REPLY BY THE MINISTER OF THE HEALTH AND SOCIAL SERVICES DEPARTMENT TO A QUESTION PURSUANT TO RULE 6 OF THE RULES OF PROCEDURE TO BE ASKED BY DEPUTY LAURIE QUERIPEL AND DEPUTY BARRY PAINT

Question 1

Could the Minister confirm that during the course of their investigations into the manufacturing of products by First Immune, as used by Guernsey residents, the MHRA, as claimed by First Immune, actually inspected the wrong laboratory which in fact was still under construction?

Answer 1

We have been informed that Investigators from MHRA carried out unannounced inspections of production sites in Cambridgeshire, after the medicines regulator in Guernsey raised concerns in relation to the product.

The inspection of these sites in the UK is within the jurisdiction of the MHRA and not of the States of Guernsey. This means that this question is for the MHRA to respond to and not the HSSD.

Question 2

Could the Minister explain why a blanket ban on the import into Guernsey of Goleic, a fully certified and approved food supplement which complies with EU regulations and is distinct from GcMAF, has been imposed?

Answer 2

On 2 February 2015, the MHRA notified the medicines regulator in Guernsey of their concerns that the products identified in the course of their inspections of facilities in Cambridgeshire were not suitable for human use.

In these circumstances, as would be the case for any licensed medicine or other unlicensed medicine that was identified as presenting a risk to public health due to its manufacturing standards and products, it was incumbent on the medicines regulator in Guernsey to take immediate and stringent action to protect Guernsey residents from this public health risk. The action taken by HSSD relates to the decision to no longer issue import licences for GcMAF products.

The information we have indicates that Goleic contains GcMAF, and it is therefore subject to the same import controls in Guernsey for the same public health reasons.

Question 3

Does the Minister understand and accept that Goleic is a product distinct from GcMAF?

Answer 3

The information we have indicates that Goleic contains GcMAF and it is therefore subject to the same import controls in Guernsey for the same public health reasons.

Question 4

Does the Minister accept that other First Immune laboratories in the UK and Europe do meet with the required manufacturing regulations?

Answer 4

The regulation of the laboratories in the UK and other countries in Europe that manufacture medicines is a matter within the jurisdiction of the MHRA and the competent authorities in the relevant country, and not for the HSSD to comment on.

Question 5

If the Minister does not accept other First Immune laboratories in the UK and Europe meet with the required manufacturing regulations what evidence has been supplied to him to support and justify his view and by whom?

Answer 5

The regulation of the laboratories in the UK that manufacture medicines is a matter within the jurisdiction of the MHRA and not the HSSD and is a matter for the relevant UK authorities to comment on.

If an import licence is sought for a GcMAF product which is claimed to be manufactured in the UK or another EU country, and the supplier of the product identifies to HSSD the manufacturing facility that produces the product, HSSD will endeavour to get into contact with the relevant regulatory authority in that country and verify whether that facility is in fact supplying that product, whether that facility meets the standards of Good Manufacturing Practice, and whether there are any other concerns relating to the safety of the product and public health.

Question 6

Would the Minister be prepared to advise the Home Department and the Guernsey Border Agency that Goleic is a registered food supplement which is distinct from GcMAF and as such request that the blanket import ban of this product into Guernsey be lifted or are islanders to be denied to access this product via importation permanently regardless of this distinction?

Answer 6

The classification or registration of any item as a food supplement in any other country or territory does not mean that it is not a medicinal product within the definition given by section 133(1) of the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law 2008.

The information we have indicates that Goleic contains GcMAF and it is therefore subject to the same import controls in Guernsey for the same public health reasons.

Question 7

Immuno Biotech claim that HSSD have not, as yet, informed them of this import ban, if that is the case, will the Department be providing the company with a notification and details of this ban?

Answer 7

The import "ban" is in fact a general policy decision taken by the Home Department's delegate on the advice of HSSD to no longer issue import licences relating to GcMAF imported for personal use, and to revoke any such licences that have been issued. These licenses are issued to individuals and not to Immuno Biotech Ltd. We understand that the Guernsey Border Agency has written to the individuals who have previously sought or obtained import licences notifying them of the decision to refuse or revoke an import licence and giving explanation of the reasons for doing so.

HSSD has met with representative of Immunio Biotech, at their request, to explain the current policy of not issuing import licences for GcMAF products on public health grounds.

Deputy Paul Luxon,
Minister
Health & Social Services Department

Date of Receipt of the Question: 11 February 2015

Date of Reply: 24 February 2015