

# IMMUNOGLOBULIN ACCESS

Recently, several media outlets have reported on access issues regarding immunoglobulin (Ig) therapies relied on by people living with primary immunodeficiencies.<sup>1,2,3</sup> The Plasma Protein Therapeutics Association (PPTA) represents the private collectors of plasma and the manufacturers of plasma-derived therapies that treat rare, serious, genetic, and — in many cases — life-threatening diseases caused by missing or nonfunctioning proteins typically found in plasma.

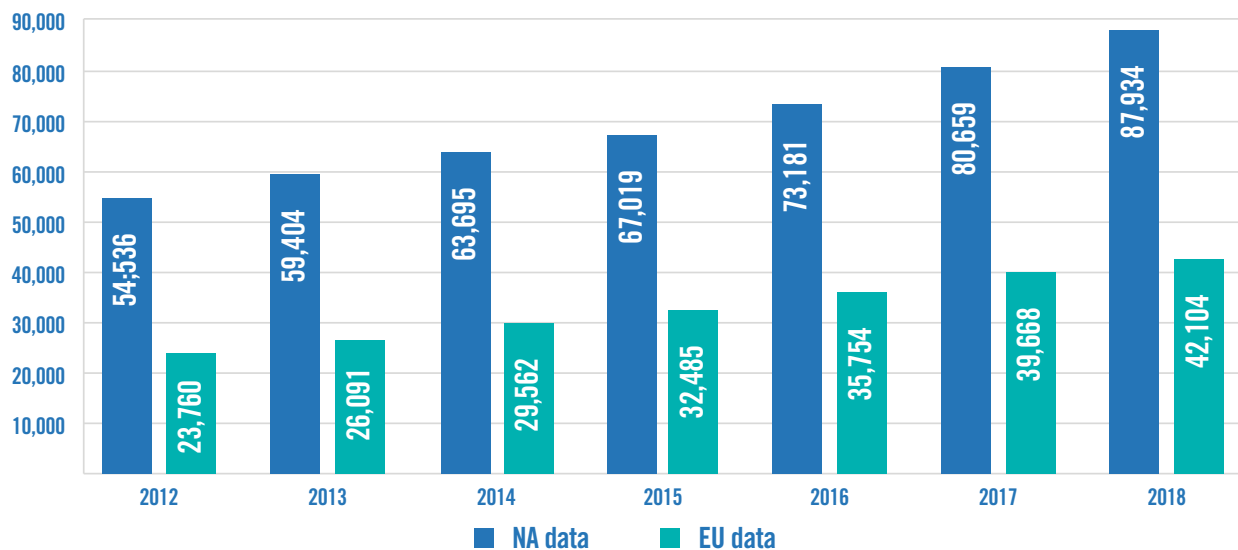
There are multiple variables that impact patient access to subcutaneous- and intravenous-administered Ig products. These variables could include manufacturer issues, distributor issues, government policies, physician and pharmacy protocols, and/or growing clinical need.

With respect to clinical need, though growth can present challenges, it is good news for patients treated with Ig therapies. As diagnostic techniques improve, more patients are identified. Likewise, as younger patients grow into adults, their dosage volumes increase. Increasing clinical need also reflects innovation and improvements in treatment. More widespread use of subcutaneous products, for example, grants patients the freedom to infuse at home but requires higher dosage volumes. Expanded treatment of secondary immunodeficiencies has helped cancer patients, but also requires more Ig.<sup>4</sup>

While PPTA does not have the ability to isolate the cause of any particular access challenge, the Association does have valuable data regarding plasma collections and Ig therapies.

PPTA makes data publicly available regarding the distribution of plasma protein therapies in North America and Europe. The data programs are voluntary manufacturer initiatives, strongly supported by leading regulatory authorities, intended to provide reliable assessments of the availability of these lifesaving therapies.

NA & EU\* Data Program — Ig Total Distribution (kg)<sup>5</sup>



<sup>1</sup> Grant, Kelly. "Canadian Blood Services warns of imminent shortage of take-home immune globulin drug." The Globe and Mail. (May 17, 2019).

<sup>2</sup> American Society of Health-System Pharmacists. "Drug Shortages List." (May 14, 2019).

<sup>3</sup> U.S. Food and Drug Administration. "FDA Drug Shortages."

<sup>4</sup> Patel, Carbone, and Jolles, "The Expanding Field of Secondary Antibody Deficiency: Causes, Diagnosis, and Management," *Frontiers in Immunology* (Feb. 2019).

<sup>5</sup> Georgetown Economic Services

\* Total IVIG and SC/IM IG in kilograms from the following countries: Austria, Belgium, Luxemburg, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Portugal, Spain, Sweden, UK