REVIEW ARTICLE
Year : 2009 | **Volume** : 3 | **Issue** : 4 | **Page** : 270--276

Herbal products: Marketing strategies and legislation

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Abstract

Marketing of herbal products in the European Union (EU) has been regulated under national legislation for years, leadi
member state, a product may be regulated as a food supplement, while in the other member state the same product is
law. To provide free movement of these products in the inner market, new legislation has been set to improve harmoniz
and marketing strategy for a herbal product will be under this new EU legislation. This review describes the legal status
products, taking into account technical requirements and interesting market perspectives . Information was collected fr
European Commission, European Food Safety Authority and the European Medicines Agency. In addition, information
from Medline and Scopus. The EU market of herbal products will change considerably in the near future. Many product
registered as traditional herbal medicinal product in the future. However, it will take years for the EU to fully implement

How to cite this article:
Hooyenga PA, Witkamp RF, Groen K. Herbal products: Marketing strategies and legislation.Int J Green Pharm 2009;3

How to cite this URL:
Hooyenga PA, Witkamp RF, Groen K. Herbal products: Marketing strategies and legislation. Int J Green Pharm [serial
Available from: http://www.greenpharmacy.info/text.asp?2009/3/4/270/59730

Full Text

Introduction

Herbal medicines have been used for thousands of years. In the European Union (EU), these products are currently ma
according to the national regulations. The European Commission (EC) has taken measures to harmonize legislation fo
inner EU market. In principle, the new European legislation on traditional herbal medicinal products permits the registra
number of cases some hurdles still need to be taken. This review discusses the present and future situation for herbal
and marketing perspectives.

Methods

This review provides for an overview of application procedures and technical requirements according to appropriate leg published in the Official Journal of the European Communities and reports from the European Commission. Technical r European Food Safety Authority (EFSA), European Medicines Agency (EMEA) and European Federation of Associatio information has been found in conference presentations and websites of the competent authorities of member states. F

Herbal Medicinal Products

Herbal products have a long history of medicinal use in many parts of the world. Especially in Asian and African countri plants continue to form a major source of medical treatment until today. Examples are Traditional Chinese Medicine, Ay Often, these 'holistic' medicinal systems are based on a philosophy and an approach to diseases and treatment that dif Traditional medicine generally aims to improve the overall health and well-being of an individual person or patient, not r This approach has shown efficacy in treating patients, especially in chronic multifactorial diseases. These results are of contain multiple active ingredients acting in synergy in restoring the body's balance or preventing potential side effects.

A herbal product has to be classified as a medicinal product based on its presentation (indications that refer to treatmer immunological or metabolic action). Herbal medicinal products can be categorized into three groups: New herbal medic application (well-established use) and traditional herbal medicinal products. For these groups, different requirements ar the proposed indicated use and the available amount of data.

European Union Legislation

Like all other medicinal products, herbal medicinal products need marketing authorization which requires a full dossier herbal medicinal products, however, have a long history of use and may have (pre)clinical data available. Legislation fo

New Herbal Medicinal Products

Herbal products without a documented history of use need to undergo a full development programme comparable to cc clinical trials to prove efficacy and safety in humans. Also herbal medicinal with historic use, but with a new proposed ir well-documented safety data are available and no additional preclinical safety testing is required.

Herbal Medicinal Products with a Well-established Use

Products with a long history of use often have been subject of scientific investigation. When the product has a recogniz apply for marketing authorization under the precondition of well-established use according to 2001/83 article 10. In this or efficacy tests. In addition to scientific evidence supporting the well-established use, it is required that the herbal prod

A bibliographical application may be sufficient for marketing authorization. Scientific evidence to support well-establishe textbooks and monographs. It is especially recommended to use information provided in a community monograph (if av On Phytotherapy [3] or World Health Organization. [4],[5],[6] Requirements on data submission to substantiate well-est

Traditional Herbal Medicinal Products

Herbal medicinal products that have a history of use do not always fulfil the requirements for well-established use. In pa allow these products on the market, herbal medicinal products may have access to the market under the registration pr products need to have market authorization, traditional herbal medicinal products only need registration. Traditional her which at least 15 years in the EU. The historical use has to be substantiated with references to sales information, textb or historically used national pharmacopoeias. [8] The product's safety and efficacy are exclusively based on the traditio posology are in line with the traditional use and information in herbal monographs. No additional data on safety and effi

Traditional herbal medicinal products may only claim mild indications that comply with the traditional use. Retailing is lic
of a medical practitioner. The safety and efficacy of traditional herbal medicinal products is substantiated by the long his
therefore contain the phrase: Traditional herbal medicine for use in… [indication]…, exclusively based on long standing

The Herbal Medicinal Product Committee (HMPC) of EMEA is working on community monographs and the community
This will facilitate the free movement of herbal medicinal products in Europe by the mutual recognition procedure.

