
**WORKSHOP OF THE PERMANENT COMMITTEE ON REGULATORY
AFFAIRS OF HERBAL MEDICINAL PRODUCTS (2009 – 2010) (1)**



**58TH INTERNATIONAL CONGRESS AND ANNUAL MEETING
OF THE SOCIETY OF MEDICINAL PLANT AND NATURAL
PRODUCT RESEARCH**



**FREIE UNIVERSITÄT BERLIN
AUDITORIUM A, HENRY FORD BUILDING**

SUNDAY, 29TH AUGUST 2010

**THEME: THE IMPORTANCE OF A RISK-BENEFIT ANALYSIS FOR THE MARKETING
AUTHORIZATION AND / OR REGISTRATION OF (TRADITIONAL) HERBAL
MEDICINAL PRODUCTS (HMPs)**

CHAIRS : A.J. VLIETINCK AND S. ALBAN

WORKSHOP OF THE PERMANENT COMMITTEE ON REGULATORY AFFAIRS OF HERBAL MEDICINAL PRODUCTS (2009 – 2010) (2)

PROGRAMME

- 14:00 A.J VLIETINCK, UNIVERSITY OF ANTWERP (UA) BELGIUM
INTRODUCTION
- 14:05 G. LAEKEMAN, CATHOLIC UNIVERSITY OF LEUVEN (KUL), LEUVEN, BELGIUM
TAKING THE RISK OF THE BENEFIT: THE UNBALANCED SITUATION OF HERBAL MEDICINAL PRODUCTS
- 14:35 J. WIESNER, FEDERAL INSTITUTE FOR DRUGS AND MEDICAL DEVICES, BONN, GERMANY
NATIONAL PRACTICE: EXPERIENCES WITH THE SAFETY ASSESSMENT FOR (TRADITIONAL) HERBAL MEDICINAL PRODUCTS
- 15.05 B. STEINHOFF, EUROPEAN SCIENTIFIC COOPERATIVE OF PHYTOTHERAPY, BONN, GERMANY
EUROPEAN PRACTICE: EXPERIENCES WITH A RISK-BENEFIT ANALYSIS OF HMPs FOR THE ELABORATION OF ESCOP-MONOGRAPHS
- 15.35 **COFFEE BREAK**
- 16:00 G. MENG, DR. WILMAR SCHWABE GmbH & Co, KG, KARLSRUHE, GERMANY
EUROPEAN PRACTICE: WELL-ESTABLISHED USE OF HERBAL MEDICINAL PRODUCTS AND CLINICAL RESEARCH
- 16:30 **PANEL DISCUSSION AND CONCLUSION**
- **IS A BENEFIT-RISK ANALYSIS INDISPENSABLE FOR THE MARKETING AUTHORISATION OR**
17: 30 **REGISTRATION OF HERBAL MEDICINAL PRODUCTS?**

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 COMMITTEE* ON HMPs AT THE EMEA
-

