

# THE REVISION OF THE EU BLOOD DIRECTIVE

considerations on Voluntary Unpaid Donations and plasma donors

**12 October 2021 14:00 - 15:30**

**CO-HOSTED BY MEPS TOMISLAV SOKOL (EPP, CROATIA), DEIRDRE CLUNE (EPP, IRELAND)  
AND RADKA MAXOVÁ (S&D, CZECHIA)**

Meeting report

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## Executive Summary

The online event entitled “*The revision of the EU Blood Directive: consideration on Voluntary Unpaid Donations and plasma donors*”, co-hosted by Members of the European Parliament (MEPs) Tomislav Sokol (EPP, Croatia), Deirdre Clune (EPP Ireland) and Radka Maxová (S&D, Czechia) and moderated by Peter O’Donnell, a Freelance reporter, took place on 12 October 2021

The roundtable event included presentations from bioethics experts, as well as Q&A interactions with policymakers and representatives from patient organisations, donor organisations, not-for-profit blood establishments and industry (public and private sectors). A summary of which is presented below.

The speaker panel consisted of the following representatives:

- Mr Lorenzo Montrasio – Senior Scientific Officer - Council of Europe/DH BIO, Staff member of secretariat; Former Head of Biological Medicines Unit at AIFA.
- Mr Richard Forde – Scientific Programme Manager EDQM - Secretary European Committee on Blood Transfusion (CD-P-TS)
- Dr Núria Terribas - Vice Chair, Catalunya Bioethics Committee, and Executive Director, Víctor Grifols i Lucas Foundation

The Q&A discussion featured the following panellists:

- Mr Johan Prevot, Executive Director of the International Patient Organisation for Primary Immunodeficiencies (IPOPI)
- Dr Stefaan van der Spiegel, Head of Sector, Substances of Human Origin DG SANTE, European Commission
- Ms Catherine Hartmann, Executive Director of the European Blood Alliance (EBA)
- Mr Maarten van Baelen, Executive Director of PPTA Europe
- Dr Karin Magnussen, Medical Committee Chairwoman of IFBDO/FIODS.

MEPs Tomislav Sokol (EPP, Croatia), Deirdre Clune (EPP, Ireland) and Radka Maxová (S&D, Czech Republic) all highlighted the importance of finding compromise on how to collect more plasma in the EU. They also brought attention to the need for the EU to overcome its dependencies and begin thinking about European sufficiency when it comes to plasma supply. All co-hosting MEPs pointed to the evaluation of the EU’s Blood, Tissues and Cells (BTC) Directives and the related revision process as the perfect opportunity for policymakers, stakeholders and experts to come together and resolve some of the most pressing issues related to the donations of plasma.

Mr Lorenzo Montrasio presented the viewpoint of the Council of Europe/ DH BIO on blood and blood donations in the context of the Oviedo Convention and the Guide on Prohibition of financial gain. During his presentation he made a specific point explaining that “The human body and its parts shall not, as such, give rise to financial gain”. This principle is present both in the Charter of Fundamental Rights of the European Union (Article 3.2) and in the Oviedo Convention (art. 21). Provided that there is no financial gain as a result of donating, reimbursement of justifiable expenses (for example, travel, donation-related expenses) and compensation for loss of earnings (justifiable and acceptable) are compatible with the principle of the prohibition of financial gain. Reimbursement and compensation must not vary according to the final objective, be it for therapeutic or research purposes, nor according to the quality of what has been donated

(blood, plasma or other blood component), or the outcome for the recipient. Reimbursement and compensation should not lead to inappropriate competition between establishments over donor recruitment. Ultimately, he underlined that justifiable fee for medical or related technical services rendered in connection with the donation, can be acceptable under the conditions provided by the Guide.

In his presentation, Mr Richard Forde, the scientific programme manager of European Directorate for the Quality of Medicines (EDQM), Council of Europe, went into details about the EDQM's Guide to the preparation, use and quality assurance of blood components, also known as the "Blood Guide" and reiterated, as well, the importance of the financial neutrality principle. He further went into detail about the work done by the EDQM in securing an adequate and safe plasma supply for European countries as well as the activities of the CD-P-TS and its role in supporting it.

