7TH JOINT MEETING OF AFERP, ASP, GA, PSE & SIF

ATHENS, GREECE, 3 – 8 AUGUST 2008

WORKSHOP: REGULATORY AFFAIRS ON HERBAL MEDICINAL PRODUCTS (HMPs)

« MEDICINAL HERBS: DRUGS OR DIETARY SUPPLEMENTS? WHAT ARE THE LEGAL CONSEQUENCES IN TERMS OF QUALITY, SAFETY AND EFFICACY OF EACH OPTION? »

VIEWPOINT OF THE EUROPEAN REGULATORY AUTHORITIES

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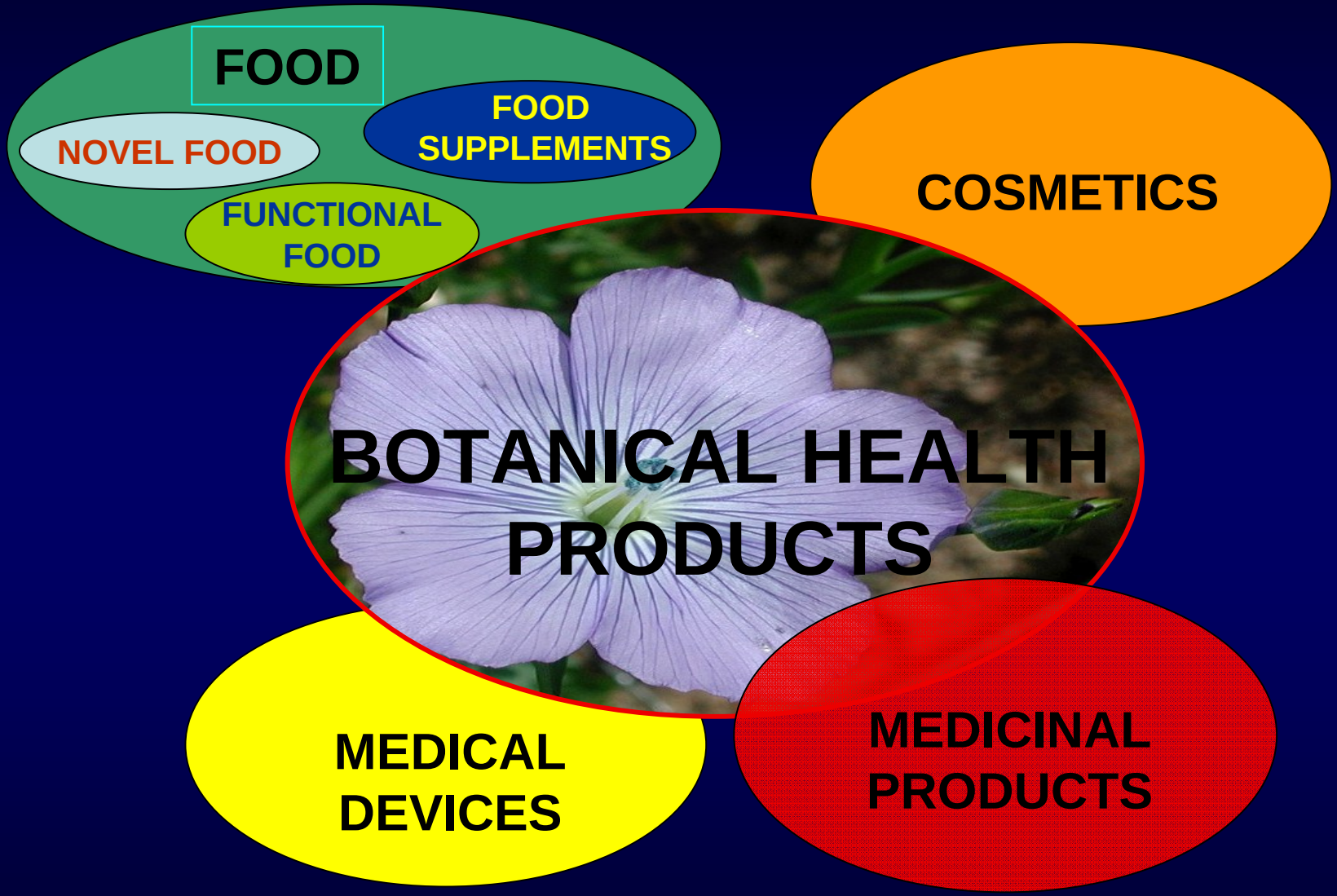
- CHAIRMAN OF THE GROUP OF EXPERTS 13A OF THE EUROPEAN PHARMACOPOEIA (EP)
- MEMBER OF THE COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC) OF THE EUROPEAN MEDICINES AGENCY (EMEA)

OUTLINE

1. INTRODUCTION
2. CURRENT LEGAL FRAMEWORK FOR HMPs IN THE EU
3. SIMPLIFIED REGISTRATION PROCEDURES OF THMPs (2004)
4. REALIZATIONS OF THE HMPC (TILL JUNE, 2008)
5. FUTURE DEVELOPMENT AND UNDISCOVERED OPPORTUNITIES OF, AND PROSPECTIVES FOR THE SIMPLIFIED REGISTRATION PROCEDURE OF THMPs
6. HERBAL PRODUCTS: FOOD OR MEDICINE?

