

If you would like to discuss the contents of this letter, please do not hesitate to contact me or one of the Homeopathic Unit's team.

Regards,

A black rectangular redaction box covers the name of the sender.

**Scientific assessor**  
**Homeopathics Team - PLAT 5**

Mr [REDACTED]  
36 New Cavendish Street  
London  
W1G 8UF

3<sup>rd</sup> January 2012

Dear [REDACTED]

I refer to your letter dated 13th September 2011 and the marketing of non registered homeopathic remedy kits.

As discussed in my previous letter dated 5th September 2011, in accordance with the Medicines Regulations a homeopathic remedy must either be registered under the Simplified Registration Scheme or be authorised under the National Rules Scheme or be the subject of a Product Licence of Right, in order to be sold or supplied in the UK.

We are unable to deviate from this legal requirement and therefore only the 33 homeopathic remedies registered under the Simplified Registration Scheme can be currently marketed in the UK. As agreed at the time of granting the registration certificates, the remedies may be included in a kit named 'Ainsworth Homeopathic Kit Number 1.'

Therefore as previously requested the following action is required:

Discontinue the sale and supply of Ainsworths Essential Remedy Kit, Ainsworths Mother and Child Kit, Ainsworths Childbirth Kit and Travel Kit because:

- a. the kit names have not been agreed by the MHRA and are not in accordance with the registration certificates granted.
- b. the kits contain remedies that are not registered or authorised.

Regarding the non registered remedies, you may submit applications for registration which we will process as quickly as possible. If the formulation is the same as that approved for the registered remedies, each registration application will be eligible for a discount (fee type: 5 or fewer stocks, formulation already assessed).

If you wish to vary the current approved kit name, Ainsworth Homeopathic Kit Number 1, a variation may be submitted and bulk discounts applied.

You should confirm in writing **within seven days** of the date of this letter that you have received it and understood the contents and provide a timeframe for discontinuing the sale, supply or advertising of the remedy kits listed above until such time the remedies are registered for use in the UK by this Agency.

If you are not able to provide in writing confirmation that you will act in accordance with the requirements of this letter, the matter will be referred to our Enforcement Group.