

## **AESGP MEMBERS' MEETING**

# ***Impact of EU Legislative and Regulatory Requirements on the National Markets of Non-Prescription Medicines***



**4 February 2009**

**Ministry of Health and Consumer Affairs  
Paseo del Prado, 18-20, Madrid, Spain**

**On the Occasion of the 30<sup>th</sup> Anniversary of the  
Association of the Spanish Self-Medication Industry (*anefp*)**

## *Programme*

### **Tuesday, 3 February 2009**

**20.00** **WELCOME DRINK** followed by

**20.30** **DINNER** at the Hotel ME Madrid, Plaza de Santa Ana, 14, E-28012 Madrid

### **Wednesday, 4 February 2009**

**09.00** **OPENING** of the Members' Meeting at the Ministry of Health and Consumer Affairs, Paseo del Prado, 18-20, Ground floor, E-28014 Madrid, Spain  
Hans van ZONEN, President, AESGP

**09.15** **WELCOME**  
José MARTÍNEZ OLMOS, Secretary General, Ministry of Health and Consumer Affairs, Spain

**09.30** **THE EU LEGAL PROVISIONS FOR NON-PRESCRIPTION MEDICINES**  
Claire SCHARF KROENER, Pharmaceuticals Unit, Directorate-General Enterprise and Industry, European Commission

**10.00** **ROUNDTABLE: IMPACT OF THE POLITICAL AND LEGAL DEVELOPMENTS IN EUROPE ON THE PHARMACEUTICAL LEGISLATION FOR NON-PRESCRIPTION MEDICINES AT NATIONAL LEVEL**

- Claudio LEPORI, President, anefp
- Hubertus CRANZ, Director General, AESGP
- M<sup>a</sup> Teresa PAGÉS, Director General for pharmacy and health products, Ministry of Health and Consumer Affairs, Spain

**10.45** **Coffee/Tea Break**

**11.15** **HOW TO ENSURE EFFICIENT AUTHORISATION AND VARIATION PROCEDURES FOR NON-PRESCRIPTION MEDICINES**  
Chair: Jaume PEY, Vice President, anefp

- Anne AMBROSE, Medicines & Healthcare products Regulatory Agency (MHRA), United Kingdom
- Christelle ANQUEZ-TRAXLER, Regulatory and Scientific Affairs Manager, AESGP
- Jordi FAUS, Partner, Faus & Moliner, Spain
- Cristina AVENDAÑO SOLÁ, Executive Director, Spanish Medicines Agency

**12.45** **Lunch**

**14.00** **HOW TO BEST COMMUNICATE ON NON-PRESCRIPTION MEDICINES**  
Chair: Rafael GARCÍA GUTIÉRREZ, Director General, anefp

**14.10** **The EMEA policy on invented names**  
Zaide FRIAS, Chair, Invented Name Review Group (NRG), EMEA

**14.40** **“Umbrella brands” in Europe**  
Mick CLAYTON, Head Operation Unit Iberia, OTC, Novartis Consumer Health

**15.00** **Best package design for non-prescription medicines**  
Helen DARRACOTT, Director of Legal and Regulatory Affairs, The Proprietary Association of Great Britain (PAGB)

**15.30** **Coffee/Tea Break**

- 16.00 THE ACCEPTANCE OF “UMBRELLA TRADE NAMES” IN NATIONAL MARKETING AUTHORISATION PROCEDURES**
- Bernard MAURITZ, Director, Neprofarm, The Netherlands
  - Anne NOLAN, Chief Executive, Irish Pharmaceutical Healthcare Association (IPHA)
  - Hermann KORTLAND, Managing Director, BAH, Germany
  - Vincent COTARD, President, AFIPA, France
  - Federico PLAZA, Member of the *anefp* Board of Directors
- 17.30 CONCLUSIONS:** Hubertus CRANZ, Director General, AESGP  
**CLOSING REMARKS:** Consuelo SÁNCHEZ NARANJO, Vice-Minister of Health, Ministry of Health and Consumer Affairs, Spain
- 18.00 End of the meeting**

**Simultaneous interpretation will be provided in English and Spanish**

**CONFERENCE VENUE**

Ministry of Health and Consumer Affairs  
 Paseo del Prado, 18-20, Ground floor  
 E-28014 Madrid, Spain

**CONFERENCE HOTEL AND VENUE FOR OPENING EVENING**

Hotel ME Madrid  
 Plaza de Santa Ana, 14  
 E-28012 Madrid, Spain

[How to get from the hotel to the meeting venue](#)

**CONFERENCE SECRETARIAT**

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To register, please use the **Registration Form** available at:  
[www.aesgp.be/Madrid2009/Madrid2009RegistrationForm.doc](http://www.aesgp.be/Madrid2009/Madrid2009RegistrationForm.doc)

**Room bookings** at the **Hotel ME Madrid Reina Victoria** can be made  
 by using the **Guest Room Reservation Request** available at:  
[www.aesgp.be/Madrid2009/MadridRoomReservationRequest.doc](http://www.aesgp.be/Madrid2009/MadridRoomReservationRequest.doc)