LEGAL STATUS OF HERBAL PRODUCTS WORLDWIDE



EUROPEAN UNION LEGISLATION

MILESTONES WITH PARTICULAR RELEVANCE FOR HERBAL MEDICINAL PRODUCTS

- **COMMISSION DIRECTIVE 1999/83/EC OF 8 SEPTEMBER 1999**

  CLARIFICATION ON PROVISIONS FOR *WELL-ESTABLISHED USE*

- **COMMISSION DIRECTIVE 2003/63/EC OF 25 JUNE 2003**

  ANNEX 1 TO CD 2001/83: *SPECIFIC PROVISIONS* FOR HERBAL MEDICINAL PRODUCTS, INTEGRATION OF CD 1999/83/EC ON WEU

- **DIRECTIVE 2004/24/EC OF 31 MARCH 2004 :**

  ***SIMPLIFIED REGISTRATION* FOR TRADITIONAL HERBAL MEDICINAL PRODUCTS**

- **REGULATION 726/2004/EC OF 31 MARCH 2004 :**

  ESTABLISHMENT OF A *SCIENTIFIC COMMITEE* ON HMPs AT THE EMEA

HERBAL MEDICINAL PRODUCTS (HMPs) IN THE EU

- **REGULATORY GUIDANCE ON SOLID GROUNDS**

REGULATION No 726/2004 (EC) OF 31.03.2004
TITLE IV, THE EUROPEAN MEDICINES AGENCY (EMEA)
RESPONSIBILITIES AND ADMINISTRATIVE STRUCTURE

ARTICLE 56
1. (d) HMPs

DIRECTIVE 2001/83/EC
AS AMENDED BY

DIRECTIVE 2004/24.EC
AND
DIRECTIVE 2004/27/EC
OF 31.03.2004

- **HMPs IN THE EU : ACCESS TO THE MARKET**

MARKETING AUTHORIZATION (MA)

1. **FULL DOCUMENTATION WITH NEW TESTS AND TRIALS**
2. **FULL BIBLIOGRAPHIC DOCUMENTATION (WELL-ESTABLISHED USE)**
3. **MIXED APPLICATIONS**

