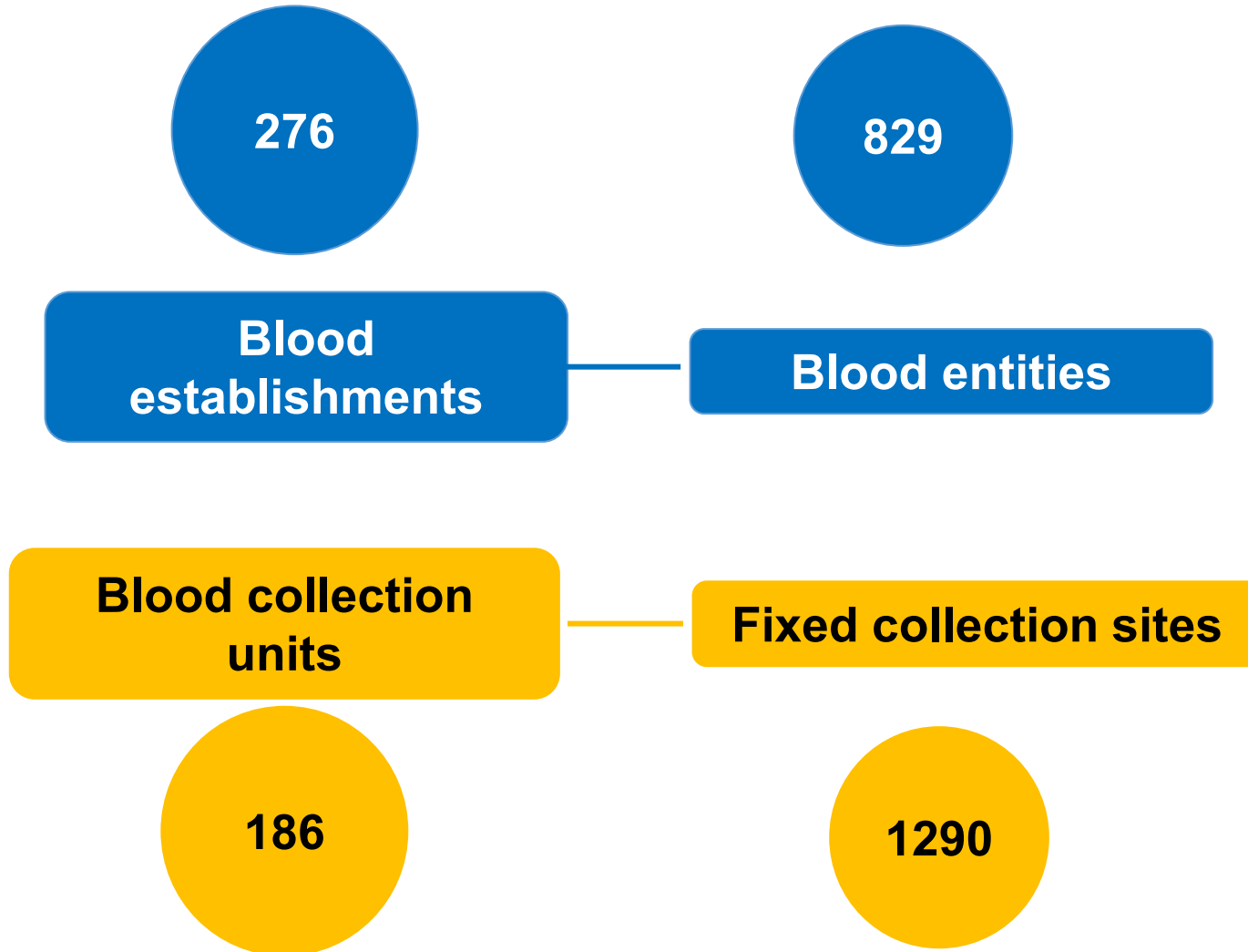
Blood Establishments: in addition to perform blood and blood component collection, processing, testing, storage and distribution, most Blood Establishments also work as hospital blood banks.



