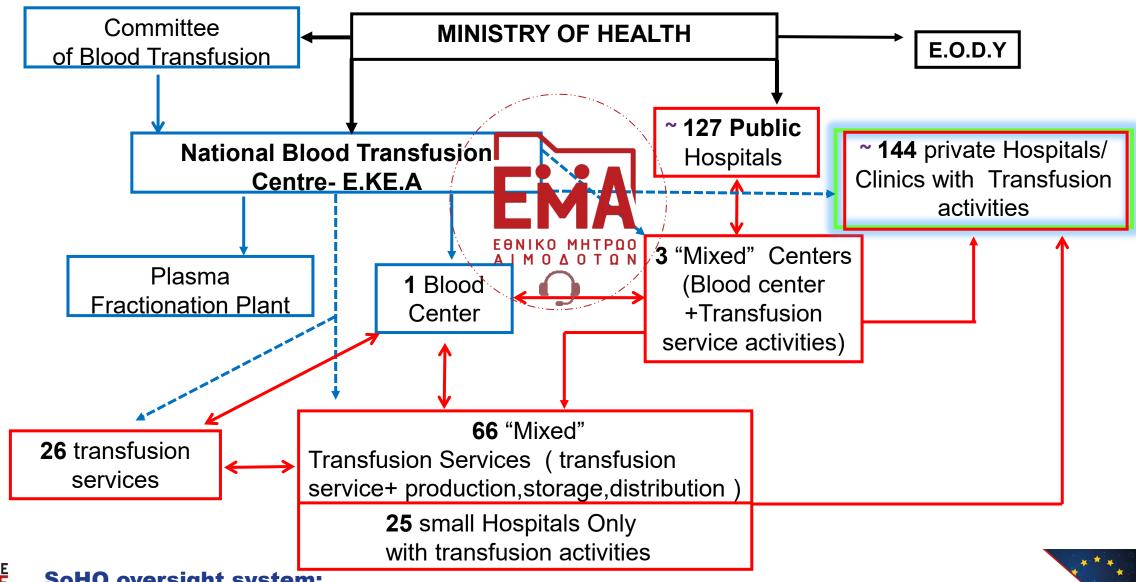


#### Hellas



- General population: 10.5 millions
- Responsibility for transfusion: Ministry of Health through
  Hellenic National Blood Transfusion Center –E.KE.A
- Competent authority for Blood : E.KE.A
- Blood donation index:55/1000 inhabitants
- Blood transfusion index: 12/bed

## Mapping Blood activities



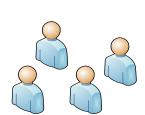


# **Blood donor registry**





**Donors** 426.201



**Donors Associations** 3.500



67 services with information system



96 **Transfusion** Services

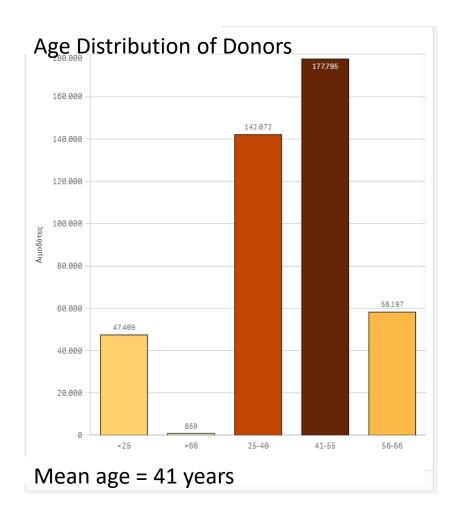
29 services without information system

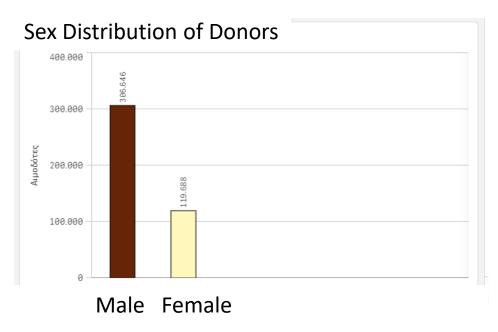
ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΙΜΟΔΟΣΙΑΣ

E.KE.a.



### **Donors Characteristics**







#### **Current situation**

- Designation of Competent authorities based on SoHO categories
  - ➤ Hellenic National Blood Transfusion Center E.KE.A
  - ➤ Hellenic Transplant Organization E.O.M
  - ➤ Hellenic Authority for Medically Assisted Reproduction
- Setting up the SoHO National Authority → EOM
  - ➤ Need for Financial Human and Regulatory efforts
  - ➤ Communication and Coordination between SoHo CAs → regulation needed
  - ➤ Cooperation with authorities of other regulatory sectors → ??
- Setting up the SCB representatives
- Setting up the representatives on SCB working groups (WG):
  - WG on "Vigilance and Traceability"
  - ➤ WG on "Supply"
  - WG on "Inspections"
  - > WG on Authorization and Assessment of SoHO preparations
- No dissemination activities related to the new SoHO regulation









## **Known Unknowns**

Registration of medical / Registry for monitoring the diagnostic facilities clinical outcomes of routine **Blood** for the care of patients components → transfusion human application Clinical outcome registration **Procedures for evaluation** and authorization of new blood components **SoHO oversight system:** the implementation of the new EU regulation with a focus on the obligations for competent authorities

Challenges

Modification of national legislation

Financial resources

SoHO preparation authorization system

Reorganization of SoHO CAs

**Human** resources

Political commitment

National emergency plans

Regulatory expertise

Application of the requirements of the new regulation to facilities → Clinics/Hospital





There is a crack in everything. That's how the light gets in.

- Leonard Cohen

