

MHRA comments on the responses to consultation MLX 325 on Directive 2004/24/EC

1. Introduction

The MHRA notes that a range of respondents expressed support for the benefits of the Directive and for the approach taken to transposing it into UK legislation

2. Transitional Period for existing products

We recognise the force of the argument advanced by some respondents that having a shorter period of transitional protection could bring forward the public health benefits of the Directive. However, on balance Ministers have taken the view that the regulatory impact of the Directive is sufficiently challenging for many companies that have been accustomed to operating in a largely unregulated environment that the full transitional period is necessary. This will help to ensure that the consumer progressively has access to a wider range of over-the-counter (OTC) herbal remedies made to assured standards. The availability of such a range will in turn serve to reinforce advice to consumers that they should not turn to less regulated sources, such as overseas internet sites.

There was little comment on other aspects of the transitional arrangements.

3. Expert report on safety

The MHRA accepts there is validity in the argument raised by a range of respondents that there may be a shortage of doctors in a position to sign the expert report on safety that is required to accompany registration applications. Accordingly the MHRA will prepare guidance shortly offering flexibility on this issue, consistent with the requirement to protect public health.

4. Advertising of registered products

Several parties expressed concern that the form of wording laid down in the Directive for inclusion in advertisements about the traditional use basis of registration was unclear and could mislead the consumer into believing that they had to take a remedy a long time for it to be efficacious. The MHRA agrees the form of wording is not ideal. We are currently in discussion with representatives of advertising regulators and industry with a view to agreeing a short additional suffix for inclusion in advertisements and which could be promulgated via guidance.

5. Product information – nature of the tradition

The MHRA proposal to permit, but not require, product information to state the nature of the tradition was generally supported in consultation. We are proceeding with this proposal.

6. Labelling of topical products

One respondent was particular concerned that products information should be adequate for consumers with contact allergies. The MHRA can confirm that for registered products for topical application all inactive as well as active ingredients would be required to be stated on labels. This is in line with requirements applying to other medicines intended for topical application.

7. Qualified Person

The MHRA notes that a number of respondents wished to see further guidance on Qualified Persons as soon as possible.

8. Notification that product has not been marketed for 3 years

Several respondents argued that a longer period than the proposed one month should be given to companies to notify the MHRA that three years has elapsed without the registered product being marketed. In general, we consider that one month should in practice be reasonable, bearing in mind that the company will have had time during the three years the product has not been marketed to decide its plans for that product and hence whether notification to the MHRA is needed. However, in recognition of the comments made we intend to make the offence one of failure to notify promptly, which would give flexibility for reasonable interpretation.

9. Regulatory impact

A number of respondents from within the herbal sector were concerned about the overall regulatory impact of the Directive and in particular on some aspects of the quality guidelines, which they regarded as unduly onerous. They also stressed that many SMEs produced multi-ingredient products for which the quality requirements are more challenging and potentially relatively expensive to fulfil. They argued that the Directive would have a detrimental affect on business viability and consumer choice, particularly on those parts of the herbal sector most involved with multi-ingredient products. Some adjustments have been made to the Regulatory Impact Assessment in the light of these comments.

The longstanding European quality guidelines for herbal medicines have a clear basis in European legislation and were developed in collaboration with the herbal industry. The MHRA intends to interpret these guidelines in a realistic and practical manner. However, the UK has no powers to change these guidelines, whether during the transposition process or otherwise, or to ignore the guidelines. The principle forum for pursuing this issue is in the relevant scientific and regulatory body, the European Herbal Medicinal Products Committee based at the European Medicines Agency (EMA). There are opportunities for industry to put forward a reasoned case for elaboration or adjustment of the guidelines, and the EMA recently held a consultation on the guidelines. The Agency believes that the existing European quality guidelines for herbal medicines are fundamentally sound in that they reflect industry good practice. They are also necessary in the interests of public health and to maintain consumer confidence that the product matches what is stated on the label. Nonetheless, the Agency agrees that there may well be scope for some further elaboration of the guidelines to reflect the practical possibilities, particularly in relation to the issue of demonstrating the qualitative and quantitative composition of

multi-ingredient products. The MHRA intends to participate actively in continuing European discussions on the issue, and has encouraged the UK industry to do likewise.

10. Impact of Directive as it affects Traditional Chinese Medicine (TCM)

A significant proportion of responses considered that the Directive is not appropriate for traditional Chinese medicine. The reason often given was the extensive use made of remedies made up by or for practitioners to reflect the individual needs of the patients. At least some of these comments may to an extent be based on a misunderstanding. The Directive was made in order to regulate manufactured OTC traditional herbal remedies on the EU market, from whatever tradition they originate. It was not intended to imply that all or most remedies in any particular tradition take the form of OTC medicines. There is different legislative provision covering remedies made up by or commissioned by practitioners, primarily Section 12(1) of the Medicines Act 1968. This legislation is under review in the UK. An initial consultation (MLX 299) was held in 2004 and there will be further consultation before any decisions are made.

Some respondents argued that TCMs generally are not suitable to be sold over the counter. The MHRA's view is that the safety of the product should be addressed on a product-specific basis and that it would be wrong to deny applicants the possibility of demonstrating that specific TCMs are suitable for OTC use.

Some respondents from the TCM sector were concerned that the registration scheme under the Directive is too restricted in scope as to the nature of the ingredients. This is not directly an issue for transposition. However, the Directive gives greater scope than existing UK arrangements for unlicensed herbal medicines in that it permits the addition of vitamins and minerals where ancillary to the traditional herbal remedy. Hitherto such a product would require a full marketing authorisation. There is a requirement within the Directive for a review of its scope by 2007. This could provide an opportunity to consider whether there are any other categories of traditional medicine for which simplified registration would be suitable.

11. Reforms of Section 12(1)

A number of respondents made other comments more directly relevant to the issue of possible reform, currently under consideration, of Section 12(1) of the Medicines Act 1968. These comments will be considered in continuing work on this issue.

12. Enforcement

Several respondents underlined the importance of enforcement in order to protect public health and ensure a level playing field for business. The MHRA will continue to enforce medicines legislation and will work to enhance co-operation with other agencies, for example in relation to the import and distribution of goods.

13. Other regulatory requirements

Several respondents referred to issues outside the immediate scope of Directive 2004/24/EC. The MHRA has no powers to phase in the requirements for user testing of leaflets, or for Braille, in relation products that will be newly registered under Directive 2004/24/EC. The MHRA has raised in Europe the frequency of the requirement for Periodic Safety Update Reports in relation to registered products and we currently await the outcome of those discussions.

MHRA
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