WORKSHOP OF THE PERMANENT COMMITTEE ON REGULATORY AFFAIRS OF HERBAL MEDICINAL PRODUCTS (HMPs)

IMPORTANCE OF HMPs COMMUNITY MONOGRAPHS AND COMMUNITY LIST ENTRIES FOR THE MARKETING AUTHORISATION AND REGISTRATION OF HMPs IN EUROPE

CHAIRS: S. ALBAN, A.J. VLIETINCK

WORKSHOP 1: 02/09/2007
13.00H - 17.00H
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

- FOOD
  - NOVEL FOOD
  - FUNCTIONAL FOOD
  - FOOD SUPPLEMENTS

- MEDICAL DEVICES
- MEDICINAL PRODUCTS
- COSMETICS

BOTANICAL HEALTH PRODUCTS
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

<table>
<thead>
<tr>
<th>PRODUCTS</th>
<th>LEGISLATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>* HERBAL MEDICINAL PRODUCTS (HMPs)</td>
<td>* MEDICINAL PRODUCTS</td>
</tr>
<tr>
<td>• FULL MARKETING AUTHORIZATION</td>
<td>CD 2001/83 EC AS AMENDED BY CD 2004/24 EC AND 2004/27 EC</td>
</tr>
<tr>
<td>• WELL ESTABLISHED USE HMPs (WEU)</td>
<td></td>
</tr>
<tr>
<td>• TRADITIONAL HMP (THMPs)</td>
<td></td>
</tr>
<tr>
<td>* HERBAL FOOD SUPPLEMENTS</td>
<td>* FOOD SUPPLEMENTS</td>
</tr>
<tr>
<td>CD 2002/46 EC</td>
<td></td>
</tr>
<tr>
<td>* HERBAL NOVEL FOODS</td>
<td>* NOVEL FOODS</td>
</tr>
<tr>
<td></td>
<td>REGULATION 258/97</td>
</tr>
<tr>
<td>* HERBAL COSMETIC INGREDIENTS</td>
<td>* COSMETICS</td>
</tr>
<tr>
<td></td>
<td>CD 76/768</td>
</tr>
</tbody>
</table>
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