

The supply of plasma-derived medicinal products in the future of Europe

Second edition

23-24
April 2024
Rome, Italy

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Ministero della Salute

Recommendations on appropriate and prioritised use of Ig

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Disclosure

- No conflicts of interest



Work Package 6 Aim

To deliver a set of recommendations on the appropriate use of immunoglobulins (Ig) at baseline and on its prioritisation in times of crisis

(Note: We did not assess the appropriateness of evidence in guidelines)



Overview of methodology



Five recommendations categorized topically



Improved understanding of Ig usage



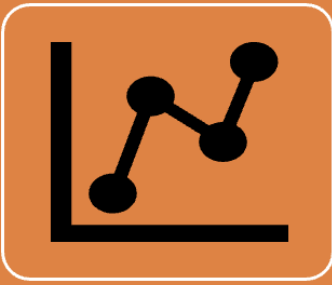
Structured and harmonised management plan for shortages



Enhanced collaboration and linkages

Understand, harmonise, and collaborate!





Improved understanding of Ig usage

Context

- Member States exhibit unequal capacities for data collection.
- Need for data on Ig use by indication.

Concrete steps

Prerequisite:

Establish robust policies and regulations on data jurisdiction, maintenance, and accessibility.

Step 1: Identify and map existing data sources on Ig use within each Member State.

Step 2: Establish a comprehensive centralised Ig-database and analytics hub.



Structured and harmonised management plan for shortages

Context

Existing EU indications and prioritisation plans are not uniform between countries;

Member States need to establish a prioritisation plan for shortages.

There is great variability on how things are done (e.g., protocols, practices) and communicated during crisis *and* non-crisis.

We recommend the creation of:

1) A harmonised **methodology for a **prioritisation plan** that includes:**

- High medical need and unmet medical need;
- Added benefit of Ig, considering alternative treatments;
- Quality of evidence;
- Quality of life for patients, with patient involvement;
- Utilising EMA's authorised indications.

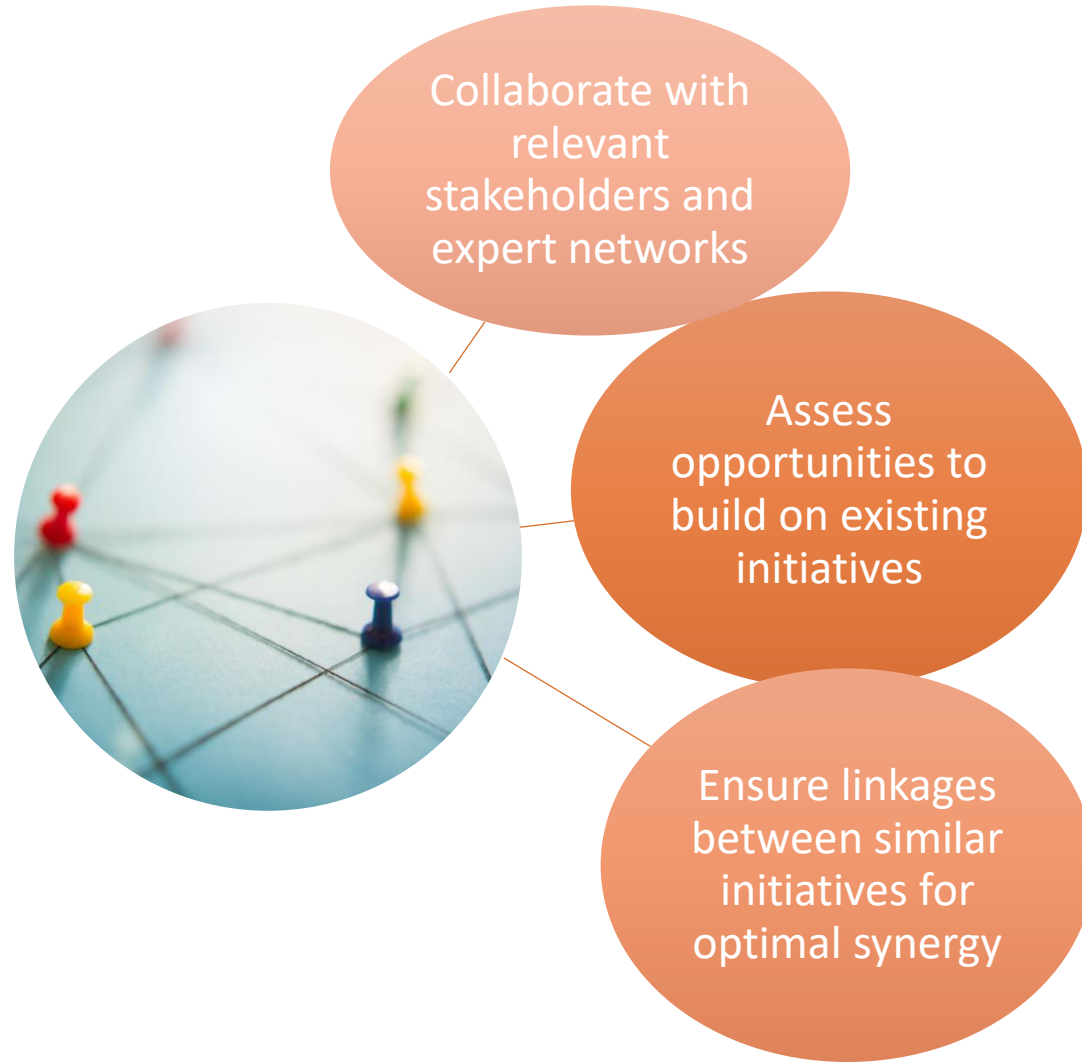
2) A harmonised **management plan that includes:**

- Include a system of checkpoints
- Align with treatment recommendations and guidelines from scientific societies.
- A coordinated communication and shortage awareness system should be set in place at the EU level.





Enhanced collaboration and linkages



Key points and next steps

01

Three key words:

“Understand”

“Harmonise”

“Collaborate”

02

Demand may be expected to increase due to Latent Therapeutic Demand and impact of SIDs

03

Further work is required to making these into actual Ig management strategies



Thank you

