Department of Health Steering Group on Acupuncture, Herbal Medicine and Traditional Chinese Medicine:

Response to the MHRA Discussion Papers on the Reform of S12(1)

A. Responses to questions posed in the consultation documents

Paper 1: Reforms of s12(1) of the Medicines Act 1968: overview

- *What is your current assessment of the case for regulation?*

We believe that there is an overwhelming case for regulation. The argument in favour of this was well made by the House of Lords' Science and Technology Select Committee in its Report on CAM published in 2000.[1] Section 5.86 of the Report says "the regulation of herbal products has emerged as presenting particular challenges for public health." The Report went on to note (5.87) "the Department of Health told us that the present regulatory arrangements for herbal medicines have significant weaknesses." The Report said (5.98) "we urge that all legislative avenues be explored to ensure better control of this unregulated (herbal) sector."

In addition to the exemptions granted to herbal remedies from licensing described sections 12 and 56 of the Medicines Act of 1968, the order (SI 1977 No.2130) provides further exemptions for herbal remedies from the controls on retail supply provided that the person selling or supplying the herbal remedy (a herbal practitioner) "has been requested by or on behalf of a particular person and in that person's presence to use his/her own judgment as to the treatment required" But no definition of "herbal practitioner" was provided in this legislation. Whilst there were few practitioners of herbal medicine working in the UK at the time of the passing of the Medicines Act of 1968, there are now thousands of practitioners using the facility of s12(1) across the UK. The MHRA website (March 19th 2007) notes that *"There are no restrictions in terms of those who operate under the regime. 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)".*[2] For this reason, a definition as to who may use the s12(1) facility and clear guidelines as to the standards expected of such s12(1) operators and their herbal medicines are now essential both to protect the public and to allow those wishing to have herbal treatment to consult well-trained practitioners who are subject to clearly established fitness to practice regimes.

- *Do you agree on the central importance of requiring systematic professional accountability for those who wish to benefit from the exemption in s12(1)?*

[1] House of Lords' Select Committee on Science and Technology Session 1999-2000 6th report, Complementary and Alternative Medicine, London : The Stationery Office, HL Paper 123, 21 Nov 2000.
[2] MHRA website http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=659 accessed 19/3/07.

We agree that there should be professional accountability for those who wish to benefit from the exemption in s12(1) to protect the public and permit those seeking herbal treatment to consult practitioners accountable to a statutory body that ensures publicly agreed standards of training, practice and conduct.

- *Do you agree that best overall approach to improving s12(1) would be through a combination of updated medicines legislation and agreement with the profession on codes of practice? If not, what approach do you advocate and why?*

We agree with the proposal that the best overall approach to improving s12(1) would be through a combination of updated medicines legislation and agreement with the profession on codes of practice. It is clear that the two go hand-in-hand. Section 12(1) currently fails to define who can utilise its exemptions and thus effectively allows anyone regardless of qualifications or fitness to practice to supply medicinal herbs, some of which (like those listed in part 111 of the Schedule to SI 1977 no.2130) are potentially powerful medicines. Limiting the use of s12(1) facility to those on a statutory register would go a long way to correct this current legislative weakness.

Paper 2: Reforms of s12(1) of the Medicines Act 1968: who should be allowed to operate under s12(1)?

- *Do you agree with the analysis of the central importance of giving the public assurance as to the professional expertise and accountability of the practitioner?*

Yes we agree that the public should have assurance as to the professional expertise and accountability of the practitioner. We are of the opinion that this can only be achieved via statutory regulation of those using the s12(1) facility.

- *If the s12(1) exemption should remain available to all practitioners, irrespective of whether they are subject to statutory regulation, how would the public be protected against poor professional practice?*

We believe the public would not be protected if this were the case and agreed standards of training, continuous professional development and revalidation would be undermined as those not participating in the statutory regulation would have similar rights to prescribe herbal medicines on a one-to-one basis as those on the statutory register. Unregistered practitioners may not know the limits of their competence because they are inadequately trained and so may put at risk those members of the public who consult them.

