

Outcome measures of MHRA strategy to bring herbal medicine into effective regulation

The strategy initially covers the period 2007 – 2011 but MHRA recognises that many elements will need to continue well beyond that period, particularly those relating to consumer understanding and behaviour. One constraint at the present time is the uncertainty as to whether, and if so how, herbal practitioners are to be regulated since this is the major determinant of whether it will be possible to progress reforms of s12(1) of the Medicines Act 1968 (the provision used by practitioners to prepare unlicensed herbal remedies to meet the needs of individual patients identified in consultation). Outcome measures may need to be adjusted when the direction of possible reforms in this area become clearer.

All measures will need to be interpreted with care. For example, many factors extending far beyond the issue of herbal medicines are likely to influence the extent of the apparently deep rooted belief across parts of society that “natural” equates to “safe”. Moreover, to the extent that communication initiatives about the regulation of herbal medicines are successful they are likely to lead to a more in depth and subtle understanding which may not be straightforward to track, eg via market research.

Objectives of the MHRA strategy:

1. Help and encourage responsible operators into regulation
2. Become the norm for operators to comply with herbal medicines regulation
3. Promote informed consumer choice of products made to acceptable (ie regulated) standards
4. Ensure effective risk detection, assessment and communication

MHRA Policy Division
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<i>Process measures</i>	<i>Intermediate or final outcome measures</i>
No of THR applications received (total)	No of THRs granted (total)
No of THR applications for combination products	No of THRs granted for combination products
No of different herbs included across all THR applications	No of different herbs included across all THRs granted
	No of the top 10/20 selling herbs included in THRs granted ¹
	No of types of indication/broad therapeutic categories included in THRs granted
No of company meetings held under pre notification scheme	No and % of total THR applications refused (with particular reference to where company has taken advantage of opportunity for regulatory advice in company meeting(s))
No of applicants for THR	No of applicants with at least one THR granted
No of existing herbal Product Licences (MAs) where agreement reached with company on proposed future regulatory status of the product	No of current or former herbal PLs where product is transferred to THR or confirmed in PL status
	Proportion of adults and herbal medicine users able to identify, unprompted, risks from taking herbal medicine (compared to baseline of 2008 survey ²)
	Proportion of adults and herbal medicine users believing that “natural” equates to “safe” in relation to herbal medicine (compared to baseline of 2008 survey)
	Proportion of herbal medicines users saying that they have used information with product packaging as source of information about herbal medicine (compared to baseline of 2008 survey)
	Proportion of herbal medicine users aware of the traditional herbal registration scheme
	Proportion of herbal medicine users recognising THR certification mark
	Annual numbers of adverse drug reaction reports for herbal medicines (total)
	Annual numbers of adverse drug reactions reported for herbal medicines (patient reports)
Extent of accurate media coverage of specific herbal medicine safety issues publicised by MHRA	
Numbers/trends in web hits for key herbal pages on MHRA website	

¹ Excluding any with safety concerns or otherwise unsuitable for THR scheme (eg lack of suitable indication), and herbs that can readily be sold under other regulatory categories; MHRA would need to rely on industry to identify information on sales.

² Ipsos MORI research for MHRA: Public perceptions of herbal medicines, 2008