

# Understanding the **specifics** of non-prescription medicines

# conference

4-5 November 2008

Hilton Arc de Triomphe Hotel, Paris

**AESGP** 

ASSOCIATION OF THE EUROPEAN  
SELF-MEDICATION INDUSTRY

# Objectives of the conference

During the UK EU Council Presidency in November 2005 and the German EU Council Presidency in February 2007 AESGP organised conferences respectively in London and Dresden to discuss how to put better regulation and administrative simplification for non-prescription medicines in reality.

During the debates, it became evident that there is a need to better clarify the difference between prescription and non-prescription medicines.

AESGP is therefore organising a conference during the French EU Presidency to analyse the specifics of non-prescription medicines. This will be held back-to-back with the Heads of Medicines Agencies meeting in the same place and has been organised in close cooperation with the French Medicines Agency AFSSAPS (Agence Française de Sécurité Sanitaire des Produits de Santé). It will allow discussing appropriate legislation and regulation for non-prescription medicines in the context of the envisaged new Communication and several legislative proposals of the European Commission, which are expected to address new challenges in the context of globalisation. To what extent the current marketing authorisation procedures (central, decentralised/mutual recognition/national) sufficiently address the particularities of the non-prescription medicines sector will be another key topic.

The conference is a major event for everybody involved in the area of self-care and interested in its future regulatory environment.

## Programme

### TUESDAY, 4 NOVEMBER 2008

19.00 Buses depart from the Hilton Arc de Triomphe Hotel for the Opening evening

19.30 Reception followed by dinner at the Pré Catelan  
Route de Suresnes, Bois de Boulogne, F-75016 Paris

Welcome by Vincent COTARD, President of the Association of the French Self-Medication Industry AFIPA

### WEDNESDAY, 5 NOVEMBER 2008

8.00 Registration and welcome coffee

9.00 PHARMACEUTICALS IN TIME OF GLOBALISATION: HOW TO BEST REGULATE NON-PRESCRIPTION MEDICINES?

Chair: Hans van ZOONEN, President, AESGP

9.10 The envisaged new measures of the European Commission

Martin TERBERGER, Head of Unit Pharmaceuticals, Directorate-General Enterprise and Industry, European Commission

9.40 The perspective of a national authority

Jean MARIMBERT, Director General, Agence Française de Sécurité Sanitaire des Produits de Santé (Afssaps)

10.00 The perspective of the EMEA

Noël WATHION, Head of Unit, Post-Authorisation Evaluation of Medicines for Human Use, EMEA

Discussion

10.30 Coffee/Tea Break

**11.00 HOW TO EVALUATE NON-PRESCRIPTION MEDICINES IN THE MOST EFFICIENT WAY?**

11.10 The perspective of the Heads of Medicines Agencies (HMA)

Jytte LYNGVIG, Chair of the HMA's Management Group

11.30 The perspective of the EMEA Committee for Medicinal Products for Human Use (CHMP)

Eric ABADIE, Chairman of the CHMP, EMEA

11.50 The perspective of the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMD(h))

Christa WIRTHUMER-HOCHE, Member of the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMD(h))

Discussion

12.30 Lunch

**14.00 PERFORMANCE OF NATIONAL AGENCIES: HOW TO BEST COPE WITH THE WORKLOAD?**

14.00 Benchmarking of national agencies

Pat O'MAHONY, Chief Executive Officer, Irish Medicines Board, Ireland

14.25 How to best balance resources between centralised, mutual recognition, decentralised and national procedures?

Johannes LÖWER, President, Paul-Ehrlich-Institut, Germany

14.50 Applying "Better Regulation" principles in a national agency

Hannes WAHLROOS, Director General, National Agency for Medicines, Finland

Discussion

15.15 Making non-prescription medicines available all over Europe

Kristin RAUDSEPP, Director General, Estonian State Agency of Medicines

15.30 Coffee/Tea Break

**16.00 MAKING CONCRETE PROGRESS AT NATIONAL LEVEL IN THE AUTHORISATION OF NON-PRESCRIPTION MEDICINES**

Panel discussion with the participation of:

- Vassilis KONTOZAMANIS, President, National Organisation for Medicines, Greece
- Vasco MARIA, President of the Executive Board, INFARMED, Portugal
- Guido RASI, Director General, AIFA, Italy
- Zsuzsanna SZEPEZDI, Director General, National Institute of Pharmacy, Hungary

17.30 Conclusions

Hubertus CRANZ, Director General, AESGP

18.00 Farewell drink

# Conference venue

Hilton Arc de Triomphe Paris  
51-57, rue de Courcelles  
F-75008 Paris / France  
Tel. : +33 1 58 36 6700 (general)  
Fax : +33 1 58 36 6777

Deluxe room (single or double use) : 280 Euro

The rate is quoted per room, per night and includes VAT. A buffet breakfast is available at 30 Euro per person.

Room reservations should be made before **23 September 2008**.

After this date, rate and availability are no longer guaranteed.

**Please make your room bookings online via the following link:**

[http://www.hilton.com/en/hi/groups/personalized/PARDTHI\\_GAESG/index.jhtml](http://www.hilton.com/en/hi/groups/personalized/PARDTHI_GAESG/index.jhtml)

## Registration

### **Conference Secretariat:**

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For more information on AESGP and its meetings, you may visit the AESGP website at [www.aesgp.be](http://www.aesgp.be).

### **Registration fee: 500 Euro**

The fee includes participation in the reception followed by dinner at the Pré Catelan on 4 November, the meeting, lunch and coffee breaks on 5 November 2008. Comprehensive conference material will be provided.

**We recommend registration before 13 October 2008.**

**Cancellations:** For cancellations received after 20 October 2008, the whole fee is withheld