

CHALLENGES IN HANDLING THE POTENTIAL OPTIONS

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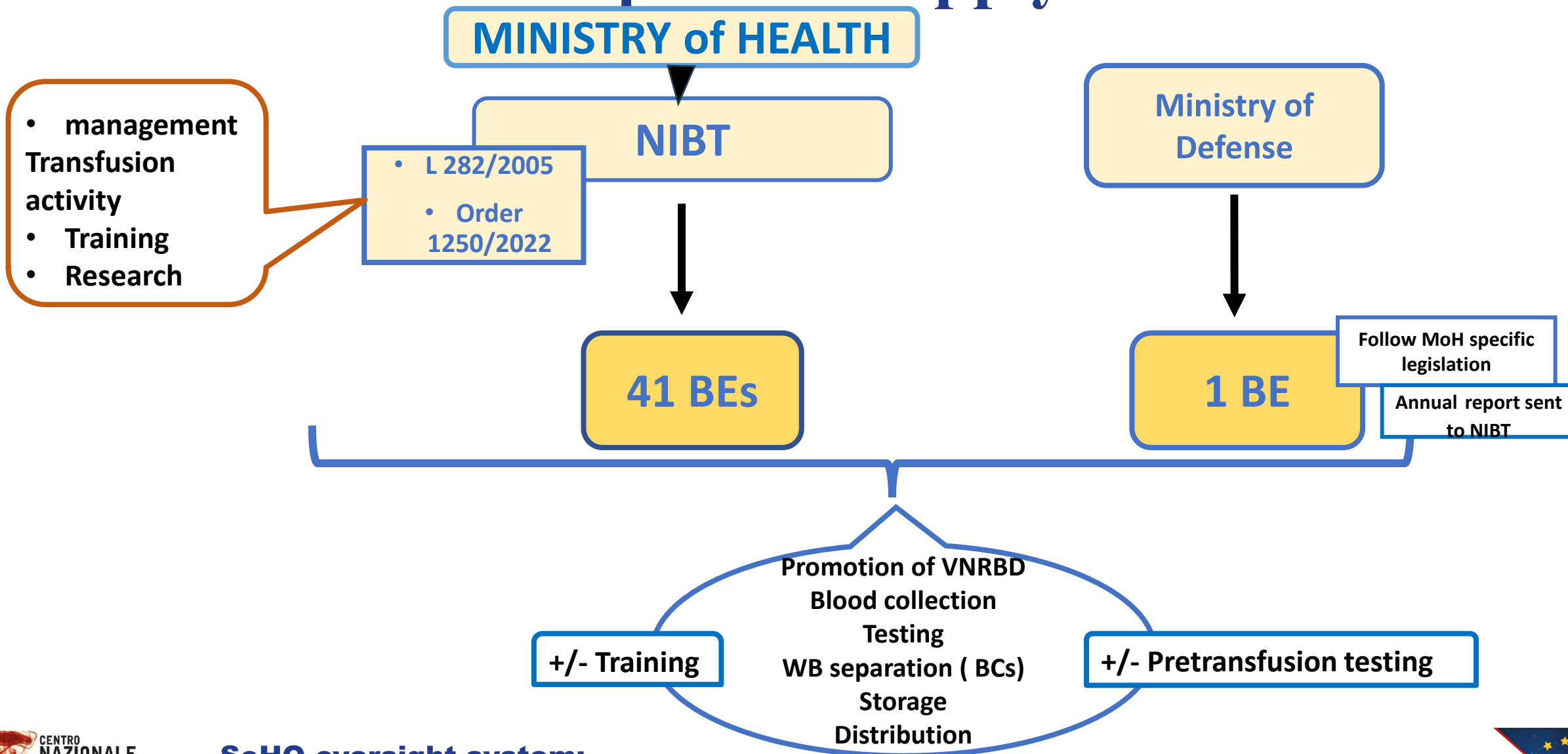
I. ROMANIA: country profile

