THE THERAPEUTIC AND ECONOMIC VALUE OF INSULIN GLARGINE AND INSULIN DETEMIR COMPARED WITH NPH INSULIN IN THE TREATMENT OF TYPE 1 AND TYPE 2 DIABETES MELLITUS

Background
Diabetes mellitus is a metabolic disorder characterised by chronically high blood sugar concentrations. Diabetes mellitus is divided into two major types, Type 1 and Type 2. However, the two types cannot be unambiguously classified as distinctly separate conditions. In Type 1 diabetes mellitus (T1DM), patients have total insulin deficiency. In Type 2 diabetes mellitus (T2DM), blood sugar elevation is due to the phenomenon that insulin produced by the pancreas does not have its full effect in the target tissues. In T2DM, patients’ insulin secretion is also disturbed to a variable degree. In those with T1DM, insulin therapy is replacement therapy, while those with T2DM use insulin therapy to complement lifestyle changes and oral medication. In Finland, an estimated 300,000 patients receive treatment for diabetes. About one in six has T1DM. There are also estimated to be more than 100,000 patients with undiagnosed T2DM.

This pilot assessment by Fimea compared the therapeutic and economic value of long-acting insulin analogues (insulin glargine and insulin detemir) with NPH insulin in patients with T1DM or T2DM. NPH insulins were first introduced more than 50 years ago, while the insulin analogues were launched in the early 2000s.

How do long-acting insulin analogues and NPH insulin differ in terms of the practical aspects of treatment?
Insulin analogues have a less pronounced peak effect and a longer duration of action than NPH insulins. They therefore produce a steadier and longer-lasting effect than NPH insulins. Insulin analogues are clear solutions that require no mixing, while NPH insulins must be thoroughly mixed prior to administration. Insulin glargine is injected once daily and insulin detemir either once or twice daily. With NPH insulin, the number of daily injections varies between one and three, possibly even more.

What are the potential health benefits of long-acting insulin analogues versus NPH insulin?
The research evidence used in the assessment is based on 26 studies. In the majority of these, the primary endpoint was glycated haemoglobin (HbA1c). The differences between insulin analogues and NPH insulin in terms of their effect on HbA1c were generally small, and interpretation of the results is difficult. The studies did not allow a reliable assessment of whether insulin analogues and NPH insulin differ in terms of their effects on overall mortality or the long-term complications of diabetes. No differences in quality of life or treatment satisfaction were reported in patients with T2DM; the results for T1DM were not consistent. No significant differences in these effects were found between the insulin analogues.
What are the potential health risks of long-acting insulin analogues versus NPH insulin?
Research evidence indicates that patients treated with insulin analogues may experience a lower rate of nocturnal hypoglycaemia compared with those using NPH insulin. Interpretation of the results is not clear with respect to either serious hypoglycaemia or to all hypoglycaemias. No differences were observed between the different insulin analogues in terms of the frequency of hypoglycaemia.

Is treatment with long-acting insulin analogues cost-effective compared to NPH insulin therapy?
The use of insulin analogues entails considerably higher medication costs than the use of NPH insulin. Based on reports by public-sector bodies, it appears that long-acting insulin analogues are not cost-effective compared with NPH insulin in the treatment of T1DM or T2DM. Their cost-effectiveness appears to be relatively better in the treatment of T1DM than T2DM.

What factors do patients find important in insulin therapy?
From the patients’ perspective, the most important aspects of insulin therapy are a satisfactory glucose balance, a reduction in diabetes comorbidities, few adverse effects, and low cost. The latter is related to the reimbursement system. Patients also find it important to be able to plan and carry out their insulin therapy on an individually tailored basis.

There is insufficient research evidence to establish any differences in the therapeutic effects of long-acting insulin analogues and NPH insulin, and this also applies to Finnish patients with diabetes
The available research evidence is insufficient to establish the actual therapeutic effects of long-acting insulin analogues compared with NPH insulin in patients with T1DM or T2DM. The studies are of a short duration and mainly focus on HbA1c, rather than the patients’ prognosis, the incidence of diabetes comorbidities or patients’ quality of life. In addition, the studies are not fully conclusive in terms of how likely it is that the effects observed could also be anticipated in Finnish patients with diabetes.

Patient summary background
This patient summary is based on an assessment by the Finnish Medicines Agency (Fimea) of the therapeutic and economic value of medicines. During the assessment, Fimea addresses the available clinical and health economics evidence. Healthcare professionals and those needing more detailed information on the matter are encouraged to read the full assessment report (The therapeutic and economic value of insulin glargine and insulin detemir compared with NPH insulin in the treatment of Type 1 and Type 2 diabetes mellitus.pdf, in Finnish).

Disclaimer
Assessments of the therapeutic and economic value of medicines are summaries of the health and economic effects of pharmacotherapy, compiled by experts. They do not replace a doctor’s or other healthcare professional’s own assessment and treatment decisions regarding the best possible treatment of an individual patient.

What is Fimea?
The Finnish Medicines Agency (Fimea) produces and compiles assessments on the therapeutic and economic value of medicines and coordinates the related collaboration. In Finland, medicines must have a marketing authorization granted by Fimea or the European Commission. To obtain a marketing authorisation, the efficacy, safety and adequate quality of the medicine must have been demonstrated. Demonstration of the therapeutic and economic value of a medicine is not a prerequisite for a marketing authorisation. Evidence on the effectiveness and therapeutic and economic value of a medicine is used to support decision-making concerning the use of medicines.