

Memorandum submitted by the Medicines and Healthcare Regulatory Agency

HO 53

MLX312: LICENSING OF HOMEOPATHIC: PROPOSALS FOR A NEW NATIONAL RULES SCHEME

RESPONSES TO CONSULTATION

Symbol	Meaning
S	Support
O	Oppose
N/c	No comment
C	Reply Confidential

	ORGANISATION		ORGANISATION COMMENTS	DATE	MHRA COMMENTS
1	Pharmaceutical Society of NI	S	Support proposals for National Rules Scheme, proposals to review PLRs and expanded remit of ABRH. Also support in the type of information listed to support efficacy of homeopathic products given that the products cannot be evaluated in the same way as other medicines; support in restricting indications to minor self-limiting conditions.	9/8/2005	MHRA noted the supportive comments.
2	Royal College of Obstetricians and Gynaecologists	S	Recognises current inconsistencies in the way homeopathic products are marketed and believe that option 4 in RIA is sensible way forward. Also some concerns with permitting indications for symptomatic relief of infections including fungal diseases concerns with regard to vulval fungal conditions as allergic reactions to excipients are common.	13/8/2005	MHRA noted the supportive comments.  Only self limiting indications would be allowed under the National Rules; indications for infections would be reviewed by the expert Committee ABRH and appropriate warning on excipients-known to causes unwanted effects would be included in product information.
3	UK Clinical Pharmacy	S	Pharmacists keen to see reduction of risks	17/8/2005	MHRA noted the supportive comments.

	<b>Association</b>			to patients from all medicines. Proposals will add scrutiny to safety and effectiveness of this type of product and enhance patient safety. Particularly supports review of PLRS and expansion of remit of ABRH		
<b>4</b>	<b>Quackwatch Inc (Stephen Barrett M.D)</b>	<b>O</b>		States that homeopathic products do not work as it is not possible to separate safety and effectiveness. In addition to limiting their use to self-limiting conditions, require that all products be labelled “There is no scientific evidence for the treatment of any health problem. The MHRA permits them to be marketed because enough people want to use them to make it impractical to try to ban them”.	22/8/2005	Homeopathic products must be labelled in accordance with Article 54 (labelling requirements), Article 59 (package insert requirements) and Article 68 (which requires that the homeopathic nature of the product is clearly stated) of the European Directive. There is no provision in the Directive for any other information to be included. In order to make the user aware that of the homeopathic nature of the product, they are clearly labelled ‘Homeopathic medicinal product’ and the indication is state as ‘A homeopathic medicinal product used within the homeopathic tradition to relieve...’  Product information for homeopathic products authorised under the National Rules Scheme clearly state that if symptoms worsen or persist after 7 days, then a doctor must be consulted.
<b>5</b>	<b>Nursing &amp; Midwifery Council</b>	<b>N/C</b>		Acknowledgement only.		
<b>6</b>	<b>Royal College of Physicians &amp; Surgeons of Glasgow</b>	<b>S</b>		Happy to support the initiative.	24/8/2005	MHRA noted the supported comments.
<b>7</b>	<b>British Association of Dermatologists</b>	<b>N/C</b>		Acknowledgement only. No comments.	25/8/2005	
<b>8</b>	<b>British International Doctor’s Association</b>	<b>S</b>		BIDA supports the basic proposals for the NR Scheme, types of information to be listed to support efficiency, Option 4 of the RIA with some concerns that additional costs may be passed on to the consumers, proposals to permit only indications for minor self-limiting conditions, and the expanded remit of the ABRH.	21/7/2005	MHRA noted the supportive comments.  Cost would be minimised, see Regulatory Impact Assessment.
<b>9</b>	<b>R K Ward – VETWARD</b>	<b>O</b>		Does not believe homeopathic remedies are	1/9/2005	The National Rules scheme does not endorse clinical