Dr Núria Terribas, the Vice Chair of the Catalunya Bioethics Committee and Executive Director of the Grifols Foundation, spoke about the ethical considerations of blood and plasma donations and how they fit in with the Voluntary Unpaid Donations (VUD) principles, emphasizing the stark difference between compensation and incentives. She further highlighted the fact that the EU relies heavily on the imports of plasma from abroad as its own supplies are insufficient – a situation that was further exacerbated by the pandemic. She stressed that EU Member States have the ethical obligations to provide care for their patients and cover their needs – which happens to be in conflict with the strong rejection of any compensation being granted to donors. Another key point of Dr Terribas' speech was the differentiation between blood and plasma donations, especially in terms of their impact on donors, the donation process itself and the frequency with which one can donate.

The panel discussion was attended by **Mr Johan Prevot, Executive Director of the International Patient Organisation for Primary Immunodeficiencies (IPOPI), Dr Stefaan van der Spiegel from DG SANTE, Ms Cathérine Hartmann, Executive Director of the European Blood Alliance, Mr Maarten Van Baelen, Executive Director of PPTA and Dr Karin Magnussen, Medical Committee Chairwoman of IFBDO/FIODS.**

All speakers and panellists discussed the challenges for plasma collection in Europe in the context of the revision of the EU's Blood, Tissues and Cells Directives and presented their respective organisation's views on which would be the best approach for the EU to tackle the situation of insufficient plasma collection and its dependency on the US.

Mr Prevot presented the viewpoint of patient organisations and explained that what is needed is a patient-centred and solution-oriented approach to the Directive's revision. He highlighted the fact that over the past 20 years, patients' concerns have largely been ignored and called for a change of approach, hoping that policymakers and stakeholders can come to an agreement that will ultimately help patients receive the treatments which they need and deserve.

Dr van der Spiegel gave a brief explanation of how the EU Commission is approaching the BTC Directives and highlighted the complexity of the issues at hand. He further reiterated that there are a lot of different understandings of the VUD principles, and that it would be good to have more common clarity.

Ms Hartmann made an argument that there is no significant difference between blood and plasma donations in terms of commitment by donors and stated that there should be more investments in public sector donations.

Dr Magnussen echoed the sentiments shared by Ms Hartmann and explained that there is no need to introduce financial compensation for blood and plasma donations and stated that it is not possible for the public and private sectors to coexist in this field.

Mr van Baelen shared PPTA's view that compensation is compliant and complementary with the VUD principles.<sup>1</sup> According to PPTA, plasma donors are not paid or remunerated for their donation, but they are volunteers. Volunteers can be compensated for their expenses, and plasma donors can also be compensated for their expenses and the inconvenience related to the donation. He further highlighted the fact that most EU Member States already provide some kind of compensation for donors. He further reiterated that out of all forms of compensation, a fixed-rate allowance is the most effective one in terms of incentivizing already motivated donors and able to increase plasma collection.<sup>2</sup>

## 1. Welcome & Introduction



**MEP Deirdre Clune** thanked all speakers and participants for joining the online roundtable and underlined the importance of the topic of plasma donors and donations in the context of the revision of the EU Blood directive.

During her introductory speech, MEP Clune brought attention to the fact that the COVID-19 pandemic laid many of the problems in the EU's healthcare framework that have so far been brushed aside – most importantly in the current context, the EU's reliance on US-imported plasma.

She further underlined that this is an issue of the EU's strategic autonomy and that the bloc has the tools it needs in order to address it – highlighting the fact that there are substantial differences between donating blood and donating plasma and that compensating donors for inconveniences is something that can be explored as a way to promote additional donations.

As she concluded her speech, MEP Clune called for attendees and stakeholders to make use of this opportunity, take a step back and reassess the EU's approach to plasma collection and make sure that patients receive the treatment they need while donors feel safe and secure.



