To all licence holders and other interested organisations

Our Ref: MLX 300

11 February 2004

Dear Sir/Madam

CONSULTATION LETTER MLX300:

REVIEW OF THE ADVISORY BODIES STRUCTURE LAID DOWN IN THE MEDICINES ACT 1968

Introduction

I am writing to seek your views on a proposed restructuring of the advisory committees, set up under Sections 2 and 3 of the Medicines Act 1968 to advise Ministers on matters relating to the Act, the exercise of powers under the Act or otherwise relating to human and veterinary medicines.

Summary

The current advisory bodies’ arrangements have remained essentially unchanged since their introduction under the Medicines Act of 1968. However, over time there have been significant changes to the environment in which the committees operate – notably a huge increase in the influence of Europe in the form of legislation that has progressively superseded many of the provisions in the Medicines Act. The creation of the European Agency for the Evaluation of Medicines (EMEA) in 1995, and the introduction of Community marketing authorisations that are valid throughout Europe, have also changed the nature of the work undertaken by the advisory committees.

The recent merger of the Medicines Control Agency and the Medical Devices Agency to create the Medicines and Healthcare products Regulatory Agency (MHRA), and forthcoming changes to European regulatory framework provide an opportunity to consider the Agency’s advisory structure for the future. The UK is keen to ensure that the MHRA is well placed to participate fully in the revised European regulatory system.
Comments

Any comments on these proposals should be sent to Ms Joy Gay MHRA (Policy Projects Group) 16th Floor, Market Towers, 1 Nine Elms Lane, London SW8 5NQ by 17 May 2004. You may also e-mail your response to joy.gay@mhra.gsi.gov.uk no later than 17 May 2004. We regret that we cannot take comments over the telephone but you may send your comments by fax on the following number: 020-7084-2387. Copies of replies will be made available to the public on request, unless you clearly state that you are replying “in confidence”.

Yours faithfully

Roy Alder
Head of Executive Support
REVIEW OF THE ADVISORY BODIES STRUCTURE LAID DOWN IN THE MEDICINES ACT 1968

Introduction

1. The Medicines and Healthcare products Regulatory Agency (MHRA) was created by the merger of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA) on 1 April 2003. European medicines legislation has changed the work of the MHRA (medicines) significantly in recent years and this has had an impact on the type and volume of work being brought before the medicines advisory committees. The European Union is being enlarged further in 2004 and is proposing changes in its scientific advisory arrangements. With so many changes externally, now is an appropriate time to review the existing advisory committee structure of the MHRA in order to decide whether optimal arrangements are in place to deal with the changing work. Also, the interests of committee chairs and members is an issue that has attracted increasing debate, and this review offers a good opportunity to consider the policy for the future.

2. The MHRA is therefore now consulting on behalf of Ministers on proposals to revise the existing medicines advisory committee structure. The proposals are detailed in this paper. The MHRA is inviting comments on the proposals, for consideration before a final decision on the changes. To implement the changes, we propose that Ministers would make regulations under section 2(2) of the European Communities Act 1972 amending the relevant provisions of the Medicines Act 1968 and related secondary legislation.

3. This review deals only with the future roles of the Medicines Commission (MC), the Committee on Safety of Medicines (CSM) and the other committees currently established under the Medicines Act 1968. As part of the review and consultation process the MC and CSM are being invited to comment on these proposals. Medical devices are regulated in UK and Europe by a different process and under different legislation and so the devices’ advisory committee structure is not included in this paper.

