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 must ensure that all conditions with regard to the safe and effective use of the medicinal product described below are implemented.

Prior to the launch in each Member State, the Marketing Authorisation Holder shall agree with the National Competent Authority the format and content of the Physician Educational Materials and must implement such programme nationally to ensure that, prior to prescribing, all physicians are provided with a healthcare information pack containing:

- educational material
- Summary of Product Characteristics (in full)
- The Patient Information Leaflet

Key elements to be included in the educational material:

- Detailed information about the risk of haematological disorders (notably anaemia) associated with Victrelis, consisting of factual description of the haematological disorders in terms of frequency and time to onset and related clinical symptoms.