EUROPE'S NEED FOR MORE PLASMA
before, during and after COVID-19: Challenges and possible solutions

WEDNESDAY
9 DECEMBER 2020
14:00 - 16:00
ONLINE ROUNDTABLE
hosted by MEPs Simona Bonafè and César Luena

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I. Executive Summary

An online roundtable event entitled “Europe’s need for more plasma – before, during and after Covid-19: challenges and possible solutions”, organized and co-hosted by Member of the European Parliament (MEP) Simona Bonafè, (S&D, Italy) and MEP César Luena (S&D, Spain), and moderated by Peter O’Donnell, a Freelance reporter, took place on December 9, 2020.

The roundtable event included presentations from healthcare, patient and industry representatives as well as Q&A interactions, a summary of which is presented below.

As a physician, Dr. Nizar Mahlaoui, Necker Hospital Paris, provided key information regarding immunoglobulin therapies which are the backbone of treatment for the majority of patients living with Primary Immunodeficiencies (PIDs).

Matthew Hotchko from MRB shared up-to-date data on plasma collection in Europe, with a focus on the balance of the market at national and global level, the role of public and private actors and the Covid-19 pandemic. The EU’s reliance on plasma collection imported from the US was highlighted as a key concern.

From a patient’s perspective, Johan Prevot/IPOPI elaborated on the role played by immunoglobulin therapies in treating primary immunodeficiencies (PIDs). He also illustrated the key challenges which have been exacerbated by the Covid-19 pandemic and suggested sustainable solutions for the future.

From a local perspective, Lluis Puig shared concrete information about the state of play of plasma collection in Spain, especially in the Catalan region. Moreover, he raised key issues of interest and put forward recommendations to alleviate the regional situation. With a Member State approach, Martina Brix-Zuleger provided detailed information concerning the current legal and organisational framework that drives plasma collection in Austria.

Stefaan Van der Spiegel from the EU Commission highlighted key policy opportunities that can have an impact on plasma collection, especially the recent publication of the Pharmaceutical Strategy and of the Inception Impact Assessment on the blood, tissues and cells legislation.

Michael Fuhr shared his personal experience as a plasma donor. He explained the main reasons that lead him to donate plasma up to 30 times a year in Germany.

Concluding the panel, Matthias Gessner from EPA provided detailed information about the ongoing challenges related to plasma donation and plasma collection in Europe. He also emphasised the concrete policy opportunities and tailored suggestions to increase the level of plasma collection in the European Union.

MEP Luena closed the panel by thanking for this timely event and highlighted a couple of asks on how EU and national policies can facilitate an increased plasma collection by:
• Establishing dedicated plasma collection programs and coordinated awareness outreach campaigns towards plasma donors in all EU Member States;
• Differentiating between whole blood for transfusion and plasma for manufacturing PDMPs;
• Considering more regulatory flexibility to optimize plasma collection in Europe.

II. Welcome & Introduction

Simona Bonafè MEP thanked all participants for joining the online roundtable.

She considers that the discussion is timely as the Covid-19 pandemic has amplified the need to ensure more plasma collection in Europe. It is essential for the European Union to propose solutions, enhance relationships between all stakeholders and build an efficient strategic autonomy on critical starting materials.

She also recalled that the European Parliament highlighted in its September 2020 Resolution on “Shortages of medicines -How to address an emerging problem” that the EU must take action to address its dependency on US plasma for the manufacture of plasma-derived medicinal products (PDMPs).

In addition, she reminded participants that the EU Commission has very recently launched a public consultation on an Inception Impact Assessment for a possible revision of the EU Blood and Tissues & Cells legislation. The revision of the legislation provides a unique opportunity to address Europe’s vulnerability as to its insufficient plasma collection.

MEP Simona Bonafè also underlined that PDMPs are essential life-saving medicines for patients with rare and often genetic conditions, such as primary immune-deficiencies and haemophilia. She acknowledged that Europe has not been collecting enough plasma to meet the patients’ needs, and significantly relies on imported plasma.

III. Setting the scene: Europe’s need for more plasma

1. Physician’s view

Dr. Nizar Mahlaoui (French national reference Center for PID and Necker-Enfants Malades University Teaching Hospital) shared key information on immunoglobulin therapies which are the backbone of treatment for the majority of patients living with PIDs.
Elaborating on the state of play of immunoglobulin therapies globally, Dr. Nizar Mahlaoui stated that around 70% of PID patients in the world have not been diagnosed yet. Recognizing that immunoglobulin therapies have been under tension for many years, he also explained that there is a discrepancy between a rising demand and lack of supply on the worldwide market. This combination of elements is adding a burden on the community, a fragile situation already exacerbated by the Covid-19 pandemic which has created new access challenges.

