

PAEDIATRIC MEDICINES



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: CA3/09



A joint meeting between TOPRA, European Federation of Pharmaceutical Industries and Associations (EFPIA), European Biopharmaceutical Enterprises (EBE) and the European Medicines Agency (EMA)



One-day
Workshop

Date:

15 September 2009

Venue:

London, UK

Paediatric medicines – a practical workshop on the Paediatric Investigation Plan (PIP)

Aims

The need to submit paediatric investigation plans (PIPs) has now been a requirement for around 2 years and there have been many new procedures and processes to master to prepare a PIP and then to follow it through. This practical workshop will enable members of the paediatric committee (PDCO) to share with Industry through case studies what should be considered when preparing and writing a PIP. This meeting is for all those persons in regulatory affairs and medical departments who are seeking approval for PIPs or deferrals or waivers within Europe for what is now obligatory for all medicines, whether intended for children or not.

Programme Committee

- Agnes Saint Raymond, EMA
- Christine Lise Julou, EFPIA
- Piers Allin, EBE
- Ali Harrison, AstraZeneca
- Angelika Joos, Merck Sharp & Dohme (Europe)
- Gesine Bejeuhr, VFA, Germany
- Christopher Bailey, TOPRA

Speakers

- Paolo M. Biffignandi, TOPRA President elect, VI.REL Pharma S.a.s., Italy
- Daniel Brasseur, Chair PDCO
- Sonja Pumplün, Actelion Pharmaceuticals Ltd
- Vibeke Viergard, Novo Nordisk

Invited members of PDCO, EMA and Industry

Registered participants are invited to send questions in advance of the meeting to TOPRA in order to include them in the discussions.

Programme

Preparing for the PIP submission

This session will cover an overview of all necessary steps and investigations to accumulate sufficient information in preparation for the writing of a PIP dossier

- How to prepare the submission dossier – procedural and scientific advice – practical aspects
- Preparing for a PIP and specific content of the paediatric investigation plan – a joint effort in companies – Specific examples

Writing the PIP and getting it approved

This session will cover important aspects to consider for writing of parts C-E and successful interactions with EMA and PDCO

- Part C, D and E: Waivers, deferrals – where things can go wrong – potential problems and how to avoid them. Issues from PDCO
- PIP Modification and Compliance – experiences to date

Workshop

This workshop will cover practical discussions on hypothetical case studies developed around important issues encountered in different procedures. Solutions and ways forward will be suggested.

Delegates will be divided into groups of 10-15 and will discuss case studies with a panel comprising PDCO member, EMA and industry expert per group.

Each workshop will report back to the whole meeting including learning points being published.

All data correct at time of print.

For more information or to obtain a booking form, please contact TOPRA via email: meetings@topra.org or tel: +44 (0) 207 538 9502 or go to the website: www.topra.org/paediatric-medicines



Lifelong learning

*For more information please visit www.topra.org/lifelonglearning

email: meetings@topra.org tel: +44 (0) 20 7538 9502 fax: +44 (0) 20 7515 7836 web: www.topra.org

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Ways to book

Please complete in block capital letters and return this form with payment to TOPRA using one of the following methods:

Post: TOPRA, 7 Heron Quays, Marsh Wall, London E14 4JB, UK

Fax: +44 (0) 20 7515 7836 **Email:** meetings@topra.org

On receipt of your booking form we will confirm your provisional place in writing and provide directions to the venue. An invoice will be sent separately. To ensure admission, payment must be received prior to the meeting.

If you have any queries, contact us on: +44 (0) 20 7538 9502 or meetings@topra.org

Dr Mr Mrs Ms Other

Family name

First name Male Female

Company name

VAT reg. no.

Job title

Telephone

Fax

E-mail

Work Address

City Postcode

Country

Invoice Address
(If different from above address)

City Postcode

Country

Special dietary requirements

Experience in the Subject Area

Negligible Average Considerable

Your current role Generics CRO European Global Local affiliate

Other

Experience in Regulatory Affairs Years Months

Terms and conditions (Please note: TOPRA's full standard Terms & Conditions are available on the website at www.topra.org/bookingTandC).

Payment:

- Cheques:** must be made payable to TOPRA and drawn on a UK bank in either Euro or Sterling.
- Debit/Credit card:** for payment by card please complete the relevant details above. Cards accepted: AMEX, Debit MasterCard, Delta, Electron, Maestro, MasterCard, Solo, Visa. All cards will be charged in Sterling.
- Bank Transfers:** may be made to Lloyds TSB Bank PLC. Please quote the delegate's name and the course reference in the transmission details. The delegate must pay all bank charges.
- Sterling Transfers:** Account No: 00340310, Sort Code: 30-00-09, IBAN: GB45 LOYD 3000 0900 3403 10, BIC LOYDGB21013
- Euro Transfers:** Account No: 86330987, Sort Code: 30-00-09, IBAN: GB19 LOYD 3000 0986 3309 87, BIC LOYDGB21013
- Your place is secured only upon receipt of full payment.

Payment method

Cheque enclosed Cheque No

Bank transfer Date of transfer / /

Please charge my debit/credit card Purchase Order No.

Fees

Paediatric Medicines Workshop

Member: €316.25 = €275.00 + €41.25 (15% GB VAT)

Non Member: €373.75 = €325.00 + €48.75 (15% GB VAT)

The VAT rate will be the prevailing rate at the time of invoicing.

Debit/credit card details

(For cards accepted, see payment section below)

Debit Card Visa MasterCard American Express (preferred)

Card No

Expiry date /

Security code Visa, MasterCard, Debit cards: the last 3 digits AFTER the card number in the signature area of the card.

Card holder name (as given on card)

Billing address for card (must be provided if different from the Work Address)

TOPRA will seek authorisation from the card-issuing company before confirming any reservation. (GB VAT Registration No.: GB 342 7398 40)

By signing below, I confirm that I agree with TOPRA's Terms & Conditions of Booking. These are available from the office or on the TOPRA website at: www.topra.org/bookingTandC

SIGNATURE

DATE