

# **AESGP WORKSHOP WITH THE HEADS OF EU MEDICINES' AGENCIES**

A new approach for the benefit-risk  
assessment of non-prescription medicines

**21-22 FEBRUARY 2012**

SCANDIC COPENHAGEN HOTEL  
DENMARK



ASSOCIATION OF THE EUROPEAN  
SELF-MEDICATION INDUSTRY

# PROGRAMME

## TUESDAY, 21 FEBRUARY 2012

- 18.45 Buses to leave the Scandic Copenhagen Hotel
- 19.00 Opening Evening at the Ny Carlsberg, Glyptotek, Dantes Plads 7, Copenhagen
- Welcome by **Jytte LYNGVIG**, Chief Executive Officer, Danish Medicines Agency and  
**Hans REGENAUER**, AESGP President

## WEDNESDAY, 22 FEBRUARY 2012

- 09.00 Opening and background of the workshop:  
**Hans REGENAUER**, AESGP President
- 09.15 **Adequate assessment of non-prescription medicines – a new approach:**  
**Professor Eric BRASS**, University of California, Los Angeles, United States of America
- 10.15 **The perspective of the Heads of EU Medicines' Agencies:**  
**Jytte LYNGVIG**, Chief Executive Officer, Danish Medicines Agency
- Discussion**
- 11.00 **Coffee/Tea Break**
- 11.30 **How to best identify the benefits of non-prescription medicines**  
**Panel discussion with the participation of:**
- **Pat O'MAHONY**, Chief Executive Officer, Irish Medicines Board
  - **Marcus MÜLLNER**, Head, Medicines and Medical Devices Agency, Austria
  - **Noël WATHION**, Head of Unit, Patient Health Protection, European Medicines Agency (tbc)
  - **Jorge TORGAL**, President, INFARMED, Portugal
  - **Patricia VELLA BONANNO**, Chief Executive Officer, Medicines Authority, Malta
  - **Werner KNÖSS**, Federal Institute for Drugs and Medical Devices (BfArM), Germany
- 13.00 **Lunch**

## 14.30 **How to best assess and communicate the risks of non-prescription medicines**

### Panel discussion with the participation of:

- **Kent WOODS**, Chairman of the EMA Management Board, Chief Executive, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom
- **Aginus KALIS**, Executive Director, Medicines Evaluation Board, Netherlands
- **Xavier DE CUYPER**, Chief Executive Officer, Federal Agency for Medicines and Health Products, Belgium
- **Grzegorz CESSAK**, President, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Poland
- **Maria SKOUROLIAKOU**, Vice-President, National Organization for Medicines, Greece

## 16.00 **Coffee/Tea Break**

## 16.30 **The way forward:**

- **Guido RASI**, Executive Director, European Medicines Agency (tbc)
- **Jytte LYNGVIG**, Chief Executive Officer, Danish Medicines Agency
- **Hubertus CRANZ**, AESGP Director General

## 17.30 **End of the meeting**

## OBJECTIVES OF THE CONFERENCE

In the context of an ageing population and social security systems that are already under a lot of pressure, self-care is bound to play a much more significant role in the future and respond to patients' growing aspiration to be empowered. However for this to happen, self-care should be given the latitude to fulfil its promises. The number of active pharmaceutical substances available to the public without a medical prescription has been growing quite slowly over the last years with a pace varying from one country to another. In addition, some well-established ingredients have been scrutinised and some have even been withdrawn from the market or were reverted to prescription status. There are concerns that this will lead to a reduction of consumer choice and, in the end, to fewer possibilities to practise responsible self-care.

In the whole pharmaceutical sector considerable efforts are underway to come to a more coherent benefit-risk assessment. A benefit-risk modelling

project was initiated by the European Medicines Agency and is expected to deliver concrete results in 2012. Complementing and building on these activities, the self-medication industry has on the global level commissioned important research aiming at reaching consensus on a more adequate benefit-risk assessment for non-prescription medicines. The research is expected to be published in early 2012 and will be the basis for a wide range of discussions with all stakeholders interested in non-prescription medicines.

The workshop in Copenhagen will provide a unique opportunity to discuss the results of this important research with the Heads of the EU Medicines' Agencies and to look at new proposals for an adequate benefit-risk assessment of non-prescription medicines.

The workshop in Copenhagen, organised under the Danish EU Presidency, is the 5th AESGP conference held in conjunction with the Heads of EU Medicines Agencies.



## OPENING EVENING

The Opening Evening on Tuesday, 21 February 2012 will take place from 19.00 hours onwards at: **Ny Carlsberg Glyptotek**, Dantes Plads 7, 1556 Copenhagen, Denmark.

Thy Ny Carlsberg Glyptotek [www.Glyptoteket.dk](http://www.Glyptoteket.dk) is holding one of the largest private art collections of this time. The Opening Evening will take place in the Wintergarden of the Glyptotek.

Buses will leave the Scandic Copenhagen Hotel at 18.45 hours and will return at 22.00 hours.

## Who should attend

The event is highly recommended to everyone interested in the assessment of non-prescription medicines and the long-term perspectives of the self-care industry.

## CONFERENCE SECRETARIAT AESGP

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Updated information on the conference programme will be provided on the AESGP website [www.aesgp.be](http://www.aesgp.be)

### • **Registration fee: 500 euro**

The fee includes participation in the AESGP Opening Evening in the Glyptotek and the workshop, lunch and coffee breaks at the Scandic Copenhagen Hotel. Please note that AESGP is unable to accept credit card payment at this point in time. Registration should be made by using the enclosed registration form.

We recommend registration **before 1 February 2012**.

### • **Cancellations**

For cancellations received after 1 February 2012, the whole fee is withheld.



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SELF-CARE: THE FIRST CHOICE IN HEALTH CARE

## VENUE OF THE WORKSHOP

The Workshop will take place on Wednesday, 22 February 2012 from 09.00 until 17.30 hours at the:

### **Scandic Copenhagen Hotel**

Vester Soegade 6  
DK-1601 Copenhagen, Denmark  
Tel.: +45 33 14 35 35  
Fax: +45 33 32 12 23  
E-mail: [copenhagen@scandichotels.com](mailto:copenhagen@scandichotels.com)  
Website:  
[www.scandichotels.com/Copenhagen](http://www.scandichotels.com/Copenhagen)



Guest rooms have been blocked at the Scandic Copenhagen Hotel for the nights of 20 to 23 February 2012. The room rate for single occupancy is DKK 1,200 and is inclusive of breakfast and Wifi.

### • **Room reservation:**

The room should be booked online by using the following link [www.scandichotels.com/copenhagen](http://www.scandichotels.com/copenhagen) and the booking code BAES200212.

**The deadline for booking is 20 December 2011.** After this date all rooms will be released and rooms and rates can no longer be guaranteed. For a valid booking credit card details must be provided.