ANNEX

CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES

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The Member States should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented.

The MAH shall provide physicians prior to launch with an educational material that will include the following components of information:

- Need and clinical importance of adverse drug reaction (ADR) reporting in general.
- Background data on erythropoietin antibody-mediated pure red cell aplasia (AEAB-mediated PRCA) associated with erythropoiesis stimulating agents (ESA) treatment.
- List of diagnoses or adverse events (AE) terms that trigger ADR reporting for MIRCERA .
- A questionnaire to gather detailed ADR report documentation.
- The MAH's offer of testing or re-testing antibody (AB) status in a reference laboratory.
- Literature to provide information on loss of effect and its differential causes, the definition of AEAB-mediated PRCA, the diagnostic work-up of potential AEAB-mediated PRCA, the need of discontinuation of ESA treatment due to cross-reactivity with other ESAs on diagnosis of AEAB-mediated PRCA..