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 should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

That at launch all physicians who are expected to prescribe INCRELEX are provided with a "physician information pack" containing the following:

Product information
Physician information about INCRELEX (information card, dosing guide, and a dose calculator)
Patient information pack

The physician information about INCRELEX should contain the following key elements:

- To educate parents on the signs, symptoms and treatment of hypoglycaemia, including injection of glucagon.
- That patients should have examinations of the ears, nose and throat periodically and at the occurrence of clinical symptoms to rule out such potential complications or to initiate appropriate treatment.
- To perform a routine funduscopic examination prior to beginning treatment and periodically during treatment or at the occurrence of clinical symptoms.
- INCRELEX is contraindicated in the presence of active or suspected neoplasia, and therapy should be discontinued if evidence of neoplasia develops.
- Slipped capital femoral epiphysis and progression of scoliosis can occur in patients who experience rapid growth. These conditions should be monitored during INCRELEX treatment.
- To inform parents and patients that allergic reactions are possible and that if this occurs treatment should be interrupted and prompt medical attention should be sought.
- Immunogenicity sampling information.

The patient information about INCRELEX should contain the following information:

- That INCRELEX should be administered shortly before or after a meal or snack because it has insulin-like hypoglycaemic effects.
- The signs and symptoms of hypoglycaemia. Instructions on the treatment of hypoglycaemia. That parents and caregivers should always ensure that the child has a source of sugar. Instructions on the administration of glucagon should severe hypoglycaemia occur.
- INCRELEX should not be administered if the patient is unable to eat for any reason. The dose of INCRELEX should not be doubled to make up for one or more omitted doses.
- To avoid engaging in any high-risk activities (such as vigorous physical activity) within 2 - 3 hours after dosing, particularly at the initiation of INCRELEX treatment, until a well-tolerated dose of INCRELEX has been established.
- Instructions to change and rotate the site of injection for each injection to avoid the development of lipohypertrophy.
- Instructions to report the onset or worsening of snoring that may indicate an increase in growth of tonsils and/or adenoids following the beginning of treatment with INCRELEX.
- To report the onset of severe headache blurred vision and associated nausea and vomiting to their physician.
- To report any onset of a limp or complaint of hip or knee pain to their physician so it can be evaluated.

In addition there will be a dosing guide, and a dose calculator, for use by physician and patients to include information on the individualised dose escalation to minimise the risk of medication errors and hypoglycaemia.