

Informal discussion papers on possible reforms of s12(1) of the Medicines Act 1968 and its associated provisions

Index

<i>Title of informal MHRA discussion paper</i>	<i>No</i>
Reforms of s12(1) of the Medicines Act 1968: an overview	1
Reforms of s12(1) of the Medicines Act 1968: who should be allowed to operate under s12(1)?	2
Reforms of s12(1) of the Medicines Act 1968: safety	3
Reforms of s12(1) of the Medicines Act 1968: quality standards where a practitioner prepares unlicensed herbal medicines	4
Reforms of s12(1) of the Medicines Act 1968: the requirement for a face to face consultation	5
Reforms of s12(1) of the Medicines Act 1968: the regulation of unlicensed herbal medicines commissioned by a registered practitioner from a third party to meet the needs of individual patients	6
Reforms of s12(1) of the Medicines Act 1968: possible extension to non herbal ingredients	7
Reforms of s12(1) of the Medicines Act 1968: issues concerning timing and transitional protection	8
<i>Glossary</i>	<i>Attached</i>

Any written comments on the proposals should be sent by 30 March 2007 to Caroline Brennan at the MHRA, Market Towers, 1 Nine Elms Lane, London SW8 5NQ. The E mail address is: caroline.brennan@mhra.gsi.gov.uk.

MHRA Dec 2006

Glossary

Directive 2001/83/EC	The principal European legislation setting out the framework for the regulation of industrially produced medicines placed on the market in the EU.
Directive 2004/24/EC	The Directive on traditional herbal medicinal products. This Directive amended 2001/83/EC to include specific regulatory provisions for manufactured traditional herbal medicines suitable for use without medical supervision.
GMP	Good manufacturing practice. Full details of the EC Guide to Good Manufacturing Practice (GMP) can be found at http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev4.htm .
GSL	General Sales List
MA	Marketing authorisation. This is a permission to place a medicinal product on the market. Products must meet requirements of safety, quality and efficacy.
MLX 299	A previous public consultation document issued in 2004 about reforms of the s12(1) exemption. MLX 299, and a summary of responses to it, is on the MHRA website (www.mhra.gov.uk) (Use A-Z index to find MLXs.)
P	Medicine on supply from a registered pharmacy
POM	Prescription only medicine
Section 12 of the Medicines Act 1968	Section 12 is an exemption from the licensing provisions in the Medicines Act 1968. It is only relevant to medicinal products which in the first place fall outside the scope of Directive 2001/83/EC (eg products which are neither prepared industrially nor prepared using an industrial process).
Section 12(1) of the Medicines Act 1968	Provides that the licensing provisions of the Act “do not apply to the sale, supply, manufacture or assembly of any herbal remedy in the course of a business where <ul style="list-style-type: none"> (a) the remedy is manufactured or assembled on premises of which the person carrying on the business is the occupier and which he is able to close so as to exclude the public; and (b) the person carrying on the business sells or supplies the remedy for administration to a particular person after being requested by or on behalf of that person and in that person’s presence to use his own judgement as to the treatment required.”.
THR	A traditional herbal registration is a permission to place a manufactured traditional herbal medicine on the market. A THR is a simplified form of a marketing authorisation. The scheme gives the consumer assurance as to safety, quality and patient information. Limited claims are permitted on the basis of traditional use. The UK scheme was launched in October 2005, following Directive 2004/24/EC.