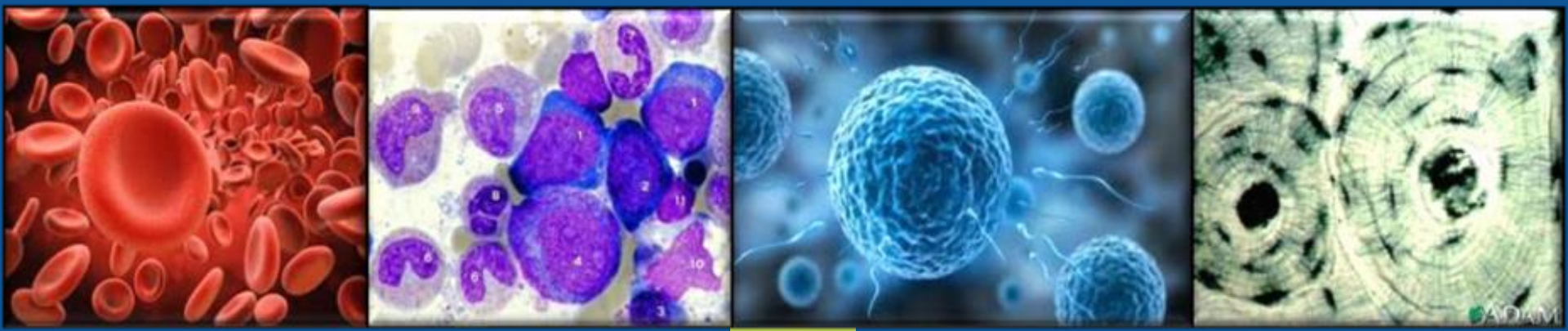
EU legislation and policy on blood and blood components

HMA/EMA multi-stakeholder workshop on shortages
1-2 March 2023 - Amsterdam

Stefaan Van der Spiegel, SoHO/SANTE, European Commission



To a (recipient) body… from a (donor) body

Plasma/ Blood

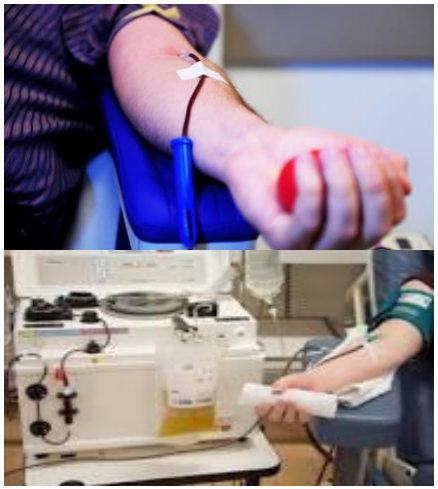
Human API

Manu-facture

Marketing Authori-sation

Pricing and Reimburs ement

PDMP (Immunogl)



Health service

Industrial setting

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Relevant Mandates for the EU

Art 168 of the Treaty on the Functioning of the European Union

- 4(a) measures setting **high standards of quality and safety of** organs and substances of human origin**, blood and blood derivatives**; …

- 4(c) measures setting **high standards of quality and safety for medicinal products** and devices for medical use

- 7. Union action **shall respect the responsibilities of the Member States** for the definition of their **health policy and for the organisation and delivery of health services and medical care** …

