Annex IV

Conditions to the marketing authorisation(s)

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Conditions ***Ulipristal acetate 5mg medicinal products***	**Date**
The MAH(s) should operate a risk management system described in a revised Risk Management Plan reflecting the revised indication for ulipristal acetate 5mg which shall be submitted to the National Competent Authorities for assessment. In addition, the MAHs shall amend the existing educational material (physician's guide to prescribing and patient alert card) to include the following additional key elements (new text **bold underlined**, deleted text ~~strikethrough~~): <u>Physician's guide to prescribing</u> • **<u>treating physicians should evaluate together with the patient using evidence-based medicine the risks and benefits of all available treatments to allow patients to take an informed decision.</u>** • **<u>during the post-marketing experience, cases of hepatic failure have been reported. In a small number of these cases, liver transplantation was required. The frequency of hepatic failure and patient risk factors are unknown.</u>** • […] • The indication~~s~~ • […] <u>Patient alert card</u> • inform the patients about ~~potential adverse reactions related to liver that could be caused by the use of [Product Name]~~ the risk of liver injury with use of [Product Name]. Explain and clarify that in a small number of cases liver transplantation was necessary. • […]	Within 3 months after Commission Decision.