

Blood and **beyond**

Competent Authority and
Inspections

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Services



Sanquin

Outline of presentation

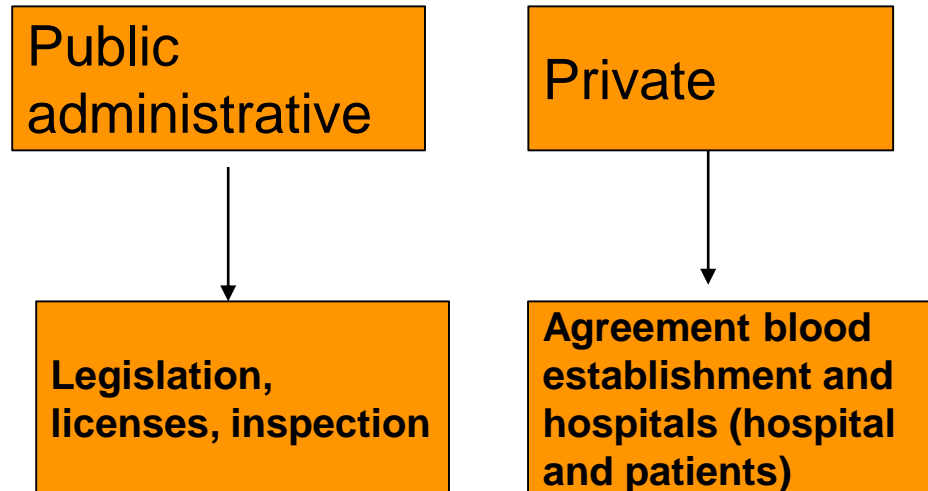
Legal Context perspective

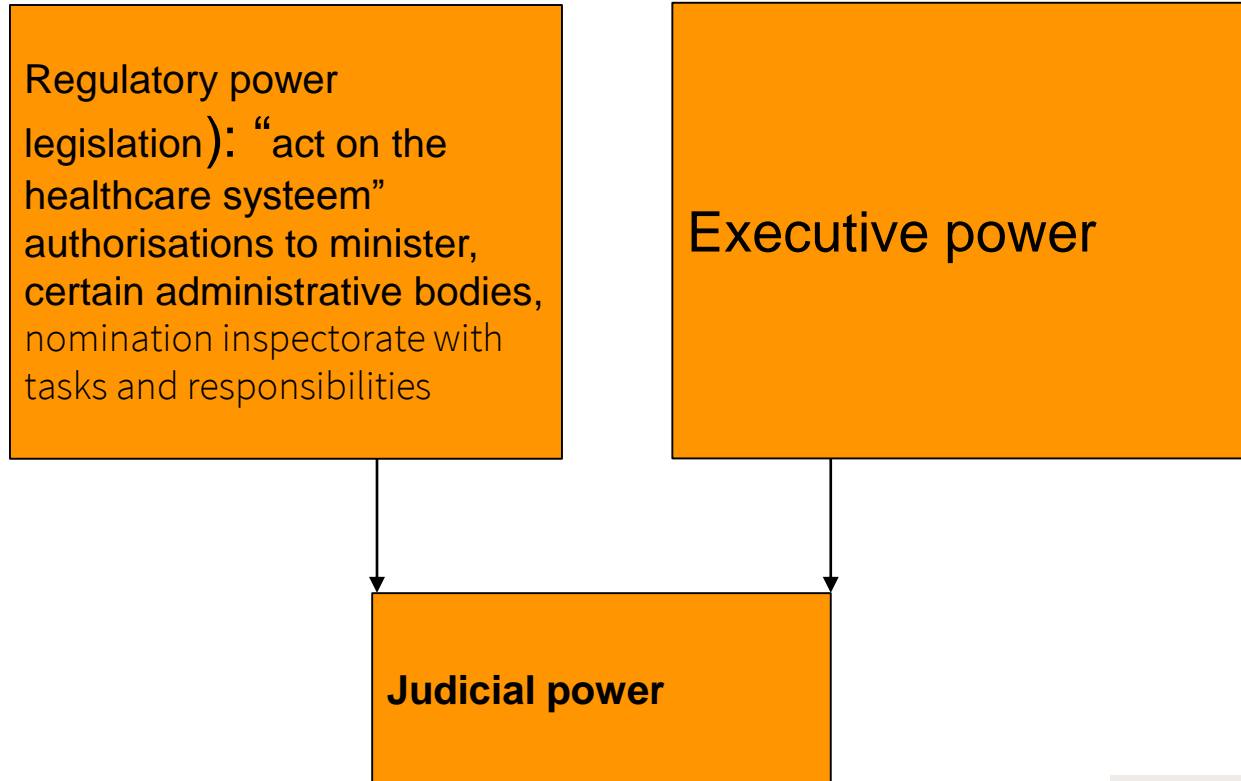
Questions

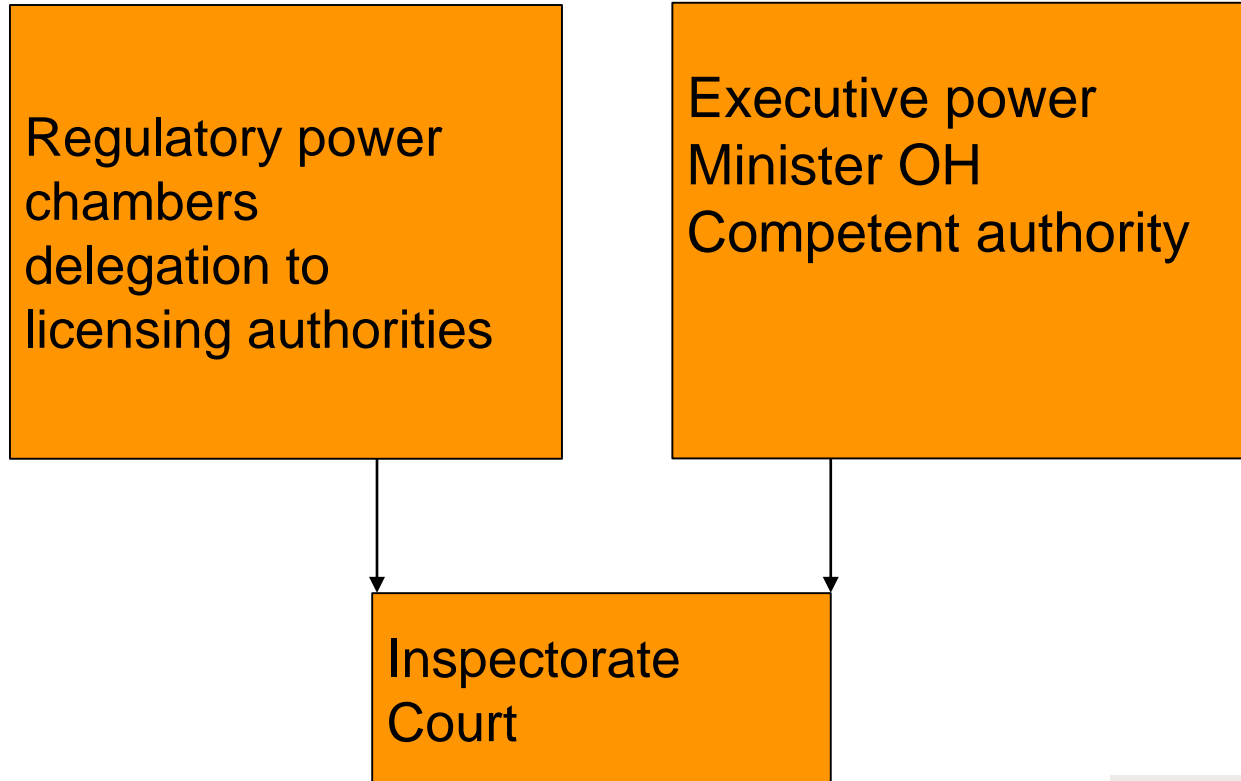
