EXPLANATORY MEMORANDUM TO

THE MEDICINES FOR HUMAN USE (NATIONAL RULES FOR HOMOEOPATHIC PRODUCTS) REGULATIONS 2006

2006 No. 1952

1. Purpose

1.1 This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency, on behalf of the Department of Health, and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 These Regulations set out rules relating to the safety and efficacy data to be supplied by an applicant for a marketing authorisation for a homoeopathic medicinal product, where that product is indicated for the relief or treatment of minor conditions or symptoms.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Background

4.1 Directive 2001/83/EC ("the 2001 Directive") sets out a comprehensive regime for the regulation of medicinal products for human use in the Community, including provisions which require applicants for marketing authorizations to demonstrate the safety, quality and efficacy of the medicinal product to which the application relates. The provisions relating to marketing authorizations have been implemented in the UK by the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 ("the 1994 Regulations").

4.2 The 2001 Directive sets out the particulars and documents which must accompany an application for a marketing authorisation, including a requirement that the applicant submit the results of pre-clinical tests and clinical trials. However, article 16(2) of the 2001 Directive permits member states to introduce national rules for the pre-clinical tests and clinical trials of certain homeopathic medicinal products. These Regulations therefore amend the 1994 Regulations to introduce UK rules in accordance with Article 16(2).

4.3 The new fees associated with the National Rules Scheme are being introduced by The Medicines for Human Use (Fees Amendments) (No.2) Regulations 2006. The MHRA charges fees at a level that reflect the costs of the work carried out and for applications under the National Rules Scheme fees of between £480-£1219 per dossier hare being introduced, depending on the nature of the application. A full application would cost £1219 for more than 5 stocks, based on the time and level of expertise needed to assess the information provided. Applicants whose products are currently authorised under the Simplified Scheme that wish to register under the National Rules Scheme, would be subject to a fee of £680 for more than 5 stocks.

5. Extent

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 The Government's overriding objective in introducing these rules for homoeopathic medicinal products is to remove the inconsistencies in the way that homoeopathic products are authorised and marketed in the UK. Currently, homoeopathic products are either licensed under a "simplified scheme", or have "product licences of right". Applicants for products under the simplified scheme are required to provide only minimal data on safety, and no data on efficacy, as the products are not permitted to have indications (ie the product information is not permitted to include any conditions that the product might be used to treat). Products with "product licences of right" are permitted to have indications, but only products which were on the market at 1971 have product licences of right. As a result, some manufacturers are able to market a wider range of dosage forms and dilutions and give indications for their products, depending upon when they placed their product on the market.

7.2 By way of background, these rules are part of a package of measures intended to deal with inconsistencies in the marketing of homoeopathic medicinal products. It is also intended that products with "product licences of right" will be reviewed, under existing legislation, to ensure that products can continue to be safely administered for the purposes indicated in the licence, and are efficacious for those purposes. In addition, it is proposed that the remit of the Advisory Board on the Registration of Homoeopathic Products will be expanded, to permit that body to provide advice in relation to applications for marketing authorisations made in accordance with the rules set out in these Regulations, and also to provide advice in relation to homoeopathic medicinal products with product licences of right. It is proposed that an order be made under section 4 of the Medicines Act shortly.

7.3 Most conventional medicinal products for human use are licensed with a "marketing authorisation". Under the rules which currently apply, obtaining a marketing authorisation requires submission of the results of pre-clinical tests and clinical trials. Because of the philosophy of homoeopathy and the nature of the products, it is difficult to establish efficacy for homoeopathic products by way of clinical trials and there are therefore no homoeopathic products which have marketing authorisations in the UK**.**

7.4 As set out earlier, article 16.2 of Directive 2001/83/EC enables Member States to introduce national rules for the safety and efficacy data to be submitted with applications for certain homoeopathic medicinal products. The new rules set out in the Regulations therefore provide that an applicant need not comply with requirements relating to the submission of the results of pre-clinical tests and clinical trials, provided that he complies with the new requirements relating to submission of safety and efficacy data. These permit the applicant to establish safety by way of "scientific data" (study reports or published scientific literature) or in some circumstances by non-scientific data. In some cases (where the product is derived from a homoeopathic substance present in food, or is derived from a substance from which a licensed product is derived, or which is sufficiently dilute), and provided certain other specified conditions are met, safety can be guaranteed and the applicant is not required to provide safety data. Under the new rules, the applicant can establish efficacy by study reports, published scientific literature, or by reference to special investigations called "homoeopathic provings".

7.5 Apart from these rules relating to safety and efficacy data, all of the other provisions relating to marketing authorisations apply. The sanctions which already apply to applications for, and holders of, marketing authorisations will also apply.