**MEP Tomislav Sokol** began his introduction by highlighting the fact that the topic of blood and plasma donations is often overlooked in the EU as it is overshadowed by discussions on cancer or COVID-19. Nonetheless, he stressed that this discussion is vital for thousands of patients across the EU.

MEP Sokol explained that while the EU's lack of competences in the field of healthcare is often used as an excuse to not take action, when it comes to donations of blood and plasma, this is not the case. In fact, the EU is uniquely positioned to have a positive impact in this space, and it can and should do what it can to protect patients and vulnerable communities.

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<sup>1</sup> Commission staff working document on the implementation of the principle of voluntary and unpaid donation for human blood and blood components as foreseen in Directive 2002/98/EC on setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC. <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:52016SC0130>

<sup>2</sup> Vintura White Paper: Key economic and value considerations for plasma-derived medicinal products (PDMPs) in Europe. <https://bit.ly/VINTURA>

MEP Sokol highlighted the importance of EU's strategic autonomy in the field of healthcare, pointing to the disruptions of supply chains and the lack of medicinal products during the pandemic which adversely impacted thousands of citizens and ultimately costed lives. In conclusion, MEP Sokol claimed that the EU can do more to enforce its high standards while simultaneously severing its dependence on foreign countries, such as the US, thereby making sure that patients in the EU get access to the best products available as fast as possible.



**MEP Radka Maxová** opened the discussion by thanking the speakers and participants for attending an event that can contribute substantially to helping citizens and patients across the EU have better access to life-saving products.

She pointed to her previous experiences working with patients from the primary immune-deficiency community and acknowledging plasma donors on World Blood Donor Day in 2021; she also highlighted her understanding of the problems that the patients face each day and how EU's dependencies on third countries makes them particularly vulnerable during times of crises.

MEP Maxová further elaborated that the EU legal framework is unable in its current form to address the issues at hand. The current insufficiencies present a challenge that must be solved in order to address the needs and expectations of patients and citizens.

Before concluding, MEP Maxová made special mention of the importance of finding common ground, reaching out to all relevant stakeholders; she also pointed to the soon-to-be appointed rapporteur MEP and shadow rapporteurs MEPs for the EU's Blood, Tissues and Cell Directive to begin their work, as it is only through a wide-ranging compromise that mutually-beneficial solutions can be found.

## 2. Setting the scene

### 2.1. DH BIO interpretation guide on the principle of prohibition of financial gain on SOHOs and the fixed rate allowance

**Mr Lorenzo Montrasio, Council of Europe/ DH BIO**, gave an overview of the [Oviedo Convention](#) and the Guide on Prohibition of financial gain in the context of blood and blood donations. He explained that the Convention on the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine is the only binding international instrument in this field and serves as a global reference for many institutions including the United Nations and the European Court of Human Rights. Mr Montrasio further highlighted two articles from the Convention – namely Article 3, concerning the Equitable access to healthcare and Article 21 focusing on the prohibition of financial gain.

In the context of Article 3, the Council of Europe is currently preparing to draft a set of Guidelines for equitable access to healthcare resources in a context of scarcity while the provisions of Article 21 are further examined under DH BIO's Guide on the implementation of the principle of prohibition of financial gain with respect to the human body and its parts from living or deceased donors. The goal of the Guide is to clarify some concepts and facilitate the implementation of Article 21 which ensures the respect of donors' dignity and their human rights. Mr Montrasio elaborated that abiding by Article 21 contributes to the promotion of altruistic donations and the safety and quality of donations.

Mr Montrasio further explained the definition of financial gains and what they constitute according to the Oviedo Convention's framework. He highlighted that the prohibition of "financial gains" includes in-kind payments and incentives to living donors and third parties. "Financial gain" may have the effect of influencing the most vulnerable people in society and expose them to exploitative actions. He clarified that, if there is no financial gain as a result of donating, reimbursement of justifiable expenses (for example, travel, donation-related expenses) and compensation for loss of earnings (justifiable and acceptable) are compatible. Justifiable fee for medical or related technical services rendered in connection with the donation, can be acceptable under the conditions provided by the Guide.

Most importantly, in his view it is vital to ensure that donations remain financially neutral – meaning that there is no financial gain as a result of donating.