- organization perspective

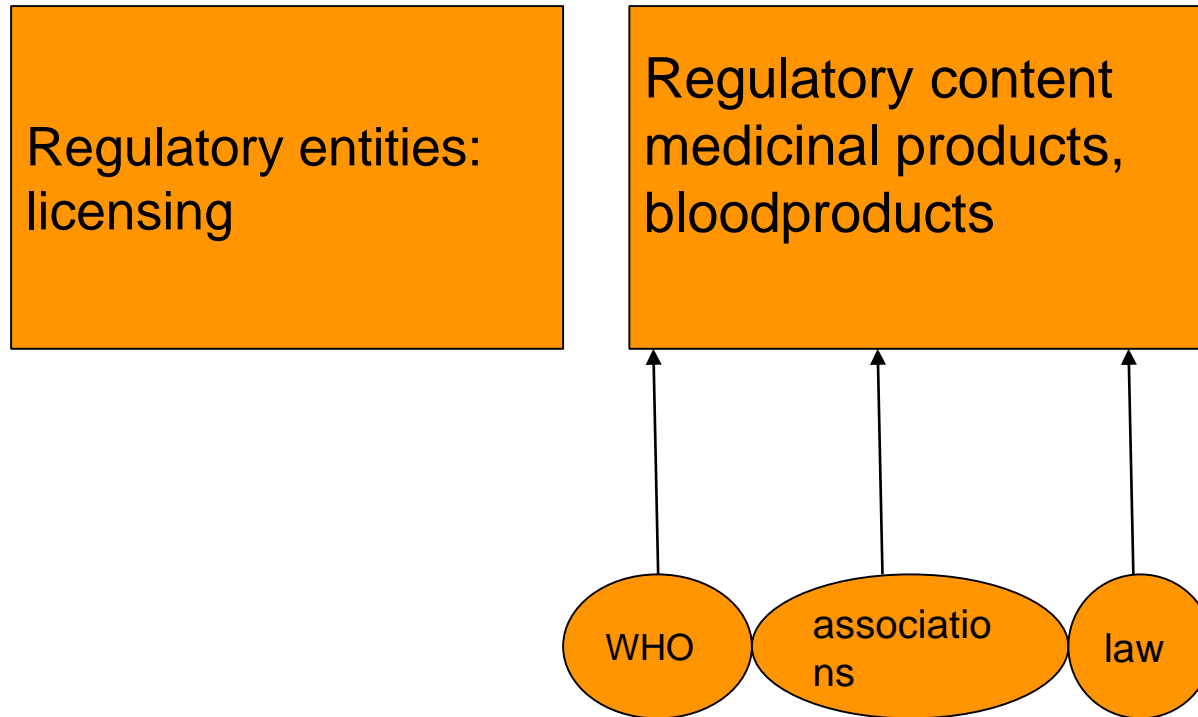
- responsibility perspective

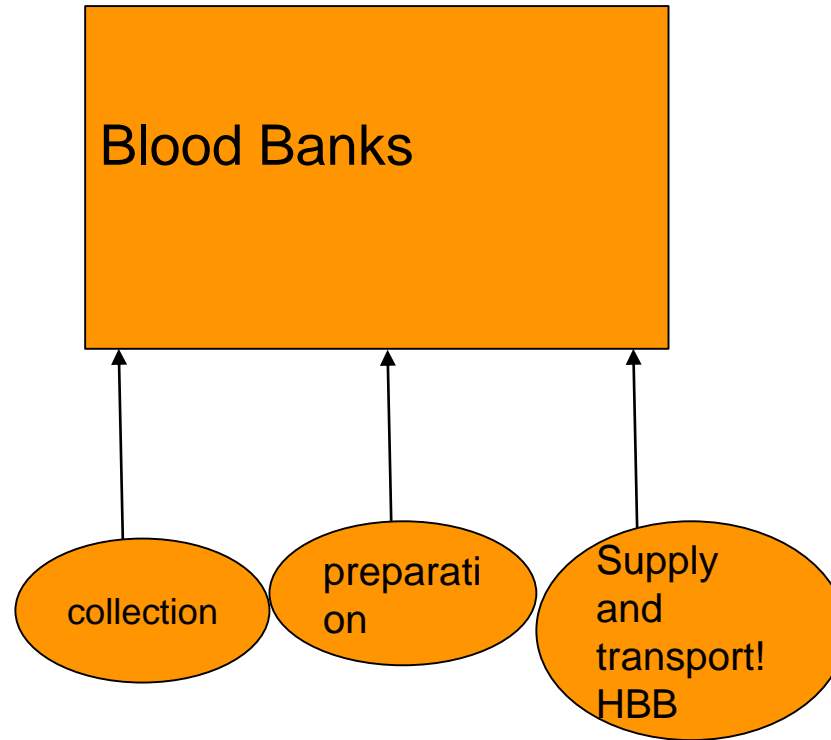
Different options in Georgia

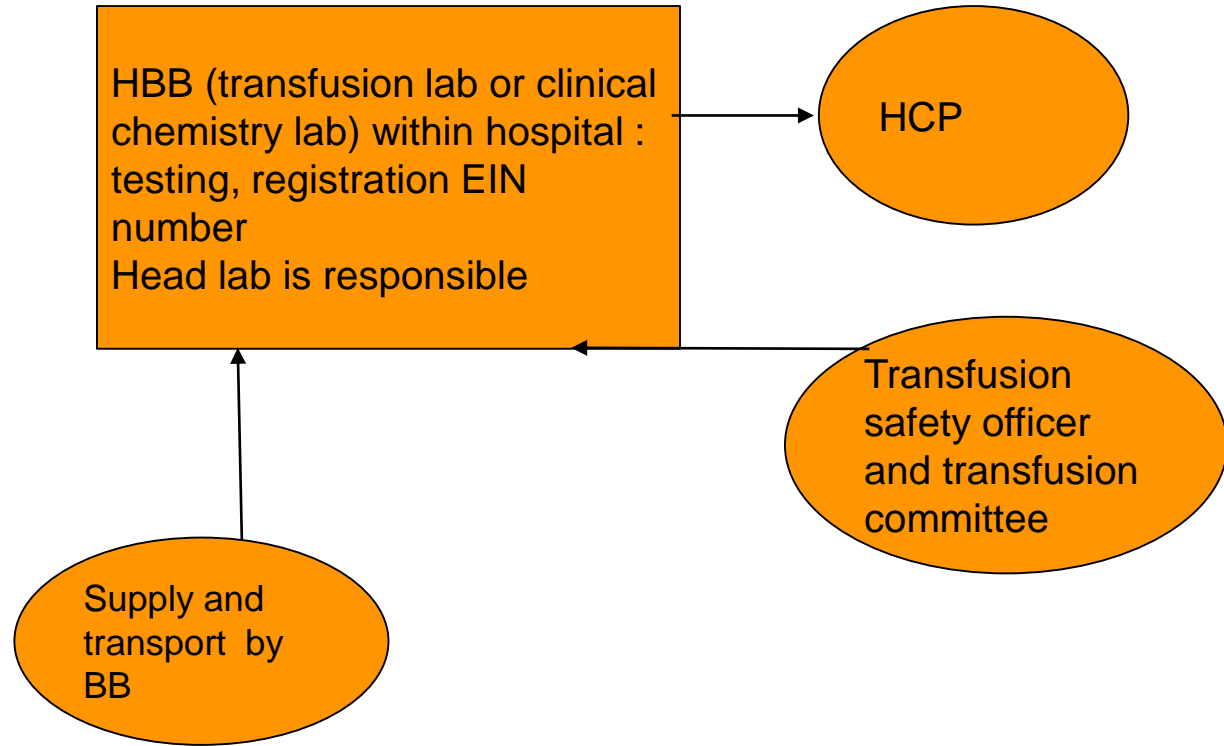












Questions

Tentative functionalities of the future blood safety system monitoring organization or unit (under three possible institutions : MoH, NCDC, Regulation Agency – STEs (LT, NL)

Potential challenges if the future NCA operated under each of these bodies: MoH, NCDC, Regulation Agency – STEs (LT, NL)

EU legal framework: responsibilities

Supervision of blood and blood components collection, testing, processing, storage and distribution

Designation, authorisation, accreditation or licensing of blood establishments

Inspection and control measures

Quality systems

Traceability

Notification of Serious Adverse Events and Reactions (SAE/SAR)

Development of standards, policy making.

