Perspectives and strategies for a common policy for European self-sufficiency for PRMP

ISS, Rome – 29 April 2020

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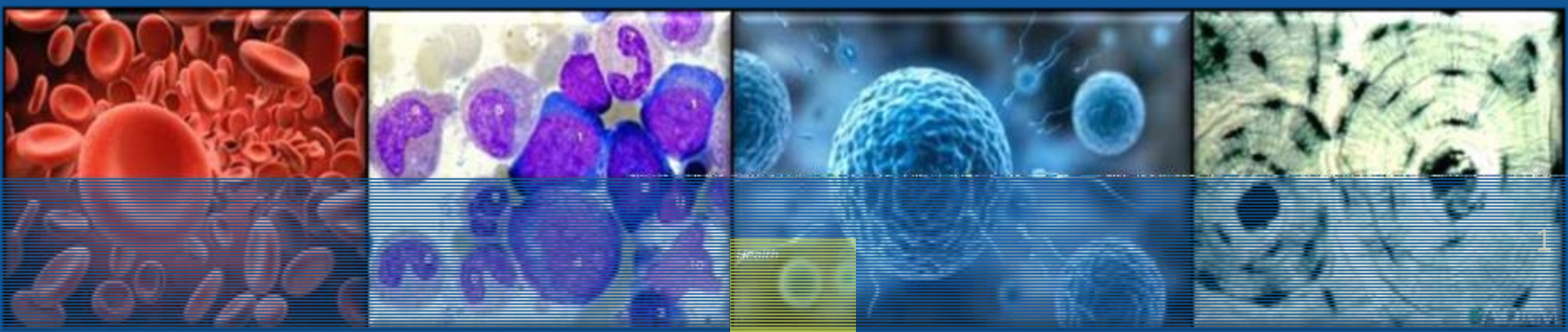
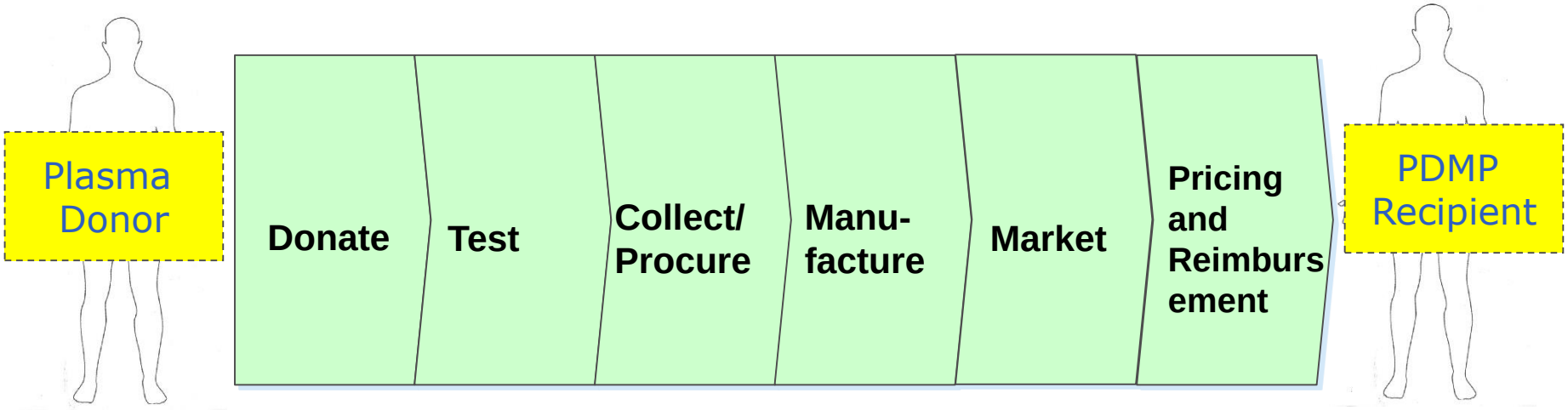
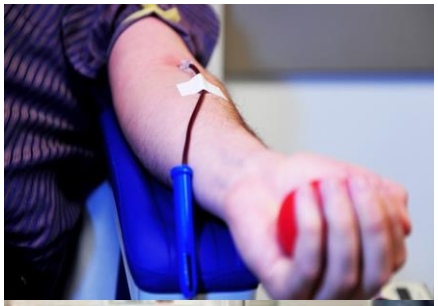