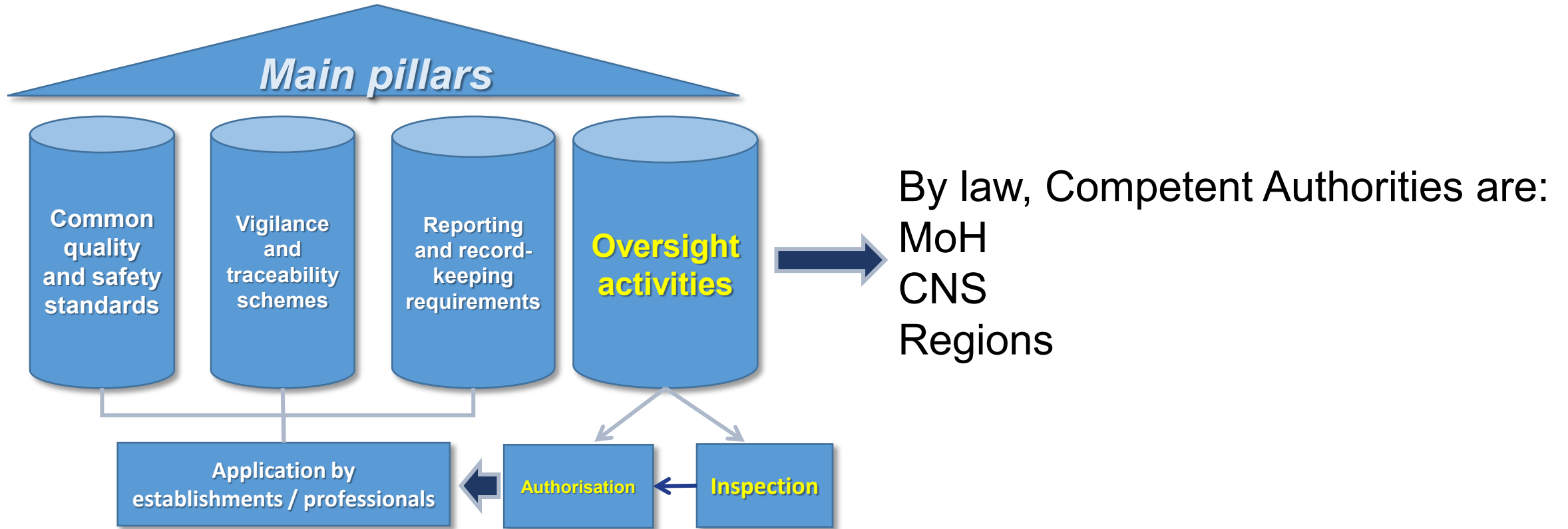
Blood Donors Associations: there are four main blood donors organizations (AVIS, FIDAS, FRATRES, CRI) that are highly involved in the blood donor management. By law, they can run Blood Collection Units upon the release of specific regional authorization and accreditation, under the technical control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