Setting of minimum standards

Oversight, inspection, notification of SAE and SAR including traceability,

Reporting on haemovigilance

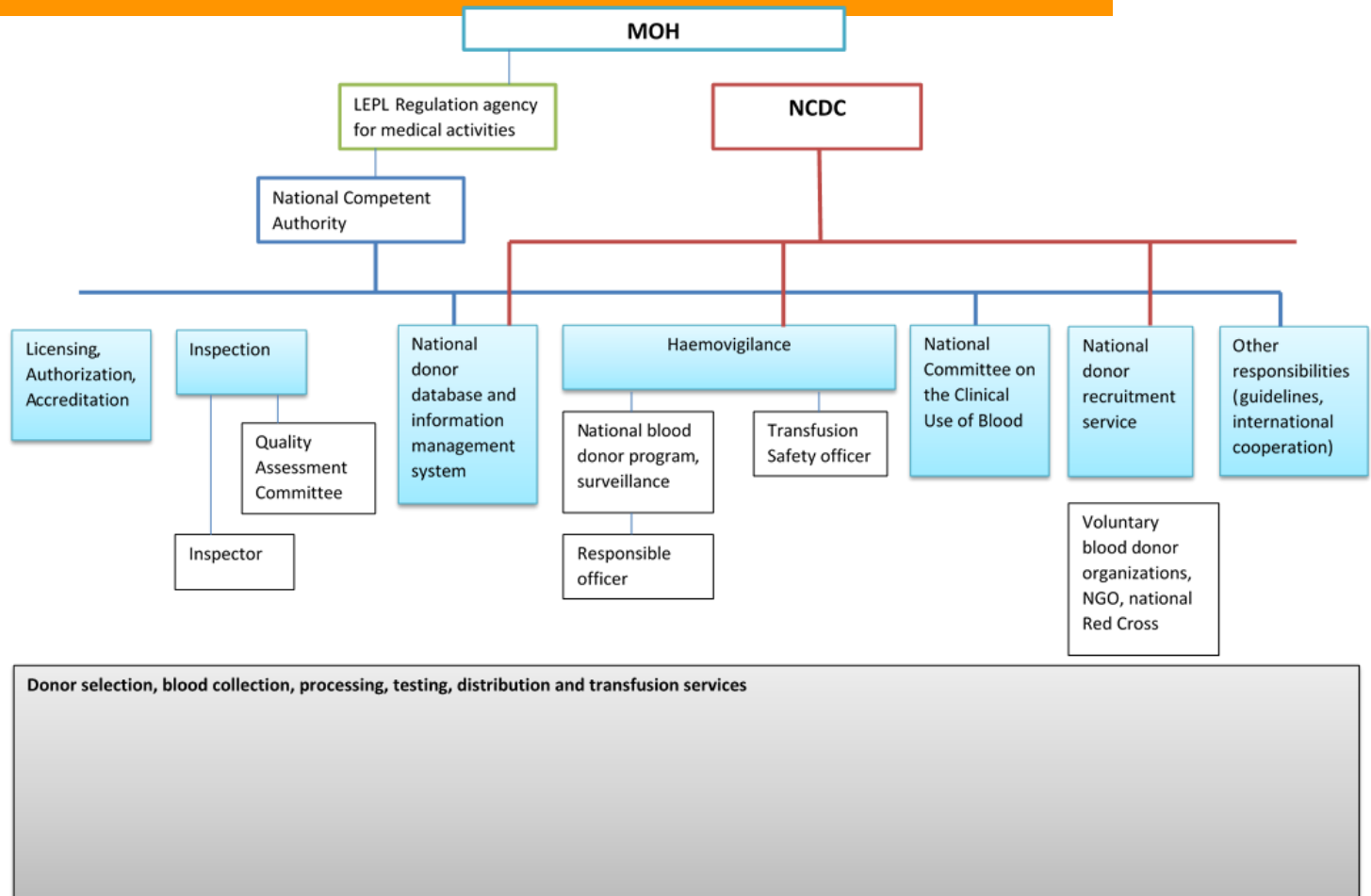
Proposed organization

MoH

Regulatory office and licensing:

