GUIDANCE NOTES TO COMPANIES ON HEARINGS AND WRITTEN REPRESENTATIONS TO THE HERBAL MEDICINES ADVISORY COMMITTEE

August 2013

GUIDANCE NOTES ON HEARINGS AND WRITTEN REPRESENTATIONS – TRADITIONAL HERBAL REGISTRATIONS

1. Information about and interpretation of these guidance notes

The guidance notes which follow are intended to help you if you wish to make written or oral representations to the Herbal Medicines Advisory Committee ("HMAC" – referred to in this guidance as "the Committee"), in respect of an application for the grant or renewal of a traditional herbal registration, or a proposed revocation, variation or suspension of such an registration.

2. Introduction

2.1 Paragraph 2 of Part 1 of Schedule 11 to the Medicines Regulations 2012 ("the Regulations") requires the licensing authority to consult the "appropriate committee" (which in most cases will be HMAC), before it refuses to grant or renew, or revokes, suspends or varies, a traditional herbal registration on grounds of safety, quality or efficacy. The Regulations also provide that an applicant for the grant or renewal of a traditional herbal registration must have the opportunity of putting his case to the committee before it gives its final advice to the licensing authority. [The requirement to consult the committee does not apply in the case of a proposed suspension where it appears to the licensing authority that is necessary to suspend the traditional herbal registration with immediate effect in the interests of safety for a period of up to 3 months.]

2.2 Although this guidance note gives a general description of the provisions of the law in this regard and the way in which the procedures operate in practice, it must not be regarded as a complete or authoritative statement of the law, nor as binding on the bodies concerned as to the way in which they conduct a particular hearing or written representation.

3. Applications for and Renewals of Traditional Herbal Registrations: Committee Procedures

3.1 As set out above, the licensing authority may not refuse to grant or renew a traditional herbal registration on grounds of safety, quality or efficacy without first consulting the Committee. The Regulations also provide that the Committee must give the applicant the opportunity to make written or oral representations if their provisional opinion is adverse at paragraph 6 of Part 1 of Schedule 11.

3.2 Applications for traditional herbal registrations are considered in the first place by professional staff (called assessors) from the Medicines and Healthcare products Regulatory Agency (MHRA).

3.3 If the licensing authority consults the Committee on an application for the grant or renewal of a traditional herbal registration, the application will be put before the Committee at one of its regular meetings. If the Committee considers that it may be unable to advise the licensing authority to grant the traditional herbal registration at all or in the form requested, or if it may have to advise that the traditional herbal registration ought to be revoked, varied or suspended, it will report its findings and advice to the licensing authority together with the reasons for that advice, further to paragraph 7(4)(b) of Part 1 of Schedule 11 to the

Regulations. Paragraph 8 of Part 1 of Schedule 11 to the Regulations allows the applicant the opportunity of asking either for an oral hearing before the Committee, or of making representations to the Committee in writing only, and specifies the grounds for the Committee's provisional opinion. A copy of the MHRA Assessment Report which was prepared to assist the Committee will also be sent to the applicant.

3.4 In many cases, if the Committee is considering reaching a provisional opinion that it may be unable to advise the licensing authority to grant the traditional herbal registration precisely in the form of the application, it may, before a formal provisional opinion letter is sent, invite the assessors to discuss the matter with the applicant in order that the application may be suitably modified or additional data supplied. This often allows matters to be resolved before the formal procedure is instituted. However, if matters cannot be resolved satisfactorily in this way, the formal procedure described above will be followed.

4. Compulsory Variation, Suspension or Revocation of Traditional Herbal Registrations: Committee Procedures

The Committee must also be consulted where the licensing authority proposes to revoke, vary or suspend a traditional herbal registration (except in cases of urgency, where immediate action is necessary in the interests of safety). If the Committee thinks that it may have to advise the licensing authority that a traditional herbal registration should be revoked, suspended or varied, it will notify the holder of the traditional herbal registration under paragraph 5(3) of Part 1 of Schedule 11 to the Regulations. As with applications for grants or renewals, the holder may make written or oral representations to the Committee.