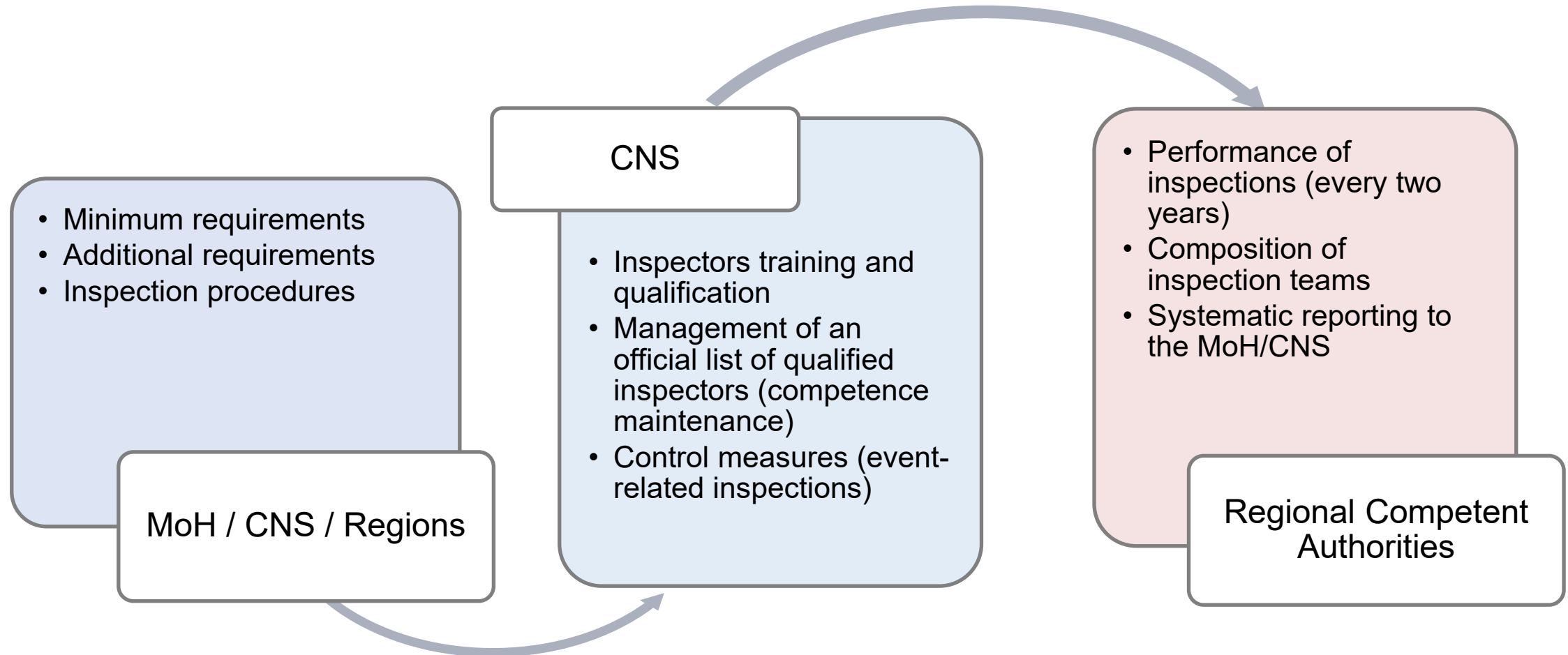
# Italian Blood System: organizational overview



