



Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

Current Challenges with Meeting Immunoglobulin Demand in Europe,

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Conflict of Interest

I have no conflict of interest to declare

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Current Challenges

Immunoglobulin Demand

- Limited supply of raw materials (plasma)
- Reduced plasma donations
- COVID-19 pandemic
- Increasing global demand for immunoglobulins

Pre-Authorisation

Research and Development

- Scientific guidelines: reflect a harmonised approach on how to interpret and apply the requirements for the demonstration of quality, safety and efficacy
- Clinical investigation of human normal immunoglobulin for intravenous administration (IVIg)
- Clinical investigation of human normal immunoglobulin for subcutaneous and/or intramuscular administration (SCIg/IMIg)
- Core summary of product characteristics for human normal immunoglobulin for intravenous administration (IVIg)
- Core summary of product characteristics for human normal immunoglobulin for subcutaneous and intramuscular use

Marketing Authorization

Assessment

- Scientific evaluation of data
- Quality, Safety, Efficacy
- Benefit-Risk-Assessment

Post-Authorisation

Availability of Medicines – Medicines Shortages

- Regulatory authorities increasingly working together
 - to prevent shortages and
 - to limit their impact whenever they occur

- The European medicines regulatory network aims to minimise the impact of medicine shortages on patients by:
 - working with pharmaceutical companies to resolve manufacturing and distribution issues;
 - sharing information with international partners about alternative sources of supply;
 - seeking input from patients and healthcare professionals on the impact of medicine shortages, to support decision-making;
 - taking measures to allow alternative medicines or suppliers to be used

Public Information

Shortages Catalogue

- EMA publishes information on specific medicine shortages that affect or are likely to affect more than one European Union (EU) Member State, where EMA has assessed the shortage and provided recommendations to patients and healthcare professionals across the EU
- National Registers

EU-Level Coordination

Medicines Availability

- HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use
- Single point of contact (SPOC) network to improve information sharing between Member States, EMA and the European Commission on important medicine shortages of human and veterinary medicines and to coordinate actions to help prevent and manage shortages
- Guidance for marketing authorization holders
- Guidance for regulators on public communication

National Communication

Austria

- Risk-based use of immunoglobulins due to reduced blood plasma donations
- Recommendations for healthcare professionals:
 - *Due to the precarious COVID-19-related situation of reduced blood plasma donations and thus reduced production capacities of drugs with immunoglobulins, a proactive risk prioritisation in the application is requested. Physicians should therefore pay attention to a risk-based application depending on the supply of immunoglobulins, so that the treatment of patients with primary immunodeficiency or in the approved indications can be guaranteed.*

Conclusion

- Challenging Situation
- Initiatives ongoing
- Multi-Stakeholder Approach
- Communication
- **Needs of Patients – treatment to be guaranteed**



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