The Growing Immunoglobulin Supply-Demand Gap in Europe: Assessing Self-Sufficiency Targets and Therapeutic Alternatives

HPR35

Guyllaume Faucher[1], Marie-Hélène Lafeuille[1], Eric Chaloux[2], Julien Patris[3]

[1]AppEco, Montreal, QC, Canada. [2]argenx, Vaughan, ON, Canada. [3]argenx, Ghent, Belgium.

BACKGROUND | METHODS

Background

- Demand for immunoglobulins (Ig) in Europe is expected to increase substantially due to population aging, improved diagnosis, and the growing number of patients with primary and secondary immunodeficiencies for whom Ig remains essential.[1]
- Ig production relies on donated human plasma, making supply dependent on both plasma collection and manufacturing capacity.[2] In several markets, domestic production remains insufficient to meet current demand, resulting in continued reliance on foreign plasma and imported Ig products.[1]
- Several European countries have therefore established national self-sufficiency targets, defined as the share of national Ig demand to be met through domestic production, to strengthen the security and sustainability of Ig supply.[3-8]
- To advance these objectives, countries have adopted different approaches to Ig supply resilience, including domestic plasma collection and production initiatives, procurement arrangements and measures supporting appropriate Ig use.
- The extent to which these approaches will keep pace with projected use of Ig, and the potential complementary role of innovative alternative therapies, remain important policy questions.

Objective

To assess the gap between published Ig self-sufficiency targets or policy ambitions and current and projected performance across six European countries, and to explore the illustrative potential of innovative alternative therapies to moderate demand pressure on constrained Ig supply.

Study design

- A country-level self-sufficiency model projected Ig utilisation and evaluated progress toward published national targets or policy ambitions across six European countries: Belgium, France, Italy, the Netherlands, Spain and the United Kingdom.

Analyses

- Self-sufficiency performance was evaluated by comparing the proportion of total Ig consumption[4,6,9-12] supplied through domestic Ig production[4,13-17] (i.e., self-sufficiency rate) with published country-specific targets or policy ambitions. [3-8]
  - National benchmarks were obtained from published government or national blood-system sources. Definitions, policy status and target years differed across countries. The benchmarks were therefore analysed as country-specific targets or policy ambitions rather than as harmonised measures
- Ig use and domestic supply were extrapolated to 2030 assuming the following historical growth rates persist
  - Ig use: continuation of country-specific 2015–2019 growth.
  - Domestic Ig supply: continuation of average European 2013–2024 growth.[18] (Structural breaks, planned capacity investments and policy changes were not modelled.)

Illustrative scenarios

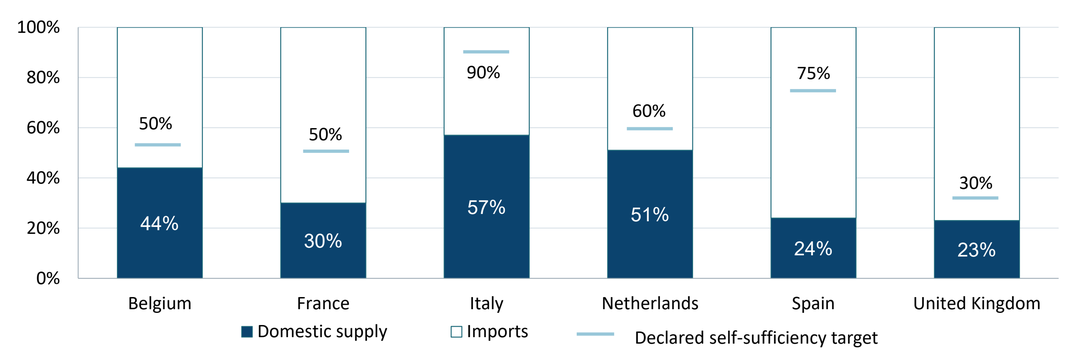
- Illustrative demand-side scenarios estimated the arithmetic effect of reduced Ig use among a modelled subset of patients with chronic inflammatory demyelinating polyneuropathy (CIDP) or generalised myasthenia gravis (gMG).
  - CIDP and gMG were selected because they account for a substantial share of Ig utilisation in the six markets analysed and innovative alternative therapies are available for some patients.
  - For modelling purposes, three illustrative assumptions about reductions in Ig use were assessed: reductions equivalent to the Ig volume attributed to 25% and 50% of the CIDP and gMG populations, and a mid scenario based on published Ig non-response estimates of 39% in patients with CIDP[19], and 30% in patients with gMG.[20-22]
- These arithmetic estimates illustrate the potential magnitude of reductions in Ig use. They do not estimate clinical eligibility, treatment uptake or individual patient benefit. The model also assumes that all Ig use in gMG is for maintenance treatment and could be switched to an alternative, although some is used for acute treatment.

RESULTS

Current self-sufficiency remains below country ambitions

- In 2024, domestic Ig production represented an average of 38% of total Ig consumption across the six markets, ranging from 23% to 57%. (Figure 1)
- All six markets remained below their respective published targets or policy ambitions in 2024; the gap ranged from approximately 6 to 51 percentage points.

FIGURE 1 Domestic Ig supply and declared self-sufficiency targets across selected European markets in 2024



Under continuation of historical growth assumptions, Ig use would outpace domestic supply

- Under continuation of historical growth assumptions, Ig use would increase by an average of 59% by 2030, with country-level growth ranging from 35% to 100%. (Figure 2)
- Assuming domestic Ig supply grows in line with the European historical rate used in the model (28% over the same period), supply growth would remain below utilisation growth in each included market, widening the gap between demand and domestic supply. These projections assume continuation of historical trends and do not incorporate structural breaks, planned capacity investments or policy changes.
- Under these assumptions, the average modelled self-sufficiency rate would decline from 38% in 2024 to 29% in 2030.

