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STATUTORY INSTRUMENTS

2011 No. 915

MEDICINES

The Medicinal Products (Herbal Remedies) (Amendment) Regulations 2011

Made - - - -	*22nd March 2011*
Laid before Parliament	*25th March 2011*
Coming into force - -	*30th April 2011*

The Secretary of State makes the following Regulations, in exercise of the powers conferred on him by section 2(2) of the European Communities Act 1972(**1**). He is designated for the purpose of section 2(2) of the European Communities Act 1972 in relation to medicinal products(**2**).

Citation and commencement

1. These Regulations may be cited as the Medicinal Products (Herbal Remedies) (Amendment) Regulations 2011 and shall come into force on 30th April 2011.

Repeal

2. Section 12(2) of the Medicines Act 1968(**3**) is hereby repealed.

(**1**) 1972 c.68; section 2(2) was amended by the Legislative and Regulatory Reform Act 2006 (c.51), section 27 (1)(a) and the European Union (Amendment) Act 2000 (c.7), section 3(3), Schedule 1, Part 1.
(**2**) S.I. 1972/1811.
(**3**) 1968 c.67.

Signed by authority of the Secretary of State for Health

Earl Howe
Parliamentary Under-Secretary of State,
Department of Health

22nd March 2011

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations repeal section 12(2) of the Medicines Act 1968 ("the Act") which provides an exemption (from the requirement to comply with the restrictions set out in sections 7 and 8 of the Act) for the manufacture, sale or supply of herbal remedies where the process to which the plant or plants are subjected consists only of drying, crushing or comminuting and certain other specified conditions are met. With effect from 30th April 2011, this exemption is incompatible with EU legal provisions set out in Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L No 311, 28.11.2001, p.67) and Directive 2004/24/EC of the European Parliament and of the Council as regards traditional herbal medicinal products (OJ L No 136, 30.04.04, p.85).

An Impact Assessment has been prepared. A copy can be obtained from the Medicines and Healthcare Products Regulatory Authority, 151 Buckingham Palace Road, Victoria, London SW1W 9SZ