**European Health Union**

**Stronger rules for greater safety and quality of blood, tissues, and cells**

**WHY THIS PROPOSAL?**

- Supporting **high safety and quality standards** based on up-to-date technical rules for substances of human origin (SoHO)
- Extending the safety and quality framework to **other donated SoHO** such as breast milk
- Implementing **digital-ready policies**
- Improving **crisis preparedness** to safeguard access to therapies
- Extending protective measures to donors and to offspring born from medically assisted reproduction
- Creating conditions for **safe, effective and accessible innovation**
- Improving **harmonisation** across Member States, facilitating cross-border exchange of SoHO and **improving patient access** to the therapies they need

**SAVING AND TRANSFORMING LIVES [FIGURES PER YEAR]**

- **15 MILLION** blood donors
- **4,6 MILLION** patients transfused
- **165 000** babies born from Medically Assisted Reproduction
- **36 000** stem cell transplants
- **14 500** cornea transplants
- **2 000** skin transplants for burn wounds and other injuries
THE KEY MEASURES

STRENGTHENED LEVELS OF HEALTH PROTECTION

- **A wider scope** to cover blood, tissues, and cells, together with other SoHO (like human breast milk or faecal microbiota)

- **High standards for safety and quality**, implemented through technical guidelines developed mostly by expert bodies¹ based on up-to-date scientific evidence

- Renewed commitment to the principle of voluntary and unpaid donation, protecting donors from exploitation and from risks to their own health without discouraging donations

- **Improved reporting and follow-up** on adverse reactions

FACILITATION OF INNOVATION

- **Common EU-wide authorisation procedures** for innovative SoHO preparations

- **Body providing advice** on regulatory status of a substance or a product

HARMONISATION, SIMPLIFICATION & SUPPORT

- **Implementation of risk-based oversight**, for more efficient use of resources (for authorising establishments and activities, carrying out of inspections...)

- Application of **common technical guidelines** while safeguarding Member States’ possibility to have more stringent rules

- **Collection of information** on supply, quality and safety of SoHO for oversight, policy and research

- **EU support to Member States** through training for authorities, joint activities and advisory mechanism

DIGITALISATION

- **Common IT Platform** to facilitate data reporting and information sharing

¹. European Centre for Disease Prevention and Control (ECDC) and European Directorate for the Quality of Medicines and Healthcare (EDQM, Council of Europe)