New SoHO regulation and plasma supply

CNS plasma supply conference, 24 April 2024

Health

Key new and changed concepts

- **Scope and advice**
- **SoHO activities, entities and establishments**
- **SoHO Preparations and their authorisation**
- **Standards and hierarchy of technical guidelines**
- **Donor Protection and Voluntary Unpaid Donation**
- **Recipient and offspring protection**
- **Vigilance**
- **Supply continuity**
- **Digitalisation – the SoHO platform**

This presentation explains the concepts in the Regulation, as proposed by the Commission and amended during negotiations.

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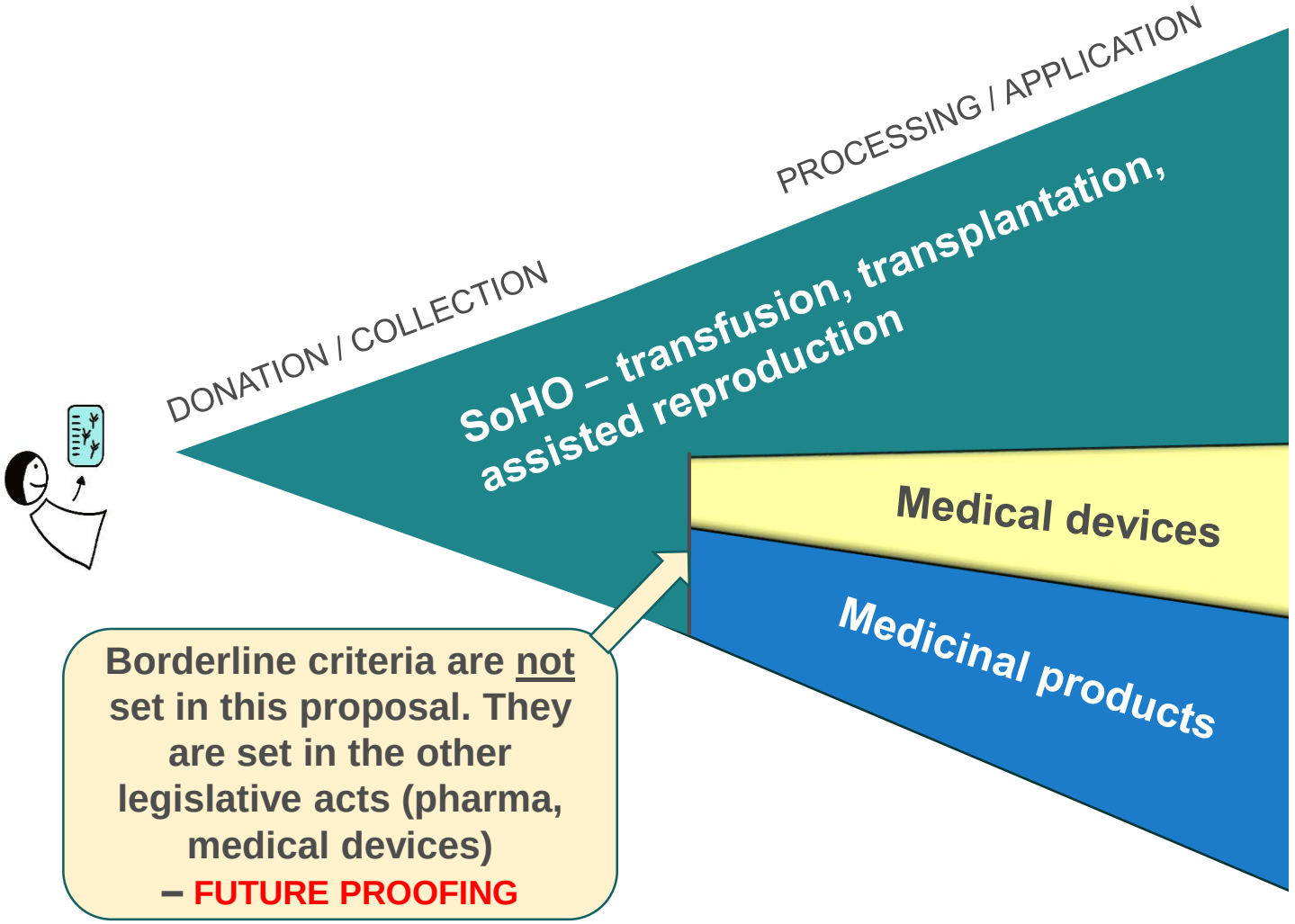
Scope: Regulation covers all steps for all SoHO (some limited provisions for autologous SoHO), unless processing or application steps fall under scope of other EU frameworks (art 2.3) – then SoHO regulation is restricted to certain relevant activities



