Gurley, Sheron

From: Darbyshire, Michael
Sent: 09 August 2005 10:58
To: Kaye, Andrew
Cc: Harris, Sue
Subject: FW: Response from The Pharmaceutical Society of Northern Ireland on Consultation Document MLX 312 with Respect to the Licensing of Homoeopathics (2)

Andrew - one for the log
Michael

From: Donna Pullan [mailto:Donna.Pullan@psni.org.uk]
Sent: 09 August 2005 10:59
To: Darbyshire, Michael
Subject: Response from The Pharmaceutical Society of Northern Ireland on Consultation Document MLX 312 with Respect to the Licensing of Homoeopathics (2)

for your information.

Regards.

Donna

Response from The Pharmaceutical Society of Northern Ireland on **Consultation Document MLX 312** with Respect to the Licensing of Homoeopathics: Proposals for new National Rules

Questions posed on page 12 of document

- Do you agree with the basic proposals for the National Rules Scheme? Yes the scheme seems appropriate.
- Do you agree with the types of information listed to support the efficacy of homoeopathic products? Information is reasonable given that products cannot be evaluated in the same way as other medicines.
- Do you agree that Option 4 is the best way to proceed with PLRs? On balance this would be the most appropriate option, to enable products that currently have a PLR to remain available until reviewed.
- Do you agree with the proposals to only permit indications for minor self-limiting conditions under the scheme? Yes, this restriction is important, as there is insufficient data available to warrant the use of homoeopathics in more serious diseases.
- Do you agree with the expanded remit of the ABRH? Yes it would appear reasonable to make use of their expertise in this area.

(2)

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Royal College of Obstetricians and Gynaecologists

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13 August 2005

Michael Darbyshire
MHRA (Policy Projects Group)
16th Floor, Market Tower
1 Nine Elms Lane
London SW8 5NQ

Our reference: PBS/jh
Your reference: MLX 312

Dear Mr Darbyshire,

Re: Licensing of Homeopathics

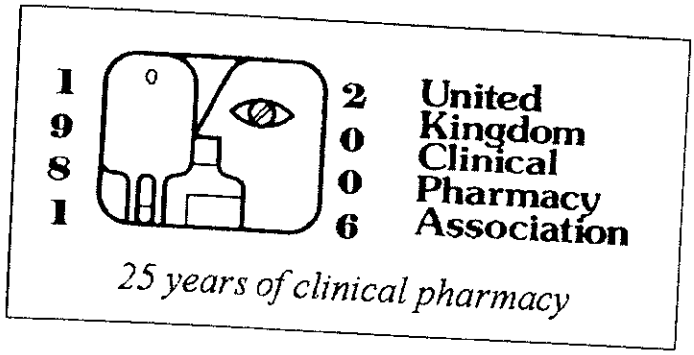
Because of the current inconsistencies in the way that homeopathic products are marketed in the UK we believe that option 4 given in Annex 5 is a sensible way forward.

With regard to Annex 2 giving examples of indications that might be permitted under the National Rules Scheme, we are somewhat concerned at Item 5 which refers to symptomatic relief of infections including fungal diseases. We would have some concerns with regard to vulval fungal conditions as allergic reactions particularly to the excipient are common.

Yours sincerely

Peter Bowen-Simpkins
Honorary Treasurer

(3)



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22.5.2005

Reply to consultation document MLX312 from the MHRA.

The above consultation document relates to the licensing of homeopathic medicines.

The UKCPA supports the principles of the review of license of right and also the extension of the remit of the Advisory Board on the registration of homeopathic products (ABRH).

Pharmacists are very keen to see reduction of risk to patients from all medicines. The proposals will add scrutiny to the safety and effectiveness of this type of product and will thus enhance patient safety.

Graeme Hall
Professional Secretary

United Kingdom Clinical Pharmacy Association
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(6)

RCPSG

PVK/fjf

24 August 2005

Mr Michael Darbyshire
Medicines and Healthcare Products Regulatory Agency
16th Floor, Market Towers
1 Nine Elms Lane
London
SW8 5NQ

Dear Mr Darbyshire

MLX 312
Licensing of homeopathics: Proposals for a new national rules scheme, for a review of product licences of right and to expand the remit of the advisory board on the registration of homeopathic products (ABRH)

Thank you for asking College to comment on the above consultation document.

The Royal College of Physicians and Surgeons of Glasgow is happy to support this initiative.

Yours sincerely

pp **Dr P V Knight, FRCPGlasg**
Honorary Secretary

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Fellowship Support Unit

Our Ref: JSAC/lhl

1 September 2005

Mr Michael Darbyshire
Policy Projects Group
MHRA
16th Floor
Market Towers
1 Nine Elms Lane
LONDON SW8 5NQ

Dear Mr Darbyshire

Consultation Letter MLX 312: Licensing of Homeopathics - Proposals for a New National Rules Scheme, for a Review of Product Licences of Right and to Expand the Remit of the Advisory Board on the Registration of Homeopathic Products

I refer to your letter dated 21 June 2005 requesting comments on *Consultation Letter MLX 312.* I am pleased to enclose the comments of the Royal College of Physicians of Edinburgh.