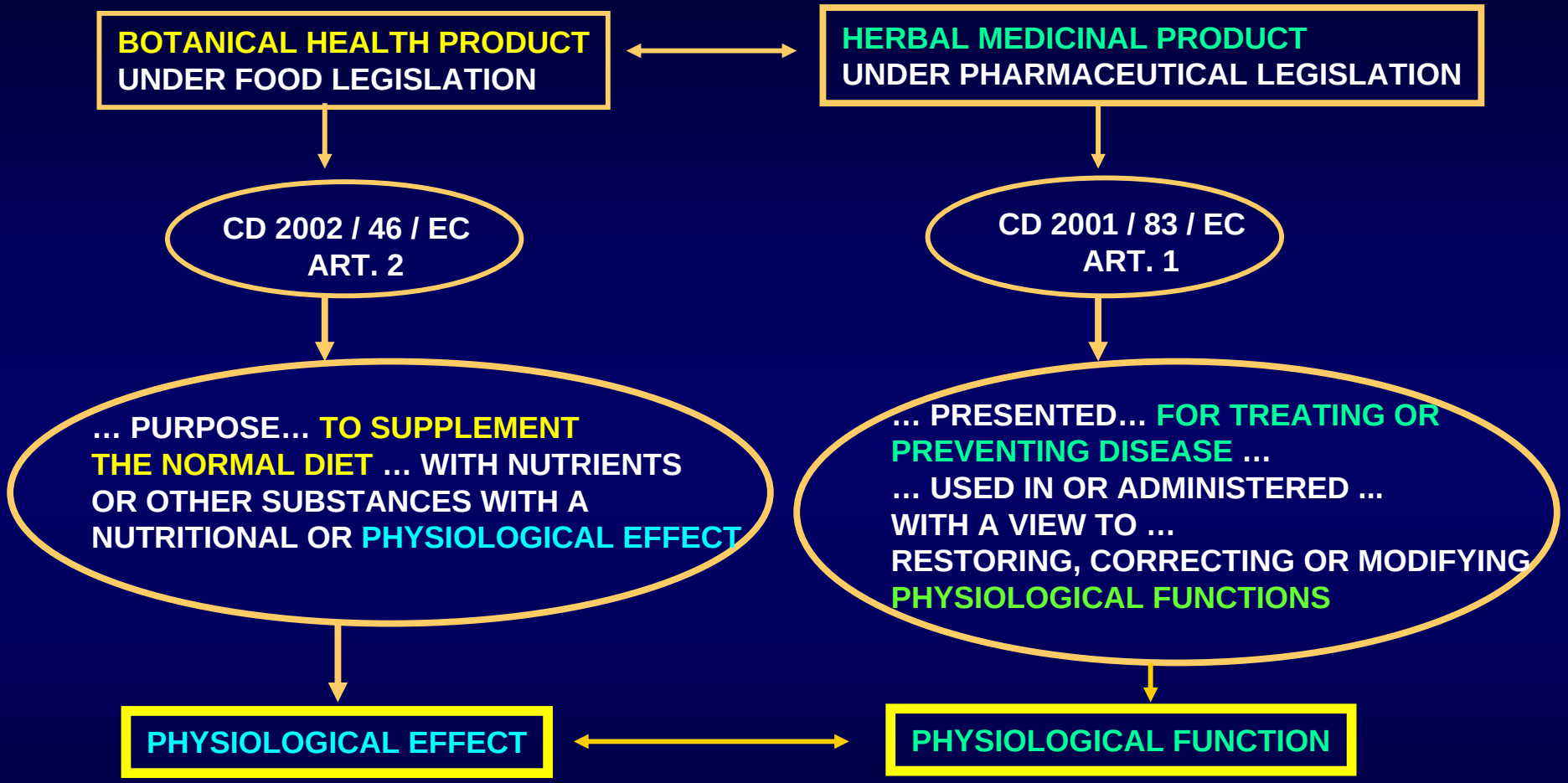
REGISTRATION

4. **SIMPLIFIED DOSSIER FOR TRADITIONAL HERBAL MEDICINAL PRODUCTS**

THE EU PYRAMID OF PERMITS FOR HERBAL PRODUCTS

PRODUCTS	LEGISLATION
* HERBAL MEDICINAL PRODUCTS (HMPs) • FULL MARKETING AUTHORIZATION • WELL ESTABLISHED USE HMPs (WEU) • TRADITIONAL HMP (THMPs)	* MEDICINAL PRODUCTS CD 2001/83 EC AS AMENDED BY CD 2004/24 EC AND 2004/27 EC
* HERBAL FOOD SUPPLEMENTS	* FOOD SUPPLEMENTS CD 2002/46 EC AND CD 2006/C80E
* HERBAL NOVEL FOODS	* NOVEL FOODS REGULATION 258/97
* HERBAL COSMETIC INGREDIENTS	* COSMETICS CD 76/768

MEDICINAL PRODUCT OR FOOD SUPPLEMENT



CONCERNS :

- DISTINCTION BETWEEN PHYSIOLOGICAL AND PHARMACOLOGICAL FUNCTION / LEVELS
- WHICH DIRECTIVE SHOULD BE APPLIED IN CASES OF DOUBT OR IN CASES WHERE THE HERBAL PRODUCT FALLS WITHIN THE SCOPE OF BOTH COMMUNITY LEGISLATIONS?

KEY ELEMENTS OF REVISED EU LEGISLATION

DIRECTIVE 2004/27/EC OF 31 MARCH 2004

ARTICLE 2 (2)

IN CASES OF DOUBT, WHERE, TAKING INTO ACCOUNT ALL ITS CHARACTERISTICS,

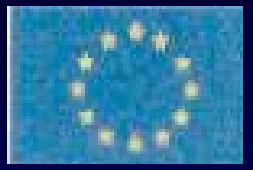
A PRODUCT MAY FALL WITHIN THE DEFINITION OF A " MEDICINAL PRODUCT"

AND WITHIN THE DEFINITION OF A PRODUCT COVERED BY OTHER COMMUNITY

LEGISLATION THE PROVISIONS OF THIS ((PHARMACEUTICAL)) DIRECTIVE SHALL

APPLY.

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



* NEW LEGAL BASIS AND PROCEDURE

- SIMPLIFIED REGISTRATION PROCEDURE OF TRADITIONAL HERBAL MEDICINAL PRODUCTS (THMPs)

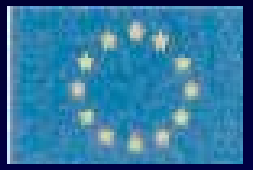
  UNDER ARTICLES 16a - 16i OF CHAPTER 2a OF DIRECTIVE 2001/83 EC

  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)

- NATIONAL PROCEDURE WITH LIMITED ACCESS TO MUTUAL RECOGNITION PROCEDURE (MONOGRAPH OR LIST FROM THE HMPC REQUIRED)

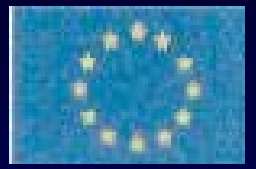
DIRECTIVE 2004 / 24 / EC ON TRADITIONAL HERBAL MEDICINAL PRODUCTS (THMPs) (2)



*** 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 (**ART 16 c 1 (c)**)
- **VITAMINS** AND **MINERALS** MAY BE ADDED IF THEIR ACTION IS **ANCILLARY** TO THAT OF THE HERBAL ACTIVE CONSTITUENT(S) REGARDING THE SPECIFIED CLAIMED INDICATIONS (**ART 16 a (2)**)

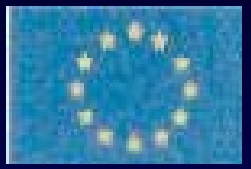
DIRECTIVE 2004 / 24 / EC ON TRADITIONAL HERBAL MEDICINAL PRODUCTS (THMPs) (3)



*** DOSSIER REQUIREMENTS** (ART 16 c)

- **ADMINISTRATIVE DOSSIER** : APPLICATION FORM, EXPERT REPORTS, SPC
- **PHARMACEUTICAL DOSSIER** : IDENTICAL TO A " FULL" MARKETING AUTHORISATION
- **BIBLIOGRAPHIC OR EXPERT EVIDENCE** THAT THE PRODUCT OR A CORRESPONDING **MEDICINAL PRODUCT** HAS BEEN IN MEDICINAL USE FOR **AT LEAST 30 YEARS** (NOT NECESSARY IF LISTED OR MONOGRAPH)
- **BIBLIOGRAPHIC REVIEW OF SAFETY DATA** TOGETHER WITH AN **EXPERT REPORT** (NOT NECESSARY IF LISTED OR MONOGRAPH)
- MS MAY REQUEST FURTHER **SAFETY STUDIES**, IF NECESSARY

