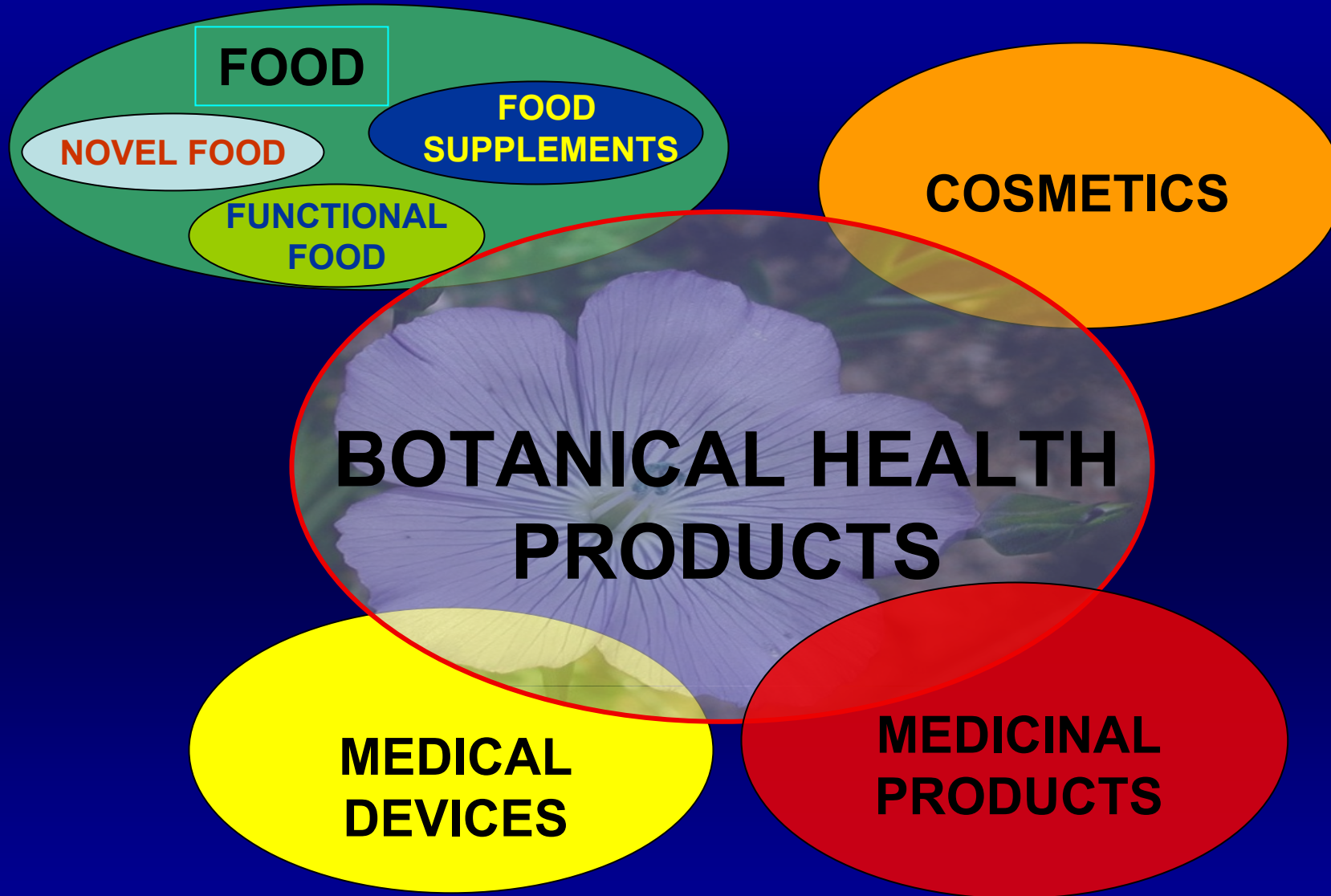

PROGRAMME

- 1. INTRODUCTION**
A.J. VLIETINCK, UNIVERSITY OF ANTWERP (UA), BELGIUM
 - 2. EUROPEAN REGULATOR'S PERSPECTIVE ON IMPLEMENTATION**
K. KELLER, HMPC, EMEA.
 - 3. NATIONAL REGULATOR'S PERSPECTIVE ON IMPLEMENTATION**
H. PITTNER, AGES PHARMMED, AUSTRIA
 - 4. PHYTOTHERAPEUTICAL ASSOCIATION'S PERSPECTIVE ON IMPLEMENTATION**
B. STEINHOFF, ESCOP, AESGP
 - 5. VIEWPOINT OF THE PHARMACEUTICAL INDUSTRY**
B. ROETHER, REGULATORY AFFAIRS, BIONORICA AG
 - 6. VIEWPOINT OF THE PRODUCERS OF FOOD SUPPLEMENTS**
P.COPPENS, EUROPEAN BOTANICAL FORUM (EBF)
 - 7. WILL THE COMMUNITY MONOGRAPHS AND LIST ENTRIES OF THE HMPs BE
HELPFUL FOR A SUCCESSFUL APPLICATION TO A REGULATORY AUTHORITY?**
 - 8. CONCLUSIONS**
S.ALBAN AND A.J. VLIETINCK
-

LEGAL STATUS OF HERBAL PRODUCTS WORLDWIDE



EUROPEAN HARMONISATION FOR HERBAL MEDICINAL PRODUCTS

- EUROPEAN PARLIAMENT
- EUROPEAN COUNCIL
- EUROPEAN COMMISSION
- EUROPEAN PHARMACOPOEIA
- EUROPEAN AGENCY FOR MEDICINAL PRODUCTS, EMEA
- NATIONAL AUTHORITIES OF EU MEMBER STATES
- INDUSTRY E.G. AESGP WORKING GROUP
- SCIENTIFIC ORGANISATIONS, E.G. ESCOP

INTERNATIONAL SOCIETY FOR MEDICINAL PLANT
RESEARCH, GA

EUROPEAN SOCIETY OF ETHNOPHARMACOLOGY

