BRITISH PHARMACOLOGICAL SOCIETY

Written submission by the British Pharmacological Society to NHS England, Medical Directorate on the proposal to establish Regional Medicines Optimisation Committees

12th September 2016

1. Background

1.1 The British Pharmacological Society (BPS) is a charity with a mission to promote and advance pharmacology and clinical pharmacology. Founded in 1931, the Society now represents over 3,500 members working across academia, industry, regulatory agencies and the health services, many of whom are medically qualified. Clinical pharmacology is the only medical specialty in the NHS focusing on the safe, effective and cost-effective use of medicines. Clinical Pharmacologists are drug experts who bring additional insight to drug introduction and have played a major role in the establishment of three major UK national health technology organisations: The National Institute for Health and Care Excellence (NICE); The Scottish Medicines Consortium (SMC) and the All Wales Medicines Strategy Group (AWMSG). The Society supports good prescribing in the UK, notably by developing the Prescribing Safety Assessment with the Medical Schools Council, and key activities are:

- Promoting and advancing high quality science, especially pharmacology and clinical pharmacology
- Supporting students and academics in research, as well as the UK university system
- Supporting UK industrial pharmaceutical discovery and development, and underpinning the role pharmacology and clinical pharmacology has to play in that environment

1.2 Consequently the daily work of our members includes membership of local and national prescribing committees and leadership in medicines introduction and optimisation. This BPS response to NHS England, Medical Directorate on the proposal to establish Regional Medicines Optimising Committees (RMOC) takes into account the views of these members.

2. What is the core purpose of the Regional Medicines Optimising Committees (RMOCs)?

- **Response to questions from the proposals document**

'4.1 Do you agree that the points above clearly outline the proposed role for the RMOCs? If not, please list and explain the specific points about which you disagree'

2.1 The proposal aims to accelerate access of patients to new medicines by removing the barriers of multiple local evaluations and providing a single, transparent and equitable system within NHS England. Whilst we applaud this aim, we have concerns

that the proposed advisory RMOCs will introduce a further tier or hurdle rather than streamlining the process. If national guidance for all new drugs to market is truly necessary, we wonder why NICE is not empowered to fill this role, rather than introducing a further tier?

2.2 The proposal for RMOC, if looking at all new medicines, formulations and indications, is what SMC does in Scotland for 5.5 million people. We understand that the committees proposed for the four English regions will act as one body, reviewing each new medicine once. In this case why not have a single body (e.g. an extension of the role of NICE). There is a risk that the committees will become four regional bodies and each review each drug separately. This would increase the risk of regional disparity in drug use and health inequality.

Our comments on the specific points relating to the proposed role are:

- *'Assume responsibility for coordinating the evaluation and publishing recommendations to guide local adoption of all new medicines and new indications which are not scheduled for review by NICE TA programme'*

2.3 We are concerned that this proposal underestimates the likely large volume of work that this will produce. Many of the proposed new indications for existing drugs may have local applicability only (e.g. unlicensed use of a medicine in a highly-specialised tertiary care service) and regional control of all approvals may delay rather than facilitate patient access to medicines.

- *'Eliminate duplication of evaluation by bringing those activities to regional level (but with full participation of those who carry responsibility at CCG. Trust and NHS England level, to ensure any evaluation activity is coordinated and shared across the four regions.'*

2.4 We support the principle of eliminating duplication of evaluation by a single regional review of each drug. However, as the proposed RMOCs will be advisory, they have potential to introduce an additional approval stage, and delay rather than accelerate patient access to medicines. For example, local/area prescribing committees (APCs) will still have to assess medicines at a local level for budgetary impact and incorporation into local clinical practice. This will inevitably lead to a review of efficacy and safety for example in comparison to existing treatments for the same indication, retaining duplication. We draw the attention of NHS England to the recently implemented Health Research Authority approvals process for NHS research. Despite this new centralised process, local approvals for research are still required. Thus there is potential for the HRA to introduce a new hurdle, rather than streamlining processes. Increasing centralisation and less local accountability also has potential to introduce frustrating delays.

- *'Provide a statement on a case by case basis which considers the need for interim advice pending the publication of NICE TAs'*

2.5 We are concerned about the concept of providing interim advice pending NICE TAs. NICE TAs require an in depth assessment of the evidence, which cannot be replicated in an interim review. If the interim review and NICE TA subsequently disagree, this may produce implementation problems, particularly in withdrawing a drug recommended by interim advice and subsequently rejected by NICE. Previous experience in implementing drug withdrawals from clinical practice, due to lack of proven efficiency, resulted in public opposition and delays[i]. Notably, lessons have been learned from the FDA experience, resulting in a number of risk management plans being proposed[ii]. Given the proposed interim advice model, have any of these risk management plans been considered?