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



* ORGANISATIONAL CHANGES

- NEW COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

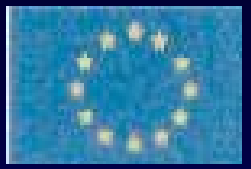
- COMPOSITION : SIMILAR TO THE COMMITTEE ON HUMAN MEDICINAL PRODUCTS (CHMP) AND

  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

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

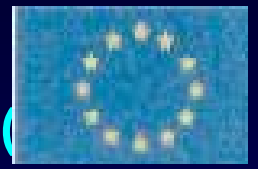


*** TASKS OF THE HERBAL COMMITTEE (HMPC)**

- ESTABLISH A LIST OF HERBAL SUBSTANCES, PREPARATIONS AND COMBINATIONS THEREOF FOR USE IN THMPs (ART 16 f)
- ESTABLISH COMMUNITY HERBAL MONOGRAPHS FOR WELL-ESTABLISHED MARKETING AUTHORISATIONS OR TRADITIONAL REGISTRATIONS OF HMPs (ART 16 h)

  MONOGRAPHS SHALL BE USED AS THE BASIS FOR ANY APPLICATION (MUTUAL RECOGNITION AND DECENTRALIZED PROCEDURES)
- 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

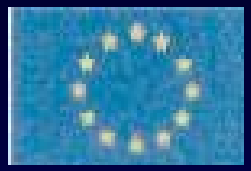
DIRECTIVE 2004/24/EC ON TRADITIONAL HERBAL MEDICINAL PRODUCTS (THMPs) (



*** POST- AUTHORISATION ACTIVITIES**

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

DIRECTIVE 2004/24/EC ON TRADITIONAL HERBAL MEDICINAL PRODUCTS (THMPs) (7)



* LABELLING AND USER PACKAGE LEAFLET

SHALL CONTAIN A STATEMENT

"THE PRODUCT IS A TRADITIONAL HERBAL MEDICINAL PRODUCT FOR USE IN SPECIFIED INDICATION(S) EXCLUSIVELY BASED UPON LONG STANDING USE"

"THE USER SHOULD CONSULT A DOCTOR OR QUALIFIED HEALTH CARE PRACTIONER IF THE SYMPTOMS PERSIST DURING THE USE OF THE PRODUCT OR IF ADVERSE EFFECTS NOT MENTIONED IN THE PACKAGE LEAFLET OCCUR

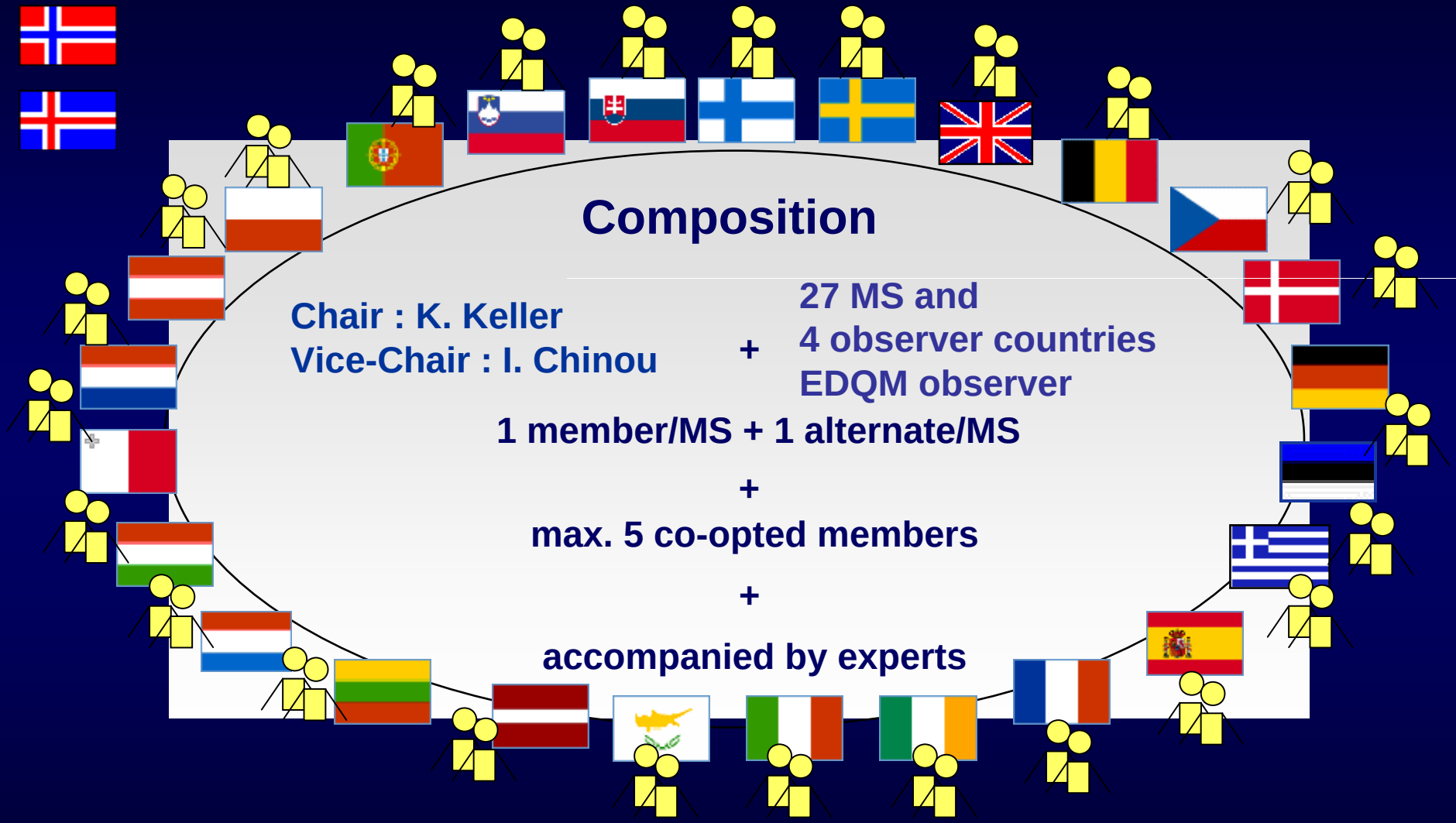
- A MS MAY REQUIRE TO MENTION THE NATURE OF THE TRADITION IN QUESTION

* ADVERTISEMENT

SHALL CONTAIN THE STATEMENT

"TRADITIONAL HERBAL MEDICINAL PRODUCT FOR USE IN SPECIFIED INDICATION(S) EXCLUSIVELY BASED UPON "LONG STANDING USE"