He further went into detail about the fixed-rate compensation scheme outlined in Article 21. Mr Montrasio gave an explanation of how it works and what are some of the rules that it abides by, including:

- Conditions of its implementation must be provided for under national law
- The upper limit for compensation must be specified by law or established by an independent body set up in accordance with national law.
- Must be transparent
- Must not act as an inducement to donate.
- Measures should be in place to minimise the risk of harm to donors which may result from the donation scheme, such as national registers or traceability systems to limit how frequently a person can donate.

Mr Montrasio clarified that the fixed-rate compensation scheme must be a transparent system aiming to facilitate practicalities connected with reimbursement and compensations of real individual expenses and loss of earnings.

In conclusion Mr Montrasio underlined that the Oviedo Convention provides a legal framework for protecting vulnerable persons, while the Guide for the implementation of the principle of prohibition of financial gain serves as a pillar to ensure its clarity and implementation. The Guide clarifies that compensating plasma donors with a fixed-rate scheme is compatible with the principle of art. 21 of the Oviedo Convention only if all the conditions set in the guide are met.

**Mr Richard Forde**, Secretary of CD-P-TS, went into the details about the Council of Europe / EDQM activities in the field of blood transfusions. He highlighted the three main guiding principles of the CD-P-TS, namely Voluntary Non-remunerated Blood Donations (VNRBD), mutual assistance and the protection of donors and recipients. He further gave an overview of the CD-P-TS' activities, which include the development of legal instruments, technical standards and policies (such as the Guide to the preparation, use and quality assurance of blood components, also known as the "Blood Guide"), monitoring data and best practices and other activities that support the implementation of technical standards and EU legislation.

On VNRBD, Mr Forde highlighted the relevant standard of the Blood Guide, which refers to the principles set out in the Oviedo convention as well as the Council of Europe Recommendation No. (R95) 14 which gives a detailed definition of what constitutes a donation that is considered voluntary and non remunerated.

In the field of plasma donations, Mr Forde first highlighted the Council of Europe / EDQM Plasma Supply Management Symposium which involved key stakeholders in the field of blood transfusions and plasma-derived medicinal products both from the public and private sectors. The highlights from the Symposium, reported by Mr Forde, included a focus on Europe's strategic independence of plasma and donor protection and fit into the Council of Europe / EDQM overall approach to promoting safe plasma collection.

Mr Forde went on to underline the importance of the principles set out in the Oviedo convention regarding financial neutrality and ensuring the safety of donors and recipients in the context of plasma donations and explained that the CD-P-TS, under the coordination of the EDQM secretariat, will continue to perform activities to support safe plasma donation in Europe, working towards ensuring Europe's strategic independence in the field and supporting awareness-raising campaigns on the need for plasma across Europe.

## 2.2. View on acceptable encouragement models for plasma donors

**Dr Núria Terribas, Vice-Chair of the Catalonia Bioethics Committee, and Executive Director, Víctor Grífols i Lucas Foundation**, began her presentation with providing background to the EU context of plasma supply. She explained that EU's patients are heavily reliant on imports from abroad with 30% of plasma coming from the US. This situation was only worsened by the pandemic, as healthcare systems were forced to prioritize among patients and pathologies.

Dr Terribas explained that Member States are ethically obliged to provide care to patients and cover their health needs by complying with the principles of bioethics – including non-maleficence, beneficence, autonomy and justice.

She further went on to elaborate on the current interpretation of VUD in Europe, describing it as one that introduces a far too rigid interpretation of altruism and discarding compensation models for donations. Dr Terribas then underlined that under the present definitions of altruism, it has become clear that the EU can't collect enough plasma and that by introducing some sort of compensation for

donors this wouldn't eliminate neither the "goodness" nor the solidarity of the donation.

