Dear [redacted] 27/9/11

HELIOS
HOMŒOPATHY
A passion for healing
telephone 01892 537254
email pharmacy@helios.co.uk
website www.helios.co.uk

Thank you for your recent letter of 5/9/11.
We have been considering the contents and its implications. The following is our response. We would like to say that Helios supports the overall objective of the MHRA in licensing unlicensed kits.

We have been manufacturing and supplying the unlicensed kits listed in your letter since 1993 through our Pharmacy remit to fulfil requests from unsolicited orders.
As you know, Helios licensed 18 remedies in 1997 and the Basic 18 Kit is a licensed kit. An attempt was made to license a further 18 remedies between 2000-2003. I am sure that you are aware of the difficulties that were evident in licensing homeopathic products during this period due to re-organisations and staffing levels at the MCA, as it was known then. Licensing the 18 remedies from 1995-1997 had been reasonably straightforward and it was unfortunate that the MCA was unable to fully conduct homeopathic assessments during the period 2000-2003 as it had done between 1995-1997. Because of this lack of progress despite numerous enquiries and eventually a complaint letter, we considered that it was not worth us continuing with an expensive and slow process when the MCA did not consider the issue of unlicensed kits to be a priority. It also should be noted that both we and our competitors had supplied unlicensed kits since the early 1990's on the request of our customers with the MCA fully aware at both regulatory and inspection level. Not once, either by an MCA/MHRA inspector or a regulatory official, were we advised to actually remove the kits from sale and this issue has not arisen until now when a small group of sceptics started lobbying the MHRA.

We appreciate the continued help, encouragement and support from the assessors throughout our submissions for five NR applications from 2008 and we are delighted and grateful that the Injury product is finally near to being completed. However the long delays over relatively minor wording changes does not give us confidence that future licensing will be any quicker than in the past. We are not alone in this frustration as our BAHM colleagues expressed at a recent meeting.

The homeopathic community and wider CAM community has become increasingly angry at the way sceptics posing as genuine members of the public have been able to abuse the neutrality of the MHRA through the complaints system. We appreciate that the MHRA have to endure persistent pressure and abuse in various blogs and realise this must be a drain on MHRA resources. Examples of recent disrespect for the MHRA are here:

http://www.quackometer.net/blog/2011/09/mhra-accused-of-clothing-naked-quackery.html

http://www.quackometer.net/blog/2010/01/mhra-and-labelling-of-homeopathic.html

These few dozen active sceptics know that the MHRA is bound by the admirable Communications Strategy 2010-2015 and the MHRA's own robust and respected complaints system, which are clearly for the benefit of genuine primary stakeholders i.e. members of the public. We would like to point out that the MHRA defines primary stakeholders *'the public - as patients and carers'* and that the aim of the MHRA is for patients and carers *'to seek and find with ease trustworthy information which helps them get the most from their treatment.'* It is important for Helios and the homeopathic community to be advised as to how these complainants can be defined as primary stakeholders, patients or carers. We are not aware of any complaints regarding unlicensed kits arising from any patients undergoing treatment or from their carers or even from other UK licensing homeopathic manufacturers. Therefore we do not consider that these complainants should be driving the resolution of the historic and complex issue of unlicensed kits and remedies. A few MPs are aware of the undemocratic sceptic campaigns, as are the homeopathic community, and some are asking us what action they can take.

I attach an example of the twitter dialogue one of the complainant's uses, which show a persistent anonymous complainant boasting about how his blitz e-mail tactics have pressurised the MHRA into generating a list of homeopathic licensed products in an attempt to push unlicensed remedies off the market completely. This was clearly the case and obviously these tactics are working.

We thought that the issue of unlicensed remedies supplied from a pharmacy had now clearly passed to the remit of the GPhC so shouldn't the request to discontinue the actual supply of kits be qualified further? We have all been waiting for the new Medicines Act public consultation, in particular to see the sections on the exemptions for pharmacists. At a recent MHRA meeting we raised the point that the face-to-face sales method is a minor method of supply, especially since the advent of e-commerce. It is also not practical with only 5 specialist homeopathic pharmacies in the UK providing responsible expertise for the several thousand remedies currently in use. Having to send remedy 'specials' to other pharmacies, with no expertise, will delay treatment and actually reduce the support and supervision for the medicines. Technology has moved on since 1968 and written, e-mail or web based ordering is actually more accurate than verbal as the nomenclature and pronunciation is often difficult for patients and carers. David Okeshott told the meeting that this section of the Act would be reviewed and may not be 'fit for purpose'.

We would like to respectfully ask whether the MHRA would consider a suitable time period for licensing kits bearing in mind the issues raised above and also the expected backlog due to the ending of PLRs. We have six applications under the simplified scheme very near to being ready for submission and do want to get the Basic 36 and Travellers kits licensed as soon as possible. Could the kit products be considered in the same light and time frame as the PLR's for their transfer to full licensing?

We are aware of the sceptic plan to lobby for homeopathic medicines to be reclassified as non-medicine i.e. confectionery. If necessary we could revise the manufacturing method,

the labelling of the bottles and kit box to present them as non-medicines and non-homeopathic and market them as 'confectionery'. Customers who have an interest in homeopathy would still know how to use them and would continue to purchase them despite limited labelling. There would of course be media repercussions and uncontrolled sources appearing and confusion among the public and MPs who would demand a full explanation for the change.
This is an option which our customers would support if it ensured a continuation of the supply of kits until they are fully licensed. However this is not our wish as we respect the remit of the MHRA, the efficacy of homeopathic remedies and their continuing status as medicines.

To conclude, we thank you for your attention to our comments and requests and would be grateful if you could let us know if the MRHA are able to give us an extended time frame for licensing the kits as mentioned above so we can be clearer as to the details of our future actions.

Thank you very much.
Yours sincerely

[redacted]
phone: +44 (0)1892 537254 Extn 250
email [redacted] website: www.helios.co.uk
Address: Helios Homoeopathy Ltd
89-97 Camden Road, Tunbridge Wells, Kent, TN1 2QR, United Kingdom