

Vaughan Gething AC/AM
Ysgrifennydd y Cabinet dros Iechyd, Llesiant a Chwaraeon
Cabinet Secretary for Health, Well-being and Sport



Llywodraeth Cymru
Welsh Government

Ein cyf/Our ref MA-PVG/5456/16

Mike Hedges AM
Chair, Petitions Committee
National Assembly for Wales

1 August 2016

Dear Mike,

As you know, the former Minister for Health and Social Services wrote to Jane Ellison MP, former Parliamentary Under Secretary of State for Public Health supporting efforts to facilitate licensed oral supplements for use in the UK. He considered a tablet formation may be more acceptable therapy for some patients and would reduce the burden on GP practices who must administer intra-muscular injections.

The Department of Health has advised about its efforts to facilitate manufacture of an appropriate UK licensed oral product with AMCo, a private company and sole manufacturer of a UK licensed preparation of oral vitamin B12 (cyanocobalamin 50mcg tablets). The outcome being that the company has no plans to supply a higher strength product to the UK market.

Medicines are very trialled very thoroughly and must meet quality standards before they are licensed. This is a very rigorous and complex process and covers a wide range of aspects including research and development, commercial, political and geographical. Licensing is therefore a matter for individual companies and there are no powers to require any company to undertake the necessary work involved in bringing a product to market.

Unlike licensed products, unlicensed medicines are not assessed for efficacy, safety, and quality; and may not be manufactured to appropriate quality standards. For these reasons the use of unlicensed medicines and dietary supplements for the management of medical conditions for which licensed medicines are available is not generally recommended. The General Medical Council advises doctors they may prescribe unlicensed medicines only on the basis of an assessment of the individual patient and where there is no suitably licensed medicine available.

Yours sincerely

A handwritten signature in black ink that reads "Vaughan Gething". The signature is written in a cursive style with a large initial 'V'.

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