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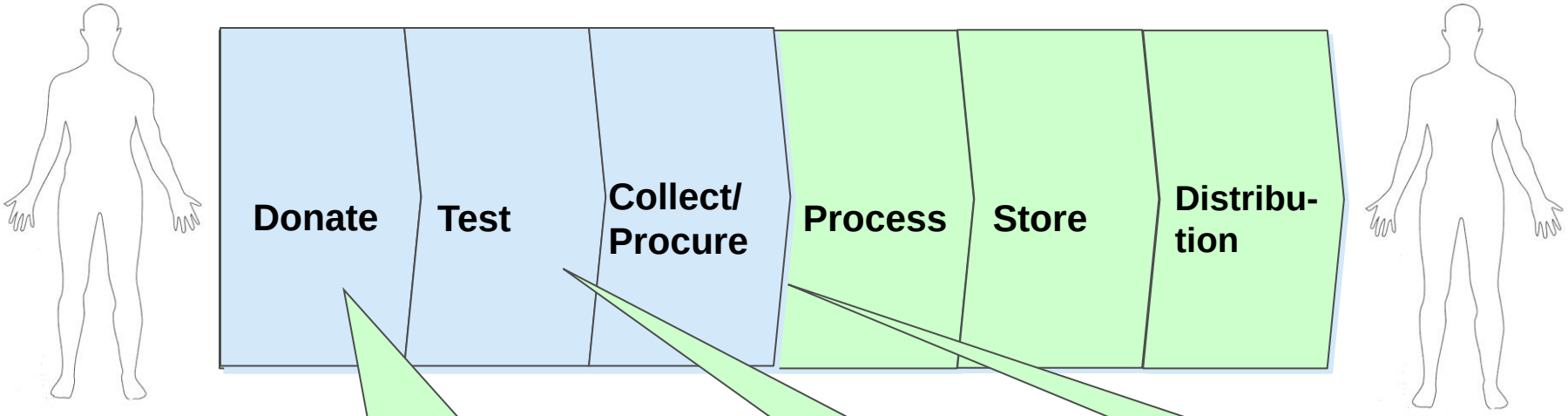
EU legal SoHO frameworks (Blood, Tissues&Cells, Organs)



① **Professionals**

Selection/deferral, consent…

HIV, Hepatitis B, Hepatitis C..

Quality requirements

② **National Competent Authorities**

Oversight: authorisation, inspection, vigilance, traceability,…

③ **European Commission**

EU-level support: coordination, alert systems,…

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SoHO Donor Protection (COM proposal SoHO Regulation)

SoHO entities shall ensure high levels of safety of SoHO living donors (…) before, during, and after the donation. (Art. 52)

Standards for Donor Protection (Art. 53)

- Including for donations by relatives
- Information & consent
- Data protection & safeguarding of anonymity
- **Donor health evaluation**
- Risk-proportionate approach to donor **monitoring**: registration of donors subject to
  - surgical procedures,
  - hormone treatment,
  - frequent or repeated donations.

+ Donor adverse occurrence reporting requirements
+ Possibility for self reporting
(Art. 35 and 47)

- Trust amongs population is essential for all SoHO-therapies to have donations, including for >15million blood/plasma donors

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Voluntary & Unpaid Donation

(COM proposal SoHO Regulation)

Charter of Fundamental Rights

Recommendations of the Council of Europe Committee on Bioethics

SoHO entities shall **not provide financial incentives** or inducements to SoHO donors or their relatives or any persons granting authorisation on behalf of the prospective donors, in accordance with national legislation (Art. 54)

SoHO entities **may compensate or reimburse** SoHO donors as provided for by their competent authorities (…)

- Compensation or reimbursement **for losses related to donation** are permissible
- Based on fixed- **…y Member State**
- Allowances mu… …n standards for VUD

Receiving a return or payment – not necessary motivator to donate

Impact on broader population and SoHO landscape

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Supply continuity (COM proposal SoHO Regulation)

- Obligation on Member States to **promote SoHO donation activities**
- Concepts of ‘critical SoHO’ and ‘critical SoHO entities’
- Mandatory **activity data reporting**
- Requirements for supply alerts
- Requirements for emergency plans
- General **standardisation of technical rules** supporting inter-MS exchanges

- EU Legal mandate is limited to safety/quality
- Link to EMA work on MP/PDMP
- Blood (health) systems are within national remit, but…
  - MS can be supported with EU budget (Emergency Support Instrument/COVID, EU4Health – SUPPLY)
  - [Coordinated national plans – Rapporteur EP SoHO proposal]

