

EMA-EFPIA INFO DAY 2011

Monday, 23 May 2011

EMA

7 Westferry Circus. Canary Wharf. London E14 4 HB. United Kingdom
Tel: +44 (0) 20 7418 8400

Purpose of the event

- To discuss the results of various actions taken by the EMA to implement the Paediatric Regulation
- To examine and discuss the results of an EFPIA survey covering 3.5 years of over 30 companies experience in relation to
 - o Experience with applications for PIPs and waivers
 - o Paediatric clinical trial protocols developed in connection with PIPs
 - o Impact of the Paediatric Regulation on the drug development process and marketing authorizations
 - o Outcome for paediatric rewards
 - o Experience with Article 45 and Article 46 procedures
- To discuss the current interpretation of various provisions contained in the Paediatric Regulation.

Who should attend the EMA-EFPIA Info - Day

Directors and senior staff responsible for Corporate strategy, Regulatory Affairs, Regulatory Policy, Regulatory law, Clinical Research and Development, the development of Paediatric Formulations.

Registration and fees

The registration form and payment details for participants are attached.

Please note that the capacity of the meeting room is limited. Seats will be attributed on a first come – first serve basis while factoring in the need to ensure that a fair number of different applicants for Marketing Authorisations for medicinal products within the scope of the Paediatric Regulation can participate in the meeting.

REGISTRATION FORM

EMA - EFPIA INFO DAY *London – Monday, 23 May 2011*

First name: Family name:

Company or Association:

Company address:

Invoicing address (please indicate the invoicing address only):

PO number (Purchase Order) – if requested on the invoice:

V.A.T. number (IMPORTANT: the VAT will be indicated on the invoice):

Telephone: Fax:

E-mail:

PAYMENT DETAILS

EURO 250- (VAT inclusive) per person (all bank charges to be paid by the forwarder). This fee covers participation in the EMA-EFPIA Info Day 2011, refreshments and buffet lunch.

- ☐ Cheque (to the order of EFPIA), to be sent to EFPIA – Leopold PLAZA Building – Box 1 – Rue du Trône, 108 – B-1050 Brussels
- ☐ Bank Transfer to the EFPIA account n° 210-0613223-41 (IBAN BE88 210.061.32.23.41, BIC GEBABEBB), Fortis, Agence Bascule, Avenue Molière 516, B-1050 Brussels.

PAYMENT BY VISA/ CREDIT CARD IS NOT POSSIBLE

Payment and Cancellation

An invoice will be mailed upon receipt of your payment. We recommend to register before **13 May 2011** at the latest. **No reimbursement will be made in the event of cancellation after 13 May 2011.** Payment must be received at the latest by 16 May 2011 to allow participation in the meeting.

ACCOMMODATION

Participants are invited to make their own arrangements. **EFPIA will not arrange any hotel booking.**

Date: Signature:

To be returned to Anita Colin (anitacoln@efpia.org)
EFPIA – Leopold Plaza Building – Box 1 – rue du Trône, 108 – B-1050 Brussels
Telephone: +32.2.626.25.55 - Telefax: +32.2.626.25.66