- *'Ensure high quality, robust and transparent evaluation activity is coordinated and done once only for each medicine and shared across the four regions.'*

2.6 If RMOCs are to be responsible for a single national evaluation of drugs, how will NHS England ensure that they are resourced to provide this evaluation to an equivalent standard to NICE? Assuming that this is the aim then wouldn't it be better if the role and resources of NICE were expanded, rather than creating separate bodies? Or if this was not cost-effective adopting a similar model to the Scottish Medicines Consortium for England could be an alternative.
If the RMOCs provide a lower standard of evaluation than NICE, this will make the process vulnerable e.g. to targeting by stakeholders or legal challenge in the courts which would be more likely than under the current piecemeal system where a local decision may not be worth challenging.

- *'Make consideration to specific issues with regard to unlicensed medicines'*

2.7 What role is envisaged for the individual practitioner in the situation of unlicensed indications for medicines? They currently take responsibility for such prescriptions. What risk is there to the RMOC of legal redress in the event of harm to a patient from the use of unlicensed medications that have been recommended by the RMOC or 'considered' to be safe? We are also concerned that the potential volume of such applications will swamp the RMOC process.

- *'Identify and make recommendations on established treatments of unproven clinical value.'*

2.8 We applaud this aim but suspect that to do this across the whole of NHS England will be a Herculean task.

- **Response to questions from the proposals document**

'4.2 Is there anything additional that you feel should be included in the role of the RMOC?'

2.9 No

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3. What are the operational governance principles under which RMOCs will operate?

- **Response to questions from the proposals document**

'5.1 Do you agree with the operational governance principles outlined above? If NO, please list and explain the specific points about which you disagree.'

3.1 We note that RMOCs will be run by the Specialist Pharmacy Service and co-designed and co-owned with CCGs. From our perspective many new drugs are first initiated in secondary care by specialists, before gradually being adopted by primary care practitioners. We feel that it is important that secondary care organisations should have a much larger stake in this process.

3.2 We are concerned about the term 'value', which is undefined and potentially vulnerable to pressure from 'expert' opinion and pharmaceutical manufacturers. How will 'value' be established in this setting and how will it be measured? NICE currently use cost/QALY as a measure of cost effectiveness. Health Technology Assessment (HTA) will be essential – whether done by the manufacturer and cross-checked/tested by the RMOC or done by an independent HTA group (which may be very expensive/unaffordable). This assessment appears to be underrepresented, with plans to 'co-opt as required'. In addition, evidence should be the main driver of decision making, with much less weight given to 'expert' opinion.

- **Response to questions from the proposals document**

'5.2 Is there anything additional which you feel should be made explicit in the governance arrangements outlined?'

3.3 We feel that the application and appeals processes should be clear. In particular, it is important to define who can apply for a drug to be approved by an RMOC. Currently applications can only be made to local DTCs or APCs by clinicians wishing to use a drug. Will this be the case for the RMOCs or will patient groups and pharmaceutical companies be able to apply? Will applicants be invited to meetings to discuss their application with the committee (as is the practice of the ethics committee)?

- **Response to questions from the proposals document**

'5.3 Please comment on issues around conflict of interest. Should members be free from conflicts of interest?'

3.4 The RMOC cannot ensure a 'high quality, robust and transparent evaluation process' if conflict of interests exist within the core committee. However, it may be difficult to find members with no conflict of interest at all. All conflicts should be fully declared and members should leave the meeting for items where specific conflicts are present.

4. What should RMOC membership look like?

- **Response to questions from the proposals document**

'6.1 Do you agree with the proposed core membership outlined above? If not, please explain.'

4.1 We are concerned that the Regional Medical Director may have other priorities and conflicts that would interfere with their ability to chair the committee. We suggest that this role should be open to application from people with expertise in this area e.g. chairs of existing local DTCs/APCs. We feel that secondary care is grossly underrepresented in the key core membership, particularly as many applications are likely to come from this sector.

- **Response to questions from the proposals document**

'6.2 Do you think there should be any additional members not listed that need to be included? If so, please list with a brief explanation of why.'