To curb the negative trends, Dr. Nizar Mahlaoui stated that a reinforced framework of conditions in prescribing and using immunoglobulin therapies is necessary to ensure the efficiency, safety and the quality of treatments to patients in need.

He added that the COVID-19 pandemic highlighted the need for evidence-based decision making and collaboration across all stakeholders (researchers, high-level institutions and nation states etc).

In addition, he put forward some solutions to ensure better conditions for patients. Regarding areas of improvement at short/middle term, he stressed the importance of:

- Risk management plans;
- Indication prioritization, especially for PIDs;
- Recognition of the specificity of biological medicines;
- Awareness campaign about PDMPs.

In the longer term, Dr. Mahlaoui suggested key areas of action, such as the development of policy and legislative instruments based on facts & science, avoid wastage of recovered plasma, the strengthening of plasmapheresis programmes and the encourage the co-existence of public & private plasma collection. He concluded that patients safety, means global sufficiency of PDMPs based on regionally balanced plasma collection.

Responding to a question from Peter O’Donnell on the potential areas of improvement, Dr. Nizar Mahlaoui affirmed that the volume of plasma collection needs to rapidly increase in order to produce enough immunoglobulin therapies and products for patients who suffer from PIDs.

2. Market researcher’s view

Matthew Hotchko (President at Marketing Research Bureau) provided to the audience with the latest data on plasma collection in Europe, with a focus on the balance of the market at national and global level, the role of public and private actors and Covid-19 pandemic.
Plasma is sourced globally, but it is not equally balanced as the United States is the dominant supplier. Matthew Hotchko considered that the role of the United States as the world’s main supplier of plasma has become a cause of concern in Europe. Europe needs to diversify the sources of plasma for fractionation in order to reduce its level of dependency and, most importantly, to meet the clinical need of patients.

He also raised concerns about the intensity of the role played by the public and private sectors in the collection of plasma in Europe. From 2010 to 2019, public plasma collection has risen by 1.4%, compared with 5.4% for the private plasma collection. Against this background, Matthew Hotchko pointed out that this level of involvement has consequences on plasma collection in Europe. There is an imbalance that requires importation of product sourced from the United States.

First, although the public sector has grown over the past decade, it has been far too slow to keep up with Immunoglobulin demand growth. Second, if the private sector has grown closer to organic Immunoglobulin growth, it is still not sufficient to reduce imports. Third, there are only four European countries (Austria, Czech Republic, Germany and Hungary) which have public and private plasmapheresis collection centers for plasma fractionation. Countries with only public plasmapheresis do not collect enough plasma for the needs of the patients, while those with public and private plasmapheresis collect a surplus of plasma.

In addition, the Covid-19 pandemic had a significant impact on blood and plasma collection in the world. For instance, the volume of source plasma collected during 2020 will likely be 10-15% lower than in 2019, both in the US and Europe. Matthew Hotchko raised the issue that if we do not change the current situation of plasma collection in Europe, the plasma surplus will grow for the US, while the deficit will increase, particularly for Europe.

Answering a question on the factors that influence plasma collection in Europe, Matthew Hotchko recalled that donors play a key part in the supply of plasma, especially when compensation measures are foreseen by public and private actors.
IV. Challenges and possible solutions to increase plasma collection in Europe

1. Patients’ view

Johan Prevot (Executive Director at IPOPI) presented the International Patient Organisation for Primary Immunodeficiencies (IPOPI) and shared with the audience key information about its activities and policy contributions.

He also presented key features of PIDs to better understand the issues at stake. Primary Immunodeficiencies represent over 430 rare diseases which are affecting the immune system of patients. Today, 60% of patients need life-long immunoglobulin replacement therapy. Johan Prevot recalled that Immunoglobulin therapies are unique for patients living with primary immunodeficiencies because they are personalized medicines capable of improving their daily-lives and are not interchangeable.

The demand for immunoglobulin therapies has been growing steadily, raising concerns about patients’ access to the right treatment and the demand management in situation of shortages.

On the impact of Covid-19 on plasma collection, Johan Prevot explained that obstructions in the manufacturing of PDMPs will mostly be felt throughout 2021.

