EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Pharmaceuticals

Brussels, 14 February 2008
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REPORT ON THE EXPERIENCE ACQUIRED AS A RESULT OF THE APPLICATION OF THE PROVISIONS OF CHAPTER 2A OF DIRECTIVE 2001/83/EC (INTRODUCED BY DIRECTIVE 2004/24/EC) ON SPECIFIC PROVISIONS APPLICABLE TO TRADITIONAL HERBAL MEDICINAL PRODUCTS, AS REQUIRED UNDER ARTICLE 16I OF DIRECTIVE 2001/83/EC

SUMMARY OF THE PUBLIC CONSULTATION RESPONSES

1. Introduction

DG Enterprise and Industry launched on 30 May 2007 a public consultation on a draft report on experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC (introduced by Directive 2004/24/EC) on specific provisions applicable to traditional herbal medicinal products, as required under Article 16i of Directive 2001/83/EC. Contributions to the public consultation were invited until 10 August 2007.

The purpose of the report is to evaluate the application of Chapter 2a of Directive 2001/83/EC and to evaluate whether there are other medicinal products which could fulfil the conditions for simplified registration and to which the simplified registration procedure could be extended.

This report gives a summary of the comments to the public consultation. Responses received can be grouped into the following categories:
- Pharmaceutical/Herbal organisations and companies
- Health care professionals and organisations
- Regulators
- Other companies
- Others

In Appendix 1 there is a full list of all responses provided.

2. Breakdown of Responses

In total, we were provided with 53 responses. The breakdown of these responses by type of respondent is shown in the attached Table.

Table. Breakdown of responses

Category	**Number of responses**
Pharmaceutical/Herbal organisations and companies	21
Health care professionals and organisations	17
Regulators	9
Other companies	2
Others	4
Total	53

Individual responses varied from short emails or letters to more in-depth papers. The majority of the responses were in English.

2.1. Pharmaceutical/Herbal organisations and companies

- Companies manufacturing or marketing herbal products supported the extension of the scope of the Directive 2004/24/EC considering composition of the product, route of administration and unsupervised use and indications.

- They were concerned about the effect of implementation of Directive 2004/24/EC to their business activities. Many of their products may not pass the simplified registration procedure. These products may have a lack of the evidence of safety use at least 15 years in the European Community, but they may have a long history of using outside Europe.

- Numerous products contain in addition to the herbal ingredients other natural substances or preparations which make it presently not possible to register such products as traditional herbal medicinal products. Other barriers for registering are the requirement of genotoxicity data and the technical challenges related to fulfilling the manufacturing and quality requirements. Also the costs of the registration application may restrict companies to launch their products on the market.

- Many traditional medicines need a presence of a qualified practitioner to supervise and monitor the treatment and can not be used as OTC-products. This will exclude many products from the simplified registration.

- Some responses highlighted that the full implementation of the Directive is limited to only a number of Member States. Companies have had difficulties in the application for marketing authorisations.

- It was suggested that the transitional period for the implementation of simplified registration procedure stipulated by Directive 2004/24/EC could be delayed to the year 2019.

- Proposed substances which could fulfil the conditions for simplified registration:
  - propolis, natural borenol, D-camphor, menthol, rutin, curcumin, silymarin
  - honey, royal jelly, fish oil
  - amino acids

- micro-organisms
- minerals with a longstanding safe use as medicinal substances such as heavy kaolin, sodium sulphate, calcite, talcum, zinc oxide
- parts of non-wild and non-endangered animals as long as the safety proof is available

2.2 Health care professionals and organisations

- Many responses were received from herbalists, who were concerned about the effects of the Directive on herbalists` and their suppliers` businesses. Applying Directive 2004/24/EC will prejudice and restrict their means to earn a living, limit choice and reduce competition and lead to a black market in herbal medicines.

- However, between herbalists, there were also other views. Traditional registration would allow free movement of goods between Member states which have different regulatory regimen for traditional herbal medicinal products.

- Most of the comments supported the extension of the Directive 2004/24/EC. Requirements of the period of 15 years of medicinal use of products within the European Community, unsupervised use and the limited routes of administration were mostly considered as too restrictive.

- It was suggested that without expert knowledge on the different medical traditions in Europe it is very difficult for the Committee on Herbal Medicinal products (HMPC) to work in this area.

- Safety issues were raised by health professionals. Herbal products have caused adverse effects which often have been caused by quality defects. Classifying certain products as medicines would give better guarantees of their safety and quality, improving patient safety and public health.