4.2 There is no inclusion of Clinical Pharmacologists despite the specialisms proven track record in providing expertise in medicines management both on a local (in DTCs) and national level. Their value has been most strikingly demonstrated by the All Wales Therapeutic and Toxicology Centre (partnership of Clinical Pharmacologists and pharmacists working to provide support to prescribers), which is thought to have saved £5.8 million in drug costs alone to the NHS in Wales (https://www.bps.ac.uk/BPSMemberPortal/media/BPSWebsite/BPS_A_prescription_for_the_NHS_FINAL_SP%281%29.pdf). Given this evidence and their proven track record, the RMOC should have a Clinical Pharmacologist as a core member. It is also imperative that there should be regional representation from Clinical Pharmacology trainees. This will ensure that an appropriate workforce will exist to help carry out the future work of the RMOCs and will increase the training opportunities for an area of the clinical workforce that HEE and the Royal College of Physicians believe should be continuing to expand.

- **Response to questions from the proposals document**

'6.3 Should the additional membership as outlined above be part of the core membership or co-opted when required?'

4.3 Clinical pharmacologists, clinical pharmacology trainees and secondary care physicians should be part of the core membership.

- **Response to questions from the proposals document**

'6.4 Should pharmaceutical industry / manufacturers representation be included as part of the core membership? If so, how should this be managed?'

4.4 No. The conflict of interest is clear. They will have a role in making applications and lobbying. The RMOC decisions should be independent from government and industry. Any decision making should be based on evidence and so should be independent of commissioning structures (as per NICE).

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5. How will RMOC work plans be determined?

- **Response to questions from the proposals document**

'7.1 Do you agree with the proposal for determining the work plan of the RMOCs? If not, please explain how you think this should be approached and why.'

5.1 Whilst the horizon scanning process and APC requests seem sensible, it is curious as to why there is no avenue for clinicians to make a direct request to the RMOC, in the way they do to local DTCs. Unless clinicians can apply directly to the RMOC, they will have to go through their local DTC/APC. This will negate the point of the RMOC by creating work, rather than reducing it. Conversely, the ability of the pharmaceutical industry to make direct requests to the RMOC is concerning. A significant risk exists in undermining the NICE TA process, as industry may find it easier and cheaper to gain approval through this process than as a NICE TA. Unless the RMOCs have the same scope in terms of resources and expertise as NICE, then they will not be able to replicate the NICE TA process appropriately.

5.2 Interestingly, delays may be inadvertently introduced, in comparison to the current system. Requests to APC which need to be forwarded to the RMOC could add an addition tier of 'red-tape'. Additionally, delays in prioritisation and consultation could compound this, rendering the model more sluggish than current DTCs/APCs.

6. What is the status of outputs from RMOCs?

- **Response to questions from the proposals document**

'8.1 RMOC outputs will be framed as advice - do you agree? If not, please explain your rationale.'

6.1 If the RMOC outputs are advisory, then their work will continue to be replicated at local DTCs. There will be none of the additional 'value' that the RMOC sets out to achieve.
DTCs/APCs will still have to review medications with regard to local clinical need and cost-efficiency in the context of their own local budget, just as they do now. These treatments are unlikely to have a clear, well defined place in therapy (otherwise they should be reviewed through NICE TA). As examples, CCGs may decide not to fund a development after recommendation from the RMOC due to financial pressures.
Local expert clinicians may not agree with a distant appraisal process by non-experts in the field unfamiliar with local practice or the financial situation for local CCGs. There is little value in the RMOC appraising technologies that no local clinician plans to use.

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7. Response conclusions

7.1 In summary, we feel that under the current proposal the RMOC would not achieve its aim to accelerate access of patients to new medicines by removing the barriers of multiple local evaluations and providing a single, transparent and equitable system within NHS England. It would be more impactful to resource national systems (e.g. NICE).

7.2 If a revised RMOC or similar committee was to go ahead, it is vital that there is more involvement of clinical pharmacologists and secondary care physicians in the scheme.

References

[i] FDA (2011). Proposal to withdraw approval for the breast cancer indication for Avastin (bevacizumab): decision of the Commissioner. Department of Health and Human Services, Food and Drug Administration. Available at: http://www.fda.gov/downloads/NewsEvents/Newsroom/UCM280546.pdf. Accessed 26th August 2016

[ii] Vitry A, Nguyen T, Entwistle V, Roughead E (2015). Regulatory withdrawal of medicines marketed with uncertain benefits: the bevacizumab case study. *Journal of Pharmaceutical Policy and Practice*. 8:25. doi:10.1186/s40545-015-0046-2.