Borderline criteria are <u>not</u> set in this proposal. They are set in the other legislative acts (pharma, medical devices) – FUTURE PROOFING

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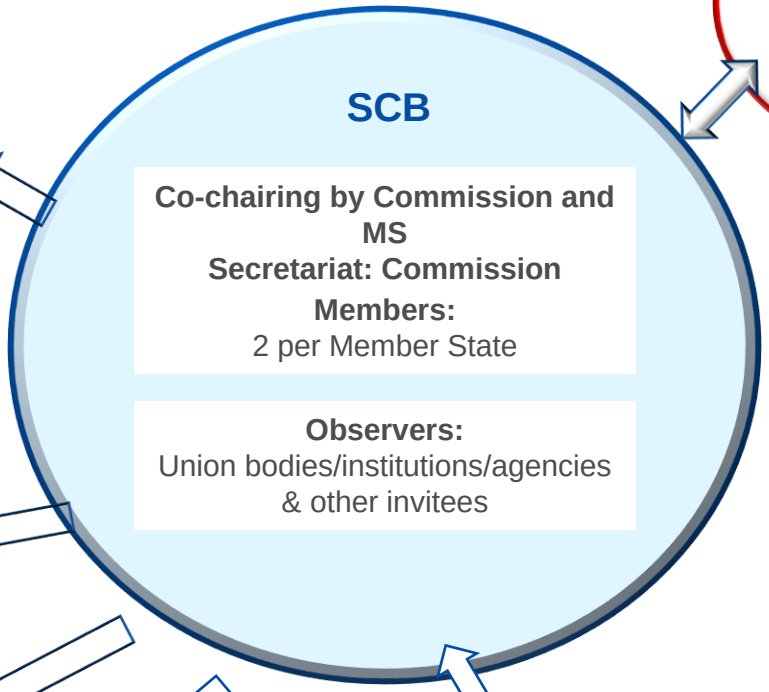
The SoHO Coordination Board (SCB) - supporting implementation in MS

Documentation of
- **best practices** for
  - supervisory functions
  - compensation conditions;
- **Indicative criteria** for critical SoHO and critical SoHO entities

Support for **joint oversight activities**
- inspections
- Preparation assessments

Support for **coordination during emergencies**

Support to COMM on the specifications for the **SoHO Platform**



Advice on whether the SoHO Regulation applies
- Advisory bodies in other legislative frameworks

Compendium on **regulatory status**

Record of:
- national decisions on regulatory status
- Compendium of advice given on regulatory status