			effective, recognise that these products may not cause physical harm but may possibly cause harm due to delay in seeking effective treatment or instil confidence in these as yet unproven effectiveness.		<p>efficacy of homeopathic products, as clinical efficacy is understood in the context of conventional pharmaceutical medicines. It provides consumer safety assurances in terms of product quality and improves patient information for users of homeopathic medicinal products.</p> <p>The indications for products authorised under the National Rules scheme are limited to the relief or treatment of minor symptoms or minor conditions i.e. symptoms or conditions which can ordinarily and with reasonable safety be relieved or treated without the supervision of a doctor.</p>
10	<b>Orchard Veterinary Group</b>	<b>O</b>	<p>Strongly opposes the licensing of homeopathic remedies as prescription only medicines without proof of efficacy. Concerns about lobbying from industry. No scientific evidence demonstrating effectiveness and its use runs contrary to scientific tenet; concerns that lay persons may regard homeopathic remedies have the same efficacy status as real medicines. Sad day if legislation is endorsed.</p>	1/9/2005	<p>The National Rules scheme does not endorse clinical efficacy of homeopathic products, as clinical efficacy is understood in the context of conventional pharmaceutical medicines. It provides consumer safety assurances in terms of product quality and improves patient information for users of homeopathic medicinal products.</p> <p>The indications for products authorised under the National Rules scheme are limited to the relief or treatment of minor symptoms or minor conditions i.e. symptoms or conditions which can ordinarily and with reasonable safety be relieved or treated without the supervision of a doctor. Products authorised under the National Rules scheme are intended for over the counter sale.</p>
11	<b>Royal College of Physicians Edinburgh</b>	<b>S</b>	<p>Proposals for National Rules Scheme are reasonable. Judgements will be needed on what constitutes minor conditions and length of time product can be used without review. MHRA may wish to build this into their thinking. Broadly agree with Option 4 of the RIA.</p>	1/9/2005	<p>MHRA noted the supportive comments.</p> <p>Product information must include a statement that users should consult a doctor if symptoms persist or worsen after 7 days. Depending on the indications for use, this time limit maybe reduced.</p> <p>Indications are considered on a case by case basis.</p>

						However, in general, minor conditions are considered to be those that can ordinarily and with reasonable safety be relieved or treated without the supervision or intervention of a doctor. Indications for serious conditions are prohibited. Furthermore the range of appropriate indications would be reviewed by the expert Committee ABRH.
12	<b>Patients Association for the Furtherance of Anthroposophic Medicine</b>	S		Supports labelling of anthroposophic medicine that is clear and helpful to the patient. Would support expert input from prescribers, pharmacists and consumers during the assessment phase.		MHRA noted the supportive comments.
13	<b>Anthroposophical Medical Association</b>	S		<p>Welcome the proposed approach which they feel is in general terms is pragmatic and realistic.</p> <p>Concerns about the cost of maintaining PLRs, as addressed in the MLX 324 response.</p> <p>Would support UK recognition of the Anthroposophic Pharmaceutical Codex and British Homeopathic Pharmacopoeia.</p> <p>Consider that PLRs are likely to remain the only status for anthroposophic medicines currently on the market</p>	29/8/2005	<p>MHRA noted the supportive comments.</p> <p>The scheme is designed for Homeopathic products and anthroposophic products that fulfil the European Directive definition of a homeopathic product will be eligible for authorisation under the National Rules Scheme.</p>
14	<b>Nelsonbach</b>	S	C	Have asked for responses to be kept confidential.	5/9/2005	
15	<b>The Royal College of Radiologists</b>	S		Proposals are important step forward. Strongly support the NR scheme. Supports option 4 in the RIA. Agrees with proposal to only permit indications for minor self limiting conditions. Strongly support expanded remit of ABRH. Recognises	7/9/2005	MHRA noted the supportive comments.

			cultural dimension in attitudes to medication generally and to alternative therapies in particular. Scheme gives ABRH sufficient flexibility to take account of history and attitudes of the UK I respect of homeopathic products and practices whilst also ensuring patient safety.		
16	<b>The Paediatric Chief Pharmacists Group</b>	S	Agree with proposals for National Rules Scheme particularly to limit indications. Agree the type of information listed to support efficacy of homeopathic products. Supports Option 4 for PLRs.	12/9/2005	MHRA noted the supportive comments.
17	<b>The Alliance of Registered Homeopaths</b>	S	In favour. List of limited indications should be expanded. Not happy with the term ‘symptomatic relief of’ as it implies suppression, not cure, which is contrary to the principles of homeopathic philosophy. Agree with the list of information to support efficacy. Agree with the expanded remit of ABRN, provided there is sufficient professional homeopathic input.	Sept 2005	MHRA noted the supportive comments.  Since rigorous clinical trial data is not required, indications for use are limited to the relief or treatment of minor symptoms or minor conditions. The ABRH consists of members of multi disciplinary backgrounds, including homeopathic practitioners.
18	<b>Laboratoires Boiron</b>	S	Welcomes the NR scheme. Supports expanded remit of ABRH, including the provision of advice on indications. Important for members of the ABRH to be familiar with products intended for self-medication for minor conditions. Quality, Safety and Efficacy.	7/9/2005	MHRA noted the supportive comments.
19	<b>Royal College of Nursing</b>	S	Support the removal of current anomalies and permitting some previously prohibited products onto the market. Welcomes proposal to print indications for use on products. Supports expanded remit of ABRH, but also supports the inclusion of representation from the nursing profession	8/9/2005	MHRA noted the supportive comments.

