WFH/WFH USA HUMANITARIAN AID POLICY

This policy is intended to regulate the WFH/ WFH USA Humanitarian Aid Program by providing guidance to donors on the criteria of accepted donations, methods of channelling their donated products, criteria of institutions/organizations receiving the donations, methods of control, and reporting on the use of these donations.

With this policy, WFH and WFH USA hope that it can provide donors assurance on the optimal use of their valuable donations and may encourage them to increase their program support.

Established in 1996, the Humanitarian Aid Program of the World Federation of Hemophilia (WFH) channels the world’s largest supply of donated clotting factor concentrates (CFCs) to people with bleeding disorders. Donated products are used in emergency cases for patients with life-threatening bleeds or who are undergoing surgery where there is limited or no access to treatment.

WFH parties¹ distribute treatment products to support ongoing development programs. For many developing countries, product donations are often the only source of treatment products for patients with hemophilia and other bleeding disorders. Although WFH parties have many other programs to promote and develop a sustainable foundation for the care of bleeding disorders, clotting factor products are life-saving and an important part of hemophilia care.

These donations also help WFH parties and WFH national member organizations (NMOs) to demonstrate to governments the benefits of CFCs and the benefits of purchasing these products on an ongoing basis.

WFH parties do not and will not promote any specific product or act as representatives, agents or intermediaries for any product supplier.

¹ The term ‘WFH parties’ represents both the World Federation of Hemophilia and its U.S.-based affiliated entity WFH-USA, a 501© not-for-profit organization. Its use throughout this document is intended to facilitate reading.
WFH PARTIES’ CRITERIA FOR ACCEPTING DONATIONS

WFH parties actively approaches companies, countries and other sources and accept donations of both plasma-derived and recombinant treatment products. WFH parties also accept products from reputable sources, including: pharmaceutical companies, home-care providers, wholesalers, distributors, hospitals, blood banks and treatment centres.

1  
Donated products must be licensed by a competent regulatory authority, for example the European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA) or the national regulatory agencies in Australia, Austria, Canada, Germany, France, Italy, Japan, Korea, Spain, Switzerland and the United Kingdom.

2  
WFH parties accept donations of products made through contract fractionation agreements by manufacturers whose products are approved or supervised by one of the regulatory agencies listed above.

3  
WFH parties do not accept expired products but are willing to accept revalidated products tested by certified laboratories. Products must have a minimum shelf life of 6 months.

4  
WFH parties will not accept a product if it has been recalled, withdrawn or quarantined (unless released) but will accept products that have been relabelled.

5  
Donors should ensure that they are properly insured to assume responsibility for the quality control, stability, efficacy and safety of donated products; WFH parties assume no responsibility in this respect. Donors are also responsible for any intellectual property infringement claim regarding the products and for product compliance with applicable regulatory requirements.

CRITERIA FOR RECEIVING DONATED PRODUCTS FROM WFH PARTIES

Donation Recipients must sign an official agreement with WFH parties in which mutual responsibilities are outlined and described.

In addition to an official acknowledgement of receipt of donations, WFH parties require a detailed report on the distribution and utilization of donated products, to the extent allowed by a country’s privacy legislation (excluding patient identification). If a recipient country does not submit a distribution report on the use of the donated product, it automatically becomes disqualified from receiving future donations.
WFH parties will issue a summary report to the donor to provide information on the results and impact of the donation; WFH parties will not disclose any individual patient data or clinical details to the donor.

**METHODS OF CONTROL AND REPORTING ON THE USE OF DONATED PRODUCTS**

Donation Recipients are required to report to WFH parties adverse events noted as a result of people using donated products, immediately upon notification. Upon receipt of this information, WFH parties will then inform the product donor.

WFH parties may, at their discretion, conduct an audit to ensure Donation Recipients have complied with the above reporting and donation process.

**METHODS TO CHANNEL DONATED PRODUCTS TO WFH PARTIES**

1. WFH parties are informed of the donation of products

2. Products must be packed in accordance with international shipping regulations

3. WFH parties must receive the certificate of analysis and Note of Release from the FDA or other equivalent document from the EMA (where applicable)

4. Products are shipped to a pharmacy or a distribution centre assigned by WFH parties for distribution to recipient countries

**METHODS TO CHANNEL DONATED PRODUCTS TO RECIPIENT COUNTRIES**

1. Unless required by the manufacturer, donated products are not shipped cold-chain

2. Each box must be labelled “Humanitarian Aid”
A packing list or letter must be enclosed in each box providing the following product details: description of product and brand name, manufacturer, lot number, expiry date, number of units/vial, number of vials, total units of concentrate.

Products are shipped as a donation with no commercial value, and as such, cannot be insured.

It is extremely important to specify that the shipment has **no commercial value** and is a **humanitarian aid donation**.

**CONTACT INFORMATION**

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Product donations are made possible and sustained through the generosity of donors.

The WFH very much appreciates continued support for its Humanitarian Aid Program.

Please contact us if you have products or supplies available for donation.