In My View

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WHO should provide Guidance on Quality and Safety of Blood Products

THE WORLD HEALTH ORGANIZATION (WHO) is recognized worldwide, especially in its guiding role for developing countries. Because WHO is a prominent source of information, it is important that documents from WHO provide clarity and guidance and not create confusion. In May 2009, the Executive Board of WHO examined the availability, quality and safety of blood products. Blood products were defined as any therapeutic substances derived from human blood, including whole blood, labile blood components and plasma-derived medicinal products. On January 22, a report was issued with more details. Although comprehensive, this report contains information that is sometimes based on unsupported assumptions and biased position statements.

Anyone involved in our sector knows the difference between whole blood and plasma-derived medicinal products. Combining labile products (blood products for transfusion in hospitals) and stable products (finished therapies after a long manufacturing process) into one category is problematic. Everything is different: collection, testing, manufacturing, regulations, administration and more. Why issue a report that combines both and creates this confusion?

WHO recognizes that all therapies save lives and dramatically improve the quality of life of millions of people. It is also understood that, *"there have to be effective policies, strategies, quality systems, legislative and regulatory frameworks in the collection, testing, processing and supply of blood components, such as red cells, platelets and plasma, for clinical use."* I agree.

Then the report states, *"These safeguards are also crucial in the preparation of plasma for fractionation, as a raw material for the manufacturing of plasma-derived medicinal products, such as blood coagulation factor concentrates and immunoglobulins, which are on the WHO Model List of Essential Medicine...Recognizing the high risk of transmission of pathogens through transfusion of contaminated blood products…the Health Assembly...urged member states to promote the development of national blood services based on voluntary non-remunerated donation...These actions are complementary to the equally essential goal of improving overall good manufacturing practices."* How can the WHO combine how a donor is compensated with good manufacturing practices? Furthermore, the report states, *"Developing countries are facing serious shortages of all products, and have a much higher risk of transmission of pathogens."* What we see in many WHO documents is that this kind of information always leads to the standard sentence (and no surprise, it is here again) *"The provision of blood and blood products from voluntary, non-remunerated donors must be the aim of all countries."*

Why does WHO do that? How can you in one report state that coagulation factors and immunoglobulins are on the "List of Essential Medicines," knowing that the availability and supply would be dramatically reduced by applying this goal linked to the remuneration status of the donor? Do the people that write these policies really care about patients or are they just interested in pursuing political ideologies?

What is critically important is the development of stringent regulatory environments with oversight that ensures that collection, testing and manufacturing are done appropriately in all countries. Having these standards in place will guarantee that effective, safe lifesaving therapies will be more widely available. This is already the case in multiple regions of the world.

The report states further: *"The limited availability of plasma-derived products in developing countries stems from various causes...Large percentage(s) of plasma collected in developing countries is categorized as waste material and destroyed...*

This occurs because appropriate technology, regulatory controls, quality systems and good manufacturing practices are all lacking, thereby rendering the plasma unsuitable for conversion into fractionated products. Unless this situation is improved, plasma from developing countries will continue to be rejected for contract programs in a regulated environment."

This statement underlies the most important concept. The current, inadequate systems in most developing countries are responsible for shortfalls in plasma, not the remuneration sta-

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tus of donors. Interestingly, all the donations in this case meet the WHO criteria for non-remunerated donors, but the quality is what makes it unsuitable for fractionation.

I agree wholeheartedly with this quote, *"It can therefore be assumed that blood services in developing countries would likewise benefit from the introduction and enforcement of the appropriate quality systems and independent and transparent quality-assurance regulations and inspection procedures."* Every member of PPTA has these systems in place and supplies safe and effective therapies all around the world.

The Director General of the WHO established a blood safety program in the late 1980's. In the year 2000, Blood Safety was declared an Organization-wide priority. The Secretariat initiated a major program to support the development of high quality systems for all aspects of blood transfusion through the global quality management program. In 2005, the WHO Blood Regulators network was established to define WHO's leadership role in supporting developing countries' regulatory authorities, which formulate regulations for the manufacture of blood products. At the present time, the results of these meetings have not been made public.

By definition, how can any agency claim a leadership role with a policy of following others? I think the WHO should demonstrate support for countries with regulatory agencies who have established their credibility and assist those countries in bringing these regulations to other (developing) countries.

This report also describes WHO's establishment of the Global Collaboration of Blood Safety—a mechanism for international collaborative relationships and partnerships with organizations and institutions working for global blood safety. I can proudly state that PPTA has been an important member from the group's inception. So, too, are many other organizations such as the World Hemophilia Federation (WHF) and the International Patient Organisation for Primary Immunodeficiencies (IPOPI). I remember that when IPOPI was admitted a few years ago, some criticized IPOPI because of its statement that patients need therapies made from all sources (compensated and non-compensated donors). Why would any individual criticize patients who receive safe and efficacious therapies made from voluntary compensated donors?

These statements from the WHO's report require close examination, *"...plasma-derived medicinal products for the treatment of haemophilia and immune diseases are included in the WHO Model List of Essential Medicines and (the WHO is conscious) of the need to facilitate access to these products by developing countries"*

"The WHO is concerned by the unequal access globally to blood products, particularly plasma-derived medicinal products, which leaves many patients in need of transfusion and with severe congenital and acquired disorders without adequate treatment."

"Recognizing that the capacity to collect plasma is limited and would not suffice to produce enough essential medicines to cover global needs, it is essential that all countries have local capacity to collect plasma of acceptable quality and safety from voluntary and unpaid donations in order to meet their needs."

WHO should be commended for taking steps to improve the world's blood safety but it also should:

- Accept that labile and stable products are different and not be part of one Guideline;
- Accept that finished products made in countries with strict regulatory oversight are safe, irrespective of the donor remuneration status;
- Accept that there is no difference in the finished therapies made from voluntary paid and voluntary unpaid donors;
- Understand that self-sufficiency programs work well for National Blood Programs;
- Accept that self-sufficiency programs do not work well for finished products; and

Accept that the recognition and handling of individuals who donate is very important both for blood AND plasma donors.

PPTA is ready to assist wherever we can and will continue as a constructive member of the WHO's Global Collaboration for Blood Safety.