7.6 Both informal and formal consultation has taken place with stakeholders. Before the publication of the formal consultation, the Government consulted widely with industry representatives and leaders in the field of homeopathic practice. A full public consultation was conducted from 20/06/05 – 12/09/05. The consultation was sent to a comprehensive list of stakeholders, and was placed on the MHRA's website. Thirty-two responses were received from a range of organisations, including: manufacturers of homeopathic products, homeopathic trade associations, professional bodies including several Royal Colleges, patient/consumer representative organisations, and the general public. There was widespread support for the introduction of national rules for the authorisation of homoeopathic medicinal products. A summary of the consultation responses was placed on the MHRA's website, which also indicated the Government's preferred course of action based on the analysis of responses.

7.7 Although there has been some media attention on the broader issue of complementary medicines, there has been little or no coverage of this specific scheme.

7.8 Although the development of national rules by Member States under the 2001 Directive is optional, failing to introduce the scheme would inhibit the expansion of the homeopathic industry. Sections of the homeopathic industry are discontented with the current situation. Most importantly this difference in the information available to users of homeopathic medicines also causes the risk of patient confusion.

7.9 Guidance for the homoeopathics industry is under preparation and will be sent to all PLR holders and Simplified Scheme registration holders and published on the MHRA website. The MHRA is also considering delivering training on the new requirements to the industry, depending on the levels on interest.

8. Impact

8.1 A Regulatory Impact Assessment has been prepared and is attached to this EM.

9. Contact

9.1 Miss Sue Harris at the Medicines and Healthcare products Regulatory Agency Tel: 020 7084 2335 or e-mail: sue.harris@mhra.gsi.gov.uk can answer any queries regarding the instrument.

FULL REGULATORY IMPACT ASSESSMENT

1. TITLE

Medicines for Human Use (National Rules for Homoeopathic Products) Regulations 2006

The Medicines for Human Use (Fees Amendments) (No.2) Regulations 2006

2. PURPOSE AND INTENDED EFFECT

2.1 Objective

To address the current inconsistencies in the way that homeopathic products are marketed in the UK in order to create a level playing field. This will be achieved by introducing national rules under Article 16.2 of Directive 2001/83/EC on 1st September 06. These rules are part of a package of measures aimed at addressing these inconsistencies. It is also proposed that Product Licences of Right (PLRs) will be reviewed in accordance with existing legislation over a 7 year period from 1st September 06.

2.2 Background

Most conventional medicinal products for human use are licensed with a "marketing authorisation". Directive 2001/83/EC ("the 2001 Directive") sets out a comprehensive regime for the regulation of medicinal products for human use in the Community, including provisions which require applicants for marketing authorizations to demonstrate the safety, quality and efficacy of the medicinal product to which the application relates. These requirements have been implemented in the UK by the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994. The 2001 Directive sets out the particulars and documents which must accompany an application for a marketing authorisation, including a requirement that the applicant submit the results of pre-clinical tests (to establish safety) and clinical trials (to establish efficacy). Because of the philosophy of homoeopathy and the nature of the products, it is difficult to establish efficacy for homoeopathic products by way of clinical trials and there are therefore no homoeopathic products which have marketing authorisations in the UK**.**

Under current arrangements, homoeopathic products either have PLRs, or have been granted certificates under the "Simplified Scheme". The Medicines Act 1968 was implemented in the UK in 1971 and all medicinal products then on the UK market, including homeopathic products, were given PLRs. Currently, there are almost 3,000 PLRs in existence. The simplified scheme was introduced in 1992 because the requirement to submit the results of clinical trials meant that, in practice, it was not possible to introduce new homeopathic medicinal products onto the market. The procedure is regarded as simplified because there is no requirement for data to demonstrate efficacy and because the eligibility criteria confer a certain reassurance on safety so that the data requirements on safety are usually minimal.

Although there has always been scope, both under previous EC legislation and the 2001 Directive, to introduce specific rules within the UK relating to the safety and efficacy data to

be provided by applicants for marketing authorisations for certain homoeopathic medicines, this has not been done before now. As the Simplified Scheme does not allow indications, but homeopathic products covered by PLRs may have indications, there are inconsistencies in whether homeopathic products have indications, depending on when they were licensed.

As a result, some manufacturers are able to market a wider range of dosage forms and dilutions and give indications for their products while others are not permitted to do so. This has the effect of creating barriers to equal access to the market and differences in the information available to users of these products. There are almost 3000 products that are currently allowed in a wide range of presentations and permitted to give indications. In addition, there are approximately 200 products which are not permitted to have indications because they have been registered more recently under the Simplified Scheme.