# Italian Blood System: oversight system



# Italian Blood System: oversight system



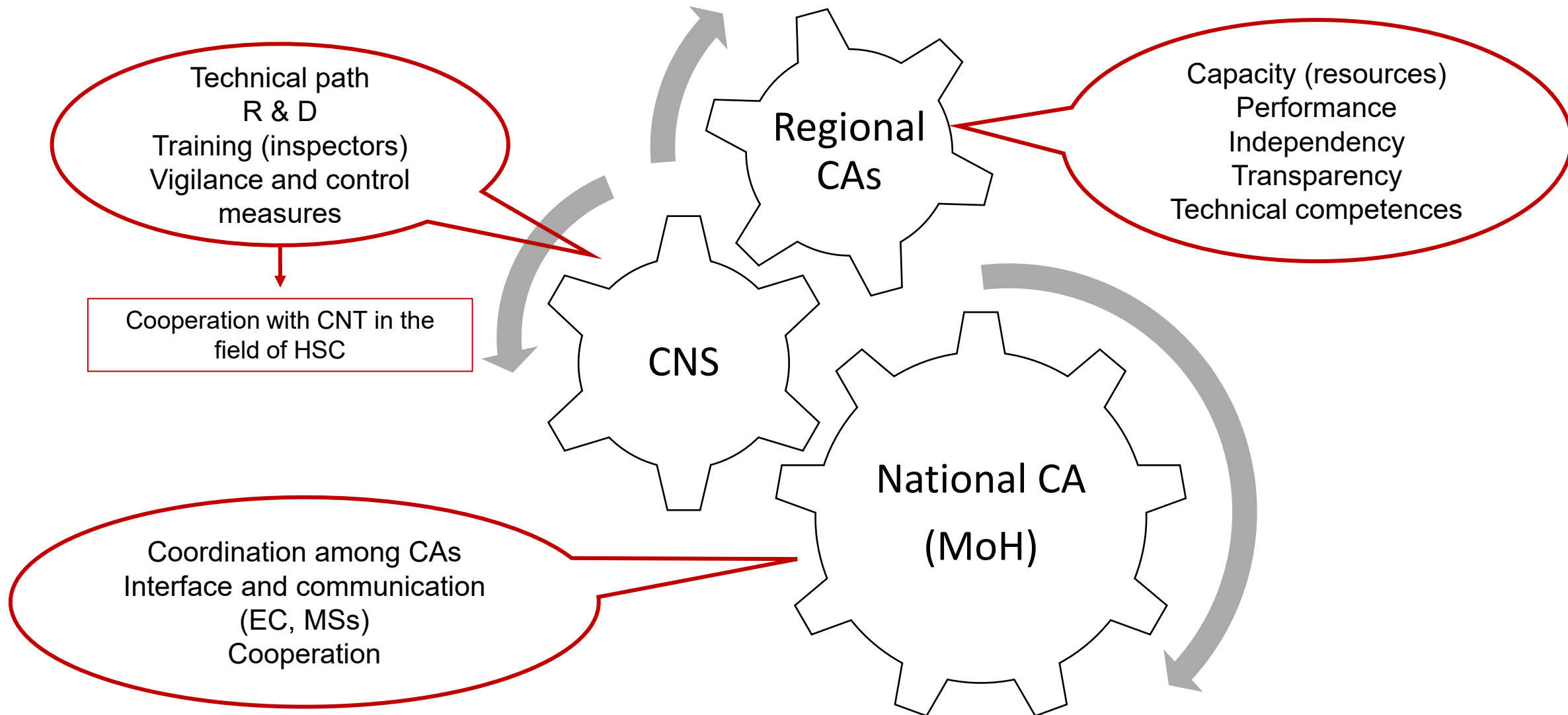


# Preliminary GAP analysis

- 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

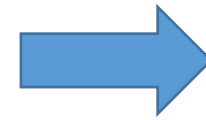


