



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, European Medicines Agency

PHARM 638

PHARMACEUTICAL COMMITTEE
23 October 2013

Subject: Advertising organic origin of traditional herbal medicinal products

Agenda item 6b, AOB

In the September 2012 meeting of the Pharmaceutical Committee, the Committee was asked if there is a possibility in the Member States to advertise the organic origin of OTC medicinal products due to a request from a member of the European Parliament. The European Commission has collated the answers from the Member States and presents them for information to the Pharmaceutical Committee.

The answers from Member States fall in 3 main groups:

- Yes: Greece, Denmark, Austria, Cyprus, Germany, Italy, Malta, the Netherlands, Spain.
- Yes with reservations, in particular national provisions equivalent to articles 87(2) and 90(h) of Directive 2001/83/EC, as amended: Hungary, the United Kingdom, Portugal, the Czech Republic and Estonia.
- No: Sweden, Ireland, Finland, Slovakia, France and Liechtenstein.

Member States' full responses are set out in the Annex.

Annex to PHARM 638

Question posed:

Is there a possibility in your Member State to advertise the organic origin of OTC medicinal products? If yes, what are the national rules for such an advertisement?

Liechtenstein: No

The Netherlands: If literally and only the term "organic or organic origin" is used, it will not be considered as a synonym for natural. So this term can be used in advertisements. For example, there is a whole line (in this case food) that is named 'essential organics'. For OTC medicinal products, the term organic has so far never been brought up in advertisements. But if this should be the case we then would argue: when the term organic would suggest that the safety or efficacy of the product is due to the 'organic' or of organic origin, we would reject the advertisement, unless this assertion is proven by studies and approved by the MEB (within the SmPC). In that case Article 28 of our Code is applicable: "the fact that a drug 'organic' or of 'organic origin' must be in relation to safety or efficacy are listed as proven correct and relevant distinctive of similar products."

Malta: Yes, it is possible to advertise the organic origin of OTC medicinal products if they are justified and if they are not considered promotional in nature. There is no separate specific national legislation beyond EU legislation.

Estonia: The advertisement of medicinal products has to comply with the requirements applicable to the certain type of advertisement and it depends on the classification of the product (OTCs or POMs). The advertisement to the general public may not give the impression that the medicinal product is effective or safety only because of the fact that it is natural.

Czech Republic: Advertising of human medicinal products is regulated by Act No. 40/1995 Coll., on Advertising, as amended. Only OTC medicinal products may be subject to advertising. Under Section 5a (7) (h) advertising to the general public shall not "suggest that the safety or efficacy of a human medicinal preparation is guaranteed only by its natural, organic origin". However, information compliant with the SmPC is allowed. Among other legal requirements, advertising shall also contain information necessary for appropriate use of the medicine and a clear message that the patient should read the package leaflet carefully.

Portugal: Herbal medicinal products are subject to the general rules on advertising foreseen in the Portuguese Medicines Act (Decree-Law 176/2006) specifically articles 145(2) and 150(3).

Therefore herbal OTCs can advertise its organic origin if that is in line with the authorized SPC, and if it's done truthfully, objectively and without exaggeration. Regarding labelling, we agree with the decision taken by the pharmaceutical committee in 2000.

Italy: In Italy there is no express prohibition on advertising the organic origin of OTC medicinal products. However, within the authorization procedure of the advertising of such products, it must be verified that the statement about the biological origin does not suggest that the safety or efficacy of the medicinal product is due to the fact that it is

essentially a "natural" (as well as provisions of Article 90, paragraph 1, letter h) of Directive 2001/83/EC.

Slovakia: No

France: Le code de santé publique français (articles L.5122-2 et R.5122-2) prévoit que la publicité en faveur d'un médicament doit "respecter les dispositions de l'AMM" et que les éléments contenus dans cette publicité "doivent être conformes aux renseignements figurant dans le résumé des caractéristiques du produit", ce qui est prévu par la directive 2001/83/CE modifiée en son article 87.2.

Aussi, en application de ces dispositions, la mention de l'origine biologique d'une plante, dans la mesure où elle n'est acceptée ni dans l'étiquetage ni dans la notice du médicament, ne saurait être autorisée dans un document promotionnel concernant ledit médicament. L'accepter reviendrait en effet de facto à valider une publicité non conforme au RCP.

