



Medicines and Healthcare products
Regulatory Agency

Safeguarding public health

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To: Interested organisations

2 March 2004

Dear Sir or Madam

CONSULTATION LETTER MLX 299: PROPOSALS FOR THE REFORM OF THE REGULATION OF UNLICENSED HERBAL REMEDIES IN THE UNITED KINGDOM MADE UP TO MEET THE NEEDS OF INDIVIDUAL PATIENTS

1. Please find the attached consultation document MLX 299. You are invited to consider and comment upon the proposals set out in the document including the draft Initial Regulatory Impact Assessment.
2. The consultation document MLX 299 contains:
 - A summary and the background to the proposals
 - The proposals
 - A list of consultation questions
 - A draft Initial Regulatory Impact Assessment (RIA)
 - A reply form.
 - A list of organisations being consulted
3. Should you have any questions regarding the proposals or the conduct of the consultation exercise, please contact Alison Daykin (Tel: 020 7084 2404, Email: alison.daykin@mhra.gsi.gov.uk).
4. Replies should arrive at the MHRA **no later than Monday 7th June 2004**. Please send your replies using the attached form to:

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Yours faithfully

Richard Woodfield
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Consultation document MLX299: Proposals for the reform of the regulation of unlicensed herbal remedies in the United Kingdom made up to meet the needs of individual patients

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MLX 299: Proposals for the reform of the regulation of unlicensed herbal remedies in the United Kingdom made up to meet the needs of individual patients

Summary

1. There are longstanding provisions in UK legislation, principally in Section 12(1) of the Medicines Act 1968, permitting unlicensed herbal remedies to be supplied to individual patients following a face-to-face consultation.
2. The existence of this regime is greatly valued by herbal practitioners and by many members of the public. However, there are widely acknowledged weaknesses in the public health protection afforded by the regulatory regime and a number of safety concerns have arisen as a result. The Government's objective for herbal medicines is that the public should have continuing access to a wide range of safe herbal remedies of acceptable quality with appropriate information about the use of the product.
3. The current regime does not ensure the full delivery of the Government's objective. Potentially, however, three areas of reform could, in combination, deliver major improvements:
 - The proposed Directive on Traditional Herbal Medicinal Products (which the MHRA expects will be formally adopted early in 2004) should give the public improved assurance as to the safety and quality of manufactured over-the-counter (OTC) herbal remedies and systematic information about safe usage of the product.
 - Statutory self-regulation of the herbal medicine profession, the subject of a related consultation by the Department of Health, (*'Regulation of herbal medicine and acupuncture – proposals for statutory regulation'*) should also serve to protect the public and enhance the accountability and standing of the herbal medicine profession.
 - the MHRA's current consultation covers the third limb of these reforms – improved assurances for the public as to the safety and quality of herbal remedies made up to meet individual needs and supplied following face-to-face consultation with a practitioner.

4. Ministers invited the Herbal Medicine Regulatory Working Group (HMRWG), established to make proposals as to the statutory regulation of the herbalist profession, also to recommend any changes needed to medicines legislation to assure the safety and quality of herbal remedies supplied under Section 12(1) of the Medicines Act. The HMRWG made a number of recommendations in its report of September 2003. The MHRA welcomes the Working Group's findings as a good basis for considering regulatory reform in this area.
5. This consultation document sets out a number of outline proposals and ideas for regulatory reform and seeks feedback on a range of questions. There are a number of ways identified to help improve the transparency and clarity of regulation. There is a particular challenge of how to reform the regulatory regime in a way that achieves the necessary improvement in public health protection but is at the same time proportionate. The MHRA is aware that many practitioners run, or are employed by, very small businesses. Views on this issue would be particularly welcome. **In the event that the Government wishes to pursue at least some of the possible reforms outlined in this document, or otherwise raised in the response to consultation, there would be further public consultation on more specific proposals.**
6. A draft initial Regulatory Impact Assessment (RIA) is also attached at **Annex A** Views on the proposals and on the draft initial RIA are invited and **responses should be submitted** to the MHRA using the enclosed reply form at **Annex B** by **Monday 7 June 2004**.

Background

7. In recent years there has been increasing interest on the part of UK consumers and patients in the use of herbal medicines from a number of different herbal traditions, notably western herbal medicine, traditional Chinese medicine (TCM) and Ayurveda. It is clear that many members of the public wish to take responsibility for their own health. This may entail either buying an OTC herbal remedy or to visit a practitioner for advice and supply of a suitable remedy made up to meet their individual needs. This growth has been part of a wider trend of increasing interest in complementary and alternative medicines (CAM) in the developed world.
8. However, expansion in the sector has been accompanied by increased concern internationally on the part of many in the herbal sector, consumer interests, regulatory authorities, health professionals and the scientific community, about the safety and quality of remedies. It has been widely recognised that there is an international trade in herbal products and ingredients of unreliable quality and doubtful provenance. Some of the problems reported, for example, the accidental inclusion of toxic herbs of similar name or appearance to the intended species, reflect clear weaknesses in systems of quality control.

9. In response to this situation the Government set as an objective for herbal medicines that ***the public should have access to a wide range of safe herbal medicines of acceptable quality with appropriate information about the safe use of the product.*** In looking towards the possibility of regulatory reform the MHRA has also set as an objective that ***regulation should follow the principles of good regulation***¹. This latter objective recognises in particular that there are many very small businesses in this part of the herbal sector.
10. In relation to ***manufactured OTC*** herbal remedies the Agency has actively pursued the Government's objectives in European negotiations. It is likely that during the course of this consultation exercise, the proposed European Directive on Traditional Herbal Medicinal Products will be formally adopted. This Directive puts in place a regulatory framework for manufactured traditional herbal medicines. This will assure the public as to the safety and quality of remedies and require systematic information to be given about the safe use of products. In line with the proposed Directive, the MHRA expects that a UK traditional use registration scheme for OTC herbal remedies will be in operation by around the latter part of 2005.
11. The subject of the present consultation is the regulation of ***unlicensed herbal remedies that are supplied, following a one-to-one consultation, to meet the needs of an individual patient.*** This primarily covers unlicensed remedies supplied under Section 12(1) of the Medicines Act 1968 but also includes a number of associated legislative provisions.

The Herbal Medicine Regulatory Working Group

12. The Herbal Medicine Regulatory Working Group (HMRWG) was formed in direct response to the recommendations made in the House of Lords' Select Committee report on Complementary and Alternative Medicine. Its terms of reference were to:
- produce a report which examines the options for achieving the successful statutory regulation of the herbal medicine profession as a whole, and makes recommendations which will form a basis for a wider consultation by the Government and subsequently for the legislation that will enable the statutory regulation of the herbal medicine profession;
 - in the light of these recommendations for the statutory regulation of the profession and the current Medicines and Healthcare products Regulatory Agency (formerly the MCA) review of Section 12(1) of the Medicines Act 1968, make recommendations for assuring the safety and quality of herbal remedies supplied under section 12(1).

¹ The five principles of good regulation are: proportionality, accountability, consistency, transparency, and targeting. Further information can be found on the website of the Better Regulation Task Force: <http://www.brtf.gov.uk>

13. The HMRWG was jointly established in January 2002 by the Department of Health, the Prince of Wales's Foundation for Integrated Health and the European Herbal Practitioners Association (EHPA). Among the many interests consulted during the course of its study, the HMRWG took account of the views of practitioner associations representing Western herbal medicine, traditional Chinese medicine, Tibetan herbal medicine, Ayurveda (an Indian and Sri Lankan tradition) and Kampo (a Japanese tradition).
14. The HMRWG reported in September 2003. A copy of the full report, as well as a summary, can be found on the Department of Health's web pages at www.doh.gov.uk/herbalmedicinergw.
15. A summary report from the HMRWG can be obtained free of charge from:
- The European Herbal Practitioners Association (EHPA)
45a Corsica Street
London
N5 1JT
Tel: 020 7354 5067
E-mail: info@euroherb.com
16. In its report, the HMRWG has made a number of recommendations for assuring the safety and quality of herbal remedies supplied under Section 12(1) of the Medicines Act. These recommendations are the subject of MLX 299 "Proposals for the reform of the regulation of unlicensed herbal remedies in the United Kingdom made up to meet the needs of individual patients". These recommendations have been made in conjunction with recommendations for the future statutory regulation of herbal medicine practitioners. These recommendations are the subject of a separate, but parallel, consultation "Regulation of herbal medicine and acupuncture – proposals for statutory regulation", run by the Department of Health. MLX 299 should therefore be read alongside the Department's consultation, which can be viewed at www.doh.gov.uk/herbalmedicinergw.

Current legislative arrangements

17. Under the main piece of European legislation regulating medicines, **Directive 2001/83 EC**, industrially produced herbal medicines placed on the market are required - like any other medicinal product - to have a marketing authorisation, based on demonstration of safety, quality and efficacy. The proposed Directive on Traditional Herbal Medicinal Products, which amends 2001/83/EC, will open up an additional route for such remedies, with a simplified registration scheme.
18. In the UK there has for many years been an exemption allowing the sale and supply of unlicensed herbal remedies. Most herbal remedies on the UK market are unlicensed. **Section 12 of the Medicines Act 1968** provides an exemption from various licensing requirements of the

Medicines Act for certain herbal remedies that are not industrially produced.²

19. **Section 12(1)** of the Medicines Act 1968, permits unlicensed herbal remedies to be made up to meet the needs of an individual patient. The remedy must be supplied for administration to a particular patient following a request for exercise of judgement as to the treatment required and a one-to-one consultation.
20. Beyond compliance with various prohibitions and restrictions on potent herbal ingredients (see below), herbal remedies supplied under Section 12 (1) are not subject to a regime of specific safety or quality requirements. Anyone – irrespective of qualifications or experience - can practise herbal medicine and, after making a diagnosis and forming a judgement about the treatment required, can make up and supply an unlicensed herbal medicine under Section 12(1) of the Medicines Act.
21. Where unlicensed herbal remedies are supplied under **Section 12(2)** there is no requirement for a consultation. The remedies, which may be subject only to simple processes (drying, crushing or comminuting) must be sold without brand names or written claims. (This is the regulatory route currently used for manufactured unlicensed herbal remedies that are sold as OTC products.)
22. **The Medicines (Retail Sale and Supply of Herbal Remedies) Order 1977 (SI 1977/2130)** is a complex legal instrument. In summary, the Order restricts the use of a number of the more potent specified herbal ingredients in unlicensed medicines in three ways. Firstly, the sale or supply of plants listed in Part I of the Schedule of the Order are prohibited in unlicensed herbal medicines, except where sold in premises which are registered pharmacies and by, or under the supervision of, a pharmacist. Secondly, plants contained in Part II of the Schedule are not permitted in unlicensed herbal remedies supplied under Section 12 (2) of the Medicines Act 1968. Thirdly, plants listed in Part III of the Schedule can only be sold in herbal medicines following a one-to-one consultation, at the dosages and by the route of administration also specified in Part III. If the dosage specified is exceeded or if the route of administration differs from that specified, the herbal medicines containing these plants can only be supplied in premises which are registered pharmacies and by, or under the supervision of, a pharmacist. In the absence of a legal definition as to who carries out the consultation, anyone can supply the potent herbs listed in Part III of SI 1977/2130 in unlicensed herbal medicines. This is subject to the proviso that the product complies with Section 12(1) of the Medicines Act, and it is supplied following a one-to-one consultation at the dosages and by the route of administration specified in Part III.
23. **The Medicines (Exemption from Licenses) (Special and Transitional Cases) Order 1971 (SI 1971/1450)** permits a third party to manufacture

² Under the Medicines Act 1968 an unlicensed herbal remedy may contain only herbal ingredients plus water or other inert substance.

non-industrially produced unlicensed herbal remedies for use in one-to-one consultations. The third party must hold a Manufacturer's (Specials) Licence. The product is made to the manufacturer's specification. There is no specific restriction as to the processes to which the herbs may be subjected. The remedies cannot be advertised to the public and no advertisement by means of any catalogue, price list or circular letter can be issued by way of wholesale dealing, or by the person who manufactures or assembles; and the sale or supply must be in response to a bona fide unsolicited order.