			<p>as the training in homeopathy for registered nurses now involves prescribing homeopathic remedies.</p> <p>Supports the quality assurance and safety elements of the scheme, the publication of the list of toxic stocks. ABRH should continually review the POM parenteral products. In relation to the compulsory variation of PLRs for more serious illnesses – this should be referred to the ABRH rather than CSM.</p>		
<b>20</b>	<b>British Pharmacological Society</b>	<b>N/C</b>	Acknowledgement only. No comments.	7/9/2005	
<b>21</b>	<b>British Association of Anthroposophic Pharmacists</b>	<b>S</b>	<p>Generally supportive – supports introduction of NR scheme, but considers it essential that the scheme ensures the continued availability of anthroposophic medicines. Those that are not eligible under the NR scheme must be safeguarded by their legitimate licensing as PLRs.</p> <p>Supports the IAAP definition of anthroposophic medicines.</p> <p>Quality – standards for anthroposophic medicines are defined in a number of national pharmacopoeias. Due to the nature of these products, it is not always possible to verify the content of the individual components of the product (therefore there is a reliance on QA measures).</p> <p>Safety – support lists of toxic stocks and proposal to consider stocks derived from food substances or GSL medicines only</p>	Sept 2005	<p>MHRA noted the supportive comments.</p> <p>The scheme is designed for Homeopathic products and anthroposophic products that fulfil the European Directive definition of a homeopathic product will be eligible for authorisation under the National Rules Scheme.</p> <p>Manufacturers holding PLRs will be encouraged to authorise the product under National Rules Scheme. For products reviewed and renewed, the indications for use will be brought in line with the requirements of the National Rules Scheme and indications for serious conditions will be removed. Applications will be referred to the ABRH for advice.</p>

			<p>requiring a reduced safety statement.</p> <p>Efficacy – anthroposophic bibliographic data should be accepted. Demonstrating efficacy should include reference to anthroposophic doctors.</p> <p>Consideration should be given to length of time products have been on the market as PFRs.</p> <p>There are a number of pharmacy only anthroposophic medicines with indications that require the intervention of a counter prescribing pharmacist (choleodoron drops, fragaria/vitis tablets etc – list in MLX response).</p> <p>Legal status – essential that pharmacy only option is retained for certain products.</p> <p>Labelling – essential that products contain the statement “an anthroposophic medicinal product”.</p> <p>Review of PLRs – supports option 4. Keen to retain a level playing field between anthroposophic and homeopathic products. ABRH needs appropriate anthroposophic expertise.</p> <p>Concerned that the review of PLRs will impose a heavy burden on license holders.</p>		
22	<b>WELEDA</b>	<b>S</b>	<p>Initial reaction to the proposals in MLX 312 was positive. Support proposals for Option 4 and will actively co-operate</p>		<p>MHRA noted the supportive comments.</p> <p>The scheme is designed for Homeopathic products and</p>

