

At the time of registering the above homeopathic remedies under the Simplified Scheme, it was agreed that the individual remedies may be presented in a kit and that the kit would be named Ainsworth Homeopathic Kit Number 1.

However, the following Ainsworths Remedy Kits are currently being marketed:

- Ainsworths Essential Remedy Kit containing 42 remedies, 34 of which are registered under the Simplified Scheme and 8 remedies are neither registered nor authorised
- Ainsworths Mother and Child Kit containing 42 remedies, 22 of which are registered under the Simplified Scheme and 20 are neither registered nor authorised.
- Ainsworths Childbirth Kit containing 10 remedies, 5 of which are registered under the Simplified Scheme and 4 remedies and a tincture that are neither registered nor authorised
- Childrens Kit containing 10 remedies, 9 of which are registered under the Simplified Scheme and a tincture that is neither registered nor authorised
- Travel Kit containing 10 remedies, 8 of which are registered under the Simplified Scheme and 1 remedy and a tincture that are neither registered nor authorised.

As you are already aware, in order to sell or supply a homeopathic remedy within the UK, it must either be registered under the Simplified Registration Scheme or authorised under the National Rules Scheme or be the subject of a Product Licence of Right. Registration or authorisation is compulsory for products new to the UK market.

The remedy kits currently being marketed by Ainsworths contain remedies that have not been authorised or registered and are being marketed under names that have not been agreed by the MHRA and are not in accordance with the registration certificates granted.

Therefore Ainsworths is in breach of the Medicines Regulations¹ and the following action is required:

Required Action

1. Discontinue the sale and supply of the Ainsworths Remedy Kits listed above 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.

If you wish to market a kit then it must be named Ainsworth Homeopathic Kit Number 1 and must only contain remedies that are registered.

If more than one kit is required, a variation application may be submitted to add an additional kit name. If you wish to include any remedies in the kit(s), other than those listed above, applications for registration certificates will need to be submitted and approved before the remedies can be marketed and included in the kit.

You should confirm in writing **within fourteen days** of the date of this letter that you have received it and understood the contents. A timeframe for discontinuing the sale and supply of the remedy kits listed above should be provided.

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.

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.

Yours sincerely,

A black rectangular redaction box covering the signature of the scientific assessor.

Scientific assessor
Homeopathics Team - PLAT 5

¹ The Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994