

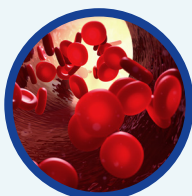


European
Commission

European Health Union

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

Extending the safety and quality framework to other donated SoHO such as breast milk



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

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 & plasma
donors



4,6 MILLION
patients
transfused



OVER 200 000
babies born
from Medically
Assisted
Reproduction



36 000
stem cell
transplants for
blood cancers



OVER 10 000
cornea
transplants



650
heart
valves

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)*