Question for written answer E-004915/2014 to the Commission Rule 117 Alojz Peterle (PPE)

Subject: Marketing authorisation of homeopathic medicinal products ('Cyprus clause')

Article 126a of Directive 2001/83/EC states that 'In the absence of a marketing authorisation or of a pending application for a medicinal product authorised in another Member State in accordance with this Directive, a Member State may for justified public health reasons authorise the placing on the market of the said medicinal product'.

This article further specifies the procedure for this kind of marketing authorisation and concludes by stating that the Commission shall present a report to Parliament and the Council concerning the application of this provision with a view to proposing any necessary amendments no later than 30 April 2008.

While additional information on the application and the use of this specific marketing authorisation procedure can be found on the Commission's website¹, the envisaged report has not been produced so far.

Can the Commission indicate when it intends to draw up and publish the report, originally foreseen for April 2008 as stipulated by Article 126a?

1027644.EN PE 534.659

http://ec.europa.eu/health/files/eudralex/vol-2/a/vol2a_chap1_2013-06_en.pdf