5. Options available following receipt of a letter issued under paragraphs 5 of Part 1 of Schedule 11 to the Regulations

5.1 Having been notified of the Committee's provisional conclusions (or in the case of a variation application, the decision of the licensing authority), your company will wish to consider its position. Before you reach a decision, you should make sure that you fully understand the implications of each of the points in the letter, as they will <u>all</u> have to be addressed. If in any doubt, seek guidance from the appropriate assessor(s). When you are confident that you can address all of the points specifically, decide the action to be taken. The Committee (or the licensing authority, in the case of variation applications) should be notified of your intention **<u>within 28 days of the date of the letter</u>**.

5.2 There are two options available:

- you can decide not to pursue your application, or to agree that the traditional herbal registration should be suspended, revoked or varied. If you do not ask for a hearing within 28 days, then in the case of an application for the grant or renewal of a traditional herbal registration, or a revocation, suspension or variation, the Committee will proceed to give its final advice to the licensing authority. In the case of an application for a variation, the decision of the licensing authority will stand. If you decide not to continue with an application, you are free to make further applications in the future, supported by the appropriate data;

- you can decide to ask for a hearing or make written representations, in which case you will need to address the points made in the Committee's provisional opinion as set out in its letter.

5.3 If you decide to make representations to the Committee, you must then consider whether these will be written only, or whether you will also want to present them at an oral hearing before the Committee. You have the right to choose. In either event, you must send to the Committee, within the relevant time limit (see below):

- an electronic copy of your written representations, or a summary of the oral representations you propose making, setting out why you disagree with the Committee's provisional opinion (or the licensing authority's decision in the case of a variation application); and
- any documents in support of those representations (or, if you have no additional documents to provide, you should confirm that you have already provided all relevant documents).

You must bring to the attention of the Committee **all** pertinent data, published or unpublished, whether or not favourable to your position. Guidance on the two different methods of making representations are in the following paragraphs. All the above documentation must be submitted **within six months** of the date you gave notice that you wanted to make representations, unless the Committee has imposed a shorter period in their notification letter. You may apply to the Committee for an extension of the time limit (see below), but such extensions will only be granted in exceptional circumstances and in any event are up to a maximum period of 12 months from the date of the notification letter.

5.4 If, having indicated that you want to make representations, you do not provide your documentation in time, the Committee will proceed to give its final advice to the licensing authority without coming back to you.

6. Written Representations, or Written Summary of Oral Representations

6.1 As set out above, if you decide to pursue this option, you must provide written reasons setting out why you disagree with the Committee's provisional opinion (or in the case of an application for a variation, the licensing authority's decision) and any supporting documents you wish to rely on. Each of the points in the letter must be addressed in turn. Sometimes the issues can be resolved readily. Where the points are being contested, a review of all of the relevant data should be provided, together with any new information or any new justification you wish to provide. Your written representations and supporting documents will be presented to the Committee after they have been assessed by the MHRA assessors.

6.2 Whilst the Committee will not wish to see additional data which are not strictly related to the letter, you **must** keep the Committee Secretary informed of any new adverse drug reaction data or other relevant information which has safety implications (regardless of the source). Such information should be notified to the Secretary **immediately** you become aware of it. It cannot be assumed that submission of such data to a different part of the Agency will be automatically linked with the matters being considered by the Committee. If it is considered necessary to submit data already seen by the Agency this should be clearly marked.

6.3 You should also note that once the time limit for submission of documents has expired, additional representations and documents can only be submitted with the Committee's

permission. If you wish to seek permission, you should write to the Secretary, setting out the reasons why an extension of time is sought. The only exception to the time limit is new adverse drug reaction data, or other information related to safety (see above) which must be notified to the Secretary of the Committee, regardless of which stage the Committee proceedings are at.

