



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Overview of immunoglobulins supply situation in the EU/EEA

Preliminary results of the survey on availability and supply of immunoglobulins
in the EU/EEA

Breakout session 2A: Immunoglobulins; HMA/EMA multi-stakeholder
workshop on shortages

Presented by Klaus Kruttwig, Supply and Availability of medicines and devices, EMA

An agency of the European Union



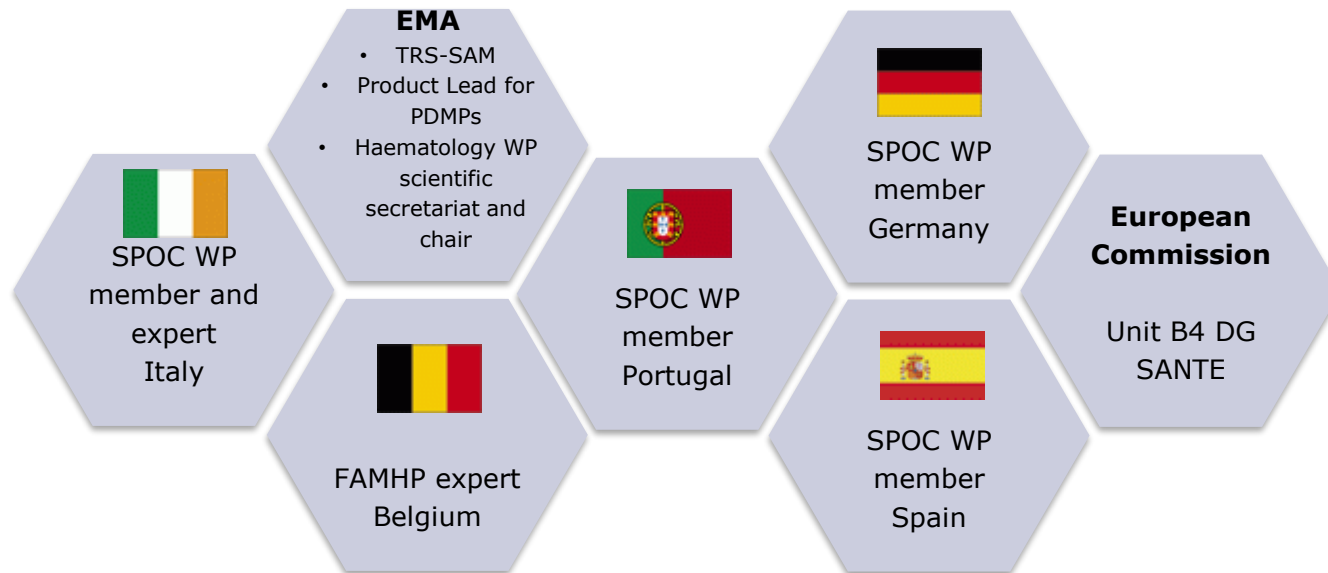
Recent initiatives for monitoring the supply of PDMP (1/2)

- Regular updates provided to the SPOC WP during its monthly meetings
- Shortages of immunoglobulins have been discussed in the SPOC WP since 2019 and brought to the attention of the MSSG.
- Regular exchange with the EC SoHO team, EDQM and ECDC as well as through the Blood cluster (with FDA and HC).
- **Two surveys** conducted in 2021 and 2022 to map shortages and availability issues of IV/SC human normal immunoglobulins and investigate root causes
- **Surveys** on the impact of **COVID-19** on PDMP supply



Recent initiatives for monitoring the supply of PDMP (2/2)

- **Drafting group of the SPOC WP** on supply and availability of immunoglobulins set up in February 2022





Surveys on impact of COVID-19 on PDMP supply (2020/2021)

3 surveys were sent to Plasma Master File Holders (PMF-Hs): April and Oct. 2020 and Feb. 2021 to understand the impact of COVID-19 on authorised medicines where plasma is used for its manufacture (impact on blood donations, plasma collection and supply and impact on medicines)

To get a forecast in months of PMF-H's current inventory for the EU Market assuming normal demand pattern

All PMF-Hs confirmed they **had activated mitigations plans** to meet their commitments to patients

Shortages of immunoglobulins have been notified to EMA in December 2020 and January 2021

All PMF-Hs confirmed that they have **sufficient inventory for the EU market. No additional shortage notification** received since January 2021.