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 AND CD 2006/C80E

* NOVEL FOODS

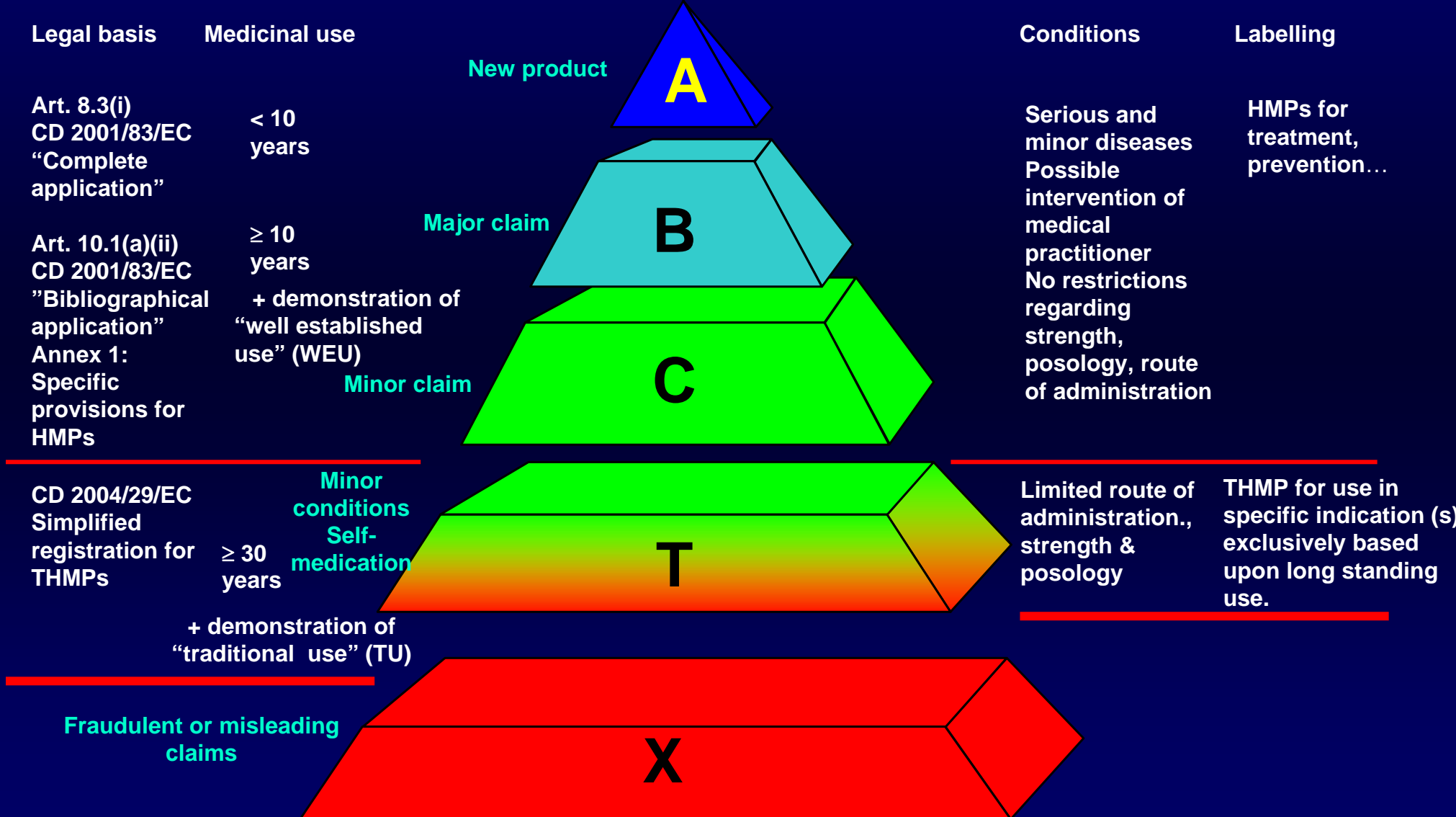
REGULATION 258/97

* COSMETICS

CD 76/768

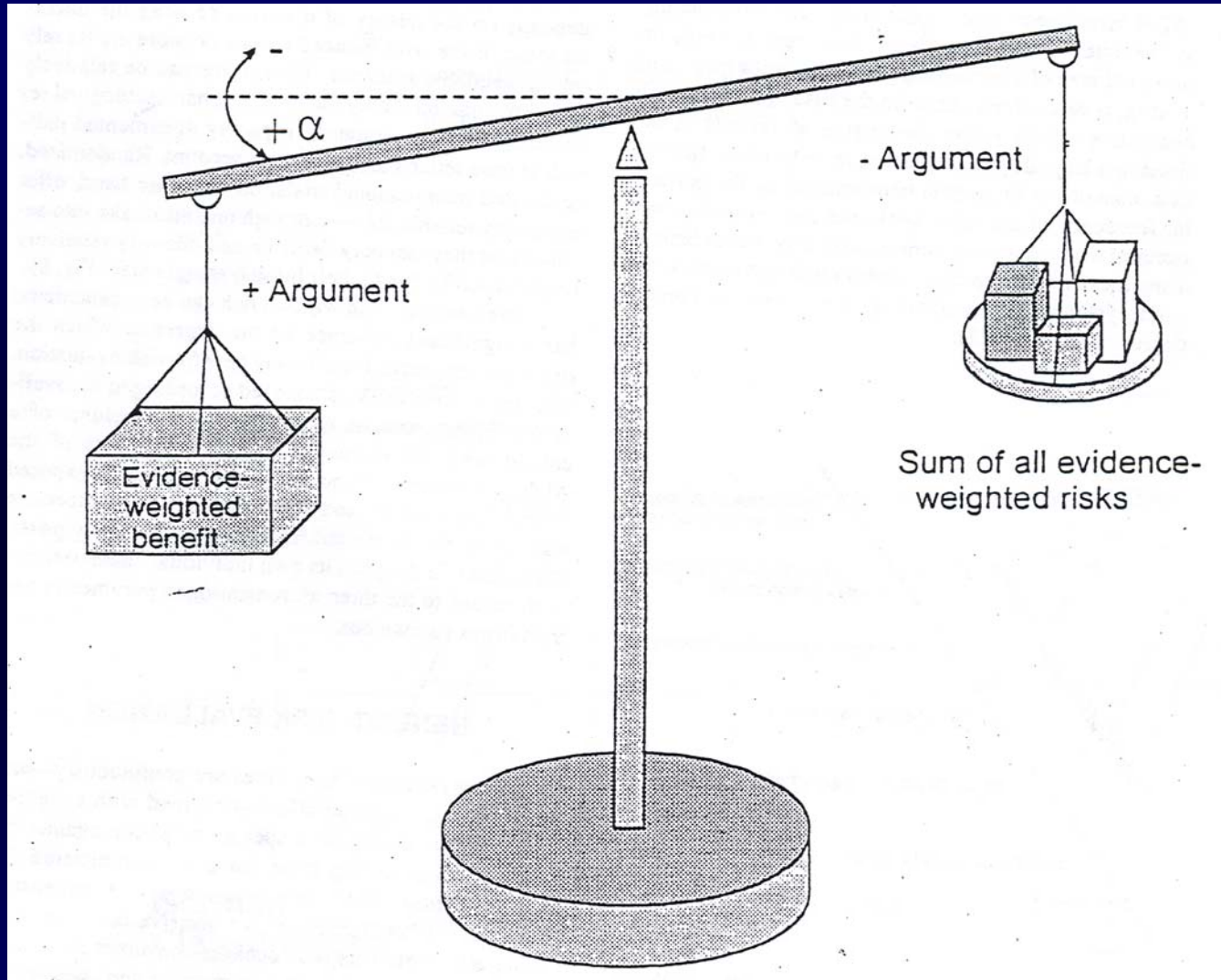
OVERVIEW OF LEGAL FRAMEWORK FOR HMPs IN THE EU

