Medicines and Healthcare Products Regulatory Agency

Andrew Howlett
Assistant Clerk to the Public Petitions Committee
T3.40
Scottish Parliament
Edinburgh
EN99 1SP

151 Buckingham Palace Road
Victoria
London SW1W 9SZ
United Kingdom

Telephone
+44 (0)20 3080 6100
Email
Chief.Executive@mhra.gsi.gov.uk
www.mhra.gov.uk

By post and email

5 August 2013

Your Ref: PE1463
Our Ref: 13249

Dear Mr Howlett,

Consideration of Petition PE1463

Thank you for your enquiry regarding the supply of the thyroid medicine Liothyronine licensed for use in the UK.

Medicine supply problems can occur for a number of reasons, such as manufacturing and stability problems, difficulties in obtaining raw materials or regulatory issues.
Unfortunately, the main difficulties of Liothyronine 20mcg tablets are due to the fact that it is a relatively unstable medicinal product, difficult to manufacture and with limited sources of active substances.

With regards to the recent interruption to supply I understand that the sole UK licensed holder responsible for the manufacture and distribution of this medicine (Amdipharm Mercury Company Ltd. formerly known as Mercury Pharma) experienced problems obtaining the active substance and, as a consequence, was unable to maintain supply of the product. I fully appreciate the difficulties and concerns that this has caused to patients.

The Medicines and Healthcare Products Regulatory Agency (MHRA) always works very closely with companies to ensure that the supply of a medicine returns to normal as quickly as possible in the event that there has been an interruption to that supply.

In the case of Liothyronine, in the interim, supplies of unlicensed alternatives to this medicine were imported from abroad to avoid shortage in the UK. The MHRA wrote to healthcare professionals on 21 May 2013 to explain the situation and to provide clinical advice on the use of imported alternatives. A communication was also published on the MHRA's website and is available at the link below.

http://www.mhra.gov.uk/NewsCentre/Whatsnew/CON279168

The responsibility for maintaining supply of medicines in the UK lies with the Marketing Authorisation Holder, in this case Amdipharm Mercury Company Ltd. However, I would like to reassure you that MHRA and the Department of Health have well established procedures for dealing with such matters and officials work closely with the pharmaceutical industry, the NHS and others operating in the supply chain to help prevent shortages and to ensure that the risks to patients are minimised when they do occur.

I am aware that in the interests of security of supply it would be beneficial to have more than one source of licensed Liothyronine in the UK. However, the MHRA is the agency responsible for licensing medicines in the UK and as such, is not in a position to hold or solicit for new product licences themselves. As a result, the only way that a Liothyronine product not currently licensed in the UK could obtain a licence would be for an application to be made to the MHRA.

Yours faithfully,

Professor Sir Kent Woods
Chief Executive