Please note that these comments have already been sent to you by e-mail.

Yours sincerely

John S A Collins MD FRCP Edin
Secretary

COMMENTS ON

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

Consultation Letter MLX 312: Licensing of Homeopathics - Proposals for a New National Rules Scheme, for a Review of Product Licences of Right and to Expand the Remit of the Advisory Board on the Registration of Homeopathic Products (ABRH)

The Royal College of Physicians of Edinburgh is pleased to respond to the Medicines and Healthcare Products Regulatory Agency on *Consultation Letter MLX 312* on the licensing of Homeopathics.

A national rules scheme is proposed for homeopathic medicines. It would exist in parallel with the simplified scheme and presumably result in removal of the product licences of right which is needed. In essence, the National Rules Scheme would be similar to a full marketing authorisation except for the requirement to demonstrate efficacy.

Efficacy would not be supported by trial data but bibliographic evidence that the product has been used in the indications sought. It would be "sufficient to demonstrate that homeopathic practitioners would accept the efficacy of the product for those indications" (page 9). The exemption from demonstrating efficacy originally established under the simplified scheme and proposed in the national rules scheme potentially establishes double standards which could be counterproductive for effective healthcare. The impact of this is minimised by allowing only "minor indications". Yet these minor indications are far from straightforward, and headache or back pain could well be due to a major underlying illness ie major condition.

1 We broadly agree with accepting Option 4.

2 Under the circumstances, the rules would be broadly acceptable. Clearly, a judgement is needed as to what constitutes a minor condition. There is also the issue as to the *length of time* for which a product can be used without some sort of review (in case the symptoms for which the product is being used, eg headache, are indicative of a serious condition). The MHRA may wish to build this into their thinking.

3 We think the basic proposals of the National Rules Scheme are reasonable.

All College responses are published on the College website www.rcpe.ac.uk.

Further copies of this response are available from Lesley Lockhart (tel: 0131 225 7324 ext 608 or email: l.lockhart@rcpe.ac.uk)

1 September 2005

(15)

THE ROYAL COLLEGE OF RADIOLOGISTS

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LONDON W1B 1JQ

From the Office of the President
Professor Janet Husband, OBE FMedSci FRCP PRCR

7th September 2005

Mr Michael Darbyshire
MHRA (Policy Projects Group)
16th Floor
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Dear Mr Darbyshire

The Licensing of Homeopathics: Proposals for a New National Rules Scheme, for Review of Product Licences of Right and to Expand the Remit of the Advisory Board on the Registration of Homeopathic Products (ABRH) - consultation letter MLX312.

We are pleased to offer comments on these proposals and feel these proposals are a very important step forward. We are in agreement with all five bullet points on p 12 para 44, page12 and strongly support the National Rules Scheme and the types of information listed to support the efficacy of homeopathic products

We agree that option 4 is the best and also agree with the proposals to only permit indications for minor self-limiting conditions. We strongly support the expanded remit of the ABRH. We feel that these proposals should correct the anomalies and inconsistencies of previous licensing regulations. The MHRA's commitment to review the PLR with more serious indications is also very important, given the lack of scientifically-based evidence about possible adverse side effects. As with all medicines, patient safety should be the main criterion, and this will apply to the efficacy and high quality of homeopathic products."

We believe opting for the National Rules Scheme in this case is sensible. There is always a cultural dimension in attitudes to medication generally and to "alternative" therapies in particular. This Scheme gives the ABRH sufficient flexibility to take account of the history and attitudes of the UK in respect of homeopathic products and practices while also ensuring patient safety. We suggest that the National Rules Scheme will also be welcome because there has been so much adverse publicity

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associated with "blanket" bans on familiar UK products (particularly food products) by the EEC.

Specific Comments

The document could be clearer – for example page 6 para 11: *"The procedure is regarded as simplified because there is no requirement for data to demonstrate efficacy (there are no indications) and because the eligibility criteria confer a certain reassurance on safety, so that the data requirements on safety are usually minimal."*

In particular, the Summary on page 1 is cryptic for an introduction to the present situation. We would recommend expanding it on along the lines of the clearer summary on pages 31-32 under 2: Purpose and Intended Effect of the Measure – 2:1 Objective and 2:2 Background.

Does the "amateur reader" need an explanation of what "indications" are? This is explained in parenthesis later in the document (see quote above) but perhaps is needed at the beginning.

Outline of Data Requirements: para 21 "Quality" and paras 23, 24 and 25 "Safety"
We are concerned about the qualifications and independence of the "experts" who are required to report on e.g. the "quality dossier" (para 22), "safety data" (para 26) etc.

We strongly support the proposal that "the onus for supporting the safety of the product will lie with the applicant".

The proposal that "the Agency should prepare and publicise a list of the stocks considered to be toxic" is welcome. We suggest that this and other information on toxicity *"should be freely available to the public in a format that is comprehensible to all".*

Advisory Board, para 18, page 8
We agree with cutting out appeals to the Medicines Commission. All reviewing bodies must be independent.

