



**IPOPI**  
INTERNATIONAL  
PATIENT ORGANISATION  
FOR PRIMARY IMMUNODEFICIENCIES

# 14th PID Forum Report

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**COVID-19 & PANDEMICS  
MANAGEMENT:  
PROTECTING THE MOST  
VULNERABLE**

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September 30, 2020, 15:00-16:30

Virtual Forum  
Hosted by:  
MEP Tomislav Sokol  
(EPP, Croatia)



an IPOPI event

## I. INTRODUCTION

On 30 September 2020, the International Patient Organisation for Primary Immunodeficiencies (IPOPI) organised its 14<sup>th</sup> PID Forum entitled “**COVID-19 & pandemics Management: Protecting the Most Vulnerable**”. The event was hosted by Member of the European Parliament (MEP), Mr. Tomislav Sokol (EPP, Croatia), and moderated by Mr Johan Prevot, IPOPI’s Executive Director. Due to the COVID-19 pandemic, the Forum was held virtually.

Opening the Forum, **Johan Prevot** spoke of COVID-19’s profound impact on the world and how important it was to understand how the pandemic affected more vulnerable groups such as rare disease and primary immunodeficiencies (PID) patients. He outlined for the audience that, throughout the event, the speakers would present their perspective on the COVID-19 pandemic and how they looked to overcome the challenges they encountered. He underlined that ensuring a more optimal approach to crisis management can and should be the EU’s objective so that together, we can ensure EU Member States are better equipped to overcome the next public health crisis.

### 1. Opening Remarks

**Tomislav Sokol (EPP, Croatia)** expressed his delight in being the host of the 14<sup>th</sup> PID Forum. He stated that rare diseases and PIDs often find themselves far from the limelight and that he is proud to champion such issues and help raise awareness of the challenges faced by these patients. While the pandemic has put healthcare in the political and social discourse, these mainly focus on the direct impact of COVID-19 and often ignore other aspects of healthcare which have also been affected. He highlighted the issue of access to treatment and the need to improve upon the existing legislation in EU Member States.

He noted the particularly vulnerable situation Croatia found itself in recent months as the country dealt not only with the pandemic, but also an earthquake which damaged the national health system’s structure. He believed that in Croatia as well, there is a need to improve the country’s infrastructure and he hopes that the Forum could contribute to improving access to healthcare in the European Union.

### 2. Setting the Scene

**Martine Pergent, IPOPI President**, spoke of the organisation’s support to PID patients during the pandemic. She pointed to IPOPI’s COVID-19 LEX initiative, an expedition to learn from IPOPI’s National Member Organisations (NMOs) about the specific needs of PID patients during the current COVID-19 pandemic. The initiative reflected the global need for more **information, communication, cooperation, innovation and access to care**. She used the example of employers often failing to understand the specific requirements of employees with PIDs. Because of these issues, IPOPI is calling for the development of concrete and harmonised information on COVID-19 and its implications for rare disease patients.



Ms Pergent was emphatic when she said there was a need to fight misinformation and improve cooperation in research and information sharing. National health coverage for chronic diseases is needed and health infrastructure must adapt to allow access to treatment and monitoring during public health crises. Indeed, while some EU Member States allowed home therapy during the pandemic, the

impact of confinement and social distancing measures in blood and plasma donations needs an open and transparent discussion of all involved stakeholders to ensure that we are prepared for any potential shortages in the coming months.

### 3. Role of patient organisations during pandemics: discussion with national patient groups

Several representatives from IPOPI's national member organisations (NMOs) presented their perspective on the pandemic and the challenges it entailed for their organisations. There was broad consensus regarding the lack of information and in particular a lack of individualised information for patients' specific conditions. Representatives also stated that digital tools and online platforms were one of their primary methods by which they sought to address the concerns of their patients.