Background

Current Advisory Structures for medicines

4. In the UK, the advisory committee arrangements for medicines have remained essentially unchanged since their introduction under the Medicines Act of 1968. Sections 2 and 3 of that Act specify that there shall be a Medicines Commission responsible for advising ministers on matters relating to the Act, or the exercise of powers under the Act, or otherwise relating to medicines. Under section 4 of the Act, Ministers may establish committees to advise in relation to functions under the Act. Such committees may be established generally or in respect of a particular class of substances. They may be established for the purpose of giving advice with respect to safety, quality or efficacy and/or the collection and investigation of information relating to adverse events. Under section 3 of the Act, the MC has a duty to make recommendations in relation to such committees and to review those committees from time to time.
The Medicines Commission (MC)

5. The MC advises Ministers on policy issues relating to drug regulation. It acts as an appellate body both for appeals for marketing authorisation applications which have been refused by the licensing authority on advice from CSM, and on proposals to revoke or suspend a national marketing authorisation, or to refuse certain applications to vary a marketing authorisation. It also provides advice to Ministers in relation to Section 4 committees, including advice on appointments. The Act requires that on the committee there must be at least one person with experience and capacity in each of the following: practice of medicine; practice of veterinary medicine; practice of pharmacy; chemistry other than pharmaceutical chemistry; and the pharmaceutical industry. The MC has some 24 members (the Act requires it to have a minimum of 8) and meets 5-6 times per year. Members are appointed for four-year terms.

6. The Medicines Act 1968 provides for the MC to perform a number of other functions. The MC is responsible for considering representations on proposals for orders prohibiting the supply of certain medicines following consultation (section 62(5)). If there was no CSM, the MC would also have to be consulted before Ministers made regulations or orders under Part III of the Act relating to the sale and supply of medicines. In certain cases the MC may also consider appeals relating to refusals to grant applications for manufacturers’ and wholesale dealers’ licences although in the case of decisions to suspend, revoke or vary such licences, the MC is not involved and appeal is direct to a “persons appointed” (see paragraph 17 below). It also acts as the appellate body on proposals to revoke a certificate of registration on advice from the Advisory Board on the Registration of Homoeopathic Products.  

7. In addition to medicines for human use, the MC is currently empowered in relation to medicines for veterinary use and advises Ministers on appeals they consider relating to veterinary medicines’ marketing authorisation applications which have been refused by Ministers on the advice of the Veterinary Products Committee (VPC) and on appointments to the VPC. However, very little business in relation to veterinary medicines is routinely referred to the MC.

8. The work of the MC has steadily diminished over recent years because of changes in licensing arrangements (e.g. the growth of EU licensing under the centralised and mutual recognition procedures) and other procedural changes within the MHRA (e.g. reclassification procedures). The MC heard a total of three appeals in 2002 and none in 2003, compared with an average of four or five per year for the previous ten years.

The Committee on Safety of Medicines (CSM).

9. The Committee on Safety of Medicines (CSM) was established in 1970 by an Order under Section 4 of the Medicines Act 1968\(^2\), to advise on the safety,

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1 See Schedule 2 to the Medicines Act as modified by the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 (S.I. 1994/105)

2 See the Medicines (Committee on Safety of Medicines) Order 1970 (S.I 1970/1257)
efficacy and quality of medicines for human use and to promote the collection and investigation of information relating to adverse drug reactions.

10. Applications for national marketing authorisations cannot be refused by the licensing authority on grounds of safety, efficacy or quality unless first referred to the CSM. Similarly, proposals to revoke or suspend a national authorisation on those grounds, or to refuse certain applications to vary a marketing authorisation, must be referred. As a matter of practice, all applications for national authorisations for medicines containing new chemical entities are also referred to CSM.

11. The CSM has other functions specified in the Medicines Act 1968. In particular, the CSM is the "appropriate committee" which must be consulted on proposals to make regulations and orders under Part III of the Medicines Act 1968, which relates to the sale and supply of medicines. For example, the CSM is consulted on amendments to the Prescription Only Medicines (Human Use) Order 1997 when changes are required in relation to matters such as nurse prescribing, and on prohibition orders under Section 62 of the Act.