Outline of Data Requirements: Efficacy para 28. page 9.
If this a disputed matter, is it sufficient/acceptable to require that information provided "should be in the form of proving, excerpts from homeopathic *material medica* or other bibliographic data and *should be sufficient to demonstrate that homeopathic practitioners would accept the efficacy of the product for those indications".* Apart from being badly expressed, this requirement entails a generally agreed definition of a (reliable) homeopathic practitioner. We assume there is a licensing system but qualifications should be emphasised.

We are concerned about Product Licences of Right page 11, para 40 which states that *"an individual practitioner's ability to supply a product for whatever he feels fit, under his own responsibility, would not be affected by the proposals".* This is poorly expressed but should it also make clear that ALL individual practitioners should advise patients and prescribe according to the recommendations of the ABRH on product safety etc. Otherwise, this leaves a loophole for practitioners to recommend substances to patients that

may be available (over the internet for example) but are not licensed, and the patient may not be aware that he/she is taking a risk.

Annex 1: Selected Text from the Directive, page 14 Article 16 para 2
We believe an added merit of the requirement that Member States "shall notify the Commission of the specific rules in force" is that we shall all learn from each other and there is likely to be a healthy, continuing debate on these matters. Another very good example is the requirement for consultation between Member States occurs in Article 65 p 20.

The detailed requirements for labelling, packaging etc look admirably comprehensive and clear. It will be interesting to see how the industry, practitioners and the general public regard them.

Annex 1 p 19 Article 63
This section raises the subject of languages. We suggest that information on herbal products *should be available for people of different ethnic languages and that* consideration should be given to supplying information *for people with disabilities e.g. eyesight, learning disabilities, the elderly etc.*

Other Issues in Annex 1
We think careful consideration has been given to the cost of compliance (reasonable); to consultation with small businesses; to the impact on businesses, small and large; to the assessment of competition; to enforcement and sanctions; and to the issue of fairness.

We think the procedures for Monitoring and Review (page 38, para 11) are very sound.

Note on Training
We suggest that consideration should be given *to who will be involved in training people involved in healthcare (GPs, pharmacists, senior nurse specialists, hospital consultants etc), to the resource implications, and the need to overcome the ignorance and prejudice against the use of herbal medicines by doctors. .*

We hope these comments are of help.

Yours sincerely

Janet Husband

Prof Janet Husband OBE FmedSci FRCP PRCR
President
janet_husband@rcr.ac.uk

(16)

Kaye, Andrew

From: Darbyshire, Michael
Sent: 12 September 2005 09:55
To: Kaye, Andrew
Cc: Harris, Sue
Subject: FW: MLX 312

-----Original Message-----
From: Wallace, James [mailto:james.wallace@yorkhill.scot.nhs.uk]
Sent: 09 September 2005 12:34
To: Darbyshire, Michael
Subject: FW: MLX 312

> Dear [Wallace, James] Michael ,
> [Wallace, James] The paediatric chief Pharmacists
> group have considered the proposals in MLX 312 and h [Wallace, James]
> ave the following comments
>
> 1 We agree with the basic proposals for the National Rules Scheme
for licensing homeopathic products.
> 2 We agree that the types of information listed could form the
basis of support for the efficacy of homeopathic medicines.
> We are pleased to note that labelling on the outer packaging will
indicate wether or not the product is suitable for use in babies or children.
> 3 We support option four as the best way to proceed with PLR's
> 4 We agree with the proposals to limit the indications permitted
under the scheme.
> 5 We support the expanded remit of the ABRH.
> best wishes
> James wallace
> [Wallace, James] Director of
> pharmacy
>
Our reply is not confidential.

19

Royal College of Nursing

The voice of nursing in the UK

Royal College of Nursing
Professional Nursing Department
20 Cavendish Square
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Celia Manson (Miss)
Adviser in Nursing Practice

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Email celia.manson@rcn.org.uk

Michael Darbyshire
MHRA (Policy Projects Group)
6th Floor, Market Towers
Nine Elms Lane
London SW8 5NQ

8 September 2005

Dear Mr Darbyshire

Consultation Letter MLX 312
Licensing of Homeopathics: Proposals for a new national rules scheme, for a review of product licences of right and to expand the remit of the advisory board on the registration of homeopathic products (ABRH)

With a membership of over a third of a million, the Royal College of Nursing (RCN) is the largest professional association and union of nursing staff and students in the UK. As such, it is an influential voice for nursing at home and aboard. The RCN promotes nursing interests on a wide range of issues by working closely with the Government, parliament, unions, professional bodies and voluntary organisations.

The RCN welcomes the opportunity to comment on these proposals. The RCN considers that the approach of removing anomalies and permitting some previously prohibited products onto the market is sensible. The RCN welcomes the proposal to print indications for use on over the counter homeopathic products.

The RCN considers it desirable that any other homeopathic treatment will be accessed via consultation with a qualified homeopath. However, the RCN has concerns that access to such treatments may be limited to those able to afford to pay for consultations. The RCN acknowledges the availability of homeopathic treatment within the NHS. However, it has concerns that this is patchy in provision and is not consistently available across the UK.