Our proposals will benefit both the general public, by strengthening the public health protection of users of homeopathic medicinal products and the homeopathic industry by levelling the playing field and increasing the range of products that can be marketed. The associated increase in costs for MHRA and the homeopathic industry are offset against the benefits outlined above.

By way of background, it is also intended that the remit of the Advisory Board on the Registration of Homoeopathic Medicines will be expanded to permit that body to provide advice in relation to applications for marketing authorisations made in accordance with the rules set out in these Regulations, and also to provide advice in relation to homoeopathic medicinal products with product licences of right. It is proposed that an order be made under section 4 of the Medicines Act shortly.

2.3 Rationale for Government Intervention

Although the development of national rules by Member States under Directive 2001/83/EC is optional, failing to introduce the scheme would inhibit the expansion of the homeopathic industry by the prevention of the development of new products with indications.

Currently, there are cases where two identical products are available, one with indications and one without, depending on whether or not the product was marketed prior to the Medicines Act (1968) coming into force. This difference in the information available to users of homeopathic medicines causes the risk of patient confusion.

3. Consultation

3.1 Informal Consultation

Prior to the formal public consultation, we consulted with Industry representatives and leaders in the field of homeopathic practice. A positive response to the proposals was received from all parties consulted informally.

3.2 Public Consultation

A full public consultation was conducted from 20/06/05 – 12/09/05. Thirty two responses were received from a range of organisations, including: manufacturers of homeopathic products, homeopathic trade associations, professional bodies including several Royal Colleges, patient/consumer representative organisations, and the general public.

There was widespread support for the proposals set out in the consultation document, including the introduction of national rules relating to the safety and efficacy data to be submitted with an application for a marketing authorisation for a national homoeopathic product. Consultees also supported the review of the existing PLRs, particularly those licensed for more serious illnesses. For products that are not eligible for the proposed scheme – for example anthroposopic products without indications – there was support for retaining the option of renewing the PLRs.

Some comments were received on the examples of minor conditions that might be permitted under the proposed National Rules Scheme. There was also widespread support for the expansion of the role of the Advisory Board on the Registration of Homoeopathic Products. A summary of the responses received to the consultation is at Annex A.

4. OPTIONS

Four options have been identified:

- Option 1 Do nothing. This was rejected as the present inequalities would continue. While there are no strong public health reasons for taking action, this option is not attractive. Sections of the homeopathic industry are known to be discontented with the current situation and are likely to pursue the issue.

- Option 2 Revoke all PLRs by making legislation under Section 2 (2) of the European Communities Act 1972. This was rejected as not all PLRs can be licensed under the New National Rules Scheme or under the existing Simplified Scheme, thus leaving some products without a regulatory home.

- Option 3 Introduce national rules which would provide that an applicant need not submit the results of pre-clinical tests and clinical trials, provided that he complies with the new requirements relating to submission of safety and efficacy data (i.e demonstrate the safety and efficacy of the products, usually by reference to by reference to relevant published literature or original data). Apart from these rules relating to safety and efficacy data, all of the other provisions relating to marketing authorisations apply.

- Option 4 Introduce a Scheme as in Option 3, but take the further step of rationalising the regulatory system for homeopathic products by reviewing PLRs, under existing legislation. Companies will be encouraged to apply for a marketing authorisation under the new scheme, or a certificate under the Simplified Scheme, on a voluntary basis. PLRs for products which companies do not wish to re-register or which are not eligible for the newer schemes will be reviewed in terms of indications. Companies will be asked to remove any indications if in the view of the licensing authority, that product can no longer safely be administered for the purposes indicated in the licence, or can no longer be regarded as efficacious for those purposes, and the company cannot reassure the licensing authority on these points. Companies will be given every opportunity to support proposed indications. Renewal will be carried out under the existing legislation of the Medicines Act.

Risks

The risk of selecting Option 1 is that the expansion of the homeopathic industry would be inhibited by the prevention of the development of new products with indications. The present inequalities would continue. Option 2 would result in the removal of all PLRs from the market. Not all PLRs are eligible to use the Simplified Scheme or new National Rules Scheme (ie anthroposophic medicines which do not carry indications) – therefore a large number of PLRs that have been proven to be safe to use would no longer be available on the market. The risks of Option 3 relate to the continuation of the present inequalities as similar or identical products already licensed as PLRs could also be registered under the National Rules Scheme. The main risk associated with Option 4 is a possible low number of applications under the National Rules Scheme. Although consultation with the industry suggests that this will not be the case, the present inequalities will continue to some degree if there is a low uptake.

