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Merck's formulation steps further for approval in 21 EU countries

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BfArM is acting as a representative of all 21 EU countries involved in the EU worksharing procedure



Singapore- Merck, a leading science and technology company, announced that the German Federal Institute for Drugs and Medical Devices has recommended to approve Merck's new formulation of Euthyrox (levothyroxine) in 21 EU countries. National approvals will be issued following this recommendation.

"The tighter specification of the active ingredient in the new formulation of Euthyrox aims to help patients have better control over their individual levothyroxine dosage," said Steven Hildemann, Global Chief Medical Officer at the Biopharma business of Merck. "Following the positive recommendation from BfArM, Merck will continue to collaborate closely with local Health Authorities, healthcare professionals and patient groups in preparation for the roll out of the new formulation in the 21 countries. Together with the respective stakeholders, and in full compliance with the local regulations, we aim to ensure that patients are appropriately informed. Therefore it is our first priority to support physicians and help them provide their patients with the best possible transition to the new formulation of Euthyrox ."

The German BfArM decision to recommend the approval of the new formulation of Euthyrox across 21 EU states was based on a study demonstrating bioequivalence between the old and new formulations.

Levothyroxine is a synthetically produced hormone that corresponds to the natural thyroid hormone Thyroxin (T4). It is used to treat hypothyroidism, goiter and to suppress TSH in the post-treatment of differentiated thyroid cancer.

The new formulation came at the request of several health authorities worldwide. It was introduced in France in March 2017 and Switzerland in April 2018. Turkish authorities have approved the new formulation and Merck expects to launch the medicine there in the course of 2018.

For thyroid drugs a small dosage variation might impact the patient's thyroid balance. Prescribing doctors are therefore encouraged to monitor patients closely when prescribing the new formulation and to adjust the individual dosage if medically required. Along with Health Authorities, Merck recommends that all patients do not switch or stop their treatment without medical advice and refer to their prescribing physician to potentially adjust the medication dose to their individual need during the transition phase.