EXPLANATORY MEMORANDUM TO THE

MEDICINES (ADVISORY BODIES) (TERMS OF OFFICE OF MEMBERS) REGULATIONS 2005

2005 No. 2788

1. This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency, on behalf of the Department of Health and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Description

2.1 This instrument replaces the Medicines Commission and Committee Regulations 1970, which are revoked by the new Medicines (Advisory Bodies) Regulations 2005. It sets out the maximum term of office for chairmen and members of the Commission on Human Medicines, committees established under section 4 of the Act and Expert Advisory Groups set up to advise them. The instrument also sets out how cessation of membership of particular committees affects membership of other committees.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument has been laid before Parliament less than 21 days before it is due to come into force (30th October 2005). The instrument was prepared and ready in draft last week, but it was not possible, in the time available, to obtain the necessary seals of the Department for Health, Social Services and Public Safety, Northern Ireland, and the Department for Agriculture and Rural Development, Northern Ireland, so as to enable the instrument to be laid more than 21 days before coming into force. The Department recognises that it should have allowed additional time for obtaining those seals.

3.2 As explained in paragraph 4.1, this instrument is part of a series of statutory instruments which make changes to the legislation for the expert advisory bodies that provide advice to Ministers in relation to medicinal products. In particular, the Medicines (Advisory Bodies) Regulations 2005 provide for the abolition of the Medicines Commission and the Committee on Safety of Medicines, and the establishment of the Commission on Human Medicines, on 30th October 2005. From that date the proposed new members of the Commission on Human Medicines will take office. The Department's view, therefore, is that the regulations governing the terms on which they hold office should come into force on 30th October at the latest.

3.3 As set out in the regulations, the precise terms on which a member will hold office will be set out in the instrument appointing the member. Also, the maximum 4 year term prescribed by the regulations is the same as the current maximum term for the existing advisory bodies. The Department's view is that no member or potential

member of any committee has been disadvantaged by the delay in making and laying the instrument.

4. Legislative Background

4.1 This is one of a series of instruments that make changes to the Medicines Act 1968 and related legislation. The changes create a new advisory body structure to provide advice to Ministers and the licensing authority in relation to medicinal products in the UK. The Medicines (Advisory Bodies) (Terms of Office of Members) Regulations 2005, which replace the Medicines Commission and Committee Regulations 1970, are made under Schedule 1A to the Act. Schedule 1A was inserted by the Medicines (Advisory Bodies) Regulations 2005, which came into force for these purposes on 31 May 2005 (for all other purposes on 30th October 2005). Schedule 1A makes provision relating to the new advisory bodies, including provision for the Secretary of State to make regulations as to the terms on which members shall hold and vacate office. A further instrument (the Medicines (Advisory Bodies) Regulations (No. 2) 2005) will complete the changes required to implement the revised structure.

5. Extent

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

No statement required.

7. Policy background

7.1 The current Medicines Act advisory committee structure has remained broadly unchanged since its introduction under the Medicines Act in 1968. However, as medicines are increasingly being developed to meet the needs of very specific diseases and conditions, and the industry is seeking engagement with the regulator at an earlier stage of product development, a greater degree of scientific specialism is needed within the committee structure.

7.2 Over time there have also been significant changes to the environment in which the UK advisory committees operate – in particular extensive development of the European system of medicines' regulation and associated EU legislation. The main impact occurred with the establishment of a European Medicines Agency (EMEA) in 1995 and introduction of a single European authorisation for certain medicines. Following a recent review of EU medicines' legislation, changes are being made to the committee structure that underpins the EU medicines regime. The EU committee system depends crucially on the expertise placed at its disposal by the Member States, and the changes to our committee structure will ensure that the UK remains best placed to participate fully in the new EU system.

7.3 The changes to the legislation of which this instrument forms a part have:

- Abolished the Medicines Commission;
- Created a new Commission on Human Medicines (CHM) by combining the functions of the Medicines Commission with those of the current Committee on Safety of Medicines;

- Removed the legislative provision that entitles the pharmaceutical industry to be represented on the Medicines Commission (now the CHM);
- Created a new committee to deal with herbal medicinal products (the Herbal Medicines Advisory Committee – HMAC), retained committees on homoeopathic products (the Advisory Board for the Registration of Homoeopathic products - ABRH) and the British Pharmacopoeia Commission (BPC) and provided for the establishment of Expert Advisory Groups (EAGs) underpinning the CHM and these committees;
- Streamlined the process that provides for the pharmaceutical industry to seek a hearing if they are dissatisfied with the advice given by the committee (or in some cases with a proposal being made by the licensing authority) and introduced a further scientific review if industry remains dissatisfied – to replace the current administrative review.

7.4 The CHM, HMAC and ABRH are able to give advice direct to Ministers and the licensing authority. The CHM will have additional tasks in advising Ministers more generally on matters relating to the Act or related legislation, on the exercise of powers under that legislation, or otherwise relating to medicines. The EAGs will advise any or all of these three committees.

7.5 This creates a structure with three clear and separate lines of accountability to Ministers for the products on which these committees advise. Each will have its own hearing and appeals structure, and be able to delegate its functions to EAGs. Where issues affect products in all sectors, it is expected that the CHM will be consulted. The main structural changes were included in the Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094) that come into force on 30th October 2005 (except as explained in paragraph 4.1 above).

7.6 As indicated in paragraph 3.3, the Medicines (Advisory Bodies) (Terms of Office of Members) Regulations 2005 provide for the maximum term of office for chairmen and members of all the new committees, and provides for the detailed terms of office of chairmen and members to be set out in the instrument by which they are appointed.

8. Impact

8.1 A Regulatory Impact Assessment has not been prepared for this instrument as it has no impact on business, charities or voluntary bodies.

9. Contact

9.1 Margaret Jackman at the Medicines and Healthcare products Regulatory Agency, Department of Health, Tel: 020 7084 2406 or e-mail: margaret.jackman@mhra.gsi.gov.uk can answer any queries regarding the instrument.