



The 5th TOPRA Annual Symposium 2008



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: SYM/08



Continuous Regulatory Evolution

TOPRA's highly successful Annual Symposium builds upon a 30 year track record in delivering the premier annual Regulatory Affairs conference for Europe and attracts excellent high-level speakers.

These speakers include government Ministers, Heads of Agencies, key officials from the European Commission, Heads of Unit from EMEA, leading pioneers and practitioners from within industry, pan-European policymakers, patient groups and consultants who examine topical issues in European and global regulatory affairs. The TOPRA Symposium provides a forum for detailed discussion of all the most important regulatory issues of the day. It is an opportunity to get right up to date with the latest information and to network with industry and agency colleagues, not only in formal sessions but also informally during breaks and in the evenings.

In addition to the traditionally strong core symposium, two additional symposia are also organised to recognise the specialised needs of the whole industry. With advice from the European Commission, the EMEA and other key bodies in the EU, TOPRA has developed parallel symposia on Veterinary Medicines and Medical Technologies.

Why attend the TOPRA Symposia?

- Hear the latest regulatory intelligence on key issues in Regulatory Affairs from our international speaker panel.
- Collect new ideas to help you and your business meet the challenges and maximise the opportunities offered by the current regulatory environment.
- Maintain and develop your network of industry and agency contacts.

Parallel Symposia 7th October, 2008



**Medical
Technologies**



**Veterinary
Medicines**



ORSZÁGOS
GYÓGYSZERÉSZETI
INTÉZET
National Institute of Pharmacy

Three-day Symposium

Date:

Monday 6th -
Wednesday 8th
October 2008

Venue:

Corinthia Grand
Hotel Royal,
Budapest, Hungary

Timings:

Symposium Registration:
12.00 – 13.00 Monday
6th October 2008
Start of Symposium:
13.00 Monday
6th October 2008
Close of Symposium:
13.15 Wednesday
8th October 2008



Lifelong Learning (LLL):

This conference contributes 14 hours of training to your LLL (sometimes known as Continuing Professional Development) and will enhance your Regulatory Skills relevant in the areas of human and veterinary medicines



2008 will see TOPRA's 5th Annual Symposium, which will take place in Budapest, Hungary. Previous Symposia were held in Paris, Berlin, Amsterdam and Copenhagen. A new feature this year are specific sessions from some of the TOPRA Special Interest groups covering 'e' technology, Biotechnology and Chemistry/Pharmacy (CMC). Building relationships is an important part of the TOPRA Symposium and this year we welcome The National Institute of Pharmacy, Hungary who will be assisting with the organisation of the programme. This meeting will be an ideal opportunity to get to know this key agency better. In addition, we are also working with HURAS, the Hungarian Regulatory Affairs Society to bring you an exciting symposium that reflects this region of Europe.

Speakers

Philippe Auby, Director International Clinical Research, Paediatric Neuro-Psychiatry, Lundbeck SAS, France

Rolf Bass, TOPRA Advisory Council, Germany

Robert Bell, AAPS and Drug & Biotechnology Development, LLC, USA

Janos Borvendeg, Institute of Pharmacy and CHMP member, Hungary

Christopher Bravery, Director Advanced Therapies, ERA Consulting Ltd, UK

Paul Chamberlain, Expert in biopharmaceutical product development and immunogenicity risk assessment, NDA Regulatory Science Ltd, UK

Gary Dodson, Manager, RA Operations Europe, Baxter Healthcare Corporation, Inc, Austria

Michael Doherty, Roche, Switzerland

Gabriele Eibenstein, Head of Unit Regulatory Affairs, BfArM, Germany

Stefan Fuehring, Unit F2 Pharmaceuticals, European Commission

Sibille Grub, Regulatory Manager, Novartis, Switzerland

Thomas Heynisch, Unit F5: Competitiveness in the Pharmaceuticals Industry and Biotechnology, European Commission

Alan Hunter, Incoming TOPRA President

Brenton E James, EU Consultant, UK*

Peter James, Managing Director, Dao-eRA Limited, UK

Margareth Jorvid, Senior Partner, Regulatory Affairs & QA, Life Science Management Group, Sweden