I attach more detailed comments on the proposal, prepared by a member of the RCN who is both a registered nurse and a member of the Faculty of Homeopathy.

With best wishes

Yours sincerely,

Celia Manson
Nurse Adviser

Annex 4

RESPONSE TO CONSULTATION LETTER MLX 312

LICENSING OF HOMEOPATHICS: PROPOSALS FOR A NEW NATIONAL RULES SCHEME

Please complete the proforma and return to Michael Darbyshire MHRA (Policy Projects Group) 16th Floor, Market Towers. 1 Nine Elms Lane, London SW8 5NQ by 13th September 2005. You may also e-mail your response to michael.darbyshire@mhra.gsi.gov.uk

Name: CELIA MANSON (NURSE ADVISER)

Company name: ROYAL COLLEGE OF NURSING

We have the following comments to make on proposals for the Homeopathic National Rules Scheme:
(Please use additional sheets as required)

Consultation Letter MLX 312

Comments on Licensing Of Homeopathics: Proposals For A New National Rules Scheme And For A Review Of Product Licenses Of Right And To Expand The Remit Of The Advisory Board On The Registration Of Homeopathic Products (ABRH)

Paragraphs:

3. Currently homeopathic products granted certificates under Simplified Scheme must not detail any specific therapeutic indication.
Comment: This limits the marketing applications and the accessibility of certain homeopathic products licensed under this scheme.

5. The proposals will correct the anomalous situation of inconsistencies arising in homeopathic products relating to when they were licensed.
Comment: They will also change the current situation in that new homeopathic products could be licensed with indications that exclude serious disease.

6.MHRA would review PLR's with more serious indications
Comment: This ensures a safety and quality assurance process in situ for the public

Advisory Board on the Registration of Homeopathic Products
17. It is proposed to expand the remit of the Committee to include advice with respect to safety, quality and efficacy on any homeopathic medicinal product for human use in respect of which a marketing authorization could be granted under Article 16.2 of directive 2001/83/EC and on homeopathic medicinal products with PLR's.
Comment: The expansion of the remit of the ABRH is necessary under the proposed National Rules Scheme with the marketing of specific homeopathic products for minor self limiting indications and review of homeopathic medicinal products with PLR'.

19. It is not proposed to change the membership of the ABRH.
Comment: The membership of the ABRH should be changed to include a representative from the nursing profession as education and training in homeopathy for registered nurses now involves the prescribing of homeopathic medicines.

Data requirements

Quality assurance
21. Additional in-process and finished product controls are likely to be needed to verify the content and uniformity of the homeopathic stock in the dosage form
Comment: Quality assurance measures is reassuring and necessary for professionals practising homeopathy and the public accessing this treatment

Safety

24. In the case of homeopathic products derived from toxicological substances the Agency will prepare and publicise a list of the stocks considered to be toxic with applicants supplying additional data to support the safety of products.
Comment: This information is important for registered health professionals when implementing regulations regarding the prescribing of homeopathic medicines

25. 26. 27 In all cases the applicant will still require to supply data to support the safety of the product and to justify the proposed product labeling and product literature. Safety of product will be maintained for the duration of authorization with Periodic Safety Update Reports and electronic reporting of adverse reactions.
Comment: This is an essential process and especially when the situation arises when a new homeopathic products is introduced in the proposed National Rules Scheme

Efficacy

28. Applicants can demonstrate efficacy in indications sought from provings, materia medica, and other bibliographic data.
Comment: The evidence must be sufficient to demonstrate that the ABRH would accept efficacy of the product for those indications

29. Proposal that products will only be permitted to have indications for minor self-limiting conditions.
Comment: The ABRH should advise in this situation

31/32. Additional safety measures are in place to ensure that any applicant wishing to claim indications not admissible under these Rules must apply for full marketing authorisation supported by evidence of efficacy from controlled trials.
Comment: For applicants claiming indications not listed under minor self-limiting conditions then more rigorous clinical data is required which is a safety measure to protect the public

Legal Status

33. All parenteral products continue to be Prescription only Medicines (POM).
Comment: This situation should continually be reviewed by the ABRH.

Proposal for Option 4

PLR's are renewed with MHRA reviewing indications licensed for especially those licensed for more serious indications. Anthroposophical medicines will be retained on market as PLR's without indications beneficial for anthroposophical practice. This would not be the case with option 2. Bach Flower Remedies might also come into this category. Option 4 allows for new homeopathic products to be licensed, which are not eligible for Simplified Registration Scheme and therefore of a benefit to patients and health

professionals practising homeopathy Option 3 would incur an increased workload as well as cost to pharmaceutical companies.

39. Legislation enabling products to be labeled with indications is considered to be of benefit to patients.
Comment: These indications are likely to target the main minor indication for the specific remedy being marketed. Additional information regarding the minor indication and remedy could be supplied in information leaflets for the general public.

41. Review of indications that PLR's are licensed for in particular more serious conditions requiring constant clinical supervision.
Comment: It is not definite how many homeopathic remedies would fit the criteria.

