Question for written answer E-002437/2014 to the Commission Rule 117 Marian Harkin (ALDE)

Subject: Enforcement of EU legislation for homeopathic medicinal products

Article 9(2) of Directive 92/73/EEC gives Member States the possibility of introducing or retaining specific rules for the preclinical tests and clinical trials of homeopathic medicinal products in their territory other than those referred to in Article 7(1) in accordance with the principles and characteristics of homeopathy as practiced in that Member State. This provision was confirmed in Article 16(2) of Directive 2001/83/EC for homeopathic medicinal products other than those referred to in Article 14(1).

The second paragraph of Article 16(2) of Directive 2001/83/EC specifies (as had Article 9(2) of Directive 92/73/EEC) that 'in this case, the Member State concerned shall notify the Commission of the specific rules in force'.

## This being the case:

- 1. can the Commission provide a list of the Member States that have implemented specific rules since this provision came into force in December 1993?
- 2. can the Commission provide (or publish) the content of these rules for those Members States that have retained existing rules or have introduced new ones?
- 3. can the Commission also provide details of rules which have been changed, deleted or updated in the Member States to date?

1021676.EN PE 531.056