The community monographs will contain information about traditional use and/or well-established use. These monograp
(well-established use) or registration (traditional use). In addition to the community monographs, the HMPC is also worl
HMPC's opinion of a herb in regard to strength, posology, permitted indications, known contraindications and known he
the HMPC on the website of EMEA. List entries will be published by the EC. Recently, the first list entries have been ac

Implementation of the New Legislation

The new legislation for traditional herbal medicinal products (2004/24) will come into force on 1 st April 2011. This will i
legislation as herbal medicinal products with well-established use, or as traditional herbal medicinal products. However
differs between member states. Therefore, the implementation and transition from national to EU regulation will probab

The Situation in Germany

In Germany, the majority of the herbal medicinal products in the market are currently authorized as herbal medicinal pr
well-established use is based on reference to herbal monographs of the German Commission E. The European definiti
and many herbal products currently on the German market will not meet these requirements. However, it is expected th
reference to Commission E monographs will remain. [11] This is not in line with the required substantiation level in othe
European harmonization process of herbal medicinal products.

A second group of herbal medicinal products is that of the traditional medicinal products. These products were on the n
based on traditional use. These products have to apply for a new registration as traditional herbal medicinal product ac
survive the transition to traditional herbal medicinal product following EU legislation, but many will. At the moment, abou
registration in the next year. According to a conference presentation, it seems likely that German organizations for the p
more solid claims for traditional herbal medicinal products, just to distinguish between herbal medicinal products and fo

The Situation in the Netherlands

In general, herbal products are marketed in The Netherlands as food supplements and sometimes as homeopathic me
legislation seems not feasible for the majority of herbal medicinal products. In The Netherlands, the Medicine Evaluatio
herbal medicinal products. As a result, no information on efficacy should be included in the dossier.

The differences in regulation for Germany compared to countries as The Netherlands reduce the chances for mutual re
establishment of community monographs will provide a base for the mutual recognition procedure, but do not complete
monographs and community list entries is progressing slowly. In December 2008, 45 community monographs have bee
that 200-300 community monographs are necessary to fully implement the Directive on traditional herbal medicinal proc

Herbal Food Supplements

Food supplements are products for use by the consumer to supplement the normal diet in order to promote health. Foo
although the line between these categories can be thin. Medicinal claims are thus prohibited for food supplements. Cla

Food supplements are subject of the general food law Regulation 178/2002. [14] Specific legislation on food supplemer Directive 1924/2006. [16] Health claims are now divided in generic health claims (1924/2006, article 13) and disease ris (both in 1924/2006, article 14).

Generic Health Claims refer to:

The role of a nutrient or other substance in growth, development and the functions of the body,Psychological or behavi effecting hunger, satiety senses and energy uptake from the diet. Generic health claims (with generally accepted scient dossiers submitted by the member states. EFSA list will have the status of advice to the EC that will decide on the defir should be available at last January 2010. When an applicant wants to use a health claim that is not on the positive list (claim), the applicant may apply for inclusion of that specific claim in the positive list. New article 13 claims may be subn market position for the product.

Claims that refer to a reduction of disease risk (1924/2006, article 14) are subject of a rigorous authorization procedure together with new article 13 claims according to the highest standards. In the mean time, several health claims have be the application of a new article 13, or an article 14 claim will be submitted to the national competent authority that will s claim and the EC will publish this in the Community Register for consultation by the member states.

In addition to the regulations on health claims, substances used in food supplements should meet the requirements of t supplements need to have a history of use as food in Europe. Food products not used in the EU for a significant time a marketing authorization according to the novel food law. A full registration procedure as a novel food will make the total attractive.

Recently, the EC published a report on the harmonization procedures of, among others, herbal food supplements. [17] rules to herbal products, because of the lack of scientific data. In addition, it is not necessary to set harmonized measu products on the inner EU market. [18] This regulation forces member states to accept an application of a product alread of the product could lead to concerns about protection of health and life of humans, animals or plants. The rejection of t proportionality' and are seen in the light of national nutritional habits and in the light of the results of international scient

Dossier Requirements

The dossier requirements for medicinal products are listed in the EMEA Directive 2003/63, the Annexes as an amendm requirements listed in the Annexes, in order to support harmonization of dossiers in the European community. The form of a herbal medicinal product is set out in a document by EMEA and in [Figure 1]. [20] A full dossier consists of module as for new herbal medicinal products. Herbal medicinal products with a well-established use or traditional herbal medic requirements for modules 1-3 are equal for all herbal medicinal products.