# SOHO Supervisory activities: what extension?

**SoHO entities registration:** sharing of common criteria and approach

**SoHo entities authorization:** homogeneity of the inspection procedures

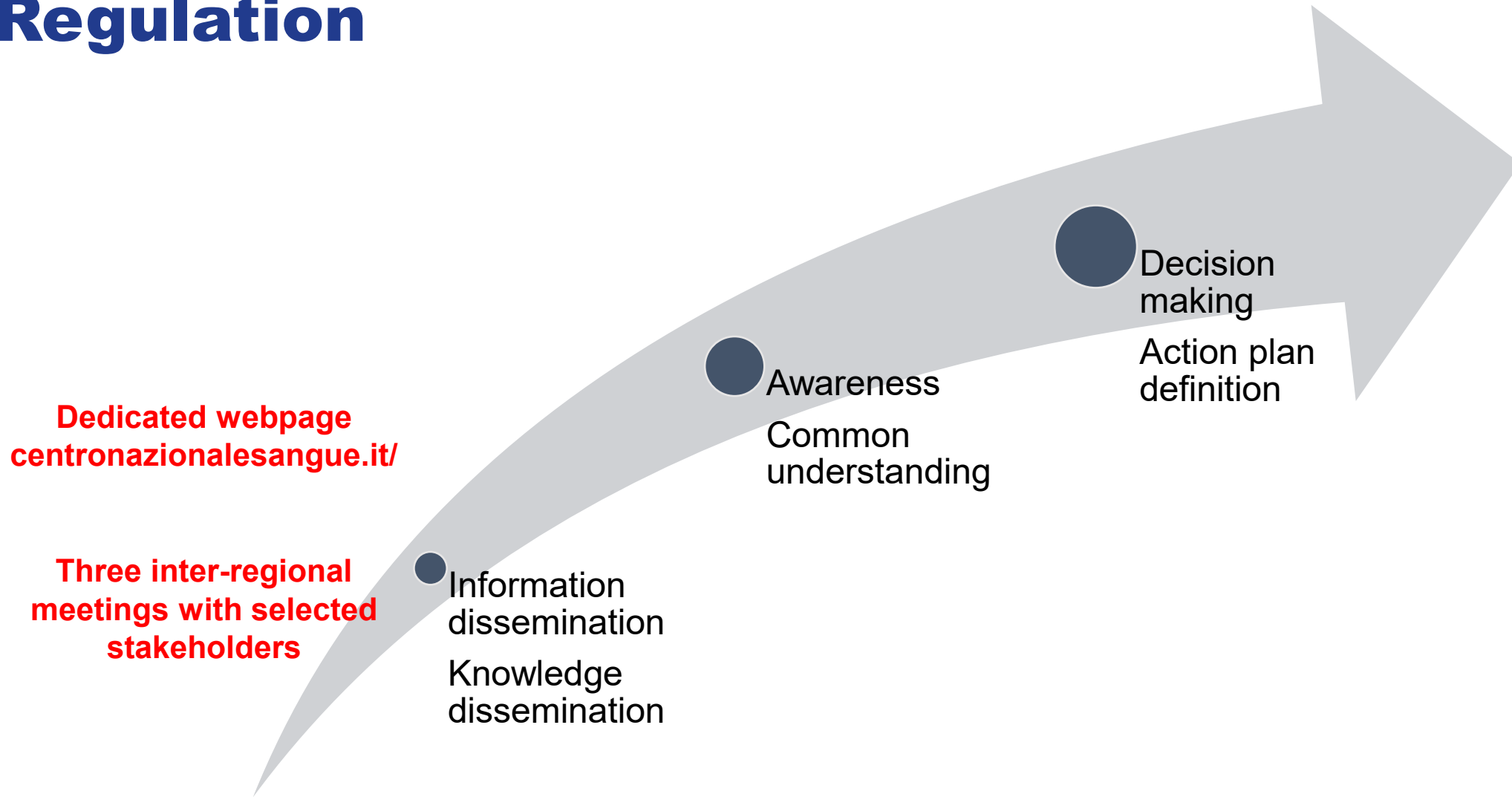
**Preparation process authorization:** building a common system, CNS role in the system