Ute Junghanns, Managing Director, EUDRAC, Germany*

Aine Kane, chair of TOPRA CMC SPIN and Pfizer, UK

Peter Karolyi, EMEA

Mária Kenéz, Head of International Regulatory Affairs, EGIS, Hungary

Gábor Koncsik, Servier Hungary/Head of Phv. Working group, Hungary

Xavier Luria Oller, Head of Sector, Safety and Efficacy of Medicines, EMEA

Craig McCarthy, TOPRA President and Campharm, France*

Patrizia Nestby, Associate Director Regulatory Affairs, ERA Consulting Ltd., UK*

Beatrice Oberlé-Rolle, Novartis, Switzerland*

Tamas Paal, Professor of Regulatory Affairs, Hungary*

Kristin Raudsepp, Director General, Ravimiamet, Estonia

Agnes Saint Raymond, EMEA

Norman Schmuft, Branch Chief, Pre-Marketing Assessment II Office, FDA, USA

Ondrej Slanar, SUKL, Czech Republic

Ilia Slavov, MSD/President of HURAS, Hungary

Nancy Smerkanich, Vice President of Regulatory Affairs Europe, Octagon Research Solutions, UK

Martin Terberger, Head of Unit F2 Pharmaceuticals, European Commission

Jean-Hugues Trouvin, Chairman of the EMEA BWP, Afssaps, France

Daniela Vasilescu, National Medicines Agency, Romania

Martina Weise, BfArM and V Chair EMEA Biosimilars WP, Germany

Lynda Wight, Executive Director TOPRA, UK

Gergely Zajzon, Head of Development and Database Department, Institute of Pharmacy, Hungary

*Working Party – Other Working Party members include:

Eva Liptak-Csekey, National Institute of Pharmacy (OGYI), Hungary

Helene Thybo, LEO Pharma, Denmark

Caroline Baillif, AMGEN, UK

Sybille Schoepf-Ward, Stiefel Laboratories, USA

Gyula Fehér, HURAS Vice-President and Registration manager, KRKA, Hungary

Monika Szabo, PLIVA and HURAS, Hungary

Venue, accommodation and travel

The Symposium will take place at the Corinthia Grand Hotel Royal which offers all the facilities of an international first-class hotel.

Corinthia Grand Hotel Royal, Erzsébet krt. 43 - 49, HU-1073 Budapest, Hungary

● Tel: +36 (1) 479 4000 ● Fax: +36 (1) 479 4333 ● Email: royal@corinthia.hu

A reservation form to book accommodation at the hotel will be sent with the letter confirming your place at the symposium.

Delegates are responsible for the arrangement and payment of their own travel and accommodation. The Symposium venue has agreed a special bed and breakfast rate of €280 for a single room and €304 for a double room, including HU VAT.

To benefit from this special rate, please complete the form which you will receive with the letter confirming your place and fax or email the form direct to the hotel as detailed on the form.

The hotel will endeavour to accommodate you at this special rate subject to availability. Please note that the number of rooms held for Symposium delegates is limited and may fill up before the cut-off date of 5th August. Directions to the venue will be provided in your confirmation paperwork.



Monday 6th October 2008

East and Central European countries: active partners in European regulatory affairs

This session will address the increasingly important and active role the East and Central European member states, including Hungary, are playing at a European regulatory level and in the European regulatory network. Topics that will be covered are, amongst others, scientific advice in Eastern Europe, role of East European national agencies in Centralised Procedure and Mutual Recognition Procedures and clinical trials in Eastern European countries.

Introduction by the Chair of the Symposium Working Party

Welcome to Budapest and introduction to the theme for the 2008 symposium

The perspective of the Hungarian agency

New Agencies in European procedures - good opportunity or new obstacle?

The industry perspective

Panel discussion: including regulators from other East/Middle European countries and industry representatives

Mutual Recognition Procedure/Decentralised Procedure

The introduction of the Decentralised Procedure has proven to be a great success. In fact the procedure is so successful that the national authorities and the CMD(h) is experiencing problems with meeting procedural deadlines and industry expectations. Furthermore, the number of referrals has been increasing. During the session, a status on the work done by the CMD(h) will be provided and possible solutions to the problems will be discussed.

Update from CMD(h)

- Update on the efforts done in 2008 and forecast 2009
- The increased number of referrals
- Harmonisation of interpretation of guidelines

Agency and Industry experience using one of the Central or Eastern European Member States as RMS

- Choice of RMS
- Experience with the procedure and the RMS
- Do's and don'ts

Referrals to CHMP

- Statistics on referrals and outcomes
- Reasons behind the increase in number of referrals and possible solution
- The referral procedure

- The TOPRA Review of the Year
- Drinks Reception
- Delegates are cordially invited to a drinks reception in the exhibition hall after which you are free to explore the delights of Budapest.

