

Dr Margaret Chan
Director-General
World Health Organization
Avenue Appia 20
1211 Geneva 27
Switzerland

Friday, June 18, 2010

Dear Dr. Chan,

On behalf of the World Federation of Hemophilia, we would like to send our congratulations on the adoption of Resolution EB126.R14, Availability, safety and quality of blood products, by the World Health Assembly last month. The WFH supports this resolution and applauds the WHO's efforts to improve blood safety and increase the capacity for blood collection around the world.

While the WFH supports the general principles laid out in this resolution, we do have concerns regarding some statements included in the resolution regarding paid donations which have a significant effect on the ongoing supply of plasma-derived clotting factor concentrates and other plasma-derived medicines.

The WFH submitted a statement to the WHA and was granted permission to address the Assembly. However, due to agenda items being suspended or postponed, we were unable to make the WFH's views known to the Assembly. We regret that we did not have the opportunity to express our support of Resolution EB126.R14 and voice our concerns.

Enclosed is the WFH's statement that would have been presented to the WHA. We ask that you take note of these concerns during the implementation of the resolution.

This resolution is a great advance for improving the availability and safety of blood products, and we would welcome the opportunity to partner with the WHO and other affected organizations in the implementation process whilst recognizing our concerns.

Sincerely,



Mark W. Skinner
WFH President



Alison Street, MD
WFH Vice-President Medical

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Statement of the World Federation of Hemophilia (WFH) to the 63rd World Health Assembly concerning Resolution EB126.R14, Availability, safety and quality of blood products

The WFH supports Resolution EB126.R14. We welcome the call to member states to accelerate development of national blood collection programmes. Self-sufficiency in safe labile components is a worthy goal. We are well aware of the risks from blood-borne pathogens. In the 1970s and 80s thousands in our community were infected with HBV, HCV and HIV through blood products. In many countries, our members continue to be infected by blood-borne pathogens through the transfusion of labile components.

We are pleased the Resolution acknowledges that plasma derivatives for the treatment of hemophilia and immune deficiencies are included in the WHO List of Essential Medicines, recognizing that access to these life-saving therapies is unequal across the globe. We estimate that 75% of people with hemophilia have little or no access to clotting factor concentrates. They live with pain and disability; life expectancy is short. Consequently, we welcome the call to increase the supply of recovered plasma.

We fear, however, that readers may incorrectly conclude that increased collection of recovered plasma from voluntary donations is a panacea. Even if this worthy goal is pursued successfully, the supply of plasma for manufacture into plasma derivatives will fall far short of global needs.

In 2007, the world produced 26.5 million liters of plasma for fractionation. Of this amount, 17.9 million liters, 70%, was source plasma collected from voluntary remunerated donors in just a few countries. Only 8.6 million liters was recovered plasma. Plasma derivatives made from source plasma are essential if we are to meet patient needs. Without these products, thousands will die.

This is not a safety issue. Today's plasma derivatives, produced in a well-regulated environment, are among the safest medicines in the world. Globally, no case of infection by HBV, HCV or HIV has been identified with these products in the last 20 years.

The report of the 2009 WHO "Global Consultation on 100% Voluntary Non-Remunerated Donation of Blood and Blood Components (VNRBD) recognized the on-going importance of VNRBD for plasma for fractionation." The report also noted challenges relating to non-remunerated donors as a source of plasma for fractionation and included recognition that "...access to supply of blood products is critical for the health and well-being of many people and ... that supply must take priority over considerations of the source of donor plasma ... Any move towards 100% VNRBD in this area must be considered inspirational and would likely take many years."

Self-sufficiency is an unrealistic goal for plasma derivatives. Only a few countries produce enough plasma to meet the needs of their citizens. Moreover, no country manufactures every type of plasma product. Many bleeding disorders are so rare that there are only one or two manufacturers of the needed treatment. To require self-sufficiency is economic folly. We will always be inter-dependent.

While we support the aims of the Resolution, we urge you not to take steps that would limit access to therapies manufactured from remunerated plasma. Whether from remunerated or non-remunerated donors, from source or recovered plasma, these plasma derivatives are equally safe, equally essential and equally life-saving. In conclusion, the WFH pledges its support in improving blood safety and increasing access to essential medicines as called for in this Resolution.