- *If, in addition to statutorily registered practitioners, the s12(1) exemption should remain open to some but not all practitioners who are not on a statutory register, how would the distinction be made in legislation?*

Permitting s12(1) exemption to remain open to some but not all practitioners who are not on a statutory register is not viable as there is no way of providing this distinction in legislation and this would undermine the process of statutory regulation since in the final analysis there would be no need for all practitioners using s12(1) to operate to legislatively enforceable standards.

- *What would the impact be on statutorily registered practitioners of permitting some or all non registered practitioners to continue to prepare herbal remedies without a licence under s12(1)?*

The incentive to gain independently quality-assured qualifications, to practise to agreed standards of conduct and to participate in continuous professional development and revalidation would be undermined since practitioners who were not statutorily regulated, without these qualifications/standards, could continue to use s12(1). In addition, the public would not be protected from poorly trained practitioners or from those with unacceptable standards of practice as there would be no legal way to prevent such individuals from using the s12(1) facility. The one exception to this principle might be considered as described in Sections 22-27 of Paper 2 where the statutorily regulated practitioner might delegate to appropriately trained members of staff certain clearly defined tasks analogous to the delegation of certain tasks by a pharmacist to non-registered pharmacy staff (e.g. pharmacy technician). We suggest that any such arrangement should be determined by the MHRA working closely with the Regulatory Council to ensure that the parameters for such arrangements are

clearly established and that such delegation can only occur where the statutorily regulated practitioner retains accountability for the provision of services by non-registered staff.

- *What would the impact be of restricting s12(1) to practitioners on a statutory register? Is your organisation in a position to quantify how many actual s12(1) users there are (as opposed to the likely larger numbers that may make use of herbal products/herbal ingredients) in any of the categories identified at para 13. Are you aware of any other comparable categories of operators not covered at para 13, and the extent of their usage of s12(1)?*

As already made clear in our previous answers, the long-term impact of restricting s12(1) to practitioners on a statutory register would be the beneficial one of assuring the public that those using s12(1) were appropriately trained and legislatively accountable. In our view, this positive outcome clearly justifies the removal of the right to use the s12(1) facility from those who are not statutorily regulated. We believe that there are perhaps as many as three thousand UK practitioners using the s12.1 facility at this time. We contend that all of these practitioners should either seek to enter the statutory register or give up the use of s12(1).

The only other comparable categories of operators not covered at para 13 that may make use of s12(1) are the homeopaths (who may prescribe drops of herbal 'mother' tinctures and thus are when doing so acting as herbalists under UK law) and anthroposophical doctors who use herbal medicines in small (but not homeopathic) doses.[3]

- *Where there are trained and experienced practitioners from CAM therapies besides herbal medicine who regularly use s12(1) and operate to acceptable professional standards are there overriding reasons why they should not be expected to join the proposed statutory register if they wish to continue to operate under the s12(1) exemption?*

No.

- *Good regulatory systems should promote proportionality, accountability, consistency, transparency and targeting in regulation. What, overall, would the regulatory impact be of (a) restricting benefit of the s12(1) exemption to statutorily registered practitioners (b) of any alternative approach that you may advocate?*

As already made clear in our previous answers, the long-term impact of restricting s12(1) to practitioners on a statutory register would be the beneficial one of assuring the public that those using 12(1) were appropriately trained and legislatively accountable. For this reason we do not advocate any alternative approach.

[3] A system of medicine founded by Rudolf Steiner in the early 1900's

Paper 3: Reforms of s12(1) of the Medicines Act 1968: safety issues

Do we agree with the following proposals?

