

ANNEX

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

Medicinal product no longer authorised

Conditions or restrictions with regard to the safe and effective use of the medicinal product to be implemented by the member states

The Member States shall agree the details of a restricted access programme and a disease registry with the MAH. They shall ensure that Glybera is only supplied if the healthcare professionals involved in the treatment of a patient have received the educational pack and if the prescriber confirms that the patient agrees to participate in the registry.

Medicinal product no longer authorised