

Organic herbal ingredients and labelling under the Traditional Herbal Medicines Registration (THR) Scheme: Guidance for Applicants/Registration Holders

This note provides guidance to businesses in response to queries received by the MHRA about the extent to which companies can refer to the organic status of ingredients/products registered under the THR scheme.

Any enquiries relating this note should be addressed to:
andrea.farmer@mhra.gsi.gov.uk.

Need for independent certification

The MHRA considers that consumers would understand “organic” claims to mean that the product meets an independently defined organic standard for herbal medicines. Producers of products presented as organic should therefore be registered and inspected by one of the Certification Bodies (CB) approved by the Department for Environment Food and Rural Affairs (Defra) and their product(s) certified by the CB as meeting these standards.

This is consistent with rulings on “organic” claims for non-food products made by the Advertising Standards Authority.

Relevant provisions of the Medicines Directive

The active ingredients of a medicine are required to be included quantitatively on the labelling. [Article 54(b) of European Directive 2001/83/EC]. All ingredients in a medicine are required to be stated qualitatively in the patient information leaflet. [Article 59(1) (a) of Directive 2001/83/EC].

Article 62 of the Directive permits the inclusion of additional information which is compatible with the summary of product characteristics, useful for the patient and non-promotional.

MHRA position on organic labelling for THRs

Under these current provisions, it is possible for an applicant to include a factual statement that the product contains materials derived from organic production methods. This factual statement must be included within the summary of product characteristics and be verifiable by reference to the data submitted in support of the THR application.

Where companies wish to make non-promotional statements on the label that the herbal medicinal product is organic, it would be the responsibility of the company to provide evidence to support the organic standards in their application for a traditional herbal medicine registration. This would lead to information in the SPC and a simple statement on the labelling and other packaging.

The wording of any such statements must be subordinate in placement and prominence to the statutory information.

Certificates /documentation to support the claim would need to be available to any regulatory body such as the MHRA or ASA in the case of a complaint.

Advertising and promotion of “organic” THR’s must comply with existing guidance as set out in the Blue Guide and the supplementary guidance on consumer advertising for registered traditional herbal medicines.

Q&A

My products are manufactured using organic ingredients/materials and production methods, can I include “organic” on the label or other packaging and leaflets?

Yes. Provided the product has been certified as organic by an approved Certification Body as meeting organic standards applicable to the production of herbal medicines, products granted a THR will be able to include a factual statement that the product contains ingredients derived from organic production methods on the product packaging and PIL. The wording of any such statements must be subordinate in placement and prominence to the statutory information.

My product is manufactured using organic materials, but I have not undergone certification. Can I claim “organic” on the packaging of my product?

No. The use of the term “organic” cannot be included on the labelling or PIL unless the product is manufactured using organic production methods and certified as such by one of the certification bodies. Such statements would need to be verifiable by reference to data submitted in support of the marketing authorisation/THR.

Can I use the term ‘organic’ in the product name?

No. Use of the term “organic” within the product name is not permitted, as this could be deemed promotional and thereby prohibited by article 62 of Directive 2001/83/EC.

Can I use my company name as part of the product name?

You will need to propose a bespoke invented name for each of your medicinal products. The Names Policy guidance <http://www.mhra.gov.uk/Howweregulate/Medicines/Namingofmedicines/index.htm> provides details on the criteria which need to be considered. In some circumstances a company name may be included as part of the invented name. However, where the term “organic” is included in the name of the traditional registration holder (THR) this may not form part of the invented name. You will nevertheless have to include reference to the THR name and address on the labelling as required by article 54(k).

Do I have to have the product certified as organic by a specific organisation?

Yes. The term ‘Organic’ is defined by European law and encompasses any food product. Producers of products presented as organic must be registered and are annually inspected by one of the Certification Bodies approved by Defra

What information can be placed on the label and PIL?

You will be able to make a simple statement along the lines of “product certified as organic by (name of certifying body)”.

The contents can also have the organic ingredients indicated for example
INGREDIENTS: Ingredient A*, Ingredient B*, Ingredient C*, Ingredient D.

*organically produced herbal ingredient

Certified to (name of certifying body) organic standards and where appropriate indicate the X% organic ingredients used.

As with other non-statutory information, it would be subordinate to any information required by law.

Will I be able to use the certifying body's logo on the packaging or PIL?

No, as this could be deemed promotional and thereby prohibited by article 62 of Directive 2001/83/EC.

What information would I need to provide to the MHRA as proof of the organic status of the product?

As evidence that the product meets organic standards, a copy of the certification documentation and details/status of the certifying body should be submitted with the registration dossier.

Who will be responsible for verifying the organic status of the products?

It will remain the responsibility of the relevant certification body to inspect and award organic certification to businesses that meet organic standards.

What role will MHRA inspectors have in ensuring that standards are met?

It would not be practical or realistic for the Agency to inspect against organic standards. This is the role of the certification body who will continue to inspect against the relevant standards.

The QP is responsible for ensuring before authorising batch release that products are compliant with the terms of the product registration. This would include confirming that the product meets the relevant organic standards and, as required, provide appropriate documentation to support this.

If on inspection, it is evident that the company was in breach of the "organic standards" and therefore "outside of its registration", action could be taken against the manufacturer and or the QP. This could include recalls and or suspension of the affected products until remedial actions are implemented.

What happens if organic certification is withdrawn or the company can no longer obtain the relevant ingredients needed to manufacture to organic standards?

Where the company fails to meet any of the requirements and the organic status of the product cannot be assured the QP cannot release the batch where the organic status of the product forms part of the SPC.

In the event that some specific certified organic material becomes unavailable for batch manufacture, the company has two options. Namely stopping production until the relevant materials can be obtained or continue to produce the products using non- organic material.

If they choose to do the latter, they will need to apply for a variation to the registration, including a change to the SPC and labelling to remove references to "organic".

What claims can be made as part of advertising and promotion for organic products?

All the requirements of the Blue Guide and the particular guidance issued for traditional herbal medicines must be complied with.

Under the general advertising requirements, it is permissible to refer to organic certification in targeted consumer advertising.

The certifying bodies logo can also be used in any such advertising and other promotional material e.g. customer display stands in store, websites etc.

Would the MHRA need to pre-vet any of the proposed advertising material using the certifying body logo or statements relating to the product's organic status.

No. In the event of a complaint about advertising, the company would be asked to submit the certification to support their claims.