STATUTORY INSTRUMENTS

2005 No. 2791

MEDICINES

The Herbal Medicines Advisory Committee Order 2005

Made - - - -	*10th October 2005*
Coming into force - -	*30th October 2005*

The Secretary of State for Health and the Department of Health, Social Services and Public Safety, acting jointly, make the following Order in exercise of the powers conferred on them by section 4 of the Medicines Act 1968(**1**) or, as the case may be, those conferred by the said provision and now vested in them(**2**).

In accordance with section 4(1) of the Medicines Act, they have had regard to the recommendations made by the Medicines Commission under section 3(2) of that Act.

In accordance with sections 4(1) and 129(6) of the Medicines Act, they have consulted such organisations as they consider appropriate and those appearing to them to be representative of interests likely to be substantially affected by the following Order.

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Herbal Medicines Advisory Committee Order 2005 and shall come into force on 30th October 2005.

(2) In this Order—

"certificate of registration" means a certificate of registration granted by the licensing authority under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**3**);

"the 2001 Directive" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use(**4**);

(**1**) 1968 c. 67; the expression "the Health Ministers" is defined in section 1 of that Act as amended by article 2(2) of, and Schedule 1 to, S.I.1969/388 and by articles 2(1) and 5 of, and the Schedule to, S.I. 1999/3142.

(**2**) In the case of the Secretary of State, by virtue of article 2(2) of, and Schedule 1 to, S.I. 1969/388 and articles 2(1) and 5 of, and the Schedule to, S.I. 1999/3142, and in the case of the Department of Health, Social Services and Public Safety, the powers vested in the Ministers in charge of that Department by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c. 47) may now be exercised by the Department by virtue of section 1(8) of, and paragraph 4(1)(b) of the Schedule to, the Northern Ireland Act 2000 (c. 1). The Department was re-named by virtue of Article 3(6) of S.I. 1999/283 (N.I.1).

(**3**) S.I. 1994/105; as amended by S.I. 1994/899, 1995/541, 1996/482, 1998/574, 1999/566, 2001/795, 2002/236 and 542, 2003/625 and 2321, and 2004/666.

(**4**) OJ No. L311, 28.11.2001, p.67. Directive 2001/83/EC has been amended by Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components (OJ No. L33, 8.2.2003, p.30), Commission Directive 2003/63/EC amending Directive

"herbal medicinal product" has the meaning given by Article 1(30) of the 2001 Directive;

"marketing authorization" means—

(a) a marketing authorization granted by the licensing authority under the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**5**), or

(b) a marketing authorization granted by the European Commission under Council Regulation (EEC) No 2309/93(**6**) or under Regulation (EC) No. 726/2004(**7**).

Herbal Medicines Advisory Committee

2. There shall be established a committee to be called the Herbal Medicines Advisory Committee for the purposes of giving advice—

(a) with respect to the safety, quality and efficacy, in relation to human use, of herbal medicinal products, other than any product—

(i) in respect of which a marketing authorization, a product licence or a certificate of registration has been granted, or

(ii) which is the subject of an application for such an authorization, licence or certificate;

(b) with respect to the safety, quality and efficacy, in relation to human use, of any herbal medicinal product—

(i) in respect of which a marketing authorization, a product licence or a certificate of registration has been granted, or

(ii) which is the subject of an application for such an authorization, licence or certificate,

where Health Ministers or the licensing authority request such advice or provide the committee with information relating to that product; and

(c) in relation to the sale, supply, manufacture or assembly of medicinal products under section 12 of the Act.

Signed by authority of the Secretary of State for Health

Liam Byrne
Parliamentary Under Secretary of State,
Department of Health

3rd October 2005

2001/83/EC on the Community code relating to medicinal products for human use (OJ No. L159, 27.6.2003, p.46), Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ No. L136, 30.4.2004, p.85) and Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ No. L136, 30.4.2004, p.34).

(**5**) S.I. 1994/3144; relevant amending instruments are S.I. 2001/795 and 2002/236.

(**6**) Council Regulation (EEC) No 2309/93 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, OJ No. L214, 24.08.93, p.1.

(**7**) Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ No. L136, 30.4.2004, p.1.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety

A.McCormick
Permanent Secretary,
Department of Health, Social Services and Public Safety

10th October 2005

EXPLANATORY NOTE

(This note is not part of the Order)

This Order establishes the Herbal Medicines Advisory Committee to advise on any issue relating to the safety, quality and efficacy, in relation to human use, of unlicensed herbal medicinal products or herbal medicinal products eligible for registration under the simplified traditional use registration procedure established by Chapter 2a of Title III of Directive 2001/83/EC as inserted by Directive 2004/24/EC(**8**). The committee may also advise on the safety, quality and efficacy, in relation to human use, of a herbal medicinal product which is already licensed with a marketing authorization, product licence or certificate of registration or where an application for an authorization, licence or certificate has been made where the Health Ministers or the licensing authority request such advice or provide the committee with information relating to that product.

In addition, the Herbal Medicines Advisory Committee is established to advise on medicinal products sold, supplied, manufactured or assembled under section 12 of the Act. Section 12 of the Act provides an exemption from the requirement to have a product licence, a manufacturer's licence or a wholesale dealer's licence for herbal remedies which are sold or supplied following a consultation, and for remedies which are not industrially produced and are sold or supplied without any written recommendations for the use of the remedy.

A full regulatory impact assessment has not been produced for this instrument as it has no impact on the costs of business.

(**8**) Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ No. L136, 30.4.2004, p.85.