Sessions include panel discussions with the session's speakers

"An excellent presence of speakers from agencies made this TOPRA conference especially worth while"



Tuesday 7th October 2008

Centralised Procedure

The scope of the Centralised procedure (CP) has expanded over the years and this session will discuss current issues with the CP: Two new mandatory therapeutic areas have been added, expansion of the CP for generics, OTC and biosimilars, capacity of the whole system and 4 years of experience with conditional and accelerated approval.

Centralised procedure performance indicators

What works well and what not so well?

Peer Review

Industry experience with a recently approved application where Hungary was (Co) Rapporteur

Chemistry Manufacturing and Controls (CMC)

Many changes are often made to the Pharmaceutical (Chemistry Manufacturing and Controls) section of a regulatory marketing authorization, especially after its first approval. However what is the best way to manage these changes in a global environment where procedures not only differ between the USA and Europe but also within Europe. This session will review the latest news on harmonising changes within Europe and also how the FDA manages changes.

Variations legislation in the European Union

Post approval changes in the USA

Pharmacovigilance – Today's risks influence our common future

This session will review the recent legislative changes concerning pharmacovigilance from the European Commission. The expectations and potential consequences will be evaluated and presented by a national competent authority and a point of view from industry on how these changes may affect pharmacovigilance practices. The session will also cover the requirements for existing medicines.

European Commission update

Implementation questions by a National Competent Authority

EU Pharmacovigilance system from industrial point of view/product related safety issues

Sessions include panel discussions with the session's speakers

Parallel Symposia



Veterinary Medicines Symposium:

09.00 – 17.15 (Registration, Coffee and Exhibition from 8.30)
Tuesday 7th October 2008



Medical Technologies Symposium:

09.00 – 17.15 (Registration, Coffee and Exhibition from 8.30)
Tuesday 7th October 2008

Single day tickets for either of the parallel sessions are available. Please see booking form for rates.

"The opportunities for networking were excellent"



Tuesday 7th October 2008

Three parallel break out sessions covering:

- a** Biotechnology: TOPRA Biotech group
- b** Electronic Regulatory Affairs: TOPRA eRA group
- c** Regulatory Careers: jointly with RAPS of USA

a **Biotechnology – Regulating a moving frontier**

In an ever changing regulatory environment this session is an opportunity to hear from eminent regulators about recent developments in Biotech/biological regulatory affairs

Overview on the EMEA Biotech Working Party (BWP) activities

- Quality by design
- PAT
- Viral safety of IMPs
- NfG on monoclonal antibodies
- NfG on allergens

Regulating Novel technologies

Biosimilars

b **The eCTD - getting it right first time and every time**

Although the major agencies and larger Pharmaceutical companies are now very experienced in the art of eCTD submissions there are a number of smaller Pharmaceutical companies and consultancies who are just starting out on the path to successful e-submissions – this session is particularly for those who are about to embark on the road to eCTD

The Experience of the Hungarian Institute of Pharmacy

- Status of eCTD
- Pros and Cons from an agency perspective

A pharmaceutical company perspective

Getting started

c **Regulatory Careers**

TOPRA is committed to supporting regulatory professionals in their careers. As part of an on-going project to research and recommend educational qualifications in this discipline, there will be an opportunity for all delegates to participate in research and discussion on topics including regulatory career pathways, existing and potential educational qualifications and Lifelong Learning (LLL sometimes known as CPD). If you have found problems recruiting effective and well-qualified staff, or are unclear how to develop your own career in the increasingly important area of regulatory affairs, you will have something to contribute!



Followed by a full evening of entertainment

- Drinks Reception
- Degree Graduation Ceremony
- Gala Dinner

"A very well organised symposium with a lot of interesting presentations."



Wednesday 8th October 2008

Paediatrics

This session will provide an update of the Paediatric Committee (PDCO) key activities during the first year of operation of the Committee and industry's perspective on the impact of the paediatric legislation and experience/challenges with PIP preparation. Furthermore, practical assessment experience and learnings from EMEA/national authority point of view will be shared. The panel discussion will provide an opportunity to explore topics of interest in the context of implementation of the Paediatric Regulation and its impact on paediatric R&D.

