

marketplace

REALISING THE SELF-CARE POTENTIAL

regulation

policy



Four Seasons Ritz Hotel
Lisbon, Portugal
5-7 June 2013

AESGP 

ASSOCIATION OF THE EUROPEAN
SELF-MEDICATION INDUSTRY

REALISING THE SELF-CARE POTENTIAL

The significant public health and economic value of self-care is undeniable and well recognised across Europe. There is however still a long way to go before one could argue that the self-care potential is fully realised to the benefit of European citizens. The 49th AESGP Annual Meeting aims precisely at examining the magnitude of the real self-care potential and identifying how to best organise health systems to effectively yield these benefits.

The 49th AESGP Annual Meeting will cover the latest developments in the marketplace and the regulatory and policy environment impacting self-care. Marketplace, regulation and policy will also be the three perspectives from which the value of self-care will be reviewed and case studies presented. The three themes will run throughout the conference to allow a structured and in-depth analysis and facilitate discussions between presenters and conference participants.

The self-care sector industry leaders present at the 49th AESGP Annual Meeting will discuss the industry's key role in promoting innovation and provide their vision on the future opportunities for self-care.

The conference programme will cover self-care products including non-prescription medicines, herbal medicines and food supplements and update participants on the latest developments concerning new legislation in the area of self-care medical devices. Key policy decision makers and regulators will join industry speakers and conference participants in examining the current environment and addressing how to overcome challenges in order to ensure and facilitate high-quality, effective and safe products reaching European citizens.

Understanding the needs of consumers and case studies of policy measures and activities to educate and empower citizens will also be presented at the conference, as will the critical role health professionals can play in realising the self-care potential. Moreover, the conference will look at obligations and opportunities in establishing a corporate environment of social responsibility.

The business programme will provide a unique forum for exchanging ideas and experiences. The 49th AESGP Annual Meeting will bring together high-level representatives from European institutions and national competent authorities, health professional organisations, academia and industry. The social programme will also provide ample opportunity for networking and informal discussions.

Wednesday 5 June 2013

12.00 Lunch

14.00 **Introduction to the conference: Setting the agenda for the self-care sector**

The conference programme, structure and objectives are presented in a session which will also provide an overview of where the self-care sector currently stands. Focus on the latest market figures will allow observations on the impact that policy and economic developments have on the market from a global perspective.

- Hans REGENAUER, President, AESGP
- Emma WALMSLEY, President, GlaxoSmithKline Consumer Health
- Andy TISMAN, Senior Principal, IMS Health

How to be successful in self-care. The industry leadership's vision for the self-care sector's future

Industry leaders will present their outlook on where the self-care sector is headed and how to achieve success in a changing environment. Challenges and opportunities for further development in the marketplace will be presented in a session where the sector's leadership will provide conference participants with the best informed insights.

- Brian McNAMARA, Division Head OTC, Novartis Consumer Health
- Erica MANN, Member of the Bayer Health Care Executive Committee and Head of the Consumer Care Division
- Briain DE BUILLEIR, CEO, PGT Healthcare (Procter & Gamble / Teva Joint Venture)
- Bridgette HELLER, President, MSD Consumer Care
- Paul L. STURMAN, President, Pfizer Consumer Healthcare
- Vincent WARNERY, Vice President Consumer Healthcare Europe and Global Development, Sanofi
- David WRIGHT, Senior Vice President and Global Head, Boehringer Ingelheim Consumer Health Care

marketplace

18.00 End of session

18.45 Buses depart for opening evening

19.15 Opening evening at the Palácio Nacional de Queluz

09.00

market place

Meeting citizens' information and communication needs: Defining, naming and promoting self-care products

This session will focus on consumers' self-care perceptions and expectations and examine whether policy measures are aligned with the public's needs. A case study on promoting awareness on self-care products will provide further practical insight and guide the discussion on whether policy measures are successfully meeting their objectives when translated into marketplace practices.