Overall assessment

- *On the overall approach to safety and in particular the central importance that all practitioners operating under s12(1) should be subject to a strong framework of professional self regulation and accountability.*

We agree with this proposition. The logical way that this can be achieved is by requiring all those using 12(1) facility to be statutorily regulated and to develop a robust Professional Code of Practice for these practitioners based on self regulation and accountability

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Control of toxic/potent ingredients

- *On the relative merits of achieving controls on potent herbal ingredients in s12(1) products via agreement with the profession, via lists set out in legislation, or a mixture of both.*

We think that these controls should be achieved by a mixture of agreement with the profession combined with legislative regulation where necessary e.g. as has occurred with the banning the aristolochia spp from medicinal use. Agreement with the profession should be reached as to restrictions regarding strength, dosage or method of preparation etc for potentially powerful herbal medicines.

Formulary for herbalists

- *On the merits and practicalities of the herbal medicine profession developing a formulary of herbal ingredients accepted as having a place within the safe practice of herbal medicine within the UK, with proposals for items to be included in the formulary subject to review by the Herbal Medicines Advisory Committee*

We agree with the proposal that the herbal profession should develop a formulary of herbal medicines accepted as having a place within the safe practice of herbal medicine within the UK. We concur with the proposal that that herbs that are included in this formulary should be subject to review by the Herbal Medicines Advisory Committee. We agree that such a formulary should not limit herbs that may be used by the profession (unless these are otherwise specifically restricted) but that usage of herbs “off list” should trigger some prearranged assessment or review action to ensure safe use of such herbal medicines.

- *If the above approach is considered undesirable or impracticable what alternative approach is proposed to give the public assurances that the safety of herbal medicine practice with regard to the extensive range of medicinal ingredients in use is subject to adequate scrutiny and accountability?*

As we agree with the proposals above, we have nothing further to add.

Paper 4: Reforms of s12(1) of the Medicines Act 1968: quality standards where a practitioner prepares unlicensed herbal medicines

- *Do you agree on the need to introduce specific quality requirements relating to the preparation by practitioners of unlicensed herbal medicines under s12(1)?*

We agree with this. In practice, we would wish to see the standards of Good Manufacturing Practice (GMP) applied in such a way as still to permit practitioners to make tinctures themselves in appropriate conditions from quality herbs either grown or collected by the practitioner him/herself or bought in from reputable suppliers.

- *On the assumption that there is to be statutory regulation of the herbal medicines profession, do you agree that the relevant quality requirements should be set out in a professional code of practice and that practitioners should be professionally accountable for compliance?*

Yes, we agree with this.

- *If you favour s12(1) remaining open to some or all practitioners who are not subject to statutory regulation (see discussion paper No2) how would you propose that relevant quality standards could be required and compliance ensured?*

We do not favour s12(1) remaining open to practitioners who are not subject to statutory regulation (with the possible exception to a limited range of delegated tasks to staff under the direction of a statutorily regulated practitioner as explained in our answers to Discussion Paper No 2). For this reason we have nothing further to add.

- *Do you agree that where practitioners buy in processed ingredients to use in preparing their s12(1) medicines, it is desirable that these should meet GMP standards? If so, do you consider this should be covered by legislation or by the proposed herbal practitioner's code?*

We agree that where practitioners buy in processed ingredients to use in preparing their s12(1) medicines, it is desirable that these should meet GMP standards. We believe that these should be covered by a practitioner's code. GMP standards should be applied with as light a touch as possible so as not to create a disproportionately adverse regulatory impact on UK herbal supply companies.

Paper 5: Reforms of s12(1) of the Medicines Act 1968: the requirement for a face to face consultation

- *Do you have comments and views on this assessment?*

We agree with the MHRA's proposal that practitioners working under the auspices of s12(1) should be required to see the patient concerned at least once in person on a "face-to-face" basis and that failure to do this would mean a practitioner was operating outside of s12(1). We regard this as an essential in-built safety feature of s12(1) operation. We would expect a practitioner having seen a person once in person, to use his/her judgment as to whether it is appropriate to prescribe at distance bearing in mind general guidelines laid down about this by the regulating Council. We anticipate that the regulating Council will agree general guidelines about good prescribing practice along the lines of the GMC guidelines "Good Practice in Prescribing Medicines (2006)" published as Annex A to this paper 5.