THE EU PYRAMID OF PERMITS FOR HERBAL PRODUCTS

PRODUCTS

* HERBAL MEDICINAL PRODUCTS (HMPs)

- FULL MARKETING AUTHORIZATION
- WELL ESTABLISHED USE HMPs (WEU)
- TRADITIONAL HMP (THMPs)

* HERBAL FOOD SUPPLEMENTS

* HERBAL NOVEL FOODS

* HERBAL COSMETIC INGREDIENTS

LEGISLATION

* MEDICINAL PRODUCTS

CD 2001/83 EC AS AMENDED BY
CD 2004/24 EC AND 2004/27 EC

* FOOD SUPPLEMENTS

CD 2002/46 EC

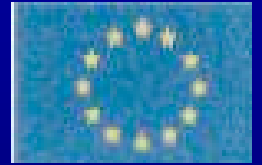
* NOVEL FOODS

REGULATION 258/97

* COSMETICS

CD 76/768

DIRECTIVE 2004 / 24 / EC ON TRADITIONAL HERBAL MEDICINAL PRODUCTS (THMPs)



* TASKS OF THE HERBAL COMMITTEE (HMPC)

- ESTABLISH A LIST OF HERBAL SUBSTANCES, PREPARATIONS AND COMBINATIONS THEREOF FOR USE IN THMPs
 - ESTABLISH COMMUNITY HERBAL MONOGRAPHS FOR WELL-ESTABLISHED MARKETING AUTHORISATIONS OR TRADITIONAL REGISTRATIONS OF HMPs.
MONOGRAPHS SHALL BE USED AS THE BASIS FOR ANY APPLICATION
 - AT THE REQUEST OF A MS DRAW UP AN OPINION ON THE ADEQUACY OF THE EVIDENCE OF THE LONG-STANDING USE
 - BE RESPONSIBLE FOR ARBITRATION / REFERRAL PROCEDURES ON THMPs
 - GIVE AN OPINION ON OTHER MEDICINAL PRODUCTS CONTAINING HERBAL SUBSTANCES REFERRED TO THE EMEA/CPMP
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