

IPFA POSITION STATEMENT

'TOWARDS A SAFE, SECURE AND SUFFICIENT NATIONAL SUPPLY OF PLASMA PRODUCTS'

July 2009

EXECUTIVE SUMMARY

The international demand for medicinal products derived from human blood and plasma donations is expected to increase for the foreseeable future. The current supply of these products is increasingly dominated by a small number of large commercial corporations. IPFA believes that further consolidation in the industry will act against the long term interests of patients in both developing and developed countries and that their interests will be better served by increasing the global capacity for collection of recovered and apheresis plasma and product manufacture.

Therefore IPFA and its members will support those organisations and countries that have chosen to create a safe and secure supply of blood and plasma products based on the principles of 'not for profit' and the voluntary non remunerated blood donor and in so doing will continue to make a vital contribution to their national health care systems.

The important relationship between blood donors, IPFA members and the communities they serve has been developed over many decades and is underpinned by essential values, principles and benefits which include:-

- An essential implied contract with voluntary non remunerated blood and plasma donors
- The vital relationship between IPFA members and the communities they serve which must continue to be based on need rather than commercial opportunity
- Maintaining a diversity of options for product manufacture and supply
- A commitment to innovation and supply of orphan and low demand products
- Providing support and assistance to countries seeking to develop blood and plasma collection programmes for the benefit of their own communities
- Creating opportunities for cooperation within the international blood services community
- The ability to contribute to national and regional public health surveillance programmes through the collection of epidemiological data

IPFA PRINCIPLES AND VALUES

The International Plasma Fractionation Association (IPFA) is committed to the principles and values of organisations that exist primarily to convert the gift of blood and plasma from a nation's donors into life saving medicinal products for the treatment of patients in their communities. IPFA supports those organisations and countries who have chosen to create a safe and secure supply of blood and plasma products based on voluntary non remunerated blood donation and the not for profit business model.

The principles and values which unite IPFA's members are:

1. The Implied Contract with Voluntary Unpaid Donors:

Many countries seek to achieve a safe, secure and sufficient supply of blood and plasma products from the altruistic or benevolent act of blood and plasma donation from within their communities. This goal is best achieved through a partnership with and between blood donors and patients underpinned by a common belief that such an outcome should not be influenced by financial or commercial gain.

This unique relationship is an important part of public and social policy and must not be sacrificed in favour of practices designed for conventional commodities.

The application of the principle of the donors' gift for the benefit of the national or regional communities is uncompromisingly supported internationally by among others, the World Health Organisation (WHO) and the International Society of Blood Transfusion (ISBT) who advocate that these principles should continue to be promoted, celebrated and respected.

National blood collection systems are a strategic necessity in meeting the demand for blood components and plasma products. Such collection systems, based on the unpaid donor principle, avoid the "trade in blood" and the potential risks of importing established and emerging infectious diseases associated with other collection systems or from other geographical regions.

IPFA believes that the use of the "donor gift" to achieve a secure base of plasma products for a community should underpin the strategic long term supply of products for the treatment of life threatening conditions such as haemophilia, immune deficiencies and infectious diseases but should not exclude the provision of additional supplies from other sources where there is a need that can not be met by this route alone.

2. The Long Term Commitment of IPFA Members for the Benefit of Their Communities:

The donation of blood and plasma serves many different patient communities. Blood components such as red cells and platelets are a vital part of modern health care systems. Similarly the plasma recovered from blood donations is a vital raw material for the preparation of products to treat infectious diseases,

immune and bleeding disorders and trauma. IPFA member organisations ensure that the communities they serve (and from whom the plasma is donated) will have access to such products irrespective of international market trends in product availability or price. This unique arrangement contrasts with that of the international commercial sector where product availability is largely determined by price as in conventional commodity markets. Whilst the latter arrangement is wholly appropriate for organisations with an exclusively commercial relationship with the providers of raw material it provides neither security of supply nor a sustainable basis for the long term commitment and loyalty of blood donors on whom a wide range of patients depend.

3. Strategic Supply of Plasma Products

Modern healthcare programmes are increasingly reliant on a safe, sufficient and sustainable supply of blood components and plasma derivatives. Moreover, plasma products such as clotting factors and immunoglobulin are included in the WHO 'List of Essential Medicines'.