Module 1 contains administrative information, a summary of product characteristics, labelling and packaging informatio types of applications and environmental risk assessments. This is equal for all sorts of medicinal products.

Module 2 merely consists of summaries of module 3, 4 and 5. This module also contains an introduction to the product, assessment [21] and traditional use specific to traditional herbal medicinal products.

Module 3 is the most important for the application of herbal medicinal products. The requirements set out in this module herbal medicinal products and the manufacturing process should be secured by adherence to the guidelines for Good A module, the following should be described: Characteristics of the raw herbal material, plant parts used compliance with control for stability of the raw materials and methods to control for the concentration of active constituents and the abse should be described for the finished product: Components of the medicinal product control for consistency of the final p This list is not complete, all requirements are found in Directive 2003/63 and other EMEA guidelines for the production

Module 4 includes all information regarding preclinical data. The registration of a traditional herbal medicinal product do product with well-established use may sustain with a bibliographic review of data. This product may also apply for mark

preclinical report. [24] New herbal medicinal products need to fulfil the complete requirements of the CTD and a report

Module 5 includes all clinical results. This module is not required for the registration of traditional herbal medicinal prod established use need to be submitted with sufficient available bibliographic data. Herbal medicinal products with a new

The dossier requirements for food supplements are set out in the technical guidance for the preparation and presentati dossier consists of four parts that contain the requirements for food/constituent characteristics and scientific data. The r strict than for herbal medicinal products. The substantiation of claims for food supplements should be based on peer-re general, the study group should be relevant for the proposed target group. Therefore, it is expected that EFSA will only the product would have a medicinal use. EFSA has established a new draft document that describes a rigorous set of t obligatory. It is the responsibility of the manufacturer to market safe products. Food supplement companies, especially This will include controls for concentrations of active constituents and impurities. Often herbal food supplements, like he fingerprint analyses. The European Federation of Associations of Health Products Manufacturers (EHPM) has establish food supplements, mainly focusing on the procedures of Hazard Analysis Critical Control Point (HACCP). The impleme regarding the size and efforts of the manufacturer. [27]

Conclusions

Different marketing strategies for herbal products are possible. To start with, three main groups of products can be disti

A product with a known effect and predefined indication. The advantage of such a product is that it can be marketed as target consumer.A product with a new indication that needs a relatively small investment to develop. This product coulc with a disease risk reduction claim ('article 14'). Such a procedure may require additional clinical testing.A product with that this development programme requires rigorous preclinical and clinical tests and is very expensive.A herb with a kn use, described under 1 can be developed as a food supplement or as a (traditional) herbal medicinal product. These pr (traditional) herbal medicinal product. It is an important question to determine whether the product is subject to food law presentation and function of the product. No herb or ingredient can be evaluated as medicinal product as such, but clas In the next few years, it is expected that the European Court of Justice will judge on borderline products in cases of disp Justice. [28] These trials will help to determine the border between food supplements and medicinal products. In additic classification as medicinal product or food supplement. [29] It is expected that a new committee of the EC will work on t products.

It is expected that the market for herbal products will shift when the new legislation for herbal medicinal products (Direc question is: What will be the impact on the herbal food supplement market? With the new Directive and the community product as a medicinal product. The possibility of having a solid medicinal claim will weigh out the higher costs for the r that of food supplements. It might therefore be expected that many food supplements will disappear because of compe smaller. In addition, the EC reported that the Directive on traditional herbal medicinal products may be extended to othe origin, medicinal honey, and certain amino acids and probiotics. Further extension, however, will not be started before t implemented. [13]

For traditional herbal products it may be wise to apply for registration. This decision, however, greatly depends on a nu marketing. In relation to marketing, one should think about their target population. Is the product intended to be delivere medicinal claim. When the product should be recommended by a physician practicing complementary medicine or a he able and willing to understand the scientific literature on the ingredients.

In addition, the economic perspectives should be taken into account. What investment is possible in product developme property and data protection should be taken into account. A new article 13 claim on a food supplement could give som not be protected by intellectual property. Decisions on the marketing strategy for a herbal product should be evaluated developments and the future perspectives for herbal products in Europe closely, as this market will evolve rapidly in the

Acknowledgment

The authors would like to thank Mr. Vincent Gielen, MSc., and Dr. Pengue Sun of Cinmar Pharma in Breda, The Nethe information.

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