Plasma Protein Therapeutics Association

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It is well accepted by all stakeholders that the plasma protein therapies currently on the market have the highest margin of safety ever. The starting material for the manufacture of these therapies is human plasma for fractionation, a raw material characterised by a safety tripod composed of

1. Site selection / donor selection
2. Testing (Serology, NAT), Inventory Hold (Source Plasma), Look back
3. Manufacturing steps with built-in virus inactivation/removal capacities

The marketing authorizations for plasma derived medicinal products are granted on the basis of their safety level.

Reporting of epidemiological data is always retrospective and at the time of the assessment of PMF annual updates the plasma collected during the reporting time frame has already been processed. A prospective analysis of epidemiological data is difficult and of limited value since the occurrence of positive donors is relatively rare.

Plasma derived medicinal products are of limited availability because of the scarcity of the starting material (human plasma) and many patients in need of these often life saving therapies remain untreated. It should thus be avoided that PMF epidemiological data reporting and analysis lead to a situation where collection centers and plasma for fractionation are considered unacceptable, while blood components from the same centers are still transfused.

There are many open questions in the context of the PMF epidemiological data reporting, mainly pertaining to the justification of measures based on the required data. PPTA strongly believes that with a viral marker standard in place an objective interpretation and assessment of data will become possible and will serve as a valuable quality control measure.

Another important issue is the data quality and integrity. How can correct and consistent data reporting be assured? There are situations where two or more fractionators receive plasma from the same center/organization and experience has shown that different organisations report differently for the same collection facility. Similar difficulties have been encountered between fractionators and regulators.

In order to avoid the discrepancies encountered and improve the system, PPTA would like to propose establishing a central Viral Marker reporting repository and a standard to enhance oversight and facilitate data evaluation. Furthermore, the requirement for reporting of “NAT only” positives should be adapted to accommodate situations where NAT testing is not performed.

In conclusion, PPTA understands that industry needs to assure all stakeholders of the safety margin of plasma derived medicinal products. This assurance can only be provided on the basis of scientific evidence and a common understanding. The establishment of scientifically based Viral Marker Alert Levels will allow for harmonized monitoring of the donor epidemiology.

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