The collection and fractionation of plasma to meet global demand is serviced by two industry models; the "for profit" sector which predominantly sources raw material from paid plasma donors and the "not for profit" sector (IPFA members) which predominantly utilise national 'recovered' plasma separated from whole blood donations donated by volunteer unpaid donors. It is increasingly necessary to maintain a diversity of product supply particularly in light of the consolidation of the industry which is now dominated by a small number of commercial companies.

Further consolidation or reduction in the number of smaller nationally focussed 'not for profit' fractionators would further reinforce the oligopolistic position of the major 'for profit' companies. Such a situation has the potential to create insecurity in the supply of life-saving products especially in countries where prices are lower and health care budgets are limited. This oligopoly may also increase product prices for all health care providers.

Therefore whilst the commercial sector of the plasma product industry plays an important role in meeting the overall international demand for plasma products, IPFA members offer a supply model better placed to meet national and regional aspirations for a stable and secure product supply. These principles, which place the donor and patient at the core of their activities and ethical framework have evolved over many decades and should continue to form the basis for a stable and secure supply of blood and plasma products.

4. Innovation and Availability of Low Demand/Orphan Products

Examples drawn from some IPFA fractionators illustrate a track record of innovation in product development and process improvement which compares favourably with that of major commercial companies. For instance the development and implementation of nanofiltration by some IPFA members preceded its adoption by the wider industry.

Their product ranges can also be comprehensive providing products for the treatment of very rare diseases which may not be available from the wider industry.

Thus in addition to high demand products such as IVIgG, FVIII and albumin, IPFA members are also committed to the supply of essential but low demand products such as immunoglobulin products for specific infectious diseases and coagulation factors for rare deficiencies (Factor XI). Whilst the manufacture and supply of such products is not economically viable and therefore unavailable from commercial sources, they are often included in product portfolios of IPFA member organisations.

Such activities are consistent with the values of IPFA and its members in placing patient and community need before commercial opportunity.

5. Support for Developing Countries

IPFA member organisations have a long tradition of supporting and assisting developing countries to increase the supply of blood components and plasma derivatives. These activities, including the provision of contract manufacturing services remain central to the values of IPFA. Its members will continue to work closely with international organisations engaged in programmes to increase the availability of blood and plasma products worldwide.

6. Cooperation within the International Blood Services Community

Underpinning the national focus of IPFA member organisations is an active programme of cooperation to support the development and transfer of technology between members and also to countries who wish to develop their blood and plasma collection programmes and build a technical capability to fractionate plasma collected in their own communities. This important activity is possible because IPFA members do not seek to control or dominate international markets and are therefore free to provide expert assistance and technology. In so doing they contribute to an international effort to increase the global availability and diversity of supply of affordable plasma products in both developed and developing countries.

7. Contribution to Public Health Surveillance

The international spread of existing and emerging infectious diseases is a key global public health issue including the potential for transmission of infectious disease through blood transfusions.

The routine collection of epidemiological data on blood borne infectious diseases such as HIV, HBV and HCV from volunteer blood and plasma donor populations provides invaluable and representative public health data in those countries with developed national blood services. These unique data, often unavailable from other sources, play an important role in the development of national public health programmes.

The development of national/regional blood and plasma collection programmes based on volunteer unpaid donors is therefore vital to the understanding of the global epidemiology of key infectious diseases and to the development of strategies to control their spread internationally.

IPFA ACTIONS

IPFA and its members will take the following actions in support of the above principles and values.

1. Continue to advocate the goal of national and regional self sufficiency in blood and plasma products based on the principle of volunteer unpaid donations and encourage European and other international agencies to invest in programmes to meet this goal.
2. Establish partnerships with patient and donor organisations to improve national and regional security of blood and plasma product supply from volunteer unpaid blood donations.
3. Support the activities of recognised international organisations such as WHO and ISBT in promoting the value and importance of volunteer unpaid donors.
4. Provide support, advice and practical assistance to organisations seeking to develop blood and plasma collection programmes based on volunteer unpaid donors.
5. Provide assistance and support for the development of contract fractionation arrangements in those countries with established blood and plasma collection programmes.
6. In partnership with industry, patient and donor organisations, national blood services and regulatory authorities assist in the development of international and European regulations which recognise the important contribution of volunteer unpaid blood/plasma donation in achieving a sustainable and secure supply of blood and plasma products.
7. Cooperate with the wider plasma products industry in promoting effective regulation and scientific and technical advances throughout the industry.

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