**Birgit Schlennert from the Deutsche Selbsthilfe Angeborene Immundefekte e.V. (DSAI)**, the German association for PID patients, relayed how they increased their collaboration with specialists to develop joint guidelines for patients to facilitate the dissemination of relevant and tailored information. They established a support network between patients as they realised the toll the pandemic could have on their mental health. Ms Schlennert also highlighted the advocacy work towards ensuring the needs of PID patients are considered in new policy measures and mentioned a letter written to the German Minister of Culture concerning younger PID patients' return to school and the need to consider this vulnerability during planning. She mentioned additional letters which were likewise sent to the various regional ministries and entities responsible for health in Germany to ensure the **continuous availability of therapies essential for patients with existing conditions**. She concluded that the DSAI are continuously working to ensure continuous plasma donation and the supply of plasma-derived therapies for their patients.

**Izabela Morawska from Immunoprotect**, IPOPI's Polish member, revealed that, in collaboration with healthcare professionals, her organisation developed the *12 Coronavirus (COVID-19) Protection Rules for People With Immunodeficiency* and maintained a presence in the media through their participation in the IPOPI "I Count on You" campaign. She revealed to the audience that Immunoprotect organised webinars to reassure patients and provide them with the most updated information on the pandemic, as well as making psychological support available for their patients. She concluded that they too also closely monitored the availability of immunoglobulin treatment to ensure continuous availability.

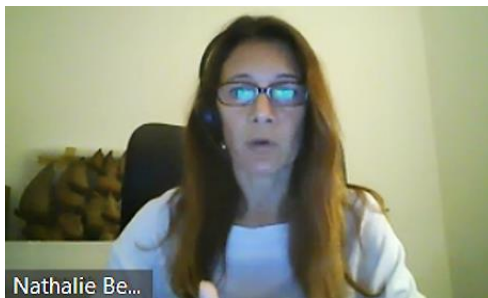
**Savvas Savva, from the Cyprus Primary Immunodeficiencies and Friends**, also emphasised on the need to fight misinformation and detailed how, through a flexible and reasoned approach, PID patients overcame the initial limited access to hospitals and their treatments. He reported that his organisation is in close contact with the national Health Ministry as well as doctors to ensure PID patients and their families are adequately informed and guided.

Finally, **Anneli Larsson, from the Primär Immunbristorganisationen (PIO)**, the Swedish PID organisation, mentioned the need for psychological support and detailed how, through the organisation

of online events and webinars, her organisation sought to address the concerns of patients who experienced difficulties in accessing healthcare, expressed feelings of isolation and loneliness, and needed to overcome economic and psychological hurdles as they progressively returned to work.

The contribution of the speakers showcased how much work still needs to be done and further underlined the added value of efficient collaboration at the European and national level, as well as across stakeholder groups when countering the effects of the COVID-19 pandemic.

#### 4. Challenges from a medical and regulator's perspective



**Nathalie Bere, responsible for Patient Engagement at the European Medicines Agency (EMA)**, talked about the development of a safe and effective vaccine against COVID-19. She spoke about the importance of meeting safety, efficacy, and quality standards and the need for the benefits of the vaccine to outweigh any side effect or potential risks. She stated that ahead of any vaccines or treatments' approval, pandemic management strategies can be used to reduce the number of deaths or severe cases.

She also spoke about the EMA's contribution to global research, its efforts to provide reliable information and the establishment of a pandemic Task Force ([COVID ETF](#)), which is the main tool used by EU medicines regulatory network for coordination. The Task Force has numerous stakeholder groups represented, including the participation of patient and healthcare professional representatives.

During the pandemic, processes were also put in place to speed up the EMA's regular regulatory procedures, such as a reduced scientific advice period and waiving the fee for COVID-19 medicines, the introduction of rapid agreement of paediatric investigation plans (PIPs), and the introduction of rolling reviews.

Finally, Ms Bere emphasised that patient engagement is a critical aspect of crisis management. The EMA has a wide network of patients and healthcare professionals through which information is disseminated. The EMA also makes use of the Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties' sessions to broadcast information.

During his presentation, **Dr Nizar Mahlaoui, Necker-Enfants Malades Hospital in Paris, and Chairman of IPOPI's Medical Advisory Panel**, highlighted the continuing uncertainty surrounding the impact of COVID-19 in individuals with rare diseases. At the very early stages of the pandemic, IPOPI worked to address these informational gaps, by publishing [COVID-19 Statements](#), which it has now made available in several languages. IPOPI has also conducted a series of COVID-19 webinars to further discuss specific issues related to the pandemic that may concern PID patients.

