EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Pharmaceuticals
Head of Unit

Brussels,
SANCO/C.8/JZ/sl/Ares.(2010)749000

Dear Mr. McArdle,

Subject: The Compassionate Use of Medical Cannabis Act 2010

I would like to thank you for your letter of the 20 September 2010 to Commissioner Dalli who has asked me to reply on his behalf.

Medicinal products have to be authorised, before they can be placed to the market in the EU, according to the EU Pharmaceutical Legislation. They can be authorised centrally for all the EU Countries (Regulation (EC) No 726/2004) or nationally in the chosen Member States (Directive 2001/83/EC).

No substance is a priori excluded, but the product has to be accepted to fall under a definition of medicinal product according to above mentioned legislation. (Article 1(2) of Directive).

In order to obtain a marketing authorisation for a medicinal product to be used throughout the EU, an application in line with the requirements of the legislation should be submitted to competent Authorities.

With respect to your particular concern, I would like to underline that a Member State may allow a compassionate use of an un-authorised medicinal product for an individual patient prescribed by an authorised healthcare professional (Article 5(1) of Directive and Article 83(1) of Regulation).

I trust that this information responds to your concern.

Yours sincerely,

Patricia Brunko

Gordon Mc Ardle
hempirl@gmail.com

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
Office: Brey 10/118 - Tel. direct line 00 32 2 2961268 - Fax +32 229-00 32 2 2998046
Jerica.zupan@ec.europa.eu