Nonetheless, there are improvements in the field of PDMPs. First, diagnosis rates in Primary Immunodeficiencies are improving. Second, there is an important increase in alternative immunomodulatory therapeutics for neurological indications.

He finally shared the key recommendations that have been made by patients. The patient group is calling for:

1. Increasing the supply and free movement of safe and efficacious PDMPs;
2. Developing guidelines, policy & legislation based on facts, science and experience;
3. Increase plasma collection at regional level to ensure global sufficiency;
4. Avoiding plasma wastage, and patient centred policy making on PDMPs;
5. Developing or strengthening plasmapheresis programmes;
6. Encouraging the co-existence of public & private plasma collection to face the needed investments and benefit from existent knowledge and experience;
7. Developing patient-centred policy making on PDMPs.
2. Member State’s region view

Lluis Puig (Director at Barcelona Blood and Tissue Bank) presented the issues related to plasma collection in Spain and proposed different scenarios to curb this complex situation.

He provided key information regarding blood and plasma management infrastructures in Spain. Spain is a country with 46.9 million inhabitants which is divided in 17 autonomous communities. Each community has its own Blood Transfusion Centre with different managing models. Furthermore, each Blood Transfusion Centre establish its own objectives and strategies.

When it comes to the Catalan region in Spain, the Barcelona Blood and Tissue Bank is the only one blood bank that provides blood components to all private and public hospitals. In addition, the volume of plasma collection for PDMPs has increased through the years in the Catalan region. However, immunoglobulin (IgG) sufficiency has significantly decreased since 2014, reaching a level of 38% in 2019.

Lluis Puig, using a quote from Prof. H H Gunson clarified that sufficiency is reached when a nation is able to provide enough blood and plasma to its population, to meet the clinical demand. In this sense it is necessary a better control of IgG use because there is evidence of an over indication of this product.

Relying on different studies, Lluis Puig expressed his concerns about the difficulties for the Catalan region to provide sufficient plasma to meet the needs of patients with primary immunodeficiency. In his view, within a short period of time, it is urgent to guarantee the 50% of immunoglobulin (IgG) sufficiency, especially for the group of patients in which IgG treatment is essential.

Lluis Puig advanced different solutions and set conditions to increase plasmapheresis based on the principle of non-economical compensation in order to reach a level of immunoglobulin self-sufficiency in the Catalan region:

- Increase information and social visibility;
- Reach a level of complicity from authorities and other social personalities;
- Have plasma donation centers close to the population;
- Facilitate transport conditions (e.g. through reimbursement of public transport tickets or parking)
- Thank and show gratitude to the donors, also through small gifts;
- Ensure Donor safety;
Increase the number of plasmapheresis centres;

Foresee national and international agreements to manage the excess of some PDMPs.

3. Member State’s view

Martina Brix-Zuleger (Federal Ministry of Social Affairs, Health, Care and Consumer) provided an overview of the current legal and organisational frameworks that drive plasma collection in Austria.

Currently, there are 18 plasma donation centres in Austria. Plasma collection and plasma donation have been regulated since 1975 with the Plasmapheresis Act and which was incorporated into the Blood Safety Act 1999. Today there are numerous legal instruments available in Austria which guarantee the safety and efficiency of the plasma collection process. For instance, the 1999 Blood Safety Act is an important piece of legislation which ensures high quality and safety of blood and blood products for donors and lays down specific rules on operating licences and inspection procedures.

Blood donation facilities require operating licences and the approval of the blood facilities is issued by the Federal Agency for Safety and Healthcare. In the licensing procedure, care must be taken to ensure blood supply and the blood donation institutions operating in the same local catchment area are to be heard. The importance of collaboration and coordination with all relevant stakeholders was also emphasized.

Martina Brix-Zuleger also provided key information regarding ongoing challenges on plasma collection in Austria. One of the most pressing issues requiring the attention of the Austrian authorities is related to the difficulties to ensure and secure the supply of both plasma and other blood products for patients. Against the background of the COVID-19 pandemic the number of plasma donations in Austria were reduced and collection of convalescent plasma was supported.

She concluded by proposing concrete solutions that are endorsed by Austrian authorities to improve the situation in the country such as:

- Maintain contact with plasma and blood establishments;
- Include all relevant stakeholders in the decision making process;
- Strengthen donors' trust in medical care;
- Raise awareness among Austrian population for increasing the supply of plasma.
4. European Commission’s view

Dr. Stefaan Van der Spiegel (Head of sector – health innovation – European Commission) presented two key topics related to PDMPs: the EU legal frameworks on the substances of human origin and the new pharmaceutical strategy. These EU legal frameworks are very comprehensive as they set multiple steps requiring safety and quality conditions from a donor body to a recipient body. Against this background, professionals, national competent authorities and the European Commission have a specific role to play.