PDMP are subject to a flow of steps from donor body to recipient body





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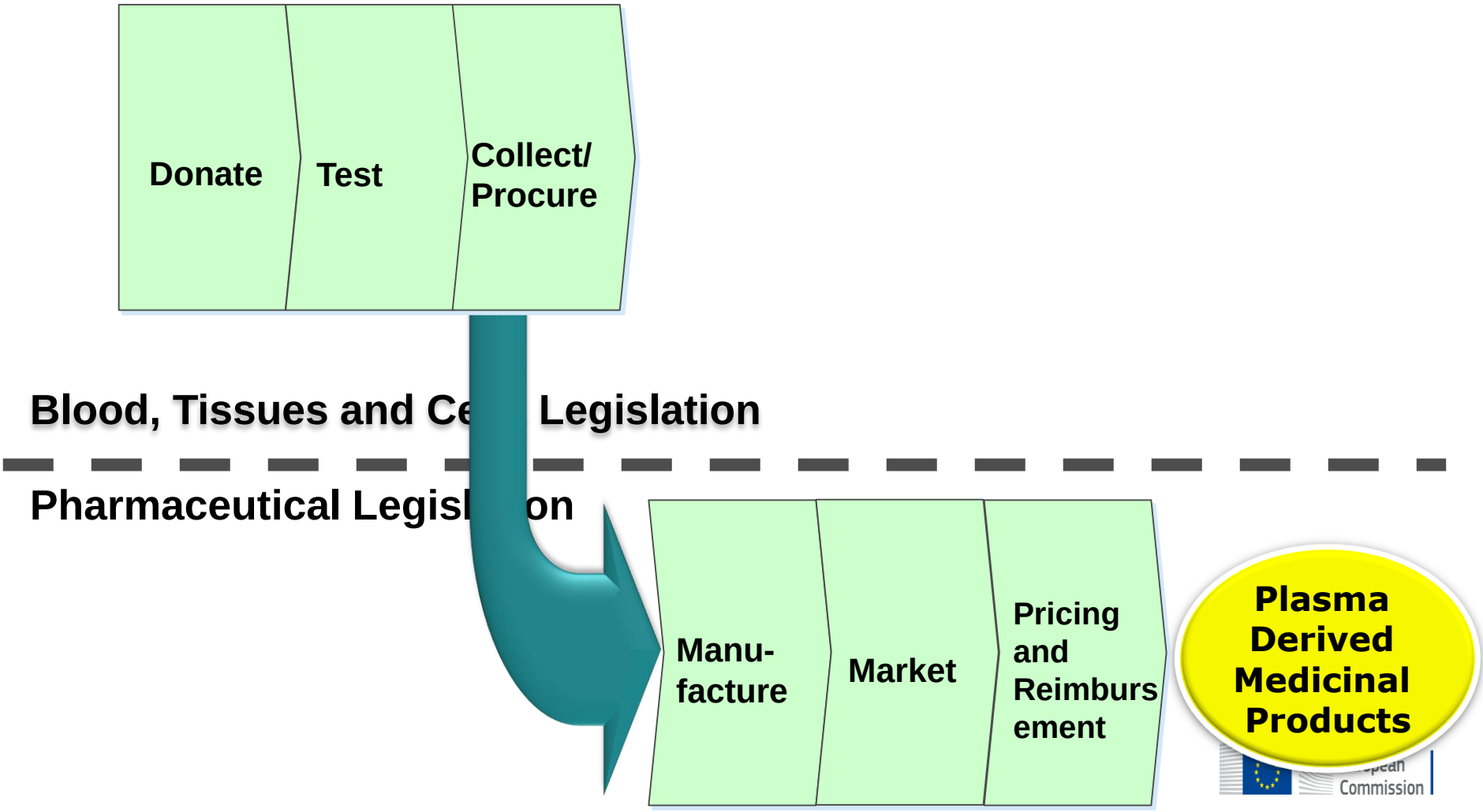
And therewith subject to a dual legal framework