Chair: Joerg OHLE, Vice President, AESGP and Head of Europe, Bayer Consumer Care

- **New research on the public's perceptions of self-care**
Anton van de PUTTE, Member of the Board, Bundesverband der Arzneimittel-Hersteller (BAH), Germany
- **The consumer's expectations**
Ilaria PASSARANI, Senior Health Policy Officer, European Consumer Organisation (BEUC)
- **How to best communicate with consumers**
Prof. Helder MOTA-FILIFE, Vice President, Autoridade Nacional do Medicamento e Produtos de Saúde (Infarmed), Portugal
- **A 2.0 strategy to connect pharmacies and citizens**
Albert PANTALEONI and Yolanda SANCHÍS, Almirall Pharmacy Club, Spain

10.30

Coffee/Tea Break

11.00

regulation

Switch: A key driver of innovation in self-care

How to appropriately respond to the public health and citizens' needs for innovation and access to effective and safe products of high quality is addressed in this session. A case study on product re-classification and regulatory considerations on switches together with the pharmacist's perspective provide a comprehensive overview of the challenges and opportunities driving innovation in self-care.

Chair: Roger SCARLETT-SMITH, Vice President, AESGP and President, GSK Consumer Healthcare Europe

- **A case study of a new self-care indication: The Flomax Relief Rx-to-OTC switch in the United Kingdom**
Paul CARTER, Global Head Consumer Health Care, Development, Medicine and Regulatory Affairs, Boehringer Ingelheim
- **Regulatory considerations for reclassification - the Portuguese case**
João CRISTÓVÃO MARTINS, Director, Medicines Evaluation Department, Autoridade Nacional do Medicamento e Produtos de Saúde (Infarmed), Portugal
- **The pharmacist's perspective on switches**
Maximin LIEBL, President, Pharmaceutical Group of the European Union (PGEU)

12.30

Lunch

14.00

regulation

Getting it right: Finding the right balance in the regulation of health claims for self-care products

This session will cover developments in the areas of herbal medicines and food supplements. The impact of the 2006 health claims legislation will be examined together with the recent experience concerning the development of monographs and list entries for herbal substances.

Chair: Udit BATRA, President & CEO Consumer Healthcare, Merck KGaA and Chair of the AESGP Food Supplements Committee

- Catherine GESLAIN-LANÉELLE, Executive Director, European Food Safety Authority (EFSA)
- Basil MATHIOUDAKIS, Head of Nutrition, food composition and information, European Commission
- Werner KNÖSS, Chair, Herbal Medicinal Products Committee (HMPC), European Medicines Agency (EMA)

15.30

Coffee/Tea Break

16.00

The role and potential of the medical devices sector in self-care

Developments in the area of self-care medical devices will be covered in this session, which will also examine this growing sector's role and potential in self-care in general.

Chair: Dagmar ROTH-BEHRENDT, Member of the European Parliament and Rapporteur for the European Parliament on the proposed Regulation on medical devices

- Despina SPANOU, Director for Consumer Affairs, European Commission
- Gert BOS, President, European Association of Notified Bodies for Medical Devices (TEAM-NB)
- Maria CARLETON, Irish Medicines Board (IMB)

17.30

End of session

National dinners



09.00

A policy framework fostering innovation and empowering citizens to self-care

A policy environment fostering innovation and empowering citizens to self-care is essential to realising self-care's full potential in Europe. This session will examine whether self-care's significant potential contributions are effectively communicated and understood. This in order to drive policy decision-making towards facilitating the practice of responsible self-care and promoting innovation through the sustainable development of the self-care sector. The session will include an update on important legislative developments in the pharmaceutical sector.

Chair: Hans REGENAUER, President, AESGP

- Tonio BORG, Member of the European Commission responsible for Health and Consumers
- Paulo MACEDO, Minister of Health, Portugal
- Dagmar ROTH-BEHRENDT, Member of the European Parliament

Policy

10.30

Coffee/Tea Break

11.00

Good governance in the self-care sector

Results of the concrete work initiated by the European Commission on a new self-care policy will be presented in this session. Activities to ensure the establishment of a transparent and accountable environment in the pharmaceutical sector will complement the discussion.

Chair: Hubertus CRANZ, Director General, AESGP

- Daniel CALLEJA CRESPO, Director-General, Enterprise and Industry, European Commission
- June RAINE, Director of Vigilance and Risk Management of Medicines, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom
- Eurico CASTRO ALVES, President, Autoridade Nacional do Medicamento e Produtos de Saúde (Infarmed)

Policy

12.30

Lunch



14.00

POLICY

Empowering citizens to practise responsible self-care

A global perspective of actions that inform and educate citizens to practise responsible self-care will be provided through case studies. By demonstrating how to involve and empower citizens in the practice of responsible self-care, the session will put the importance and value of realising the full self-care potential in context.

