

PAFAM
Patients & Friends of Anthroposophic Medicine
35. Franche Road.
Wolverley.
Kidderminster.
Worcs.
DY11 5TP

October 27th 2010

Dear Sir/Madam,

It has just come to our attention that there is a proposal to remove the Product Licences of Right (PLRs).for Anthroposophic Medicines in the U.K.

As the association that represents the users of Anthroposophic Medicine in the U.K. we have clear concerns about this proposal.

At the inception of the Medicines Act of 1968 about 2000 Anthroposophic Medicines were covered by Product Licenses of Right. This number has now been reduced to about 350 largely because of licensing fees and the associated documentation work limit the number of licenses the manufacturer's resources can carry. Currently, without PLRs, which we hear is the latest proposal, no more than 12 Anthroposophic Medicines would remain licensed.

Termination of Product Licenses of Right without the introduction of appropriate licensing regulations would mean that Anthroposophic Medicines could only be prescribed and supplied as "Specials". Consequences of this would be that the availability of these medicines cannot be guaranteed because of the restrictions on import procedures and the limitations of quantities of unlicensed "Specials" that manufacturers, distributors and pharmacies can hold. It also would mean that anthroposophic doctors would be "forced" to prescribe unlicensed medicines which should rather be an exception than the norm. Apart from the fact that it compromises the recognition of anthroposophic medicines, medicines that have been manufactured and used in the UK as well as in continental Europe for almost 90 years, that are known to be safe and don't produce dangerous side-effects. May I bring to your attention that the 1968 Medicines Act was introduced as a response to the danger and side effects of the thalidomide tragedy caused by conventional / allopathic medicine.

Another great concern to us is the fact that Anthroposophic Medicines in the UK which is named alongside Herbal, Homeopathic and Biochemic Medicines in **SI 41 (1978)** has also been deleted and not replaced in the current draft consolidated medicines regulations thereby erasing the very concept of Anthroposophic Medicines from U.K. legislation.

For the Homeopathic Medicine and the Traditional Herbal Medicine appropriate regulatory frameworks have been developed and are in place. These regulations require documentation of manufacturing and quality control procedures to ensure the quality of preparations. Also the safety of the products must be assured. As conventional proof of efficacy can rarely be evidenced the following measures are in place to prevent claims of efficacy: the simplified Homeopathic Registration excludes any indications at all on the products and the Homeopathic National Rules and Traditional Herbal Registration only allows claims for minor and self-limiting conditions which are consistent with their traditional use.

The users of Anthroposophic Medicines would like to see a similar kind of regulatory framework into place, including injectables which are by definition Prescription Only Medicines used generally for conditions which would not fall into the category of minor or self-limiting. We do not consider as appropriate, nor honourable, the removal of PLRs. There is a need for an effective parallel framework for Anthroposophic Medicines to the framework that exists for the Homeopathic Medicines and Herbal Medicines.

A further concern is as to why you have not actively encouraged a member of the public who is a user of Anthroposophic Medicines onto the consultation committee. Twice members of our association applied and twice we were turned down. It is not helpful to find that proposals such as the ones we have discussed here are quietly being pushed through without due consultation with the public who will be adversely affected by your current decision making. The Government advocates Patient Choice whereas this would amount to the absolute opposite experience.

Yours Truly

Cathie Green

Chairperson of the Patients & Friends Association for Anthroposophic Medicines