NCDC

Policy making



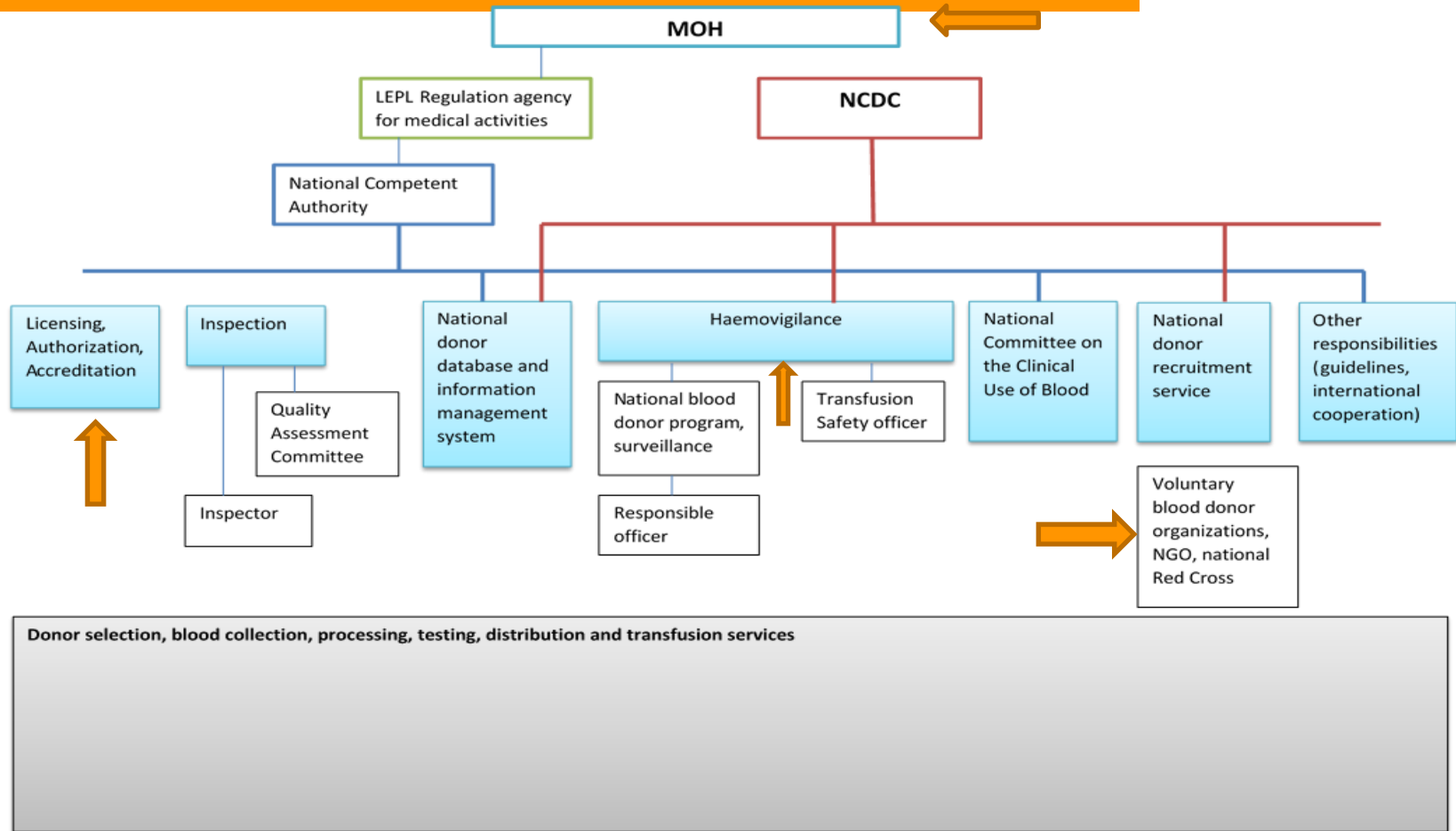
	MoH policy	Regulation Agency	NCDC
Licensing			
- Standards	+	?	
- Assign license		++	
Inspections		++	
- Regular		++	
- directed		++	
Traceability	+	+	+
Notification SAE-SAR		++	
Donor			
- Qualification	+	+	
- Data	+		
- Information	+		
Haemovigilance			
- SAE SAR		++	+
- Adverse reaction			++
- “ACUB”			+
- Reporting	+		+
Good Practices	+ professionals		+

“Organization follows function”

Existing departments

New, activities some related to already existing ones.

Licensing and inspection can be easily incorporated in the existing departments/units (knowledge and experience available)



Haemovigilance

Notification of SAR and SAE is mandatory part of CA.

Haemovigilance includes non SAR and SAE, these are important to monitor quality of the blood transfusion chain at hospital level (patient), blood bank level (product) and reporting (national)

Should involve BE and hospitals and nationally organized

Donor recruitment

Consider the blood transfusion chain: involved are donor organisations (red cross), blood bank, collection centers and hospitals and transfusion laboratories

Government decides on and has oversight on the required donor criteria, the mandatory donor information, and the data protection (privacy). The recruitment can be done by donor organizations as long as they comply with the regulations.