HMPC – HERBAL COMMITTEE



Composition

Chair : K. Keller
Vice-Chair : I. Chinou

+

27 MS and
4 observer countries
EDQM observer

1 member/MS + 1 alternate/MS

+

max. 5 co-opted members

+

accompanied by experts

+ CO-OPTED MEMBERS

REALIZATIONS OF THE HMPC (JUNE, 2008) (1)

*** THE EU SCIENTIFIC COMMITTEE ON HMPs : HMPC**

- FIRST TERM : SEPT. 2004 – SEPT. 2007
- SECOND TERM : OCT. 2007 – OCT. 2010
  - * 27 MS : 27 MEMBERS/ALTERNATES
  - * 4 CO-OPTED MEMBERS
  - * OBSERVERS FROM ICELAND, NORWAY, CROATIA, TURKEY
  - * PERMANENT OBSERVER FROM EDQM

*** THINK TANKS/WORKBENCHES INSTALLED**

- WORKING PARTY ON MONOGRAPHS AND LIST ENTRIES
- DRAFTING GROUP ON QUALITY
- DRAFTING GROUP ON ORGANIZATIONAL MATTERS (ORGAM)

*** EMEA RESOURCES ALLOCATED**

- SECRETARIAT FULLY ESTABLISHED (2006)
- FINANCIAL RESOURCES/BUDGET FOR LITERATURE (2007)

REALIZATIONS OF THE HMPC (JUNE, 2008) (2)

* COMPREHENSIVE GUIDANCE : REGULATORY AND SCIENTIFIC REQUIREMENTS CLEARLY ADDRESSED

  ORGAM (DRAFTING GROUP : E. VAN GALEN)

  APPLICATION FORMAT, TEMPLATES, PROCEDURES, …

  QUALITY (DRAFTING GROUP : B. KROES)

  GMP, GACP, TESTING, SPECIFICATIONS, COMBINATION PRODUCTS,…

  SAFETY/EFFICACY (WORKING PARTY, H. PITTNER) : (MLWP)

  NON-CLINICAL SAFETY, CLINICAL SAFETY AND EFFICACY, FIXED COMBINATIONS,…

REALIZATIONS OF THE HMPC (JUNE, 2008) (3)

* TRANSPARANCY ON HMPC ACTIVITIES

European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

London, 13 November 2007
Doc. Ref. EMEA/HMPC/521358/2007

COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 31 October 2007

The Committee on Herbal Medicinal Products met for the 20th time at the EMEA on 31 October 2007.

This October plenary meeting saw the election of the Chair and Vice-chair of the Committee. Dr K. Keller was re-elected as Chair and Dr I. Chinou as the new vice-Chair, both with a 3-year mandate that started on 31 October 2007.

Upon recommendation from the HMPC Working Party on Community Monographs and Community List (MLWP), the HMPC adopted the following Community herbal monographs and related documents:

Final Community herbal monographs:

- final 'Community herbal monograph on *Melissa officinalis* L., folium' (EMEA/HMPC/5341/2007)
- final 'Community herbal monograph on *Mentha x piperita* L., aetheroleum' (EMEA/HMPC/349466/2006)
- final 'Community herbal monograph on *Thymus vulgaris* L. and *Thymus zygis* L., herba' (EMEA/HMPC/234113/2006)*
- final 'Community herbal monograph on *Rheum palmatum* L. and *Rheum officinale* Baillon, radix' (EMEA/HMPC/189624/2007)

The final Community herbal monographs as well as their respective HMPC opinions, assessment reports and overview of comments received during the consultation period, will be published in due course on the EMEA website at:
http://www.emea.europa.eu/htms/human/hmpc/hmpcmonographsadopt.htm

*The HMPC decided to prepare a separate monograph on Thymi aetheroleum and the essential oil has therefore been removed from the preparations covered by the final monograph on Thymi herba.

REALIZATIONS OF THE HMPC (JUNE, 2008) (4)

COOPERATION

1. WITHIN EMEA

- HMPC MEMBER/OBSERVERS IN

  WG WITH HEALTH CARE PROFESSIONALS, WP WITH PATIENTS AND CONSUMERS, CHMP SAFETY WP, CHMP QUALITY WP

- CLOSE COOPERATION WITH

  CHMP PHARMACOVIGILANCE WP, BIOTECH WP, EMEA GMP/GDP INSPECTOR'S WG

2. OUTSIDE EMEA

- EFSA : DISCUSSION MEETINGS/EXCHANGE OF COMMENTS (HEALTH CLAIMS,SAFETY OF BOTANICAL PREPARATIONS)
- EDQM : PERMANENT OBSERVERSHIP
- EXTERNAL INTERESTED PARTNERS : REGULAR AND AD-HOC MEETINGS

REALIZATIONS OF THE HMPC (JUNE, 2008) (5)