According to Dr Terribas, there must be a major re-think take place on how the EU should approach the issue of plasma collection. She explained that first and foremost it should be understood that there are vast differences between blood and plasma donations (in terms of frequency of donations, the longer donation process of plasma, which takes around 90 minutes, as well as the accompanying costs and expenses). Furthermore, she reiterated the position that these donations must not lead to a financial loss for the donors – which also touches to the ethical questions whether it is fair to ask donors for their efforts without any return and compensation. Dr Terribas asked whether societies should accept to limit the availability of medicines or accept a different way of defining altruism. Whether it is fair to solve the supply problem by accessing plasma obtained in other countries where donors are compensated directly.

The answer, according to Dr Terribas, lies in being flexible, especially in the course of changing circumstances. She also mentioned that the Article 3 of the Oviedo Convention clearly states that parties should take appropriate measures in order to provide citizens with equitable access to healthcare opportunities. To address and facilitate plasma collection it is important to look towards the possibilities of compensation and according to Dr Terribas it is vital to differentiate between "compensation" and "remuneration" as the former does not equal incentives and guarantees financial neutrality.

She further elaborated that compensation as a means of promoting donations should not come at the expense of public awareness campaigns that promote solidarity. In fact, according to Dr Terribas, compensation could be the last piece of information provided as a reason for people to donate.

Finally, Dr Terribas provided several recommendations that could increase plasma supply in the EU and ensure that patients receive the care they need. They included:

- The possibility of compensation being included in the VUD principle as this doesn't delegitimize the act of donation or eliminate its altruistic nature.
- Getting a common definition & interpretation of compensation in the revised EU BTC legislation, that would allow states flexibility to specify its compensation model (in kind, monetary or mixed), according to health systems and their social and cultural context.

### 3. Discussion and Q&A

**Mr Peter O'Donnell, independent journalist and moderator of the event**, introduced panellists taking part in the Q&A session..

**Mr Prevot Executive Director of IPOPI** was asked to comment on the patients' perspective on Voluntary Unpaid Donations (VUD) and how compensation can fit into the narrative, especially for plasma donors. He responded that the common view of many patient organisations is that they have always supported the coexistence of the two systems: non-compensated, as well as those who are compensated for their efforts when donating plasma. He underlined that in the end what matters to patients is their access to a stable supply of safe and effective treatments and that combining the two systems is absolutely necessary to ensure patient needs in plasma derived medicinal products such as immunoglobulins are met appropriately

The moderator then asked **Dr Stefaan van der Spiegel from DG SANTE** whether the EU Commission can be more proactive in recommending Member States to take a more nuanced and flexible approach to VUD, taking into account the specifics of plasma donations. In his response, Dr van der Spiegel first

pointed to the legal basis and Commission's mandate for (the revision of) the BTC directives which is setting high standards for safety and quality of substances of human origin (Article 168(4)(a) of the Treaty on the Functioning of the European Union). Nevertheless, ensuring access to therapies for patients who need them is also a safety topic. To achieve that however, the EU needs to be able to collect enough plasma on its own, and the way to achieve results is up to Member States. On top of that there are additional concerns regarding an increase in demand, costs of reimbursement, etc. making the topic very complex and stretching somewhat out of this Commission's mandate. Mr van der Spiegel mentioned that there are currently ambiguities in Member States' approach to compensation as part of the VUD principle, which calls for additional clarity in the future.

Mr O'Donnell then gave the word to **Ms Catherine Hartmann, Executive Director of the European Blood Alliance**, asking her whether there should be a distinction made between donating blood and donating plasma, given the associated differences in time spent donating and related inconveniences. In her answer, she highlighted that a survey have shown that some donors did not know whether they were donating blood or plasma, therefore according to her making the related inconveniences somewhat not relevant. She further declared that the time difference between the two boils down to around 30 minutes in total.

Ms Hartmann made the argument that fixed-rate compensation could not work as different donors would have different needs for compensation, based on their own personal circumstances. She further highlighted that the EBA is fully supportive of ethical forms of compensation for donations that do not lead to financial gain but stands firmly against any fixed-rate mechanisms as they might end up financially benefiting some individuals, thereby breaching the Oviedo Convention's principle of financial neutrality.

