SOCIETY FOR NEW AGE HERBALS

VIEWS & REVIEWS

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Taking Control of our Herbals -- The Global Initiative to bring Herbal Medicines (including Ayurveda) into a Regulatory Framework

with a questionable, unjustifiable and confusing positive and negative list of ingredients

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In India, we are working with such a diversity of biologically active ingredients that it clearly has a lot of significant implications for quality and safety which are a precursor to any registration and licensing needs.

A number of countries worldwide publish their own permitted and non- permitted lists of substances that can be used in various categories of products (medicine, dietary supplements, food supplements and cosmetics) based on quality and safety parameters. There is however, no universal comprehensive or harmonized listing or database available and as such one has to check and confirm with each individual list of the targeted exports market. Most of the countries have such listing on the websites of their national health regulatory authority.

The EU legislation on Food, Medicines and Cosmetics is all set to ban many of the food supplements and herbal ingredients. Even the United Nations Codex Alimentarius Commisssion is seeking to adopt this restrictive EU legislation and apply it worldwide in the name of 'trade harmonization'. This will have an adverse affect on the Natural Health Industry as a whole including the herbal manufacturers, distributors, health food stores, natural health practitioners and most importantly the consumers they serve.

The key factors that contribute to this sort of restriction include:

- Pressures from severely restrictive legislation guidelines
- Pressures from existing International trade agreements and

- Negative perception of natural products arising out of pressures from main stream media, etc.

The principle underlying the creation of a positive list that will be established at the Community level by the HMPC (Herbal Medicinal Products Committee) is to remove the need for many companies each to have to produce similar evidence of traditional use and safety where this has already been clearly accepted . It is not yet clear how the list will be implemented in relation to multi ingredient formulations /combinations. However, the absence of a substance on the positive list will not prevent a traditional use registration subject to safety, quality and traditional use requirements being met.

The issue is emerging as an epic battle with a clash of conflicting world views, scientific reductionism (studying the herb in its individual components) versus the herbal holism. There are also strong views that **'if it works, it must be regulated and evidence based'** versus the view that **'if it works, let us use it'**. It appears that only when the **International harmonization** of Herbal Regulations is more settled and definitions of herbal supplements, herbal drugs and herbal food ingredients, traditional medicines, etc. are more clear, a review of the complete category will take place.
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Cited below are a few examples regarding the lists from some selected countries:

CANADA

The Natural Health Products Directorate of Canada maintains several lists of natural ingredients that may occur in natural health products (NHPs) either as medicinal ingredients or as non-medicinal ingredients. The lists are available in the Health Canada official website as

- List of acceptable non-medicinal ingredients for NHPs
- List of single ingredients monographs for NHPs
- List of product monographs for NHPs.

EUROPEAN UNION

The EMEA (European Medicines Evaluation Agency) is developing community herbal monographs and a community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products for registration at various levels. There are official and non official national lists as well which are often referred to for marketing, registration and authorization at this stage. Countries like Italy and Spain have their own specific lists and products are permitted as per those lists.

Reference to EMEA website and HMPC links give some guidance on the issue of TRADITIONAL HERBAL MEDICINES DIRECTIVE SCHEME.

UNITED KINGDOM

Although UK is part of EU legislation, just for clarity of understanding it is advisable to have a look at the MHRA (Medicines and health care regulatory agency) website where a number of lists under the Traditional herbal medicinal products registration scheme are available.

- List of herbal ingredients and their reported uses at www.mhra.gov.uk/home/groups/is-pol/documents/websiteresources/con009277.pdf

- List of herbal ingredients which are prohibited or restricted in medicines at www.mhra.gov.uk/home/groups/es-erbal/documents/websiteresources/con009294. pdf

UNITED STATES OF AMERICA

There is a separate regulatory framework for the finished product, i.e. cosmetic, dietary supplement, drug, or food product.

Cosmetic Ingredients - The list of ingredients that are prohibited and restricted for use in cosmetics is available at www.cfsan.fda.gov/~dms/cos-210.html

Dietary Supplements - For a natural ingredient to be permitted as a dietary supplement there must be documentary evidence that such species was marketed in the US prior to 15th October 1994. If a natural ingredient was not marketed in the USA prior to 1994, it is classified as New Dietary Ingredient (NDI) and is subject to the 1997 regulation of Premarket notification. Reference to DSHEA (Dietary supplements health and education act) guidelines would clarify a lot of issues.

Drug Ingredients - For a natural ingredient to be permitted for use in an OTC or prescription drug product , it must be classified as GRASE (Generally regarded as safe and effective) by the FDA and included in the positive therapeutic monographs published in the Title 21 of the Code of Federal Regulations (21CFR) which are available online. However, there are some tentative final monographs not yet entered in the current edition of the CFR. Natural ingredients that are classified as GRASE in the CFR monographs include Psyllium-husk, Senna extract, and Karaya gum; they have corresponding quality standards monographs published in the USP.

Food Ingredients - To be permitted for use in a food product, the natural ingredient must be classified as GRAS (Generally regarded as safe) by the FDA . There is a database available online at www.cfsan.fda.gov/~dms/eafus.html

Other countries like Australia and Japan too have their lists and so must be considered for any in-house framing of guidelines for formulation development and manufacturing in order to meet their specific exports requirements.

For references log on to:

www.mhra.gov.uk/home/groups/is-pol/documents/websiteresources/con009277.pdf
www.mhra.gov.uk/home/groups/es-erbal/documents/websiteresources/con009294
www.cfsan.fda.gov/~dms/cos-210.html www.cfsan.fda.gov/~dms/eafus.html