12. In addition, the views of the CSM are sought by the MHRA on those centralised applications to the European Medicines Evaluation Agency (EMEA) where the UK is rapporteur or co-rapporteur, and also on applications under the decentralised (mutual recognition) system where a marketing authorisation is sought in the UK. The CSM’s views are also sought on matters relating to the safety of marketed medicines. To fulfil these roles, the CSM has created three subcommittees: The Chemistry, Pharmacy and Standards Subcommittee (CPS); The Biologicals Subcommittee and The Subcommittee on Pharmacovigilance (SCOP) all of which report to the main committee. In addition, the CSM creates Working Parties to deal with specific regulatory issues, usually relating to safety, and where it considers that it requires advice which is not available from within its membership. The CSM currently has 34 members and meets twice monthly, most members attending one meeting per month. Members are appointed for three-year terms.

Other Section 4 committees

13. In addition to the CSM and their sub-committees, there are currently three other committees established by orders under Section 4 of the Medicines Act. These are: the Advisory Board on the Registration of Homoeopathic Products; the British Pharmacopoeia Commission and the Veterinary Products Committee. Under the current committee structure, the MC advises Ministers on the establishment of such committees. Appointments are made to the committees by Ministers on the basis of recommendations made to them by the MC.

14. The Advisory Board on the Registration of Homoeopathic Products was established to give advice with respect to the safety and quality of homoeopathic medicinal products that satisfy the conditions to be eligible for the simplified

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registration scheme for homoeopathic medicinal products. Applications for the grant of a certificate of registration cannot be refused by the licensing authority on grounds of safety or quality unless first referred to the Advisory Board. Similarly, proposals to suspend or revoke a certificate of registration must be referred to the Advisory Board.

15. The British Pharmacopoeia Commission⁴ (BPC) was established with the purpose of preparing future editions of the British Pharmacopoeia (BP) and any amendments to the 1968 edition and future editions (under section 99(1) of the Medicines Act); preparing lists of names suitable for use as headings for monographs appearing in the BP and any amendments of such lists (see section 100); and preparing any compendium of substances or articles used in veterinary medicines or veterinary surgery (see section 99(3)(b)). When the BPC has prepared a new edition of the BP, a compendium, or list of names, the MC is responsible for recommending whether this should be published. The MC may also direct the BPC to prepare other publications on medicinal products for human or veterinary use. If there was no BPC the MC would be responsible for carrying out its tasks.⁵

16. The Veterinary Products Committee⁶ was established to advise on the safety, quality and efficacy of medicinal products for veterinary use and to promote the collection and investigation of information relating to adverse drug reactions.

**Persons Appointed**

17. If an applicant or MA holder is not satisfied with the MC's advice on an appeal to it, following advice from the CSM, they have, in certain cases a right to be heard by a person - in practice, persons - appointed by the Licensing Authority⁷. A similar procedure exists for veterinary medicines, and where the Licensing Authority proposes to suspend, vary or revoke manufacturers' or wholesale dealers' licences. In effect, the persons appointed provides the final tier of appeal on licensing issues. The procedure is rarely invoked (twice in the last ten years or so).

**Europe**

18. The EMEA obtains its scientific advice from the Committee on Proprietary Medicinal Products (CPMP), which considers all centralised applications and all decentralised (mutual recognition) applications referred to the EMEA for arbitration. Scientific assessment of centralised applications is carried out not by EMEA staff but by rapporteurs (in practice assessors and advisory committees) from the regulatory agencies of individual member states. CPMP has 30 members, two nominated by each national regulatory agencies of the 15 current member states of the European Union. The CPMP meets once a month for three days.

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⁵ See section 99(7) of the Medicines Act.
⁷ “Persons appointed” hearings are conducted in accordance with procedural rules set out in the Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986
similar but separate arrangement applies for veterinary medicines through the Committee on Veterinary Medicinal Products (CVMP).

19. The CPMP has created several subcommittees to help it manage its business. These deal with issues similar to the CSM subcommittees described above. Following a review of the structure and function of the CPMP and the EU licensing process, there will be an extension to the range of products obliged to use the procedure operated by the EMEA (the “centralised procedure” (CP)) that results in a marketing authorisation valid throughout the EU. Currently, only new active substances developed by means of biotechnology, certain innovative products and veterinary products for use as performance enhancers must use the CP. From, probably late 2005, the following range of products for human use will be added: new active substances to treat HIV/AIDS, cancer, neurodegenerative disorder, diabetes and products defined as “orphan” medicinal products. Four years later, this list will be further extended to include products containing new active substances to treat auto-immune diseases and other immune dysfunction and viral diseases, and may be further extended to include other new active substances, following review. These changes are increasingly diminishing the role of the decentralised (mutual recognition) system.

