



Immunoglobulins Breakout Session: HMA-EMA Multi-stakeholder workshop on shortages

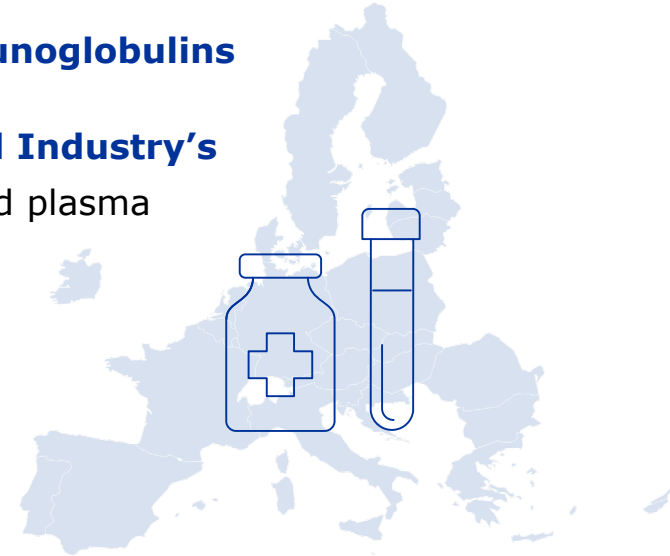
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Regulatory Science and Innovation Task Force, EMA



Objectives of the session on immunoglobulins

- ❑ Inform of the **regulatory landscape** and **initiatives** undertaken in the EU/EEA
- ❑ Discuss the **link between plasma** supply and supply of **immunoglobulins**
- ❑ Understand the **Patients and Healthcare Professionals and Industry's perspective** on availability and supply of immunoglobulins and plasma collection
- ❑ Facilitate and **strengthen interaction** between the involved **stakeholders**



Topics presented

1 Overview of immunoglobulins supply situation in the EU/EEA (EMA)

EMA initiatives for monitoring the supply of plasma-derived medicinal products (PDMPs).

Preliminary results of the survey to the Medicine Shortages SPOC WP and CAP Marketing Authorisation Holders on availability of immunoglobulins in EU/EEA.

2 EU legislation and policy on blood and blood components (DG SANTE, EC)

Proposal for a Regulation on standards of quality and safety for substances of human origin (SoHO) intended for human application.

Need for multistakeholder collaboration (*from donor to patient*) on supply and demand actions.

3 SUPPLY project (ISS and European Blood Alliance)

Initiatives to strengthen unpaid plasma collection capacity in Europe, including recommendations for the development of a proposal of common EU policies.

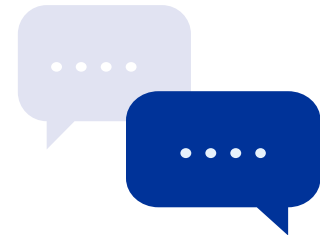
Preliminary outcomes of the survey to competent authorities on plasma collection and PDMP production from national plasma.

Outcome of the discussion – issues identified

- ❑ Imbalance between the **supply and demand** of immunoglobulins - lack of continuous access to appropriate treatment for patients **resulting in severe consequences**. Impact on patients health taking into consideration the existing guidelines should be undertaken (evidence-based prescriptions).
- ❑ **Fragmented legal frameworks**/policies for plasma and PDMPs at the Member State level.
- ❑ Imbalance between plasmapheresis and whole blood collection procedures, and the consideration to **increase plasma collection** through the **increase of plasmapheresis procedures incl. increase in the number of plasma collection centres** is needed.
- ❑ **Harmonisation and streamlining production efficiency** to increase yields for the supply of immunoglobulins.
- ❑ Need for **timely and accurate supply forecasting data** from industry and other stakeholders involved to allow regulators take preparatory actions to prevent and mitigate potential and actual shortages.
- ❑ Need for further analysis on the **root causes** of the shortages.
- ❑ Further information and analysis is needed on the **role of pricing and reimbursement of the products**.

Outcome of the discussion – possible actions

- ❑ **Support from the EC to the MSs** with financial actions and coordinated plans for increasing plasma collection. **Investments** in the public (*donor recruitment*) and private sector (*novel technologies*) for plasma collection, production and product development.
- ❑ **Harmonisation in different areas** e.g., donation of whole blood or plasma, donor deferrals.
- ❑ **Regulatory flexibilities** for Plasma Master Files, mutual recognition agreement (MRA) for GMP Inspections, new plasma collection centres.
- ❑ Development of **harmonised clinical recommendations** (*to prioritise indications*) and monitoring their application/adherence.
- ❑ Close **collaboration between all stakeholders** to ensure patient access to PDMPs, including immunoglobulins.



Thank you for listening

Further information

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is
an agency of the European Union

