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 Marketing Authorisation Holder will provide healthcare professionals with educational materials for healthcare professionals and patients. The educational materials are aimed at risk minimisation and will support safe and effective use of the product by the patient.

Educational material shall consist of information aiming to minimise adverse events and support effective use through adequate education about:

a) The need for consistent and standard inhalation technique to ensure both optimal and consistent product delivery
b) Special precaution with the insulin inhaler
c) Hypoglycemia
d) 1 mg and 3 mg dose inequivalence
e) Magnitude of titration steps and resulting precautions
f) The change in pulmonary function and the need for pulmonary function monitoring
g) Smoking in relation to induced alteration in pharmacokinetics
h) Rare pulmonary events
i) Increased insulin antibody levels
j) Recommendation for special populations; underlying lung diseases such as asthma and COPD, congestive heart failure, pregnancy, children and adolescent