6.4 If you have only asked to make written representations, the papers you have submitted will be reviewed by the MHRA assessors dealing with your case and presented to the Committee at one of its meetings. The Committee will reconsider its provisional opinion (or will consider the licensing authority's decision, in the case of an application for a variation) in the light of your written representations and decide what advice to give to the licensing authority. The licensing authority will then consider that advice, make a decision and communicate its decision to you. It will also notify you of the advice of the Committee and the reasons for that advice. Provided you have made representations within the appropriate time limits and the decision of the licensing authority was not in accordance with the advice of the Committee, you will be offered the opportunity of making further representations. A copy of the Assessment Report will be sent to help you decide how to proceed.

7. Oral Hearings

7.1 Submission of Additional Data

The written summary of the representations you wish to make at the hearing and supporting documentation should be prepared as set out under paragraphs 6.1-6.4 above. All new data to be presented to the Committee in relation to each of the specific points in the letter should be provided in the written documentation and confirmation provided that this is the **complete** package to be considered, as new data cannot be presented to the Committee at a hearing.

7.2 Pre-hearings

Generally, the MHRA assessors will complete the assessment of your data a few weeks before the planned hearing date. The papers will then usually be considered by the Committee at a meeting before the date fixed for your oral hearing (this is referred to as a "pre-hearing") At the pre-hearing the Committee will consider your representations and supporting documents, as it would consider written representations. If the Committee is completely reassured by your written data, the hearing will be cancelled and the Committee will advise the licensing authority in your favour. If the Committee is not reassured on all or some of the points, you will be sent a letter in good time to help you plan your oral presentation.

8. Composition of the Committee and layout of the Conference Room

8.1 At the hearing the Chairman sits facing the members of the Committee. Alongside him are the Administrative Secretariat and officials of the Agency. **Annexed** is the current membership of the Committee.

8.2 At one end is a table raised on a dais, and it is from here that your presentation is made. Five company representatives can be seated comfortably, although more can be accommodated if required. You should nominate one of your representatives to act as

"team leader" or "chief spokesperson". Details of the 151 Buckingham Palace Road Conference Suite and its facilities are given at the end of this guide at paragraph 11.

9. Procedure at the hearing

9.1 All the additional written data submitted by your company will have been made available to the Committee well in advance of the meeting. This will have been discussed either at the "pre-hearing" described in paragraph 7.2 above (after which a letter will have been sent to you advising you of the points which are not yet resolved) or before the hearing commences, in which case you will be asked to restrict your representations to the points which remain outstanding.

9.2 When the Committee has completed its preliminary discussion, you will be invited into the Conference Room. The Chairman will welcome you, introduce the Committee and ask you to confirm that you have brought to the licensing authority's attention all pertinent data, published or unpublished, whether or not favourable to your position. He will then reiterate any points which the Committee is satisfied with and which it is not necessary for you to address in your presentation. He will also point out, however, that this will not prevent members of the Committee, or professional staff from the Agency (including the assessors) from asking questions on those points arising out of anything mentioned in response to the outstanding issues, or raising questions of clarification.

9.3 You will then be free to present your case. The most effective presentations are those which are concise and to the point, addressing **only** the issues in the Committee's provisional opinion or licensing authority's decision letter in the case of a variation application. You are requested to restrict your presentation to a **maximum of 15 minutes**. This time does **not** include answering questions from members.

9.4 If you think that you will need to take longer than this over your presentation, you should seek advice from the Secretary as soon as you possibly can and in any event at least 5 working days before the hearing date.

9.5 You should bear in mind that members will have read, discussed and become familiar with your representations and supporting documents before the hearing, and will not wish you to spend time repeating application data or deploying arguments not relevant to the grounds specified by the Committee in its notification letter.