The significance of whether herbal remedies are regarded as "industrially produced"

24. Medicines (herbal or otherwise) that are industrially produced and placed on the market of a EU Member State are required to comply with Directive 2001/83/EC including its detailed regulatory requirements relating to safety, quality, efficacy and patient information. Directive 2001/83/EC itself includes several derogations, where in certain situations the requirements of the Directive are modified or do not apply. Until the development of the proposed Directive on Traditional Herbal Medicinal Products there has been no such derogation relating to herbal medicines.
25. The reason that remedies placed on the UK market under Section 12 have hitherto not been required to comply with Directive 2001/83/EC (and its predecessor, Directive 65/65/EEC) is that such remedies have been regarded as non-industrially produced.
26. However, given the increased scale and sophistication of production methods of herbal remedies supplied under Section 12(2) it has become increasingly clear that in future the more secure position legally would be to regard OTC manufactured herbal remedies (of the kind typically found in supermarkets, pharmacies and health food shops or sold by mail order) as industrially produced. Thus in future, such products would require either a simplified registration under the Directive on Traditional Herbal Medicinal Products or a full marketing authorisation.
27. In contrast, the Agency regards it as reasonable that Section 12(1) herbal remedies, made up on the premises of a practitioner for their use in one-to-one consultations, should normally continue to be regarded as non-industrially produced and therefore not subject to the provisions of Directive 2001/83/EC.

Public health risk

28. There is considerable evidence from the UK and internationally to demonstrate public health risk from unlicensed herbal medicines of poor and unreliable quality. While many of the affected products are supplied by OTC retail sale (where discussion of Section 12(2) and the proposed Directive on Traditional Herbal Medicinal Products is more relevant) it is also the case that a considerable proportion of such products are prepared

for use by herbalists following consultation. The Agency's web-site publication "Herbal Safety News" reports on a number of examples of public health risk and many others have been reported in professional journals.

29. An example of the problem was identified by the MHRA in its investigations relating to *Aristolochia*:

Substitution of one plant species for another, often a completely different genus, is a recognised practice in parts of traditional Chinese medicine. Furthermore, herbal ingredients are traded using their common Chinese Pin Yin names and this can lead to confusion. This is highly problematic in relation to *Aristolochia* species that are associated with kidney failure and cancer. For example, the name Fangji can be used either to describe the roots of the toxic *Aristolochia fangchi* or *Stephania* or *Cocculus* species (the latter two are not believed to be inherently harmful). Similarly the name Mu Tong can be used to describe the stem either of the toxic *Aristolochia manshuriensis* or of *Clematis* or *Akebia* species (again the latter two are not believed to be inherently harmful).

The widespread substitution with *Aristolochia* species in traditional Chinese medicine was confirmed in an MHRA study. In addition to the problems of substitution found in OTC products, samples of raw herbs from TCM outlets also tested positive for aristolochic acids, which indicate the presence of *Aristolochia*. The positive samples were referred to as Mu Tong and appear to have been intended for use in Section 12(1) remedies supplied by the clinic. This inadvertent supply of *Aristolochia* highlighted the public health issues that can arise when herbal ingredients are not authenticated properly.

30. The Agency has also identified illegal unlicensed "herbal" remedies used in practitioner clinics containing ingredients not permitted in such remedies. Products have included ingredients such as Glibenclamide, Fenfluramine and corticosteroids.

The weaknesses of the current regime

31. There is a range of weaknesses with the current regulatory regime where herbal remedies are supplied following consultation to meet the needs of individual patients:

- (i) **The lack of a systematic regulatory regime relating to the safety and quality of remedies, leading to inadequate public health protection.** It is the case that some of the products that pose the greatest risk are already illegal under the existing regime. However, the underlying issue is the lack of a systematic, fully enforceable, regime that would safeguard the public by reducing the risk of such products entering the supply chain in the first place. There are also problems with **information**. The provision of patient

information in English to allow the safe use of the product is also essential for the protection of public health. Current provisions in this area are unclear, limited and require improvement to assist compliance and MHRA enforcement;

- (ii) There is **no statutory definition of who is entitled to carry out a one-to-one consultation, followed by the diagnosis and supply of a herbal remedy**. Potentially anyone who has undertaken minimal training, or even none at all, can make up and supply herbal medicines under this regime. This implies the possibility that a diagnosis by such a practitioner may be incorrect or that the person carrying out the consultation may fail to appreciate the significance of other medication that the patient may be taking or of the need to refer the patient to a doctor in some situations. Such a practitioner may also fail to give the patient instructions about the safe use of the product, keep inadequate records and not be up-to-date in professional knowledge of safety issues;
- (iii) There are **no requirements as to professional competence, and hence no assurance for the public, over who is permitted to carry out the one-to-one consultation required for the use of certain potent herbal ingredients** as listed in the relevant 1977 Order. The lack of a statutory definition of who is a suitably qualified or experienced professional herbalists is also currently hindering work to update the list of restricted ingredients since there are some ingredients that are suitable for use provided there can be an assurance as to professional competence and supervision of the patient;
- (iv) There is a **lack of clarity over the circumstances in which a herbalist can commission a third party to manufacture a herbal remedy**. There is currently no legal provision that would permit a herbalist to commission a third party to manufacture industrially produced herbal remedies to the herbalist's specification and to standards of Good Manufacturing Practice. On the other hand there is currently a provision that allows someone holding a Manufacturer's (Specials) Licence to manufacture to their own specification non-industrially produced remedies for use in one-to-one consultations.

32. In discussions over a number of months, many in the UK herbal sector have told the MHRA that they share the Agency's view that there is a need for reform of the legislative framework in order to improve public health protection, improve the public's ability to make an informed choice and to enhance the clarity and relevance of the regulatory regime.

**The House of Lords Select Committee on Science and Technology
report on Complementary and Alternative Medicine (CAM)**

33. After taking evidence from a wide range of sources, the cross-party House of Lords Select Committee on Science and Technology report on Complementary and Alternative Medicine, published 28 November 2000 (<http://www.parliament.the-stationery-office.co.uk/pa/ld199900/ldselect/ldsctech/123/12301.htm>), identified herbal medicines as posing a risk to public health:

“We are concerned about the safety implications of an unregulated herbal sector and we urge that all legislative avenues be explored to ensure better control of this unregulated sector in the interests of the public health (para 5.97).”

“We support the view that any new regulatory regime should respect the diversity of products used by herbal practitioners...[and allow for simplified registration of stocks]. Nevertheless, any such regime must ensure that levels of quality and assurance of safety are not compromised (para 5.98).”

34. The ‘Government response to the House of Lords Select Committee on Science and Technology’s report on Complementary and Alternative Medicine’, published in March 2001, said:

(<http://www.archive.official-documents.co.uk/document/cm51/5124/5124.pdf>)

“The Government agrees that future regulatory arrangements relating to the ingredients and products used by individual herbal practitioners should safeguard quality and safety standards while recognising the diversity of practice. We aim to clarify and if necessary improve regulatory arrangements covering the varied situations which can arise, ranging from the practitioner using crude or partially processed herbal ingredients to make up individual remedies to the situation where the herbalist buys in mass produced finished products. Regulatory arrangements should in particular reflect the extent to which the practitioner is in a position to take personal responsibility for the safety and the quality of the remedy supplied to the consumer.

The Government will hold discussions with herbal interest groups to consider the way forward. In the light of this we will consider whether any changes in domestic legislation would be required in order to reach a satisfactory regulatory position and the extent to which requirements for responsible good practice attaching to the herbalist profession could play a greater role in ensuring the safety and quality of materials practitioners use”.

Proposals

35. The proposals of the HMRWG form the starting point of the present consultation. The Agency has identified several possible additional reforms that potentially could complement the proposals of the HMRWG and these are also put forward for consideration and comment. In order to help those wishing to comment, the Agency has sought to convey an overall picture of what the regulatory framework could look like following reform.

36. **The proposals set out in this document apply only to those herbal products classified as medicines³ and in particular to those supplied to meet the specific needs of individual patients** in the United Kingdom. The proposals would have no bearing on the many other products (whether herbal or otherwise) that are not classified as medicines, which may legally be supplied by many practitioners of CAM. The MHRA Guidance Note 8 sets out guidance on how the Agency determines whether a product is a medicine.

A) Herbal medicines made up by, or to the specification of, a statutorily registered herbalist

(i) remedies made up on the herbalist's premises

a) general criteria

37. The HMRWG made no proposals to change the current provision in Section 12(1) under which there is an exemption from the requirement for a product or manufacturer's licence where the unlicensed herbal medicine:

- "is manufactured or assembled on the premises of which the person carrying on the business is the occupier and which he is able to close so as to exclude the public; and
- the person carrying on the business sells or supplies the remedy for administration to a particular person after being requested by or on behalf of that person and in that person's presence to use his own judgement as to the treatment required".

b) efficacy

38. It is implicit in HMRWG's proposals and in the wording of Section 12(1) of the Medicines Act that the efficacy of the remedy would be a matter for the professional judgement of the statutorily registered herbalist.

³ A medicine is defined in European legislation (Article 1 of Directive 2001/83 EC) as: "Any substance or combination of substances presented for treating or preventing disease in human beings or animals" *or* "Any substance or combination of substances which may be administered to human beings or animals with a view to making a diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals is likewise considered a medicinal product".

c) safety

39. HMRWG recommends that the supply of potent herbs not suitable for OTC sale should be restricted to those practitioners with appropriate training who are on a statutory register. The MHRA also notes that statutory registration of herbalists would helpfully widen the existing range of options for regulating potent herbal ingredients. (The options available would thus include: prescription only medicine (POM), supply by registered pharmacy (P), prohibition in unlicensed medicines and restriction to statutorily registered herbalist.) The Agency proposes that it would be desirable to consider what is the appropriate and proportionate control in the interests of public health on a case-by-case basis.
40. In relation to the use of those herbal ingredients that are not explicitly restricted or prohibited, the registered herbalist would be able to apply his or her professional judgement. There are many herbal ingredients in normal use by herbalists that are likely to pose a relatively low safety risk when used in accordance with professional good practice. However, overall, there are many ingredients in the plant kingdom that are toxic. It is inherently unlikely that any statutory list of restricted or prohibited ingredients would cover every single ingredient that a herbalist might conceivably consider using. It would be the professional responsibility of the herbalist to satisfy him or herself as to the safety of the ingredients used.
41. The MHRA suggests that in order to give the public additional and more systematic protection it may be helpful if an arrangement under professional self-regulation was to be instigated, perhaps under the auspices of the future Council regulating herbal medicine. For example, herbalists wishing to use herbal ingredients not on a list maintained by the profession could be given a professional obligation to notify their use of such an ingredient, thereby giving the profession an opportunity either to extend the list or to advise the practitioner of any concerns about safety.

d) quality

42. The HMRWG proposes that public health protection in relation to quality issues would be strengthened by use of a herbalists' Code of Conduct (analogous to the Pharmacists' Code) setting out good practice, for example, over the use of reliable suppliers.
43. The MHRA shares the view, implied by HMRWG comments, that it would be difficult to set out in legislation the step-by-step process required to assure the quality of products made up by herbalists in response to the needs of individual patients. However, there are steps that could be taken. A key issue is how can herbalists be assured that the raw or processed ingredients that they purchase for use in Section 12(1) remedies are of acceptable quality. In many cases suppliers could demonstrate independent evidence that the necessary quality controls are in place. For example, suppliers may also manufacture licensed or registered herbal

medicines and they may therefore hold a Manufacturer's Licence; or they may hold a Manufacturer's (Specials) Licence in relation to unlicensed herbal remedies; they may be accredited by another independent body such as the Soil Association.

44. The MHRA proposes an additional measure that may be of benefit to suppliers wishing to demonstrate independent evidence to herbalists. To address the situation in which some companies may intend only to supply ingredients, the Agency is considering setting up an arrangement, which potentially could be achieved either on a voluntary or compulsory footing, whereby a supplier of partially processed active ingredients could apply for a certificate of Good Manufacturing Practice (GMP). As a Trading Fund the MHRA would need to recover its costs by charging for the inspection leading to the award of such a certificate.

e) information

45. The HMRWG noted that labelling and advertising requirements for Section 12(1) products require careful consideration. As regards **labelling** the MHRA considers that there are two main options:

- setting out labelling requirements in legislation;
- covering this issue as a matter of professional guidance through the Herbalists' Code of Conduct.

