PLUS
PLATFORM OF PLASMA PROTEIN USERS

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cc:
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Subject: WHO public consultation on the draft WHO Principles for the donation and management of Medical Products of Human Origin (MPHO)

Dear Dr. Chan,

We are writting to you on behalf of PLUS, the Platform of Plasma Protein Users, to express our serious concern and surprise regarding the publication of the consultation draft of WHO policies regarding the principles for the donation and management of Medical Products of Human Origin (MPHO) and request a meeting to address our main concerns.

PLUS is a consortium of several patient organisations representing people living with treatable rare plasma related disorders such as haemophilia, primary immunodeficiencies and alpha1 anti-trypsin deficiency among others.

The draft WHO Principles for the donation and management of Medical Products of Human Origin has been drafted without any consultation or input from the organisations represeting patients with treatable rare plasma related disorders. It is therefore with surprise that we only learnt about this consultation process just before the deadline, in spite of having been in contact with the Directorate of Health Systems and Innovation since 2014. In communications with representatives from this Directorate, we were assured in writting that PLUS would be requested to collaborate in order to ensure access to a sustainable quality plasma supply and to safe blood products globally.

This is why we have read with suprise that the feedback of the Platform representing patients whose lives depend on plasma derived-products was not sought for the development of this draft.

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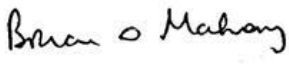
Patients whose continued health is dependent on the use of blood components or plasma-derived medicinal products have a right, through their representative organisations, to be consulted on any issue which may have an impact on the safety, efficacy or supply of the treatment they receive. This has been recognised and supported in the PLUS Consensus Statement by 29 patient organisations and other stakeholder organisations active in the field.

The Consultation documents (survey and principles) are in our view extremely biased and do not take into account the life saving impact of plasma-derived medicinal products (PDMPs) such as immunoglobulins and coagulation factors which the WHO itself has classified as Essential Medicines. The circulation of these documents drafted as such could have seriously negative repercussions and ultimately pose a serious threat to the optimal supply and therefore access by patients to PDMPs, the large majority of which are produced from remunerated plasma donations. As the European Medicines Agency stated already in 2002, "*there is no evidence from clinical studies and pharmacovigilance that donor remuneration increases the risk of viral transmission via plasma-derived medicinal products, which have been subject to proper screening at donation and a validated viral inactivation/removal step*". The EMA has also stated that "*a requirement for unpaid or non-remunerated donors would create major supply problems and product shortages without any justification on grounds of safety*" (CPMP Position Statement on Non-Remunerated and Remunerated Donors: Safety and Supply of Plasma-Derived Medicinal Products, EMEA/CPMP/BWP/1818/02/Final). PLUS has since 2010 led a process through which all stakeholders in the field of PDMPs have provided input on vital issues such as those. Several consensus statements have been produced as a result. The survey and principles are not well informed and in complete contradiction with the contents and spirit of these important expert statements.

We therefore request a stop to this consultation process until patients' views have been incorporated in the draft document and the major concerns addressed. We would also like to request a meeting to address how to ensure effective involvement of PLUS in the policy-development process.

We look forward to hearing from you on this important issue,

Yours sincerely,



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On behalf of PLUS Steering Committee

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