Thyroid Hormones

Patient Statement 2017

The correct dosage has an enormous impact on the quality of life

- **Thyroid replacement hormones must be available in all – including small – dosages at all time**
- **The quality and stability of the medication must be guaranteed**
- **Transparent patient information is critical in case of formula changes**

SMALL DOSAGES ARE NEEDED !

Hypothyroidism is treated with LT4 (levothyroxine), in some cases associated with LT3 (liothyronine).
These drugs have a narrow therapeutic range: a few micrograms make a big difference for the patient in terms of morbidity and quality of life.

In many countries, only a small number of different dosages of LT4 and LT3 is available. This makes it extremely difficult, or not possible, to precisely adjust the dosage as recommended in medical guidelines 1.

Individual adjustment ("fine-tuning") requires that LT4 and LT3 are available in small dosages.

BRANDS ARE NOT INTERCHANGEABLE !

The formula of the thyroid replacement hormone has a tremendous influence on its absorption – different brands can also have a different bioavailability with variations up to 20%. When patients switch between brands, there is a need to re-check blood values and to re-adjust the dosage2. As a consequence, it can take several months before the patient is stabilized again and returns to his or her previous physical and psychological status and quality of life. This also increases the cost for the healthcare system, in terms of physician consultants and symptomatic treatments, as compared to the production costs for thyroid hormones and their cheap market prices.

In the last years, there have been shortages of levothyroxine in several countries. In some cases, companies left the market and patients had to switch to other brands. This has an enormous effect on the stability of the patient thyroid health and quality of life.

The availability of thyroid replacement hormones must be guaranteed at all times and in all dosages. Patients must have the possibility to always stay on their usual brand.

SAFETY AND STABILITY FIRST !

Thyroid hormones are among the most prescribed chronic medicines in the Western industrial countries. Patients are on thyroid hormone replacement for a lifetime.

In the past years, this has led to strong competition between manufacturers. This has been intensified by the pressure of national health authorities to make the prices even lower. As a consequence, less and less money is invested in the reliability and quality of the production process, leading to shortages and quality issues.

The national health authorities must look not only at the sale price of the thyroid replacement hormones, but also at the reliability and quality of the medication.

PATIENT INFORMATION IS CRITICAL !

Side effects resulting from changes in the formulation or switch in brands of levothyroxine impact the patients' quality of life. These side effects, even if they subside after dosage adjustment, can have important consequences in patients' lives – stress and anxiety, lack of sleep, palpitations, chronic pain, rashes, inability to work or perform daily activities.

Extensive patient information is the key: patients need to be informed that their formula will be changed, why it will change, and what side effects they might possibly expect; while reassuring them on the outcome of this transition period and informing them of the steps to take. During the transition period, communication between doctors, patients, and the manufacturer is of paramount importance.

The examples of formula changes in various countries and for various brands, over the past years, have shown that when patients were duly and extensively informed, no major problems were encountered during the transition period. In countries where patients had insufficient information or did not even know that their medicine had changed, the transition period led to inappropriate media coverage, rumors, fake information and even - as presently in France - a "protest movement" which eventually harms all parties involved – not only the patients, but also the regulatory authorities, manufacturing companies and health professionals.

Pharmaceutical companies, health authorities and health professionals must work together with patient organizations, as soon as a change in formulation is envisaged and throughout the development and marketing periods, so that all critical issues can be identified and addressed early enough.

Extensive, transparent complete information for doctors and patients must be prepared well in advance and adequate resources must be identified to support the transition and rapidly identify issues for positive patient outcomes.

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