Chair: Hans REGENAUER, President, AESGP

- **A practice promoting better lives for all citizens across the world**
Zhenyu GUO, Chair, World Self-Medication Industry (WSMI)
- **Self-care school education programmes in Japan**
Akira UEHARA, Chair and CEO, Taisho Pharmaceutical Co, Japan
- **Self-care policy in Portugal**
Maria de BELÉM ROSEIRA, Member of Parliament, former Minister of Health, Portugal
- **Making concrete progress: The UK Self-Care Week**
Sheila KELLY, Executive Director, Proprietary Association of Great Britain (PAGB)

15.40

Realising the self-care potential

Conclusions and invitation to the 50th AESGP Annual Meeting and 8th WSMI General Assembly in London, 3-5 June 2014

16.00

Coffee/Tea at the end of the business programme

18.30

Buses depart for the closing event

19.00

Closing event, reception and dinner

www.aesgp.eu/49





CONFERENCE VENUE AND ROOM BOOKING

The 49th AESGP Annual Meeting will take place at the :

Four Seasons Ritz Lisbon Hotel

Rua Rodrigo da Fonseca, 88
Lisbon 1099-039 - Portugal

Tel: +351 (21) 381 14 00 (general)

Tel: +351 (21) 384 30 01 (reservations)

Fax: +351 (21) 383 17 83 (general)

Fax: +351 (21) 384 30 34 (reservations)

E-mail: maria.ribeiro@fourseasons.com

Web: <http://www.fourseasons.com/lisbon>

The hotel is located in the city centre near the Eduardo VII Park and about 7 km from the International Airport. Transfer by taxi takes around 15 minutes.

The conference sessions will take place in the Ballroom of the Four Seasons Ritz Lisbon Hotel.

Room booking and rates

Block reservations have been made at the Four Seasons Ritz Lisbon Hotel from Monday 3 June 2013 until Sunday 9 June 2013.

Room rates:

Single room: € 250.00

Double room: € 250.00

The rates quoted are per room, per night, and include American buffet breakfast, complimentary internet access in the conference area, service charge and the current VAT rate of 6%. Check-in time is 15.00 hours and check-out time 12.00 hours. The rates are valid for reservations made until 29 March 2013; after this date rates are no longer guaranteed and rooms are attributed upon availability.

Reservations can be made using the Four Seasons Ritz Lisbon Hotel Reservation Form posted on the conference website aesgp.eu/49.

ADDITIONAL GUEST HOTELS

Tiara Park Atlantic Lisboa

Rua Castilho, 149

1099-034 Lisboa - Portugal

Tel: +351 (21) 391 87 00

Fax: +351 (21) 389 05 00

E-mail: margarida.janeiro@tiara-hotels.com

Web: www.tiara-hotels.com



Room booking and rates

Block reservations have been made at the Tiara Park Atlantic Lisboa Hotel from Monday 3 June 2013 until Sunday 9 June 2013. The Tiara Park Atlantic Lisboa Hotel is situated opposite the Four Seasons Ritz Lisbon Hotel.

Room rates:

Single room: € 145.00

Double room: € 165.00

The rates quoted are per room, per night, and include buffet breakfast, service charge and the current VAT rate of 6% as well as complimentary internet in the bedrooms and public areas.

Reservations may be made by using the Tiara Park Atlantic Lisboa Hotel Reservation Form posted on the conference website aesgp.eu/49 or by using the online registration system (link available on the conference website).

Sana Lisboa Hotel

Av. Fontes Pereira de Melo, 8
1069-310 Lisboa - Portugal

Tel: + 351 (21) 006 43 00

Fax: + 351 (21) 006 43 01

E-mail: grp2.lisboa@sanahotels.com

Web: www.lisboa.sanahotels.com

Room booking and rates

Block reservations have been made at the Sana Lisboa Hotel from Monday 3 June 2013 until Sunday, 9 June 2013. The Sana Lisboa Hotel is situated at about 700 metres from the Four Seasons Ritz Lisbon Hotel.