Paper 6: Reforms of s12(1) of the Medicines Act 1968: the regulation of unlicensed herbal medicines commissioned by a registered practitioner from a third party to meet the needs of individual patients

A. Meeting the special needs of individual patients

- *The activity must be practitioner driven to meet the needs of individual patients, and not a covert way to avoid the requirements for an MA or a THR.*

We agree with this.

- *Therefore, it should not be permitted for manufacturers, importers or wholesale dealers to advertise or market specific products to herbal practitioners.*

We agree with this.

- *It should also not be permitted for manufacturers, importers, wholesale dealers or practitioners to advertise these unlicensed products to the public.*

We agree with this.

- *It should, however, be possible for manufacturers, importers or wholesale dealers of these unlicensed products to advertise to practitioners that they can provide a service of supplying these unlicensed herbal medicines (in accordance with the parameters of the scheme).*

We agree with this.

- *It should not be permitted for a practitioner to commission an unlicensed herbal medicine under this scheme where there is an existing suitable product with a THR or an MA.*

We agree with this.

- *However, the above point is qualified as follows: it should be recognised that a patient's personal preference for herbal medicine can constitute a special need. Therefore, the fact that there is a conventional, non herbal, medicinal product with an MA should not itself be a bar to the application of the proposed scheme.*

We agree with this.

- *The purchaser should specify to, or agree with, the manufacturer or assembler the qualitative and quantitative specification of the product required (unless the purchaser is a wholesaler in which case there would need to be a clear communication through the wholesale chain of the requirements).*

We agree with this.

- *Stocks of unlicensed herbal medicines may be prepared in advance, eg experience can be used to anticipate demand. Levels held should be consistent with the purpose of the scheme.*

We agree with this.

- *Wholesalers may hold a stock of specials in anticipation of orders.*

We agree with this.

- *In the scheme that applies in conventional medicine there is a limit on the stocks to be held by the practitioner. This helps to ensure that such medicines are genuinely being used for special needs.*
- *Such limits may be inappropriate for herbal medicine, where the significant use of practitioner commissioned medicines is likely to be integral to the activity of some registered herbal practitioners (eg in TCM and Ayurveda).*

We agree with the notion that such limits may be inappropriate for herbal medicine where the significant use of practitioner commissioned medicines is likely to be integral to the activity of some registered practitioners .

- *However, the absence of limits would only be possible if the scheme overall complied with the requirements of article 5 of Directive 2001/83/EC (see para 10 above). Other elements of the scheme might need to be adjusted accordingly.*

We agree with this.

B. What ingredients would be permitted for use under this scheme?

- *There should be a positive list of permitted herbal ingredients/classes of ingredients for which it was not necessary for the licence holder (see section C below) to notify MHRA in advance of an intention to supply.*

We agree with this.

- *There should be a negative list of ingredients/classes of ingredients that are explicitly excluded from this scheme.*

We agree with this.

- *In any other cases there should be a requirement for the relevant licence holder to notify the MHRA in advance of the supply of the unlicensed herbal medicine and the MHRA would have a period (eg of X days) within which it would have the opportunity to object to the supply.*

We agree with this.

- *The profession would have the opportunity to propose items for inclusion in the lists. The MHRA would seek the advice of the Herbal Medicines Advisory Committee on the positive list and negative lists*

We agree with this.

- *In principle a limited range of non herbal ingredients used in traditional medicines could be permitted for inclusion on the positive list; however, this would be subject to full assessment on public health grounds, which would include not only issues inherent to the ingredient and its use, but also an assessment of potential safety issues arising from quality (for example in relation to TSE and transmission of viruses).*

We agree with this.

C. What licensing requirements would apply to manufacturers, importers, wholesale dealers?

- *Manufacturers in the UK would be required to hold a special manufacturer's licence permitting the manufacture of these unlicensed products. To get licence standards of GMP would have to be demonstrated.*

We agree with this.