- 2007: **UE Membership**
- Population: **19.053.815** (2021)
- Formal language: **Romanian**
- Administrative organisation:
41 counties+ Bucharest
- Health system: **public & private** institutions for health services
- Ministry of Health: **Central health Authority for public health**
- Blood:
 - **41 civil, public BEs + 1 military BE**
 - **aprox. 330 HBBs**





Blood components supply



SoHO oversight system:

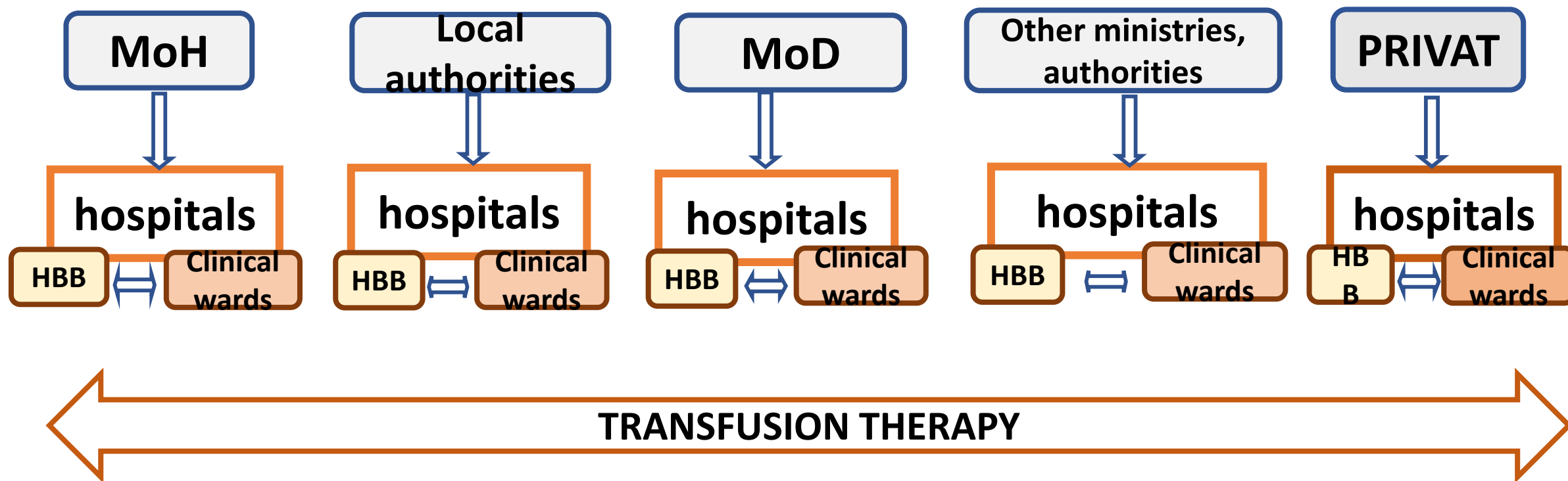
the implementation of the new EU regulation with a focus on the obligations for competent authorities





