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. HANSSEN, EHPM
• CURRENT EUROPEAN REGULATIONS ON HERBAL PREPARATIONS AS MEDICINAL OR FOOD PRODUCTS : K. KELLER, EMEA
• DISCUSSION

WORKSHOP 6, 03.09.2003, 12.30h - 14.00h
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.