PHARMACY GUILD OF NEW ZEALAND (INC)

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TO: All Guild Members

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Update on Eltroxin (levothyroxine) formulation change

- In response to the increase in adverse reaction reports received by CARM, Medsafe reassessed the new formulation and confirmed that all international criteria for quality, safety and bioequivalence were satisfactorily met.

- Medsafe has initiated further independent testing of the new formulation to assess whether the presence of contaminants, or the supply of a poor quality product could be a factor in the adverse reactions observed.

- Treatment of thyroid dysfunction is subject to significant inter patient variability.

- Medsafe advice is

    1. Check dosing and administration.

    (Swallowed whole with a full glass of water on an empty stomach preferably 30 minutes before breakfast, Doses requiring 25mcg increments should be administered on alternate days with 50mcg tablets)

    2. Monitor thyroid function

    (TSH levels are the best indicator. Due to long half life of levothyroxine tests should be performed no earlier than 4 – 6 weeks after any change in dose or formulation.).

    3. Report adverse reactions to CARM

    If possible include in the CARM report:

    - Pre- and post-formulation change thyroid function tests (and previous dosage stability generally)
    - Information on whether the patient has changed the timing of their dosage (i.e. did they take the previous formulation before or after food; and are they taking the new formulation before or after food?)
    - Confirmation the patient is not halving the tablet
    - When the patient was changed to the new formulation
    - Whether symptoms are seemingly hyper- or hypo-thyroidism
    - If any acute management was necessary

- Eltroxin is the only brand of levothyroxine tablets that has approval for distribution in New Zealand. Currently Medsafe does not have any applications for alternative brands of levothyroxine tablets from other pharmaceutical companies.

- Although Medsafe is working to encourage another brand of levothyroxine to be supplied in New Zealand, the decision to market in New Zealand is not within Medsafe's control.

- Any alternative brand of levothyroxine can only be supplied as an unapproved medicine. Unapproved medicines can be supplied under provisions in the Medicines Act (Section 25 & 29) that allows an authorised prescriber to request or obtain the medicine for a specific patient under their care.

- The use of unapproved medicines would not usually be advocated. This is a last resort measure for people who experience significant adverse effects with Eltroxin and are unable to tolerate it. Unapproved medicines should not be routinely used in other circumstances.

- Medsafe has not assessed other brands or formulations of levothyroxine for quality, safety or bioequivalence. Transfer to another brand should only be considered in patients:
    - With hypersensitivity or intolerance type reactions
    - Exhibiting hypothyroid type symptoms that have not responded to dose adjustment.

- Patients transferred to another brand of levothyroxine will require ongoing monitoring in the same way as the current GSK product.

Acknowledgement: This is a summary of key points from Best Practice Advocacy Centre Article. For the full article see
http://www.bpac.org.nz/magazine/2008/august/eltroxin.asp

We also acknowledge the help of Medsafe in the preparation of this information.