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### **Eltroxin: Impact on Israeli thyroid patients with formula change by the company**

Dear Minister of Health of Israel,

Thyroid Federation International, an umbrella organization for thyroid patient associations all over the world, has been informed about the problem Israeli patients have encountered in the past months, due to a formula change in the only thyroid medication available in Israel, Eltroxin.

The changes to the excipients in Eltroxin, led to patients experiencing side effects, many of them severe. The fact that doctors and patients were not informed of the changes contributed to the problem and resulted in unnecessary waste and costs to the medical system.

Because of the situation in Israel at this moment, Thyroid Federation International urges you, in order to avoid further consequences for patients, to:

- ensure **correct information** concerning the drug change is provided immediately to all doctors and patients,
- recommend **blood tests** for all hypothyroid patients to check if their thyroxine levels are still correctly balanced,
- make available at short notice **alternative drugs** with other excipients.

### **Thyroid Disease in Israel**

As you undoubtedly know, an estimated 200,000 to 400,000 people in Israel have some form of thyroid disease. The physical symptoms of thyroid dysfunction are unpleasant and can affect self-esteem, quality of life, and prejudice the ability to work. Without medication hypothyroid patients suffer from symptoms such as:

- Fatigue, drowsiness and/or weakness
- Cold intolerance (not being able to tolerate the cold like those around you)
- Impaired memory
- Weight gain or increased difficulty losing weight (despite sensible diet and exercise)
- Depression
- Constipation
- Abnormal menstrual periods and/or fertility problems
- Joint or muscle pain
- Thin and brittle hair or fingernails and/or dry flaky skin

More worrying, if left untreated patients can have serious and potentially life-threatening complications, in particular, cardiovascular disease, recurrence of thyroid cancer, and complications in pregnancy.

The excipients in the only drug available for thyroid patients, Eltroxin, were changed without informing patients or doctors. This has caused major problems for many patients. An estimated 10% of these thyroid patients have experienced serious physical symptoms, leading to at least one visit to their doctor.

Because the doctors, as the patients, didn't know about the changes in the drug, they began looking for other causes, resulting in important costs for the Israeli economy: sick leaves, visits to the doctor, blood tests and other examinations.

An estimated 1% of the thyroid patients have experienced severe symptoms, leading to repeated visits to the doctor, problems at work, in traffic (increased risk of traffic accidents) and in family life. It is crucial that the appropriate medication be maintained for each patient, as even small changes in the amount of the active ingredient or in the excipients that influence the absorption of the drug in the gastrointestinal tract, can cause changes to health and alter the wellbeing/quality of life for the patient.<sup>1</sup>

**Therefore it is essential to patients and their doctors to be properly informed about any change in the medication.**

### **Similar Occurrences in Other Countries**

The circumstances of pharmaceutical companies making changes to thyroid medication without informing the public has occurred in other countries. In 2007 in New Zealand, the excipients in the only drug available for thyroid patients, Eltroxin (formerly owned by GlaxoSmithKline, now by Aspen), were changed without informing patients or doctors.<sup>2</sup> This caused major problems for many patients. GlaxoSmithKline expected no problems from changing the excipients, because these excipients are not known to cause allergic reactions. They hadn't considered the influence on the absorption of the drug in the gastrointestinal tract, and that Eltroxin is a drug with a "narrow therapeutic range", where even a small change can have big repercussions on the patient's well-being. GlaxoSmithKline promised to improve its policy in the future.

In 2009 in Denmark, again the excipients in the only drug available for thyroid patients, Eltroxin, were changed without informing patients or doctors.<sup>3</sup> Again this caused major problems for many patients. Again GlaxoSmithKline promised to improve distribution policy in the future. In both New Zealand and in Denmark, patients were reported to have allergic reactions to the new excipients.

Now in 2011 the same situation has occurred in Israel!

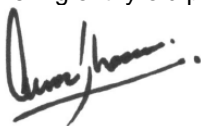
Because thyroid drugs have such a great influence on the wellbeing of patients, any changes to the drug should always be accompanied by at least one blood test to be sure that the patient is maintaining the right dose in combination with the correct absorption of the drug in the gastrointestinal tract.

**A test for blood values of all hypothyroid patients is recommended, so that the dose of the drug can be adjusted accordingly if necessary.**

Because of the lack of alternatives for Eltroxin, it is hard to correctly treat these patients. Additionally, patients may be allergic to the new excipients when drugs are changed. Therefore Thyroid Federation International is opposed to changes in thyroid drugs. If changes are absolutely necessary, alternatives should be made available.

**Because in New Zealand and in Denmark, patients were reported to be allergic for the new excipients, we ask you to make alternative drugs with other excipients available at short notice.**

As in all developed countries, patients in Israel expect their healthcare system to provide them with proper and reliable drugs. It is the responsibility of the government and drug companies to alert doctors and patients of any changes to their medication. We ask you to take action without delay to prevent further suffering of thyroid patients in Israel.



Ashok Bhaseen  
President



Beate Bartès  
Secretary

<sup>1</sup> [http://www.endo-society.org/advocacy/legislative/upload/Joint\\_Statement\\_Levothyroxine-Thyroxine.pdf](http://www.endo-society.org/advocacy/legislative/upload/Joint_Statement_Levothyroxine-Thyroxine.pdf)

<sup>2</sup> <http://www.health.govt.nz/news-media/media-releases/eltroxin>

<sup>3</sup> <http://laegemiddelstyrelsen.dk/en/topics/side-effects-and-trials/side-effects/news/side-effects-from-eltroxin---status-july-2010>

Thyroid Federation International aims to work for the benefit of those affected by thyroid disorders throughout the world.

The objectives of Thyroid Federation International are:

- To encourage and assist the formation of patient oriented thyroid organizations.
- To work closely with the medical professions to promote awareness and understanding of thyroid disorders and their complications.
- To provide, through member organizations, information and moral support to those affected by thyroid disorders.
- To promote education and research related to thyroid disorders.

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