

Annex IV

Conditions to the marketing authorisations

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National Competent Authorities of Member States or reference Member States, if applicable, shall ensure that the following conditions are fulfilled by the MAHs:

Conditions	Date
<p><i>For 0.01% w/w estradiol containing medicinal products for topical use</i></p> <p>The maximum duration of a treatment course with 0.01% w/w estradiol containing medicinal products for topical use is limited to 4 weeks (not repeated use). Therefore pack sizes of 100g should be withdrawn from all EU member states where they are currently authorised.</p>	<p>Within 3 months of Commission Decision</p>
<p><i>For 0.01% w/w estradiol containing medicinal products for topical use</i></p> <p>As the maximum duration of a treatment course with 0.01% w/w estradiol containing medicinal products for topical use is limited to 4 weeks (not repeated use), the MAHs should provide a detailed plan including precise short timelines on the adaptation of the lower pack size (25g) and the withdrawal of the 35g and 50g pack sizes, in all EU member states where they are currently authorised.</p>	<p>Within 3 months of Commission Decision,</p>