

Guidance on Transitional arrangements for the Directive on traditional herbal medicinal products (Directive 2004/24/EC, amending Directive 2001/83/EC)

On 30 April 2011 transitional protection under the Directive on traditional herbal medicinal products (Directive 2004/24/EC) expires. This means that the “herbal exemption” from licensing under Section 12(2) of the Medicines Act 1968 will not longer be available.

This note updates guidance previously issued about the application of transitional protection under the Directive, providing additional advice on issues businesses will need to bear in mind as the transitional period ends. **Changes include the addition of a section on the impact on herbal practitioners and their suppliers and can be found question 15 onwards.**

Please note that this guidance represents MHRA’s view and cannot be taken to be a definitive statement of the law, which only the courts can give. Where you have any doubts about your obligations, you should always consult your own professional advisors.

If you have any questions about the transitional arrangements or this note they can be sent to andrea.farmer@mhra.gsi.gov.uk.

Provisions of the Directive on Traditional Herbal Medicinal Products that determine dates of introduction

Article 3 provides that the Directive shall enter into force on the day of its publication in the Official Journal of the European Union. The Directive was published in the Official Journal, and so came into force, on 30 April 2004.

Article 2.1 provides that Member States shall take the necessary measures to comply with the Directive by 30 October 2005.

Article 2.2 provides that for traditional herbal medicinal products that are covered by the Directive which are already on the market on the entry into force of the Directive, the competent authorities shall apply the provisions of the Directive within seven years after its entry into force. The UK is therefore required to apply the Directive fully by 30 April 2011.

Relevant provisions of the Regulations on Traditional Herbal Medicinal Products

Regulation 4(1) of the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (“the Herbals Regulations”) of the regulations states that:

No traditional herbal medicinal product shall be (a) placed on the market, or (b) distributed by way of wholesale dealing, unless a traditional herbal registration has been granted by the licensing authority (which is in force, and been granted in accordance with the Community provisions).

Provisions made under Schedule 6 mean that:

- Where a product has been placed on the market, lawfully, under Section 12(2) on or before 30th April 2004 regulation 4(1) would not apply until 30th April 2011 to products, which were on the market under Section 12(2) on 30th April 2004

Q&A

General Transitional Arrangements

1) What are the key dates?

- 30 April 2004 -the date the Directive entered into force by publication in the Official Journal.
- 30 October 2005 - by which date Member States were required to take measures to comply with the Directive.
- 30 April 2011 - by which date Member States must apply the Directive to products that have benefited from the transitional period.

2) Is there any discretion over these actual dates?

The first two dates are determined by the Directive and are fixed. 30 April 2011 is the date set in the Directive by when Member States must end transitional protection for products on the market at 30 April 2004. There was discretion for individual Member States to set an earlier date for ending these transitional arrangements if they so chose. Following consultation, the then Ministers agreed that the transitional period in the UK should run until 30 April 2011; UK legislation reflects this.

3) What products can benefit from transitional protection?

Only products legally on the UK market under Section 12(2) of the Medicines Act 1968 on 30 April 2004 can benefit from the period of transitional protection.

This means that any unlicensed herbal medicines with added vitamins and minerals, or with brand names or claims, cannot benefit from transitional protection. Such products require a traditional herbal registration or a marketing authorisation.

Industrially produced herbal medicinal products placed on the market between 30 April 2004 and 30 October 2005; also require either a traditional herbal registration or a marketing authorisation.

Products that benefit from the transitional protection arrangements, because they were legally on the market at April 2004 under Section 12(2) of the Medicines Act 1968, must continue to comply with the prevailing requirements of the Medicines Act.

For the purposes of this guidance, manufactured over-the-counter herbal remedies (of the kind typically sold in supermarkets, pharmacies, health food stores and by mail order) are regarded as industrially produced. (See also paragraph 21 onwards about herbal practitioners.)

4) Do companies need to take any specific action in order to benefit from transitional arrangements for their products?

Companies should retain evidence that can be produced if necessary to demonstrate that a product was on the market on 30 April 2004, and hence is entitled to benefit from transitional protection in the period between 30 October 2005 and 30 April 2011. Keeping such records will minimise the regulatory burden that could arise in the event, for example, that a competitor company complains to the MHRA that a specific product on the market is

not entitled to benefit from transitional protection.

5) What constitutes evidence that a product was already on the market on 30 April 2004?

The MHRA would consider, on the facts of the case, evidence that a company presented. This might conveniently be, for example, evidence of an appropriate transaction, demonstrating that the product in question had been placed on the market by 30 April 2004. Such a transaction could be in the form of a sale by a manufacturer or other supplier, whether to a wholesaler, retailer, herbal practitioner or other party. Dated catalogues of available products might also be a source of evidence.