		<p>during the review of PLRs for serious indications. However, have concerns about the status of anthroposophic medicines – they should be afforded the same opportunity to participate in the NR scheme as homeopathic products. NR scheme should reflect the special circumstances applicable in different Member States. Specifically, the NR scheme should allow an anthroposophic PLR the possibility of obtaining a UK NR license.</p> <p>Specific comments re anthroposophic products –</p> <p>Medical definition need to recognise anthroposophic pharmaceutical codex. Anthroposophic products should be clearly labelled as such. Anthroposophic literature should be accepted. Relevant experts should include anthroposophic professionals.</p> <p>Review of PLRs – involves more products than simply the number of existing PLRs as in many cases one PLR will relate to several products. In terms of resources, the task of reviewing 1600 PLRs as well as new applications, with current resources, would probably take longer than 5 years. Weleda would also suffer resource concerns.</p> <p>Quality assessment – little in the MLX relating to the approach to quality for PLRs. For those manufactured under GMP</p>	<p>anthroposophic products that fulfil the European Directive definition of a homeopathic product will be eligible for authorisation under the National Rules Scheme.</p> <p>Manufacturers holding PLRs will be encouraged to authorise the product under the National Rules Scheme. For products reviewed and renewed, the indications for use will be brought in line with the requirements of the National Rules Scheme and indications for serious conditions will be removed. Applications will be referred to the ABRH for advice.</p>
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			<p>certified conditions, there should be little concern.</p> <p>Labelling – how would reviewed PLR products be labelled?</p> <p>Review of indications – strongly support enlisting the support of the Anthroposophic Medical Association. Front line assessors in the MHRA would have little experience of anthroposophic products, and the ABRH will not be involved in all assessments.</p> <p>Fairness – anthroposophic medicines need to be included. Proposals would resolute in an unfair regulatory burden for established companies.</p>		
23	<b>Royal College of General Practitioners</b>	<b>S</b>	<p>Whilst the approach (with no rigorous scientific data on safety or efficacy but with assurances on quality of production) is attractive for those with faith in homeopathy, a more scientific alternative would have been to withdraw all PLRs with indications unless there was proven evidence of effectiveness.</p> <p>But think that MHRA proposals are acceptable provided the MHRA and the ABRH are content that the public is fully protected.</p> <p>Supports introduction of fees – this will ensure quality control in their production.</p> <p>Ask how homeopathic remedies be assessed for safety and quality, as they are</p>	13/9/2005	<p>The MHRA believes that the NR scheme provide a sound basis to regulate quality and safety of homeopathic products used within the homeopathic tradition. The homeopathic nature and its use within the tradition are clearly labelled and are only suitable for self-limited conditions.</p> <p>Homeopathic products are expected to meet the same quality standards as required for conventional products. The applicant is required to submit a dossier describing how the homeopathic stocks are obtained and controlled and rigorous assessment of this data is critical to sufficiently guarantee reproducible product quality. The safety of a product is often closely linked to its quality and the two issues need to be considered together.</p> <p>As with applications for conventional medicines, information must be provided in order to demonstrate the pharmaceutical quality and safety of the products</p>

			<p>merely water containing vibrations from many products at infinite dilution.</p> <p>Ask if herbal teas and other infused drinks be included.</p>		<p>concerned.</p> <p>Only products which fulfil the European Directive's definition of a homeopathic medicinal product are eligible for the National Rules Scheme.</p>
24	<b>Royal College of Paediatrics and Child Health</b>	S	<p>Agree with basic proposals for the National Rules Scheme. Agree that types of information listed could form the basis of support for the proposal. Agree that indication should be limited. Pleased to note that packaging will indicate whether product is suitable to use in babies and children. Supports Option 4. Supports expanded remit of ABRH.</p>	13/9/2005	MHRA noted the supportive comments.
25	<b>British Association of Homeopathic Manufacturers</b>	S	<p>Broadly supportive of proposed scheme, with the following comments:</p> <p>Efficacy – anthroposophic products and bio chemic tissue salts should be covered – provided sufficient data for anthroposophic and bio chemic practitioners could demonstrate efficacy.</p> <p>Labelling – the words anthroposophic and bio chemic should be used on labelling where appropriate.</p> <p>PILS/Braille – reducing the regulatory burden brought about by the user testing and Braille requirements (transitional facilities) would be welcomed.</p> <p>Pharmacovigilance should not be too onerous for the products in question.</p> <p>Review of PLRs – Option 4 is the best way</p>	12/9/2005	<p>MHRA noted the supportive comments.</p> <p>Homeopathic products must be labelled in accordance with Article 54 (labelling requirements), Article 59 (package insert requirements) and Article 68 (which requires that the homeopathic nature of the product is clearly stated) of the European Directive.</p> <p>The MHRA will consider to extend the review period to 7 years and keeping the cost to a minimum, see Regulatory impact assessment.</p> <p>Noted.</p>

			<p>forward. 5 years is less than adequate, both in terms of workload and cost.</p> <p>Indications – further consideration is needed on the preamble to Annex 2 – i.e. homeopathic medicine is not concerned with the symptomatic relief of illness. It seeks to deal with the cause of the problem. Psychiatric conditions should also be covered.</p> <p>ABRH – special arrangements for expert groups should apply to section 4 committees.</p> <p>RIA – concerned about the overall cost burden of the capital fees (see response to MLX 324). NR application fees for products that already hold a HR registration should be substantially lower. In addition, the 5 year transition period should be extended to spread the overall compliance costs.</p>	
26	<b>Royal College of Physicians</b>	S	<p>Use of homeopathic medicines is not supported by many physicians who strive for robust evidence of efficacy, safety and quality, via randomised CT.</p> <p>Welcome proper regulation as homeopathic products are widely used. Provided it is not misconstrued by the public as official endorsement of unfounded claims of efficacy.</p> <p>Use of homeopathic produce for minor self limiting condition sis often preferable to real medicines, which carry the risk of</p>	<p>MHRA noted the supportive comments.</p> <p>The MHRA believes that the NR scheme provides a sound basis to regulate quality and safety of homeopathic products used within the homeopathic tradition. The homeopathic nature and its use within the tradition is clearly labelled and is only suitable for self-limiting conditions.</p> <p>Indications are considered on a case by case basis. However, in general, minor conditions are considered to be those that can ordinarily and with reasonable safety be relieved or treated without the supervision or intervention of a doctor. Indications for serious conditions are</p>