Proposals

Europe

20. The expansion of the EU by ten members in 2004 will make continued composition of the CPMP described above, difficult, as a committee of 50 members will be unwieldy. Europe has decided on a model that includes one member per member state plus an alternate – with voting rights. In addition, up to five members may be co-opted onto the CPMP by the committee for their particular expertise, also with voting rights.

21. The CPMP will also be able to create Therapeutic Advisory Groups (TAGs) in defined therapeutic areas. According to one model, TAGs will comprise assessors from national regulatory agencies as well as experts from academia and health services from various member states and will work with the rapporteurs and co-rapporteurs of all new applications and present an assessment report to CPMP. Another model proposes that only experts and not national assessors should be members of a TAG. As a pilot, EMEA/CPMP is already in the process of setting up TAGs in three therapeutic areas-infectious diseases, cancer and diagnostics.

UK

22. It is appropriate first to consider the changes being proposed by the EMEA and the European Commission, since one of the main aims of the MHRA is to position itself to make maximum contribution to any new European structures and procedures. With these proposed European changes in mind, therefore, we consider that a change in the UK regulatory advisory committee structure on medicines is required. The principles underlying a new structure are:
a) Any change should be beneficial to the effectiveness and accountability of drug regulatory decision making, particularly in relation to protecting public health, and should not disadvantage industry;

b) Any new committee structure should be compatible, as far as possible, with the proposed European advisory structures;

c) Good practice, in line with the policy and code of practice on personal interests of members of Advisory Committees must be applied.

We should be grateful for comments on the case for changing the structure, and on the principles outlined here.

Commission on the Safety of Medicines

23. With these principles in mind, we propose that a **Commission on the Safety of Medicines** for the UK should be created by amalgamating the responsibilities of the present Medicines Commission and Committee on Safety of Medicines for human medicines. Proposals for veterinary medicines are at paragraph 28 below. As these proposals are related to the UK's obligations under EU medicines legislation, we propose to effect the changes by regulations under Section 2(2) of the European Communities Act 1972, amending the relevant provisions of the Medicines Act 1968, the Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994 and other related secondary legislation.

24. The new Commission would be a newly-appointed body, rather than an amalgamation of the current bodies. Its membership would be subject to a full appointments exercise, starting in the second half of 2004, with a view to appointing the Chairman and members to begin in January 2005, if possible, though it may be later.

Functions of the new Commission

25. The new Commission would take on the functions currently performed by the MC and the CSM in relation to medicines for human use. In particular it would be responsible for:

- Advising Ministers and the Agency on policy matters relating to the regulation of medicinal products;
- Advising on the safety, quality or efficacy of medicinal products (e.g. advising the Agency on those licensing applications that are currently considered by the CSM);
- Promoting the collection and investigation of information relating to adverse reactions;
- Advising on the establishment and membership of committees established under section 4 of the Medicines Act 1968 (but see paragraphs 28 and 29 below).

Sub-Committees and Therapeutic Advisory Groups (TAGs)

26. To facilitate our fullest participation in the new EU regulatory environment we propose that, in addition to the new Commission, provision would be made for the establishment of Therapeutic Advisory Groups (TAGs) in defined therapeutic
areas. TAGs would be established by the new Commission, and would advise them on scientific issues which apply across therapeutic areas, or which relate to relatively self-contained substance-types. We propose that TAGs would be expert groups set up to advise and make recommendations to the new CSM on specific issues, and they would not themselves have decision making powers.

27. There is also likely to be a continuing need for some subcommittees of the new Commission, such as those serving the present CSM. Although their current role and remit in relation to the CSM would not change under the new arrangements, we propose that these, too, should become known in the future as TAGs.

