



EBE Risk Management Regulatory Seminar

28 November 2008

Renaissance Hotel - Brussels, Belgium

PROGRAMME

Registrations		08.30-09.15
Welcome: Emmanuel Chantelot (EBE Executive Director)		09.15-09.20
Introduction: Dr Catarina Edfjäll (Celgene)		09.20-09.30
1	EU Risk Management Plan and expectations- EMEA latest developments <i>Presentation by Dr Stella Blackburn (EMEA)</i>	09.30-10.00
	Questions & Answers	10.00-10.10
2	The early implementation of Risk Management in the development process <i>Presentation by Dr Per Nilsson (Actelion)</i>	10.10-10.40
	Questions & Answers	10.40-10.50
	Coffee break	10.50-11.10
3	The regulator's view: Considerations at the time of marketing authorization <i>Presentation by Dr Ingemar Persson (MPA)</i>	11.10-11.40
	Questions & Answers	11.40-11.50
4	Thalidomide – a case study <i>Presentation by Dr John Scott (Celgene)</i>	11.50-12.20
	Questions & Answers	12.20-12.30
	Lunch	12.30-13.30
5	Special considerations on RMPs for biotech proteins <i>Presentation by Dr Nathalie Schulze (Roche)</i>	13.30-14.00
	Questions & Answers	14.00-14.10
6	Implementation and monitoring of Risk Management Plan <i>Presentation by Dr Robin Geller (Baxter)</i>	14.10-14.40
	Questions & Answers	14.40-14.50
	Coffee break	14.50-15.10
7	Latest FDA developments: REMS and Risk Maps <i>Presentation by Dr Adrian Thomas (J&J)</i>	15.10-15.40
	Questions & Answers	15.40-15.50
8	Review of Commission proposal on EU Pharmacovigilance and next steps <i>Presentation by a European Commission representative</i>	15.50-16.20
	Questions & Answers	16.20-16.30
9	Workshop Closing Remarks	16.30-16.40

THE SEMINAR: A one-day meeting to present an up-to-date overview of the current requirements for the preparation and implementation of an EU Risk Management Plan.

It is anticipated that the Commission proposal to "Strengthen and rationalise EU Pharmacovigilance" will be released in Q4 2008. The programme provides a blend of the regulator's perspective and input from industry experts who will provide advice on the key elements for the Risk Management Plan.

The Seminar will be interactive with opportunities for the participants to raise questions following each presentation.

Participation is open to all but priority will be given to EBE members.

VENUE: Renaissance Brussels Hotel, Rue du Parnasse 19, 1050 Brussels

ABOUT THE ORGANISER: EBE is the voice of biopharmaceuticals in Europe. We promote a favourable scientific, business and regulatory environment for biopharmaceutical companies operating in Europe. We have developed a wide range of services embracing policy advocacy, business development support, regulatory intelligence, technical guidance, communications, networking and education.

FOR MORE INFORMATION:

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REGISTRATION FORM - TO BE COMPLETED AND RETURNED TO EBE BEFORE 31 OCTOBER 2008

- Prof. Dr. Mr. Mrs. Ms. EBE Member's fee €250 incl. VAT (€207 excl. VAT)
 Non-member's fee €425 incl. VAT (€351 excl. VAT)

First Name..... Last name.....

Company/Organisation.....

VAT Number*.....

Job Title Department.....

Address

Postal Code City

State/Province..... Country

Tel. Fax.....

Email

Invoicing Address*

***This information is important. Please note that the invoice will be issued using only the invoicing address and the VAT number supplied.**

Please return the registration form to Joëlle Baruti either by email (events@ebe-biopharma.org), fax (+32 2 626 25 66), or post (European Biopharmaceutical Enterprises - EBE, Rue du Trône 108, B-1050 Brussels, Belgium)

MEANS OF PAYMENT (by bank transfer only)

Your bank transfer should be made payable to:

FORTIS BANQUE (Agence Bascule): Avenue Molière 516, B - 1050 Brussels, Belgium

Account No. : 210-0615919-21, IBAN Code : BE17210061591921, SWIFT/BIC Code : GEBABEBB

Please note that:

- All bank charges to be paid by the Forwarder
- Payment for registration must be received to gain entry to the workshop.
- Cancellations received before 1 November will be refunded. No reimbursement will be made after this date.

EVENT CANCELLATION: EBE reserves the right to modify the material or instructions without notice or to cancel an event. If an event must be cancelled, registrants will be notified by EBE in writing as soon as possible and will receive a refund. EBE will not be responsible for airfare penalties or other costs incurred due to cancellation.

- I will attend the EBE Risk Management Seminar of 28 November 2008. I will make a bank transfer of €250 (EBE member) or €425 (non-member) to the EBE bank account indicated above.

Date Signature.....

EBE USE ONLY : Date:..... Check:..... Amount:..... Account:

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