Survey on the availability of IV/SC human normal immunoglobulins in the EU/EEA in 2022



The **main objectives** of the survey conducted by the SPOC WP subgroup on immunoglobulins:

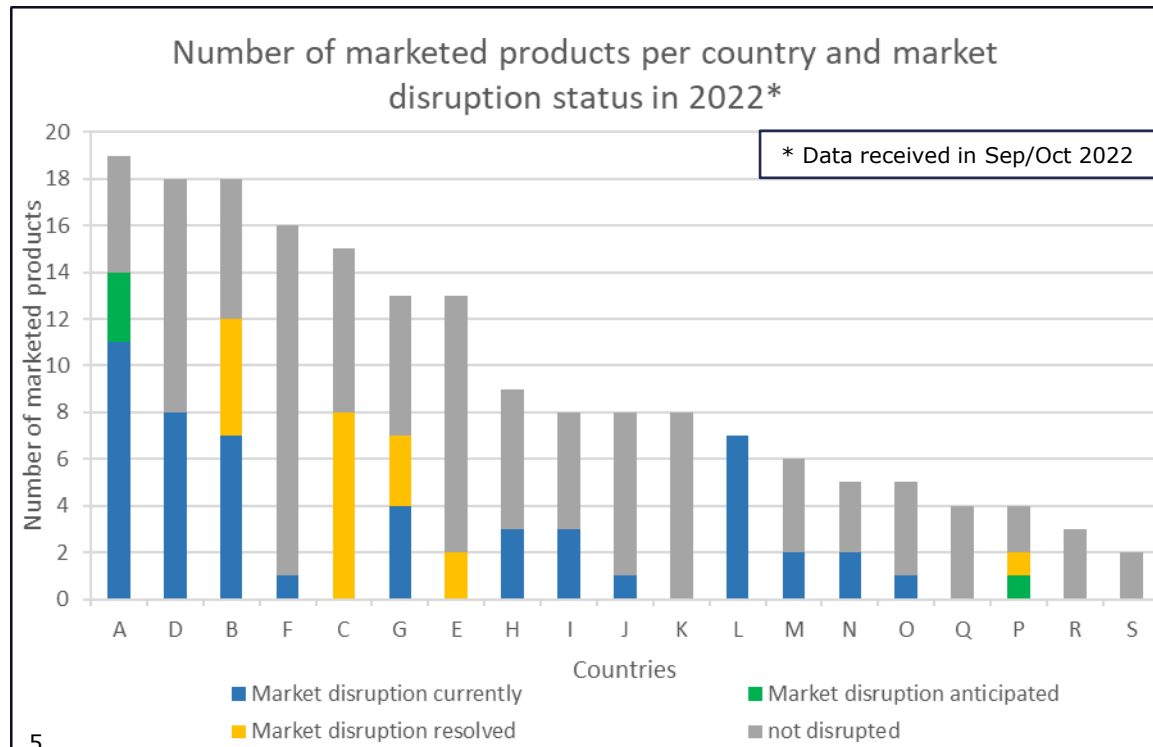
- To receive an overview of the **availability and shortage situation of the products** in the individual countries
- Availability of **stock level information**
- Overview of the **historical consumption and forecast** demand data

Scope of the survey:

- Information from nationally authorised products (NAPs) was submitted by the National competent authorities (NCAs); For centrally authorised products (CAPs) Marketing authorisation holders (MAHs) were contacted directly by EMA.
- 21 Member States submitted information; currently data included from 19 Member States

