



Medicines and Medical Devices Agency of Serbia
is organising

Symposium on Biosimilar Medicinal Products

under the auspices of the Ministry of Health of the Republic of Serbia

Second Announcement

Dear colleagues,

We would like to inform you that the Symposium on **Biosimilar Medicinal Products** organized by the Medicines and Medical Devices Agency of Serbia under the auspices of the Ministry of Health of the Republic of Serbia, is to be held in the Atrium Hall of the Avala Congress Centre in the Best Western Hotel M, Belgrade, on **24th November 2008**, according to the following Programme:

Monday, 24th November 2008

08:00-08:45 *Registration of participants*

09:00-09:15 *Symposium Official Opening and Welcome Speeches*

09:15-09:45 *Jean-Hugues Trouvin (Chair BWP, EMEA):*
General aspects, importance of caregivers and patient management

09:45 -10:15 *Fotis Fotiou (Johnson&Johnson):*
Manufacturing process - what makes biotechnology medicinal products different

10:15-10:45 *Pierrette Zorzi (AFSSAPS, BWP, BMWP):*
Biosimilar medicinal products: quality aspects

10:45-11:15 *Coffee Break*

11:15-11:45 *Christian Schneider (Chair BMWP, EMEA):*
Demonstration of comparability of biosimilar medicinal products: non-clinical and clinical aspects (efficacy, safety, immunogenicity)

11:45 -12:15 *Valentina Stamouli (EMEA):*
Regulatory requirements of biosimilar medicinal products in EU

12:15-12:45 *Mira Pavlovic (AFSSAPS, BMWP, SAWP, EWP EMEA):*
Biosimilar medicinal products: general and product-specific guidelines

12:45 – 13:15 *Discussion*

13:15 – 14:15 *Lunch break*

14:15-14:45 *Zoran Todorovic (School of Medicine, University of Belgrade):*

Biotechnology medicinal products and immunogenicity – clinical implications

14:45-15:15 *Milena Miljkovic (ALIMS):*

Biosimilar medicinal products safety – general requirements and key concerns

15:15-15:45 *Coffee Break*

15:45 – 16:15 *Ljiljana Kapetanovic (AFSSAPS):*
Experience gained from biosimilar medicinal products recently approved in the EU - Growth hormones

16:15 – 16:45 *Mira Pavlovic (AFSSAPS):*
Experience gained from biosimilar medicinal products recently approved in the EU - Epoetins

16:45 – 17:15 *Discussion*

17:15-17:30 *Conclusions and closing remarks*

For information on application please contact:

Thank you for your applications.
We are glad you are going to participate in the Symposium.

We are looking forward to seeing you soon,
Programme and Organising Committee

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