Annex IV

Conditions to the marketing authorisation(s)

The marketing authorisation holder(s) for oral retinoids acitretin, alitretinoin and isotretinoin shall complete the below conditions, within the stated timeframe, and competent authorities shall ensure that the following is fulfilled:

A visual reminder on the outer package to warn patients about the harm to unborn baby and the need for effective contraception when using the medicinal product should be implemented in all medicinal products-containing oral retinoids acitretin, alitretinoin and isotretinoin. The details of the visual reminder should be agreed at national level further to a user test taking into account input from local patient representatives.	Within 3 months after Commission Decision
The MAHs of oral retinoids containing acitretin, alitretinoin or isotretinoin shall develop and submit educational materials according to the agreed key elements. These materials should ensure that prescribers are informed and the patients understand and acknowledge the risks associated with oral retinoids acitretin, alitretinoin and isotretinoin in-utero exposure. These should be submitted to the National Competent Authorities:	Within 1 month of Commission Decision.
In order to assess the effectiveness of the updated risk minimisation measures in women of childbearing potential resulting from this referral procedure, MAH(s) of oral retinoids acitretin, alitretinoin and isotretinoin should conduct and submit the results of a drug utilisation study (DUS). The study design should aim to evaluate and quantify the effectiveness of the Risk Management Measures, and should include a pre- and post-implemented analysis and assessment. The clinical study report should be submitted to the relevant National Competent Authorities:	Within 48 months after Commission Decision