The Commission decided to run in 2017 an evaluation on the Blood, Tissues and Cells (BTC) legislation to see if it is still fit for purpose. The evaluation report published in 2019 highlight the key findings and shortcomings in relation with PDMPs. First, there are concerns regarding the sustainable sufficiency of and access to PDMPs because of a strong reliance on the United State for sufficient plasma for the manufacture of PDMPs in Europe. Second, there are concerns on whether donors are sufficiently protected, which is important as PDMPs are available only if there are sufficient donors.

In this regard, the European Commission has recently published an Inception Impact Assessment on the BTC legislation. The main objectives are to manage supply issues through the strengthening of the supply monitoring and of emergency supply measures. On the donor side, the Commission will also aim to set new protecting measures to maintain high levels of donation and public confidence in the system.

Furthermore, Dr. Stefaan Van der Spiegel insisted that the European Commission, the European Directorate for the Quality of Medicines (EDQM), Member States, manufacturers, blood establishments, patient associations, donor associations and professional societies should work together to address the challenges related to the access to PDMPs.

He also pointed out to risks for interruptions caused by Covid-19 pandemic on plasma donor motivation and collection capacity, and, in turn, its impact on plasma collection.

Dr. Stefaan Van der Spiegel also mentioned the recent release of the EU Commission’s EU Pharmaceutical Strategy. This new initiative comes at the right time as Covid-19 crisis shed light on key issues of interest such as innovation, medicine shortages and crisis preparedness.
Most importantly, the EU Pharmaceutical Strategy is a necessary tool to advance the discussion around medicines’ Pricing and Reimbursement mechanisms, as well as with regard to the value of medicines. This will be critical for ensuring better access to PDMPs.

5. Plasma donor’s view

Michael Fuhr (plasma donor) from Berlin/Germany shared his experience in donating plasma. He described the main reasons that lead him to donate plasma.

He has been a donor for six years thanks to his contribution he is helping people living from rare diseases. It is a moral duty for him. He also explained that plasma donation changed his life. Michael Fuhr feels healthier since he has started donating his plasma at donation centers. He also really appreciates the way healthcare professionals are treating him when he accesses donation centers.

Michael Fuhr is convinced that more can be done when it comes to raising awareness. People need to receive more information about the impact of plasma donation on the daily lives of patients living with complex and rare diseases.

6. Plasma collector’s view

Dr. Matthias Gessner (Chair of European Plasma Alliance) presented the European Plasma Alliance (EPA). Composed by 10 European private sector plasma collectors and 140 centers in Europe, the European Plasma Alliance promotes safe plasma collection practices in the EU with a focus on donor health and donor safety to ensure patients access to safe products.
Dr. Matthias Gessner also provided more information about the current challenges related to the level of plasma donation and plasma collection in Europe:

- There are large differences in PDMPs usage between European countries:
- There is a significant number of undiagnosed and untreated patients in Europe;
- Only four European countries (Austria, Hungary, Czechia and Germany) ensure 39% of Europe’s plasma collection in private plasma centers;
- The high-level of European patients’ reliance on plasma collected in US plasma centers.

Dr. Matthias Gessner stressed the need to increase the volume of plasma collected in Europe in order to reduce Europe’s dependency on plasma imports from third countries and mitigate any risks for supply disruption. Against this background, he highlighted some key EU policy findings and opportunities which support his claims. In line with the references of other speakers, he mentioned the EU Parliament resolution of September 2020 on shortage of medicines, the European Commission’s evaluation report and related Inception Impact Assessment on the BTC legislation and the Pharmaceutical Strategy.

Given the growing clinical need of patients in Europe, he considered that there is an imperative need for policy makers to change EU and national policy frameworks to facilitate collection of significantly more plasma. He put forward some suggestions to reach this goal:

- The establishment of plasmapheresis programmes and outreach campaigns in all EU member states;
- Protection of donors’ health with regulations for plasma collection based on scientific data;
- Allowing compensation of donors for inconveniences and efforts;
- Enabling the contribution of privately owned plasma collection centres;
- Differentiating between whole blood for transfusion and plasma for manufacturing PDMPs, by setting up definitions on what is plasma, and plasma donor compensation.
V. Panel Discussion and Q&A

Peter O’Donnell, Freelance reporter and moderator of the roundtable, introduced the Question & Answers (Q&A) session.

