

51st ANNUAL CONGRESS OF THE SOCIETY FOR MEDICINAL PLANT RESEARCH

MEDICINAL PLANT RESEARCH : FASCINATION - FACTS - FUTURE

KIEL, 31.08 - 04.09.2003

WORKSHOP OF THE PERMANENT GA COMMITTEE

“REGULATORY AFFAIRS ON HERBAL MEDICINAL PRODUCTS (HMPs)”

- **INTRODUCTION : A.J. VLIETINCK, GA**
- **HERBAL PREPARATIONS AS MEDICINAL PRODUCTS : O. PETRINI, AESGP**
- **HERBAL PREPARATIONS AS FOOD SUPPLEMENTS OR NUTRACEUTICALS :
M. HANSEN, EHPM**
- **CURRENT EUROPEAN REGULATIONS ON HERBAL PREPARATIONS AS MEDICINAL
OR FOOD PRODUCTS : K. KELLER, EMEA**
- **DISCUSSION**

WORKSHOP 6,

0.3.09.2003,

12.30h - 14.00h

LEGAL STATUS OF PLANT PREPARATIONS WORLDWIDE



DIETARY SUPPLEMENTS

NUTRACEUTICALS

PLANT PREPARATIONS

FUNCTIONAL FOODS

HERBAL MEDICINAL PRODUCTS

- DESIGNER FOODS
- FITNESS FOODS
- FOODACEUTICALS
- LONGEVITY FOODS
- MEDICINAL FOODS
- NUTRITIONAL FOODS
- THERAPEUTIC FOODS

- PHARMACEUTICAL FOODS
- PHARMACOFOODS
- PHARMAFOODS
- PHARMAFOODICALS
- PRESCRIPTION FOODS
- SUPER FOODS

EUROPEAN PHARMACEUTICAL AND FOOD LEGISLATION (1)

- FOOD SUPPLEMENTS

- **DIRECTIVE 2002/46/EC (10.06.2002)**

EUROPEAN PARLIAMENT AND COUNCIL ON FOOD SUPPLEMENTS

- **MAXIMUM AMOUNTS OF VITAMINS AND MINERALS**
- **PERMIT PRODUCTS IN COMPLIANCE : 01.08.2003**
- **PROHIBIT PRODUCTS NOT COMPLYING : 01.08.2005**
- **DRAFT PROPOSAL FOR A REGULATION OF THE E.P. AND THE COUNCIL ON NUTRITION AND HEALTH CLAIMS**

EUROPEAN PHARMACEUTICAL AND FOOD LEGISLATION (2)

* MEDICINAL PRODUCTS (1)

• FUTURE MARKET ACCESS FOR HERBALS

1. REGULAR MARKETING AUTHORISATION

- FULL SCIENTIFIC DATA

- * SAFETY TESTS AND CLINICAL TRIALS

- * WELL-ESTABLISHED USE

2. SIMPLIFIED REGISTRATION

- BASED ON INFORMATION ON TRADITIONAL USE

- ELIGIBLE ONLY WHEN “TRADITIONAL HERBAL”

EUROPEAN PHARMACEUTICAL AND FOOD LEGISLATION (3)

* MEDICINAL PRODUCTS (2)

- LEGISLATION

- HERBAL MEDICINAL PRODUCTS WORKING PARTY (HMPWP)

- ASSESSMENT OF QUALITY, SAFETY AND EFFICACY

- INTRODUCTION OF A DRAFT DIRECTIVE ON TRADITIONAL HERBAL MEDICINAL PRODUCTS AMENDING THE DIRECTIVE 2001/83/EC.