46. The MHRA proposes that minimum requirements should be covered in legislation, given that accurate information on the contents of a remedy is fundamental to effective regulation and it is also important on public health grounds that the patient is given clear instructions about the safe use of the product. This also recognises the likelihood that a legislative approach is in any case likely to be necessary on public health grounds on account of any continuing use of Section 12(1) by practitioners who are not on a statutory professional register.

47. Suggested requirements are that the medicine's primary container should include the name of the person for whom the medicine is intended; the product name where appropriate; directions for use; the name and address of the person supplying the product; the date upon which the product is dispensed; a list of ingredients.

48. On **advertising**, the MHRA proposes that it should not be lawful to advertise specific herbal medicines under Section 12(1). Otherwise there is a clear risk of undermining genuine consultation about the specific needs of individual patients.

Q1. Do you agree that the proposals for the supply to the public of unlicensed herbal remedies under Section 12(1) by registered herbalists will give the public adequate safeguards, particularly as to safety, quality and information? Do you have comments about the specific proposals?

Q2. Do you agree that the proposals strike an effective balance between statutory provisions set out in medicines legislation and effective statutory self-regulation by the herbalist profession?

Q3. Do you consider that it would be helpful for the MHRA to establish a scheme that would enable suppliers of partially processed active herbal ingredients to demonstrate to purchasers their compliance with GMP? Do you have a view on whether this scheme should be voluntary or compulsory?

ii) remedies made up by a third party for the registered herbalist to use in their one-to-one consultation

a) general criteria

49. The HMRWG recommends that a scheme be created that would permit herbalists and other suitably qualified health professionals on a statutory register to request a third party to make up a herbal remedy to the practitioner's specification to fulfil the special needs of a patient.

50. Such a scheme for herbalists could be created under Article 5 of Directive 2001/83/EC. This allows Member States to exclude, from the provisions of the Directive in order "to fulfil special needs", "medicinal products supplied in response to a bona fide unsolicited order formulated in accordance with the specifications of an authorised health care professional and for use by his individual patients on his direct personal responsibility". The exemption can only be used in order to fulfil special needs which, in MHRA's view, means that the practitioner has taken a professional judgement that there are no suitable equivalent licensed herbal medicines or registered herbal medicines available.

51. It would be implicit in the creation of such a scheme under Article 5 that the remedies commissioned in this way by herbalists would be regarded as industrially produced. The MHRA believes that this would better reflect the reality of the market and give greater legal stability. Under the scheme, herbalists on the statutory register would be regarded as "authorised health care professionals". At present only doctors and dentists are considered to be "authorised health care professionals".

52. It is implicit in such a scheme under Article 5 that registered herbalists would only be able to commission the manufacture of remedies in areas in which they had expertise. (The question of whether such a scheme could extend to traditional remedies containing non-herbal ingredients is considered further below.)

b) Efficacy, safety and quality

53. Efficacy and safety would be a matter for the herbalist's professional judgement in setting the specification for the remedy. The patient's use of the remedy would be under the herbalist's direct personal responsibility.
54. Quality would be safeguarded principally by the requirement that the UK manufacturer should hold a Manufacturer's (Specials) Licence. This is in line with existing requirements where doctors or dentists commission "specials".
55. Under such a scheme registered herbalists would also be able to commission remedies to be imported to the UK and there may be difficulties in determining measure(s) that give comparable protection to a Manufacturer's (Specials) Licence. In this situation it would seem appropriate for the importer to hold a Wholesale Dealer's (Import) Licence although this of itself would not guarantee the quality of imported remedies. For the limited number of countries where there is a mutual recognition agreement, a GMP certificate could be supplied on request. A possible requirement to test on importation could provide some reassurances, although falling short of an assurance of adequate quality control and assurance through the supply chain. This issue requires careful consideration given the evidence, particularly in the TCM sector, that some unlicensed imported traditional Chinese medicines are prone to variable standards of quality and safety.

c) Information

56. The MHRA suggests that for **labelling** the main requirements should be as follows:
- where the product is supplied by the manufacturer to the practitioner for use in more than one patient in one-to-one consultation, the following information would seem necessary:
 - name of the product
 - description of the pharmaceutical form
 - statement of the qualitative particulars of the product (quality of the product in weight, volume, capacity or number of dosage units)
 - any special requirements for handling and storage
 - the expiry date
 - manufacturer's batch reference
 - the name and address of the manufacturer/person who put the medicinal product in its container;
 - the person supplying the product to the individual patient (ie the herbalist or the manufacturer acting on the request of the herbalist) should ensure that the necessary dispensing information is provided on the labelling of the primary container:
 - the name of the person for whom the medicine is intended
 - directions for use

- the name and address of the person supplying the product
- the date upon which the product is dispensed
- a list of ingredients.

(Full details – e.g. batch number – could be provided by the manufacturer to the herbalist).

57. It would not be possible for a manufacturer holding a special licence to **advertise** specific remedies to herbalists, although the company could advertise the fact that it operated a service to supply “specials”. Likewise, the herbalist could not advertise specific remedies made under this arrangement.

Q4. Do you support the proposal that would permit a registered herbalist to commission remedies made to the herbalist’s specification from the holder of a Manufacturer’s (Special) Licence? In order to do this registered herbal practitioners would need to be regarded as authorised health care professionals – is this acceptable?

Q5. What regulatory requirements to ensure the quality of the product would be necessary, particularly where a registered herbalist wished to commission such a remedy to be imported?

B. Herbal medicines made up by, or to the specification of, someone who is not a statutorily registered herbalist

(i) remedies made up on the practitioner’s premises

a) Background

58. The HMRWG noted that, besides herbalists, there are likely to be a variety of other practitioners from one or more of the various complementary and alternative medicine (CAM) groups (or indeed not allied to any particular grouping) who regularly or occasionally make up herbal remedies under the legal cover of Section 12(1). This may include a significant number of acupuncturists, some aromatherapists, homeopaths, naturopaths, various other multi-disciplinary CAM professionals from a range of different traditions. There is also a minority of shopkeepers who make up specific remedies for the individual patient following a form of consultation.

59. The MHRA notes from previous informal discussions with a range of parties in the herbal sector that it would be difficult to form reliable estimates of the extent of usage of Section 12(1) outside the main herbalist groupings. Whether a product is a medicine is determined by the MHRA on the basis of consideration of an individual product against the legal definition of a medicinal product. It is not determined by looking at whole classes of products – e.g. all essential oils or flower essences – or

the type of practitioner who is using a product, e.g. naturopath or aromatherapist.

60. The HMRWG expressed reservations on public health grounds about the desirability of an indefinite continuation of a position where people are operating a business entailing holding personal consultations and making up and supplying medicinal products without a reliable assurance that such operators are working under adequate professional accountability. However, the HMRWG also took the view that it would not be realistic for the foreseeable future to restrict use of Section 12(1) to those on the statutory register. Such a course of action could have a significant adverse regulatory impact on those affected.
61. The MHRA recognises the difficulties that the HMRWG found in making recommendations in this area and agrees that it will not necessarily be possible to move to an ideal regulatory position in the short to medium term. A possible approach is set out below. The MHRA's initial assessment is that the approach, particularly in relation to efficacy, safety and quality, falls some way short of what is desirable but that, *if* self-regulation is genuinely effective, there could be a considerable improvement on the present unsatisfactory position.

b) General criteria

62. The HMRWG recommended that:
- continued use of Section 12(1) should be permitted by operators not on the statutory (herbalists or CAM) register;
 - the growth of voluntary self regulation in this sector should be encouraged. (A number of ideas are raised on Page 148 of the HMRWG report and the HMRWG urged those CAM professionals who are not statutorily registered to develop secure systems of voluntary self-regulation, including independently audited, clearly defined training standards, codes of ethics and disciplinary standards);
 - the situation should be kept under review, as to whether responsible self-regulation was providing sufficient public health protection over the continued use of Section 12(1) by operators not on the statutory register.
63. The HMRWG also recommended that during further discussions or consultations on its proposals it would be helpful if CAM groups could have further opportunities to identify the pattern of current usage of Section 12(1) by CAM practitioners. The MHRA would welcome any such information in response to this consultation. **Given the complexity of identifying usage of Section 12(1) by non-registered practitioners the MHRA considers that it would be helpful for the Agency to convene meeting(s) of relevant interest groups in the CAM sector during the consultation period to explore this issue further.**

64. The MHRA's preliminary view is that, if there is broad support for a package based on ideas outlined in this consultation, it may be helpful to plan the proposed reforms in two stages as set out below:

Stage 1 (*in progress*)

- Decide and implement revised arrangements for the regulation of the herbal medicines used in one-to-one consultation - based on a combination of one or more of statutory regulation, professional self-regulation, and other voluntary self-regulation

Stage 2 (*2 or 3 years after the introduction of a statutory scheme for self regulation of herbalists*)

- Review and, if necessary, revise these arrangements based on consideration of the following questions:
 - Are herbal medicines made up by, or to the specification of, a statutorily registered herbalist considered safe and of an acceptable quality?
 - Is voluntarily self-regulation working effectively in relation to non-registered practitioners choosing to participate in these arrangements?
 - Are there other practitioners operating under Section 12(1) who are operating outside *both* statutory registration and voluntary self-regulation and, if so, what are the implications, especially for public health?

c) Efficacy

65. This would be a matter for the practitioner, irrespective of the level of their competence – which may be limited in some cases. The HMRWG suggest that systematic self-regulation should include a definition of the extent of training and levels of responsibility associated with various qualifications; also the importance of appropriate referral to a more qualified person should be emphasised and audited.

d) Safety

66. It would largely be a matter for the practitioner to act within the limits of their competence and to follow good practice as may be developed through self-regulation. The MHRA notes the possible weakness that there may be non-registered practitioners who choose not to participate effectively - or at all - in self-regulatory arrangements and who may not recognise the limits of their competence to operate safely. The HMRWG propose that, in the interests of public health, practitioners not on the statutory register should be precluded from use of potent herbs that are not suitable for OTC sale. However, this restriction would not necessarily achieve the degree of public health protection sought: practitioners who do not have the necessary qualifications or experience might accidentally use

these potent herbs due, for example, to their inability to distinguish between similar looking species.

e) Quality

67. Under the HMRWG's proposals it would again be largely a matter of self-regulation for practitioners to follow good practice, for example over the use of reliable suppliers. The MHRA shares the view implied in HMRWG's comments that this situation will not be ideal in all situations. For example, some non-registered practitioners may choose not to participate effectively - or at all - in self-regulatory arrangements and may not recognise the crucial significance for safety of having adequate quality control and quality assurance.
68. Individuals that do not opt for robust voluntary self-regulation may not be alert to other quality issues that have safety implications. There are a number of such issues associated with the growth of herbal ingredients such as the use of pesticides and fumigants or the quality of water. Some countries exporting herbal ingredients that potentially might be used in Section 12(1) remedies in the UK may use agrochemicals which are banned on safety grounds in the UK and Europe.
69. However, in considering any alternatives to relying predominantly on self-regulation, the Agency's current view is that it may well not be practicable to set out in medicines legislation the specifics of a detailed scheme of requirements for quality control and assurance to regulate the quality of products made up for individual patients. However, non-registered practitioners would be able to benefit from any voluntary or compulsory scheme (as referred to above) for manufacturers of active ingredients to meet standards of GMP.

f) Information

70. The MHRA considers that systematic patient information is essential for the protection of public health and that requirements should be covered in legislation. This is in recognition that there may well be some operators who choose not to participate effectively in self-regulatory arrangements and also that legislation would appear more feasible on this issue than is the case with quality requirements. The MHRA has occasionally encountered practitioners who have put forward the view that remedies with secret or undeclared ingredients should be permitted. The Agency does not believe that this would be in the interests of public health.
71. Suggested requirements are, (as for herbal remedies supplied by registered herbal practitioners) are that the medicine's primary container should include: the name of the person for whom the medicine is intended; the product name where appropriate; directions for use; the name and address of the person supplying the product; the date upon which the product is dispensed; a list of ingredients.

