Petition PE01463

Petitioners letter to the Scottish Parliament Petitions Committee & response to the evidence given by Alex Neil, Cabinet Secretary for Health

26th June 2013

Dear Convener and committee members,

We would like to thank you for inviting the Cabinet Secretary for Health to give evidence on the liothyronine drug shortage at the petitions committee meeting on 25th June. We appreciated him taking time to do this in what we know to be a hugely busy diary. Sadly, however, we feel there was nothing new learned from Mr Neil's evidence and several areas where we question the accuracy of statements.

For example, Mr Neil states that the raw materials for liothyronine are expensive. We have no data to dispute that as yet, however, we seriously question how this can be the case when European countries can sell one hundred tablets for just over £1. The manufacturing process is not more expensive or complicated than for other generic medicines. We have been given to understand that manufacturers have to re-calibrate their whole mechanical set up for each new drug they make and so estimate the demand for a particular drug years in advance. It's possible as demand for liothyronine has grown, supply dried up quicker than was estimated. Equally possible is the merger of Mercury with Andipharm that took place in May was a reason for manufacturing delays. Whatever the true cause, shortages of this vital drug are not minor irritants to hypothyroid patients. From the psnc website - From a **patient** perspective, stock shortages can lead to delays in patient care and can result in increased visits to pharmacies to collect supplies of medicines when the full prescribed order is not initially available. Evidence from the US shows that stock shortages can also lead to increased adverse reactions, for example when alternatives are prescribed and can cause confusion and decreased compliance.

From the **NHS** perspective, shortages can also be very costly. As well as the increased costs of sourcing alternatives, the unavailability of a key medicine or decreasing a patient's compliance with their medication regimen can lead to the exacerbation of a patient's medical condition, increasing hospital admissions and treatment costs. http://www.psnc.org.uk/pages/ncso_supply_issues.html

The figures for prescriptions of Liothyronine in Scotland do not in any way reflect this drug as a niche drug for a minority of hypothyroid patients. GPs and labs routinely refuse to test a patient's T3 levels which would accurately show the need for this medication where they were not converting their T4 medication to the active T3.Patients are often refused Liothyronine on cost grounds and claims that it is unsafe and the numbers do not reflect the true demand for this medicine.

It's worth pointing out that the information on the shortage was brought to the attention of the MHRA by patients and not the manufacturer. Patients had been experiencing problems obtaining Liothyronine from the end of April. The MHRA finally put a notification of the shortage on their website on 22nd May. When supply was resumed on the 30th May, it then appeared as though the duration of the problem was a mere 8 days – quite inaccurate. Mercury-Andipharm also gave patients contradictory dates for when supply would be restarted, varying from 'we don't know' to 'late June'.

With regard the 'clear guidance' the MHRA provides clinicians on unlicensed drugs, it must be stated that the reality is this says nothing of use other than prescribe these at your own risk, a risk not embraced by the majority of GP's, understandably. As it's genuinely the Health Secretary's intention to get to the bottom of the petitioners concerns, we believe there must be less reiteration of the status quo and more probing of why protocols are failing patients. The MHRA are currently investigating the efficacy of certain batches of Mercury Liothyronine as there have been numerous Yellow Card warnings filed. Many patients, including petitioner Sandra Whyte, have reported better results with their privately purchased Mexican Liothyronine.

Thyroid patients are getting a very raw deal with not only the delayed diagnosis but also the availability and efficacy of medications. One of the other petitioners, Lorraine Cleaver, was prescribed Liothyronine and Eltroxin (T4) by her endocrinologist as she was unhappy at having to source her Desiccated thyroid online from the USA. The Liothyronine was not available in the strength prescribed, this had to be changed to a higher dose by the GP and this was unavailable too. After a further week, seventeen tablets were found, literally in the back of a drawer at the pharmacy which were almost out of date. The brand of T4 medication prescribed, Eltroxin, was also unavailable and Mercury can still give no date as to when it will be available. The justification of expensive raw materials and manufacturing of this simply does not apply here either. Seven weeks down the line and Lorraine can still not obtain the endocrinologists' prescribed medications. Simply advising an alternative drug does not work. T4 is not a viable alternative to T3 if there is a conversion problem, something that seems to be misunderstood by pharmacists .

Finally, the day after Alex Neil gave this evidence to the committee, the British Medical Association voted to make non publication of trial results research misconduct. This is an issue we feel strongly relates to why thyroid patients are being left ill and under medicated. We have referenced it before to the committee with regard to the Scottish Governments intention to re-examine the published evidence. The published evidence only ever tells half of the story if approximately half of all trials, usually the unflattering results, are not published. http://www.alltrials.net/2013/bma-votes-that-non-publication-of-trials-results-is-research-misconduct/

It is for these reasons we welcome the Round Table meeting and attendance of the Minister for Public Health, Michael Matheson.