Other Section 4 committees

28. We are also considering the status of the other existing Section 4 committees. For each of these the issue is whether, if the MC and the CSM are replaced by a new Commission, they should continue as Section 4 committees, or whether their functions should be carried out by appropriately appointed TAGs. Our proposals currently are that we should:

- retain the British Pharmacopoeia Commission (BPC) as a Section 4 committee as now, reporting to the new Commission.
- Retain the Veterinary Products Committee (VPC) as a Section 4 committee as now. The new Commission’s role would comprise (as now) receiving nominations for membership and making recommendations to Ministers on appointments, as well as hearing appeals against VPC decisions. The VPC would continue, as now, to provide advice to the licensing authority through Department for Environment, Food and Rural Affairs (Defra) Ministers.

29. In relation to the Advisory Board on the Registration of Homoeopathic Products, we consider it would be more appropriate – and in line with the proposed new structure consisting of groups advising the new Commission on specific issues - if the Advisory Board were to be abolished and replaced by a TAG. Changing from a section 4 committee to a TAG would mean that it would not advise the licensing authority directly, but would report its recommendations to the new Commission. For example, the TAG would consider applications for certificates, proposals to revoke certificates etc. But it would be for the new Commission to advise the licensing authority, taking into account the recommendations of the TAG. Any appeal against a decision to refuse would be made under the "person appointed" procedure (see paragraph 42 below). A possible list of TAGs is at Annex A.

Herbal medicine

30. In the light of the proposed Directive on Traditional Herbal Medicinal products there will be an increased need for independent expert advice covering the range of herbal traditions present in the UK. In Europe, a Committee on Herbal Medicinal Products is to be established that will be distinct from the CPMP. The MHRA proposes to adopt an approach that minimises the risk of divergent standards of advice emerging in relation to different categories of medicine. This is desirable in the interests of public health protection. Equity in regulation is also important – a consistent approach should be taken to issues such as the standards
of efficacy required for a marketing authorisation. Accordingly, we propose to establish a TAG for herbal medicine.

**How the Commission and TAGs would operate**

31. We propose that the new Commission might operate under the following arrangements:

- It would comprise approximately 10-12 core members, appointed by Ministers. 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 expertise 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. A possible list of new Commission members to reflect relevant fields or expertise is at Annex B;
- A number of TAGs would be created by the new Commission, with members selected and appointed by them and comprising national experts.
- Recommendations from TAGs to the new Commission would be in the form of either a paper or personal presentation by the TAG Chair who would attend as an invited member;
- The majority of TAGs would exist as standing committees, each with certain members "on retention". Permanent members would include the Chair; and one or two permanent experts. MHRA would supply the secretariat and MHRA designated assessors may need to attend. Other experts would be invited for specific topics. Referrals from and between the various committees and groups would be arranged as necessary;
- It will be an important task of the secretariat both to manage the logistics of TAG membership and to ensure that appropriate issues are referred to TAGs for their timely consideration;
- The new Commission would meet once monthly;
- TAGs would meet as required depending on the nature of the advice required by the new Commission. It would be possible for a TAG to ‘meet’ by tele-or TV-conference rather than by holding an actual meeting. UK representation at a European TAG could, where relevant, be provided from a national TAG.

32. Consideration would also be given to establishing a panel of lay members from patient groups, whose advice would be sought on a range of issues, such as product information for patients and other relevant regulatory matters.

33. We recognise that our proposals for membership of the new Commission (see Annex B) would require amendment to the membership of the Commission as set out in paragraph 5 above. We consider that veterinary medicine would be covered adequately by the proposals we have set out in paragraph 28 above. We also consider that a representative of non-pharmaceutical chemistry may not fundamental to the needs of the new Commission and should be dropped. In relation to representation from the pharmaceutical industry, the proposed arrangements – and in particular the proposals for handling interests in the pharmaceutical industry (see paragraphs 35 – 40 below) - would preclude representatives from the pharmaceutical industry becoming members of the new Commission.
34. The establishment of TAGs would represent an important change in the advisory structure in the UK. If the results of this consultation were to be favourable, we would envisage piloting the new TAG arrangements in advance of adoption of the complete new Commission structure.