- *Importers of products from a third country would be required to hold a manufacturer's (importers) licence. This means that practitioners would not be able to import these products themselves, unless they held a manufacturer's (importers) licence. (MHRA notes that on a number of occasions when unsafe products have been identified in clinics it has transpired that practitioners may have directly or indirectly procured supplies from unsafe sources, such as relatives abroad).*

We agree with this

- *Importers should not use overseas manufacturers that follow standards below those equivalent to European GMP.*

We agree with this. It would be useful to engage with the herbal supply sector to establish precisely what European GMP standards will require of overseas manufacturers (e.g. in India and China) so that these standards can be met. Such a review should also make clear the scope and cost of any required MHRA inspection regimes.

- *Wholesale dealers would be required to hold a wholesale dealers licence for the procurement and distribution of the product within the EU.*

We agree with this.

- *Individual practitioners commissioning an unlicensed product directly from a manufacturer based in the EU would similarly be required to hold a wholesale dealer's licence.*

We agree with this.

- *These licence holders would need to comply with the conditions of their licence, the requirements of The Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003 and all relevant requirements of the scheme described in this paper, eg no advertising of specific products, the requirement to notify the MHRA etc.*

We agree with this.

- *MHRA would inspect these various licence holders in the normal way.*

We agree with this.

- *There would be a requirement for detailed record keeping by these licence holders as well as by practitioners and these would be subject to inspection/enforcement by the licensing authority. This would enable recall of products; also MHRA would be able to check compliance with the terms of the scheme. Records to be kept available to the licensing authority would include those relating to manufacture and/or assembly, importation, any relevant testing, and sale or supply.*

We agree with this.

- *In view of known public health risks, the audit by MHRA of importers would include a strong focus on what steps the importer had taken to assure themselves of the quality and safety of imported medicines.*

We agree with this.

- *The MHRA would have the power to require the importer to have imported products tested eg for the presence of heavy metals. (This is not intended as a substitute for the importer ensuring that the overseas manufacturer had systematic quality controls).*

We agree with this.

D. How is it envisaged that Good Manufacturing Practice requirements would apply?

- *The manufacture and/or assembly of the unlicensed products must be carried out under such conditions as to ensure that the product is of the qualitative and quantitative specifications required by the customer.*

We agree with this.

- *The product must comply with any relevant monograph of the EP or BP.*

We agree with this.

- *Other than when a product is required for the immediate use (e.g. before standard tests can be completed and not for stockholding) of a single patient or a small number of patients, QC testing on each batch should be the same as performed on comparable registered or licensed products. Views would be welcome on what kind of testing should be performed or other assessment in circumstances where testing is not feasible.*

As the Committee on Herbal Medicinal Products within the European Medicines Agency (EMEA) has now recognised, there are significant difficulties in applying the quality-control guidelines attached to the Directive on Traditional Herbal Medicinal Products to assay compound herbal products (i.e. those containing more than one herbal ingredient). The EMEA is pledged to revise these guidelines to make them compatible with the need to audit compound herbal products. Until these are finalised, it is obviously impossible to be certain about the viability of such guidelines to assay compound herbal products. Bearing in mind the fact that compound herbal formulations account for the vast majority of traditional Chinese, Ayurvedic, Tibetan and Japanese (Kampo) herbal remedies as well as some used by Western herbalists, the need for clarity on this matter is essential. There would be no point in granting the right to have unlicensed herbal medicines commissioned by a registered herbal practitioner from a third party to meet the needs of individual patients if the quality-control guidelines effectively made it impossible to produce such products because the assay requirements were unworkable for these products. In addition, whilst agreeing that the quality of such products should be assured, were the costs of achieving this standard unreasonably high (bearing in mind that these products are not held out for general sale and thus the revenue from their sale will be relatively insignificant compared to products with a traditional medicines licence), this too would have the effect of preventing such supplies from being available for patients. We submit that this should be born in mind and that practical measures should be taken to introduce quality-control guidelines appropriate for this type of product and to keep the cost of this process within reasonable limits.