*We need even more collaborative efforts than what we, as a rare disease community, are used to on an everyday basis.*

**Dr Nizar Mahlaoui**

A survey known as [COPID-19](#) was launched to better understand the effects of the pandemic on PID patients. While underlining the continuous efforts to collect more COVID-19 data, Dr Mahlaoui said that

although risk factors predisposing to severe disease in PID patients appears to be similar when compared to the general population, admission rates to intensive care units tended to be higher and the median admission age also appears to be lower for PID patients. He emphasised that most PID patients are often dependent on access to Plasma Derived Medicinal Products (PDMPs), and there are concerns about potential upcoming shortages of supplies due to a potential drop in the collection of plasma during the pandemic. He also said that the vaccination of PID patients may come with some specific requirements and limitations for individual PID strains. He concluded that herd immunity will be important for PID patients unable to take the vaccine against COVID-19.

## 5. Lessons Learnt from the Pandemic

**MEP Tomislav Sokol's** presentation focused on the EU's ineffective approach during the early stages of the pandemic and said this was mainly due to the lack of a common approach between Member States. He underlined that Article 168 of the Treaty of Functioning of the European Union (TFEU) meant that the EU could only complement Member States' actions in public health during the pandemic. For these reasons, the European Parliament acted through three different types of activities.



Firstly, throughout the pandemic, MEPs worked to raise awareness of specific challenges and called on the European Commission to act on these. He personally highlighted the delays experienced by non-COVID-19 patients when accessing healthcare.

The second type of activity is through regulatory action. Although the European Parliament does not have the power to formally initiate legislative procedures, MEPs have, for instance, called on the European Commission to improve access to medicines through the internal market regulations.

*More than 1,500 questions were tabled by the Members of the European Parliament to the European Commission relating to the pandemic, myself included.*

**MEP Tomislav Sokol (EPP, Croatia)**

Finally, the European Parliament along with the Council is the budgetary organ of the EU, and the negotiations of the Multiannual Financial Framework (MFF) for the coming seven years is underway. He underlined how crucial a reinforced approach to health is and mentioned the unprecedented increase to the budget currently on the table.

**Wolfgang Phillip, DG SANTE C3, Head of Unit of Health Security and Vaccination from the European Commission,** began his presentation by stating he was looking forward to receiving the recommendations IPOPI will gather during the event. He stated that the European Commission is still far from a complete understanding of the pandemic as there is a steep learning curve. The European Centre for Disease Prevention and Control (ECDC) provide regular risk assessments and recommendations on the current situation.

He stated that the EU saw a time of lower transmission rates in the summer months and used this time to reinforce its preparedness and response capacity. He mentioned a Commission Communication on short-term EU health preparedness which lays down concrete measures that should be taken to prepare for future waves. Active discussions are also taking place within the Health Security Committee (HSC) to improve the EU response to the pandemic. Moreover, the Commission will also put forward an economic recovery package by the end of November. He added that the HSC will prepare a package consisting of a proposal directly related to cross-border healthcare. This will also include the revision of regulatory framework regulation and mechanisms for the exchange of information. He concluded that Ms von der Leyen, President of the EU Commission, is working towards the creation of an agency for biomedical research & development and the Commission will continue to play a key coordination role while stepping up its efforts as it seeks to manage the pandemic in the best possible way.

*Lessons learned may be hard, but we are still looking into the future to ensure that we are better prepared for a future wave.*

**Wolfgang Phillip, Head of Unit, DG SANTE**

## 6. Open Floor for Discussion

During an interactive open floor discussion with the audience, many questions were asked by members of the audience.

**Ms Susan Walsh**, from Primary Immunodeficiency UK, asked how we can ensure that there is no discrimination in the workplace with regards to COVID-19 vulnerability. She also called for more ideas on building resilience, the use of digital tools and how patient organisations can better deal with patients' uncertainty. **Ms Bere** responded that social media and online collaboration provide people with the means to connect with the world around them which subsequently helps improve a group's resilience. **Ms Pergent** added to her answer by saying that, in light of her experience in France, online platforms quickly demonstrated their added value by providing the opportunity to engage with patients as well as policymakers.