LEVEL OF EVIDENCE



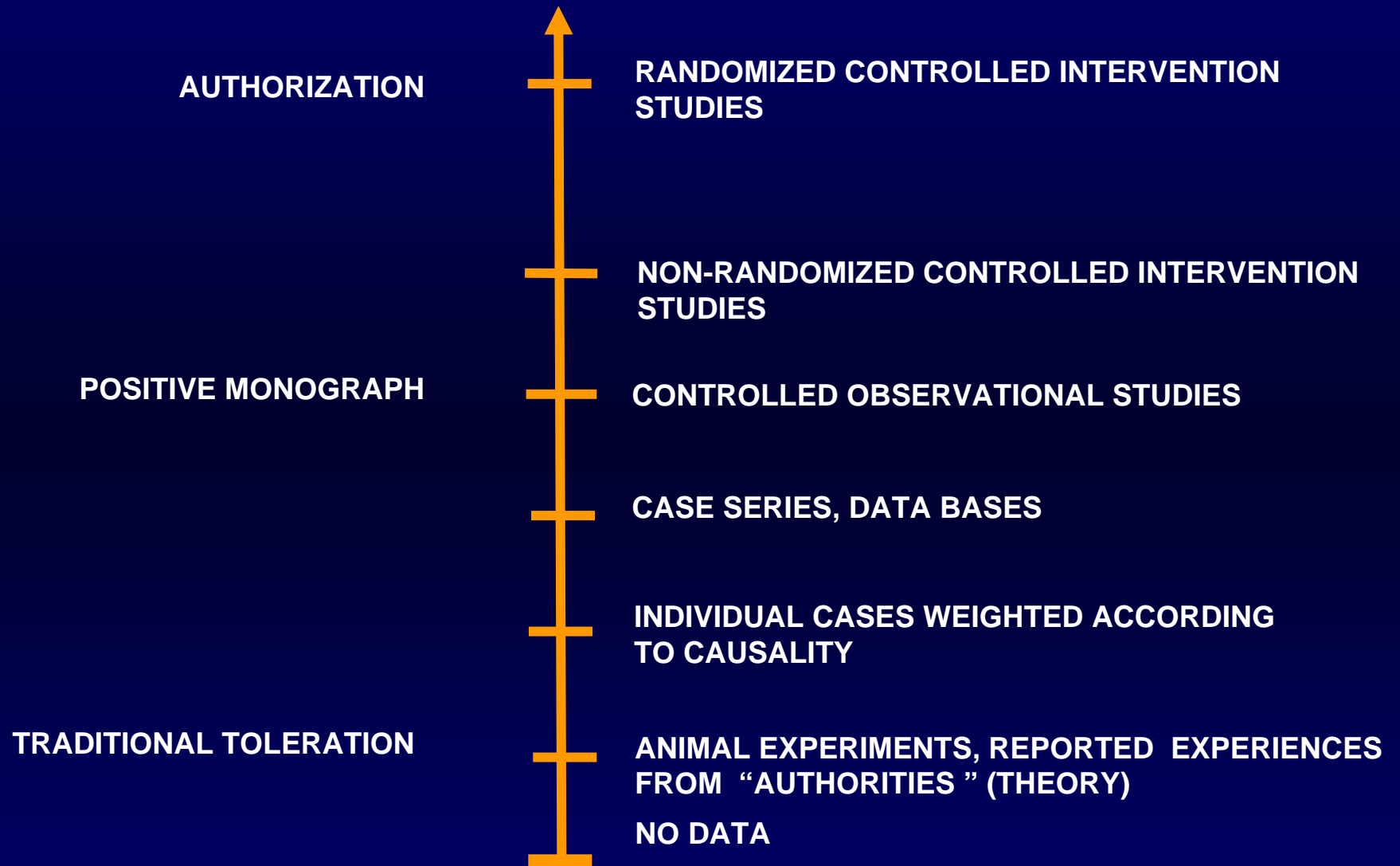
OVERVIEW OF LEGAL FRAMEWORK FOR HMPs IN THE EU

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



EVALUATION OF THE POSITIVE BENEFIT ARGUMENTS AGAINST THE NEGATIVE RISK ARGUMENTS WHEN ASSESSING A MEDICINAL PRODUCT

AFTER BECKMANN, 1999



HIERARCHY OF SOURCES

AFTER BECKMANN, 1999