Interests

35. As with all committees or other bodies that provide advice to Government, the medicines advisory bodies are subject to rules and practices governing the holding and declaration of interests. The aim is to ensure that interests do not affect the independence of the advice provided. Similar rules would have to apply to the new Commission.

36. Interests usually arise where there is a financial benefit, but they can also be non-financial. A personal interest arises when a member receives a personal financial benefit, for example arising from share-holding or from payment of a consultancy fee. A non-personal interest arises when members do not themselves benefit directly, for example, when a research grant is paid to the academic department for which the member is responsible. A specific interest is related to products under consideration.

37. The current rules that apply to such holdings are set out in a Code of Practice for Members of the Medicines Commission and Section 4 Committees and Sub-Committees. In summary, the Code of Practice requires the chairmen of advisory bodies to relinquish any current personal interests they may have in the pharmaceutical industry before they take up post and specifies different types of interests and how they must be declared by members. It indicates what action the Chairman, advised at each meeting by a Departmental lawyer, should take in various circumstances. Where, for example, a member has shares in a company whose product is coming before the committee for consideration, that “personal” interest is declared and the member will leave the meeting and will not take part in the proceedings relating to that particular product.

38. The Code of Practice is included in full in the Advisory Committees’ Annual Report (the Annual Report is available on the MHRA website at: http://medicines.mhra.gov.uk/aboutagency/annualreports/advbodreport02.htm)

39. Ministers have for some time been considering ways of tightening the approach to the holding of such interests by members appointed to advisory bodies in the UK. We are therefore consulting on a proposal that the chairman and members of the new Commission should hold no personal interests in the pharmaceutical industry. Under our proposal the chairmen of TAGs would, as necessary, participate in the meetings of the new Commission and it could follow that they, too should have no personal interests in the pharmaceutical industry.

40. The issues in relation to members of TAGs are not so clear cut. Meetings of some of the TAGs are likely to be relatively infrequent and it could be unreasonable to require members of such TAGs to divest themselves of all such personal interests. However, important changes have recently been agreed at EU level to the rules on
financial and other interest held by individuals involved in taking decisions on the authorisation and surveillance of medicines. The full implications of these changes are not yet entirely clear. This consultation document does not therefore deal with these changes which we will be considering later this year.

Appeals

41. Under the Medicines for Human Use (Marketing Authorisations etc) Regulations 1994, the Medicines Act, and regulations made under its powers, an applicant has the right to a hearing, in prescribed circumstances, before the CSM, the VPC, the Advisory Board on the Registration of Homoeopathic Products, the Medicines Commission and/or persons appointed by the Licensing Authority. In view of the low numbers of appeals to the Medicines Commission and the CSM, and the increasing use of clarification meetings, where applicants meet MHRA assessors to resolve issues before matters reach the appeal stage, there seems to be a case for streamlining the appeals procedure. Under the proposed new arrangements, if a marketing authorisation for a product (or a certificate of registration) was refused by the licensing authority, after a hearing before the Commission, the applicant would still be able to appeal to a “person appointed” as provided for in the legislation. In particular, there would be scope for involving TAGs in clarification meetings to maximise predictability of outcome for companies and to resolve issues without the necessity of involving formal statutory appeals procedures.

42. The proposed procedure (a hearing before the new Commission and an appeal to a person appointed) would also apply to those applications to vary marketing authorisations and those applications for the grant of a manufacturer's or wholesale dealer's licence that currently benefit from the existing CSM/Commission appeal mechanism. Similarly, if the licensing authority proposed the suspension or revocation of a marketing authorisation or a certificate of registration, the holder would be entitled to a hearing before the new Commission and, if necessary, an appeal to a person appointed. Proposals for the suspension, revocation and variation of manufacturers' and wholesale dealers' licences would, as now, be subject only to the person appointed procedure.

