EXPLANATORY MEMORANDUM TO THE

MEDICINES (ADVISORY BODIES) (No. 2) REGULATIONS 2005

2005 No. 2754

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.

2. Description

2.1 This instrument ("the No. 2 Regulations") supplements the Medicines (Advisory Bodies) Regulations 2005 ("the No. 1 Regulations"), which make changes to the structure of the statutory bodies which provide advice in relation to medicinal products. For reference, a copy of the Explanatory Memorandum relating to those regulations is attached. The No. 2 Regulations set out transitional arrangements, to make provision for cases which are currently subject to the existing rules, and also make some changes to other legislation, including the Medicines for Human Use (Clinical Trials) Regulations 2004, to reflect the changes to the advisory body structure. The No. 2 Regulations also make further, minor amendments to the Medicines for Human Use (Marketing Authorisation Etc. Regulations) and to the Medicines Act 1968 (the amendments to the Medicines Act 1968 are explained in more detail in section 4.1 below).

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

3.1 None

4. Legislative Background

4.1 This is one of a series of three 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 No. 1 Regulations were made in April of this year and come into force on 30th October 2005, except for one provision which inserted a new Schedule 1A into the Medicines Act 1968, including some new regulation making powers. That provision came into force on 31st May 2005 for the purpose of making those regulations – which are being made at the same time as the No. 2 Regulations and are called the Medicines (Advisory Bodies) (Terms of Office of Members) Regulations 2005. They are the subject of a separate Explanatory Memorandum.

4.2 The No. 2 Regulations are the third in the series and set out transitional provisions, as well as making a number of amendments to other legislation. They also make minor amendments to the Medicines Act 1968, which are consequential on the Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 2005 and the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005. These regulations implement two European Directives and are the

subject of separate Explanatory Memoranda, to which Transposition Notes have been attached.

5. Extent

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

The Minister of State for Quality and Patient Safety, Jane Kennedy, has made the following statement regarding Human Rights:

In my view the provisions of the Medicines (Advisory Bodies) (No. 2) Regulations 2005 are compatible with the Convention rights.

7. Policy background

7.1 The policy background to the No. 1 Regulations, including details of the consultation which was undertaken, is set out in the Explanatory Memorandum to those regulations, which is attached.

7.2 In outline, the current Medicines Act advisory committee structure has remained broadly unchanged since its introduction under the Medicines Act. 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. 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. The EU committee system depends crucially on the expertise placed at its disposal by the Member States.

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;
- Made provision for the arrangements which apply when the new CHM, or other advisory committees, is consulted on proposals or decisions relating to licences and authorisations for medicinal products.

7.4 As set out above, the main changes were made by the No. 1 Regulations. The No. 2 Regulations complete these changes by providing for transitional arrangements and

completing the amendments to legislation related to the Medicines Act 1968, to reflect the changes to the committee structure and the new arrangements which apply when the CHM or other committee is consulted.

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

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EXPLANATORY MEMORANDUM TO THE

MEDICINES (ADVISORY BODIES) REGULATIONS 2005

1. This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency (MHRA), and executive agency of the Department of Health, and the Department for Environment, Food and Rural Affairs is laid before Parliament by Command of her Majesty.

2. **Description**

2.1 The instrument amends the Medicines Act 1968 and the 1994 Marketing Authorisation Regulations. It implements changes to the statutory committees that advise Ministers on matters relating to medicines …..

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

3.1 None.

4. **Legislative background**

4.1 The instrument is made under section 2(2) of the European Communities Act 1972 and implements certain changes to the Medicines Act 1968.

5. **Extent**

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1 The Parliamentary Under Secretary of State, Lord Warner, has made the following statement regarding Human Rights:

In my view the provisions of the Medicines (Advisory Bodies) regulations are compatible with the Convention rights.

7. Policy background

7.1 The Department of Health is making changes to the Medicines Act 1968 to update the independent committee structures that it contains which provide advice to Ministers on the safety, quality and efficacy of medicines on the UK market.

7.2 The current Medicines Act advisory committee structure has remained broadly unchanged since its introduction under the Medicines Act in 1968. The advisory bodies provide advice to Ministers who are the Licensing Authority (LA) for medicines in the UK. The current structure has served Ministers well over the years. 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.

7.3 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.

7.4 The current medicines committees structure comprises a Medicines Commission, specified in the Medicines Act, responsible for advising Ministers on matters relating to the Act or the exercise of powers under the Act, or otherwise relating to medicines. Under the Act, Ministers may establish other committees (under Section 4 of the Act – the so-called "Section 4" 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, or for giving advice on safety, quality or efficacy, or on the collection and investigation of information relating to adverse effects of medicines. Under the Act, the Medicines Commission has a duty to make recommendations in relation to these committees, and to review them from time to time.

7.5 There are currently four Section 4 committees – the Committee on Safety of Medicines (CSM), the Veterinary Products Committee (VPC), the Advisory Board for the Registration of Homoeopathics (ABRH) and the British Pharmacopoeia Commission (BPC). The CSM and BPC have a number of sub-committees and working parties.

7.6 In recent years, the role and workload of the Medicines Commission has reduced significantly. In the same period, the role and workload of the CSM has significantly increased, both in terms of reviewing applications to market products in the UK, and in giving Ministers advice on proposals to authorise products for use across the EU. There has also been a significant increase in their work on surveillance and advice on safety of products on the UK market.

7.7 In addition, Ministers have decided to establish the Herbal Medicines Advisory Committee (HMAC) which is a new committee to give advice on the regulation of certain herbal products. More recently, Ministers have also decided to consult on proposals to remove the regulation of veterinary products from the Medicines Act that would result in separate arrangements for advising on veterinary medicines.

7.8 In February 2004 the Medicines and Healthcare products Regulatory Agency (MHRA) launched a three month public consultation on proposals to amend the medicines advisory committees. We proposed:

- Abolishing the Medicines Commission;
- Creating a new Commission on Human Medicines (CHM) by combining its functions with those of the current CSM;
- Removing the legislative provision that entitles the pharmaceutical industry to be represented on the Commission;
- Leaving the VPC and BPC as Section 4 committees, – working via the new Commission;

- Making any other committees and sub-committees – including the ABRH and new HMAC – into Expert Advisory Groups (EAGs) underpinning the Commission;
- Streamlining the process that provides for the pharmaceutical industry to seek a hearing if the committees cannot support the application they have made, and introducing a further scientific review if industry remains dissatisfied – to replace the current administrative review.

7.9 The consultation produced 91 responses. Most were broadly supportive of the proposals, except for proposed arrangements for the new HMAC and for the ABHR. In response to these concerns, Ministers have decided to amend the proposed structure so that the CHM, HMAC and ABRH will be able to give advice direct to Ministers. The CHM – which will be the only committee established under the Act - will have additional tasks in advising Ministers more generally on matters relating to the Act, on the exercise of powers under the Act, or otherwise relating to medicines. The EAGs will advise any or all of these three committees.

7.10 This creates a structure with three clear and separate lines of accountability to Ministers for the products that they regulate. Each will have its own hearing and appeals structure, and be able to commission their own advice from the EAGs. Where matters (for example safety issues) affect products in all sectors, the CHM will have an overarching responsibility to advise, especially if views differ.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

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