



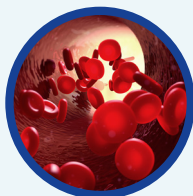
European  
Commission

# European Health Union

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

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



Extending protective measures to donors and to offspring born from medically assisted reproduction



Improving **harmonisation** across Member States, facilitating cross-border exchange of SoHO and **improving patient access** to the therapies they need

### WHY THIS PROPOSAL?

Implementing **digital-ready policies**



Creating conditions for **safe, effective and accessible innovation**



Improving **crisis preparedness** to safeguard access to therapies

## 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 bodies<sup>1</sup> 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

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