Update on progress over the first year of operation of the Paediatric Committee

- PIP/waiver review, links with Scientific Advice WP
- Worksharing project (Article 45)
- Collaboration between EMEA and FDA Office of Pediatric Therapeutics
- PDCO working group on paediatric formulations and neonatal immunisation
- Priority list for studies into off-patent medicines

Industry Experience with Implementation of Paediatric Regulation

- PIP submissions
- Issues, challenges and Learnings

EMA Experience with PIP/Waiver assessment

- PIP/Waiver Assessment experience
- Issues, Challenges and Learnings

Hot topics from the European Commission

Innovation & Competitiveness

- Boosting innovation in the EU
- Role of agencies & common framework for regulatory agencies

Globalisation

- Protection of patients against counterfeiting
- Global collaboration between Agencies & common training programs

The Common Market

- Availability of medicines

Industry viewpoint

- Industry expectations for EU system improvement
- EU Resource constraints
- Mutual transparency expectations (e.g Pharmaceutical Forum)

Closing Remarks

Thanks and TOPRA Closing Remarks

Sessions include panel discussions with the session's speakers



Parallel Symposia



Medical Technologies Symposium Tuesday 7th October, 2008

Session I: Medical Device Directive Revisions and the Consequences – how are they working in practice?

Last year, the revisions to the Medical Device Directive were published. In this first session we look at how these changes have impacted all stakeholders in the Medical Device arena and also speculate as to what the impact of further change might be, following the decision of the European Commission to revise the Medical Device Directives once more. An essential session for anyone concerned with, or requiring an update of, CE Marking of medical devices in the EU. The perspectives of the Notified body, the Regulator and the Industry will be presented.

Session II: Medical Device Vigilance - Development and Impact

Medical Device vigilance not only forms part of the Medical Device Directive but also supports ISO 13485 accreditation. Recent developments in vigilance include an updated MEDDEV with revised time lines. This session concentrates on how the updated MEDDEV has impacted the Regulator, Notified Body and Industry.

Session III: Combination Products and the Drug-Device Interface - Current and Future Challenges

Combining established pharmaceutical compounds with medical technology is a growing feature of R&D in the healthcare arena. This session will look at the regulatory challenges facing manufacturers and regulators in determining the regulatory strategy for combination products and also in deciding whether a healthcare product could or should be regulated as a medicine or a medical device.

Session IV: The International Update

Legislation is continually moving forward on a global scale. In this session we aim to highlight the main changes to legislation and practice of Regulatory Affairs connected with Medical Devices in the global arena: a session not only useful for those working in a global setting, but also for those wanting to keep themselves up to date with requirements which may eventually impact on their own sphere of work. This session will cover the global harmonization task force and global medical device nomenclature and include updates on US and Japan.



Veterinary Symposium Tuesday 7th October, 2008

Keynote presentation

Challenges identified in the HMA Strategy document and how they are being addressed

Challenges arising from the new legislation; BEMA outcome/input, Centres of excellence, improving EU efficiency, avoiding duplication of effort, maintaining expertise, e-submissions, changing cost structures, removing barriers to mutual recognition

Session I: Urgent disease threats in the EU

This session will address how the European Commission is dealing with the need for emergency vaccination of livestock and the increasing scope of activities involving the EMEA in the Community Animal Health Policy in general and in urgent disease threats in particular

Session II: Evolution of Harmonised Data Requirements

This session will provide an update on the revision of Annex I to Directive 2001/82/EC, crucial for applicants as it contains the requirements for dossier submission. The session will also review the progress being made in solving intractable issues that arise during the MRP and DCP procedures and the precedents set by the CVMP in managing referrals

Session III: Consumer and Environmental Safety: Fairness in Data Protection

Following a review of the latest version of the draft Regulation that will replace 2377/90 this session will examine legal base and technical issues concerning the requirement for environmental safety for Article 13 applications. The following Panel Session will enable participants to discuss the limitations of protection of data that are afforded to originator companies.

Session IV: Improving the Regulatory Framework

The review and update of European legislation is an almost constant process, beginning with wide ranging stakeholder discussions. Several review projects and discussions are on-going. This session will hear reports from two very different projects. Firstly a joint project between industry and CMDv to minimise hurdles caused by packaging requirements, and secondly examples from the Pharmaceuticals Unit contributing to the European Commission's Better Regulation objectives.