**Ms Stela Pirvu**, from Asociatia Romana a Pacientilor cu Imunodeficiente Primare (ARPID), also tabled a question on how many PID patients have been infected with COVID-19 across Europe and more insights on the disease's progression. Finally, when asked whether the EMA is considering any strategy to fight fake news, **Ms Bere** also explained that the EMA's press is constantly working on ways to increase their outreach through social media platforms such as Twitter and LinkedIn. She expressed her belief that the best way to fight misinformation is to educate people and be transparent.

## 7. Concluding remarks

As he moved towards the concluding remarks, **Mr Prevot** reassured the audience that IPOPI would look to answer unanswered questions by email. He thanked all speakers and participants for the valuable contributions they made to the 14<sup>th</sup> PID Forum and highlighted some of the key identified concerns during the event.

There is a need for more collaboration, a need for accurate data, and the role of patient organisations was highlighted. The short-term, medium-term, and long-term effects of the pandemic on PID patients

can be felt by the decline of the plasma donations and how this could impact the supply of essential medicines. He underlined how important it is to enumerate the actual decline of donations and calculate how these shortcomings may impact the supply of plasma-derived medicinal products towards the end of the year. He also noted several positive accomplishments such as the recent approval of the [report on shortages of medicine](#) by the European Parliament.

Finally, he concluded that IPOPI will be gathering the concerns and recommendations made during this Forum and incorporate them into a single document to be sent to relevant actors within the European Union such as the European Parliament, the EMA and relevant entities within the European Commission.

You can find Forum presentations and more resources available at <https://ipopi.org/our-work/early-diagnosis-and-care/>

## II. LIST OF PARTICIPANTS

### Panellists

- Tomislav Sokol, Member of the European Parliament, EPP, Croatia
- Johan Prevot, IPOPI
- Martine Pergent, IPOPI
- Birgit Schlennert, Deutsche Selbsthilfe Angeborene Immundefekte e.V. (DSAI)
- Izabela Morawska, Immunoprotect
- Savvas Savva, Cyprus Primary Immunodeficiencies and Friends
- Anneli Larrson, Primaer Immunbristorganisationen (PIO)
- Nathalie Bere, European Medicines Agency (EMA)
- Dr Nizar Mahlaoui, IPOPI and Necker-Enfants Malades Hospital in Paris
- Wolfgang Philipp, DG SANTE C3, Head of Unit of Health Security and Vaccination from the European Commission

### Attendees

- Mario Rasic, MEP Sokol Head of Office
- Alberto Casaca, APDIP
- Aleksandra Filip, ARPID
- Amy Efantis, PPTA
- Athina Giannoutsou, PPTA
- Cesar Rubio, Grifols
- Charles Waller, RPP
- Christine Jeffery, IPOPI
- Cristian Filip, ARPID
- Dorota Napierska, Health Care Without Harm (HCWH) Europe
- Ernest Bilić, University Hospital Centre
- Françoise Rossi, IPFA
- Frank Willersinn, PLUS group

- Gocha Gogvadze, Circular Economy Club Batumi
- Iva Slavica Ilić, Liberta.hr / PR, media
- Ivana Ivkovic, Specialty hospital St. Catherine, Zagreb
- Joelle Khraiche, CSL Behring
- John Seymour, IPOPI, IDF
- Jose Versteegen, Stichting voor Afweerstoornissen
- Julia Nordin, IPOPI
- Kinga Wójtowicz, RPP
- Leire Solis, IPOPI
- Magda Lourenço, IPOPI
- Maria Kanariou, IASO Children's Hospital (Greece)
- Melina Raso, Health First Europe
- Neda Ferencic Vrvan, Croatian league against cancer
- Nicole Fischer, Vida por la Vida
- Otilia Stanga, ARPID
- Roberta Anido, IPOPI
- Sergio Vicentini, AIP
- Stela Pirvu, ARPID
- Susan Walsh, Primary Immunodeficiency UK
- Toni Zufic, Representative office of Slavonia, Baranja and Srijem in Bruxelles
- Vlad Aura, ARPID
- Yoline Kuipers, DG SANTE, European Commission

