EXPLANATORY MEMORANDUM TO THE

MEDICINES (ADVISORY BODIES) REGULATIONS 2005

2005 No. 1094

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of her Majesty.

2. **Description**

2.1 The instrument abolishes the Medicines Commission and the Committee on Safety of Medicines (the CSM), the statutory bodies established to advise Ministers on matters relating to medicinal products, and in their place establishes the Commission on Human Medicines. It also makes provision for the arrangements under which the new Commission, or other advisory committees established under the Act, may be consulted on proposals or decisions relating to licences and authorisations for medicinal products.

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 makes provisions arising out of, or related to, the UK's obligations under the Community legislation in relation to medicinal products. In particular, it makes provisions arising out of the UK's obligations relating to the grant, renewal, variation, suspension and revocation of authorisations under Directive 2001/83/EC on the Community code relating to medicinal products for human use ("the 2001 Directive"). Directive 2001/83/EC is the main piece of EC legislation governing medicinal products for human use and consolidates most of the previous EC legislation in this area. Directive 2001/83 is amended by Directive 2004/27/EC, which must be transposed into UK law by 30th October 2005. This is the date this instrument is to come into force.

4.2 The provisions of Directive 2001/83/EC relating to marketing authorisations for medicinal products are implemented in the UK by the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 ("the 1994 Regulations"). The provisions of Directive 2001/83/EC relating to manufacturing and wholesale distribution authorisations are implemented by the provisions of the Medicines Act 1968, and secondary legislation under that Act, relating to manufacturers' and wholesale dealers' licences. A small number of products falling outside the scope of Directive 2001/83/EC are covered by the Act's provisions relating to product licences.

4.3 The Medicines Commission, established by section 2 of the Act, and the CSM, established under section 4 of the Act, are responsible for advising Ministers and the licensing authority under the Act on matters relating to medicinal products, in particular on the safety, quality and efficacy of such products. The existing legislation makes provision for the licensing authority to consult these bodies on proposals to refuse applications for the licences and authorisations referred to in the previous paragraph, and on proposals to vary, suspend or revoke such licences and authorisations. See, in particular, sections 20 to 22 of, and Schedule 2 to, the Act and Schedule 2 to the 1994 Regulations, which are amended by this instrument. The bodies also advise on matters such as orders prohibiting unlicensed medicinal products under section 62 of the Act and on orders under Part 3 of the Act relating to the supply of prescription only medicines.

4.4 This instrument amends the Act and the 1994 Regulations, so as to provide for the establishment of the new Commission and for it to take on the functions currently performed by the Medicines Commission and CSM. Schedule 1 to the Act is amended to provide, in particular, for the Commission and committees established under section 4 of the Act, to appoint sub-committees to be known as Expert Advisory Groups. The Medicines Commission is abolished and the Medicines (Committee on Safety of Medicines) Order 1970, which established the CSM, is revoked.

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 2005 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 provided for in that Act, 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 1970. 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. In particular, a number of expert scientific groups is being established to underpin the work of the Committee for Human Medicinal Products (CHMP), which is the main EU scientific committee responsible for advising the European Commission on medicines' regulatory matters. 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 In addition to the Medicines Commission established by section 2 of the Act, there are currently four committees established under section 4 of the Act. These are 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. In the future any such bodies will be known as Expert Advisory Groups.

7.5 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.

7.6 In addition, Ministers are consulting on proposals associated with establishment of a Herbal Medicines Advisory Committee (HMAC) which will be a new committee to give advice on the regulation of certain herbal products.

7.7 The current Medicines Commission deals with both human and veterinary medicines. However, Ministers are currently undertaking a public consultation on proposals that veterinary medicines should be dealt with by a separate regime and the Medicines Act advisory bodies should be concerned solely with human medicines. Depending on the outcome of the public consultation, regulations that would be needed to provide that the Act no longer applies to veterinary medicines would be made later in the year.

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 bodies. 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 proposed HMAC and existing ABRH would be able to give advice direct to Ministers, without referral to CHM. The CHM 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 its 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

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REGULATORY IMPACT ASSESSMENT

1. Title of proposal

The Medicines (Advisory Bodies) Regulations 2005 - making amendments to the Medicines Act 1968, the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 and other related legislation.

2. Purpose and intended effect of the measure

(i) Objectives

The objectives of the restructuring of the UK medicines advisory bodies effected by these Regulations are:

- To create an advisory body structure that best meets the needs of the UK today;
- To ensure that the UK's advisory body structure is best placed to participate fully in a revised EU medicines regulatory structure;
- That the contribution the medicines advisory bodies make to the regulatory system ensures that in the UK the highest standards of public health protection is maintained.

(ii) Background

The current Medicines Act advisory body structure has remained broadly unchanged since its introduction under the Medicines Act 1968 ("the Act"). The advisory bodies provide advice to Ministers, often in their capacity as the Licensing Authority (LA) responsible for the licensing of 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.

Over time there have also been significant changes to the environment in which the UK advisory bodies 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.

The current medicines advisory body structure comprises the Medicines Commission and committees established under section 4 of the Act. The Commission is a body established by the Act to advise 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 (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 section 3 of the Act, the Medicines Commission has a duty to make recommendations in relation to these committees, and to review them from time to time.

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 is responsible for advising on the safety, quality and efficacy of medicines for human use and, in particular, advises the LA on applications for, and proposals to suspend, revoke or vary, marketing authorisations. The CSM and BPC have a number of sub-committees and working parties.

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.