42. Compulsory variation of PLR"s as a result of not being reassured regarding the continuing use of a homeopathic product for more serious illnesses. The licensing authority is required to consult an appropriate Section 4 advisory committee before proposing a compulsory variation of license.
Comment: With the proposed expansion of the remit of the ABRH, PLR's would be referred to ABRH rather than CSM, which would provide expert knowledge in the field of homeopathy and most appropriate in this situation

(29)

Annex 4

RESPONSE TO CONSULTATION LETTER MLX 312

LICENSING OF HOMEOPATHICS: PROPOSALS FOR A NEW NATIONAL RULES SCHEME

Please complete the proforma and return to Michael Darbyshire MHRA (Policy Projects Group) 16th Floor, Market Towers. 1 Nine Elms Lane, London SW8 5NQ by 13th September 2005. You may also e-mail your response to michael.darbyshire@mhra.gsi.gov.uk

Name: ~~BRITISH PHARMACOLOGICAL SOCIETY~~ SARAH-JANE STAGG

Company name: BRITISH PHARMACOLOGICAL SOCIETY

We have the following comments to make on proposals for the Homeopathic National Rules Scheme:
(Please use additional sheets as required)

We have no comments to make.

7/9/05

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(23)

Royal College of General Practitioners

Dr. Maureen Baker CBE DM FRCGP
Honorary Secretary of Council

Mr Michael Darbyshire
MHRA (Policy Projects Group)
16th Floor, Market Towers
1 Nine Elms Lane
London SW8 5NQ

For enquiries please contact: Dr Maureen Baker

E.mail: housec@rcgp.org.uk
Direct line: 020 7344 3123
Fax: 020 7589 3145

13 September 2005

Dear Mr Darbyshire

MHRA Consultation Letter MLX 312 – Licensing of Homeopathics

1. The College welcomes the opportunity to comment on the MHRA's proposals concerning the homeopathic matters set out in consultation letter MLX 312.

2. The Royal College of General Practitioners is the largest membership organisation in the United Kingdom solely for GPs. It aims to encourage and maintain the highest standards of general medical practice and to act as the "voice" of GPs on issues concerned with education; training; research; and clinical standards. Founded in 1952, the RCGP has over 22,500 members who are committed to improving patient care, developing their own skills and promoting general practice as a discipline.

3. Because of the existing situation with regard to the marketing of homeopathic remedies, as described in consultation letter MLX 312, where only Product License of Right (PLR) allowed indications to be cited, many homeopathic products could not be marketed for specific indications. The current proposal is to use new EU regulations to *'introduce ... specific rules.. in accordance with the principles and characteristics of homeopathy as practised in that Member State'* to, in effect, license new or existing homeopathic medicines with indications on the basis of no rigorous scientific data on effectiveness or safety but assurances mainly on quality of production. Whilst this has attractions for those with faith in homeopathy, a more scientific alternative would have been to withdraw the right for any of them to be able to state an indication and be marketed on that basis unless, of course, there was proven evidence of effectiveness. That said, if the MHRA is intent on following through its proposals we agree that the approach it is suggesting is not an unacceptable one provided MHRA (and the Advisory Board on the Registration of Homoeopathic Products – ABRH) are content that the public are fully protected.

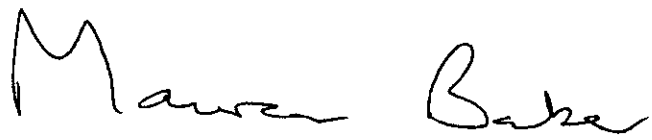
4. We would support the concept of the introduction of fees for herbal and homeopathic substances as this should ensure that quality control in their production is assured and that only reputable sources would be used for the production of these products.

5. Looking at the detail of the proposals we ask how homeopathic remedies can be assessed for safety and quality, as they are only water containing "vibrations" from many products at infinite dilution. It is impossible to identify whether a product has been subject to the base constituent or is purely water taken from a tap. Some of these may be Pharmacy only preparations which would seem to be a remarkable situation for what is tantamount to the sale of water.

6. A further detailed comment we have concerns the inclusion or otherwise of herbal teas. Both coffee and traditional tea contain drugs. Would these be included within the scope of these proposals or would they be specifically excluded? And what would be the situation of other 'fruit' teas such as camomile – some of which are reputed to have medicinal properties. Are these to be excluded or included within the proposals and if not – why not – and if so – why not other infused drinks?

7. I acknowledge the contributions of Dr Graham Archard, Dr Tony Crockett and Dr Ross Taylor towards the above comments. While contributing to this response, it cannot be assumed that those named all necessarily agree with all of the above comments.

Yours sincerely



Dr Maureen Baker
Honorary Secretary of Council

PATRON
HRH The Princess Royal

Royal College of Paediatrics and Child Health

50 Hallam Street, London W1W 6DE

Telephone: (020) 7 307 5600 Fax: (020) 7 307 5601 E-mail: enquiries@rcpch.ac.uk

From the Registrar
Dr Sheila Shribman

13 September 2005

Ref: 079/05

Mr Michael Derbyshire
MHRA (Policy Projects Group)
16th Floor
Market Towers
1 Nine Elms Lane
London
SW8 5NQ

Dear Mr Derbyshire

Consultation Letter MLX 312: Licensing of Homeopathics

The Royal College of Paediatrics and Child Health welcomes the opportunity to submit comments on the above consultation document. The College's response was developed following consultation with the Joint RCPCH/NPPG Medicines Committee, chaired by Mr James Wallace.