- **STATUS OF ASSESSMENT WORK ON COMMUNITY MONOGRAPHS AND LIST ENTRIES**

MONOGRAPHS		LIST ENTRIES	
FINAL	22	FINAL OPINION	2
PRE-FINAL	10	DRAFTS UNDER CONSULTATION	4
DRAFTS PUBLISHED	7		
DRAFTS UNDER DISCUSSION	5	DRAFTS SUSPENDED (LACK OF GENOTOXICITY DATA)	2
RAPPORTEURSHIPS ASSIGNED	57		

REALIZATIONS OF THE HMPC (JUNE, 2008) (6)

* ADOPTED MONOGRAPHS (22)

LAXATIVES (10)

ALOE (WE), FRANGULAE CORTEX (WE), LINI SEMEN (WE,T), PLANTAGINIS OVATAE SEMEN (WE), PLANTAGINIS OVATAE SEMINIS TEGUMENTUM (WE), PSYLLII SEMEN (WE), RHAMNI PURSHIANAE CORTEX (WE), RHEI RADIX (WE), SENNAE FOLIUM (WE), SENNAE FRUCTUS (WE)

EXPECTORANTS (9)

ANISI AETHEROLEUM (T), *ANISI FRUCTUS* (T), *FOENICULI AMARI FRUCTUS* (T), *FOENICULI AMARI FRUCTUS AETHEROLEUM* (T), *FOENICULI DULCIS FRUCTUS* (T), *MENTHAE PIPERITAE AETHEROLEUM* (WE,T), *PRIMULAE FLOS* (T), *PRIMULAE RADIX* (T), *THYMI HERBA* (T)

SEDATIVES (3)

MELISSAE FOLIUM (T), *PASSIFLORAE HERBA* (*T*), *VALERIANAE RADIX (WE,T)*

* ADOPTED LIST ENTRIES (2)

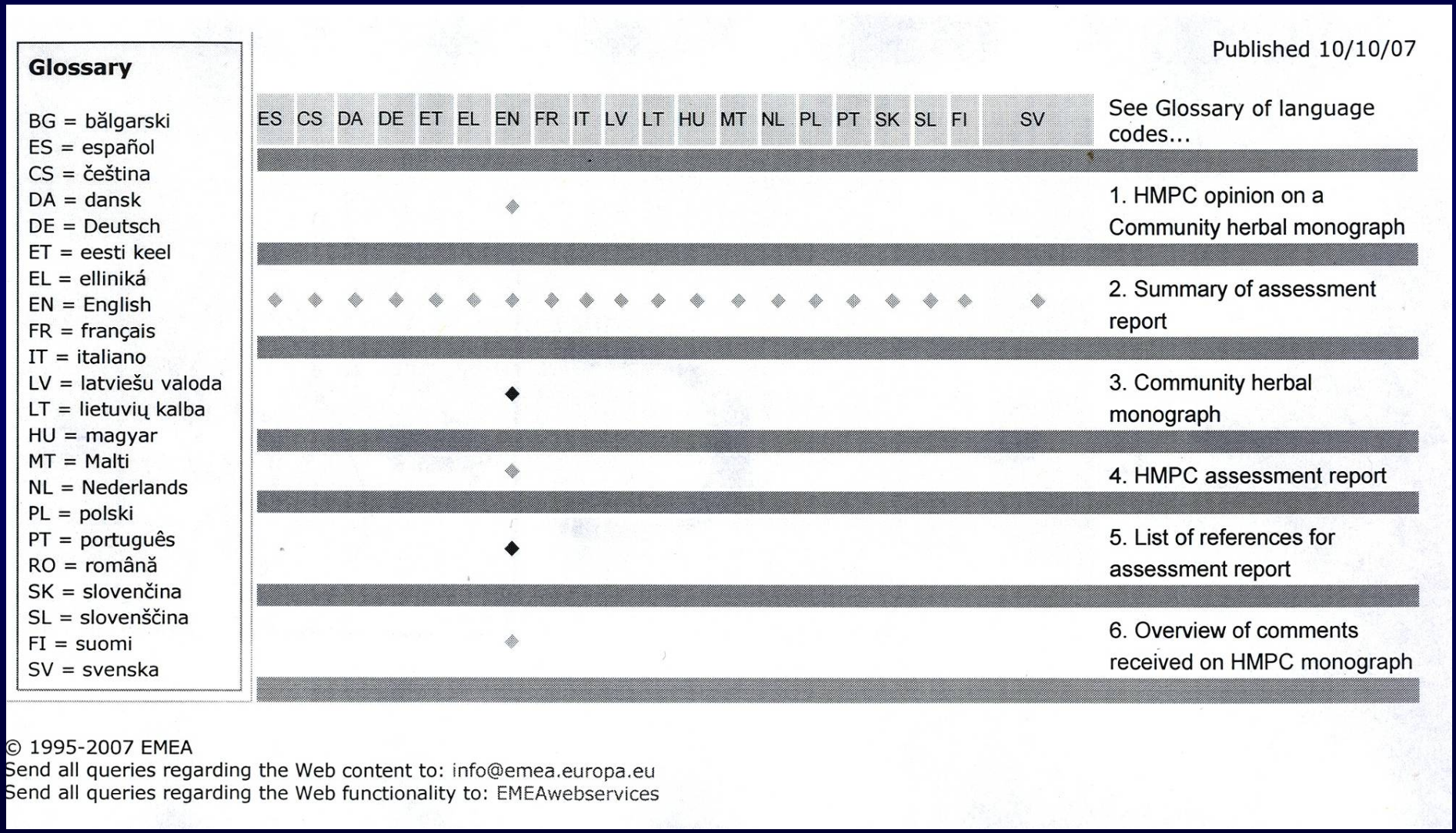
FOENICULI AMARI FRUCTUS, FOENICULI DULCIS FRUCTUS

* SUSPENDED LIST ENTRIES (2)

LINI SEMEN, VALERIANAE RADIX

REALIZATIONS OF THE HMPC (JUNE, 2008) (7)

INFORMATION PROVIDED ON COMMUNITY MONOGRAPHS



THE IMPACT OF EU HERBAL MONOGRAPHS

ARTIICLE 16 h (3)
COMMUNITY HERBAL MONOGRAPHS

3.

