



[Redacted]

Helios Homeopathics Ltd
89-97 Camden Road
Tunbridge Wells
Kent
TN1 2QR

5th September 2011

[Redacted]

Re: Helios Homeopathic Remedy Kits

We have received a number of complaints concerning Helios Homeopathic Remedy Kits. The complaints concern the names of the kits and that the kits contain homeopathic remedies that are neither registered nor authorised under one of the UK homeopathic regulatory schemes.

Helios currently holds registration certificates, without indications for use, for the following 18 homeopathic remedies:

[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]

Authorisation Number	Licensed Product Name
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

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 Helios Basic 18 Kit.

However, the following Helios Homeopathic Kits are currently being marketed:

- Basic 18 Kit containing the 18 remedies which are registered under the Simplified Scheme.
- Basic Plus 36 Kit containing 36 remedies, 18 of which are registered under the Simplified Scheme and 18 remedies that are neither registered nor authorised
- Accident & Emergency Kit containing 18 remedies, 12 of which are registered under the Simplified Scheme and 6 remedies that are neither registered nor authorised.
- Child Birth Kit containing 18 remedies, 6 of which are registered under the Simplified Scheme and 12 remedies that are neither registered nor authorised
- Travellers Kit containing 36 remedies, 18 of which are registered under the Simplified Scheme and 18 remedies 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.

Apart from the Basic 18 Kit, the remedy kits currently being marketed by Helios contain remedies that have not been authorised or registered, are marketed under names that have not been agreed by the MHRA and are therefore not in accordance with the registration certificates granted.

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

Required Action

1. Discontinue the sale and supply of the following remedy kits

- Basic Plus 36 Kit
- Accident & Emergency Kit
- Child Birth Kit
- Travellers 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.

The only kit that may currently be marketed is the Basic 18 Kit.

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 also 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 sender.

Scientific assessor
Homeopathics Team - PLAT 5

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