Annex IV

Conditions to the marketing authorisation

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National Competent Authorities of Member States or Reference Member State(s), if applicable, shall ensure that the following conditions are fulfilled by the MAHs:

Conditions	Date
Each Marketing Authorisation Holder of adrenaline auto-injectors shall perform a PK/PD study to understand the influence of different factors on distribution, exposure and activity of adrenaline when administered via their adrenaline auto-injector device. The protocol shall be submitted to the National Competent Authorities: The final study report shall be submitted to the National Competent Authorities:	 Within 6 months of the Commission Decision for this procedure Within 20 months of the Commission Decision for this procedure
The Marketing Authorisation Holders of adrenaline auto-injectors shall submit to the National Competent Authorities a Risk Management Plan containing key elements as described in the CHMP assessment report (including educational materials). The educational materials should ensure that healthcare professionals and patients/carers are able to successfully administer the product based on the instructions in the product information.	Within 6 months of the Commission Decision for this procedure