- *When required for the immediate use of a single patient, generally the following minimum controls should be applied:*
    - *all raw materials should have an adequate assurance of freedom from TSE risk*
    - *there should be an assurance that any raw materials that are subject to a BP/EP monograph are in compliance*
    - *confirmation of identity*
    - *traceability.*

We agree with these measures in principle but until the detail of their implementation is clear, it is obviously impossible to be clear as to workability. Accordingly, we ask that the MHRA at the earliest opportunity specifies proposed detailed measures to ensure freedom from TSE risk as well as those to certify traceability. For example, would traceability require good agricultural and collection practice (GACP) for these types of herbal products designed for practitioner use?

- *Licensed or registered herbal medicinal products used as ingredients do not need to be tested.*

We agree with this.

- *As applicable, the specification of the product should include QC tests to be carried out.*

We agree with this but see our answer to the question of QC testing above.

- *Where stockholding is routine, stability data should be available to justify the shelf life.*

We agree with this in principle but every effort should be made to minimise the costs of these procedures as these products have a relatively small market (as they are not for general sale) and high costs of stability testing and other QC measures may effectively make their production uneconomic.

E. How will it be possible to identify manufacturers that can supply these unlicensed herbal medicines made under GMP conditions?

- *The MHRA puts forward the proposition that it would not be consistent with registered herbal practitioners' professional status if they were using medicines procured from manufacturers where there is no reliable assurance that standards equivalent to EU GMP are being followed.*

We agree with this.

- *Many products made up for herbalists are likely to be complex and multi ingredient. Once the product is manufactured it would not be possible for a third party, e.g. an importer or practitioner, to determine what was in the product. This underlines the critical importance that the manufacturer is operating to assured GMP standards and that compliance with these standards is regularly audited.*

We agree with this in principle. It would be helpful if the detail of such audit were elucidated so that its implications can be fully understood by the sector.

- *UK manufacturers of these products will be required to hold a special manufacturer's licence in the UK and therefore will be readily identifiable.*

We agree with this.

- *There will be a range of other manufacturers in the EU who hold a manufacturer's licence for herbal medicines with a marketing authorisation or traditional herbal registration and therefore are likely to be able to make these unlicensed herbal medicines for practitioners to high standards, (if they choose to operate in this part of the market).*

- *It is likely that there will progressively be a number of overseas sites which manufacture registered traditional herbal medicines; these manufacturers will have demonstrated high standards and might therefore be a suitable choice for manufacture of these unlicensed practitioner products; however, it is uncertain how many traditional Chinese or Ayurvedic products will be registered under Directive – and when - given the proportion of medicines intended for practitioner only supply in response to individual needs in these traditions.*

- *Overseas manufacturers that meet their own national GMP standards will not necessarily operate to standards equivalent to those regarded as acceptable in the EU – such standards, and their enforcement, may vary widely. They may also be affected by cultural differences, eg over the acceptability of including heavy metals in unlicensed traditional medicines.*

- *If a site, eg an overseas one, is not already operating to the necessary standards it must be very doubtful in many cases whether the size of the UK market in unlicensed manufactured practitioner medicines would be such as to create a significant incentive to invest in standards. It must also be doubtful whether an importer would have sufficient leverage to require the manufacturer to improve standards.*

- *Taking TCM as an example, there is persistent evidence of erratic and unreliable standards in imported manufactured unlicensed herbal medicines intended for practitioner use. The MHRA would wish to ask what steps would the herbal sector envisage to ensure that unlicensed TCM herbal medicines would consistently be of acceptable standards, consistently containing the stated, legal ingredients, and free from contamination and adulteration?*

The Register of Chinese Herbal Medicine is already running an “approved supplier scheme” that provides independent audit of suppliers to ensure the reliability and consistency of quality assurance systems. We suggest that this “approved supplier system” is extended to all herb companies supplying practitioners and that the code of practice which is agreed for statutorily regulated users of s12(1) should require that all s12(1) operators only buy in stock from suppliers on the “approved supplier list”. The regulating body should work closely with the MHRA in setting up a robust “approved suppliers” system that should work to deliver agreed standards of GMP.

