



European Medicines Agency
Human Medicines Development and Evaluation

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Procedural Announcement

Temporary derogations to certain eligibility criteria for whole blood and blood components donors in the context of a risk of shortage caused by the Influenza A(H1N1) pandemic

European Commission Directive 2009/135/EC allows Member States confronted with a serious risk or actual shortage in the supply of blood and blood components directly due to the A(H1N1) Influenza pandemic, to apply temporary derogations to certain eligibility criteria for donors.

(<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:288:0007:0009:EN:PDF>).

The EMEA considers that implementation of the above mentioned directive does not require the submission of a variation to update the PMF, where only a confirmation of compliance with the selection/exclusion criteria for blood/plasma donors in Directive 2001/83/EC, Directive 2002/98, Directive 2004/33/EC and the requirements of the European Pharmacopoeia Monographs (see Guideline on the Scientific data requirements for a plasma master file PMF-EMEA/CHMP/BWP/3794/03 current version) is included in the PMF.

For any additional queries regarding PMF dossiers, please contact the Agency's PMF contact person.