72. On **advertising**, the MHRA proposes that it should not be lawful to advertise specific herbal medicines under Section 12(1). Otherwise there is a clear risk of undermining genuine consultation about the specific needs of individual patients.

Q6. Do you agree that individuals operating under Section 12(1), and not on the statutory register should be permitted for the foreseeable future to continue to supply remedies under Section 12(1) – subject to continuing review of the effectiveness of self-regulation and the wider public health implications? If not, what view do you take of the possible consequences for practitioners who might be adversely affected by a restriction on use of Section 12(1) to statutorily registered herbal practitioners?

Q7. Do you support the HMRWG proposals for developing a system of voluntary self-regulation covering training and quality control/assurance, in this part of the sector? If so, what criteria would you suggest for assessing whether such self-regulation is effective in protecting the public from public health risks?

Q8. If you do not believe voluntary self-regulation would be sufficiently effective in protecting public health are there other options that would adequately protect public health short of requiring that any practitioner wishing to operate under Section 12(1) would need to take any necessary action to meet the requirements of, and join, the statutory register of herbal medicine practitioners?

Q9. Do you agree that, in the interests of public health, those not on the statutory register of herbal medicine practitioners should be precluded from use of potent herbs that are suitable only for use in products requiring professional supervision by a registered herbalist or other health care professional?

Q10. Do you have views on the long term future direction of policy towards practitioners not on a statutory register and their use of Section 12(1) to make up remedies to meet the health needs of individual patients following consultation?

ii) remedies made up for by a third party for the non-registered practitioner to use in their one-to-one consultation

a) General criteria

73. The HMRWG doubted whether it would realistically be feasible to regard CAM operators not on a statutory register as “authorised healthcare professionals” for the purposes of Article 5 of 2001/83/EC and hence concluded that it would not be possible to extend to them legal cover to commission industrially produced herbal remedies from a third party using

a scheme set up under that Article. The MHRA fully supports this assessment.

74. The MHRA does not believe that it would be legally sustainable to argue that, while remedies commissioned from a third party by registered practitioners should be regarded as industrially produced, remedies commissioned by other CAM operators should not be regarded as industrially produced. This therefore implies that there is no clear legal basis available for unregistered practitioners to be able to commission a third party to make up unlicensed herbal remedies for use in one-to-one consultation.

Q11. Do you agree that practitioners who are not on the statutory register should not be permitted to commission a third party to make up unlicensed herbal remedies to the practitioner's specification for use in one-to-one consultations?

C. Possible extension of Section 12(1), and/or an Article 5 scheme, to traditional medicines of non-plant origin

a) background

75. Currently unlicensed herbal remedies placed on the UK market under Section 12 of the Medicines Act 1968 are not permitted to include non-plant material (other than water or other inert substances). The use of non-plant ingredients is an established feature of a number of traditional medicines systems, not least in TCM and Ayurveda. In future, in relation to manufactured OTC remedies, the simplified registration scheme under the proposed Directive on Traditional Herbal Medicinal Products, if agreed, will cover products that include vitamins and minerals where these have well documented safety and are ancillary to the action of the active herbal ingredients.

b) HMRWG recommendations

76. The HMRWG recommends that the scope of Section 12(1) should be extended to allow statutorily registered practitioners to supply traditional medicine remedies of a non-plant origin provided these remedies can demonstrate safe use and are subject to required standards of quality assurance.

77. The MHRA considers that the feasibility of the idea requires careful investigation from both legal and public health perspectives.

c) Legal issues

78. The legal position for a non-herbal traditional medicine can be summarised as follows:

- if regarded as *non-industrially* produced, such a product would currently require a product licence under UK medicines legislation;
- if regarded as *industrially* produced, a product would need a marketing authorisation under European medicines legislation, unless covered by a specific derogation in Directive 2001/83/EC.

79. The MHRA believes that, in legal terms, while it is reasonable to justify the continued retention of Section 12(1) on the basis that *herbal* remedies made up by practitioners for use in their one-to-one consultations should normally be regarded as non-industrially produced it does not necessarily follow that this legal base would be equally applicable in relation to an extension to *non-herbal* traditional medicines. Production methodologies, for example, in the latter case may differ considerably. The MHRA will therefore invite representatives of the traditional medicine sector during the consultation to supply specific information about non-herbal traditional medicinal products, including production methodology, where they consider these might be made up by registered practitioners. This will help the Agency reach a view on whether or not non-herbal traditional herbal medicines, where made up by practitioners for use in one-to-one consultation, could reasonably be regarded as non-industrially produced. In turn this would help to show whether it was legally feasible to extend the Section 12(1) regime to some other forms of traditional non-herbal medicine (assuming that proposals were also acceptable on other policy grounds).

80. Where non-herbal traditional medicines were regarded as industrially produced, the MHRA's view is that the feasibility could be investigated of including at least some such medicines in a scheme under Article 5 of 2001/83/EC whereby registered herbalists, acting as authorised health care professionals, could commission a third party holding a Manufacturer's (Specials) Licence to make up a traditional remedy to meet the special needs of patients.

81. However, achieving a legally sustainable position would depend, among other things, on two linked issues: it being possible to define clearly the kind of non-herbal traditional medicines to be covered by such a scheme and for practitioners genuinely to be regarded as authorised health care professionals in relation to those medicines.

d) Public health issues

82. Currently non-herbal traditional medicines require a product licence or marketing authorisation requiring demonstration of safety, quality and efficacy. The HMRWG recognised that the possibility of lifting or modifying these regulatory safeguards is an issue requiring careful consideration on public health grounds. The MHRA supports the need to set public health protection at the heart of any reform in this area. The point is illustrated by the kind of declared or undeclared non-herbal ingredients the Agency has found illegally included with unlicensed "herbal" medicines used by some operators: heavy metals, pharmaceutical ingredients and animal excreta.

83. Ingredients of non-plant origin used in traditional medicines include materials of biological origin such as substances derived from animal or human tissues. Such substances present potential risks for the transmission of infectious agents, for example of microbial contamination (eg. with mycoplasma, fungi, bacteria, viruses) or transmission of spongiform encephalopathies (TSEs). If such risk materials were to be permitted for use by registered herbalists in unlicensed traditional remedies consideration would need to be given as to how the quality of such materials could be assured and public health protected.
84. In considering this issue it is important to remember that although animal parts have long been a feature of certain, mainly non-western systems, of traditional medicine, this is no guarantee of current safety – indeed safety issues may change and develop over time. For example, at the time this consultation was being drafted, subjects on the international agenda included avian flu in South East Asia and linkages between the civet and SARS in China. The MHRA is also concerned that those including bat excreta in traditional medicines may not have considered the risk of rabies.
85. In relation to the risk from TSEs, the Government introduced legislation in 2003 to apply the European Commission's guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products administered to humans to unlicensed medicines. All manufacturers, importers and exporters of unlicensed medicinal products for human use except unlicensed herbal medicines are now required to comply with the provisions of the Regulations. (Guidance is set out on the MHRA web site.) The current exclusion of unlicensed herbal medicines from these provisions will need to be reviewed.
86. The known toxicity of certain heavy metals often found in medicines of certain traditions is such that on public health grounds they are only justified for use in a medicine on the basis of positive risk benefit following detailed assessment for each product. This will not be applicable in this area of medicine.

e) MHRA position on non-herbal ingredients

87. The MHRA is willing to look constructively with the herbal and traditional medicines sector at the possibilities for extending the Section 12(1) regime and/or related provisions, into the areas of non-herbal traditional medicines. However, it is evident that there are important legal and public health issues to be considered and it is not necessarily clear at this stage that it will be feasible and practicable to extend the regime. There are important definitional issues and if these are not adequately resolved there is a risk of undermining public confidence in regulation – for example if practitioners' permitted use of unlicensed traditional medicines were to be based simply on a time period for which such medicines had been used, e.g. of several decades, this would embrace many allopathic medicines. The MHRA further considers that any extension to the regime should only

be undertaken if the provisions are transparent - based on clear, justifiable, definitions of permissible activity where obligations associated with that activity are fully enforceable.

88. The MHRA also notes that there may also be wider environmental policy issues, extending beyond medicines regulation and the remit of the Agency. Opening up the regime to permit unlicensed medicines legally to contain parts from a wide range of animal species might help enforcement authorities internationally to monitor compliance with *CITES* requirements. Alternatively or as well, a growth in demand for parts of exotic or endangered species that tend to feature in long-standing lists of traditional medicine ingredients could result in increased pressure on some species. This consultation allows an opportunity for wider views on these issues to be brought to Ministers' attention.

Q12. If further investigation were to provide evidence that non-herbal traditional medicines made up by a registered practitioner for their use in one-to-one consultation should normally be regarded as non-industrially produced, do you support the principle that at least some such medicines should in future no longer require a product licence but instead be covered by an extended Section 12(1) regime?

Q13. Do you support the principle that it should be possible for registered herbal practitioners acting as "authorised health care professionals" to commission a third party holding a Manufacturer's (Specials) Licence to make up traditional non-herbal medicines (under a scheme under Article 5 of 2001/83/EC), instead of such a product requiring a marketing authorisation?

Q14. How can the "traditional" use of a medicine be defined - in the context of individual practitioner use - in a way that is sufficiently specific as to be capable of inclusion in legislation and being adequately enforced?

Q15. How should any permitted non-herbal ingredients be defined? What categories of ingredients should be permitted or excluded? Do you envisage non-herbal ingredients being permitted only as excipients for herbal remedies or being permitted as active ingredients?

Q16. What mechanism should be used to identify which ingredients are safe for use?

Q17. What regulatory requirements should be included to give the public assurance that appropriate quality and manufacturing systems are in place to prevent poor quality and unsafe products being given to patients?

Q18. In the case of a scheme for products manufactured by a third party where products are imported from a country outside the EU and with no mutual recognition agreement, what manufacturing and quality

requirements could be applied?

Q19. If it is envisaged that parts of animal or human origin are to be permitted, what regulatory requirements are required to ensure that quality problems do not give rise to safety issues, such as TSE, hepatitis, HIV, rabies?

Q20. Do you agree that requirements relating to TSE that currently apply to other categories of unlicensed medicines should extend to unlicensed traditional medicines?

Q21. Do you agree that it would be inappropriate on public health grounds to extend the ability to use non-herbal ingredients in unlicensed remedies to practitioners not on a statutory register? If not, how would public health be assured?

D. Reform and clarification of complex and/or unclear legislation

(i) The Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971

89. The HMRWG took the view the provisions of this Order relating to herbal medicines are outdated and recommended that the Order should be repealed or substantially revised. The MHRA's current view is that the provisions of this Order relevant to unlicensed herbal medicines should be revoked.

90. The Agency takes the view that the proposal to create a scheme, under Article 5 of 2001/83/EC, to allow a registered herbalist to commission a third party holding a Manufacturer's (Specials) Licence to manufacture a remedy to the herbalist's specification to meet special needs would be likely to provide an alternative, and more legally secure, option for allowing herbal remedies to be commissioned from a third party in place of the relevant provisions of the 1971 Order. (The latter relies on the premise that such "third party" remedies are not industrially produced, which is unlikely to be legally sustainable in the longer term.)

(ii) The Medicines (Retail Sale and Supply of Herbal Remedies) Order 1977

91. The HMRWG noted that this Order needs updating and simplifying. The MHRA agrees that the drafting of this Order is over-complex; also the list of restricted ingredients does not reflect developments in the market since 1977. The creation of the statutory register for herbalists should facilitate redrafting of the instrument to achieve greater transparency and clarity in line with the principles of good regulation. This development would also facilitate the MHRA to progress a wider review to update the list of

restricted ingredients. Clearly there would need to be a full public consultation on specific proposals.

Q22. Do you agree with the suggested way ahead for rationalising these two Orders?

E. Should it be possible for a practitioner to mix different, industrially produced, finished herbal remedies, which hold a marketing authorisation or a traditional use registration?

