

## Patients with PID need sustained & continued access to their Ig therapies!

Primary immunodeficiencies (or PIDs) are chronic and rare diseases caused when some components of the immune system do not work properly or not at all. Around 60% of PID patients need immunoglobulin replacement therapies (Igs) throughout their lives to keep the levels of antibodies within a “suitable” threshold to fight life-impairing or life-threatening infections. No alternative treatments are available for these patients.

**Igs are plasma-derived medicinal products (PDMPs)** that require healthy donors to give their plasma either through plasmapheresis (source plasma) or from a blood donation (recovered plasma) for the development of these medicines

<sup>1</sup>.

**Each Ig is a unique biological medicine.** The different manufacturing processes will affect the individual patients’ tolerability to a given therapy<sup>2</sup>.

**Igs are not generic medicines and cannot be interchanged.**

- Igs are not generic products. Each Ig differs from one another other<sup>3</sup>.
- Igs differ in terms of their ingredients and production and individuals can respond differently to each of them.
- The variations in the development processes affect the final product and some Ig therapies may cause specific severe side effects or even anaphylactic reactions in patients<sup>4</sup>.
- The mode of administration can have an impact on the patient’s tolerance towards a particular Ig therapy<sup>5, 6, 7, 8, 9, 10, 11</sup>.
- There is no single Ig product or method of administration that is suitable for all PID patients<sup>12</sup>.

**All recognised routes of Ig administration should be made available to patients<sup>13</sup>.**

- Igs can be administered intravenously or subcutaneously.
- The route of administration must be based upon patients’ personal and clinical needs<sup>14</sup>.
- Individuals respond differently to different Igs. Personalised treatment is key to ensure that patients can lead active and productive lives<sup>15</sup>.

**Igs are considered essential medicines for children and adults with PIDs by the World Health Organisation<sup>16,17</sup>, the Council of Europe<sup>18</sup> and the Asia Pacific Economic Cooperation Forum<sup>19</sup>.**

**Patients with PIDs should have access to their Igs with no financial hardship, as health is a fundamental human right.**

- The World Health Organisation believes that countries should provide access to essential medicines as part of their policies towards Universal Health Coverage<sup>20, 21</sup>
- The UN recognises that it is essential to take into consideration the needs of vulnerable segments of society, including [...] persons with disabilities [...] in order to enhance their ability to realize their right to the enjoyment of the highest attainable standard of physical and mental health<sup>22</sup>.
- Patients with PIDs should have access to Ig therapies to keep them healthy, independent from their income or wealth.

*This statement was prepared by the IPOPI SAFE Task Force*

*About the SAFE Task Force: The Supply and Access for Everyone (SAFE) Task Force has been created by the International Patient Organisation for Primary Immunodeficiencies (IPOPI) to*

*monitor plasma collection and the availability of immunoglobulin replacement therapies for patients with PIDs worldwide. The taskforce is composed of experts from different parts of the world and IPOPI staff (in alphabetical order): Ms Roberta Anido de Pena, Ms Jose Drabwell, Dr Nahla Ewra, Prof Stephen Jolles, Dr Nizar Mahlaoui, Ms Martine Pergent, Mr Johan Prevot, Prof John Seymour, Prof Surjit Singh, Ms Leire Solis.*

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