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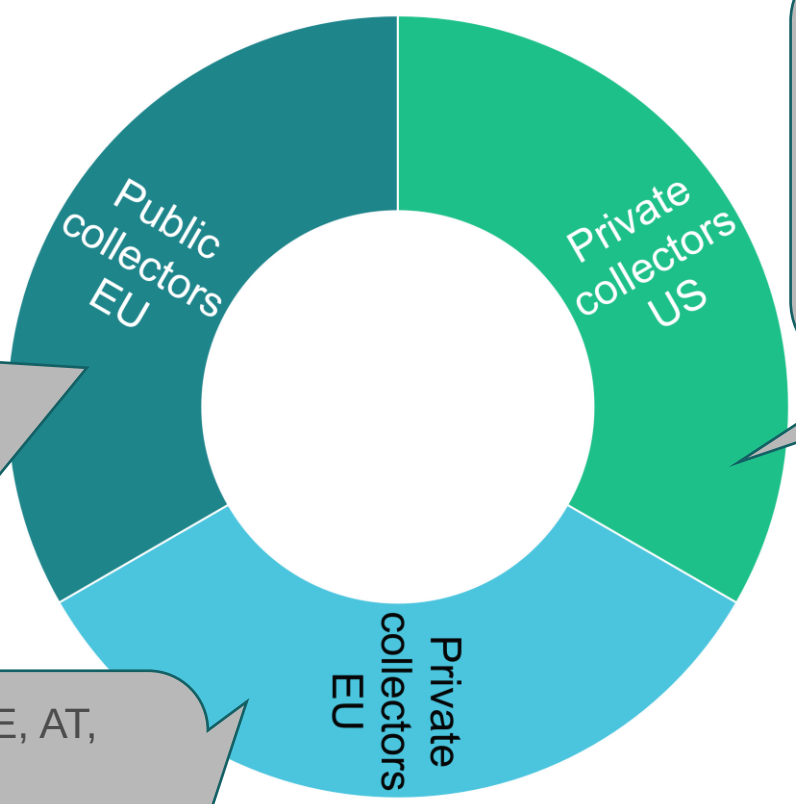
Source of Plasma for EU-Immunoglobulines

- In all 27 EU MS
- Public HC service or NGOs
- Recovered from whole blood donations
- Increasing plasmapheresis programmes
- 15million regular donors



- Fills the (increasing) gap
- Plasmapheresis donors only
- Collecting for US and rest of world
- (strategic dependency)

- In 4 MS (DE, AT, HU, CZ)
- Plasmapheresis donors only
- Few 100,000s frequent donors

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EU Plasma Collection

(Liters/1000inh, 2019-2021)