92. The HMRWG raised the issue as to whether registered herbalists might be permitted to make a new product from two or more different finished manufactured herbal medicines which will hold a marketing authorisation or, in the future, a traditional use registration under the Directive on Traditional Herbal Medicinal Products.
93. At the time of its report the HMRWG was unclear as to whether registered herbalists might wish or need to use such a provision and concluded that further work needs to be undertaken to investigate the case for permitting herbalists to mix two or more industrially produced herbal remedies.
94. There are possible safety issues with such medicines interacting – in effect combining two or more licensed or registered medicines would result in a new product. There is also a potential risk of undermining the position of licensed and registered medicines that have met the necessary regulatory conditions. The MHRA's current assessment is that there is insufficient a case to justify moving in this direction, but would welcome any views on the issue.

Q23. Is there any case for permitting for registered herbalists to combine licensed/registered herbal medicines?

F. Should other statutorily registered health professionals who are not on the herbalist's register be able to undertake activities restricted to registered herbalists?

95. Paragraph 50 of the related DH consultation document '*Regulation of herbal medicine and acupuncture – proposals for statutory regulation*' covers the statutory registration of herbal practitioners who are already registered with an existing statutory regulatory body. Dual registration in this situation is not generally a favoured option in view of the need to ensure clear accountability for regulated healthcare professionals.
96. Under the proposals in this MHRA consultation there are several activities that would be restricted to registered herbalists, for example: use of some potent herbs suitable for use only in one-to-one consultation with a qualified professional; the ability to commission a third party to manufacture a remedy to meet special needs; and (if the option is

pursued) the ability to commission a third party to make up unlicensed traditional remedies containing non-herbal ingredients.

97. The issue arises as to which other groups of statutorily regulated health care professionals should also be permitted to undertake some or all these activities. Under existing arrangements doctors and dentists are already able to commission a third party to manufacture a medicine to meet special needs – irrespective of whether the medicine is made of herbal ingredients. Given the extent of pharmacists’ training and knowledge about medicines, there would seem to be a case for ensuring that registered pharmacists could also legally undertake activities permitted for registered herbalists. In doing so they would need to comply with the pharmacists’ code of conduct. In the case of other statutorily regulated health care professionals, dual registration of the individual practitioner has the drawback that it may not give maximum clarity over accountability. On the other hand, however, only a very small proportion of members of many statutorily regulated professions would have knowledge about the safe use of potent herbal remedies. This may suggest a need to limit the number of statutorily regulated professions that could be given the power to use restricted potent herbs.

Q24. Where it is proposed that certain activities be limited to registered herbalists, what should be the position in relation to other groupings of health professionals who are subject to statutory regulation?

Conclusion

98. Comments would be welcome on any of the questions raised within this consultation document, on the draft initial Regulatory Impact Assessment (RIA) and on any other points that are relevant to the issues under consideration.

Q25. Are there any comments, not covered elsewhere, on the proposals or any additional ideas that help to ensure that any reforms adequately address the need to protect public health issues while doing so in a way that is proportionate, and improves accountability, consistency, and transparency and targeting in regulation? Do you have any comments or information that would help to develop the RIA?

Timetable

99. The consultation period will close on 7 June 2004.

Publication of comments

100. To help informed debate on the issues raised by this consultation exercise, and within the terms of the Code of Practice on Access to Government Information (“Open Government”), the Agency intends to

make publicly available a summary of responses received to this consultation.

101. The Agency's Information Centre at Market Towers will supply copies of the results of the consultation on request. Copies may be further reproduced. An administrative charge, to cover the cost of photocopying and postage, may be applied.
102. *We will assume that your comments can be made publicly available in this way unless you indicate on the reply form that you wish all or part of them to be treated as confidential and excluded from this arrangement.* Under the Code of Practice on Access to Government Information, the Agency will not release confidential replies or replies containing personal confidential information.
103. Should you have any questions regarding the proposals or the conduct of the consultation exercise, please contact Alison Daykin (Tel: 020 7084 2404, Email: alison.daykin@mhra.gsi.gov.uk). If you consider there are other organisations that should be invited to comment on these proposals, please either pass a copy of the documents to them or contact the MHRA and we will arrange for a consultation pack to be sent to them.

List of consultation questions

Q1. Do you agree that the proposals for the supply to the public of unlicensed herbal remedies under Section 12(1) by registered herbalists will give the public adequate safeguards, particularly as to, safety, quality and information? Do you have comments about the specific proposals?

Q2. Do you agree that the proposals strike an effective balance between statutory provisions set out in medicines legislation and effective statutory self-regulation by the herbalist profession?

Q3. Do you consider that it would be helpful for the MHRA to establish a scheme that would enable suppliers of partially processed active herbal ingredients to demonstrate to purchasers their compliance with GMP? Do you have a view on whether this scheme should be voluntary or compulsory?

Q4. Do you support the proposal that would permit a registered herbalist to commission remedies made to the herbalist's specification from the holder of a Manufacturer's (Special) Licence? In order to do this registered herbal practitioners would need to be regarded as authorised health care professionals – is this acceptable?

Q5. What regulatory requirements to ensure the quality of the product would be necessary, particularly where a registered herbalist wished to commission such a remedy to be imported?

Q6. Do you agree that individuals operating under Section 12(1), and not on the statutory register should be permitted for the foreseeable future to continue to supply remedies under Section 12(1) – subject to continuing review of the effectiveness of self-regulation and the wider public health implications? If not, what view do you take of the possible consequences for practitioners who might be adversely affected by a restriction on use of Section 12(1) to statutorily registered herbal practitioners?

Q7. Do you support the HMRWG proposals for developing a system of self-regulation covering training and quality control/assurance, in this part of the sector? If so, what criteria would you suggest for assessing whether such self-regulation is effective in protecting the public from public health risks?

Q8. If you do not believe self-regulation would be sufficiently effective in protecting public health are there other options that would adequately protect public health short of requiring that any practitioner wishing to operate under Section 12(1) would need to take any necessary action to meet the requirements of, and join, the statutory register of herbal medicine practitioners?

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use of potent herbs that are suitable only for use in products requiring professional supervision by a registered herbalist or other health care professional?

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Q11. Do you agree that practitioners who are not on the statutory register should not be permitted to commission a third party to make up unlicensed herbal remedies to the practitioner's specification for use in one-to-one consultations?

Q12. If further investigation were to provide evidence that non-herbal traditional medicines made up by a registered practitioner for their use in one-to-one consultation should normally be regarded as non-industrially produced, do you support the principle that at least some such medicines should in future no longer require a product licence but instead be covered by an extended Section 12(1) regime?

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Q21. Do you agree that it would be inappropriate on public health grounds to extend the ability to use non-herbal ingredients in unlicensed remedies to practitioners not on a statutory register? If not, how would public health be assured?

Q22. Do you agree with the suggested way ahead for rationalising these two Orders?

Q23. Is there any case for permitting for registered herbalists to combine licensed/registered herbal medicines?

Q24. Where it is proposed that certain activities be limited to registered herbalists, what should be the position in relation to other groupings of health professionals who are subject to statutory regulation?

Q25. Are there any comments, not covered elsewhere, on the proposals or any additional ideas that help to ensure that any reforms adequately address the need to protect public health issues while doing so in a way that is proportionate, and improves accountability, consistency, and transparency and targeting in regulation? Do you have any comments or information that would help to develop the RIA?

DRAFT INITIAL REGULATORY IMPACT ASSESSMENT (RIA)

Outline proposals for the reform of the regulation of unlicensed herbal remedies made up to meet the needs of individual patients

PURPOSE AND INTENDED EFFECT OF MEASURE

Summary of the issue

1. Current UK legislation in relation to unlicensed herbal remedies has widely acknowledged weaknesses and fails adequately to protect public health.
2. There are a number of reasons why the current regulatory framework relating to unlicensed herbal medicines used in one-to-one consultations to meet the needs of individuals needs to change. These include:
 - evidence of a risk to public health
 - the lack of any legal definition as to who is permitted to carry out a one-to-one consultation
 - other deficiencies in parts of existing medicines legislation.
3. Reforms in this area of regulation potentially could introduce a much clearer regulatory framework that improves public health protection and increases the confidence of both practitioners and public in the safety and quality of medicines supplied. Reforms would potentially affect practitioners supplying remedies to meet individual needs, as well as the businesses that supply medicines and ingredients to practitioners for this purpose.

Policy objective

4. The objectives of the proposed reform is as follows:
 - to improve public health protection
 - to give the public better information about herbal remedies and their regulation so as to enable them to make a more informed choice
 - to improve the proportionality, accountability, consistency, transparency, and targeting of regulation in this area in line with principles of good regulation.

Background

Legislative framework

5. The legislative framework for the UK affecting the regulation of herbal remedies used in one-to-one consultation is set out, principally in:
 - **Section 12(1) of the Medicines Act 1968**, under which anyone can supply unlicensed herbal remedies to meet individual patient's needs following a face-to-face consultation
 - **The Medicines (Retail Sale and Supply of Herbal Remedies) Order 1977** that sets out restrictions applying to the sale and supply of listed potent herbal ingredients
 - **The Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971** which in certain circumstances permits a third party to manufacture unlicensed herbal remedies for use in one-to-one consultations.
6. Further information about these legislative provisions is contained in the consultation document MLX 299.

Why does the regulatory framework need to change?

7. The current regulatory framework relating to unlicensed herbal medicines used in one-to-one consultations needs to change for a number of reasons which include:
 - to respond to evidence of public health risk (see risk assessment – below)
 - to achieve a more systematic approach to assurance as to safety and quality
 - to provide stability in which practitioners and others in the sector can plan,
 - to update and clarify the legal basis on which the herbal remedies are exempt from various licensing requirement
 - to make good the lack of a legal definition as to who is permitted to carry out a one-to-one consultation. This is a major defect affecting all three pieces of legislation; it is also liable to limit the options for proportionate regulation where a safety issue arises affecting a specific herbal ingredient that potentially would remain acceptable for use by a skilled herbalist
 - to deal with deficiencies in existing medicines legislation. The 1971 SI is poorly understood and, to a significant extent, not applied. The 1977 SI is a very complex piece of legislation that falls short of current expectations in relation to transparency and clarity.
8. Overall, this regulatory framework remained largely unchanged for many years. There are a number of specific reasons for pursuing regulatory reforms now:
 - growing awareness of the public health issues
 - support within the herbal sector itself for reform
 - the proposed Directive on Traditional Herbal Medicinal Products that would serve to highlight weaknesses in other aspects of legislation and in particular to emphasise the need to clarify the legal basis for Section 12(1) and associated legislation

- the proposed statutory self-regulation of the herbal medicine profession that would create new opportunities to resolve issues relating to the regulation of unlicensed herbal medicines used in one-to-one consultations.
9. The Government gave a commitment in 2001 to review this area of regulation in response to a report from the House of Lords Select Committee on Science and Technology and the opportunity to take this work forward has been provided by the recent report of the Herbal Medicines Regulatory Working Group (HMRWG) which, at the Government's request, put forward a number of proposals for reform as well as identifying issues for further consideration.

Strategic programme of reform

10. The proposed reform is part of a wider strategic programme of reform of the regulation of herbal medicines. This also embraces the proposed statutory regulation of the herbal medicine profession (the subject of a parallel consultation) and the proposed European Directive on Traditional Herbal Medicinal Products (which is expected to be formally adopted shortly). The Directive will put in place a simplified registration scheme to regulate manufactured over-the-counter traditional herbal medicines, giving the public assurances as to standards of safety, quality and patient information.