6) What happens on 30 October 2005 where a company put a legal Section 12(2) unlicensed remedy on the market after 30 April 2004 but before 30 October 2005?

Such a Section 12(2) product does not benefit from the transitional protection, as it would not have been on the market on 30 April 2004.

Stocks of such a product that were already legally placed on the market before 30 October 2005 can remain legally on the market after 30 October 2005, i.e. they do not need to be recalled. An offence (relating to placing a medicinal product on the market without the necessary MA or THR) would be committed if the company placed further stocks of such a product on the market after 30 October 2005.

7) What are the implications of these transitional arrangements for products close to the borderline between medicines and other regulatory categories such as foods or cosmetics?

This Directive relates only to medicinal products. Therefore, products sold legally in other regulatory categories are not required to comply with the Directive. The MHRA's Guidance Note 8 provides further information on how the MHRA determines whether a product should be classified as a medicine.

As Guidance Note 8 indicates, some products potentially can be sold legally in different regulatory categories, depending on the presentation of the product. The Directive does not affect this position.

8) Where a product benefits from transitional protection, and there are subsequent changes to the product what effect does this have on transitional protection?

In this situation the MHRA would consider whether the change was such that, if the product were a licensed product, a new application would be required or instead was of a minor nature that could be dealt with by a variation to a marketing authorisation. If the change were such that it could be dealt with by way of a variation application, MHRA would generally expect the product to be covered by the transitional arrangements (assuming of course that the other requirements were met).

However, the analogy with licensed and unlicensed products is a broad guideline, which will not apply in all circumstances. Whilst MHRA seeks where possible to provide guidance in particular cases, companies should take their own legal advice if they are in doubt about their obligations. It is also important to bear in mind that the purpose of transitional protection arrangements is to allow companies time to adapt and prepare to comply with the new requirements. It is not intended as an opportunity to allow an expansion of

products and companies operating outside the requirements of Directive 2001/83/EC (as amended by Directive 2004/24/EC) in the period up to 2011.

9) Does the act of re-labelling/re-packaging a product remove the benefit of transitional protection?

In principle, the MHRA is of the view that the simple re-packaging including "own branding" of a product that was lawfully on the market as at 30 April 2004 would not constitute the placement of a new product on the market, thereby depriving it of the benefit of transitional protection.

As indicated above the MHRA would need to consider whether the change was such that, if the product were a licensed product, a new application would be required or instead was of a more minor nature that could be dealt with by a variation to a marketing authorisation. A simple change of packaging as a result of "own branding" would not of itself require a new marketing authorisation if it were a licensed product and would not therefore deprive a Section 12(2) product of transitional protection under the guidelines set out above. However, this can only be the case where the product was lawfully on the market under Section 12(2) as at 30 April 2004. If the product falls outside the protection of Section 12(2), for example, by virtue of including a written recommendation as to its use, then a company could not simply re-label the product and expect it to continue to benefit from transitional protection, whether under its own label or under another label.

10) Where a product benefits from transitional protection will that protection be kept if the company changes one of the active ingredients?

No. Assuming the product was still classified as a medicine; it would be viewed as a new medicinal product and so would not receive transitional protection. It would require either a marketing authorisation or a traditional herbal registration.

11) If a company has two products each benefiting from transitional protection and now wishes to market the two products in a combination pack would this combination product benefit from transitional protection?

No. The product would be viewed as a new medicinal product and so it would not receive transitional protection. It would require either a marketing authorisation or a traditional herbal registration.

12) Where one company markets a product that has transitional protection what is the position if another, unrelated, company now wishes to market a product that is an exact copy of the product?

The product marketed by the second company would not receive transitional protection. It would require either a marketing authorisation or a traditional herbal registration.

13) What is the position where a product has transitional protection and there are then changes in the ownership of, or manufacturing arrangements for, the product?

It is not possible to give guidance on all possible circumstances that might arise and companies should take legal advice if they are in any doubt. As set out earlier, it is important to bear in mind that the purpose of the transitional protection is to allow companies time to adapt and prepare to comply with the new requirements – it is not

intended as an opportunity to allow an expansion of products and companies operating outside the requirements of Directive 2001/83/EC (as amended by Directive 2004/24/EC) in the period up to 2011.

Where a company owns a product that has transitional protection and the company decides to change manufacturer the MHRA's view is that this would not generally nullify transitional protection. Likewise, where there is a straightforward change of ownership of a product with transitional protection, e.g. where a company owning the product is taken over, or one company no longer wishes to make this Section 12(2) product and sells it to another company, the MHRA's view is that transitional protection would not generally be nullified by the change.

14) Where a company owns a product that has transitional protection could a second company reach some form of licensing agreement to allow it also to benefit from transitional protection for that product?