...

WHEN COMMUNITY HERBAL MONOGRAPHS WITHIN THE MEANING OF THIS PARAGRAPH HAVE BEEN ESTABLISHED, THEY SHALL BE TAKEN INTO ACCOUNT BY THE MEMBER STATES WHEN EXAMINING AN APPLICATION...

WHEN NEW COMMUNITY HERBAL MONOGRAPHS ARE ESTABLISHED, THE REGISTRATION HOLDER SHALL CONSIDER WHETHER IT IS NECESSARY TO MODIFY THE REGISTRATION DOSSIER ACCORDINGLY. THE REGISTRATION HOLDER SHALL NOTIFY ANY SUCH MODIFICATION TO THE COMPETENT AUTHORITY OF THE MEMBER STATE CONCERNED.

THE IMPACT OF THE EU LIST ENTRIES

ARTICLE 16 f

2. IF AN APPLICATION FOR TRADITIONAL- USE REGISTRATION RELATES TO A HERBAL SUBSTANCE, PREPARATION OR A COMBINATION THEREOF CONTAINED IN THE LIST REFERRED TO IN PARAGRAPH 1, THE DATA SPECIFIED IN ARTICLE 16c(1)(b)(c) AND (d) DO NOT NEED TO BE PROVIDED. ARTICLE 16e(1)(c) AND (d) SHALL NOT APPLY

APPLICANT DOES NOT NEED TO SUBMIT:

- INFORMATION ON PREVIOUS AUTHORISATIONS/REGISTRATIONS
- EVIDENCE ON TRADITIONAL USE
- BIBLIOGRAPHIC / EXPERT EVIDENCE ON SAFETY

COMPETENT AUTHORITY CANNOT REFUSE THE APPLICATION:

- BECAUSE THE PRODUCT COULD BE HARMFUL
- BECAUSE OF LACK OF PLAUSIBILITY / SUFFICIENT TRADITIONAL USE

THE IMPACT OF MONOGRAPHS AND LIST ENTRIES

ARTICLE 16 d

WITHOUT PREJUDICE TO ARTICLE 16b(1), CHAPTER 4 OF TITLE III SHALL APPLY BY ANALOGY TO REGISTRATIONS GRANTED IN ACCORDANCE WITH ARTICLE 16a, PROVIDED THAT:

a) A COMMUNITY HERBAL MONOGRAPH HAS BEEN ESTABLISHED IN ACCORDANCE WITH ARTICLE 16b(3), OR

b) THE HERBAL MEDICINAL PRODUCT CONSISTS OF HERBAL SUBSTANCES, PREPARATIONS OR COMBINATIONS THEREOF CONTAINED IN THE LIST REFERRED TO IN ARTICLE 16 f.

ACCESS TO MUTUAL RECOGNITION AND DECENTRALIZED PROCEDURE FOR TRADITIONAL HERBAL MEDICINAL PRODUCTS

OVERVIEW OF LEGAL FRAMEWORK FOR HMPs IN THE EU

<table>
<tr><td colspan="3">PHARMACOVIGILANCE</td><td rowspan="2">APPLIES TO REGISTERED AND TO AUTHORIZED HMPs</td></tr>
<tr><td colspan="3">CONSUMER INFORMATION, LABELLING, ADVERTISING</td></tr>
<tr><td colspan="2">EFFICACY</td><td rowspan="2">TRADITIONAL USE</td><td rowspan="4">MAY BE REPLACED BY A MONOGRAPH OR
THE LIST FROM THE HMPC IN REGISTRATIONS</td></tr>
<tr><td>NEW TRIALS</td><td>BIBLIOGRAPHY</td></tr>
<tr><td colspan="2">SAFETY</td><td rowspan="2">EXPERT REPORT
BIBLIOGRAPHY
NEW TESTS</td></tr>
<tr><td>NEW TESTS</td><td>BIBLIOGRAPHY</td></tr>
<tr><td colspan="3">QC</td><td rowspan="3">IDENTICAL FOR MA AND R</td></tr>
<tr><td colspan="3">GMP</td></tr>
<tr><td colspan="3">GACP</td></tr>
<tr><td>NEW</td><td>WELL-ESTABLISHED (WE)</td><td>TRADITIONAL (T)</td><td></td></tr>
<tr><td colspan="2">MARKETING AUTHORISATION (MR)</td><td>REGISTRATION (R)</td><td>AFTER KELLER, 2006</td></tr>
</table>

FUTURE DEVELOPMENT OF THE SIMPLIFIED REGISTRATION PROCEDURE OF THMPs

DRAFT REPORT FROM THE EUROPEAN COMMISSION
30 MAY 2007

- EXTENSION TO OTHER PRODUCTS THAN HERBAL SUBSTANCES (ALONE OR IN COMBINATION WITH HERBAL INGREDIENTS) COULD BE CONSIDERED;
- THE LIMITATION TO PRODUCTS WITH 15 YEARS USE IN THE COMMUNITY, TO CERTAIN ROUTES OF ADMINISTRATION AND TO PRODUCTS WHICH DO NOT NEED THE SUPERVISION OF A MEDICAL PRACTITIONER, SHOULD BE MAINTAINED.
- CONCERNS THAT OBSTACLES TO THE USE OF THE SIMPLIFIED REGISTRATION BY THE ECONOMIC OPERATORS MAY LEAD TO THE PLACING ON THE MARKET OF SOME PRODUCTS UNDER ANOTHER QUALIFICATION WHICH WOULD NOT NECESSARILY OFFER THE SAME GUARANTEES OF QUALITY, SAFETY AND EFFICACY.