Risk assessment

Public health risk

11. The House of Lords Select Committee on Science and Technology noted in 2000: *“we are concerned about the safety implications of an unregulated sector and we urge all possible avenues be explored to ensure better control of this unregulated sector in the interests of public health.”*
12. The public health risks associated with unlicensed herbal medicines have been considered in some depth in the context of the proposed Directive on Traditional Herbal Medicinal Products. Issues identified in that context included: confusion of similar looking ingredients or those with similar names leading to the accidental inclusion of toxic ingredients; contamination of remedies, e.g. with heavy metals; adulteration with inclusion of illegal ingredients; poor labelling.
13. These problems of safety and quality for the Directive apply not only to products the Directive is intended to cover (i.e. manufactured remedies intended for OTC sale) but also to remedies used by practitioners in their one-to-one consultations – the subject of the current consultation. Moreover, the problems can occur both in relation to herbal ingredients supplied to practitioners for them to make up remedies under Section 12(1) and in relation to manufactured remedies that are sold to practitioners for their use in consultations. It is not possible to quantify the extent of public health risk: research shows that many people do not tell their doctor that they are taking herbal remedies and so the latter may have no basis for knowing that a health problem may be associated with use of a herbal remedy. Where a health problem arises with a herbal remedy that is mislabelled as to its actual contents this makes it even less likely that a doctor would be aware as to the

linkage with a herbal remedy. The persistent appearance of random examples of poor quality, unsafe remedies is a widely recognised international problem, fully acknowledged by the World Health Organisation.

14. The following examples illustrate the safety problems:

- in the Journal of the Royal Society for the Promotion of Health, December 2002, clinicians report on cases of women being hospitalised after being prescribed Chinese herbal slimming remedies found to contain Flenfluramine – a POM banned Europe wide due to association with pulmonary hypertension and valvular heart disease
- substitution of one plant species for another, often from a completely different genus, is a recognised practice in parts of traditional Chinese medicine (TCM). Furthermore, herbal ingredients are traded using their common Chinese Pin Yin names and this can lead to confusion. This is highly problematic in relation to *Aristolochia* species that are associated with kidney failure and cancer. For example, the name Fangji can be used either to describe the roots of the toxic *Aristolochia fangchi* or *Stephania* or *Cocculus* species (the latter two are not believed to be inherently harmful). Similarly the name Mu Tong can be used to describe the stem either of the toxic *Aristolochia manshuriensis* or of *Clematis* or *Akebia* species (again the latter two are not believed to be inherently harmful)
- the widespread substitution with *Aristolochia* species in TCM was confirmed in a study by the Medicines Control Agency (the MHRA's predecessor). In addition to the problems of substitution found in OTC products, a number of samples of raw herbs sampled from TCM outlets tested positive for aristolochic acids, which indicate the presence of *Aristolochia*. The positive samples were referred to as Mu Tong and seem to have been intended for use in Section 12(1) remedies supplied by the clinic. This inadvertent supply of *Aristolochia* highlighted the public health issues that can arise when herbal ingredients are not authenticated properly
- a product called Fufang luhui jianoang was reported to the Agency as containing Mercury. Recent MHRA investigations, confirm that this product contains in the region of **11.7% mercury by weight** and a range of other toxic heavy metals in smaller quantities. The Agency has acted to ensure that the product be recalled from the 35 TCM clinics across the country known to be supplying Fufang luhui jiaoanang.

15. **There are potential public health risks that are specific to unlicensed herbal remedies supplied to meet the specific needs of patients following one-to-one consultation.** These include:

- the lack of any requirement for professional competence or experience on the part of the person carrying out the consultation may be associated with incorrect diagnosis or incorrect response to a diagnosis. These may lead to supply of a remedy which does not meet the needs of the patient or potentially could be positively harmful or could deflect or delay the patient from consulting their GP or a pharmacist

- the ability of the person carrying out the one-to-one consultation, legally to use a range of more potent herbal ingredients, notwithstanding the potential lack of professional competence or experience, poses a clear risk.

Other risks

16. The current inadequate regulatory framework contributes to an ongoing risk to the reputation of those responsible herbal practitioners who follow good professional practice within a professional herbalist organisation and whose reputation (and business) may suffer following publicity given to poor practice by other practitioners.

Options

17. The main regulatory options under consideration at this stage are:

Option	Achieved by:		
	<i>A. Legislation</i>	<i>B. Statutory Professional self regulation</i>	<i>C. Voluntary self regulation</i>
1. Do nothing			
2. Reform regulatory framework including restrict ability to operate under S12(1) to those on statutory register; do <i>not</i> extend scheme to non-herbal traditional medicines	✓	✓	
3. As for option 2 but <i>include</i> extension to at least some non-herbal traditional medicines	✓	✓	
4. Reform regulatory framework including maintaining ability of practitioners not on statutory register to operate under S12(1); do <i>not</i> extend scheme to non-herbal traditional medicines	✓	✓	✓
5. As for option 4 but include extension to at least some non-herbal traditional medicines, but only in relation to practitioners on statutory register	✓	✓	✓

18. The accompanying consultation document explains the detailed range of measures or broader ideas that are under consideration. It will be evident that there is a large range of sub-options for possible consideration. For example:

- a possible extension of the regulatory regime to cover some non-herbal traditional medicines might be limited and tightly constrained or it might be broader and, in effect, introduce a major new category of unlicensed medicines
- there are a number of intermediate points between preventing non-registered practitioners operating under a reformed Section 12(1) provision and allowing

them to continue to do so indefinitely. These might involve, for example, transitional provisions or a subsequent review.

19. Consultation should enable any necessary of refinement of options and any other sub-options further, and in particular it should help:
- in adjusting or confirming the suggested balance between different mechanisms for achieving reform, notably legislation, statutory self-regulation and voluntary self-regulation (*Options 2 – 5*)
 - determine the overall feasibility and viability of voluntary self-regulation among those users of Section 12(1) who will not be on the statutory register (*Options 4 and 5*)
 - determine whether the extension of the regime to at least some non-herbal ingredients is a realistic option (*Options 3 and 5*).

Benefits and risks of the options

20. This represents an initial assessment that will need to be developed in the light of responses to consultation and subsequent work.
21. **Option 1** presents clear ongoing risks to public health and to the reputation of responsible herbal practitioners and to herbal medicine as a whole. Under this option the risk would be likely to grow: the international trend towards the introduction of effective regulation for herbal medicines, (e.g. the proposed EU Directive on Traditional Herbal Medicinal Products, and other comparable measures in countries such as Canada and Australia) is likely to mean that those wishing to place low grade unregulated products and ingredients on the market are likely to target areas of ineffective regulation in order to off-load their stocks. Depletion of some species of medicinal plants owing to the world-wide popularity of herbal medicines is likely to increase the commercial incentive for some less scrupulous suppliers internationally to include substitute species in place of scarce and expensive ingredients. Overall, there are no obvious benefits to the option of inaction and the continuing examples of unsafe, poor quality, remedies coming to the market clearly make the case for reform.
22. **Option 2** would deliver benefits in improved public health protection, depending on how effectively the proposed package of measures could be developed in the light of consultation. Potentially this option is beneficial for professional herbalists who intend to join the statutory register. The twin actions of creating a statutory register of herbalists and improving the regulation of the products they use could have a major impact in enhancing the standing of herbal medicine as practised by practitioners on the statutory register. However, this option potentially could well have an adverse regulatory impact on at least some of the unknown number of those currently operating under Section 12(1) who would *not* otherwise intend to join the proposed statutory professional register for herbalists. Such unregistered practitioners would need to adjust their activities in order to stay within the law. While this adverse regulatory impact might be fully justified in some cases on grounds of public health this would not necessarily be the case for all current users of Section 12(1). This issue is considered in more detail later in the RIA.

23. **Option 3** would deliver the same benefits and risks as Option 2. In addition, extending the scheme to enable registered herbalists to use non-herbal traditional remedies has both possible benefits and risks. It would extend practitioner and patient choice. There is particular interest in the TCM and Ayurvedic medicine sectors in the use of such medicines. However, there are some doubts as to whether it would be possible to construct this option in a way that was legally robust and sufficiently clear as to be fully enforceable. Also, unless adequate and practicable regulatory controls can be identified during consultation to protect public health, it could also extend risk, bearing in mind that non-herbal ingredients found by the MHRA in illegal “herbal” medicines have included a range of potent and toxic materials such as heavy metals, POM pharmaceutical ingredients and animal excreta.
24. **Option 4** could deliver some benefits in terms of improved health protection. The benefits may be somewhat less than those of Option 2 *if* the hypothesis is valid that voluntary self-regulation among non-registered practitioners will be somewhat less effective for the remaining Section 12(1) operators than would be the statutory regulation that would apply to registered herbalists. It may be that voluntary self-regulation among other Section 12(1) users might be effective *only* in relation to those who are already members of certain practitioner or trade associations. Reasons why this hypothesis might be valid are, principally, that:
- non-registered practitioners are very far from a homogeneous group; they are drawn from a diverse range of complementary and alternative medicine (CAM) professions and beyond (e.g. some shopkeepers). Potentially it could be difficult for these groups collectively to organise effective self-regulation in relation to their use of herbal remedies under Section 12(1). This problem would be accentuated to the extent that it can be problematic for people to identify whether they are actually using Section 12(1) – bearing in mind that there are many herbal products used in CAM that would not be classified as medicines by the MHRA
 - there may be a proportion of operators under Section 12(1) who have no intention of participating in any form of effective regulation.
25. On the other hand, unlike Option 2, Option 4 avoids the potentially adverse regulatory impact on these users of Section 12(1) who will not be on the statutory register.
26. **Option 5** would appear broadly to achieve the risks and benefits associated with Option 4 together with those additional risks and benefits of Option 3 that are particularly associated with extension of the regime, to registered herbalists only, of at least some remedies including non-herbal ingredients.
27. However, these two elements could interact to create additional risks or benefits. An additional risk could be that the message that it was acceptable for registered herbalists to use non-herbal ingredients in their unlicensed medicines could also serve to increase (illegal) and potentially dangerous use of such ingredients by non-registered practitioners. Alternatively, an additional benefit could be that this

additional privilege, restricted to registered herbalists, over the use of non-herbal ingredients, could encourage a greater proportion of practitioners to see the benefits of joining the statutory register.

Business sectors affected

Practitioners

28. The principal sector affected would be practitioners of various kinds operating under Section 12(1). HMRWG estimated that there are currently approximately 1,300 herbal medicinal practitioners who are members of voluntary professional registers within the UK. This is split fairly evenly between practitioners of western herbal medicine and TCM with much smaller numbers of practitioners of Ayurvedic and Tibetan medicines. HMRWG notes that there is an unknown number of other practitioners in the Chinese herbal medicine sector who are not members of a voluntary register. This may bring total numbers up to 2,000.
29. In addition there is an unknown number of other practitioners from various CAM therapies and traditions who, from time to time, may operate under Section 12(1). Also a minority of shopkeepers e.g. in the health food sector may make up herbal remedies to meet individual needs following consultation. It is not at all straightforward to determine how many people use Section 12(1). Many herbal products used in the CAM sector would not be classified as medicines by the MHRA. However, such classification can, in law, only be carried out on a case by case basis.
30. One example of a complex area is that of aromatherapy. Where aromatherapists blend essential oils to meet the needs of patients, in general it is unlikely that many such typical remedies would be regarded by the MHRA as medicines. This matches the situation for OTC aromatherapy products which, in typical cases, the MHRA would be unlikely to regard as medicines. However, some aromatherapists may provide information, e.g. through practice leaflets, stating or implying that their products have a medicinal effect, thereby creating a possibility that in those particular cases products might be brought within the definition of a medicine.
31. Practitioners operating under Section 12(1) will typically be micro businesses, often consisting of a single practitioner. Some practitioners, particularly in the TCM sector, are employed within chains of clinics.

Suppliers of ingredients and manufacturers of remedies for use in one-to-one consultation; importers of these products and ingredients; wholesale dealers for ingredients

32. Practitioners buy their ingredients from an unknown number of different suppliers. Further information on this may usefully be obtained during consultation. In many cases the businesses concerned will also be involved in the supply chain for OTC herbal remedies to be covered by the Directive on Traditional Herbal Medicinal Products and to that extent the impact of the current proposals and ideas

would be more limited as such businesses would in any case be needing to ensure that they had the necessary quality control systems in place.