5. COSTS and BENEFITS

5.1 Business Sectors Affected

The only business sector directly affected is the homeopathic medicines manufacturing industry.

There are currently four major UK companies (NelsonBach, Weleda, Ainsworth and Helios), but it is expected that companies from other Member States, some of whom currently market homeopathic products registered under the Simplified Scheme in the UK, will wish to licence products under the National Rules Scheme. In a report published by Mintel (Complementary Medicines in the UK, Market Intelligence, March 2005), the most recent figures available, it was estimated that the market for homeopathic remedies in the UK was around £32m in 2004.

5.1.1 Benefits

Option 1 No benefits for business or people using homeopathic medicinal products, the present inequalities will continue.

Option 2 No benefits for business as not all PLRs can be authorised under the new National Rules Scheme or registered under the existing Simplified Scheme, leaving some products without a regulatory home.

Option 3 This option would mean that users of homeopathic medicinal products will have access to products marketed with consistent patient information with competition between manufacturers on an equal footing. The industry as a whole will benefit from the opportunity to gain indications for products for which use within the homeopathic tradition can be demonstrated, but cannot currently carry indications. In addressing equal access to the market, those manufacturers who previously had the advantage of being able to claim indications while others could not, will lose that advantage.

In addition the National Rules Scheme proposals will in practice allow new products that are not eligible for the Simplified Registration Scheme and are not already marketed under a PLR to gain access to the market for the first time. Legislation enabling the products to be labelled with indications is also

considered to be of significant benefit to patients. Improving market access will increase competition and therefore, reduce prices.

Informal discussions with representatives of the homeopathic sector suggest that the proposals for the National Rules Scheme would be well received.

Option 4 As for Option 3. In addition, there would be a beneficial effect of this approach for certain types of PLR product. PLRs for products which companies do not wish to re-register or which are not eligible for the newer schemes will be reviewed in terms of indications**.**

Some of these products are so-called anthroposophic medicines and do not carry indications. (An anthroposophic medicine is a medicine prepared following homeopathic manufacturing procedures and prescribed based on the physical and spiritual features of a patient in accordance with the principles of Dr. Rudolf Steiner). It is not possible to register a product under the National Rules Scheme without any therapeutic indication. Leaving these products as PLRs without indications will allow companies to retain them on the market for use in accordance with anthroposophic practice.

Reviewing the PLRs will provide an opportunity to rectify any cases where products are being marketed with inappropriate indications.

5.2 Costs

5.2.1 Compliance Costs for Business

A summary of the costs to the industry and to the MHRA can be found below. No substantive environmental or social costs have been identified in relation to the proposed scheme. Further information on the nature of these costs can be found in the narrative below the table.

	Ongoing costs to industry	Other costs to industry	Ongoing costs to MHRA	Other costs to MHRA
Option 1	£0	£0	£0	£0
Option 2	£410 per PLR re-registered.	£2,444 per ML	£216,000	£0
Option 3	£752.- £1,219 per product	£1,250-£5,000 per dossier £2,444 per ML There will be an additional cost of £63 service fee per annum after the first year of authorisation.	£216,000 per annum	£0
Option 4	£752 - £1,219 per product. .	£1,250-£5,000 per dossier £2,444 per ML There will be an additional cost of £63 service fee per annum after the first year of authorisation under the National Rules. For PLRs, there will be an annual service fee of around £63.	£216,000 per annum	£0

Option 1 (Do nothing)

No direct figurable cost to business. However, unequal access to the market may impact on competition between manufacturers, and could keep prices artificially high for those products which legitimately carry indications. Only manufacturers applying the current registration scheme incur the costs of application fees and the cost of compiling dossiers.

Option 2 (Revoke all PLRs)

Applicants would pay a fee for each product previously covered by a PLR to be registered under the Simplified Scheme or authorised with a marketing authorisation under the National Rules Scheme. This option would result in products which do not "fit" under either scheme being lost to the market. For example, there are currently some 35 Bach Flower Remedies and several hundred anthroposophic products which hold PLRs and do not fit within either of the newer schemes.

Option 3: (new national rules allowing indications)

Option 3 would give manufacturers of registered homeopathic products an additional option to apply for an authorisation that would allow therapeutic claims to be made. If they chose not to, there would be no cost involved. MHRA would charge a fee for assessing an application and as with all fees charged by the Agency, this would be set at a level to reflect the work actually carried out. The current fee for a registration under the Simplified Scheme (without indications) varies between £148 and £960 per product, depending (amongst other things) on whether the product or a similar one has been assessed by the Agency before. A similar scale of fees could be used for the assessment of products under the new scheme but with an additional element for the assessment of data provided for indications. This element of the work would cost in the region of say £350 (options: £300, £400) per product i.e. giving a total fee between £752 and £3,219.

