An Open Letter from IPOPI:
Ensuring sufficient blood and plasma supply during and after the COVID-19 Outbreak

IPOPI calls on authorities to ensure appropriate supply of immunoglobulins

The International Patient Organisation for Primary Immunodeficiencies (IPOPI) calls on international, regional and national health authorities to ensure that patients with primary immunodeficiencies (PIDs) can continue having access to an adequate supply of their life-saving treatments including immunoglobulin replacement therapies which are produced from human plasma both during and after the COVID-19 outbreak

Whilst SARS-CoV-2 is not a concern for the viral safety of plasma derived medicinal products (PDMPs) thanks to donor screening/testing and viral inactivation during the manufacturing process, the main concern for patients relying on these life-saving therapies is that the COVID-19 outbreak and associated confinement and movement restriction measures will impact supply of blood and plasma collection, medicinal product circulation and supply. Indeed these measures are already leading to tensions or even shortages in blood donations as currently observed in several countries and there are good reasons to believe a similar drop in plasma donations will be observed. As the plasma necessary to produce PDMPs is either collected from plasma donors (apheresis plasma) but also from blood donations (recovered plasma), this will almost inevitably impact the availability of these life-saving therapies, although it may take a few months before PDMPs shortages start to be observed. This is due to the fact that it usually takes 7-10 months from the time plasma is collected from a human donor to reach the patients, given the lengthy and complex production process.

In times of the pandemic, as recognised by the World Health Organisation[1] [2], there is an absolute need to maintain a safe, sufficient and accessible blood and plasma supply in the face of widespread disease. This has also been addressed by the European Centre for Disease Prevention and Control (ECDC) when it called for a prioritisation of "*essential substances of human origin" such as plasma for the manufacture of medicinal products and plasma for fractionation*[3]". As such, we would like to warmly thank all the volunteers who donate their blood and plasma. We appreciate that even in trying times, people are willing to contribute to other people's needs. Thank you!

We would like to call on to all responsible health authorities to ensure that donors can donate their labile products and plasma in the best and safest settings and ensure that additional hygienic measures are put in place, such as clinical-grade cleaning measures. Guidelines such as the one developed by the ECDC ("Coronavirus disease 2019 (CoVID-19) and the supply of substances of human origin in the EU/EEA") are of high value for the different stakeholders involved in the collection and manufacturing process and should be followed.

[1] WHO Director-General's opening remarks at the media briefing on COVID-19 – 11 March 2020. https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020

[2] World Health Organisation. Maintaining a safe and adequate blood supply during pandemic influenza. Guidelines for blood transfusion services. July 2011. https://www.who.int/bloodsafety/publications/WHO_Guidelines_on_Pandemic_Influenza_and_Blood_Supply.pdf

[3] European Centre for Disease Prevention and Control (ECDC). Coronavirus disease 2019 (CoVID-19) and the supply of substances of human origin in the EU/EEA. 20 March 2020. file:///C:/Users/leire/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/VE5QFMZ6/covid-19-supply-substances-human-origin.pdf

From the donor side, it should be clearly explained what are the criteria potential donors should meet in order to be able to donate. If new measures have been put in place to defer donations from donors who may have SARS-CoV-2 or have been in countries and/or regions with a high number of infections, this should be clearly mentioned and explained to donors. Allowing donors, for instance, to leave their homes to get to their closest donation centre is a measure that should be considered in those countries that have confined their population or part of it to stop the spread of the virus.

We have been informed that patients with PIDs are already experiencing problems in their access to the immunoglobulin replacement therapies. These may be due to confinement measures, not being able to access hospital treatment facilities due to prioritisation in hospitals, eviction from hospitals or not having subcutaneous immunoglobulins available, amongst others. We invite the different health authorities and administrations to follow the World Health Organisation's recommendations and prioritise access to immunoglobulin replacement therapies to those patients who have no alternative treatment, such as PIDs. This prioritisation has been enshrined in the inclusion of PIDs as a priority indication for the access of immunoglobulins in the List of Essential Medicines for adults[4] and the paediatric population[5] and different international organisations such as the Council of Europe[6] or the Asia Pacific Economic Cooperation Forum[7]. In line with these international recommendations and guidelines, IPOPI calls on all governments to ensure that all patients with PIDs in need of immunoglobulin replacement therapies can continue to access them in quantities sufficient to be clinically effective. We urge all countries to implement strategies to assure continued supply of immunoglobulin replacement therapies to PID patients, including in times of shortages.

IPOPI call on health authorities to develop strategies that would allow to mitigate the expected drop in donations of labile products and/or plasma, to ensure that patients in need of plasma-derived medicinal products such as patients living with a primary immunodeficiency, can continue to access them in the medium/long term.

About primary immunodeficiencies (PIDs):

Primary immunodeficiencies (PIDs) are a large group of over 400 different chronic and rare diseases caused when some components of the immune system (mainly cells and proteins) do not work properly. These deficiencies lead to increased susceptibility to a wide range of infections and means that infections can reoccur and leave the individual vulnerable to permanent organ damage, physical disability or even death. PIDs can be treated and, when the right diagnosis and treatment has been given, patients can live normal lives.

About IPOPI:

The International Patient Organisation for Patients with Primary Immunodeficiencies (IPOPI) is closely following the SARS-CoV-2 outbreak and its potential impact for the health of patients with primary immunodeficiencies (PIDs) globally. With this in mind, IPOPI is in close contact with the medical and scientific immunology societies to ensure that the data and information provided to patients with PIDs is accurate and widely available (for more information, click here).

[4] World Health Organisation. WHO Model List of Essential Medicines. 21st list (2019). https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf?ua=1

[5] World Health Organisation. WHO Model List of Essential Medicines for Children. 7th List (2019). https://apps.who.int/iris/bitstream/handle/10665/325772/WHO-MVP-EMP-IAU-2019.07-eng.pdf?ua=1

[6] Sewell, W. A. C., Kerr, J., Behr-Gross, M.-E., Peter, H.-H. and on behalf of the Kreuth Ig Working Group (2014), European consensus proposal for immunoglobulin therapies. Eur. J. Immunol., 44: 2207–2214. doi:10.1002/eji.201444700

[7] APEC Recommendations for Enhancing Access to Safe Therapy for Persons with Immunodeficiency and Bleeding Disorders, 2017. http://apec.wordpress.member365.com/wpcontent/uploads/2018/01/17_lsif2_agn05.7_Access-to-Safe-Therapy-recommendations-FINAL.-docx.pdf