Exchanges on good practices with Expert bodies – ECDC/ EDQM and with EMA

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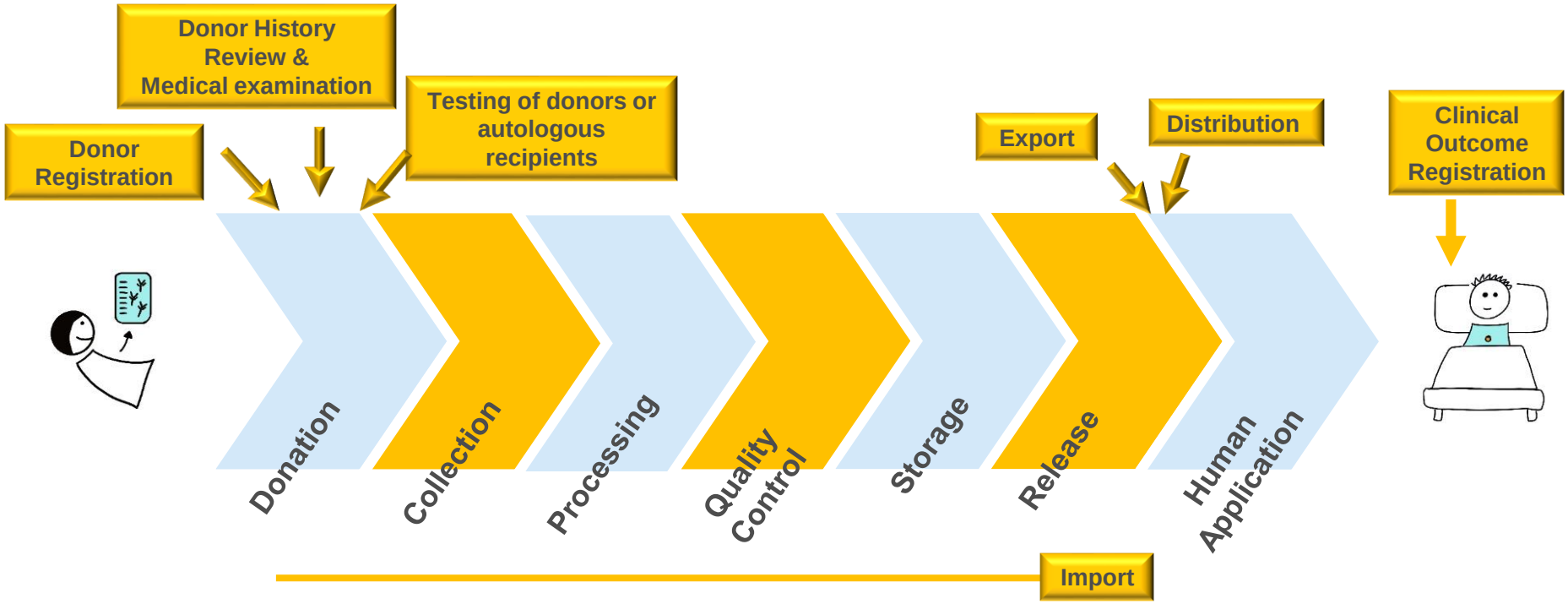
Supervision of all SoHO Activities that directly impact safety, quality or effectiveness



Any actor organising one or more SoHO activity/ies needs to register as SoHO entity with the Competent Authority

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….but risk-based authorisation, ensuring efficient use of authority resources