The quality requirements for the National Rules Scheme are the same as that for the Simplified Scheme. However, unlike the Simplified Scheme, the applicant needs to provide data to demonstrate safety and efficacy. In most cases, it is anticipated that the data will be bibliographic data.

Generating this data will usually involve literature searches and providing an overview of the literature submitted. It is estimated that for well known products, this will take 2-3 hours per product. This equates to approximately £45 - £65 more than costs of applying under the Simplified Scheme for each product, although the benefits in terms of sales are likely to be greater under the National Rules Scheme as the patient will be guided by the indications on the pack. Costs could be reduced arranging for the trade associations to carry out the work and sharing the results with its members.

Option 4: (reviewing existing PLRs**)**

The costs associated with the implementation of Option 4 would be the same as for Option 3 above.

It is not possible to charge fees for the review of PLRs. However, products remaining as PLRs will be subject to a service charge (around £63), and those re-registered under the newer schemes will have had appropriate fees paid on application.

5.2.2 Other costs

In addition to the application fees there will be other 'once only' costs associated with making an application:

- Compilation of dossiers: No information is available on the cost of compiling a dossier for homeopathic medicinal products. Depending on whether or not the product is currently registered or licensed, little or no new technical information will need to be generated for the application dossiers. Based on this fact, it is suggested that the average cost of the dossiers will be similar to that of a simple abridged application for a marketing authorisation for a conventional medicinal product which was estimated to be about £1,250. The cost is likely to vary considerably from lower than the average figure, if the cost is spread over several applications using the same data generated from one application, to costs which could rise as high as £5,000 in some cases if complexities arose, for example, in a few cases where generation of additional technical data may be required.

- Manufacturer's licences (MLs). Companies which do not already hold an ML will need to obtain one. The current fee for an ML is £2,444 for a standard licence and £142 for a non-orthodox practitioner's licence. Currently, it is not possible to estimate how many new companies will apply under the National Rules Scheme, but further information will be obtained once the proposed pre-submission notification scheme is implemented in the second quarter of 2005. .

- Revision of labelling: There will also be costs to the generation of revised labelling and product information, including user testing for existing authorised products.

Proposals to introduce new fees as a result of this exercise were included in a separate public consultation, which began on 17th June 05 (MLX 324).

There is no cost to local authorities or to the NHS.

There is no cost on the environment nor are there any social costs.

Cost to the MHRA are estimated at £216,000 per annum.

5.2.3 Costs for a typical business

It is not possible to estimate this at present as a suitable 'typical' business does not exist

There is the option for companies holding registrations for homeopathic medicines obtained under the Simplified Scheme already in existence to apply for authorisations for these products under the New National Rules Scheme. Such applications will attract a reduced fee, say £350 per product as quality and safety aspects will have already been addressed and only efficacy issues will need to be assessed. Thus a small business with applications for two products will pay £700 in fees, a medium business with thirty products will pay £10,500 and a large business with 70 products £24,500. There will be the additional cost of assembling the evidence for use in the indications sought. An annual fee of around £63 would be payable after the first year of authorisation, and in addition, a fee would be payable at the renewal of the licence after 5 years.

Applications for products not previously registered under the Simplified Scheme will attract a higher fee, as quality and safety assessments will need to be carried out. Using the same number of applications as above and assuming that the products contain more than five homeopathic stocks which have not previously been seen by the Licensing Authority, (such applications attract the highest fees of, say, £1219 per application), the fees would

be £2,438 for the small company, £36,570 for the medium company and £85,330 for the large company. Annual and renewal fees would be the same as above. It is assumed that applicants will phase their initial applications to avoid a large financial outlay for fees and other costs.

6. Consultation with small business

Informal and formal written consultation has taken place with key industry representative associations and with experts in the field of homeopathic practice over the past three years. They have been broadly supportive of the proposed scheme because it will enable them to market a wider range of products and products with indications.

7. Competition Assessment

The competition filter test has been carried out in relation to homeopathic companies both in the UK and in other EU member States and suggests that a full assessment is not required, a simple competition assessment being sufficient.

The affected market will be the over-the-counter medicines sector. Currently only homeopathic medicines with PLRs are labelled with indications for their use. (The majority of these are held by three companies. Implementation of the National Rules Scheme will enable all companies to market more products with indications. This will increase consumer choice and ensure equal access to the market. The National Rules Scheme is voluntary and its costs will depend on the number of products a company wishes to authorise. The number of companies with homeopathic authorisations is likely to increase. Some of the companies concerned already hold registration certificates granted under the Simplified Scheme and will have the option of re-applying for homeopathic authorisations under the National Rules Scheme, which will enable them to market these products with indications..

