European Federation of Associations of Health Product Manufacturers

Regulating Botanicals: Creating a Genuine Internal Market for Consumers & SMEs

10 December 2014

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Botanicals: Options on the Table & Commercial Implications

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10 December 2014

EHPM Mission

European Federation of Associations of Health Product Manufacturers

"EHPM represents the interests of specialist health product manufacturers and distributors in Europe.
It works towards developing an appropriate regulatory framework throughout the EU for its members' products,
and promotes industry best practice for product quality and safety"

Presentation Overview

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1. Introduction to EHPM
2. Key Pieces of EU Legislation
3. Botanicals Status Quo
   - Different national rules
   - Mutual recognition
   - Health Claims
4. Options on Table & Implications
5. Conclusion

1. Introduction to EHPM

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General Info

- European Federation of Associations of Health Product Manufacturers (EHPM)
- Representing the industry since 1975
- Gathering national associations of food supplement manufacturers & distributors
- 1,750 Enterprises (Over 90% SMEs)
- 13 Member States

1. Introduction to EHPM

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Food Supplement Products

- Vitamins & Minerals (55% of sales)
- Botanicals
- Combination Products
- Other substances (fish oil, probiotics, etc.)

Examples of botanicals used in FS:

Artichoke, Gingko, Chamomile, Borrage

2. Key Pieces of EU Legislation

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- Directive 2002/46/EC on food supplements
  - Provides definition for food supplements
  - Harmonises labelling requirements
  - Provides a process for label notification
  - Lists vitamins and minerals that can be used in food supplement
- Regulation (EC) No 1924/2006 on nutrition and health claims
  - Led to list of approved EU wide nutrition and health claims
  - Provides for 'Generic Descriptor' status for terms describing certain categories of products

3. Botanicals – Status Quo Different National Rules

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- No EU rules in place to harmonise the use of 'other substances' in food supplements in the EU
- The use of botanicals in food supplements is subject to different rules in different Member States – approved for Food Supplement in one country but considered a medicine in another

Ginkgo *(Ginkgo biloba)* is used in FS in the UK but considered a medicine Ireland

- European Commission is considering creating specific regime for botanicals that recognises tradition in assessing health claims and also harmonising quality and safety rules
- Some countries already working on botanicals harmonisation (Belgium, France and Italy) have developed the BELFRIT list

3. Botanicals – Status Quo Mutual Recognition

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- Regulation (EC) No 764/2008 on mutual recognition
  - Due to lack of harmonisation at EU level on other substances, national rules can mean that a substance that can be used in a FS in one country can only be used in a medicine in another (example: melatonin)
  - Mutual recognition regulation intended to resolve this as if legal in one Member State, a product should be accepted in others
  - Unfortunately not all Members States fully implement mutual recognition
  - Fully applied in Spain for example but this is not the case in all Member States
  - Result: market access issues for companies seeking to sell product in all EU Member States

3. Botanicals Status Quo Different National Rules

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Example: Greece

- Saw palmetto (Serenoa repens) used in a prostate food supplement. Widely used for the same purpose as a FS across EU
- When the product was being registered to be placed on the market in Greece, status as a FS was challenged on the basis that there was also a licensed medicine for prostate problems on the market using the same botanical.
  - FS Health Claim: It contributes to the maintenance of the normal function of the male prostate (36 mg plant extract per capsule)
  - Medicinal Indication: anti-androgen, antiflammatory, prostate diseases, benign prostate hyperplasia – (80 mg of plant extract per tablet)

3. Botanicals – Status Quo Health Claims

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- Regulation (EC) No 1924/2006 on nutrition and health claims
  - Assessment of over 2,000 botanical health claims is currently on hold
  - Traditional use taken into account in assessment of efficacy in traditional herbal medicines law
  - European Food Safety Authority (EFSA) assessment process for health claims in FS does not consider tradition and requires clinical trials

4. Options on the Table

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Option 1: Treat botanicals health claims in the same manner as all other health claims.

Outcome:

- Health Claim approval would require clinical trials
- Tradition of use would not be taken into account in assessment
- Inevitable rejection of claims currently used and widely accepted
- Only large companies could afford cost of clinical trials (€250K- €1 million)
- SMEs would be driven out of the sector

4. Options on the Table

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Option 2: Create a specific Regulatory Regime for botanicals that addresses quality, safety and health claims.

Outcome:

- Harmonise quality and safety requirement for botanicals in the EU
- Acceptance of tradition as a factor in health claims assessment – consistent with herbal medicines
- Creation of genuine internal market for botanical food supplements
- Proportionate approach that guarantees quality and safe products and is workable for SMEs

5. Conclusion

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- EHPM supports, develops and promotes quality standards – EHPM Quality Guide
- Option 2 offers consistency with treatment of botanicals under medicinal law
- A template for Option 2 already exists in national systems for regulating botanicals
- Option 1 would drive SMEs out of the botanical food supplement sector
- Botanicals estimated to make up €2.5 billion of the EU's €9 billion FS market

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Thanks for Your Attention

10 December 2014