MHRA considers that transitional protection would not extend to the product marketed by the second company and so it would require either a marketing authorisation or traditional herbal registration (MA or THR).

End of Transitional Arrangements and how this will operate

15) What is the regulatory position at 30 April 2011?

On 30 April 2011 the period of transitional protection for unlicensed herbal medicinal products placed on the market under Section 12(2) of the Medicines Act 1968 will come to an end. It will therefore be illegal for manufacturers, wholesalers and importers to sell unlicensed herbal medicines to retailers or directly to consumers.

16) Can a product continue to benefit from transitional protection after April 2011 if the company has made an application by 30 April 2011?

No. From 30 April 2011, no product may be placed on the market, or distributed by way of wholesale dealing, unless a registration has been granted. It is not enough that an application has been made - it must have been granted.

17) Will products legally placed on the market before 30 April 2011 need to be removed from retail sale after 30 April 2011?

Stocks of products that were already legally on the market before 30 April 2011 will not need to be recalled. Retailers, including online and mail order companies, will be able to sell through any such unlicensed product purchased before the end of the transitional period that they have in stock.

An offence (relating to placing a medicinal product on the market without the necessary MA or THR) would be committed if a company (Manufacturer, Wholesaler or Importer) placed further stocks of such a product on the market after 30 April 2011.

18) What are the timetable requirements for MHRA in processing applications for traditional herbal registrations?

Under article 17 of Directive 2001/83/EC, Member States must take all appropriate measures to ensure that the procedure for granting a marketing authorisation is completed

within 210 days after the submission of a valid application. This provision also applies to traditional herbal registrations. In certain situations, there is provision for "clock stops"

19) What action will the MHRA be taking to ensure that the regulations are complied with?

The MHRA will continue to investigate cases and where appropriate, take compliance/enforcement action against products found in breach of requirements. In addition in the run up to April 2011, the MHRA will continue to provide on request from businesses advice on the status of their products. The Agency will also be making direct contact with suppliers, identifying products that need to have a MA or THR and communicating our view on the status of their products.

Post April 2011 the Agency will continue to issue determinations on products which do not have the appropriate authorisation, provide advice on the status of products in response to requests. Enforcement/compliance action will be targeted on products which pose a risk to public health.

20) What constitutes evidence that a product was already on the market before 30 April 2011?

The MHRA would consider, on the facts of the case, evidence that a company presented. This might conveniently be, for example, evidence of an appropriate transaction, demonstrating that the product in question had been purchased prior to 30 April 2011. Such a transaction could be in the form of a sale by a manufacturer or other supplier, whether to a retailer or herbal practitioner.

How the end of the transitional period affects herbal practitioners

21) Will herbal practitioners still be able to supply unlicensed herbal medicines to patients under Section 12(1) after 30 April 2011?

Yes. Products supplied legally under Section 12(1) are regarded by MHRA as non industrially produced, and hence outside the scope of Directive 2001/83/EC as amended by Directive 2004/24/EC. Products supplied under Section 12(1) therefore do not require a MA or THR to remain on the market.

Specifically, Section 12(1) 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:*

- (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."*

22) Which of the various types of herbal preparations used by herbalists will require a licence from 30 April 2011?

In summary:

- Products prepared and supplied by herbal practitioners in accordance with Section

- 12(1) do not require MA or THR
- Unprocessed or processed ingredients sourced by herbal practitioners to prepare unlicensed herbal remedies supplied under Section 12(1) do not require an MA or THR
 - Manufactured herbal medicines commissioned by herbal practitioners come within the scope of Directive 2001/83/EC as amended by Directive 2004/24/EC and therefore require an MA or THR. (If, such products are legally supplied under Section 12(2) and satisfy the requirements for transitional protection, the requirement for an appropriate product licence applies from 30 April 2011.)

23) What counts as an ingredient and what counts as a product?

Examples of what would be regarded as ingredients are:

- Unprocessed herbal ingredients
- Tinctures or extracts the herbal practitioner buys in bulk in order to blend to make products tailored to meet the needs of individual patients.

Examples of what would be regarded as products are:

- Tablets, capsules and other such pharmaceutical finished dosage forms bought in by the practitioner (whether or not the practitioner sources them in bulk)
- Any medicine the herbal practitioner sources in the form and packaging it is to be supplied to the patient.

MHRA cannot cover all possible circumstances in guidance, as the position will depend on the facts of each case. Bear in mind that some pharmaceutical forms, eg a tincture, could be either an ingredient or a product, depending on the facts of the case.

24) Will unlicensed products purchased before 30 April 2011 need to be withdrawn?

As with the retail sector, where herbal practitioners purchased stocks of unlicensed products before 30 April 2011 that were legally supplied under the transitional arrangements applying to Section 12(2) these products will not need to be withdrawn from sale and can continue to be sold through.