INTERNATIONAL CONGRESS AND 53rd ANNUAL MEETING OF THE SOCIETY FOR MEDICINAL PLANT RESEARCH (GA)

AND THE

SOCIETÀ ITALIANA DI FITOCHIMICA (SIF)

21.08 - 25.08.2005, FLORENCE, ITALY

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

HOW TO IMPLEMENT THE NEW LEGISLATION ON HERBAL MEDICINAL PRODUCTS (HMPs) IN EUROPE ?

WORKSHOP 3 : 23.08.2005
12.30 - 14.00
CONGRESS CENTER, PALAZZO DEI CONGRESSI, AUDITORIUM

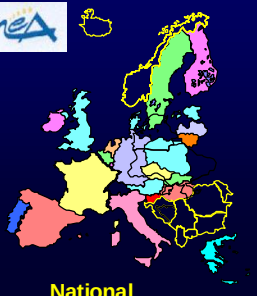
WORKSHOP 3 : PERMANENT GA COMMITTEE ON REGULATORY AFFAIRS OF HMPs

SUBJECT HOW TO IMPLEMENT THE NEW LEGISLATION ON HMPs IN EUROPE?

PROGRAMME

- INTRODUCTION
  A.J. VLIETINCK
  UNIVERSITY OF ANTWERP (UA), ANTWERP, BELGIUM
- VIEWPOINT OF THE EUROPEAN REGULATORY AUTHORITIES
  K. KELLER
  EUROPEAN MEDICINE AGENCY (EMEA), HERBAL MEDICINAL PRODUCTS COMMITTEE, LONDON, UK
- VIEWPOINT OF THE NATIONAL REGULATOTY AUTHORITIES
  V. SILANO,
  MINISTERO DELLA SALUTE, ROME, ITALIA
- VIEWPOINT OF THE PHARMACEUTICAL INDUSTRY
  L. KABELITZ
  PHYTOLAB, VESTENBERGSGREUTH, GERMANY
- DISCUSSION AND CONCLUSIONS

CURRENT LEGAL FRAMEWORK FOR HERBAL MEDICINAL PRODUCTS
MA PROCEDURES



National

Mutual recognition

Centralised (?)

Marketing authorisation :

"A medicinal product may only be placed on the market in the European Union when a marketing authorisation has been issued by the competent authority of a Member State for its own territory (national authorisation) or when an authorisation has been granted in accordance with Regulation (EEC) No. 2309/93 for the entire Community (a Community authorisation)."

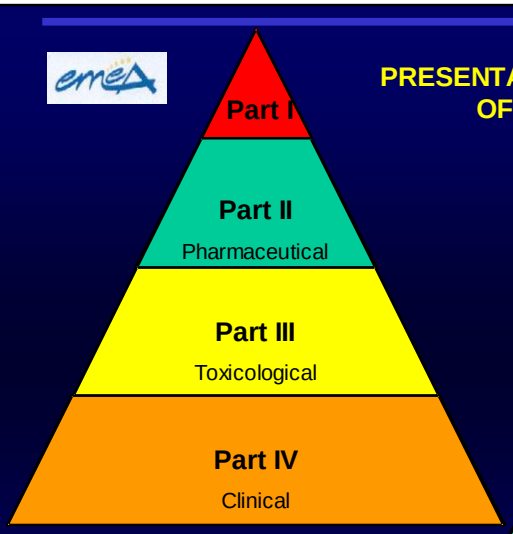
CURRENT LEGAL FRAMEWORK FOR HMPs IN THE EU

* ANNEX 1 TO CD 2001/83EC AMENDED BY CD 2003/63 (25.06.2003)

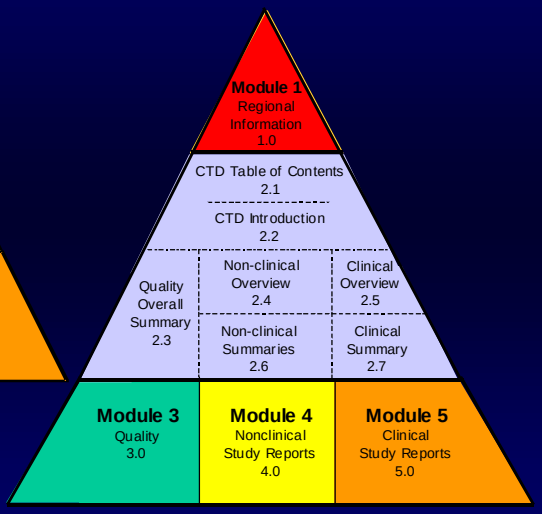
DOSSIER REQUIREMENTS

- SPECIFIC REQUIREMENTS FOR THE DOCUMENTATION AND EXPERT REPORTS ON QUALITY, SAFETY AND EFFICACY
  - SPECIFIC PART ON APPLICATIONS FOR HMPs
  - SPECIFIC PART ON BIBLIOGRAPHIC APPLICATIONS : WELL-ESTABLISHED USE (WEU) DEMONSTRATION : PERIOD OF USE NOT LESS THAN 10 YEARS FROM FIRST AND SYSTEMATIC USE AS A MEDICINAL PRODUCT
- PRESENTATION AND FORMAT OF AN APPLICATION
  - OLD NOTICE TO APLLICANTS (NTA) 1998 EDITION (PARTS I- IV)
  - NEW COMMON TECHNICAL DOCUMENT (CTD) 2001 EDITION (MODULES 1 - 5)
    - TRANSITION FOR "OLD" HMPs APPLICATIONS UNTIL 30.04. 2005
    - MANDATORY FOR "NEW" HMPs APPLICATIONS SINCE 01.07.2003

