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THE IMPACT OF THE PLASMA MASTER FILE ON BLOOD AND PLASMA COLLECTION ORGANIZATIONS

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The Plasma Master File (PMF) is documentation on human plasma as starting material for manufacture of plasma-derived medicinal products, from donor to fractionation pool. It covers quality and safety aspects and is part of the CTD Module 3.2.S.2.3 of a European medicinal product application. The PMF is centrally evaluated by the EMEA since 2004, this on an annual basis.

The PMF requests detailed information on organizations and establishments used for blood/plasma collection, or in which testing of donation and plasma pools is carried out. Update of inspection and audit status as well as epidemiological data of the blood/plasma collection are also needed. All that information is complex and has placed collection organizations in front of new challenges, particularly for small blood collection centers which are primarily dedicated to collect blood for transfusion. Furthermore, the harmonization of regulatory requirements in the medicinal field is a challenge more for collection centers which are mainly regulated by national, not harmonized, authorities. The implementation of the European Blood Directive has only increased the gap between local requirements and global requirements.