Sessions include panel discussions with the session's speakers

Please note that all programmes covered in this brochure could be subject to changes

Single day tickets for either of the parallel sessions are available. Please see booking form for rates.



The 5th TOPRA Annual Symposium 2008



Date: 6-8 October 2008 Venue: Corinthia Grand Hotel Royal, Budapest, Hungary

Reference: SYM/08

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

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

Please indicate if in your regulatory experience you have worked in one or more of the following areas:

1) CMC 2) EU clinical trials 3) Variations 4) Medical Technologies

Discounted fees

Personnel in full-time education, working in academia (full-time) or working for a regulatory body may be entitled to a discount on the fees. Please contact the TOPRA office for details.

Payment method

Cheque enclosed Cheque No.

Bank transfer Date of transfer / /

Please charge my credit/debit card Purchase Order No.

Terms and conditions (Please note: new TOPRA bank details)

Payment: Payment may be made in Euro or Sterling by cheque or bank transfer. Credit/debit cards will be charged in Sterling.

- Cheques:** must be made payable to TOPRA and drawn on a UK bank.
- Credit/debit card:** for payment by credit/debit card please complete the relevant details above. Cards accepted: AMEX, Debit MasterCard, Delta, Electron, Maestro, MasterCard, Solo, Visa. Cards will be charged in sterling only.
- 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 on receipt of full payment.

Price note: Fee excludes accommodation and travel. The delegate ticket includes refreshments at coffee breaks, buffet lunches and drinks reception. Unless stated otherwise the official language of all our meetings is English. It may be necessary for reasons beyond the control of the organisers to alter the dates, venue, timing and content of the programme (including speakers) without prior notice; TOPRA regrets that it cannot accept liability for losses incurred by delegates in these circumstances. Meals requiring special preparation (such as Kosher) may incur additional costs.

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Credit/debit card details

(For cards accepted, see payment section below)

Visa MasterCard American Express Debit cards

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. (HU VAT Registration No: HU 269 670 28)

SIGNATURE <input type="text"/>	DATE <input type="text"/>
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Prices

3 day ticket - Main Symposium

Member: €1,790.00 +20% HU TAX (€358.00) = €2,148.00

Non Member: €2,190.00 +20% HU TAX (€438.00) = €2,628.00

Gala Dinner: *Three-day delegate rate includes a ticket to the Gala Dinner. Please tick this box if you do not want to attend the Dinner*

Single day ticket Parallel Session

Please indicate which Parallel Session you would like to attend

Veterinary Symposium Medical Technologies Symposium

Member: €740.00 +20% HU TAX (€148.00) = €888.00

Non Member: €815.00 +20% HU TAX (€163.00) = €978.00

This fee includes the opportunity to attend the Opening Session and Session 2 of the Pharmaceutical Symposium on Monday 6 October.

This fee does not include the Gala Dinner, but attendees may purchase Gala Dinner tickets. Please indicate below whether you would like to purchase a Gala Dinner Ticket.

I would like to attend the Gala Dinner €250.00 + 20% HU VAT (€50.00) = €300.00

Cancellations: All cancellations must be received in writing 21 calendar days before the start of the course and will be subject to an administration fee of €150. Payment can be in Euro or Sterling. For cancellations after this time, or if the delegate fails to attend the course, no refund of fees will be given. Substitutions may be made at any time. TOPRA reserves the right to cancel the course at any time without liability. In these circumstances, delegates will be offered an alternative date, a credit note or a full refund.

Data protection: TOPRA is registered under the Data Protection Act 1998. Your details will not be passed to other companies. If you would like us to change any details or if you do not wish to be sent mailings about our meetings please write to TOPRA e-mail address: membership@topra.org

Additional support: Please advise TOPRA, at least one month before the meeting date, if you have any disability that may require additional support. TOPRA makes no distinction in its admission policy with regards to disability. TOPRA will make every reasonable effort to supply delegates with services that meet their needs.

Liability: TOPRA regrets that it cannot accept liability for losses incurred by delegates in the event of postponement or other alterations to the meeting, i.e. timing, venue, etc. Normal TOPRA terms and conditions apply; please contact the TOPRA office for further details.

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We may occasionally send you promotional or product information from organisations and companies other than TOPRA. If you do not wish to receive this information, you can opt out by ticking this box