

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 shall ensure that prior to launch the MAH provides health care professionals in dialysis centres and retail pharmacies with:

- Educational leaflet
- Summary of product characteristics (SPC) and Package Leaflet and Labelling

The educational leaflet shall contain the following key elements:

- That the use of epoetin alfa products can cause immunogenicity which in rare cases may lead to Pure Red Cell Aplasia (PRCA)
- That with other epoetin products, the risk of immunogenicity in Chronic Kidney Disease (CKD) is increased with the subcutaneous (sc) route.
- There is insufficient data on Abseamed to know the size of any increased immunogenicity risk with sc use
- Therefore, the sc route is not recommended for patients with CKD
- The loss of efficacy or other symptoms of the development of immunogenicity should be investigated
- Any suspected case of Pure Red Cell Aplasia or development of immunogenicity should be reported to the MAH