ANNEX RELATED TO THE ART. 127A

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

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 (MS) should ensure that all conditions or restrictions with regards to the safe and effective use of SPRAVATO, as described below, are implemented.

Prior to its launch in each MS, the Marketing Authorisation Holder (MAH) must agree with the National Competent Authority (NCA) all aspects of the controlled access programme (CAP) for SPRAVATO, implemented to prevent/minimise the important identified risk of drug abuse.

SPRAVATO is intended to be self-administered by the patient under direct Healthcare Professional (HCP) supervision and should be dispensed to the healthcare settings where administration takes place, as agreed at the MS level, based on local legal requirements and/or local healthcare systems. When the administration is intended for outpatients, it should only be reserved to an environment where the patient is appropriately followed-up.

SPRAVATO may induce transient sedation, dissociative and perception disorders and/or increase blood pressure. Patients must, therefore, be monitored by an HCP during and after each treatment session, including an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting. In patients with clinically significant or unstable cardiovascular or respiratory conditions, SPRAVATO should be administered in a setting where appropriate resuscitation equipment and healthcare professionals with training in cardiopulmonary resuscitation are available.