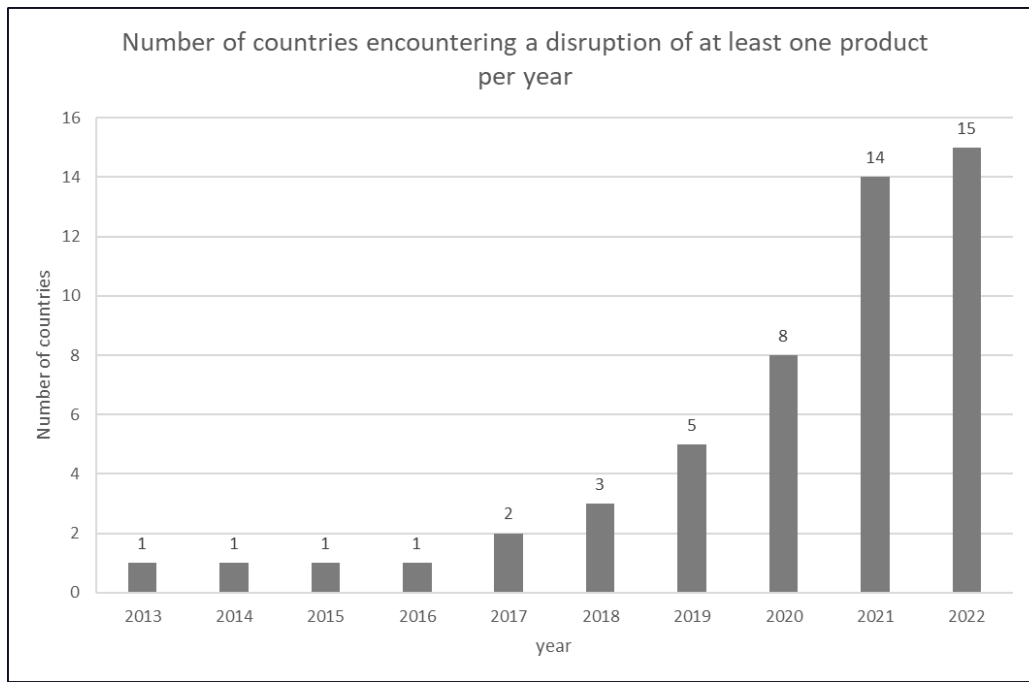


Preliminary results: overview of products marketed in EU/EEA and number of products affected by a market disruption in 2022



- ❑ 4/19 countries were not affected by a market disruption in 2022

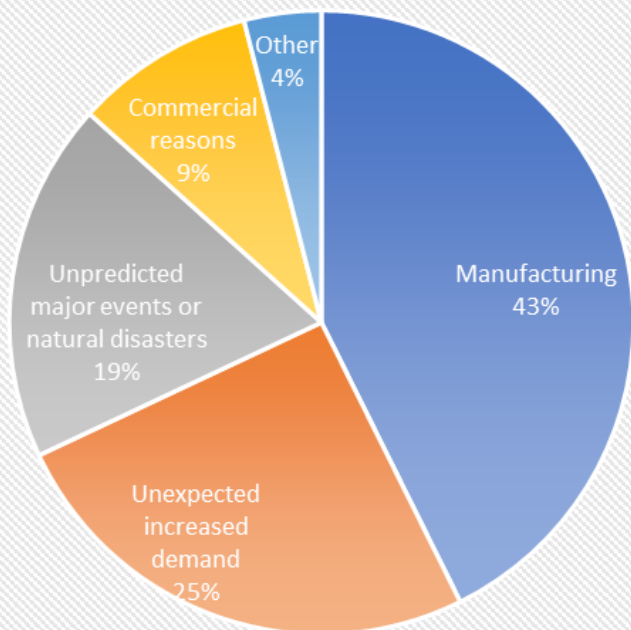
Preliminary results: Number of countries affected by a disruption of at least one product per year (2013 – 2022)



- ❑ As of 2018 the number of shortages are increasing



Preliminary results: Root causes of the market disruptions



- ❑ SPOC Network definitions and classification of different shortage root causes applied
- ❑ Further analysis of the detailed root causes is ongoing



Conclusion and next steps

- Number of countries impacted by the shortage of Immunoglobulins is increasing
- Only 4/19 countries were not affected by a market disruption in 2022
- Analysis of the demand and supply data is ongoing (only data related to the shortages of the medicinal products was analysed)
- Detailed analysis of the root causes and mitigation measures will also be performed
- EMA continues to monitor shortages of immunoglobulins through the EU-SPOC WP
- EMA will continue to facilitate regular dialogue with MAHs to obtain a detailed overview of the availability of immunoglobulins and to discuss potential support measures to prevent or mitigate shortages in the EU/EEA.



Any questions?

Further information

AvailabilitySPOC@ema.europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Telephone +31 (0)88 781 6000

Send us a question Go to www.ema.europa.eu/contact

Follow us on  **@EMA_News**