The Dublin Consensus Statement 2012

"Optimised Supply of Plasma Derived Medicinal Products"

A discussion of the relevant issues and draft recommendations

It is accepted that the need for and supply of plasma proteins has increased consistently over the last decades. However, it is also accepted that most people who need plasma proteins recieve inadequate treatment or no treatment at all.

This statement is intended to provide strategic considerations for healthcare stakeholders to:

- Increase the availability of plasma proteins to meet the global need for these therapies
- provide policy makers with a basis for prioritising resources to ensure optimal patient benefits while ensuring donor safety
- propose approaches to consistently improve the treatment of people whose health depends on regular access to plasma proteins

Strategic Considerations

1. Plasma collection

    - Promote and support the wider adoption of quality systems for plasma collection (source and recovered).

    - The adequacy of plasma supply should be based on the identified clinical needs of patients

    - In countries and regions where PDMPs shortages exist, increase the availability of high quality plasma suitable for fractionation

    - Align strategies to meet the needs of all patients requiring whole blood, blood component or plasma product therapies.

    - Ensure that plasma collection is underpinned by the principles established in the Dublin Consensus (2011)

    - Ensure that the contribution of donors is highly valued and their welfare and safety is protected

    - Promote the recovery in developed countries of unused plasma proteins that are undersupplied around the world (e.g. Factor VIII)

- Implement measures to avoid the wastage of plasma recovered from whole blood.

- Maximise the benefit derived from whole blood donations through collaboration and strategies that avoid the discarding of recovered plasma of sufficient quality, thereby enabling fractionation into products for patients.

- Design national and regional strategies to optimise plasma collection to meet the needs of patients in their communities.

2. Regulation

- Support and encourage strategies and programmes to widen international expertise in the regulation of blood and plasma.

- Support convergence and harmonisation of international regulation of blood/plasma collection to help secure the supply of quality PDMPs.

- Support future regulatory developments that recognize and take account of potential implications on international product supply.

- Support the development of integrated risk management strategies to manage the inter relationship of risk tolerance and supply of blood, plasma and PDMPs

3. Access to manufacturing technology

- Facilitate access for developing countries to efficient, safe and proven manufacturing technologies for PDMPs through access to contract manufacturing and technology transfer.

4. Supply is a Safety Issue

- Recognise that plasma and PDMP supply is a basic healthcare need and a safety issue, mainly depending on accessibility and affordability for healthcare systems. An insufficient supply is a major safety risk to patients.

- Support the strengthening of healthcare systems to increase the accessibility and affordability of PDMPs

5. Patient Needs, Clinical Protocols and Optimisation of Indications

   - Promote national and/or regional programmes to improve systems for case finding (detection and diagnosis), assessment of patient needs and access to care and treatment.

   - Promote national treatment and optimal use protocols prepared in collaboration with clinical experts and patient organizations within the framework of national health systems that take into consideration international best practices.

6. Patient and Donor vigilance and Patient Outcomes

   - Promote the collection, sharing and benchmarking of data on serious adverse reactions from use of PDMPs and blood and plasma donation to help continuously improve patient and donor safety

   - Promote data collection on and shared assessment of patient outcomes

   - Achieve these goals by encouraging the rapid application of electronic tools in compliance with standards to protect personal information.

7. Contributions to Supply of PDMPs

   - Promote national and regional approaches to the development of solutions suitable for their differing healthcare environments

   - Recognise that both private and public sectors are needed to meet global demand for plasma derived products in line with the Dublin Consensus (2011).

8. Evidence for use of PDMP in Rare Diseases

   - Recognise that a pragmatic and practicable approach should be taken in evaluating the evidence base for the use of PDMPs in the treatment of rare disorders.

9. Cost, Healthcare Resources and Economic assessment

- Promote the principle that optimal treatment of patients with rare plasma related disorders requiring PDMPs should form a benchmark for funding.

- Ensure that economic assessments of PDMPs in the treatment of rare plasma related disorders use appropriate comparators and recognise the macro-economic and societal benefits associated with early diagnosis, adequate treatment levels and improved quality of life

- Reaffirm that in this context: “patients whose continued health is dependent on the use of blood components or PDMPs 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. Health authorities should ensure that robust mechanisms are in place to ensure that this happens”. (Dublin Consensus 2011)