



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

7th EGA South East Europe Pharmaceutical Symposium

MEETING THE EUROPEAN CHALLENGE
FOR NATIONAL DRUG REGULATORY AGENCIES
AND THE GENERIC MEDICINES INDUSTRY

18 January 2012

Radisson Blu Portman Hotel
22 Portman Square, London W1H 7BG, UK

Wednesday 18 January 2012

11:30 Registration and welcome buffet lunch

13:00 **Welcome speech** | *Greg Perry, Director General, European Generic medicines Association (EGA)*

Session I - Overview of the regulatory environment for generics in South East Europe
Co-chairs | *Vesna Koblar, Deputy Director of the Slovenian Medicines Agency (JAZMP)*
and Beata Stepniewska, Regulatory Affairs Director, EGA

The latest development in the regulatory environment in South-East Europe.
Presentations by regulatory authorities from:

- Bosnia and Herzegovina
- Croatia
- Macedonia
- Montenegro
- Serbia

Q&A session

14:30 Coffee break

**MOVING IN THE SAME DIRECTION: TO CREATE A HARMONISED ENVIRONMENT
FOR GENERIC MEDICINES IN THE EU AND IN SOUTH-EAST EUROPE**

15:00 **Session II - Changes in the EU regulatory and legal environment for generic medicines -
Implications for regulatory authorities and the generic medicines industry in the SEE
Region**

Co-chairs | *Tamas Paal, Hungarian Medicines Agency and Greg Perry, Director General,
European Generic medicines Association (EGA)*



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What has taken place in the EU regulatory and legal environment since the last EGA SEE Conference? Possible implications on non-EU countries | *Vesna Koblar, Deputy Director of the Slovenian Medicines Agency (JAZMP)*

- New pharmacovigilance legislation
- Legislative proposals in the pipeline: Industry Information to Patients, revision of the Price Transparency Directive, revision of the Clinical Trials Directive

Implication of the implementation of new measures against falsified medicines as a part of new legislation | *Julie Maréchal-Jamil, Sr Manager Quality & Regulatory Affairs, EGA*

- Reinforcement of the GMP for APIs, particularly coming from non-EU countries
- Implementation of safety features

Possible impact on the non EU countries | Exchange of views and experiences by authorities and industry from Bosnia and Herzegovina, Croatia, Macedonia, Montenegro, Serbia

16:15 Coffee break

16:45 **Session III - Moving in the same direction - specific aspects of market authorisations Chair** | *Beata Stepniewska, Regulatory Affairs Director, EGA*

Dialogue between the competent authorities and the industry on outstanding regulatory issues

- Improvement of fast track procedures | *Beata Stepniewska, EGA*
- Readiness to accept eCTD application in non-EU countries - the way forward | *Beata Stepniewska, EGA and Vito Strasberger, Electronic Submissions Expert, Nanokinetik*
- Packaging/leaflet | *Marija Milovanovic, Actavis*
- Biosimilar medicinal products | *Paul Greenland, Biosimilars and Proprietary Marketing Director, Hospira*
 - How are they regulated in the EU and non-EU countries?
 - Experience with the market uptake of biosimilar medicines in the EU - Points to be considered by non-EU countries?

Exchange of views and experiences by authorities and industry from Bosnia and Herzegovina, Croatia, Macedonia, Montenegro, Serbia

18:00 End-of-symposium

19:30 Symposium dinner

For further information please visit www.egagenerics.com