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

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

We received 91 responses to the consultation, 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.

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.

Under the revised structure it is proposed, although not specified in legislation, the committees and EAGs would include at least two lay members to ensure that the advice of the committees takes account of not just scientific views, but also considers the presentation of wider considerations of risk and benefit increasingly of interest to the public.

Ministers have also, for some time, been considering ways of tightening the approach to interests held by experts appointed to advisory bodies and a three month public consultation on proposals concluded on 11 February 2005. The changes to the medicines advisory committee structure provide an opportunity to introduce the changes on interests and to apply them to those appointed to the new committees. These arrangements are not set out in the legislation, but will be available as published guidance. They will require chairmen and members of the committees that directly advise Ministers to hold no current interests in the industry that their committees regulate. All other interests, and interests held by the other Section 4 committees and EAGs will continue to be declared and managed under a revised Code of Practice.

(iii) **Risk assessment**

The changes to the advisory body structure set out in the legislation are intended to maintain the highest level of public health protection in the regulation of medicines in the UK, and to enable the UK to continue to play a leading role in the revised EU regulatory regime. The risks of not introducing changes to the advisory body structure are:

- Ministers may not be able to call on relevant expertise to advise on the safety, quality and efficacy of certain medicines – particularly those that are highly specialised or that use new technologies - for use in the UK;
- The UK may not be able to provide relevant expertise to the European scientific committees and thus lose its place as a leading contributor to the EU medicines regulatory regime.

3. **Options**

Option 1
Do not change the current medicines advisory committee structure

Option 2
Amend – but with a different structure

Option 3
Amend as proposed.

4. Benefits

Option 1

The provisions of the Medicines Act relating to the advisory bodies have remained largely unchanged for nearly 40 years, but during this time the approach to medicines regulation has changed significantly. There is an increasing need to provide advice in very specialist areas, whilst the overarching role of the current Medicines Commission has diminished. The developing European medicines regulatory regime often requires national authorities to undertake a rapid review of products to contribute to an EU debate, and the revised structure will enhance the UK's ability to contribute to that debate, and to provide expertise to sit on various EU committees. This will ensure that the UK's high standards of public health protection are taken into account in EU regulatory decisions. Failure to update the legislation to take account of the changing world would represent a significant missed opportunity.

Option 2

We considered carefully the most appropriate changes to be made to the advisory body structure, and whether the structure developed represents the best approach. The public consultation on proposals to revise the structure undertaken in 2004, provided an opportunity for stakeholders and other interested parties to offer their views on restructuring. Most contributors supported the model proposed, although the corporate view of the current Medicines Commission was not supportive of the proposed changes. Some concerns were also expressed about future arrangements for handling homoeopathic products and certain herbal medicines, and Ministers have revised their proposals to take account of these concerns.

Option 3

On the basis of the outcome of the public consultation, and the amendments made to take account of certain concerns expressed, we consider that the revised legislation and the structure that it introduces, provides a sound way forward, and one with the majority support of stakeholders and other interested parties. It will also enable us to meet the

objective of maintaining a high standard of public health protection and strength of regulation within the UK and the EU.

4(i) Business sectors affected

These proposed changes will create no additional costs to the pharmaceutical industry. However, developing an increased range of EAGs will provide the industry with a greater opportunity to interact with the regulatory process in advance of a committee opinion. There will also be provision for a hearing before the relevant statutory committee if a company remains dissatisfied with the view reached by the MHRA and the EAG, with a subsequent right to a hearing before persons appointed by the LA, who will review the science as well as the administrative procedures followed by the LA. Industry has, however, expressed concern that the revised structure removes their entitlement to be represented on the statutory committees established under the revised structure. This will be addressed by establishing an industry forum that will meet periodically to ensure that the regulatory agency and the advisory committees can receive the views of all sectors of the industry.

4(ii) Issues of equity and fairness

The revised structure will not favour one sector of the industry over another. It will, however, ensure that applications from all sectors of industry for marketing authorisations for their products, or for changes to those authorisations, can be handled in a fair and efficient manner.

5. **Costs**

There will be no direct costs to the industry from implementing the revised committee structure. However, there will be an increased range of specialist groups (EAGs) to deal with specific types of product. The costs of running the additional groups will be partly offset by the abolition of the current Medicines Commission, which meets around five times per annum. Costs of running the committee system overall is borne by the MHRA. However, the resources of the MHRA derive solely from fees charged to the pharmaceutical industry and so indirectly additional costs will be paid for by them.

6. **Consultation with small businesses: the Small First's Impact Test**

These proposals will not have any specific impact on small businesses.

7. **Competition Assessment**

These changes will have no effect on competition within the pharmaceutical industry.

8. **Enforcement and sanctions**

Not relevant to these changes.

9. **Monitoring and review**

The MHRA will carefully monitor the operation of the revised structure, and the business of the committees will be presented in annual reports which are laid before Parliament.

10. Consultation

(i) Within Government

Consultation has taken place with Department of Health, Department for Environment, Food and Rural Affairs and with the devolved administrations.

(ii) Public consultation

A public consultation took place between February and May 2004. Responses were broadly supportive, with the exception of the current Medicines Commission. Where concerns were expressed, (for example, about future handling of certain herbal and homoeopathic products) careful consideration has been given to those views and in certain cases changes to the proposals have been incorporated. The results of the public consultation have been made public on the MHRA's website.

11. Declaration

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs.

Signed…….

Date…….

Lord Warner, Parliamentary Secretary of State, Department of Health

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