



British Association Of Anthroposophic Pharmacists

9th February 2011

RE: MHRA: Review of UK medicines legislation: informal consultations on issues relating to the PLR regime and homeopathy (17th Jan 2011)

INTRODUCTION

The BAAP is an independent Association of professional Anthroposophic Pharmacists working in various areas of Anthroposophic Pharmacy in the UK, including retail, education, industry and consultancy. It was founded in 2001 and is a member of the International Association of Anthroposophic Pharmacists (IAAP).

As a professional group of pharmacists - some members with over 20 years experience in Anthroposophic Pharmacy - the BAAP is ideally placed to comment on the **impact of the proposals** contained in the MHRA consultation paper as they have serious implications on the **future availability of Anthroposophic medicines** in the UK.

Comments from the BAAP were submitted in March 2009 when the initial concept paper was published.

COMMENTS

The BAAP is **extremely concerned** by the current proposals.

○ **PLR's**

As no suitable alternative to the PLR licensing scheme for Anthroposophic medicines is being proposed, **the majority of Anthroposophic preparations** - not being eligible under the HR or NR schemes - **will be lost**.

Whilst schemes have been developed in the UK under EU legislation to cover homeopathic medicines (HR's and NR's) and herbal preparations (THMP's), Anthroposophic medicines granted PLR's in 1971 **are not provided with an adequate future licensing scheme**.

Anthroposophic medicines with PLR's - acknowledged as different from homeopathic medicines in SI 1978 No 41 – **are not being given the chance to be properly reviewed**, as the spirit of the original PLR scheme intended (item 8 and 12).

Consequently the proposals to revoke the PLR's in April 2013 (item 14) are, in effect, the equivalent to "cancellation without the right to be heard".

British Association of Anthroposophic Pharmacists (BAAP)
Company Reg No 4565490 Registered Charity No: 1094580
8 Taptonville Head, Sheffield, S10 5AY. Email: judith.klahreparker@hotmail.co.uk

Member of International Association of Anthroposophic Pharmacists (IAAP)
www.iaap.org.uk



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The MHRA position paper indicates that PLR's not transferrable (item 16) will continue to be available as unlicensed specials (item 19). However this does not take into account the resultant effect that the majority of Anthroposophic medicines will, in future, **ONLY** be available **via clinicians**, according to *special clinical needs*.

A significant number of the Anthroposophic PLR's are OTC products available as GSL or Pharmacy only preparations and not only prescribed by doctors (item 19).

If the PLR's are revoked, these preparations will be **completely lost** to the professional Pharmacist. Based on their training and expertise in Anthroposophic Pharmacy, many Pharmacists in the UK have been safely counter-prescribing Anthroposophic medicines to the benefit of the public. Large numbers of the public have come to rely upon these OTC GSL or P medicines from their local Pharmacy, as first line treatment for minor and self-limiting conditions.

By ceasing the availability of these OTC Anthroposophic medicines, it is not only curtailing our professional activity, but also denying the choice of medicines for patients and members of the public.

Whilst some of these OTC PLR's may be converted to NR's, there are a number of reasons why this is likely to be a small minority, or may not even be possible:

- many may not be eligible under the current restrictions of the scheme – indication, manufacturing method, tradition of use
- there is no guarantee that the NR scheme will accept evidence of an Anthroposophic tradition, as the scheme is heavily weighted to proving Homeopathic tradition as part of the clinical particulars
- due to labelling restrictions, the medicines would not indicate their true nature, according to the system of medicine from which they are derived
- the costs and time involved in putting together a submission under the NR scheme is likely to place a heavy burden on the small scale manufacturers of Anthroposophic medicine and therefore only a small number (if eligible) could be converted in the 2 year timescale being proposed

Consequently, if these GSL or Pharmacy-only PLR medicines are no longer available, the freedom of choice of the consumer/patient will be severely curtailed, and the role of the professional Pharmacist undermined, as Anthroposophic medicines become de-licensed and available **ONLY on prescription.**



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Whilst current exemptions under the Medicines Act (SI 1997 No1830, SI 1994 No 3144 SI 1980 No 1924 and SI 1972 No1200) allow for homeopathic preparations at certain levels of dilution to be supplied without a prescription (for administration or in accordance with a judgement as to the treatment required), it is extremely unclear whether these exemptions will continue to be part of the consolidated UK medicines legislation.

Furthermore, the Anthroposophic medicines not eligible for the homeopathic schemes due to pharmaceutical form (injections), serious indication (item 17) or no-indication (item 18), are only given the option of a full Marketing Authorisation (item 11 & 16), which would, by its very nature, exclude non-indicated products. This full MA route is completely unrealistic financially and technically. The only possible route that may be available for important injectable Anthroposophic preparations with indications would be Well Established Use (not included under item 11).

○ **NR information for patients**

In principle the proposals contained in items 22 to 26 for rewording the information for patients for products under the NR scheme are acceptable.

However, given the MHRA are encouraging the transfer of Anthroposophic PLR's into the NR scheme for OTC medicines (where eligible), the proposed new wording for the NR scheme should include the possibility of substitution of "homeopathic tradition" with "anthroposophic tradition".

SUMMARY

1. The MHRA should seriously re-consider the option that is available under EU legislation, but rejected in item 9, to continue *national arrangements... in existence.... before the end of 1993* for homeopathic and anthroposophic medicines that fulfil the relevant definition (2001/83/EC)
 - PLR's could be allowed to continue, but undergo a system of gradual review, where the Safety, Quality and Efficacy is documented, similar to the process undertaken in the 1990's for Herbal medicines (item 8)
 - No formal review of Anthroposophic PLR's has ever been undertaken (item 12)
 - Similar updating arrangements have been adopted in other European countries for "old" products that have been safely on the market for many years
 - Suitable timescales should be set up in agreement with the manufacturers

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2. The NR scheme must be expanded to allow Anthroposophic medicines with PLR's to be transferred:
 - As well as the Anthroposophic manufacturing methods contained in the GHP (and now Ph Eur), methods of manufacture included in the APC (Anthroposophic Pharmaceutical Codex) should be recognised
 - Anthroposophic references and tradition should be clearly stated as acceptable in the NR application guidance notes
 - Details for the labelling should include, in addition to the current NR requirements, reference to the Anthroposophic nature of the product, either by manufacturing method or by therapeutic tradition
 - The timescales should be reviewed – 2 years for conversion is not sufficient
3. Consideration should be given to the supply regulations for unlicensed medicines, allowing preparations to be available through registered health professionals, including pharmacists for counter-prescribing
4. Consideration should be given to assisting Anthroposophic licence holders to apply for licences under the Well Established Use scheme where appropriate

CONCLUSION

If these measures are not taken the **majority of Anthroposophic medicines will be lost**, undermining the professional role of the informed Pharmacist in their counter-prescribing and curtailing the freedom of choice of the public, as Anthroposophic medicines will become de-licensed and available **ONLY** on prescription via the clinician.