		<p>adverse reactions. Placebo effect is potentially helpful and should not be discouraged in the case of harmless but comforting measures unless it is at the expense of actually misleading patients.</p> <p>RCP think that factually correct statements in the product information or labelling regarding traditional use should be compulsory qualified by statement to be agreed with regulator along the lines of “but there is not evidence that it is more effective than dummy treatment”.</p> <p>Draw attention to risks to misdiagnosis and inappropriate use.</p> <p>RCP could not support an option that did not make it mandatory for the indication to be stated on the product literature. ABRH should set the stand for ‘serious conditions’.</p> <p>Recognise that RCT provides the best evidence of efficacy but in most circumstances, this will not be available for homeopathic products.</p> <p>Practitioners unlikely to accept bibliographic data unless efficacy evidence was robust, thus “efficacy” would be acceptable for minor, self-limiting conditions where a placebo response is acceptable.</p> <p>Support self-limiting conditions, rigorously</p>	<p>prohibited.</p> <p>To avoid misdiagnosis or delay in treatment, users are advised to consult a doctor if symptoms worsen or persist after 7 days. The time frame within which a doctor should be consulted maybe reduced depending on the condition.</p> <p>The suggestion comments regarding making users aware that there is no evidence for the use of homeopathic products has been noted. Homeopathic products must be labelled in accordance with Article 54 (labelling requirements), Article 59 (package insert requirements) and Article 68 (which requires that the homeopathic nature of the product is clearly stated) of the European Directive. There is no provision in the Directive for any other information to be included. Consequently the suggested statement would not be permitted. In order to make the user aware that of the homeopathic nature of the product, they are clearly labelled ‘Homeopathic medicinal product’ and the indication is stated as ‘A homeopathic medicinal product used within the homeopathic tradition to relieve...’</p> <p>Noted The range of appropriate indications would be reviewed by the export Committee ABRH.</p>
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			defined.  Support option 4.		
27	<b>National Eczema Society</b>	<b>S</b>	Agrees in general with proposals and the type of information listed to support efficacy of homeopathic products. However, concerned that patients should be given some information about lack of rigorous clinical trials, even for minor self-limiting conditions. Support indications for self-limiting conditions and expanded remit of ABRH.	13/9/2005	MHRA noted the supportive comments.  MHRA noted the suggestion that patients should be given some information about lack of clinical trials.  However, homeopathic products must be labelled in accordance with Article 54 (labelling requirements), Article 59 (package insert requirements) and Article 68 (which requires that the homeopathic nature of the product is clearly stated) of the European Directive. There is no provision in the Directive provide for any other information to be included.
28	<b>Royal Pharmaceutical Society of GB</b>	<b>N/C</b>			
29	<b>British Veterinary Association</b>	<b>O</b>	BVA considers the licensing and thus endorsement of homeopathic remedies by the MHRA to be a serious cause for concern for the following reasons: Products will be licensed with no requirement for any proof of efficacy. The permitting of remedies to be marketed with “indications” which are scarcely distinguishable from therapeutic claims.  No genuine “provings” of homeopathic remedies have ever successfully been performed in animals. Wild extrapolation of disproven human therapeutic modality to animals is therefore an offence to animal welfare.  <b>Providing homeopathic remedies with</b>	15/9/2005	The National Rules scheme to be set up is intended for Human use.

			<b>yet more official licences and endorsement, even permitting “indications” (essentially therapeutic claims), is a retrograde and damaging step, and we urge the MRHA to reject this course.</b>		
<b>30</b>	<b>Scottish Consumer Council</b>	<b>N/C</b>	Acknowledging letter only	28/6/2005	
<b>31</b>	<b>Health Professionals Wales</b>	<b>N/C</b>	Acknowledging letter only	28/6/2005	
<b>32</b>	<b>Stewart France Ltd</b>	<b>S</b>	Reject Options 1,2 and 4. Supports Option 3. Would like Candida Albicans and cholesterol to be allowed under the NR scheme as self-limiting conditions as they occur naturally in the body.	27/7/2005	MHRA noted the supportive comments.  Comments are from a homeopathic manufacturer that does not currently hold a PLR and their objections are related to financial matters.

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