8. Enforcement and Sanctions

Enforcement and control of the legislation will be achieved within the existing enforcement mechanisms i.e. Schedule 3 of the Marketing Authorisation Regulations. Offences in the Marketing Authorisation regulations will be relevant as all the requirements of the 2001 Directive will apply to products licensed under the National Rules Scheme. Penalties imposed on summary conviction of such an offence, are a fine not exceeding £5,000 or an indictment to a fine or imprisonment for not more than two years.

9. Implementation and delivery plan

The proposed National Rules Scheme will be implemented on 1st September 06.
The PLRs will be reviewed over a seven year period.

10. Post implementation review

Initially, applications received will be monitored on a monthly basis and regular meetings with stakeholders and trade associations will be used to monitor the effectiveness and success of the new scheme. The regulations will be reviewed three years after the date of implementation. The associated fees regulations will be reviewed annually.

11. Summary and Recommendations

Option 4 is recommended as the best solution available as it will create a level playing field for the industry. In addition, users of these products will have consistent information. We consider that the costs to both the MHRA and the homeopathic companies associated with setting up and operating systems under this option are outweighed by the benefits to both the homeopathic industry and to public health. Thus the MHRA recommends the adoption of Option 4.

Option	Total benefits per annum: economic, environmental, social	Total costs per annum: economic, environmental, social - policy and administrative
1	None	None
2	None	Loss of revenue to companies holding PLRs
3	More equal access to market as new products authorised under the scheme can carry indications. This will remove the current anomalies.	£0-£85,330 (See 5.2.3 above) based on anticipated costs of £350-£1,219 per product and £1,250-£5,000 per dossier. There will be an additional cost of £63 service fee per product per annum after the first year of authorisation
4	As above, with the additional benefit of reviewing PLRs with inappropriate indications.	£0-£85,330 (See 5.2.3 above) based on anticipated costs of £350-£1,219 per product and £1,250-£5,000 per dossier. There will be an additional cost of approximately £63 service fee per product per annum after the first year of authorisation. There will be an additional cost of around £63 service fee per annum per PLR

Declaration:

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by the responsible Minister: ***Andrew Burnham***

Date: 19th July 2006

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ANNEX A

SUMMARY OF MLX 312 RESPONSES

FOR PUBLICATION ON THE MHRA WEBSITE

Thirty two responses were received. There was widespread support for the proposals set out in the consultation document. Specific comments are set out in relation to the five questions posed in the MLX:

Do you agree with the basic proposals for the National Rules Scheme?

Overall, consultees expressed support for the proposals for a National Rules Scheme (NRS) – the proposals were seen to be pragmatic and realistic in their aims. The main reservations related to the effectiveness of homoeopathic products, and their claims for efficacy. Other concerns related to the application of the proposed Article 16 scheme to anthroposophic medicines – consultees felt that most anthroposophic medicines would be ineligible as they do not have indications. Therefore, specific provisions for anthroposophic medicines would need to be built into the NRS to ensure a level playing field between those and homoeopathic products. Although supportive of the NRS, consultees considered it essential that anthroposophic products that do not fit the scheme can continue to be registered as PLRs. If they are to be included in the scheme, appropriate bibliographic evidence should be accepted. Expertise from the anthroposophic field should be accepted as sources of evidence (re quality and safety) and the ABRH should include requisite expertise.

Agency Comment

Indications permissible under the National Rules Scheme are being restricted to minor conditions and will be worded in such a way that the public will not be mislead with regard to efficacy.

Directive 2001/83/EC defines conditions that must be fulfilled for an anthroposophic medicinal product to be considered in the same way as a homeopathic. The National Rules are being set up under the Directive and eligible anthroposophic products will be treated in the same way as homoeopathic products. It is clear from the MLX that any PLRs that do not fit the more modern schemes may remain as PLRs. All products will be looked at on a case by case basis.

Definitions

There were a small number of comments on UK definitions of homoeopathic and anthroposophic products. Some consultees supported the use of the Anthroposophic Pharmaceutical Codex and the British Homoeopathic Pharmacopoeia. There was also support for an IAAP monograph which defines and describes anthroposophic medicines products from a pharmaceutical perspective

Agency Comments

Definitions used are those in Directive 2001/83/EC as amended. Neither the Anthroposophic Pharmaceutical Codex nor the British Homeopathic Pharmacopoeia are officially recognised in either the EU as a whole or in the UK on a national basis.