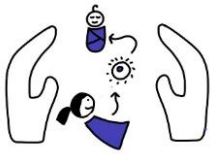


Why a revision of the BTC legislation?

-> To address 5 gaps/shortcomings identified during the 2019 evaluation

- **1. Patients are not fully protected from avoidable risks**

EU safety and quality requirements are incomplete and have failed to remain up to date with frequently changing scientific and epidemiological developments. The outdated provisions are technical in nature



- **2. Avoidable risks for BTC donors and for children born from donated eggs, sperm or embryos**

Donor adverse reactions (including serious ones) are not systematically reported and the requirements for testing egg and sperm donors for genetic conditions are limited.

- **3. Divergent approaches to oversight cause unequal levels of safety and quality and barriers to the exchange of BTC across the EU**

Lack of general principles, provisions for verification of effective implementation of inspection, authorisation, vigilance.

- **4. BTC legislation lags behind innovation**

Limited clinical data on safety and efficacy of new ways of processing donations. Difficulties in defining the borderlines for novel BTC with other regulatory frameworks

- **5. EU vulnerable to interruptions in supply of some BTC**

High dependence on plasma import. Lack of supply monitoring for crisis management.

Directive on Blood & blood components: 2002
Directive on Tissues & Cells: 2004

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Reliance on US for sufficient plasma for the manufacture of plasma-derived medicinal products

Global plasma supply is out of balance, dependent on one country/region – should we be concerned?

BTC Legal Measures explored:
Manage supply issues through…

- strengthening supply monitoring
- emergency supply preparedness

(+ structural dialogue / pharma strategy)

Non-legal BTC measures possible (cfr support national services)

