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Press Office

Press release

European Medicines Agency recommends approval of first higher-strength insulin for treatment of patients with diabetes mellitus in the EU

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has made a recommendation to give marketing authorisation to insulin degludec, a new basal analogue insulin for the treatment of diabetes mellitus in adults. It is introduced in a pre-filled pen in two formulations – 100 units/ml and 200 units/ml.

This is the first insulin approved in Europe at a higher strength than the EU-wide standard of 100 units/ml, for many years the only strength of insulin available across the EU. It will be marketed under the trade name Tresiba.

The approval of a 200 units/ml insulin, allowing doses up to 160 units in a single injection, is expected to respond to the growing need for higher-dose insulin. Weight gain, less healthy diets and less physical activity often mean that patients may experience higher levels of insulin resistance and require insulin injections in higher doses to achieve glycaemic control. It is estimated that between 200,000 and 700,000 diabetes patients in the EU require insulin injections of over 80 units per injection to manage their blood-sugar levels. The maximum dose that can be given with a single injection of a 100 units/ml product is 80 units.

Addressing the risk of medication errors

During the evaluation of Tresiba, the CHMP considered ways to minimise the possible risk of medication errors associated with a 200 units/ml formulation, which could lead to over- or under-dosing. Patients and healthcare professionals as well as diabetes experts were extensively consulted during the process, especially on the design of the pre-filled pen, pack design, product information and educational material for patients and for healthcare providers.

The main risk-minimisation activities to reduce the risk of medication errors between the 100 units/ml and 200 units/ml strengths are that the 200 units/ml strength is only presented in a pre-filled pen, that both strengths are dialled-in units, that the pack design of the two strengths has been clearly

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differentiated and that an educational programme, including a Direct Healthcare Professional Communication, has been agreed.

There was consensus among patients, healthcare professionals, experts and the CHMP that the introduction of a new insulin strength is a significant change and will require careful preparation to introduce it safely on the market. The Agency will use its network of EU organisations representing patients and healthcare professionals to encourage national diabetes patient associations and learned societies to prepare their members for the market introduction of the new strength.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for a marketing authorisation for Tresiba is Novo Nordisk A.S.
3. More information on the Agency's work with patients' organisations and healthcare professionals' organisations is available on its website.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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