EXPLANATORY MEMORANDUM

1. (i) Title of Statutory Instrument

The Medicines (Advertising) Amendment Regulations 2004 No. 1480

(ii) Laying Authority and Purpose

This explanatory memorandum is laid before Parliament by Command of Her Majesty.

(iii) Department responsible

Department of Health. The responsibility for the subject matter of this instrument rests with the Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health.

2. Description

This instrument amends the Medicines (Advertising) Regulations 1994 ("the 1994 Regulations") to reduce the number of diseases in respect of which advertising to the public is prohibited.

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

Not applicable

4. Legislative Background

The 1994 Regulations implemented Directive 92/28/EEC on the advertising of medicinal products for human use and article 6 of Directive 92/73/EEC on homeopathic medicinal products, which have now been consolidated in Title VIII of Directive 2001/83/EC (OJ L311 28.11.2001 p67). Article 88 (2) of Directive 2001/83 specifies that member states must prohibit the mentioning in advertising to the general public of therapeutic indications such as tuberculosis; sexually transmitted diseases; other serious infectious diseases; cancer and other tumoral diseases; chronic insomnia; diabetes and other metabolic illnesses. This requirement was implemented by regulation 6 of the 1994 Regulations. In addition to the diseases listed in article 88 (2), the 1994 Regulations also prohibited advertising to the public of medicinal products for certain other therapeutic indications.

For policy reasons (see below), the 1994 Regulations are being amended to reduce the number of diseases in respect of which advertising to the public is prohibited, while remaining compatible with the requirements of Article 88 (2).

5. Extent

The 1994 Regulations and this instrument apply to the whole of the UK, including Wales.

6. European Convention on Human Rights

The Minister is satisfied that this instrument is compatible with Convention Rights.

7. Policy Background

Currently, the 1994 Regulations prohibit medicines for various disease areas from being advertised to the public. These include bone diseases; cardiovascular diseases; joint, rheumatic and collagen diseases, and serious muscular, respiratory, gastrointestinal, skin, renal and eye/ear disorders. As stated above, these are in addition to the indications listed in Directive 2001/83/EC.

The UK specific list of prohibited conditions is seen as a barrier to the provision of information to the public and the Government's intention to provide a greater range of medicines over the counter. The pharmaceutical industry has identified the UK list of prohibited diseases as a disincentive to reclassify products in these areas. This instrument reduces the list of therapeutic indications to the minimum list required by the Directive.

The amendments being made by this instrument were subject to public consultation in November 2002 and the responses received were substantially in favour of the proposals. The Medicines Commission (established under the Medicines Act 1968 to advise Ministers on matters related to medicinal products) considered the outcome of the consultation and advised that they supported the proposals.

8. Impact

The Regulatory Impact Assessment is attached. It identified no significant costs to either the public or to the Exchequer.

9. Contact

Any queries on the proposed legislation should be directed to Jeremy Mean at the Medicines and Healthcare products Regulatory Agency (MHRA), Room 14-111, Market Towers, 1 Nine Elms Lane Vauxhall, London, SW8 5NQ.