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# The Royal College of Pathologists

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Ellen Raphael  
Programme Manager  
Sense About Science  
60 Cambridge Street  
London SW1V 4QQ

Dear Ms Raphael,

## **Re- MHRA Regulations on homeopathic products**

The Royal College is aware that from 1st September 2006, new regulations allow homeopathic products to be marketed alongside conventional medicines while exempting them from providing any scientific evidence that they are effective (as set out in Statutory Instrument 2006 No. 1952). With these new rules, for the first time in its history the regulation of medicines has moved away from science and away from clear information for the public. The College is deeply alarmed by these developments. I understand that you are collating responses for the annulment debate and I would be grateful if you could record our objections.

**The Royal College of Pathologists' mission is to promote excellence in the practice of pathology and to be responsible for maintaining standards through training, examinations and professional development.**

Pathologists study the causes of disease and the ways in which disease processes affect our bodies. By recognising the patterns that disease takes allows us to understand what's at the root of a problem, enabling accurate diagnosis. Following up this understanding helps treatments to be devised and preventative measures to be put in place. In this context we fully appreciate the importance of evidence-based decision making in all our work.

Many of our members are directly involved in patient care, in addition to their role as pathologists, and I have particularly received a number of comments from those involved in the care of patients with haematological cancers. We are aware that many patients will take homeopathic and complementary medicines usually in addition to their standard therapy, we do not encourage this but do not oppose it if there is no evidence of detriment. There is a special concern, however, that the endorsement of such therapies without appropriate pre-clinical tests and clinical trials and without rigorous safety and efficacy data may encourage patients to use them as an alternative to conventional treatments. We do not believe that this is in the patient's best interests.

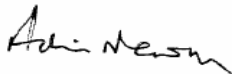
Those of us who have experience of the long and proud record of drug safety evaluation and regulation are concerned that the barrier should be lowered for homeopathic products and do not accept that the use of non- scientific evidence such as study reports, published scientific literature or reference to special investigations called 'homeopathic provings' is in any way comparable.

It is our understanding that this was a national decision to take this approach and that the EC directive allowed the government to decide how to regulate homeopathy beyond basic safety of manufacturing requirements. We believe that the government could have decided simply to bring the old licenses (PLRs) under the Simplified Scheme (1992). This required basic safety compliance that would still allow the products to be sold but would prohibit any poorly substantiated therapeutic claims.

This is surely the only rational approach and one that would be supported by the College. In the current academic climate, where we are trying to enhance the quality of clinical science in the NHS through the UK Clinical Research Collaboration, and with the creation of the National Institute of Health Research, with 'ring-fenced' funding from the Chancellor of the Exchequer it would be a major retrograde step to allow these regulations to continue as they are formulated.

We must be seen to continue the evidence-based approach to the delivery of medicine that we have all striven to develop.

With best wishes



Professor Adrian Newland  
**President**