F. Other issues

- *Various other features of medicines regulation would need to apply*
    - *adverse reaction reporting*
    - *patient information provisions*
    - *sanctions (up to and including the loss of licences).*

We agree in principle with all these measures. We ask that in particular the MHRA spells out what is required for patient information provisions.

- *The position as regards the use of these arrangements by any other statutorily regulated healthcare professionals who supply unlicensed herbal medicines to meet the special needs of individual patients following one to one consultation would need to be considered in the light of developments on professional regulation.*

We agree with this.

- *As proposals develop, other issues will need careful consideration in order to ensure the overall coherence of regulatory arrangements, including how the scheme will tie in with the existing specials scheme. For example, should the arrangements discussed in this paper apply to all herbal medicinal products, or only to products which would otherwise be required to obtain a traditional registration? How should products with non herbal ingredients be treated?*

We think that the arrangements discussed in this paper should probably only apply to products that would otherwise be required to obtain a traditional registration or (given the fact that s12(1) operators may be treating disorders which are not of a minor or self-limiting nature) to products specifically required for the treatment of individual patients that might in other circumstances require full market authorisation.

We see no reason why products with non-herbal ingredients able to demonstrate traditional use and to satisfy all required standards of quality and safety should not be included in the scheme set out in this paper.

Paper 7: Reforms of s12(1) of the Medicines Act 1968: possible extension to non-herbal ingredients.

A. Overall

- *The possibility should be available of creating a positive list of specific non herbal ingredients, permitted to be supplied under S12(1) where these ingredients meet certain criteria.*

We agree with this.

- *Any extension of the s12(1) scheme in this way should not take place unless and until there is a statutory scheme for the regulation of herbal practitioners, and should be limited to practitioners subject to statutory regulation.*

We agree with this.

- *The list should not include any ingredients where, for reasons of practicality or safety, it would be necessary for the practitioner to use industrial processes in preparing the medicine. (A medicine made using industrial processes could not come within the scope of the s12(1) exemption.).*

We agree with this.

- *The MHRA envisages that possible candidates for inclusion on the positive list could include some food stuffs, certain minerals and certain ingredients that would be acceptable as excipients in licensed or registered medicines.*

We agree with this.

- *Where a non herbal ingredient was included on the positive list there would be no equivalent restriction to that in the THR scheme under which non herbal ingredients (specifically vitamins and minerals) are only permitted for inclusion in a product where they are ancillary to the traditional herbal medicine.*

We agree with this.

B. Criteria for considering inclusion of ingredients in positive list

- *Is it necessary as a pre-condition for possible inclusion on the positive list to demonstrate that the ingredient has traditional use in herbal/traditional medicines system(s) used by practitioners subject to statutory regulation? This should be determined as follows:*

    - *where an ingredient, if supplied on its own without medicinal claims, would not normally be regarded by MHRA as medicinal [4] it would not be necessary to demonstrate traditional usage of that ingredient*

    - *where an ingredient, if supplied on its own, would normally be regarded as medicinal by the MHRA it would be necessary to demonstrate traditional usage. This is necessary to ensure that the*

[4] I.e. in accordance with the definition in Article 1(2)(b) of Directive 2001/83/EC

s12(1) is not opened up to supply types of medicinal product in which registered practitioners have little or no expertise.

We agree with these propositions. We suggest that the MHRA explains what data it considers necessary to demonstrate traditional use in this case.

- *Conventional active ingredients used in medicines should not be considered for inclusion on the positive list other than where they have a tradition of use in traditional/herbal medicines.*

We agree with this.

