



IPFA/PPTA Joint Communication

March 9th, 2021

**New position statement by CHMP regarding donor deferral criteria
for sexual behaviour helps assessment of PMFs**

The International Plasma and Fractionation Association and the Plasma Protein Therapeutics Association are pleased with the recent publication by the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) '[CHMP Position statement on quality and safety assessment for the Plasma Master File \(PMF\) certification with regard to donor deferral criteria for sexual risk behaviour](#),' as such a position was highly needed, especially regarding men-having-sex-with-men (MSM). It clarifies that the application of these nationally defined deferral periods will from now on also be considered when assessing appropriateness of locally collected plasma to be included in a PMF.

Until now, each European Member State (MS) and third-party country has adopted different acceptance criteria for MSM donors according to their respective national epidemiology studies. This diversity of donation requirements has led to confusion and the exclusion by some users of any plasma from MSM donors. The Associations welcome that the EMA and the European Commission now state that whatever the national decisions on donor acceptance criteria vis-à-vis MSM and other sexual risk behaviour can be recognised as bringing the same level of quality and safety to plasma for fractionation if sound risk assessments and mitigations measures for safety based on local epidemiology studies are in place.

We look forward to the effective implementation by all MS, leading to more regulatory harmonisation of the PMF assessments and the inspection processes. By accepting plasma collected from MSM, fractionators will benefit from more plasma available to manufacture plasma-derived medicinal products and to reduce unnecessary wastage of this valuable material from donors.

To further enhance the harmonisation based on scientific evidence and its positive effects of availability of plasma, IPFA and PPTA urge the EMA to continue reviewing their guidelines and regulations for other donor deferrals.