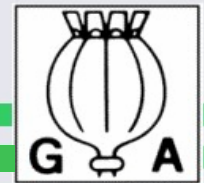




WORKSHOP of the GA on
Regulatory Affairs on Herbal Medicinal Products:

**Medicinal Herbs:
drugs or dietary supplements?**

**What are the legal consequences in terms of
quality, safety and efficacy of each option?**



U.S.A.

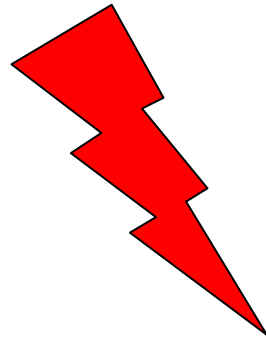
- > 30.000 botanical dietary supplements
- 1 approved botanical drug product
- despite of „Guidance for Industry, Botanic Drug Products“ (2000)

European Union

- heterogenous products in EU-MS
- **UK:** mostly food supplements
- **Germany:** 2444 HMP incl. 595 THMP (§109a AMG)
- Traditional HMP Directive 2004/27 EC amend. 2001/83/EC
- Food Supplements Directive (FSD) 2002/46/EC



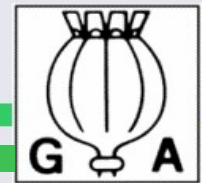
HMPC Community
Herbal Monographs
and List on THMP



Draft EU Consolidated
List on Health Claims
of Botanicals

Valeriana officinalis, Radix





HMPC Monograph - Traditional Use

- THMP for relief of mild symptoms of mental stress and to aid sleep.
- "The product is a traditional herbal medicinal product for use in specified indications exclusively based on long-standing use."
- Daily dose: 0,3-12 g of root

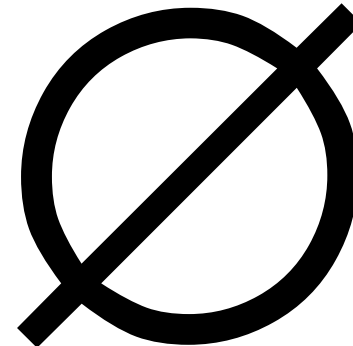
List on Health Claims of Botanicals

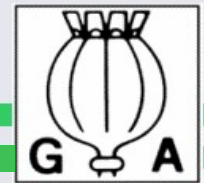
- Helps to maintain a natural sleep
- helps maintain normal quality of sleep
- helps you cope calmly with the stress of a busy lifestyle
- support of mental wellbeing in cases of tension and temporary stress
- contributes to optimal relaxation
- Daily dose: 1-10 g of root

HMPC Monograph - Traditional Use

- 4.3. Contraindications
“not in children < 12 years”
- 4.4. Special Warnings
- 4.5. Interactions
- 4.6. Pregnancy and Lactation
- 4.7. Effects on ability to drive
and use machines
- 4.8. Undesirable effects
- 4.9. Overdose (~ 20g)

List on Health Claims of Botanicals





HMPC Monograph
- Traditional Use

List on Health Claims
of Botanicals

What will the Consumer choose ?

What would the expert advise him to use ?

- 4.7. Effects on ability to drive and use machines
- 4.8. Undesirable effects
- 4.9. Overdose (~ 20g)



List on Health Claims of Botanicals

- ➔ NATURE OF EVIDENCE
 - textbook
 - monographs
 - clinical trials
 - systematic reviews of RCT
 - metaanalysis of RCT
 -



List on Health Claims of Botanicals

- ➔ NATURE OF EVIDENCE
 - textbook
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 -
- = **medical use to treat diseases**

List on Health Claims of Botanicals

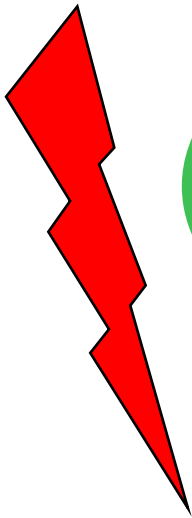


➔ *adequate to put out a candle light?*

= medical use to treat diseases

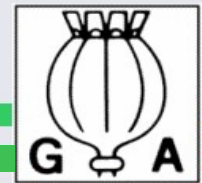
HMP / THMP

Various
Herbal Products



- ✓ Quality
- ✓ Efficacy or Tradition
- ✓ Safety
- ➔ Marketing Authorization

- ✓ Access to the market
- ✓ Cost – prize
- ✓ Innovations



- 13:05 A. Vlietinck, Member of the Committee of Herbal Medicinal Products (HMPC),
European Medicines Agency (EMA)
Viewpoint of the European Regulatory Authorities
- 13:30 W. Knöss, Head of Dep. Complementary + Alternative Medicines + Traditional
Medicines, Federal Institute for Drugs and Medical Devices (BfArM), Germany
Viewpoint of the German Regulatory Authorities
- 13:55 H. Sievers, Phytolab GmbH & Co, KG, Germany
Viewpoint of the European Pharmaceutical Industry
- 14:20 Coffee break*
- 14:50 V. Frankos, Director of Division of Dietary Supplement Programs,
Center for Food Safety and Applied Nutrition (CFSAN), USA
Viewpoint of the US Regulatory Authorities
- 15:15 M. McGuffin, President of the
American Herbal Products Association (AHPA), USA
Viewpoint of the US Industry
- 15:40 Panel discussion
- 16:50 Conclusions (S. Alban, A. Vlietinck)



PANEL DISCUSSION



CONCLUSION



*Thank you
for your attention and
your contributions !*