- *Each ingredient for consideration for inclusion on the positive list should be assessed for safety to determine whether it could be safely used in medicines supplied under s12(1) by a registered practitioner.*

We agree with this.

- *The safety assessment should include:*

    - *inherent safety of the ingredient*
    - *possibility of interactions with other ingredients*
    - *safety issues arising from quality. This will include, for example, issues relating to GMP and specifically for example to risks of transmission of infectious agents and of TSE and the feasibility of practitioners operating the necessary quality controls.*

We agree with these propositions.

C. Process

- *Herbal practitioner organisation(s) that are actively participating in preparations for statutory regulation of the profession should be invited to identify non herbal ingredients/category of ingredients and complete a template to enable assessment of suitability for possible inclusion within the s12(1) scheme.*

We think this is a sensible step.

- *The template requirements would be targeted, with fuller information and assessment required depending on the nature of the substance and possible risks.*

We agree with this.

- *The MHRA would review submissions received and seek the advice of the Herbal Medicines Advisory Committee on the suitability of the list.*

We agree with this.

- *Following this process any specific proposals would be subject to public consultation.*

We agree with this.

- *The list would be kept under review.*

We agree with this.

Paper 8: Reforms of s12(1) of the Medicines Act 1968: issues concerning timing and transitional protection

Issues for discussion

- *Are there additional issues concerning transitional protection that the MHRA should bear in mind?*

We agree with the MHRA that "it is necessary to ensure that the timetable for the s12(1) reforms take account of the timetable and arrangements for establishing the proposed register for herbal practitioners." Conversely, we would also highlight the need for the statutory regulation process to take into account the pressure coming from current medicines legislation to achieve statutory regulation of the sector by 2011 at the latest. The reason for this is that the Directive on Traditional Herbal Medicinal Products will be fully implemented throughout the EU in 2011. This will effectively see the end of the sale and supply of s12(2) over-the-counter of herbal medicines - at which time any herbal medicine that is industrially produced must either have a traditional herbal registration (THR) or a full market authorisation. As many herbal remedies used by practitioners are currently finished products (especially those used in the TCM, Ayurvedic, Tibetan and Japanese-Kampo sectors) and the majority of these products are not suitable for direct THR sale to the public, it follows all such products will disappear off the market unless the profession has achieved statutory regulation by this date. If statutory regulation is achieved, these products will remain available because they can be prescribed by authorised health professionals on the basis of the need of individual patients (see proposals in Paper 6). Given the considerable amount of time that must be allowed for the legislative procedures to take their course, including process through the devolved assemblies, there is obvious need to press on with statutory regulation of the sector without delay. It is to be hoped that Ministers will recognise and accept the need for this process to be given the priority it needs. Failure to achieve statutory regulation by 2011 is likely to deprive many patients of the herbal medicines they have come to rely on over the years and to undermine the financial basis of UK herbal supply to the professional sector.

- *Do you agree with the analysis in this paper? If not, what are your views and why?*

Yes, we are in support of the analysis in this paper.

- *Do you agree that if there are to be restrictions under the s12(1) reforms they would need to apply equally to existing and new operators?*

Yes, we agree.

B. Comment on the Regulatory Impact Assessment (RIA) of changes to s12(1) and s12(2) of the Medicines Act 1968.

As most manufactures and suppliers to the professional herbal sector are dependent on over-the –counter sales for their economic survival, we ask the MHRA to publish a RIA on the UK herb manufacturing and supply sector of the implementation of the Traditional Herbal Medicinal Products Directive (which will see the phasing out of s12(2)) and the reforms of s12(1) together. It seems appropriate for the regulatory impact of changes to the medicines legislation regarding the sale and supply of herbal medicines to be assessed as a whole taking into account the changes to s12(1) and s12(2). It is obviously vital that every effort be made to reduce the cost of implementation of changes to the legislation without sacrificing quality or safety.