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Office of Global Affairs  
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13<sup>th</sup> May 2020

Dear Ms Elvander, Dear Mr Lin,

The International Patient Organisation for Primary Immunodeficiencies (IPOPI) commends the APEC's efforts and dedication to ensure that APEC economies take a coordinated approach to mitigate the health and economic impact caused by COVID-19, while supporting the health needs of APEC member populations, including those affected by rare diseases such as primary immunodeficiencies (PIDs).

As highlighted by the APEC Health Working Group, it is key that APEC economies take action to further enhance the resilience, scalability and sustainability of health systems even in times of epidemic. One key aspect in which the APEC economies have been working in the past years and should be continued in spite of the epidemic is the development of safe and sustainable blood and plasma supply chain. The APEC Blood Supply Chain Roadmap has been a key instrument guiding APEC economy to enhance the safety of blood and plasma-derived products in the Asia Pacific region. As recognised by the World Health Organisation (WHO), "plasma-derived medicinal products (PDMPs) in particular, are critical for the prevention and treatment of major morbidities associated with a wide range of inherited and acquired medical conditions and diseases<sup>1</sup>", such as PIDs.

The different containment and social distancing measures could jeopardize appropriate and sufficient collection of blood and plasma in all EU member states. In times where social distancing and reduction of movements to avoid contagions is becoming the norm, we suggest that APEC economies develop and/or support communication campaigns to raise awareness about the importance of donating both blood and plasma whilst also communicating on the measures to guarantee donor safety.

The current COVID-19 outbreak and the potential drop in blood and plasma donation frequency are a tragic examples that show, more than ever, the need to establish and regulate robust quality systems to optimise the safety of the blood and plasma supply and avoid delay for regulatory approval, allowing faster access to high quality plasma-derived medicinal products such as immunoglobulin replacement therapies. There are currently several on-going clinical trials studying the efficacy and safety of a COVID-19 hyperimmune plasma derived product (hyperimmune). Should any of these be successful and approved, it would enlarge the number of patients in need for plasma-derived medicinal products at large and of immunoglobulin therapies more specifically. Without a robust national and regional blood service and blood regulator, with effective hemovigilance and

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<sup>1</sup> Action framework to advance universal access to safe, effective and quality-assured blood products 2020–2023. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO.

pharmacovigilance systems for monitoring the safety of blood and plasma donations and blood product use, APEC economies will not be able to respond to the expected increased demand of immunoglobulins and other plasma-derived medicines and or react in emergency situations, including humanitarian crises and emerging infectious threats as pointed out by the WHO<sup>2</sup>.

Another aspect to avoid any potential tension in the availability of plasma-derived medicinal products in the coming months, is the development of a contingency plan for the different plasma-derived medicinal products in collaboration with the different relevant stakeholders including relevant patient organisations. These plans should be fact-based and include concrete measures to ensure that, in terms of shortages, the demand would be managed in a way that would be allocated to the different indications depending on their prioritisation, so as to ensure that patient populations can continue to access according to their needs. In the case of patients with PIDs, for around 60% of the patient population their only possible treatment is immunoglobulin replacement therapy, with no alternative treatment available.

IPOPI has a solid experience of contributing to policy, medical and technical documents and position papers, through the different partnerships established at international (WHO) and European level (European Medicines Agency, European Commission, European Parliament, Council of Europe) and has also participated in many APEC for a, such as the Blood Policy Forum in Vietnam (2016), the APEC Blood Safety Initiative (2017) or the APEC Rare Disease Policy Workshop in Chile (2019). We would like to offer our participation and knowledge to integrate the panel of experts to be consulted thereof in upcoming documents, to ensure that patients are also included in the development of guidelines and policies that will, in the end, have an impact on their possibility of having access to their treatments they need to lead normal lives.

We thank you very much for your attention and we look forward to a fruitful collaboration in the areas that affect patients with PIDs that heavily rely on immunoglobulin replacement therapies.

Yours sincerely,



Johan Prevot  
Executive Director  
IPOPI



Martine Pergent  
President  
IPOPI



Bruce Lim  
Treasurer  
IPOPI

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<sup>2</sup> Ibid.