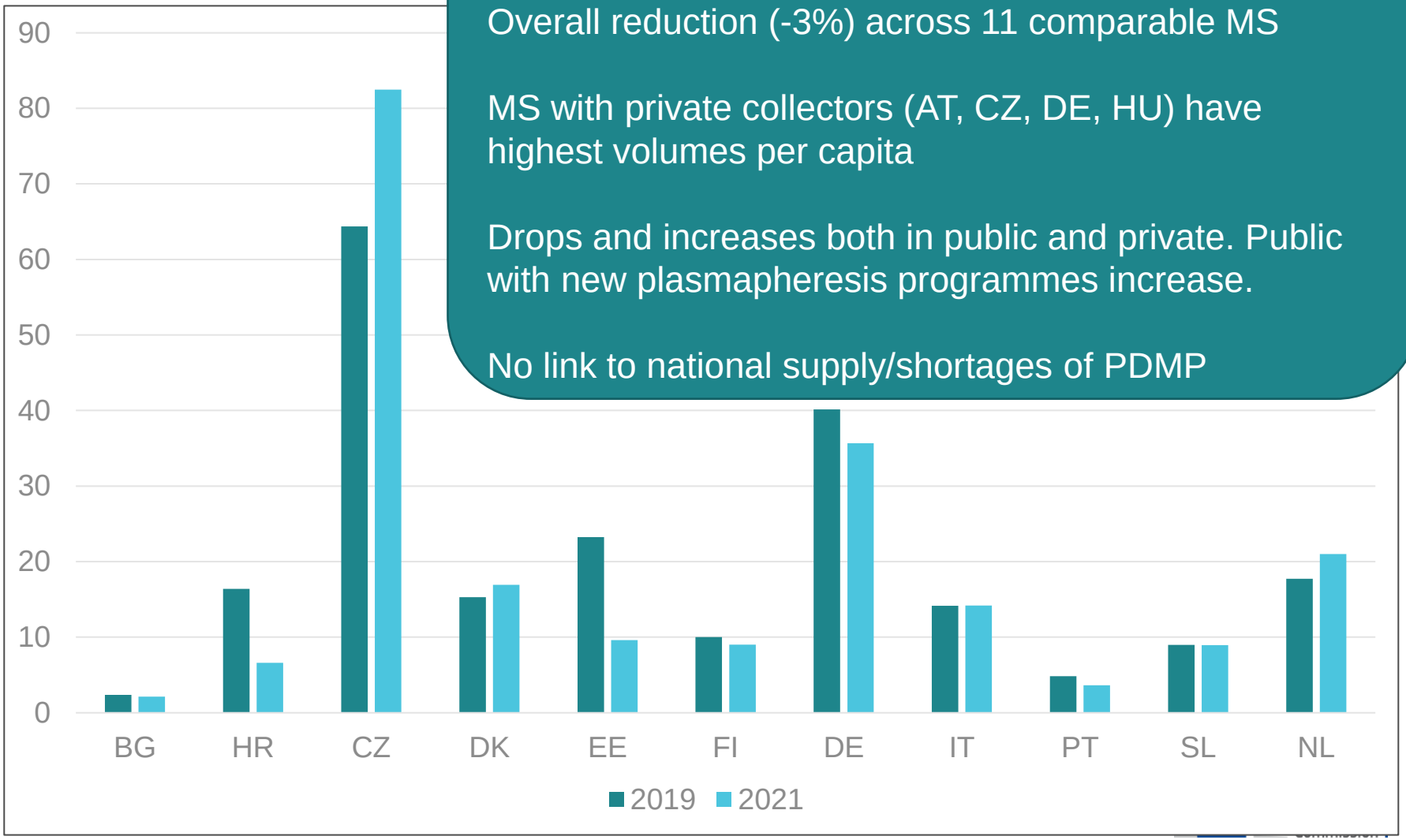
Fragmented reporting

Overall reduction (-3%) across 11 comparable MS

MS with private collectors (AT, CZ, DE, HU) have highest volumes per capita

Drops and increases both in public and private. Public with new plasmapheresis programmes increase.

No link to national supply/shortages of PDMP



Source: data reported to EDQM, Eurostat

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Pharma legislation/revision

- Structured dialogue - pointed to dependency of API supply from 3rd countries
- EMA mandate - reinforced role in crisis preparedness/management
- Joint Action - root causes, monitoring/reporting, preventive strategies, best practices
- Pharma Revision – stronger supply and transparency obligations, earlier notifications of shortages and withdrawals, enhanced transparency stocks and stronger EU coordination/mechanisms
- EMA monitoring of plasma/PDMP supply during COVID-19

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Coherence between two frameworks needed to facilitate supply

- Alignment of **technical guidelines** for plasma collection (GMP annex 14 (Manufacture of Products derived from Human Blood or Human Plasma)
- Alignment **oversight**
  - Traceability and pharma/biovigilance
  - Inspections and authorisations (e.g., SoHO Inspection Working Group + PICS)
- **Coordination**
  - Ad-hoc: EMA (BPWP, PMF) and National Competent Authorities Blood, e.g., COVID
    - Flexibility in donor deferral criteria (MSM, tattoos, …)
    - GMP inspections 3rd countries (distant inspections, validity, …)
  - Structural: COM proposal SoHO regulation:
    - Coordination at national level between respective authorities
    - Coordination at EU-level (SoHO Coordination Board)

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Need for supply+demand actions - across chain from donor to patient, with centralised support

(EDQM/SANTE 2019 stakeholder workshop - Recommended actions)

- Donor Association (awareness building amongst 15m blood donors)
- Blood Establishments (increase collection/organisational, ensure donor safety, good practice exchange)
- Manufacturers (data and knowledge sharing (supply, SARE, best practice, decision support (including on optimal use), collaboration)
- Professional societies, patient associations (optimal use, good practice)
- Member States/National Competent Authorities (national targets for collection/use, monitor/report, contingency plans, donor vigilance)
- EDQM (Council of Europe) (data reporting, awareness building evidence based guidance, networking and conference on optimal use)
- European Commission, EMA (donor protection and vigilance, support awareness building, support strategic independence, optimize S&Q legal framework, …)

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Concluding remarks

- API of PDMP = donations of plasma and blood by citizens

- API can therefore be available in every EU country, and depends on
  - Public awareness/willingness to donate (high)
  - Capacity to collect

- Current capacity to collect plasma differs per country
  - Presence of private collectors (DE, AT, HU, CZ)
  - Potential to convert blood donors in public services (SUPPLY)

- High volumes of collected plasma ≠ local supply of PDMP (allocation)

- Shortages of PDMP
  - Supply/demand disbalance: EU growth collection < growth in use of PDMP, compensated by increasing import of US plasma
  - Will require actions across the chain from donor to patient

- EU legislation, on SoHO + pharma, can improve, be more coherent and facilitate supply… but supply/demand balance requires organisational measures at national level

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Thank you

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