We have the following comments:

1. We agree with the basic proposals for the National Rules Scheme for licensing homeopathic products.
2. We agree that the types of information listed could form the basis of support for the efficacy of homeopathic medicines. We are pleased to note that labelling on the outer packaging will indicate whether or not the product is suitable for use in babies or children.
3. We support option four as the best way to proceed with PLRs.
4. We agree with the proposals to limit the indications permitted under the scheme.
5. We support the expanded remit of the ABRH.

I hope this is helpful. Please let me know if we can be of any further assistance.

Yours sincerely

Dr Sheila Shribman

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Setting higher medical standards

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Mr Michael Darbyshire
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16th Floor
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1 Nine Elms Lane
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From The Registrar
Rodney Burnham MD FRCP

Telephone extension 235
Direct facsimile +44(0) 20 7487 5218
rodney.burnham@rcplondon.ac.uk

13 September 2005

Dear Mr Darbyshire

Consultation Document: MLX 312
Licensing of Homeopathics: Proposals for a new national rules scheme

The Royal College of Physicians welcomes the opportunity to comment on the above consultation document. We wish to make the following points.

- The use of homeopathic medicines is not supported by many physicians, who strive for robust evidence of efficacy, safety and quality, most frequently though Randomised Controlled Trials with suitable placebo or positive controls.

- However, homeopathic products are and will continue to be widely used, and their regulation is to be welcomed, provided it is not misconstrued by the public as official endorsement of unfounded claims of efficacy. The use of homeopathic products in certain, mild self limiting conditions is often preferable to the use of 'real' medicines which carry the risk of adverse drug reactions; the placebo effect is potentially helpful, and should not be discouraged in the case of harmless but comforting measures (eg massage) unless it is at the expense of actually misleading patients. In this regard it is important that unsubstantiated or false claims of efficacy are absolutely prohibited. Factually correct statements in the product information or labelling regarding traditional use along the lines "product X has been used for many years in treating muscular discomfort" should be compulsorily qualified by a statement to be agreed with the regulatory agency along the lines of "but there is no evidence that it is more effective than dummy treatment".

- Two major risks with the use of homeopathic medicines are:
  a) If a serious and treatable disease has been misdiagnosed
  b) Inappropriate use of a homeopathic remedy when the diagnosis is correct
  In (b) it might be argued that even if safety was not a concern, if the product is not effective then the risk/benefit balance may be in the wrong direction. An internet site advertising a homeopathic remedy for both the treatment and prophylaxis of malaria (!) provides a recent example. This raises the spectre of internet advertising and advertising in general which is not mentioned in the MLX. No doubt the ABRH will be attending to this.

- The College could not support any option which did not make it mandatory that the indication must be stated on the product and accompanying literature.

- We would strongly support that the ABRH sets the standard for 'serious conditions' and rules on use of homeopathic products against the list. This will not be easy.

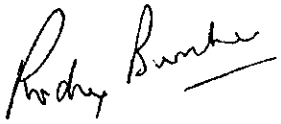
- We would prefer to see all homeopaths brought under the New Rules Scheme, but realise the burden that would place on industry, the MHRA and the ABRH. Therefore we would support the preferred option 4.

- In answer to the specific proposals:
  a) We support the introduction of the National Rules Scheme
  b) Efficacy. There is no question that the prospective RCT provides the best evidence of efficacy. In most circumstances, this will not be available for homeopathic products. It is not clear what 'provings' are in para 28.

- In response to the questions posed in para 44:
  Q2 It is hard to believe that any practitioner would accept bibliographic data unless the efficacy evidence was robust. Thus, 'efficacy' would only be acceptable for minor, self-limiting conditions where a placebo response is acceptable. But, as stated before, the risk of misdiagnosis remains. Thus, in Annex 2, there are a number of diseases/conditions that would not be acceptable eg dysmenorrhoea, psoriasis, local treatments of the eye/ear.
  Q3 As stated above we agree with option 4
  Q4 Yes: Self-limiting conditions, rigorously defined
  Q5 Yes

This response may be made freely available.

Yours sincerely



Dr Rodney Burnham
Registrar

Kaye, Andrew

From: Darbyshire, Michael
Sent: 13 September 2005 15:25
To: Kaye, Andrew
Cc: Harris, Sue
Subject: FW: Licensing of Homeopathics:
Attachments: LICENSING OF HOMEPATHICS-response.doc

From: Sue Ward [mailto:sward@eczema.org]
Sent: 13 September 2005 15:30
To: Darbyshire, Michael
Subject: Licensing of Homeopathics:

Dear Michael,

I attach a response from the National Eczema Society to consultation paper.