9.6 The Committee is concerned only with the scientific evidence. Marketing and commercial aspects cannot be taken into consideration and should be omitted from your presentation.

9.7 If you elect to make a visually supported presentation, it is requested that you provide the Secretary with a copy of the presentation 3 working days before the date of the hearing so that the Chairman can review it.

9.8 After the presentation, Committee members may wish to ask questions. You should, therefore, ensure that your party of representatives is able to address all technical issues as well as having sufficient authority to take decisions on behalf of the company. You should also ensure that your representatives are fluent in English.

9.9 At the end of the hearing and after you have left the Conference Room, the Committee will reconsider its provisional conclusions (or the licensing authority's decision in the case of a

variation application) in the light of what you have said and decide what final advice to give to the licensing authority. The licensing authority will then consider that advice, make a decision and communicate its decision to your company. It will also notify you of the Committee's advice and the reasons for that advice. If the licensing authority's decision is not in accordance with the advice of the Committee, then provided you have made representations and provided your documents within the relevant time limits, you will be offered the opportunity of making further representations. A copy of the Assessment Report placed before the Committee will be sent to you to help you decide how to proceed.

10. Some General Points

10.1 Your Company's additional data to be presented to the Committee should be submitted on a CD-Rom, which should be as concise and relate directly to the grounds referred to in the Committee's letter. Your representations should also be submitted in Word format, whenever possible.

10.2 A letter stating that all sets of data have been dispatched to their correct destinations should also be sent to the Secretary.

Please note that no paper copies of the data are required.

10.3 Wherever possible, you should not submit parts of your data separately. Data are assessed only when the complete package has been received.

10.4 You should be aware that a **minimum** period of between three to four months may be required for assessment, and appeals are not usually scheduled until after the complete package of appeal data are received.

10.5 If you wish to inspect and familiarise yourselves with the Conference Room in which your hearing will be held, or if you have any questions relating to procedural matters, please contact the Secretary.

11. The Conference Suite at Buckingham Palace Road

A large display screen is available for presentations using a choice of the following facilities:

- Powerpoint presentations are welcomed and you should email the Secretary with your presentation at least 5 days before the actual hearing.

- a laptop computer can be connected to the system and can be operated by mains electricity to avoid loss of battery power during a hearing. The display screen will show all of the images on the computer's monitor.

12. Contact point

Secretary
Ms Ebru Agca
Tel: 020 3080 7723
Email: ebru.agca@mhra.gsi.gov.uk

Assistant Secretary
Mr Fred Huckle
Tel: 020 3080 6455
Email: fred.huckle@mhra.gsi.gov.uk

Medicines and Healthcare Products Regulatory Agency (MHRA)
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ANNEX A

MEMBERSHIP OF THE HERBAL MEDICINES ADVISORY COMMITTEE

(CHAIR) Professor Philip A Routledge OBE MB BS MD FRCP FRCPE FRCGP FBTS FFPM FBPharmacolS
Professor of Clinical Pharmacology and Head of the Department of Pharmacology, Therapeutics and Toxicology, Cardiff University and Honorary Consultant Physician/Clinical Pharmacologist in Cardiff and Vale University Health Board

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Ms Alison M Denham BA (Soc) FNIMH, FHEA
Herbal Practitioner and Senior Lecturer in Herbal Medicine, University of Central Lancashire, Preston

Dr Michael R Evans MB ChB
Principal in General Practice, St Lukes Medical Centre Stroud, Clinical Teacher in General Practice University of Bristol & Faculty Member, British Postgraduate Training in Anthroposophic Medicine

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Mrs Christine A Gratus BA MBA
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Professor Paul T C Harrison BSc PhD CBiol FSB FRSA FBTS
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Professor Michael Heinrich MA MSc PhD
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Professor Peter Hylands BPharm PhD FRSC
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Consultant Physician, University Hospitals of Leicester NHS Trust, Professor of Gastroenterology, University of Leicester

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