Quality

There was overall support for the proposals outlined in paragraphs 21-22. In relation to anthroposophic medicines, quality standards are defined in a number of national pharmacopoeias. The IAAP has also recently published standards specific to anthroposophic manufacture and control, cross referencing to existing national standards in the Anthroposophic Pharmaceutical Codex. One consultee considered that due to the nature of these products, it may not always be possible to verify the content of the individual components of the product (therefore there is a reliance on QA measures).

In relation to paragraph 22, some consultees sought clarification on what constituted an 'expert' for the production of the expert report on the quality dossier. Experts should be appropriately qualified and independent. Experts in Anthroposophical medicine should be acceptable for those products.

Agency Comments

In the absence of quality standards from officially recognised pharmacopoeias, applicant's may set 'in-house' specifications justified by suitable data. The acceptability of any expert is depend on their qualifications and experience in the designated area.

Safety

There was overall support for the safety proposals outlined in paragraphs 23-27 of the MLX. There was specific support for the publication of a list of stocks that the MHRA considered to be toxic – in respect of which applicants will need to supply additional safety data.

In relation to paragraph 26, some consultees sought clarification on what constituted an 'expert' for the production of the expert report on the safety data. Anthroposophical experts should be acceptable for those products.

Agency Comments

The acceptability of any expert is depend on their qualifications and experience in the designated area.

Efficacy – see below

Legal Status

A number of existing anthroposophic medicines are available on a Pharmacy-Only basis, with the intervention of a counter prescribing pharmacist – there was support for retaining these products as Pharmacy-Only.

Agency Comment

Legal status will be considered during the PLR review.

Labelling and product literature

Consultees supported labelling that is clear and helpful to the patient. Many consultees stated that anthroposophic medicines should be adequately labelled as such – perhaps by the inclusion of a simple statement "an anthroposophic medicinal product". A similar case was made for bio-chemical products. Questions were raised about the review of the product literature and whether a fee would be involved. There was support for including the indication on the product literature.

Agency Comment

Labelling must comply with the requirements of the Directive and will be assessed by the Homeopathic Unit. Any additional labelling will be considered on a case by case basis.

Fees

Many consultees provided comments on the fees consultation (MLX 324). There were comments on the relatively high costs reviewing the PLRs – particularly for those companies with upwards of 1000 licenses.

Agency Comment

Further consideration is being given to the issue of fees with respect to the PLR review.

Do you agree with the types of information listed to support the efficacy of homoeopathic products?

There was general support for proposals outlined in paragraphs 28-32, and for the types of information listed to support efficacy at Annex 2. Support for the expanded remit of ABRH, including the provision of advice on efficacy. Some consultees provided additional examples of indications that might be permitted under the NR scheme. For example, it was considered that certain self-help homoeopathic remedies that are suitable for psychiatric conditions should not be excluded. For anthroposophic products, anthroposophic bibliographic data should be accepted. Anthroposophic professionals should be in a position to demonstrate efficacy. In addition to anthroposophic products, bio-chemic tissue salts should be covered by the scheme - provided sufficient data could be verified by bio-chemic practitioners.

There was general opposition to the term 'symptomatic relief of' as it suggests suppression of illness, rather than cure, which is contrary to the principles of homoeopathic philosophy.

Agency Comment

The list of indications appended to the MLX was intended to be examples and is not exhaustive. The indications will be considered during assessment and advice on the acceptability sought from the ABRH where appropriate. Wording on the label must not mislead patients into thinking that the product has had efficacy proven by clinical trials.

Do you agree that Option 4 is the best way to proceed with PLRs? If not, which option would you prefer, any why?

Option 4 (PLRs which do not 'fit' the newer schemes or where the PLR holder does not wish to re-register their product under theses schemes are renewed and remain in force with the MHRA reviewing the indications that the PLRs are currently licensed for) was the most supported course of action. However, a small number of concerns were raised in relation to the timescale – respondents with a high number of PLRs considered the 5 year transition period too ambitions taking into account the resource input needed from license holders and the MHRA. The review will involve more products than simply the number of PLRs – in many cases each PLR relates to several products. Consultees supported the need for a clear timetable for the review – prioritising more serious indications if necessary

Consultees re-emphasised the need to keep the majority of anthroposophic medicines as PLRs if they are not eligible for the NRS. It was thought that any compulsory variation of PLRs should be undertaken with ABRH, rather than CSM input. The ABRH would need specific anthroposophic expertise if it is tasked with reviewing those products under PLR. Questions were raised about plans to re-label reviewed PLRs.