Human application of BCs

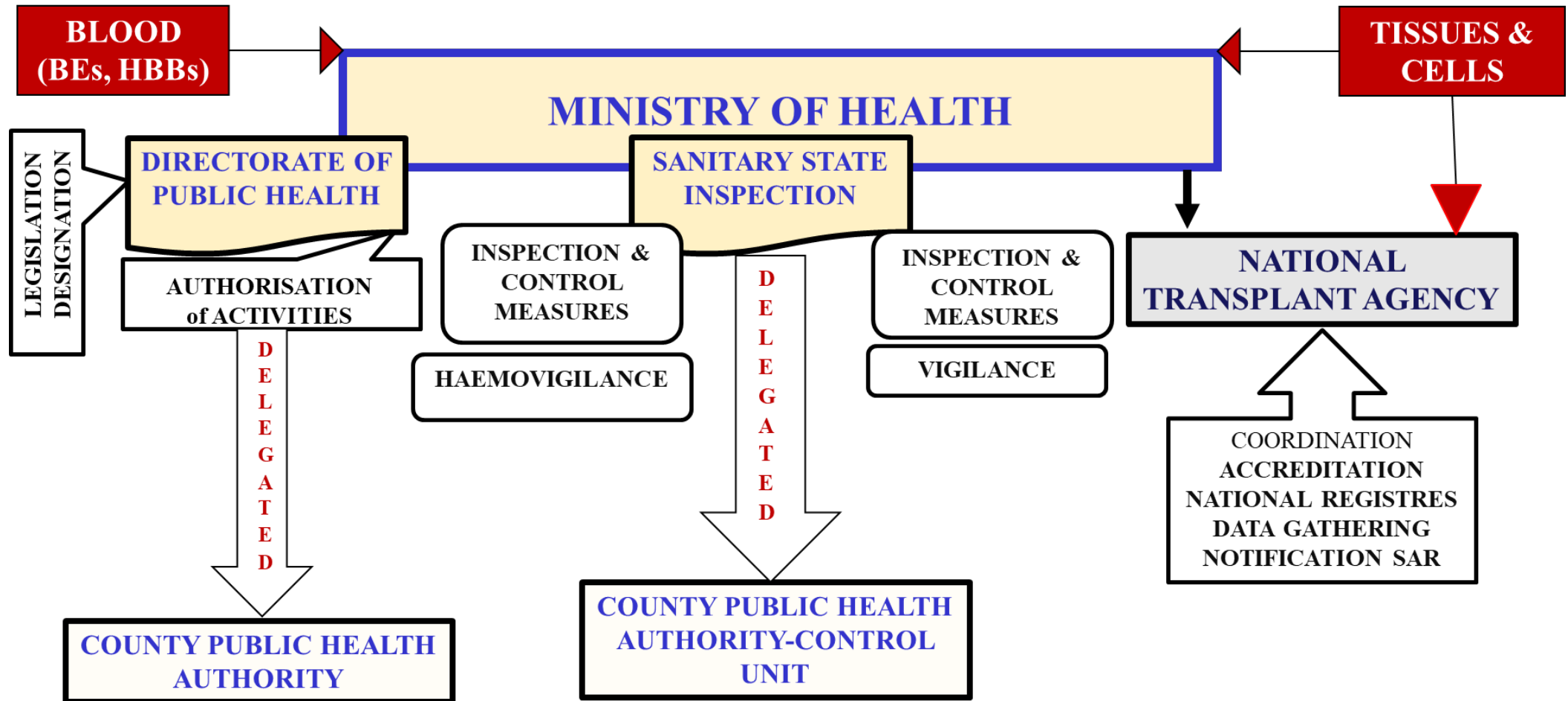
- L **282**/2005, Order **1224**/2006 \Rightarrow clinics, hospitals- HBB
 - Text





II. COMPETENT AUTHORITIES

CURRENT STATUS





III. Regulation 2024/1938 - new requirements

- ✓ **SCB & 6 WG & Regulatory Committee**
 - ✓ designation of a **SOHO National Authority** - responsibilities & requirements
 - ✓ **SOHO CA** – 1/ more & possibility to delegate certain activities
 - ✓ **New supervisory activities for CAs** – requirements
 - registration
 - SOHO preparation authorisation
 - Activity data collection and reports
 - ✓ new classification of institutions (based on activities) : **entities & establishments**
- ! staff
- ! resources
- ! principles
(conflict of interest)





IV. Gap analysis for blood- at first glance

❑ CA= **MoH – PH Directorate** (designation, legislation, authorisation of BE s & HBBs- delegated)

- lack of dedicated structure & staff



{ external experts, from BEs
national subcommittee – consultative (BE& HBB)

Reduced capacity- risks (conflict of interest?!, multitasks, delays, difficult communication with decision makers, etc.)