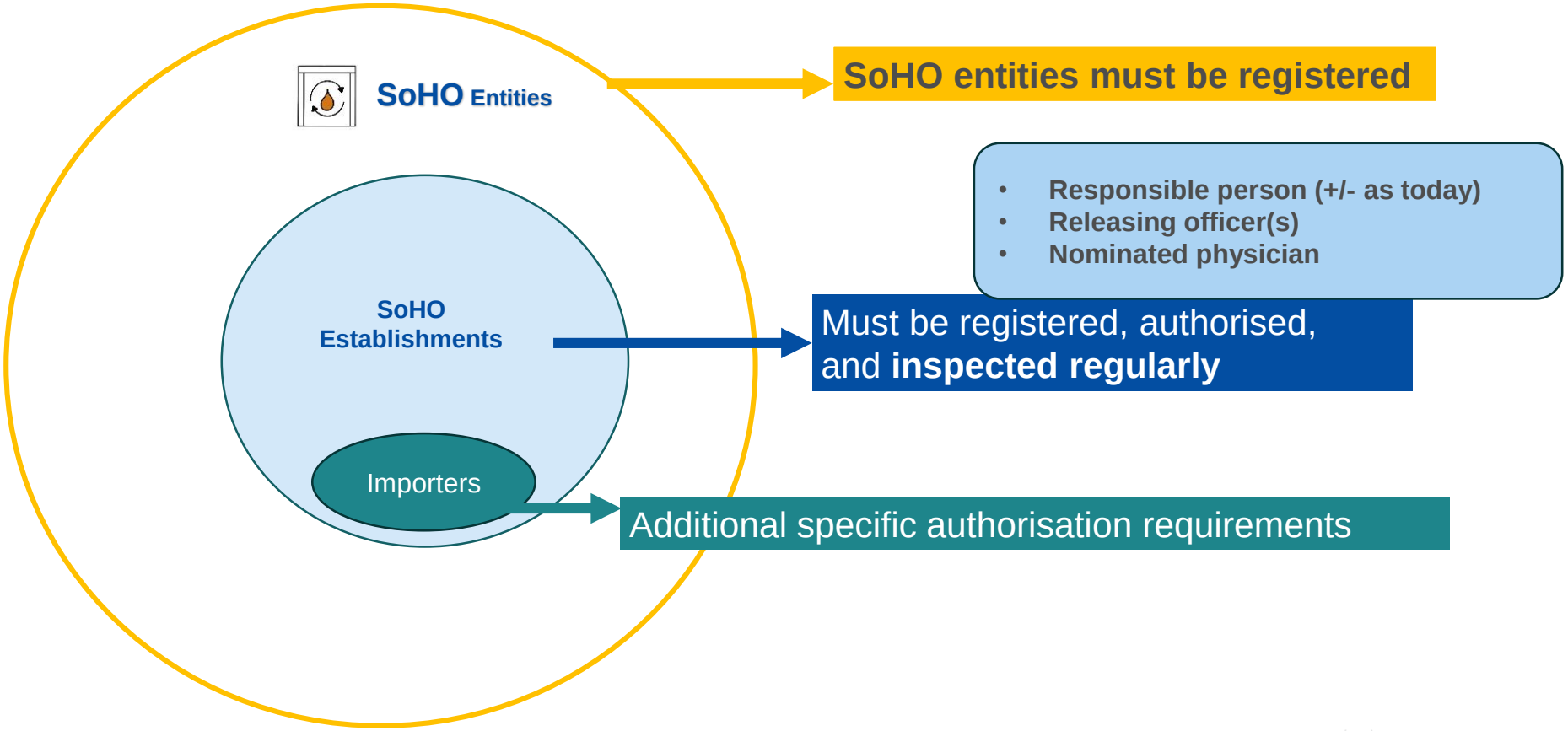
A **SoHO entity** carries out **one or more SoHO activities**

A **SoHO establishment is a SoHO entity that** carries out at least

- **Both processing and storage, or**
- **Release, or**
- **Import, or**
- **Export**

Note: ***CAs may regulate a SoHO entity as a SoHO establishment, even if it does not meet the criteria above, if it considers that the entity has a particularly important impact (e.g. a testing laboratory that tests donors for a whole region or country, a register that identifies and selects donors for one or more Member States).***

The concept of **SoHO entities** and **SoHO establishments:** graded approach to oversight - high level of transparency



Note: ***CA may inspect any SoHO entity, as it considers necessary and may "upgrade" an entity to establishment status***