The moderator then approached **Mr Maarten Van Baelen, Executive Director of PPTA**, for his organisation's position on the BTC legislation. He explained that according to PPTA's views, plasma donors are not employees and are not paid, but should rather be compensated for their efforts, according to the principles laid out in, for example, article 12 of the tissues and cells directive<sup>3</sup>, the Nuffield Guide<sup>4</sup> and the DH BIO Guide<sup>5</sup> on prohibition of financial gain, with final conditions being set by Member States. He underlined that compensation for efforts is perfectly in line with the altruistic focus of donations and pointed to the DH BIO guide<sup>6</sup> which allows for a form of fixed-rate allowance under specific national law. According to Mr Van Baelen, most EU Member States<sup>7</sup> already provide some form of compensation for donors, all in line with the principles of VUD. Some countries apply fixed-rate allowances, others reimburse specific expenses or compensate with time off from work, tax reductions,

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<sup>3</sup> Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells - <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32004L0023>

<sup>4</sup> Nuffield Council on Bioethics - Human bodies: donation for medicine and research <https://www.nuffieldbioethics.org/publications/human-bodies-donation-for-medicine-and-research>

<sup>5</sup> Committee on Bioethics (DH-BIO) - Guide for the implementation of the Principle of Prohibition of Financial Gain with respect to the human body and its parts, as such, from living or deceased donors (articles from 20 to 28) <https://rm.coe.int/guide-for-the-implementation-of-the-principle-of-prohibition-of-financ/16807af9a3>

<sup>6</sup> Idem

<sup>7</sup> "Thirteen Member States (BG, CZ, DE, EE, FI, IE, HU, LT, LU, LV, NL, PL, RO) reported having guiding principles regarding the possibility of giving compensation to donors of blood and blood components" p.7 and Figure 1

Commission staff working document on the implementation of the principle of voluntary and unpaid donation for human blood and blood components as foreseen in Directive 2002/98/EC on setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC. <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:52016SC0130>

vouchers or by other means<sup>8</sup> but what matters is that all these forms are ultimately altruistic-focused incentives for those already motivated to donate. Yet, according to Mr van Baelen, compensation as a direct allowance, to compensate for expenses and inconveniences relate to the donation, seems to be by far the most efficient approach when it comes to increasing plasma collection.<sup>9</sup>

Following up, Mr O'Donnell asked **Dr Karin Magnussen, Medical Committee Chairwoman of IFBDO/FIODS**, her opinion on the compatibility of a well-regulated financial compensation model with the VUD principle for plasma donors. She agreed with Ms Hartmann that no such compatibility can exist and that according to EBA there is no difference between blood and plasma donors when it comes to donations. Furthermore, she underlined that there is no good reason to introduce financial compensation for either.

The moderator then brought in **MEP Radka Maxová** in the conversation, asking her how patients and donors can make their voices heard in the upcoming revision of the BTC legislation and can their interests be represented by policy makers. MEP Maxová explained that there have already been extensive consultations with key stakeholders prior to the legislation's future submission to Parliament, but underlined that whoever is chosen as rapporteur for the file will have a duty to reach out to everyone in order to find a commonly beneficial solution.

On the topic of sustainable plasma supply, Mr O'Donnell approached **MEP Deirdre Clune**, asking her of her opinion on the role of donor motivation and whether it would be possible to find a better definition of VUD that includes compensation for blood and plasma donors. MEP Clune stated that the most important thing is to follow already existing guidelines on compensation, while simultaneously increasing the number of donations in Europe to sever the bloc's reliance on foreign-imported plasma. One possible way to achieve that, she explained, could be by finding a good balance that fits into the already existing definitions of compensation, as well as raising awareness to boost donations.

Coming back to **Mr Montrasio and Mr Forde**, the moderator asked whether there is a need to review already existing guidelines in light of new developments and technological breakthroughs **Mr Montrasio** explained that conventions like the Oviedo Convention have specific mechanisms for revising their texts, based on well-documented scientific texts and data. He also stated that in most cases, when it comes to human rights, technological advances can rarely change definitions and understandings and that so far, no governments have explicitly stated their desire to change the Convention.