Regards

Sue Ward
Information & Education Manager
National Eczema Society
sward@eczema.org

LICENSING OF HOMEPATHICS: PROPOSALS FOR A NEW NATIONAL RULES SCHEME.

RESPONSE FROM THE NATIONAL ECZEMA SOCIETY

The National Eczema has read with interest the consultation paper sent to them by the MHRA and we would support the MHRA proposals as follows:

The Society in general agrees with the basic proposals for a National Rules Scheme and the proposals for the types of information listed to support the efficacy of homeopathic products. However, the Society is concerned that patients should be given some information about the lack of rigorous clinical trials, even for minor, self limiting conditions. Without such information there is a danger that patients will assume that rigorous trials have been carried out simply because the products are registered under the National Rules scheme.

We agree that the current proposals should permit only indications for minor self-limiting conditions under the scheme.

We support the expanded remit of the Advisory Board on the Registration of Homeopathic Products.

Sue Ward
Information & Education Manager
On behalf of the National Eczema Society

Kaye, Andrew

From: Darbyshire, Michael
Sent: 15 September 2005 09:59
To: Kaye, Andrew
Cc: Harris, Sue
Subject: FW: MLX 312 consultation
Importance: High

From: Angela Johnson [mailto:angela.johnson@rpsgb.org]
Sent: 14 September 2005 16:58
To: Darbyshire, Michael
Subject: MLX 312 consultation
Importance: High

Dear Mr Darbyshire,

Apologies for the delay in responding.

Please note that the Royal Pharmaceutical Societyy of Great Britain will not be commenting on the above.

Yours sincerely

Angela Johnson
Corporate and Strategic Development Directorate
Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street
London SE1 7JN
TEL: 020 7572 2205/Voicemail
FAX: 020 7572 2500
Email: angela.johnson@rpsgb.org

Kaye, Andrew

From: Darbyshire, Michael
Sent: 15 September 2005 13:29
To: Kaye, Andrew
Cc: Harris, Sue
Subject: FW: licensing of homeopathics
Attachments: Licensing of homeopathics.doc

From: Jane Virgoe (BVA) [mailto:JaneV@bva.co.uk]
Sent: 15 September 2005 12:17
To: Darbyshire, Michael
Subject: licensing of homeopathics

Dear Mr Darbyshire

Please find attached the British Veterinary Association's response to the above consultation. I am sorry for this slight delay in its submission but hope that our views may still be taken into account.

With kind regards

Jane Virgoe

Jane Virgoe
Policy Development Manager
BVA
7 Mansfield Street
London
W1G 9NQ

Tel: 020 7636 6541
www.bva.co.uk

Please see http://www.gsi.gov.uk/main/notices/information/gsi-003-2002.pdf for further details.

In case of problems, please call your organisational IT helpdesk

(29)

BRITISH VETERINARY ASSOCIATION

Consultation Response to the MHRA:

1. **Licensing of Homœopathics: proposals for a new national rules scheme and for a review of product licences of right**
2. **Implementation of the Directive on Traditional herbal Medicinal Products: Directive 2004/24/EC**

Introduction:

1. The British Veterinary Association (BVA) is the national representative body for the veterinary profession in the United Kingdom and represents circa 10,000 members. Our chief interest is to protect and promote the interests of the veterinary profession in this country and we therefore take a keen interest in all issues affecting the veterinary profession, be they animal health, animal welfare, public health or employment concerns.

2. The BVA welcomes the opportunity to comment on the above consultations and has consulted with the relevant representative BVA divisions. The response below includes comments from individual members and the following Divisions: the British Small Animal Veterinary Association (BSAVA), the Society of Practising Veterinary Surgeons (SPVS) and the Central Veterinary Society.

Licensing of Homœopathics

Overview:

3. BVA considers the licensing and thus endorsement of homœopathic 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 homœopathic remedies have ever successfully been performed in animals. Wild extrapolation of a disproven human therapeutic modality to animals is therefore an offence to animal welfare.
4. Providing homœopathic remedies with 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.

The concept of 'Indications'

5. It is believed that "indications" will be interpreted as evidence of therapeutic claims, which is a major cause for concern. The grounds for such indications, "bibliographic evidence that the product has been used in the indications sought", are hugely at variance with the rigorous proof of efficacy required for all other newly-licensed medicinal products. Describing claims merely as "indications" appears to be a deliberate attempt to use words that would equate in the mind of the consuming public with a proper therapeutic claim even if, for those in the know, there is a technical difference. The use of such terminology is a tactic much used and abused in the world of alternative medicine and it should be resisted. The idea of generalised "indications" also flies in the face of the homœopathic principle of individualisation that its advocates are supposed to adhere to.

6. The suggestion that such licences should be granted only for indications in which the condition is expected to self-cure is nonsense. The public should be able to expect that licensed medical products are fit for the purpose for which they are sold. This can only be achieved by proper clinical trials and there should be no difference in the principle of proper assessment, no matter what the clinical indication.

