B.V. Changes to a marketing authorisation resulting from other regulatory procedures

B.V.a) PMF/VAMF

B.V.a.1 Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure)	**Conditions to be fulfilled**	**Documentation to be supplied**	**Procedure type**
a) First-time inclusion of a new Plasma Master File affecting the properties of the finished product	1		**II**
b) First-time inclusion of a new Plasma Master File not affecting the properties of the finished product	1	**1, 2, 3, 4**	**IB**
c) Inclusion of an updated/amended Plasma Master File when changes affect the properties of the finished product	1	**1, 2, 3, 4**	**IB**
d) Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product	**1**	**1, 2, 3, 4**	~~**IA IN**~~ notification *
Conditions			
1. The updated or amended Plasma Master File has been granted a certificate of compliance with legislation of the Union in accordance with Annex I of Directive 2001/83/EC.			
Documentation			
1. Declaration that the PMF Certificate and Evaluation Report are fully applicable for the authorised product, PMF holder has provided the PMF Certificate, Evaluation report and PMF dossier to the MAH (where the MAH is different to the PMF holder), the PMF Certificate and Evaluation Report available e.g. at EMA replace the previous PMF documentation for this Marketing Authorisation.			
2. Reference to PMF Certificate and Evaluation Report, available at EMA.			
3. An expert statement outlining all the changes introduced with the certified PMF and evaluating their potential impact on the finished products including product specific risk assessments.			
4. The variation application form/ notification should clearly outline the "present" and "proposed" PMF EMEA Certificate (code number) in the MA dossier. When applicable, the variation application form/ notification should clearly list also all the other PMFs to which the medicinal product refers even if they are not the subject of the application.			

* Documentation shall be forwarded without delay to the concerned competent authorities, but inclusion in electronical sequence of product dossier is not required