Agency Comment

A review period of 7 years is recommended for PLRs, based on the fact that there is a 7 year transition period for herbals. Current membership of the ABRH includes anthroposophic expertise. Labelling for reviewed PLRs should comply with current labelling requirements to ensure consistency across the market.

Do you agree with the proposals to only permit indications for minor self-limiting conditions under the scheme?

There was overall agreement to the proposals to only permit indications for self-limiting conditions. There were also a small number of suggested additions to the list of examples provided in the consultation document.

Agency Comment

Noted

Do you agree with the expanded remit of the ABRH?

There was widespread support for the expansion of the remit of the ABRH. There were a small number of comments on the representation on the committee – some consultees supporting anthroposophic expertise. There was also support for including a nursing representative, as training in homoeopathy for registered nurses now involves prescribing homoeopathic remedies. There was support for applying the special arrangements for expert groups to the ABRH. ABRH should set the standard for 'serious conditions'.

Agency Comment

Noted.

Conclusion and agreed way forward

That the new National Rules Scheme should be implemented on 1st September 06 and all PLRs be reviewed over a 7-year period.

ANNEX B TO THE FULL RIA

Detailed Implementation and Delivery Plan

Delivery objectives and outcomes

The objective of this measure is to address the current inconsistencies in the way that homoeopathic medicinal products are marketed in the UK in order to create a level playing field. This will be achieved by introducing a National Rules Scheme (NR scheme), which will enable homeopathic products to be marketed with limited indications, in line with current Product Licenses of Right (PLRs).

Success criteria

The introduction of the NR scheme will be judged to be a success if there is a sufficient uptake of the new Scheme by homoeopathic companies. In the light of the approximate numbers of homoeopathic products on the market (Simplified Scheme + PLR), in the region of 100 applications under the new scheme would be considered a success.

Consultation

Both informal and external consultation has taken place with the homoeopathic sector. The public consultation (MLX 312 at www.mhra.gov.uk) produced 32 responses, including replies from homoeopathics manufacturers, trade associations, professional bodies and consumer/patients organisations, and the general public. The consultation included information on the intended delivery of the measures, including the launch date of the NR scheme, and the timescale for reviewing existing PLRs. Both dates were revised, partly due to the comments received from consultees.

Key Milestones

Guidance on the NR scheme will be placed on the MHRA website by mid/late August 06. The NR scheme is due to be launched on 1st September 06. In the early stages of the scheme, we intend working closely with companies wishing to make applications to ensure that they have the correct documentation in place. The remit of the ABRH will have been expanded by 1st September 06. The review of PLRs will begin on 1st September 06 and will take up to 7 years. The majority of PLRs are held by two companies – Nelsons and Weleda – and it is intended to meet with both companies individually to establish a mutually acceptable review programme.

Risk assessment and management

Failing to implement the NR scheme by 1st September 06 could be considered a risk, but this will be managed by good project planning and close working within the MHRA and DH. There are risk associated with failing to review the PLRs within the intended 7 years is that products may continue to be marketed with inappropriate indications.

Bodies involved in implementation

The MHRA is responsible for implementing these measures, with specialist input from Department of Health solicitors and parliamentary officials. An MHRA project group meets regularly to review key milestones. All those involved in the introduction of the NR scheme

are fully engaged in the implementation process. The Advisory Board on the Registration of Homoeopathic Products will be extended to provide advice on the safety, quality and efficacy of products for which an assessment under the NR scheme is underway or a licence has been granted.

Resource requirements and costs

MHRA has developed an internal project plan, which outlines the time needed to complete each stage of the implementation phase. The project group reviews the project plan at its meetings. A Complementary Health Team is being established to carry out the assessment of applications under the NR scheme from 1st September 06. The ongoing costs associated with this new team will be fully recouped via fees paid to the MHRA for handling NR scheme applications. There are no costs associated with expanding the remit of the ABRH.

Enforcement & sanctions

The MHRA's existing inspection and enforcement capabilities will be extended to cover the new activities introduced by this scheme.

Communications strategy

The MHRA is engaging with stakeholders on an ongoing basis, and intends to publish guidance on the new scheme by mid/late August 06 at the latest. The MHRA meets with the British Association of Homoeopathic Manufacturers at least yearly, and with individual companies on an ad-hoc basis. We anticipate meeting with companies on a more regular basis in the short term so we can progress the review in a mutually acceptable manner.

Further information

Further information on the implementation of the NR scheme will be made available on the MHRA's website at www.mhra.gov.uk as the delivery phase progresses. Guidance on the new scheme will also be published on the site when developed.