Room rates:

Single room: € 90.00

Double room: € 100.00

The rates quoted are per room, per night, and include buffet breakfast, service charge and the current VAT rate of 6% as well as complimentary internet in the bedrooms.

Reservations may be made by using the Sana Lisboa Hotel Reservation Form posted on the conference website aesgp.eu/49 or by using the online registration system (link available on the conference website).

CONFERENCE LANGUAGE

All presentations on 5, 6 and 7 June 2013 will be given in English.

PLANNING YOUR PARTICIPATION

The 49th AESGP Annual Meeting will open on Wednesday 5 June 2013 at 12.00 hours with a lunch at the Fernando Pessoa restaurant of the Four Seasons Hotel Ritz and will end on Friday 7 June 2013 with a reception and dinner.

The AESGP welcome desk, at the Four Seasons Ritz Lisbon Hotel, is open on:

Wednesday 5 June 2013
from 11.00 till 18.00 hours.

Thursday 6 June 2013
from 08.00 till 17.30 hours.

Friday 7 June 2013
from 08.00 till 16.30 hours.

REGISTRATION

Conference Secretariat:

AESGP
7, Avenue de Tervuren
B-1040 Brussels / Belgium
Tel.: +32 2 735 51 30
Fax: +32 2 735 52 22
E-mail: b.klimka@aesgp.eu

REGISTRATION FEES:

Congress participant: € 1,350
Accompanying family member: € 300

Both fees include participation in the opening reception and dinner on Wednesday 5 June 2013 at the Palácio Nacional de Queluz and in the reception and dinner on Friday 7 June 2013. The fee for congress participants also



covers participation in the conference as well as the lunches on Wednesday 5 June, Thursday 6 June and Friday 7 June 2013. The fee for accompanying family members includes participation in the tour to Sintra and Cascais (lunch included) on Thursday 6 June 2013.

A conference website has been set up at aesgp.eu/49 on which the updated programme, speaker profiles and available presentations will be posted. Registrations can be made online via the conference website or by using the Conference Registration Form posted on the conference website aesgp.eu/49.

Please note that AESGP is unable to accept credit card payment at this point in time.

We advise registration before 15 May 2013.



SOCIAL PROGRAMME

All participants and accompanying persons are invited to attend the opening evening at the Palácio Nacional de Queluz on Wednesday 5 June 2013 and the reception and dinner on Friday 7 June 2013.

On Wednesday 5 June 2013, buses will depart from the Four Seasons Ritz Lisbon Hotel for the Palácio Nacional de Queluz at 18.45 hours. They will return to the hotels from 22.30 hours onwards.

On Friday 7 June 2013 buses will depart from the Four Seasons Ritz Lisbon Hotel at 18.30 hours. A shuttle bus service back to the hotels is available from 22.30 hours onwards.

Accompanying family members not attending the conference are invited to take part in a guided tour to Sintra and Cascais on Thursday 6 June 2013 from 9.00 to 17.00. The tour bus will depart from the Four Seasons Ritz Lisbon Hotel at 09.00 hours. Please indicate on the registration form whether you intend to participate in any of these social events.

ATTIRE Business attire is recommended for the opening reception and dinner at the Palácio Nacional de Queluz on Wednesday 5 June 2013. Casual dress is recommended for the reception and dinner on Friday 7 June 2013.

WHO SHOULD ATTEND The programme is designed for executives and professionals from the pharmaceutical industry, the health professions, regulatory and governmental authorities and universities seeking information on market and regulatory trends on non-prescription medicines, food supplements and self-care medical devices. The social programme will allow networking with representatives from national and international authorities and organisations, the health professions, academia and industry.

CANCELLATIONS:

Cancellations received before 15 May 2013 will be refunded less a handling charge of 50 Euro.

For cancellations received after 15 May 2013, 50% of the fee is withheld.

For cancellations received after 21 May 2013, the whole fee is withheld.

Updated information on the conference programme will be provided on the conference website aesgp.eu/49

49th AESGP Annual Meeting

Four Seasons Ritz Hotel
Lisbon, Portugal
5-7 June 2013

AESGP

7, Avenue de Tervuren
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Web : www.aesgp.eu

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on the conference website

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Self-care: the first choice in health care



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