

Conference with
the Heads of
EU Medicines
Agencies

AESGP 

LISBON

26 - 27 February 2018

Public and Consumer Health Future Priorities for EU Medicines Agencies



Objectives of the conference

Self-care is nowadays recognised as a key element of healthcare. The report on "Good governance of non-prescription medicines", which was endorsed by all EU Member States and relevant stakeholders, explains concrete ways how to further strengthen the role of self-care as the first choice in healthcare.

This report paved the way to the inclusion of specific recommendations in the first ever European Union Medicines Agencies Network Strategy and multi-annual work programme calling for improved access to well-established including non-prescription medicines, e.g. through efforts related to regulatory optimisation. In addition, the Co-ordination Group for Mutual Recognition and Decentralised Procedures (CMDh) advocates in its 2020 Strategy easier access to non-prescription medicines and suggests a number of concrete actions in its Multi-Annual Work Plan.

In addition to this, the final report on the Pilot project on the promotion of self-care systems in the European Union (PiSCE) calls for additional efforts to include guidance to self-care in school education and in curricula for health professionals.

All this together is an excellent basis for discussing the implementation of policy orientations with the heads of the EU medicines agencies and their colleagues taking into account the proposals of the AESGP Self-Care Agenda 2020. Particular attention will be paid to the impact of Brexit, but also to the potential use of real world / big data for regulatory decision making in the context of non-prescription medicines. One session will be dedicated to substance-based medical devices in order to discuss the significant impact of new legislation on medicines agencies.

The conference follows a long standing tradition to facilitate exchange between the Heads of the EU Medicines Agencies and the European Self-Care industry. Results of previous meetings are available at www.aesgp.eu/events/previous/.

**Opening
Event**

Monday, 26 February 2018

19.30 Reception and Dinner

Welcome by **Maria do Céu Machado**, *President, Infarmed, Portugal*, and **Birgit Schuhbauer**, *AESGP President*

PROGRAMME

Tuesday, 27 February 2018

08.30 Welcome coffee

09.00 Session 1

Self-Care as the First Choice in Healthcare – Which Issues Need To Be Addressed By Medicines Agencies?

Moderated by **Christa Wirthumer-Hoche**, *Chair of the Management Board of the European Medicines Agency (EMA) and Head of the Austrian Medicines and Medical Devices Agency (AGES MEA)*

- **Klaus Cichutek**, *Chair of the HMA Management Group*
- **Assena Stoimenova**, *Executive Director, Bulgarian Medicines Agency*
- **Rui Santos Ivo**, *Vice-President, Infarmed, Portugal*
- **Andreja Čufar**, *Executive Director, Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (JAZMP), Slovenia*

10.30 Coffee / Tea

11.00 Session 2

Regulatory Optimisation

Moderated by **Hugo Hurts**, *Director, Medicines Evaluation Board (MEB), The Netherlands*

- **Ian Hudson**, *Chief Executive, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom*
- **Karl Broich**, *Director General, Federal Institute for Drugs and Medical Devices (BfArM), Germany*
- **Zaide Frias**, *Head of Human Medicines Evaluation Division, European Medicines Agency (EMA)*

12.30 Lunch

14.00 Session 3

The Impact of the New Medical Device Regulation

Moderated by **Xavier de Cuyper**, *Chief Executive Officer, Federal Agency for Medicines and Health Products (FAMHP), Belgium*

- **John Wilkinson**, *Director, Medical Devices, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom*
- **Lorraine Nolan**, *Chief Executive, Health Products Regulatory Authority (HPRA), Ireland*
- **Nicolae Fotin**, *President, National Agency for Medicines and Medical Devices, Romania*
- **Sinisa Tomic**, *Director, Agency for Medicinal Products and Medical Devices, Croatia*

15.30 Coffee / Tea

16.00 Session 4

Future Challenges

Moderated by **Guido Rasi**, *Executive Director, European Medicines Agency (EMA)*

- **Andrzej Rys**, *Director, Health Systems, Medical Products and Innovation, Directorate General Health and Food Safety, European Commission*
- **Thomas Senderovitz**, *Director General, Danish Medicines Agency, Denmark*
- **Belén Crespo Sánchez-Eznarriaga**, *Director General, National Agency for Medicines and Health Products, Spain*
- **Hubertus Cranz**, *Director General, AESGP*

17.30 End of the meeting

Practical information

Reception and Conference venue

SANA  LISBOA
★★★★

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

Hotel room rates

Single room: €110.00
Double room: €125.00

The above rates are per room, per night and inclusive of breakfast buffet, tax and service charges.

City tax: €1 per person and per night will be charged to each guest at the check-out.

Registration and hotel reservation through the conference website

Registration fee: 500 Euro

The fee covers the reception and dinner on Monday 26 February 2018, and the conference, lunch and coffee breaks on Tuesday, 27 February 2018. Please note that AESGP does not accept credit card payments.

Registration can be made online or by using a form that can be downloaded from the conference website. We recommend registration before 15 February 2018.

Cancellations

For cancellations received after 15 February 2018, the whole fee is withheld.

Conference Secretariat

For all questions on participation and registration, please contact the Association of the European Self-Medication Industry (AESGP):

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