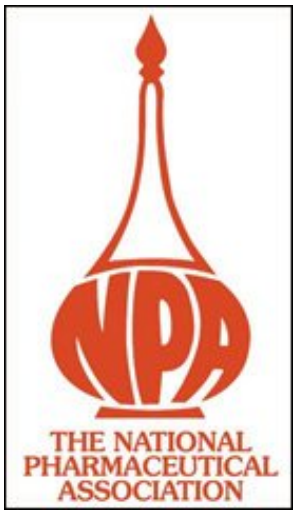

Response to MLX 300

Response of the National Pharmaceutical Association to Consultation MLX 300

Review of the advisory bodies structure laid down in the Medicines Act 1968

Thank you for giving the National Pharmaceutical Association (NPA) the opportunity to comment on consultation letter MLX 300 on proposals to restructure the advisory bodies laid down in the Medicines Act 1968.

The NPA represents the interests of community pharmacies. We have in voluntary membership around 11,000 community pharmacies which comprise the majority of the 12,000 pharmacies in the UK. The NPA provides a representative voice for its members, as well as a range of services to help them with both commercial and professional aspects of running their businesses.

As a member of the Pharmaceutical Group of the European Union, the NPA has followed closely the recent developments at EU level concerning both the review of the pharmaceuticals legislation (human and veterinary) and in relation to the structure and functions of the EMEA. In the light of these developments, we agree that changes to the advisory structure at the MHRA are necessary.

The NPA supports in principle the proposal to amalgamate the responsibilities of the Medicines Commission (MC) and the Committee on Safety of Medicines (CSM). We also support the proposal to name the new body the Commission on Safety of Medicines, not only because that will retain the well recognised acronym of CSM but also the term properly describes the main function of the proposed new body. Furthermore, we agree that the Commission on Safety of Medicines should be a newly appointed body rather than an amalgamation of the current bodies, and its membership should be subject to a full appointments exercise.

The MHRA asks specifically for views, comments and suggestions on proposals set out in paragraph 44 of MLX 300. In brief, we agree with all the proposals highlighted in paragraph 44 except that relating to the range of competencies required of the members of the new Commission. We would also like to comment on the proposals relating to personal interests of members of Therapeutic Advisory Groups (TAGS), as described in paragraph 40 and raise one question about TAGS, for clarification.

- **Competencies required of members of the new Commission**

We are very concerned that it is intended to remove the requirement that one person should have a wide and recent experience of the practice of pharmacy, as is the case currently under the Medicines Act 1968 in relation to the Medicines Commission. It is our view that this proposal, if implemented, would create a serious deficiency in the membership of the new Commission, particularly bearing in mind its proposed functions. In addition, in our opinion, the omission cannot be justified by the arguments in the consultation document when considered alongside the proposed constitution of the new Commission, as set out in Annex B.

In paragraph 31, it is suggested that:

> "*Rather than restricting membership within the areas currently specified in the Medicines Act for the MC, the new Commission would need members with high level scientific experience and an ability in critical appraisal, a capacity to contribute beyond individual speciality and, where possible, experience in NHS clinical practice and the regulatory field.*"

However, the proposed membership, as set out in Annex B, comprises not only individuals who would fit this description but also a general practitioner and a nurse representative. I wish to emphasise that we support fully the proposal that the expertise gained from the general practice of medicine and from nursing would be invaluable to the new Commission. But it is difficult, if not impossible, to see how these members would meet the criteria for appointment to the Commission better than a pharmacist with wide and recent experience of practice. If anything, a pharmacist practitioner is more likely to meet the criteria considering the proposed functions of the new Commission, as set out in paragraph 25. There should be no question that an experienced pharmacist should not be represented on the Commission if it is to:

> "*Advise Ministers and the Agency on policy matters relating to the regulation of medicinal products.*"

Furthermore, if the new Commission is to be consulted on issues highlighted in paragraph 11, which relate to the sale and supply of medicines, the experience of a practising pharmacist member is vital. It is also mentioned that the new Commission may be consulted on changes relating to nurse prescribing. Presumably, in the future, consultation on pharmacist prescribing will also be involved. A pharmacist with wide and recent experience of practice would have an important contribution to make on this issue.

The new Commission is also to advise on "the establishment and membership of committees established under section 4 of the Medicines Act 1968" and on the establishment of the new Therapeutic Advisory Groups. The possible TAGS listed in Annex A include those for herbal medicinal products, homeopathic products and pharmacovigilance. As the members of these TAGS will be appointed by the new Commission, there is, in our view, an obvious case for inclusion of a pharmacist within the membership of a body which makes such appointments.

We believe that, in the preceding paragraphs, we have made a very strong case that a pharmacist with wide and recent experience of pharmacy practice should be included, as of right, in the membership of the new Commission on Safety of Medicines.

We would be grateful to have confirmation that this will be done.

- **Personal interests of members of TAGS**

  We agree that the members of the new Commission and the Chairmen of TAGS should hold no personal interest in the pharmaceutical industry. This will ensure that the allegations of industry bias heard in the past (however unfounded) can no longer be made. So far as members of TAGS (not including Chairmen) are concerned, we understand that the implications of changes made in Europe will have to be fully considered before a final decision can be made. However, we would suggest at this stage, that to require all those selected for membership of TAGS to have no personal interest in the pharmaceutical industry would be likely to delay appointments and probably limit unnecessarily the choice for appointment of well qualified candidates. Since TAGS will not have decision-making powers, nor report directly to Ministers, we would suggest that it would be sufficient for their interests to be declared and to withdraw from a meeting if that personal interest relates to the product of a company which is under consideration at a specific meeting.

- **Clarification regarding the "pharmacy standards TAG"**

  A pharmacy standards TAG is listed in Annex A as a possible advisory group. We would like to seek clarification of whether it is intended that this TAG will be the equivalent of the current Chemistry, Pharmacy and Standards (CPS) Sub Committee mentioned in paragraph 12, or if it is proposed that this TAG will have a different or wider remit related to any aspect of the practice of pharmacy.

We would be grateful if you could inform us of how the consultation process will proceed after 17 May. We would also welcome the opportunity for representatives of the NPA to discuss our major concern – the absence of a pharmacist member of the new Commission – with representatives of the MHRA before a final decision is taken on the recommendations to be made to Ministers on the composition of this new body.