KELLER, 2007

UNDISCOVERED OPPORTUNITIES OF THE SIMPLIFIED REGISTRATION PROCEDURE OF THMPs

- USE OF THE EDQM CERTIFICATE OF SUITABILITY IF THE HERBAL SUBSTANCE IS COVERED BY A MONOGRAPH OF THE EUR. PH. ⇒

  OPPORTUNITY TO SIMPLIFY THE DOCUMENTATION ON QUALITY

- ART. 16c1(c) ON MEDICINAL USE WITHIN EU AND OUTSIDE EU (30Y OR 15Y + 15Y), ⇒

  OPPORTUNITY FOR THMPs WITH A LONG TRADITION IN ONE EU MS, BUT LESS KNOWN IN OTHER MS : "INNOVATIVE"

- AFTER REFERRAL OF A MS, HMPC SHALL DRAW A COMMUNITY MONOGRAPH ON THMs LESS THAN 15 YEARS WITHIN THE EC ⇒

  OPPORTUNITY FOR THMPs WITH A LONG STANDING TRADITION OUTSIDE THE EU AND A GOOD QUALITY AND SAFETY DOSSIER (E.G. TCMs)

- ART 16c ON COMPARABLE PRODUCTS ⇒

  OPPORTUNITY FOR SIMPLIFYING AND MODERNIZING COMPLEX COMBINATON PRODUCTS : "SHARING HISTORY" FOR DIFFERENT PRODUCTS ; MOVING FROM TRADITIONAL FOOD SUPPLEMENTS TO MEDICINAL PRODUCTS

PERSPECTIVES ON CURRENT LEGAL FRAMEWORK FOR (T)HMPs IN THE EU

* LEGISLATION HAS BEEN IMPLEMENTED IN MOST OF EU MS ; EC ENFORCES IMPLEMENTATION, THROUGH ECJ

* ESSENTIAL GUIDANCE ON QUALITY, SAFETY, EFFICACY AND PROCEDURES IS FINALISED AND AVAILABLE TO APPLICANTS

* AMPLE USE OF THE MUTUAL RECOGNITION / DECENTRALIZED PROCEDURE ON THE BASIS OF AN EU MONOGRAPH SHOULD BE PROMOTED

* EMEA OFFERS SCIENTIFIC SERVICES TO APPLICANTS

* BROADER DISCUSSION IS NEEDED ON THE IMPLEMENTATION OF THE PROVISIONS OF WEU MA, SINCE THE SIMPLIFIED REGISTRATION SCHEME IS NOT APPROPIATE TO ADDRESS ALL "OLD" PRODUCTS

* ISSUES ON BORDERLINE MEDICINE / FOOD PRODUCTS SHOULD BE SOLVED : DISCUSSIONS BETWEEN EMEA / DG SANCO AND HMPC/EFSA SHOULD BE ENCOURAGED

HERBAL PRODUCTS : FOOD OR MEDICINE (1)

* PERSPECTIVES FOR HERBAL PRODUCTS UNDER FOOD LAW : PROGRESS!

  - REGULATION 1924/2006/EC ON NUTRITION AND HEALTH CLAIMS MADE ON FOOD

  - EFSA NDA DRAFT OPINION ON THE SCIENTIFIC AND TECHNICAL GUIDANCE FOR THE PREPARATION OF THE APPLICATION FOR AUTHORIZATION OF A HEALTH CLAIM (SP/NDA/CLAIMS/WD/1/REV3)

* DIVERGENT SCIENTIFIC OPINIONS BETWEEN EFSA AND HMPC E.G.

  - QUALITY :
    - HACCP (HAZARD ANALYSIS AND CRITICAL CONTROL POINT) VERSUS GACP/GMP

    - MINIMUM AMOUNT OF ACTIVE COMPONENTS

    - STABILITY STUDIES

HERBAL PRODUCTS: FOOD OR MEDICINE (2)

- SAFETY :
  - TRADITIONAL SAFETY OF THMPs VERSUS HAZARD IDENTIFICATION AND CHARACTERISATION OF BOTANICALS IN FOOD SUPPLEMENTS
  - PHARMACOVIGILANCE OF THMPs VERSUS POST LAUNCH MONITORING (PLM) OF FOOD SUPPLEMENTS
- ACTIVITY :
  - PHARMACOLOGICAL EFFECTS OF THMPs VERSUS PHYSIOLOGICAL EFFECTS OF FOOD SUPPLEMENTS.
  - MEDICINAL CLAIMS VERSUS HEALTH CLAIMS.

* HARMONISATION OF LEGISLATION ON FOOD SUPPLEMENTS THROUGHOUT THE EC
  - CRITERIA TO DISTINGUISH BETWEEN BOTANICAL HEALTH PRODUCTS AND THMPs IN THE EC

HERBAL PRODUCTS: FOOD OR MEDICINE (3)

- HOW TO FIND THE RIGHT BALANCE FOR HERBAL MEDICINAL PRODUCTS AND FOOD SUPPLEMENTS ?
- COORDINATION
  - EFSA / EMEA
  - COMMISSION / MEMBER STATES
  - EUROPEAN PARLIAMENT