Issues of equity and fairness

33. There are various issues of equity and fairness, and MHRA hopes that analysis can be amplified as a result of consultation.
34. The limitations of the current regime make enforcement on a number of issues problematic. This is not equitable for those practitioners who seek to comply with the law. The current regime also too readily allows the reputation of responsible practitioners to be damaged by the activities of those less responsible operators who take insufficient care to protect public health, for example by purchasing low quality products and ingredients.
35. Inequity between businesses could arise if the current proposals for reform led to lower standards being acceptable in relation to suppliers of ingredients and manufactured products than would be the case in relation to the proposed Directive on Traditional Herbal Medicinal Products.
36. Inequity between businesses could arise under various of the options if some practitioners undercut registered herbalists by legally or illegally following lower standards, purchasing low grade materials and products. This could happen in a range of different circumstances, including for example if voluntary self-regulation was ineffective under Option 4 and 5 or if enforcement under Option 2 or 3 provided insufficient of a deterrent. However, in relation to each of Options 2–5 the power of information and advice to the public could help to redress any inequities. This would represent a major improvement over the current position where it is not easy to give the public advice in relation to the safe use of unlicensed herbal remedies.

Costs of options 2 - 5

37. It is not possible at this early stage to quantify costs associated with the proposals or ideas for regulatory reform that are part of the initial outline package that, with variations, forms the core of Options 2 – 5. **As a clearer idea of reforms that may be pursued emerges during and following consultation it will be important to discuss any cost implications in more detail with representative organisations and individual practitioners.** The proposals currently do not envisage the herbal practitioners in most circumstances having to hold licences or authorisations (e.g. Traditional Use Registrations or Manufacturer's Licences) or to conduct specific tests on ingredients.
38. The MHRA considers that it is likely that three of the main areas of additional costs arising from the kind of reforms under consideration will be:
 - herbalists (whether from the requirements of statutory or voluntary self-regulation) will want to buy ingredients and products for use in one to one consultation of adequate safety and quality. This may lead to higher costs to practitioners – particularly in the TCM sector where there does appear to be a

significant incidence of low grade products that have been subject to minimal quality control

- manufacturers who supply remedies for use by practitioners in one-to-one consultation would be required to hold a Manufacturer's (Specials) Licence. The requirement to have the necessary premises, equipment and processes for the safe conduct of this business would have a significant impact on any businesses operating to low standards. This new requirement would replace an existing requirement that is not fully applied at the moment and therefore would create a new cost for some businesses
- certain manufacturers (notably among some overseas manufacturers of patent medicines in the TCM sector) may have been manufacturing remedies on large scale that are intended for use in practitioner consultations. These remedies sometimes do not comply with current regulation for unlicensed herbal medicines (e.g. they sometimes include non-herbal ingredients or are accompanied by brand names or written claims) and the MHRA takes appropriate regulatory action. In future, under the proposals it would be clear that manufactured products of this kind would require either the appropriate marketing authorisation or traditional use registration or the product would need to be commissioned by a registered practitioner to meet special needs. This would mean a potential requirement for some companies (probably mainly overseas) substantially to reappraise their product strategy. There is a strong public health case for a major upgrade in quality and safety standards for these products.

Consultation with small business: The small firms' impact test

39. A number of those involved in the preparation of the HMRWG report were themselves practitioners with a very wide and detailed knowledge of the practical issues facing herbal practitioners. The MHRA has long been aware that in discussions with herbal practitioners regulatory impact is a major issue: some practitioners may well be faced with the practical issue of whether to cancel a clinic in order to attend a meeting about regulation. The MHRA will therefore discuss with leadership of relevant practitioner organisations (a) how to ensure that they are able to engage effectively in the discussion of possible reforms and (b) how best to evaluate the practical impact of proposals. It will be important to consider this issue alongside that of the proposed statutory regulation of the herbal medicine profession.

The competition assessment

40. The MHRA has considered the impact of the proposal on competition. There are two markets mainly affected:

- the provision by practitioners of remedies tailored to meet individual needs following face-to-face consultation. Some information about the numbers of practitioners is given above (*see business sectors affected*)
- various businesses in the supply chain for materials and products used in one-to-one consultation (growers, manufacturers, wholesalers and importers).

41. The markets affected can, however, also be viewed in a number of different ways:

- as far as practitioners are concerned the MHRA believes that the markets for western herbalism, TCM and Ayurveda are relatively distinct in the sense that it is likely to require a substantial effort for a practitioner to acquire skills in a completely different herbal tradition; (the Agency is, however, aware that there are some practitioners who practise both western herbalism and TCM)
- for patients there may be a greater overlap in the market; while some may be strong adherents of a particular tradition others may well be amenable to trying different traditions in response to factors such as price, convenience, experience and personal recommendation
- there may be some interaction with the OTC herbal medicines. On the one hand improved standards and information in OTC herbals following the Directive on Traditional Herbal Medicinal Products may mean the public see less need to consult an expert herbalist; on the other hand the higher standing of the herbalist profession and more effective regulation of the products they use following the proposed statutory regulation of the profession and the reform of medicines legislation covered by this RIA may draw some people away from using OTC herbals in favour of consulting expert herbalists for a more customised service
- there is also an overall market for CAM. Typically, articles in newspapers and magazines will feature a range of different CAM therapies and it is likely that an increase or reduction in use of one CAM therapy (brought about e.g. by changes in public confidence or price) will be reflected in changes in *relative* use of individual therapies as well as change in the *absolute* numbers.

Practitioners

42. Subject to the future direction of the development of the package of possible reforms, the MHRA does not believe that the proposals will have a substantial impact on competition in relation to herbal practitioners, bearing in mind that the sector is characterised by very large numbers of micro businesses. Other factors supporting this assessment are that the sector is not characterised by rapid technological change and the emerging proposals would not impose higher costs on new entrants than existing participants in the market. The MHRA's current view is that the proposals would be unlikely to lead to any major change in the market structure, although Options 2 and 3 would have a significant effect on the number of practitioners operating under Section 12(1).
43. The MHRA considers that within herbalism the result of improved regulation and improved public information *may* be some shift in the relative position of TCM, although the effects are difficult to predict and feedback would be welcome. The reputation of TCM is regularly put at risk where examples of dangerous and illegal products are found in use in parts of the sector. Overall, it is likely that TCM may make a considerable reputational gain if there is a positive response to reform of regulatory arrangements. Equally, parts of the TCM sector may need to make more strenuous efforts and incur greater costs than average if they are to ensure that they are consistently supplying medicines that are safe and of acceptable quality.
44. There is one specific area of competition which the MHRA would wish to review carefully in the light of consultation - and subsequently in the light of what

package is chosen. This is the possible differential impact on competition as between categories of practitioner – an issue that could arise particularly under Options 4 and 5: statutorily regulated practitioner; non-statutorily regulated practitioner participating in voluntary self-regulation; and non-registered practitioner choosing not to participate in self-regulation. The costs (and standards) of the latter are likely to be considerably lower than that of the former, with those of the non-statutorily regulated practitioner choosing to participate in voluntary self-regulation possibly occupying an intermediate point. The fairness of competition will be heavily dependent on the provision of information in order for the public to make an informed choice. In this context the linked proposals for the statutory regulation of the herbal medicine profession include reserving the use of certain titles for registered practitioners. This should be of considerable benefit both to the profession and to the public. **Overall, throughout the process of developing reforms the MHRA will need to be mindful that differential effects on competition between different categories of practitioner could lead to greater or reduced public health risk.**

45. Many CAM practitioners when making up and using herbal products in their consultations (particularly where herbal ingredients are at the milder end of the spectrum) are likely to be using products that are borderline in terms of whether they are defined as medicines. There is likely therefore to be a degree of substitutability. A product containing certain ingredients may fall within different regulatory categories depending on its presentation, or it may be that minor adjustments in a product are sufficient to move it into a different regulatory category. It is likely to be difficult accurately to predict or monitor any such effects.

Suppliers of ingredients and products for use in one- to-one consultation

46. The MHRA's initial assessment is that the emerging proposals would lead to some changes in the market but these potentially would enhance fair competition in that practitioners would have better information than now on which to judge whether the quality of ingredients or products was adequate. The MHRA's current understanding, (more specific information would be welcome during consultation), is that there are a significant number of companies involved in the supply chain in this part of the sector.
47. It is possible that some existing suppliers operating to low standards, particularly in TCM, will withdraw from the market rather than, for example, seek to meet the requirements for a Manufacturer's (Specials) Licence as would be required under some elements of the proposals. However, overall it is likely that there will be a significant pool of companies variously holding a Manufacturer's Licence, a Wholesale Dealer's (Import) Licence or meeting accreditation standards of external bodies such as the Soil Association. Companies in this position should readily be able to meet the standards that would apply. In the consultation document the MHRA raises options of either creating a further voluntary arrangement under which the MHRA could award a Good Manufacturing Practice certificate for suppliers of partially processed ingredients, or of establishing a requirement for suppliers of active ingredients to meet GMP. This could further

enhance information available to practitioners purchasing supplies, and hence competition.

Enforcement and sanctions

48. Medicines legislation would be enforced by the MHRA, as in other areas. This would include inspection of manufacturers premises for which a fee would need to be charged. However, depending, on the option chosen, certain aspects of the proposals would be subject to professional self-regulation, (for example a code of professional good practice on the part of registered herbalists as to the use of reliable suppliers). It would be important for there to be appropriate liaison between the statutory regulatory body and the MHRA over the handling of incidents that are potentially both illegal and unprofessional.

Monitoring and review

49. Depending on which proposals are worked up further and adopted, it is likely that reform may take place in more than one stage and/or there may be an explicit commitment to keep certain elements of policy under review with a view to possible further change. For example, if Option 4 or 5 is pursued there would be a specific need to keep under review whether in practice the option provided sufficient public health protection in relation to practitioners not on a statutory professional register.
50. A major difficulty in determining a possible second stage or final outcome to the programme of reform is the uncertainty over how many current practitioners under Section 12(1) would remain outside the statutory register and what proportion would participate in effective voluntary self-regulation. If Option 4 or 5 is pursued this potentially would allow for monitoring and increased possibilities for a more informed review after several years on the basis of the *actual* numbers and types of practitioners found to be (a) on the statutory professional register (b) coming within voluntary self-regulation (c) operating outside either the above arrangements. It should also be possible after several years to start to form a picture of the impact of the reforms on public health protection, e.g. whether detected incidents of the use of contaminated and adulterated remedies are concentrated among practitioners who are outside statutory or voluntary self-regulation.
51. The MHRA's provisional view is that this kind of approach to a further review would offer higher prospects of achieving an eventual outcome that was proportionate and well targeted. It would also allow different models of regulation to be tested in practice before definitive decisions were taken about the longer term outcome.

Consultation

52. The linked consultation document covering these proposals contains an extensive list of bodies that are to be consulted on the proposals. In Government there will be continuing dialogue with, among others, the Small Business Service, the Cabinet Office Regulatory Impact Unit and the Office of Fair Trading. Among

external interest groups covered are various CAM professional bodies, orthodox healthcare professions, consumer interests, scientific bodies and trade associations. The consultation period will be 12 weeks, and the MHRA would intend to call meeting(s) of some interested parties in order to explore some of the more complex issues. Assuming that the MHRA intends to proceed with at least some proposals following consultation, there would be a further public consultation exercise covering more specific proposals at a subsequent date.

Summary and recommendations

53. The MHRA considers that **Option 1** (the status quo) is clearly inferior. It would not protect public health and does not meet principles of good regulation. It is not recommended.
54. The MHRA is currently minded to take the view that although there is a public health case for **Option 2** there is currently too great an uncertainty over its likely regulatory impact (both in terms of numbers and effect in practice) on those practitioners who use Section 12(1) and who will not be on the statutory register.
55. The same drawback applies to **Option 3**.
56. The MHRA is currently minded to favour either **Option 5** (if suitably rigorous arrangements to protect public health can be devised in relation to non-herbal ingredients) and a range of definitional issues can be resolved or **Option 4** if this is not the case. The MHRA shares the concerns of the HMRWG as to whether the position in relation to non-registered practitioners is fully sustainable in the longer term.
57. As the HMRWG stated⁴: *“The HMRWG has some reservations on public health grounds about the desirability of an indefinite continuation of a position where people are operating a business entailing holding personal consultations and making up and supplying medicinal products without a reliable assurance that such operators are working under adequate professional accountability.....The view of the HMRWG is that, for the time being, the most realistic and feasible approach would be to allow continued use of Section 12(1) by operators not on the herbalist or CAM register while encouraging the growth of voluntary self-regulation to give the public assurance. This would be on the understanding that the situation would be kept under review, particularly as to whether responsible self-regulation was providing sufficient public health protection. This would be a relatively flexible approach keeping the longer term options open.”*
58. If therefore Option 4 or 5 is selected the MHRA considers that it would be necessary to keep the situation under careful review.