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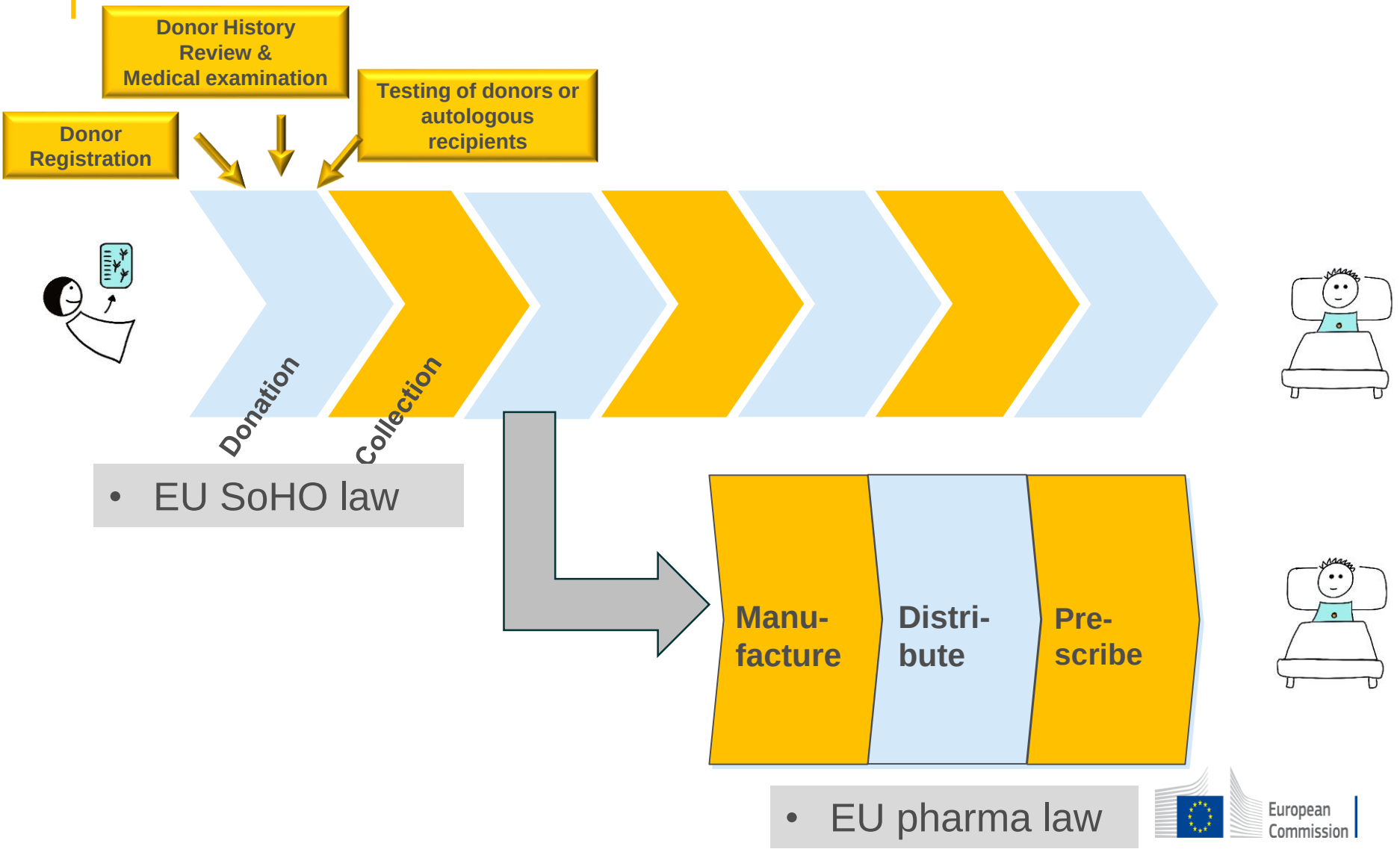
Dual set-up…



- EU SoHO law
- EU pharma law

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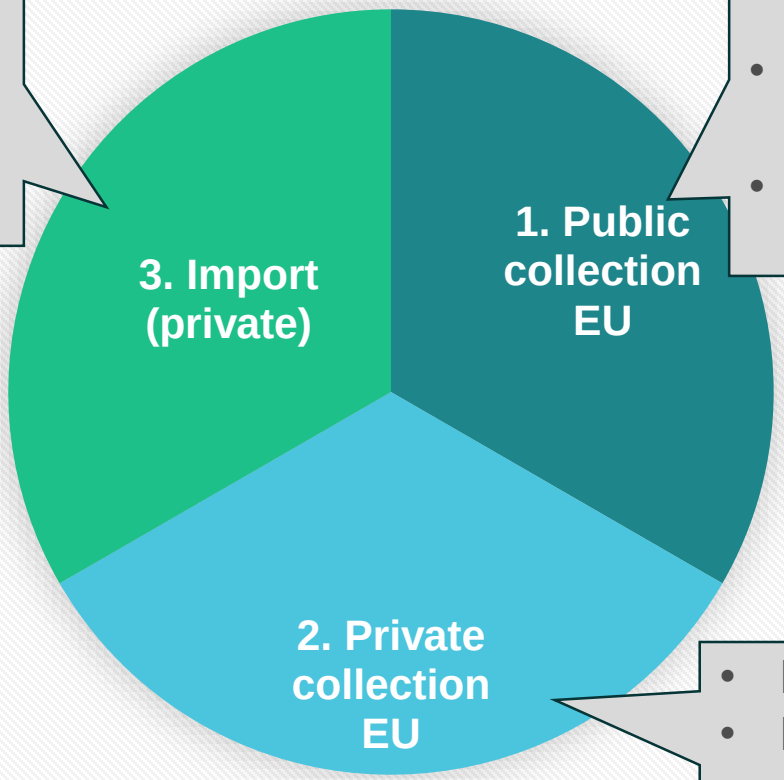
Sources of plasma for PDMP