Cette position contribue en outre, d'une part, à éviter toute confusion avec les médicaments traditionnels à base de plante, dont la publicité prévoit des mentions spécifiques, d'autre part, à parer tout risque de dérive en la matière, consistant par exemple à inciter à la prescription et à la délivrance de certains médicaments, indépendamment de considérations de santé publique.

(Unofficial translation: The French Public Health Code (Article L.5122-2 and R.5122-2) provides that the advertising of a medicinal product must "comply with the license of AMM" and that the information contained in this advertisement "must be in conformity with the information contained in the summary of product characteristics", which is provided by Article 87.2 of Directive 2001/83/EC as amended.

Moreover, according to these provisions the reference to the organic origin of a plant, taking into consideration that it is accepted neither in the labelling, nor in the package leaflet, shall not be authorised in a promotional document concerning these medicinal products. To accept it would mean validation of an advertisement not in conformity with the SPC.

This position also contributes, on one hand, to avoid confusion with the traditional herbal medicines, whose advertising includes specific references, and on the other hand, to counter the risk of drift in the matter, consisting for example to encourage the prescribing and dispensing of certain medicines, without any consideration of public health.)

Austria: We had this discussion one or two times with applicants, who wanted to write the organic origin on the labelling. The question concerning the labelling is not regulated in our law. Nevertheless applicants finally did not state it on the labelling. Concerning advertisement: As to our knowledge no company uses this phrase. § 53 Abs. 1 Z 9 of the Austrian Medicinal Product Act states: Business-to-layman advertising shall contain no elements that, suggest that the safety or efficacy of the medicinal product is attributable to its being a "natural product". We think that this provision does not apply to the question in case. So we think that advertising with organic origin of herbal OTC products is possible.

Finland: Not possible.

Germany: In Germany exists no specific regulation concerning the advertising with the organic origin of a medicinal product. Such an advertising is generally permissible. However, the advertising has to be clear and not misleading.

Ireland: The Irish Medicines Board (IMB) does not accept the advertisement of the “organic origin” of any medicinal product.

Cyprus: Advertising of the organic origin of OTC medicinal products is not prohibited in Cyprus. However, the provisions of directive 2001/83/EEC with regards to advertising apply. There are no additional national rules.

Sweden: The advertising of a medicinal product must be in line with the SmPC. If the organic origin is not part of the SmPC it is not allowed.

Spain: We don't have specific rules other than that contained in regular information on products to advertise the organic origin of OTC medicinal products.

Hungary: In answering this question it is supposed that the term „organic” is used in the meaning as specified in the Council Regulation (EC) No 834/2007 (of 28 June 2007) on the organic production and labelling of organic products and repealing regulation (EEC) No 2092/91.

In Hungary, the 98th Act of 2006 on the general rules of the safe and rational medicine and medical device supply and marketing orders as follows:

Art. 17(2): “No advertisement... [intended to the public] may contain any reference or expression that

...

d) would derive the efficacy and safety of a medicinal product exclusively from its natural origin”.

Advertisements in the electronic or written media are, after their publication, evaluated whether they violate this piece of law. The qualifier “organic” or “bio” origin in an advertisement, although not prohibited per se, might almost surely directly or indirectly violate the mentioned rule. No such cases have been detected in the recent past.

Naturally, if a longer description (Summary of Product Characteristics, written pamphlet, etc.) informs the user, independently from the efficacy and safety of the product, that it may be classified as “organic” because of its production, even suggesting that some impurities are excluded this way, it would not be classified as an advertisement.

It should be added, however, that the abovementioned is valid for medicinal products exclusively and the very great majority of herbal products, even former “medicines” have been re-classified and marketed as dietary supplements nowadays.

Denmark: It would not be contrary to the legislation on advertising of medicinal products to state “organic origin” in an advertisement for a medicinal product.

Offhand we would consider such a statement/information would have promotional purpose and not allow it in the labeling of a medicinal product. However, we have not been requested to decide on the issue and since each decision is case by case we might reach another result in a concrete case, depending on the circumstances.

United Kingdom: 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.

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.

For more information see: <http://www.mhra.gov.uk/home/groups/es-herbal/documents/websiteresources/con114427.pdf>

Greece: there are no national rules for the advertisement of the organic origin of an OTC product. If an OTC contains a substance of organic origin (e.g. a herbal one) it may be included in the advertisement.