He asked Martina Brix-Zuleger whether she noticed a drop in the amount of plasma and blood collected from donors in Austria. Martina Brix-Zuleger replied that there is at the moment enough volume of blood and plasma to support all countries. The risk of supply and the safety of the donors are the most important points for Austria.

Asked by Peter O’Donnell, Matthew Hotchko also provided more information regarding the impact of Covid-19 on the supply of plasma in the United States and consequences caused by Brexit at EU and UK levels. Regarding the situation in the United States, he informed that due to the covid-19 pandemic the collection of plasma went down by 10-15% in 2020, compared to the volume collected in 2019. Concerning Brexit, he explained that it seems that the United Kingdom has recently been inclined to change its policies regarding the use of collected plasma for fractionation.

Stefaan van der Spiegel reflected on an ask of Peter O’Donnell by talking about the possibility for the EU to adopt public health emergency measures in 2021 to counteract the effects of covid-19 on plasma collection. The potential responses will be discussed at a higher level in the EU. However, he confirmed that shortages of pharmaceuticals are of great concerns for EU policymakers as it has already been pointed out in the new Pharmaceutical Strategy. Supply disruptions and EU’s reliance on third countries are key topics of interest.

Stefaan Van der Spiegel also shared some elements on the prospect of merging the Blood Directive with the Tissue and Cells Directive. He explained that the European Commission is considering this option, and this possibility will be further explored. The question will be to know whether that decision would help ensuring the safety and quality in the sector. Although there are a lot of similarities between the two Directives, specific elements for plasma and different tissues and cells therapies will need to be taken into consideration. Against this background, Stefaan Van der Spiegel also stated that they will be looking at a secondary legislation that might be needed.

In addition, Mr Van der Spiegel provided more information on convalescent plasma at the EU level. He explained that there are different studies and support mechanisms that have taken place in the EU. Those measures are still running.
VI. Concluding remarks

Peter O’Donnell summarised the main points discussed during the roundtable. He recalled that panellists raised common concerns about the increasing demand for plasma, the complexity in the provision and gaps in the sufficiency. Some solutions have also been shared among the panellists to address the issues raised during the event, such as raising awareness among donors, better monitoring supplies and adopting clear definitions of basic terms.

At the same time, stakeholders also advanced specific issues in relation with their respective sectors, for instance, the coexistence between private and public actors in the collection of plasma.

Moreover, Peter O’Donnell stressed that the exchange between all stakeholders seems crucial to solve key challenges and assess ongoing challenges related to plasma collection at EU level. He closed his remarks by recalling that 300,000 patients who rely on PDMPs are still waiting for reinsurance and progress to suitably meet their clinical needs.

MEP César Luena thanked all participants for their strong commitment to engage in a dialogue to collect more plasma in Europe. He stated that this event was very useful to learn more about the uniqueness and importance of PMDPs and the supply of safe plasma. He highlighted that more plasma needs to be collected in Europe and this process should start now.

MEP Luena presented three asks on how EU and national policies can facilitate an increased plasma collection by:

- Establishing dedicated plasma collection programs and coordinated awareness outreach campaigns towards plasma donors in all EU Member States;
- Differentiating between whole blood for transfusion and plasma for manufacturing PDMPs;
- Considering more regulatory flexibility to optimize plasma collection in Europe.

He also considered as essential that the speakers highlighted the significant additional pressure which the COVID-19 pandemic has brought on the delicate balance between plasma collection and the availability of PDMPs.

For MEP Luena, increasing collection of plasma is crucial to ensure that patients get the therapies they need to survive. The collaboration between all stakeholders, particularly between public and private, as well is one of the key element to reach this common goal.
In this regard, MEP Luena advocates that policy-makers at EU land national level must take strong action, and modernise legal frameworks and policies to generate concrete effects, in order to significantly collect more plasma in the EU. In addition, he pointed out that changes to frameworks should be made on the basis of scientific evidence and facts, not ignoring certain societal historical realities, but confronting them with today’s hard facts. It is also important to keep a donor and a patient-centric approach.

Reiterating what MEP Simona Bonafè has previously said at the beginning of the roundtable, MEP César Luena stated that the EU Pharmaceutical Strategy and the revision of the Blood and Tissues &Cells legislation represent a timely opportunity for policy-makers to ensure that sufficient plasma is collected in Europe.