❑ **Low capacity** to nominate experts in the WGs

❑ Supervisory activities:

- **Registration**: a. by entities Not having English as a formal language might generate risks ?!
b. by MoH (**who?!**) or by a delegated body (?!)
- **Authorisation of BEs: NOT YET achieved** (Order under approval procedure in MoH- based on Directive)
- **Authorisation of BCs preparation**: no qualified personnel to act as assessors; **BE expert?!**
! question: art.20(1) «review of all SOHO activities..performed for that preparation..» , (3)....
Isn't there an overlapping of verification steps, for processing?!





IV. Gap analysis for blood- at first glance

☐ Supervisory activities:

- **Inspection** training programs needed;
- **Vigilance & rapid alert** CA to be identified, reporting system developed, regulation updated, guidelines, trainings for officers, BEs, hospitals



FUNCTIONAL VIGILANCE SYSTEM

- **Data collection & reporting** CA to follow the reporting process, tools, communication, networking...
! Revise the NIBT role in data collection from BEs since each entity will have to report - platform

The current CA for blood = MoH does not have the capacity to fulfill the requirements in terms of qualified personnel in proper number, premises, QMS.... without dedicated measures for urgent capacity building (political decision, dedicated budget...)





Potential options under discussion(scenarios)

❑ SOHO NA

- MoH
- National Agency for Transplant

❑ CA for blood

A. MoH

- *registration → to be delegated to County PHA or to the NIBT (conflict of interest?!)
- * BEs authorisation → to be delegated to County PHA
- * **BCs preparation authorization ?!** → To be delegated to National Agency of Drugs and ...?! (not yet put under discussion)
→ BEs experts trained as assessors and employed part-time by County PHA (conflict ?!)
- * Inspection → Sanitary State Inspection +/- County PHA – control units (to be decided by SSI)
- * **Vigilance?** → **Maintain it under Sanitary State Inspection?! (would it be compliant with req and principles?!) or create a specific structure/committee?!**
- * Data collection & reporting → Directorate of PH





Potential options under discussion(scenarios)

❑ CA for blood

B. 2 CAs, following the existing system for t&c:

a. National Agency for Transplant

- *registration
- * BEs authorisation
- * BCs authorisation
- * data collection & reporting

NEEDS:

- *Government decision
- *Reorganization
- *Investments
 - Employment
 - Training

! Options for delegation like in the previous scenario

b. MoH- SSI

- * inspection
- * **vigilance?!**





Potential options under discussion(scenarios)

□ CA for blood:

C. 2 CAs:

a. **NIBT**

- *registration
- * BEs authorisation
- * BCs authorisation
- * data collection & reporting

- *Ministerial Order for the reorganization of both NIBT & BE of Bucharest
 - Several structures (reference laboratories) transferred to BE of Bucharest
- * Transfer of experts from BEs to NIBT

**RISK of BEs
system
destabilization**

b. **MoH- SSI**

- * inspection
- * **vigilance?!**

D. CA = **a new institution, dedicated for blood (except for inspection)**

- *Government decision
- *Time, Building
- * Financial, human resources





Potential options under discussion(scenarios)

Conclusion:

- Any option (A-D) requires **considerable government efforts to ensure financial and human resources** to transform the selected scenario into an operational organisation and system in due time
- **2025:** Government **measures to reduce the expenses in all public institutions**, including ministries; limitation of employment
- **Observation:** Shortage of medical personel, reduction of interest to participate in competition for employment, in BEs (to reduce the workload for the few experts, to be involved at national level)
- Considerable time/ work needed to contribute, from external experts —→ **difficulties without dedicated teams at CAs level, employed**



MoH: thorough analysis of requirements, current state (to ID the organisations that might be involved as CAs & delegated body with reduced expences) , **detailed gap analysis used as background for the PoA to create the basis for compliance.**



Government support





THANK YOU!