Proof of efficacy

7. There is confirmation in the consultation document that there will continue to be no requirement for proof of efficacy of these homœopathic products. The proposal is that a license will be issued if the manufacture of the products is proven to meet certain criteria, and that they have some proof that they have no adverse effect. One of the golden rules of medicine is 'at first do no harm.' If these products are issued with labels which have an authority behind them proving they are 'approved' this could make people raise their expectations of what they can do for them or their pets, and still there is no requirement of proof of efficacy. This is potentially dangerous and misleading for the public.

8. Although it is clear to any diligent enquirer that this category of MHRA licensing does not require proof of efficacy, this is not clear to the general public, in whose minds the existence of such licences implies endorsement and thus implication of efficacy. This misapprehension is commonly fostered and encouraged by homœopathic proponents, who routinely represent the requirement for regulation as evidence that the preparations have significant physiological or pharmacological activity, and the granting of licences as evidence of proven therapeutic effectiveness.

9. BVA supports the view that if the manufacturer wants to claim efficacy for a specific condition then they have to show efficacy and safety data as standard. While accepting that EU regulations require such licensing to some extent, we would urge that the bare minimum be undertaken for EU compliance.

Evidence of physiological or therapeutic effects for homœopathic remedies in animals

10. All controlled trials of homœopathic treatment of veterinary patients (four in total) have shown no effect compared to the placebo control groups. There is no evidence whatsoever of a physiological or therapeutic effect in such patients. Instead, the homœopathic ritual of case-taking and remedy matching appears to influence the owner to perceive the animal's condition in a more favourable light, attributing coincidental recovery to the remedy, and even imagining improvement where none is present. While a positive change in attitude to an illness may arguably be of real benefit to a human patient, such an effect on the owner of an animal patient does not help the animal. However, licensing of homœopathic remedies by bodies such as the MRHA makes it very difficult to argue against the adoption of the practice in veterinary medicine, as the counterargument that since the practice is endorsed by medical regulating bodies it is a respectable and effective branch of medicine is difficult to refute.

11. This is not purely a concern as regards pet animals - the danger is arguably even more serious in farm animal medicine, where homoeopathy is encouraged within the organic farming industry as being free of side-effects and residues. The question of how any preparation can have a physiological effect and yet be absolutely safe as regards adverse reactions or residue concerns never seems to be addressed, and the consequences for animal welfare of denying these patients proven effective medicines is a grave concern.

12. If the homœopathic practitioners claim that each substance has to be used within the advice of a homoeopath who can practice holistic medicine, then the advice on the label should be 'you need to consult your doctor or vet before using this product on a human or an animal'.

Self-medication

13. The suggestion that only the claims for more serious conditions should be further regulated is also dangerous because some people may wait too long before consulting a doctor or a vet and this could have very serious consequences, even fatalities. One example recently involved a client who had been treating her Bulldog for an illness with homœopathic remedies for 6 weeks before she came to a veterinary practice. By that time, the dog was irretrievably ill with Cushings Disease. It was too late for proper medical intervention and the dog died within 2 days.

14. It is sad that normally vets are expected to practice medicine with highly regulated and tested drugs and medical practices, but the lack of requirement of proof of efficacy with homœopathic substances is not stated clearly enough on the labels or in the accompanying literature. This makes the job of the veterinary or medical practitioner in the consulting room more difficult.

15. Although a true Homœopathic Remedy in itself could cause no actual harm to a patient, it seems bizarre that any official endorsement could be given to a product that is so widely believed to be ineffective. The real danger will be that, once an ineffective product has been given tacit approval, the animal's keeper will be encouraged to consider it as an alternative to products which have had to demonstrate effectiveness in order to win a licence. There is a significant risk that the onset of effective treatment will be delayed. There is a fundamental difference between freedom of choice of therapy for people and an animal's inability to choose for itself.

Confirmation of Ingredients

16. If the licensing procedure is implemented as in the proposals there should at least be a requirement for independent confirmation that the "remedy" contains nothing more than the stated ingredients. In the past there have been reports of pharmaceutically active, rogue additives within "homœopathic" products. The public needs to be able to trust that licensed product will at least cause no inadvertant harm. There should also be more control on "home-made" homœopathics. At present there seems to be nothing to stop an individual from making and selling remedies.

Veterinary Homœopathic Regulation:

17. It is interesting to note that there is an EC Directive on Veterinary Homœopathics and that veterinary homœopathic products come under the remit of the ABRH. It would be useful to know whether the ABRH had ever considered a veterinary product and if has any veterinary members. It is suggested that it would be more appropriate for veterinary homœopathics to be assessed by the VPC.

Herbal medicines Consultation:

18. With regards to the consultation on Herbal medicinal products, it is difficult to interpret whether or not compulsory reporting of adverse events will be implemented (Section 4.2 in Annexe A) – it is stated in the consultation document that the relevant section doesn't apply to herbals and that the provision would be helpful in the face of emerging safety issues. BVA believe that it should be compulsory - if a product has therapeutic efficacy then it has potential toxicity that should be reported. There is no mention of veterinary products in the consultation document. If veterinary homœopathic treatments are encompassed within legislation, it is believed that herbal medicines should also be included.

09/09/05