- Increasing importance, as EU growth in collection (1. and 2.) < EU growth in demand
- Mainly US (Mexico)



- Split out from whole-blood donation + (increasingly) plasma-only donation
- Low frequency donations
- Huge (potential) donor basis (15million)

- Plasma-only donation
- High frequency donations
- Low nr of donors (x00,000)

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SoHO Donor Protection – significantly strengthened

Protection of SoHO living donors before, during, and after the donation.

- Including for donations by relatives
- Information & consent
- Physical and mental integrity, non-discrimination, data protection & safeguarding of anonymity (with some exceptions e.g. ID of MAR parents when allowed or obliged in MS)
- Donor health evaluation
- Risk-proportionate approach to donor monitoring: registration of donors subjected to
    - surgical procedures,
    - medicinal product treatment,
    - frequent or repeated donations implying risk to health.
- Required reporting of serious adverse reactions in donors

Protection of the dignity and integrity of SoHO deceased donors

- Information & consent by relatives, when applicable

Voluntary & Unpaid Donation

Principle maintained
Based on Recommendations of the Council of Europe Committee on Bioethics

- **NO financial incentives or inducements** to donate
- **Compensation** of living donors for losses can be allowed in accordance with the principle of VUD
- When a Member State allows compensation – **upper limit to be set in national legislation** – transparent criteria based on best practices established by the SCB
- Compensation conditions set in MS to be **shared** with the other MS via the SCB
- Donation **promotion and publicity activities** must not refer to compensation (without prejudice to national laws on information provision)

Considerable elaboration of recitals (4) to explain provisions

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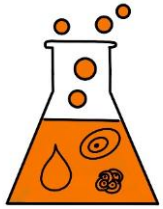
Resilience of Supply



Critical SoHO

'Critical SoHO' are SoHO that for which an insufficient supply will result in serious harm or risk of harm to patients or a serious interruption in manufacture of critical products regulated by other legislation.

A '**critical SoHO entity**' is a SoHO entity that carries out activities contributing to the supply of critical SoHOs and the scale of those activities is such that a failure to carry them out cannot be compensated by activities of other entities or alternative substances or products for recipients.

Supply of **critical SoHO** is protected by:

- **Obligations on Member States** to ensure a sufficient, adequate and resilient supply
  - Facilitate donation
  - Communication and education
  - Optimal use
- **Activity data collection** and monitoring
- Supply **alerts**
- National **SoHO emergency plans**
- SoHO Entity **emergency plans**
- **Derogations** and additional measures in emergency situations

New article!

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Next steps
Entry into Force and Date of Application

- Formal approval by the Council and the European Parliament
- The Regulation will enter into force 20 days after its publication in the Official Journal of the European Union – during **2024** (~ before summer)
- 3 years before the provisions become applicable - **2027** (an additional year for some provisions)

Need for comprehensive end-to-end actions

- Improve organisational efficiency (public sector)

Donation

Collection

- Public awareness building
- Donor recruitment and retention
- …

- Plasma sale with supply conditions
- Toll/contract manufacturing
- …

Manu-facture

Distri-bute

Pre-scribe

- On/off-label use,
- Central approval system
- Prioritization schemes
- …

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Thank you

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