- Proposed substances which could fulfil the conditions for simplified registration
  - boldine, codeine, caffeine, rutoside, esculin, camphor, menthol, thymol, cineole, alantoine, dehydrocholic acid, propolis, natural borneol
  - kaolin, sodium sulphate, calcite, talcum
  - animal derived by-products with a longstanding use such as calcined molluscae shells
  - honey, ghee (butter fat)
  - preparations and compounds consisting minerals, metals or animal products

2.3. Regulators

- Most of the drug regulatory authorities were in favour of the suggestions for extension of the scope of the draft report. However, many were of the opinion that before allowing the extension of the scope of the traditional registration scheme to other products/substances, more experience with the current system should be gained.

- A question about timing was raised. Companies need to take action now to prepare registration applications if they are to have products legally on the market in 2011, when the transitional period ends.

- There were mixed views regarding the requirement of longstanding use. Some regulators considered that no changes are necessary, while others considered that the requirement was too difficult to meet.

- One response was received from non-EU states. The fact that in HPMC there is no participation of experts outside Europe, the requirement of 15 years use in the European Community and the requirements of genotoxicity data and quantitative determination of ingredients were complained of.

- Proposed substances which could fulfil the conditions for simplified registration
  - boldo, caffeine, rutosid, esculin, camphor, menthol, thymol, cineol, allantoin, dehydrocholid acid, cineole
  - lecithin, bioflavonoids
  - amino acids
  - minerals (e.g. zinc oxide, calamine)
  - substances of animal origin (e.g. shells)
  - "pepsine vine" containing pepsin and hydrochlorid acid
  - fish oil, cod-liver oil, royal jelly, bee pollen propolis)
  - substances from animal origin including micro-organisms, mineral origin, metallic origin, nutritients and herbal constituents

2.4. Other companies

- This category included responses from health food manufacturer and training and consulting service. Responses highlighted a need to increase the transition period so that herbal products exempt from licensing can continuing being sold while new measures take effect.

- Proposed substances which could fulfil the conditions for simplified registration
  - glucosamine

2.5 Others

- Problems in the borderline in the food-medicine continuum were raised.

- Proposed substances which could fulfil the conditions for simplified registration:
  - boldine, caffeine, codeine, rutoside, esculin, camphor, menthol, thymol, cineole, alantoine, dehydrocholic acid, propolis

Appendix 1. List of responses

	Respondent
Pharmaceutical/Herbal organisations and companies	
1	Aflofarm Farmacja Polska, Poland
2	APIPOL-FARMA, Poland
3	Association of the European Self-Medication Industry (AESGP)
4	Association Europeenne des Fabricants de Medicaments Utilises en Therapeutique Antrosophique (AEFMUTA)
5	Ayurvedic Trade Association
6	China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE)
7	Chinese Medicine Association of Supplier (CMAS)
8	Dachverband Antroposophische Medizin in Deutscland (DAMID), Germany
9	European Chamber of Commerce for Traditional Chinese Medicine (ECCTCM)
10	European Coalition on Homeopathic and Anthroposophic Medicinal Products (ECHAMP)
11	Federation of Traditional Chinese Medicine (FTCM), UK
12	German Pharmaceutical Industry Association (BPI)
13	Herbal Forum, UK
14	Herbapol, Poland
15	International Ayurveda Foundation (IAF), UK & India
16	Pharmaceutical Laboratory Labofarm, Poland
17	Polish Herbal Committee
18	Phytopharm Kleka SA, Poland
19	PPF HASCO-LEK S.A., Poland
20	Wala, Netherlands
21	WZZ Herbapol SA, Poland
Health care professionals and organisations	
22	Ayurvedic Practitioners Association (APA)
23	Chris Caton, UK
24	Nathalie Chidley, UK
25	European Traditional Chinese Medicine Association (ETCMA)
26	European Initiative for Traditional Asian Medical Products (EITAM)
27	herboscy@blueyonder.co.uk
28	International Association of Anthroposophic Pharmacists (IAAP)
29	International Federation of Anthroposophic Medical Associations (IVAA)
30	Chistopher Menzies-Trull, UK
31	Milena Moore, UK
32	Neil Pellegrini, UK
33	Pharmaceutical Group of the European Union (PGEU)
34	Royal College of Physicians, UK
35	Sekcja Fitoterapii Polskiego Towarzystwa Lekarskiego, Poland
36	Maria Verge, UK
37	Sally Viney
38	Jennifer Wharam, UK
Regulators	
39	Belgian Federal Agency for Medicinal Products
40	Danish Medicines Agency
41	European Medicines Agency (EMEA)

42	Federal Ministry of Health, Germany
43	INFARMED, Portugal
44	Irish Medicines Board
45	Medicines and Healthcare products Regulatory Agency, UK
46	Ministry of Health, Poland
47	Ministry of Heath & Family Welfare, India
Other companies	
48	Holland and Barrett Group, UK
49	Margaret Anderson & Associate, UK
Others	
50	British Association for Nutritional Therapy
51	Polish Union of Employers in Pharmaceutical Industry, Poland
52	Research Institute of Medicinal Plants, Poland
53	Robert Woodward