Other statutory functions of the committees

43. The Medicines Act 1968 confers other functions on the CSM and MC. Other proposed amendments to the Act would cover:

- Regulations and orders under Part 3 of the Act, for example, amendments to the POM Order, where there would be a statutory duty to consult the new Commission.
- Prohibition orders under section 62 - this provision requires Ministers to consult the "appropriate committee" (currently the CSM) on the proposal, as well as representative groups. After consultation, any written representations must be considered by the MC and any representative organisation consulted.

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888 As provided for in Schedule 2 to the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 and section 21 of the Medicines Act 1968 (as applied by Schedule 4 to the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994.
has a right to be heard by the MC. The proposed new Commission's role would be to carry out these functions.

- British Pharmacopoeia Commission - the Act currently gives various powers to the MC to give direction to that committee. It is proposed that the new Commission would have the same powers.

44. The MHRA would therefore be grateful for your views, comments and suggestions on the proposals set out above. We would particularly welcome your views on the following matters:

- the name of the new Commission: the acronym CSM has a strong and widely-recognised identity in the UK (paragraph 23);
- the size of the new Commission and the competences required of its members (paragraph 31);
- the establishment of TAGs, their number and role and their relationship to the new Commission (paragraphs 26, 27, 30 & Annex B);
- proposals for the existing Section 4 committees (paragraph 28&29);
- proposals on holding personal interests in the pharmaceutical industry by members of the new Commission and chairs of TAGs (paragraph 39);
- suggestions for input of industry views, as it is proposed that the current provision in the Medicines Act for industry representation should be removed (paragraph 33);
- the proposed new appeals arrangements and the increased use by the MHRA and companies of scientific and regulatory advice meetings, as well as clarification meetings before applications or other issues are considered by the new Commission (paragraphs 41&42);
- the establishment of a patients advisory panel (paragraph 32);
- the proposals for other MC or CSM functions under the Medicines Act (paragraph 43);
- should the new Commission continue to advise Ministers on appointments to the VPC (paragraph 28);
- should the new Commission provide an appeals procedure for veterinary products, as for human medicines (paragraphs 41&42).

45. A proforma for responses is at Annex C, which you may return by post or e-mail, no later than 17 May 2004.
POSSIBLE ADVISORY GROUPS (TO THE NEW COMMISSION)

- Pharmacovigilance
- Biologicals
- Pharmacy Standards
- Paediatric
- Herbals - to advise on applications for marketing authorisations and registrations under the future EU Directive
- Homoeopathic Products - to advise on homeopathic applications and certificates
- Cardiorespiratory
- Cancer
- Endocrine and Obs/Gynae
- Gastrointestinal
- Anti-infectives and HIV/AIDS
- Neurology and psychiatry
- Plus additional "as required" ad hoc topic-specific TAGs
- Patients Panel
POSSIBLE MEMBERSHIP OF THE NEW COMMISSION TO REFLECT RELEVANT FIELDS OR EXPERTISE

- Chair
- Clinical Pharmacologist
- Clinical Epidemiologist/Medical Statistician
- Paediatrician
- Toxicologist
- General Practitioner
- Nurse representative
- Chair of Pharmacy Standards TAG
- Chair of Biologicals TAG
- Chair of Pharmacovigilance TAG
- Lay Member
- Supplemented, as agenda requires, by
  - relevant Chairs of other TAGs
  - veterinary members as necessary, for appeals and appointments to the VPC
Annex C

RESPONSE TO CONSULTATION LETTER MLX 300

REVIEWS OF THE ADVISORY BODIES STRUCTURE FOR MEDICINES IN THE UK

Please complete the proforma and return to Ms Joy Gay MHRA (Policy Projects Group) 16th Floor, Market Towers, 1 Nine Elms Lane, London SW8 5NQ by 17 May 2004. You may also e-mail your response to joy.gay@mhra.gsi.gov.uk

Name: ...........................................................................................................

Company name: ...........................................................................................

We have the following comments to make on the review proposals:
(Please use additional sheets as required)