⁴Page 147 & 148 of HMRWG Report

ANNEX C – Reply form

MLX 299

To:

**Miss Alexandra Williamson
Medicines and Healthcare Products Regulatory Agency
16/131 Market Towers
1 Nine Elms Lane
LONDON
SW8 5 NQ**

From:

Please tick box as appropriate

- **We have no comments to make on the proposals in MLX 299**

- **Our comments on the proposals in MLX 299 are attached.** *We will assume that your comments can be made publicly available unless you indicate below that you wish all or part of them to be treated as confidential.*

- **My reply is confidential**

- **My reply is partially confidential** (indicate clearly in the text any confidential elements)

Signed: _____

Date: _____

ANNEX D – distribution list

ABPI
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Age Concern London
Ainsworths
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Aromatherapy Consortium
Arthritis Care
Arthritis Research Campaign
Assn of Respiratory Nurse Specialist
Assoc of Anaesthetists of GB and Ireland
Assoc of British Cardiac Nurses
Assoc of British Dispensing Opticians
Assoc of British Health Care Industries
Assoc of Clin Res in the Pharmaceutical Industry
Assoc of Clinical Research Contractors
Assoc of Community Health
Assoc of Contacts Lens Manufacturers
Assoc of Ind Clin Research Contractors
Assoc of Independent Multiple Pharmacies
Assoc of Medical Research Charities
Assoc of Palliative Medicine
Assoc of Traditional Chinese Medicine UK
Association for Nurse Prescribing
Association for Residential Care
Association for Sick Children
Association of Chinese Medicine Practitioners
Association of Hospice Management
Association of Master Herbalists
Association of Natural Medicine (ANM)
Association of Optometrists
Association of Pharmaceutical Importers
Association of Scottish Trusts CP(ASTCP)
Association of Surgeons of GB & Ireland
Association of Traditional Chinese Medicine UK
Association of Veterinarians in Industry
Asthma & Allergy Research
ATC
Aventis Pharma Ltd
Ayurveda UK Foundation
Ayurvedic Medical Association UK
Ayurvedic Trade Association
BAAAP
BBSRC
Besselaar Clinical Research Unit
BHMA
Bio-Health Ltd
Bioindustry Association
Birth Control Trust
BMA (Wales)
BMA Scottish Branch
Bristol-Myers Squibb
Brit Assoc for Nutritional Therapists
Brit Assoc of European Distributors
Brit Assoc of European Pharm Distributor
Brit Assoc of Pharmaceutical Physicians
Brit Assoc of Pharmaceutical Wholesalers
Brit Assoc of Research Quality Assurance
Brit Cardiac Patients Association
Brit Oncological Association
British Acupuncture Council
British Assoc of Chemical Specialities
British Assoc of Dermatologists
British Assoc of European Distributors
British Association of Nutritional Therapies,
British Complementary Medicines Association
British Contact Dermatitis Group
British Dental Association
British Dental Association (N Ireland)
British Dental Association (Scotland)
British Dental Association (Wales)
British Diabetic Association
British Dietetic Association
British Epilepsy Association
British Heart Foundation
British Herb Trade Association
British Herbal Medicines Association
British Homeopathic Association
British Institute of Regulatory Affairs
British Medical Association
British Medical Association (N Ireland)
British Osteopathic Association
British Pharmacological Society
British Pregnancy Advisory Service
British Retail Consortium
British Society For Allergy & Clinical Immunology
British Society for Allergy, Environmental and Nutritional Medicine
British Society of Chinese Medicine (BSCM)
British Standards Institute
British Toxicology Society
CAMedica
Cancer Research Campaign
Cancer Research UK
CARE
CCCPH
CEMVO
Central Medical Advisory Committee
Cephalon UK Ltd
Chemist & Druggist
Chinese Competent Authority
Chinese Medical Institute & Register
CMAS
College Of Pharmacy Practice
Commission For Racial Equality

Commonwealth Working Group on Traditional
 & Complementary Health
 Community Pharmacy Magazine
 Community Pharmacy Wales
 Company Chemist Association Ltd
 Consumers Association
 Consumers For Health Choice
 Consumers in Europe Group
 Council for Comp & Alternative Medicine
 Council For Responsible Nutrition
 Council of Ethnic Minority Voluntary
 Organisations
 Councils of Heads of Medical Schools
 CPHVA
 CTPA LTD
 CWS LTD
 David Shepherd Wildlife Foundation
 DEFRA - Global Wildlife Division
 Department for Constitutional Affairs
 Diabetes UK
 Dispensing Doctors Association
 Doctor Magazine
 Dr China
 Drug & Therapeutics Bulletin
 Drug Information Pharmacists Group
 DTI
 Earthforce,
 East West Natural Products,
 EISAI Ltd
 English National Board for Nursing
 EPSRC
 ESCOP Secretariat
 Essential Oil Trade Association
 European Assn Hospital Pharmacists
 European Council for Classical Homeopath
 European Herbal Practitioners Assoc
 Faculty Of Homoeopathy
 Faculty of Pharmaceutical Medicine
 FDC Reports
 Food & Drink Association
 Food Commision UK Ltd
 Foundation for Integrated Medicine
 Foundation for Intergrated Health
 FSID
 General Council of Traditional Chinese
 Medicine
 General Dental Council
 General Medical Council
 General Practitioners Association (NI)
 General Practitioners Committee
 General Practitioners Committee (Wales)
 GNC
 Guild of Healthcare Pharmacists
 HCSA
 Health & Safety Executive
 Health Development Agency
 Health Food Business Magazine,
 Health Food Manufacturer's Association
 Health Professions Council
 Health Promotion England
 Health Service Commissioner
 Health Which
 Heathfield Family Centre
 HFMA
 HM Customs & Excise
 Hoechst Marion Roussel
 Holland & Barrett
 Home Office – Operational Policing Policy
 Unit
 Icon Regulatory Division
 IDRAC SAS
 IFA
 IFAW
 IHRC
 Independent Healthcare Association
 Institute for Optimum Nutrition,
 Institute of Health Food Retailing
 Int Society for Pharmaco-Epidemiology
 Internal Holistic Aromatherapy
 International Federation of Prof
 Aromatherapists
 International Register of Consultant Herbalists
 International Society of Pharmacovigilance
 Intl. Federation of Aromatherapists
 Joint Consultants Committee
 Joint Formulary Committee
 Kings College Hospital
 LACOTS - Co-ordinating Body on Food and
 Trading Standards
 LIFE
 London College of Traditional Acupuncture &
 Oriental Medicine
 London School of Acupuncture &TCM,
 University of Westminster
 Long Term Medical Conditions Alliance
 Maharishi Ayurveda Products
 Margaret Anderson and Associates
 Medical Protection Society
 Medical Research Council
 Medical Toxicology Unit
 Medical Womens Federation
 Medicines Monitoring Unit
 Menarini Pharmaceuticals UK Ltd
 Milton Keynes PCT
 MIMMS
 MIND
 National Aids Trust
 National Assembly for Wales
 National Assoc of Women Pharmacists
 National Association of GP Co-operatives
 National Association of Health Stores
 National Asthma Campaign
 National Board for Nursing, Midwifery &
 Health Visiting for NI
 National Consumer Council
 National Council for Hospices And Specialist
 Palliative Care Services
 National Eczema Society
 National Federation of Badger Groups
 National Institute of Medical Herbalists

National Patient Safety Agency
 National Pharmaceutical Association
 Naturopathic Forum (UK)
 Natural Medicines Manufacturers' Assn UK
 Natural Medicines Society
 NCH & SPCS
 NelsonBach,
 Neurological Alliance
 NHS Alliance
 NHS Confederation
 NHS Information Authority
 NHS Pharmaceutical Quality Control Comm.
 Northern College of Acupuncture
 Northern Ireland Consumer Council
 Novartis Consumer Health
 Nursing & Midwifery Council
 Only Natural Products,
 OTC Bulletin
 OTC Business News
 OTC News & Market Report
 Paediatric Chief Pharmacists Group
 Pain Society (The)
 Pan European Federation of TCM Societies
 Patients Association
 Pavilion Healthcare International Ltd
 PECMI
 Peninsula Medical School
 Peter Black Healthcare Ltd
 Pfizer Consumer Healthcare
 Pharmaceutical Journal
 Pharmaceutical Quality Group
 Pharmaceutical Society For N Ireland
 Pharmacia Ltd
 Pharmacy Insurance Agency
 Pharmag
 Pi Pharma
 Plantlife
 Postlethwaite's Herbal Products,
 Potters (Herbal Supplies) Ltd.
 Primary Care Pharmacists Assoc
 Proprietary Association of Great Britain
 Public Health Laboratory Service Board
 Quality Improvement Scotland (NHS)
 Queens University
 Reckitt Benckiser
 Register For Chinese Herbal Medicine
 Rethink
 Royal Botanic Gardens, Kew
 Royal College of Anaesthetists
 Royal College of General Practitioners
 Royal College of General Practitioners
 Royal College of Midwives
 Royal College of Midwives
 Royal College of Midwives
 Royal College of Nursing
 Royal College of Nursing (N Ireland)
 Royal College of Nursing (Wales)
 Royal College of Nursing Scotland
 Royal College of Obstet & Gynaecologists
 Royal College of Ophthalmologists
 Royal College of Paediatrics & Child Health
 Royal College of Pathologists
 Royal College of Physicians
 Royal College of Physicians & Surgeons
 Royal College of Physicians (Edinburgh)
 Royal College of Physicians (London)
 Royal College of Psychiatrists
 Royal College of Radiologists
 Royal College of Surgeons
 Royal College of Surgeons (Edinburgh)
 Royal Colleges of Physicians
 Royal Pharm Society of GB (Scotland)
 Royal Pharm Society of GB (Wales)
 Royal Pharmaceutical Society Of GB
 Royal Society for the Promotion of Health
 Royal Society of Chemistry
 RPSGB (Scotland)
 RPSGB Welsh Executive
 RSPB
 Scottish Association of Health Councils
 Scottish Consumer Council
 Scottish Deans Medical Curriculum Group
 Scottish General Medical Services Comm
 Scottish General Practitioners Committee
 Scottish Pharmaceutical Federation
 Scottish Pharmaceutical General Council
 Scottish Wholesale Druggists Association
 SCRIP
 Shadow Nursing & Midwifery Council
 Skin Care Campaign
 Small Business Service
 Smithkline Beecham Plc
 Social Audit
 Society for Promotion of Nutritional Therapy
 Society of Homoeopaths
 Society of Pharmaceutical Medicine
 Solgar Vitamins Ltd.
 Suffolk Port Health Authority
 SWITCH
 TAPASI
 The British Association of Flower Essence
 Producers
 The British Flower and Vibrational Essences
 Association
 The British Medical Journal
 The British Society for Allergy
 The British Thoracic Society
 The Exotic Animal Welfare Trust
 The Herb Society
 The Institute For Complementary Medicine
 The International College of Oriental Medicine
 The Lancet Publishing Group
 The Mammal Society
 The Organic Herb Trading Company
 The UK Inter-Professional Group
 TIC-TAC Administration
 Traditional Herbal Medicinal Producers
 TRAFFIC International
 Tutssels Enterprise IG
 UK Clinical Pharmacy Assn

UK Homeopathic Medical Association
UK Inter-Professional Group
Ulster Chemist Review
Unified Register of Herbal Practitioners
Veterinary Medicines Directorate (VMD)
Viatrix Pharmaceuticals Ltd

Volunteer Development Scotland
Welsh Consumer Council
Welsh National Board for Nursing
WILDAID
WWF-UK