

Medicinal product no longer authorised

ANNEX

**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 ADDRESSED TO THE MEMBER STATES

➤ The Member States must ensure that the education plans for health care professionals and patients contain the measures to minimise the risks as detailed below,

- An educational plan for physicians and health care providers, which is aimed at risk minimisation and to support safe and effective use for the product. This plan should address the following:
 - Overdose/ underdose
 - Accidental exposure
 - Misuse/abuse/diversion
 - Mechanical failures
 - Use in patients with a history of drug abuse
 - Disposal according with the local legal requirements
- An educational plan for patients, which is aimed at risk minimisation and to support safe and effective use for the product. Training for the patients will be via a healthcare professional. This plan should address the following:
 - Overdose/ underdose
 - Accidental exposure
 - Misuse/abuse/diversion
 - Mechanical failures
 - Disposal according with the local legal requirements

Medicinal product no longer authorised