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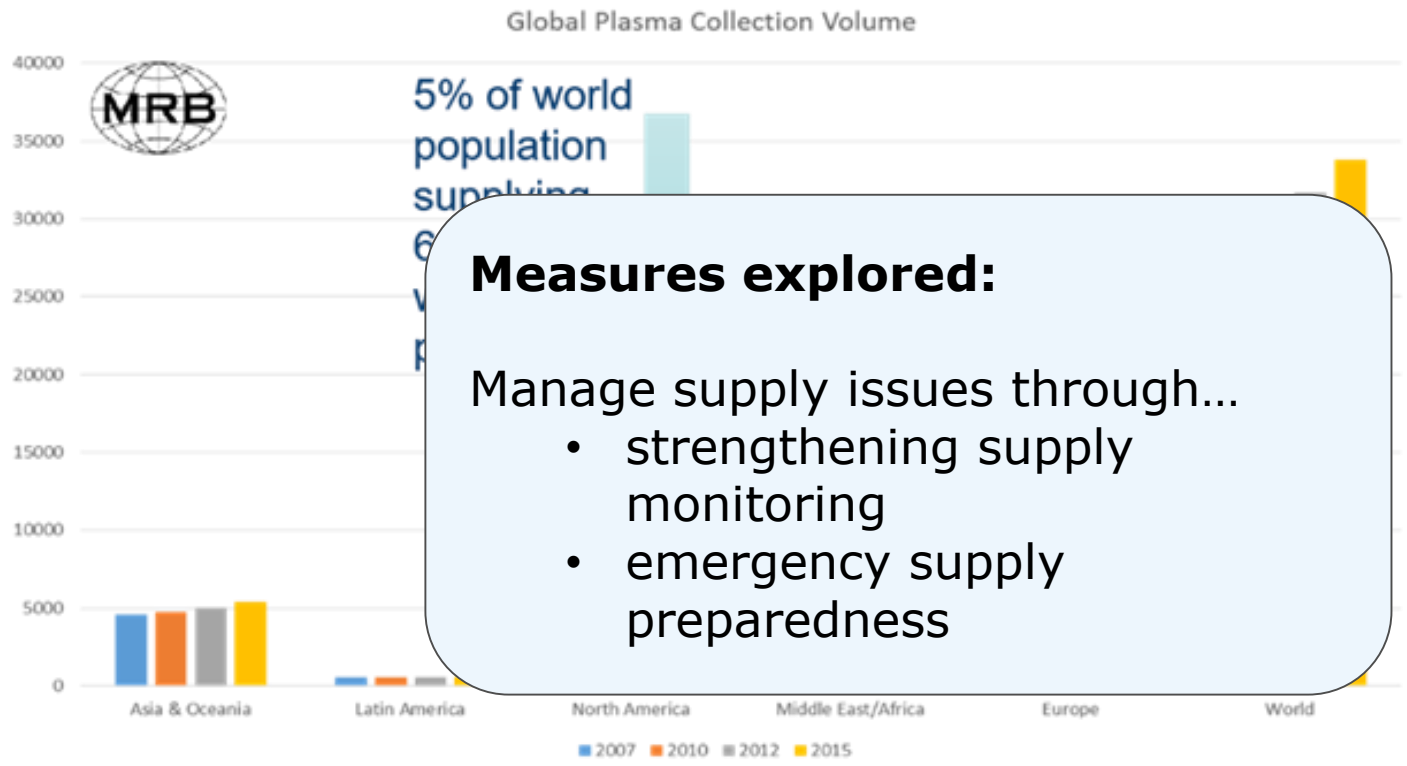

Measures explored:

Manage supply issues through…

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EDQM/EC Symposium plasma supply (2019)

Recommended actions

- European Commission (donor protection and vigilance, awareness building on need for collection, support strategic independence, optimize legal framework, …)
- EDQM (Council of Europe) (data reporting, awareness building evidence based guidance, networking and conference on optimal use)
- Member States/National Competent Authorities (national targets for collection, monitor/report, contingency plans, donor vigilance)
- Manufacturers (Collaboration on optimal use, data and knowledge sharing (SARE, best practice, decision support)
- Blood Establishments (increase collection, donor safety, good practice exchange)
- Patient Associations, Donor Association, Professional Societies (awareness building, optimal use, good practice)

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Structured dialogue on the security of supply of medicinal products

- To strengthen the resilience of pharmaceutical supply chains and ensure the security of supply of medicines, without compromising the affordability of medicines.
- Reports prepared by pharmaceutical manufacturing value chain actors: public authorities, research community, health professionals and patient organisations.
- Commission developing a policy paper, using the reports generated in the first phase as an input. Publication planned for Q2 2022
- Next steps will include further engagement with actors
- This is linked to the ongoing review of the pharmaceutical legislation under the Pharmaceutical Strategy and the work of HERA

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on **a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices**

- The Agency can facilitate a coordinated EU-level response to health crises by:
  - monitoring and mitigating the risk of shortages of critical medicines and medical devices;
  - providing scientific advice on medicines that may have the potential to treat, prevent or diagnose the diseases causing those crises;
  - coordinating studies to monitor the effectiveness and safety of medicinal products intended to treat, prevent or diagnose diseases related to the public health crisis;
  - coordinating clinical trials for medicinal products intended to treat, prevent or diagnose diseases related to the public health crisis;
  - transferring the expert panels of the Medical Device Regulation to the Agency.
- The legislation formally establishes the Medicines and Medical Devices Shortages Steering Group, NCA Single Point of Contact (SPOC) Working Party and the Emergency Task Force, working on the above tasks.

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Thank you for your attention !