

**Jacqueline de Souza Alves da Silva**

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**De:** Sen. Rodrigo Pacheco  
**Enviado em:** sexta-feira, 24 de março de 2023 09:43  
**Para:** Jacqueline de Souza Alves da Silva  
**Assunto:** ENC: Carta Aberta aos Senadores em apoio a PEC 10 2022  
**Anexos:** IPOPI support letter in favour of PEC final - English.docx

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**De:** Michele Santos [<mailto:eulutopelaimuno.org@gmail.com>]  
**Enviada em:** quinta-feira, 23 de março de 2023 13:57  
**Para:** Sen. Rodrigo Pacheco <[sen.rodrigopacheco@senado.leg.br](mailto:sen.rodrigopacheco@senado.leg.br)>  
**Assunto:** Re: Carta Aberta aos Senadores em apoio a PEC 10 2022

Você não costuma receber emails de [eulutopelaimuno.org@gmail.com](mailto:eulutopelaimuno.org@gmail.com). [Saiba por que isso é importante](#)

original letter attached

Em qui., 23 de mar. de 2023 às 12:48, Michele Santos <[eulutopelaimuno.org@gmail.com](mailto:eulutopelaimuno.org@gmail.com)> escreveu:

Prezado Senador Rodrigo Pacheco,

Segue em anexo carta aberta da IPOPI Associação Internacional de Pacientes com Imunodeficiências Primárias e as Associações Nacionais ANPIC e ELPIB.

Att,  
Juçáira S. M. Giusti  
Vice Presidente ELPIB



## Open letter to the Senators of the Federal Senate of Brazil

It is with great interest that we have learnt about the proposal of amendment to the Constitution nº10 from 2022 (Proposta de Emenda à Constituição nº10, de 2022) and would like to invite all Senators to positively consider it when it is time to vote.

We represent patients with primary immunodeficiencies (PIDs). PIDs are a group of more than 480 rare and chronic conditions in which the immune system does not work appropriately or at all. If left untreated, people with PIDs are prone to severe and recurrent infections, autoimmune diseases and dysregulated inflammation. When PIDs are left underdiagnosed or are misdiagnosed, the defective immune system leads to illness, disability, permanent organ damage and even death. **Over 50% of affected PID patients** suffer from antibody deficiencies for which **the only treatment is immunoglobulin replacement (Ig) therapy**. Ig are medicines obtained from the fractionation of human plasma. The treatment can be administered intravenously (IVIg) or subcutaneously (SCIg), lifelong, at regular intervals and aims at increasing Ig trough levels to physiologic concentrations to protect against bacterial and viral infection. **Patients with PIDs in need of Ig therapies do not have any alternative therapy. The World Health Organisation (WHO) Essential Medicines List states immunoglobulins as essential therapies in the treatment of PIDs** in adults<sup>i</sup> and paediatric populations<sup>iii</sup> and therefore as a medicinal product that is considered to be most effective and safe as to meet the most important needs of national health systems.

For patients with PIDs having access to their immunoglobulin therapy, as prescribed by their treating physician, is key. One of the main concerns for patients is that there is **no sufficient plasma** for the development of plasma-derived medicinal products such as immunoglobulins. The proposal for amending the Constitution would allow for the development of a system for plasma collection around **plasmapheresis**, a system that allows for the collection of greater volumes of plasma while returning the rest of the blood components to the donor. This way, the donor is able to donate more frequently than with blood donation. Plasmapheresis programmes by public and private institutions have been in place for many years in many countries in the world, such as Germany, Austria, the Czech Republic, Hungary or the United States. This is also a model supported by the World Health Organisation in its *Guidance on increasing supplies of plasma-derived medicinal products in low- and middle-income countries through fractionation of domestic plasma*. If done following the legal, manufacturing and safety standards required, plasmapheresis can become the way for countries to **increase their collection of plasma to meet their nationals' demands** and **contributing to plasma collection worldwide**.

Patients with PIDs are grateful and acknowledge blood and plasma donors for their gift of life. We are extremely thankful for their altruistic gesture that allows for the development of the therapies that we need. Patients with PIDs support the concept that the donation of blood and plasma should be based on the **principle of altruism of the donor and the solidarity between donor and the recipient**. At the same time, **donors should not be disadvantaged by their donation** and, therefore, some type of compensation could be established as long as it would not be a way of



commercialising the human body and would be defined following the country's law to ensure that it would compensating the donor for the inconveniences associated to the donation. The WHO also recognises that the existing "*compensated plasma donation systems are managed in a way not to affect the well established system for collection of whole blood from voluntary non-remunerated donors and the infrastructure to supply blood components for transfusion to domestic patients*"<sup>iii</sup> and this should be the way also for Brazil to consider and implement.

For all the mentioned reasons, we encourage Senators of the Federal Senate to vote for the amendment of the Constitution nº10 as a way of increasing plasma availability so that Brazilian patients with PIDs and others have access to the therapies their need in a sustained manner.

Thank you for the attention,



Juçaíra Stella Martins Giusti  
Vice-President



Marta auxiliadora Ferreira Reis  
President



Martine Pergent  
President

**About Eu Luto pela Imuno Brasil – ELPIB** : Non-for-profit National Patient Organisation for Primary Immunodeficiencies

Vice-president: Juçaíra Stella Martins Giusti

CNPJ 34.374.632/0001-37

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**About ANPIC**: Non-for-profit National Patient Organisation for Primary Immunodeficiencies

President: Marta Auxiliadora Ferreira Reis

CNPJ 01.383.625/0001-42

[www.anpic.org.br](http://www.anpic.org.br)

**About IPOPI**: The International Patient Organisation for Primary Immunodeficiencies (IPOPI) is a non-for-profit international organisation dedicated to improving awareness, access to early diagnosis and optimal treatments for primary immunodeficiency (PID) patients worldwide. IPOPI collaborates with supranational organisations such as the World Health Organisation, the European Commission, the European Medicines Agency, or the Asia-Pacific Economic Cooperation (APEC). More information: [www.ipopi.org](http://www.ipopi.org).

<sup>i</sup> World Health Organization. World Health Organization Model List of Essential Medicines: 22nd List 2021. Geneva: World Health Organization (2021). Available at: <https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.02>.

<sup>ii</sup> World. Health Organization. World Health Organization Model List of Essential Medicines for Children: 8th List 2021. Geneva: World Health Organization (2021). Available at: <https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.03>.

<sup>iii</sup> Guidance on increasing supplies of plasma-derived medicinal products in low- and middle-income countries through fractionation of domestic plasma. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO. Available at: <https://www.who.int/publications/i/item/9789240021815>