Speaking about the potential need to change Council of Europe / EDQM Recommendations and Guides, where related to VNRBD, and the evident need for more plasma, **Mr Forde** underlined that the EDQM's "Blood Guide" has a specific standard which refers to the principles set out in the Oviedo convention that states that measures should be taken to promote VNRBD – and that this standard remains relevant today, as it also serves as a central principle of the CD-P-TS. The definition of VNRBD provided for in Council of Europe Recommendation 95(14) which supports this standard is also endorsed by the WHO, IFBDO/FIODS and governments around the world. He further explained that there have been no immediate changes that would necessitate the text's adaptation and that the current guidelines do not exclude direct reimbursement and compensation of costs related to a donation as long as they do not

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<sup>8</sup> Figure 1, Commission staff working document on the implementation of the principle of voluntary and unpaid donation for human blood and blood components as foreseen in Directive 2002/98/EC on setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC. <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:52016SC0130>

<sup>9</sup> Vintura White Paper: Key economic and value considerations for plasma-derived medicinal products (PDMPs) in Europe. <https://bit.ly/VINTURA> (figure 10)

breach the principle of financial neutrality.

Mr O’Donnell then opened the floor for a discussion between the panellists and speakers. Ms Hartmann raised the point that definitions of VUD between the different parties are not aligned and that the existence of compensation in some EU member states makes it harder to implement a purely non-remunerated form of donations across the bloc. She also affirmed that according to the EBA the only way to ensure the safety of donors and patients is to invest more in the public sector as its sole reason to exist is to provide services, while, according to her, private enterprises can close down at the behest of their shareholders.

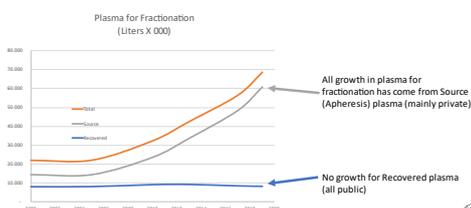
Mr Van Baelen also joined the discussion, stating that while it is good to see that the public sector is willing to increase plasma collection, however the public sector already had that objective and there has hardly reached any increase in plasma collection for the past 20 years. Meanwhile, the private sector, wherever it is allowed to compensate its donors, collects more and more plasma to meet the growing clinical need of patients.<sup>10</sup> He explained that PPTA is advocating for the co-existence of private and public entities in the field to boost plasma collection, but that, unfortunately, this still remains impossible in many EU countries.

Mr Johan Prevot, speaking on behalf of patients’ organisations within the Platform of Plasma Protein Users (PLUS) , stated that a lot of the debates surrounding the BTC revision, sound much like the debates held back during the adoption of the Blood Directive in 2001 and remain very philosophical or whether donors donate for altruism or not. He explained that patients need solutions which require change – and that the current system obviously doesn’t work for those who need it the most, since the EU is increasingly relying on plasma from the US. He reminded the audience and the panel that plasma donors can donate far more frequently, that their donations yield a greater amount of product compared to blood donations and yet EU’s current capabilities are still not enough. Today, the EU relies on plasma from the U.S. for about 30 percent of its need. This dependency is now negatively impacting patient access to immunoglobulins. Mr Prevot underlined the need for a more collaborative approach, evidenced by the fact that whatever the EU has been doing for the past 20 years that has been, in the end, obviously not effective. He called for a patient-centred approach that leads to tangible solutions which would ultimately increase plasma donations and allow easier access to life-saving medical treatment.

*To conclude the Q&A session, Mr Peter O’Donnell gave the floor to the speakers and panellists to present their takeaway remarks and their ideas for potential solutions to the previously discussed issues.*

Dr Stefaan van der Spiegel underlined that it is vital to have sufficient supply for patients to be able to access therapies and at the same time ensure safety of donors. Furthermore, he explained that while VUD certainly plays a role, it is not the only solution – both the public and the private sector have a role

Globally, Source (Apheresis) plasma is providing all the volume growth for fractionation



to play and must be able to step up to satisfy the needs of patients. It is up to the Member States' authorities to decide what role each sectors play within their country, and the Commission and EU legislation respect that.

