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

European Union

- heterogenous products in EU-MS
- UK: mostly food supplements
- Germany: 2444 HMP incl. 595 THMP (§109a AMG)
- 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
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)
4.3. Contraindications

"not in children < 12 years"

4.4. Special Warnings

4.5. Interactions

4.6. Pregnancy and Lactation

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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
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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
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 (EMEA)
      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!