PRESENTATION AND CONTENT OF THE DOSSIER



1998 EDITION- NTA



2001 EDITION- CTD

DIRECTIVE 2004 / 24 / EC OF 31.03.2004 ON TRADITIONAL HERBAL MEDICINAL PRODUCTS (THMPs) (1)

* NEW LEGAL BASIS AND PROCEDURE

- SIMPLIFIED REGISTRATION OF TRADITIONAL HERBAL MEDICINAL PRODUCTS (THMPs) UNDER ARTICLE 16A

  DOES NOT APPLY IN CASE THE "TRADITIONAL" HERBAL PRODUCT FULFILS THE CRITERIA FOR A FULL MARKETING AUTHORISATION

- APPLICATION TO THE COMPETENT AUTHORITY OF THE MEMBER STATE (MS)

- TIMEFRAME FOR IMPLEMENTATION
  - REVIEW : 210 DAYS
  - EMEA/MEMBER STATES : MAX. 18 MONTHS : ENTERING INTO FORCE : 10.2005
  - THMPs ALREADY ON THE MARKET IN THE MS : COMPLIANCE WITHIN 7 YEARS (04.2011).

DIRECTIVE 2004 / 24 / EC OF 31.03.2004 ON TRADITIONAL HERBAL MEDICINAL PRODUCTS (THMPs) (2)

* SCOPE

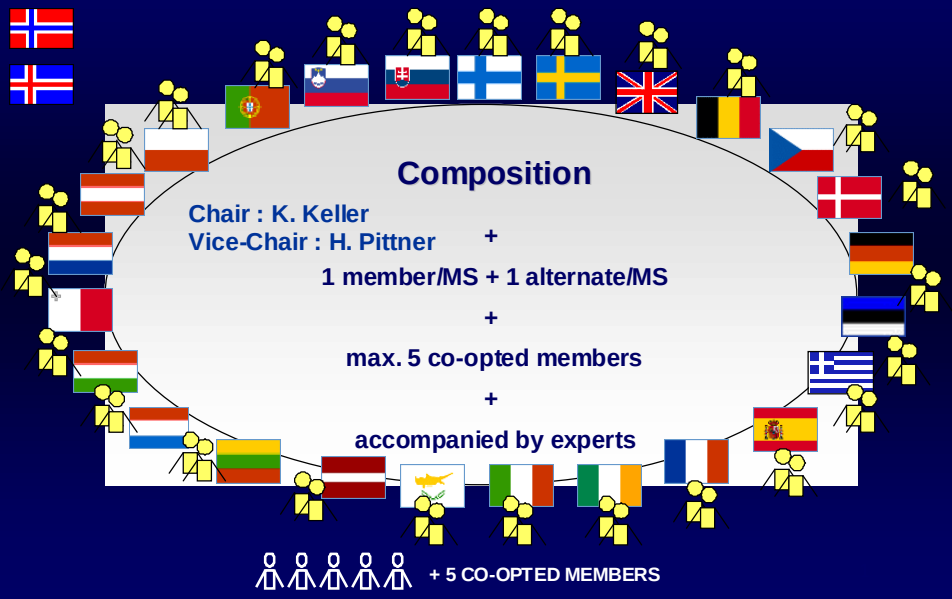
- INDICATION (S) EXCLUSIVELY APPROPRIATE TO THMPs AND DESIGNED FOR USE WITHOUT SUPERVISION OF A MEDICAL PRACTITIONER FOR DIAGNOSIS, PRESCRIPTION OR MONITORING OF TREATMENT
- SPECIFIED STRENGTH AND POSOLOGY
- ONLY ORAL OR EXTERNAL USE AND INHALATION
- PERIOD OF TRADITIONAL USE : 30 YEARS (15 YEARS IN AND 15 YEARS OUTSIDE THE EU), UNLESS OTHERWISE DECIDED BY THE HMPC
- VITAMINS AND MINERALS MAY BE ADDED IF THEIR ACTION IS ANCILLARY TO THE HERBAL CONSTITUENT(S)

DIRECTIVE 2004/24/EC OF 31.03.2005 ON TRADITIONAL HERBAL MEDICINAL PRODUCTS (THMPs) (3)

* ORGANISATIONAL CHANGES

- NEW COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)
- COMPOSITION : SIMILAR TO THE COMMITTEE ON HUMAN MEDICINAL PRODUCTS (CHMP) AND THE COMMITTEE ON VETERINARY MEDICINAL PRODUCTS (CVMP)
- GENERAL PROVISIONS FOR CHMP AND HMPC APPLY BY ANALOGY
  - ESTABLISHMENT OF STANDING AND TEMPORARY WORKING PARTIES
  - EMEA ADMINISTRATIVE, TECHNICAL AND SCIENTIFIC SECRETARIAT
  - CONTACTS WITH INTERESTED PARTIES
  - INVITATION OF REPRESENTATIVES OF INTERNATIONAL ORGANISATIONS AS OBSERVERS E.G. EP, WHO

HMPC – HERBAL COMMITTEE



DIRECTIVE 2004 / 24 / EC OF 31.03.2005 ON TRADITIONAL HERBAL MEDICINAL PRODUCTS (THMPs) (4)

* 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/CHMP

DIRECTIVE 2004/24/EC OF 31.03.2005 ON TRADITIONAL HERBAL MEDICINAL PRODUCTS (THMPs) (5)

* POST- AUTHORISATION ACTIVITIES

- PHARMACOVIGILANCE REQUIREMENTS
- MANUFACTURING AND IMPORT PROVISIONS
- VARIATIONS - TAKING INTO TECHNICAL PROGRESS
- INSPECTION ACTIVITIES
  - ⇒ GMP
  - ⇒ COMPLIANCE WITH EU PHARMACOPOEIA MONOGRAPHS
  - ⇒ PHARMACOVIGILANCE