Dr Karin Magnussen stated that if given the chance, the public sector can supply sufficient plasma to European patients through public fundings.

Ms Catherine Hartmann highlighted that everyone agreed with the fact that the EU needs to become self-sufficient in terms of plasma and that the rate of donations must be increased but that must be done by public entities. According to EBA, Blood services have witnessed<sup>11</sup> in the 90ies, that commercial plasma suppliers entering and leaving the market have left some blood systems disrupted, both in terms of donor bases and supply.

Dr Núria Terribas stated that it is obvious from this discussion that the EU has a very big problem related to this question and that since for the past 20 years there has barely been any progress perhaps it is time for a change in approach that delivers justice to patients and donors.

Mr Richard Forde highlighted the need for a self-sufficiency in supply and pointed to the role that VUD plays as a main principle– but stated that there are many other aspects such as: optimal use of medicines, optimal use of PDMPs and appropriate diagnosis of patients –

Mr Lorenzo Montrasio pointed to the successes of the current regulatory framework – the ensuring of a safe environment and the fact that the clinical needs of most patients eligible for the indications of blood derived medicinal products are satisfied by the current blood system and other therapeutic alternatives. That, however, does not mean that there isn't a need for improvements provided that the need to increase the availability of human blood products does not lead to competition between the right of patients to access the products they need and the right of donors to respect for dignity and human rights.

Mr Johan Prevot stated that the best way forward is to have a Blood Directive that takes stock of the past 20 years, that looks at best practices from around the EU, that better defines blood and plasma, recognizing the differences between them, that encourages coexistence between the public and private sector, allowing flexibility to Member States and letting them find the solutions that fit them best. He again called for a more patient-centred Blood Directive that takes into account their interests.

MEP Radka Maxová called for more dialogue and more cooperation between different stakeholders and institutions.

Mr Maarten Van Baelen stressed the fact that there is more critical to the discussion than compensation alone, but in order to drive plasma collection up, it is critical to clarify in a future Blood Directive that compensating plasma donors by using a fixed-rate allowance is compatible with the VUD principle<sup>12</sup>, and noted that the Council of Europe Guide on interpreting the principle of prohibition of financial gain clearly mentions the term “fixed-rate compensation scheme”. He mentioned that similar terms are also

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<sup>11</sup> According to Prof. Dr. Philippe Vandekerckhove, CEO of the Flemish Red Cross and Sanquin in the Netherlands.

<sup>12</sup> This approach is considered ethically acceptable by bioethical bodies such as the Council of Europe Committee on Bioethics (DH-BIO) and the Nuffield Council on Bioethics Nuffield Council on Bioethics - Human bodies: donation for medicine and research <https://www.nuffieldbioethics.org/publications/human-bodies-donation-for-medicine-and-research> Committee on Bioethics (DH-BIO) - Guide for the implementation of the Principle of Prohibition of Financial Gain with respect to the human body and its parts, as such, from living or deceased donors (article 23, 24) <https://rm.coe.int/guide-for-the-implementation-of-the-principle-of-prohibition-of-financ/16807af9a3>

present in other ethical guidelines related to the topic.

#### 4. Concluding remarks

**MEP Clune** thanked the moderator and all speakers and panellists for their participation and underlined the importance of such varied discussions for decision makers.

She highlighted the fact that the word “solutions” was especially prevalent during this discussion and that is something that the European Parliament is committed to working towards them. Among the chief concerns she pointed towards ensuring enough plasma for patients and making certain that their interests are at the heart of the legislation’s revision.

MEP Clune also brought attention to Europe’s reliance on US plasma imports which are obtained thanks to financial compensation and stressed that this is something that should be looked into.

Remarking on the roles of the public and private sectors, she stated that both should work together rather than compete. Making sure that the donation environment remains as safe as it has been for the past 20 years remains a priority, but so too must be the collection of more plasma that satisfies the needs of patients.

**MEP Deirdre Clune** concluded by pointing out that the issues at hand are incredibly complex and would require substantial dialogue between and among institutions, stakeholders and interested parties, but should ultimately lead to an outcome that ensures the health and safety of European patients and donors.