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



# Roadmap toward the full application of the EU Regulation





## 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

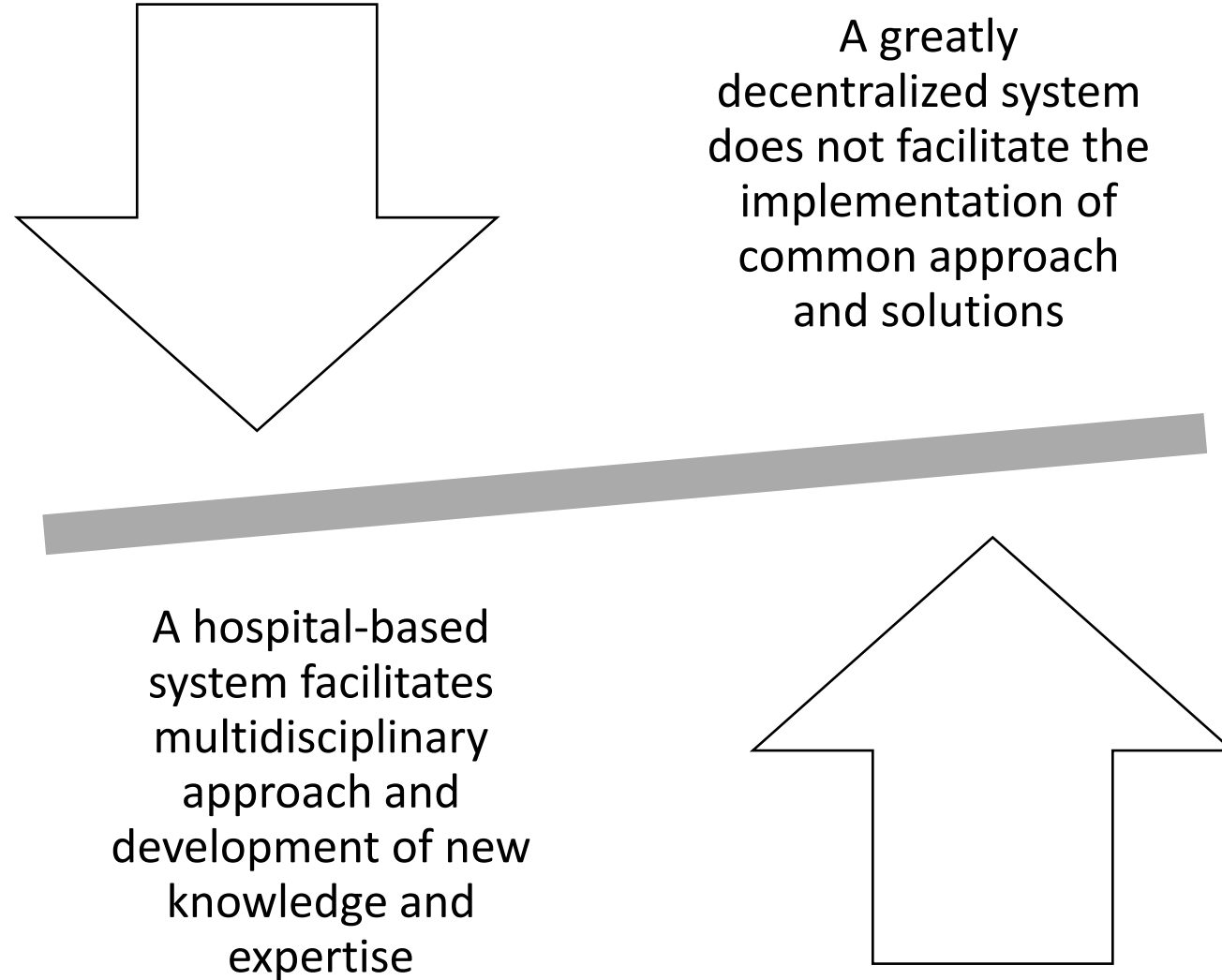


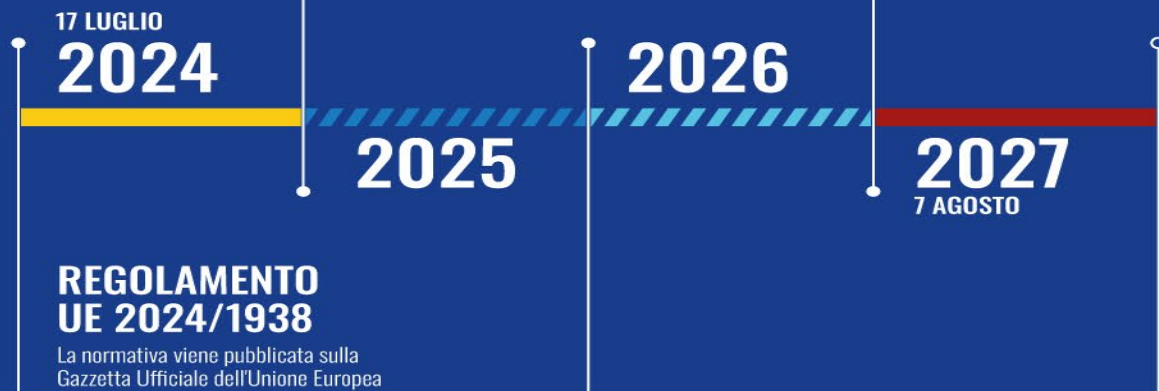
# Main challenges: gap analysis

- 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





**CHALLENGE**

**Thanks for your attention**