FIGURE 2 Projected Ig utilisation growth by 2030 compared with projected domestic supply growth

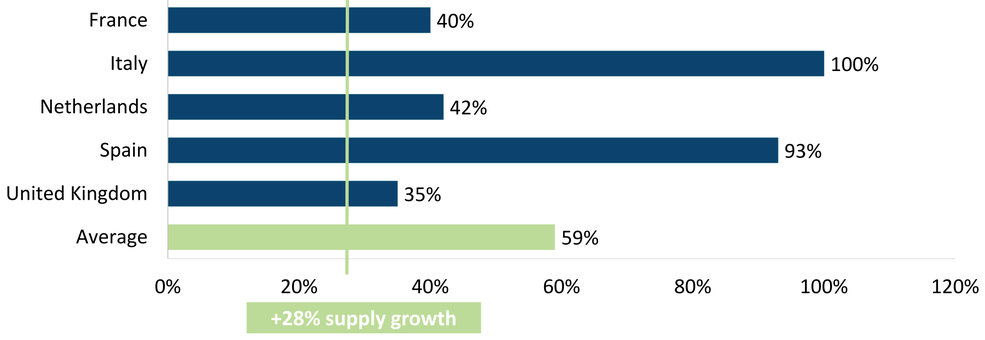


TABLE 1 Estimated share of total Ig utilization attributable to CIDP and gMG across selected European markets[9, 17, 18]

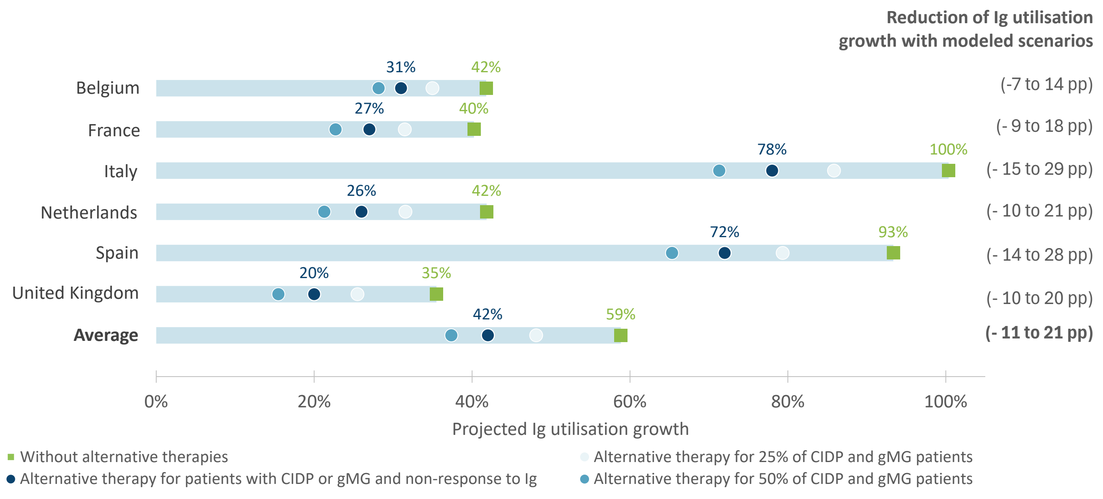
	CIDP patients	gMG patients	Total
Belgium	19 %	0.1 %	19 %
France	22 %	3 %	25 %
Italy	25 %	4 %	29 %
Netherlands	25 %	4 %	29 %
Spain	25 %	4 %	29 %
United Kingdom	26 %	4 %	30 %
Average	**24 %**	**3 %**	**27 %**

CIDP= chronic inflammatory demyelinating polyneuropathy; gMG = generalised myasthenia gravis.

Considering alternative treatments could reduce future demand pressures

- CIDP and gMG together account for an average of 27% of total Ig utilisation across the six markets included in the analysis. (Table 1)
- In the illustrative demand-side scenarios of reduced Ig use in the modelled CIDP and gMG populations, projected Ig utilisation growth was lower by approximately 11 percentage points in the 25% reduction scenario; 16 percentage points in the mid scenario, and 21 percentage points in the 50% reduction scenario across the six markets. (Figure 3)
- These arithmetic scenarios are illustrative and assumption-based. They are not a clinical recommendation and don't predict treatment eligibility, choice or uptake. Patient benefit and individual clinical circumstances must remain the primary basis for treatment decisions. No specific innovative alternative therapy was assessed.

FIGURE 3 Projected Ig utilisation growth under illustrative reductions in Ig use



CIDP= chronic inflammatory demyelinating polyneuropathy; gMG = generalised myasthenia gravis; pp = percentage points.

CONCLUSION

Domestic Ig supply remained below national targets or policy ambitions in all six countries in 2024. Under continued historical trends, Ig utilisation would outpace domestic supply through 2030, increasing reliance on imported Ig and plasma.

Expanding plasma collection and production capacity remains essential to supply resilience. Where clinically appropriate, innovative alternative therapies could complement these measures by moderating demand growth.

These findings support further evaluation of both supply- and demand-side strategies, including their clinical feasibility, health-system effects and implications for patients who depend on Ig and have limited alternatives.

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ABBREVIATIONS

CIDP, chronic inflammatory demyelinating polyneuropathy; **gMG**, generalised myasthenia gravis; **Ig**, immunoglobulin; **pp**, percentage points.

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