2013/07

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

Preamble

Further to our earlier exchange of correspondence on the matter, I would like to again raise with HSSD, via Rule 6 of the Rules of Procedure, the issue of GcMAF. This cancer and immunity disorder treatment was the subject of much attention and some acclaim at the recent Baden Baden medical conference. It is a treatment that is growing in popularity across Europe. Immuno Biotech Ltd, the company behind GcMAF currently has its banking and administration activities based here on-island but the operational aspect is based elsewhere. I realise that certain restrictions render the company unable to base their operations here.

Question 1

However, considering the increasing use and apparent effectiveness of GcMAF, would HSSD review Guernsey's current position and ascertain whether in fact, Immuno Biotech Ltd *could be based entirely on-island?*

Answer

GcMAF is in the opinion of HSSD and the Medicines and Healthcare products Regulatory Agency (UK) (MHRA) is a medicinal product. This means GcMAF is a product regulated under the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008 (the Medicines Law).

In order for a medicinal product to be placed on the market, it must have the following:

a. Be registered with the MHRA UK as a medicinal product and has been issued with a marketing authorisation by them. (Part II, Section 7, subsection 2)

b. The manufacture is in a plant approved by the MHRA, complying with the provisions of a marketing authorisation granted under paragraph 7, 2 of the Medicines Law.

or

c. Be registered as an investigational medicinal product for the purpose of conducting a clinical trial (Part II, paragraph 7, subsection 5).

The Company would then have to follow the required process to obtain a marketing authorisation by submitting sufficient evidence to satisfy the MHRA of the safety and efficacy of GcMAF. If they can meet the criteria required by the MHRA then the product would be granted a Marketing Authorisation which would enable the product to be placed on the UK and Guernsey market.

In order to gather the above evidence, then the Company may need to obtain a clinical trials exemption from the MHRA, to carry out the necessary research to obtain a Marketing Authorisation.

The Department as a matter of policy has decided only to recognise Marketing Authorisation issued by the UK and the European Medicines Evaluation Agency (EMEA) and not to issue any on its own authority, and by agreement through a Memorandum of Understanding with the MHRA.

These requirements are embedded in subsidiary legislation approved under the Medicines Law in 'The Medicines (Human) (Exemptions and Recognition of Marketing Authorisations) (Bailiwick of Guernsey) Regulations, 2009'.

Question 2

Bearing in mind the present difficulties being experienced in relation to health expenditure, might this not result in significant gains for Guernsey both from a financial and health services perspective?

Answer 2

The HSSD would be keen to explore opportunities that result in significant gains for Guernsey. However, any initiative or development must comply with extant legislation, be evidence based and meet current safety requirements an good practice.

Date of Receipt of the Question: 14th December 2012

Date of Reply: 15th January 2013