



Joint DIA/HESI/SAPS Conference on Environmental Assessment of Human Medicines

May 22-23, 2006, Scandic Infra City Hotel, Stockholm Upplands Väsby, Sweden

BioLogue

University of Copenhagen, Denmark



HESI

ILSI Health and Environmental Sciences Institute



LÄKEMEDELSAKADEMIN
SWEDISH ACADEMY OF
PHARMACEUTICAL SCIENCES

Swedish Academy of Pharmaceutical Sciences

EXHIBITION

At this conference, DIA will provide an international platform for pharmaceutical industry support organisations to exhibit their materials and services. This yields increased networking opportunities for attendees. To obtain details on exhibiting space and facilities, please contact: phyllis.suter@diaeurope.org

CALL FOR ABSTRACT FOR SCIENTIFIC POSTER SESSION

You are invited to submit an abstract for a poster (no more than 300 words) to be displayed at the Conference in Sweden. The abstract should at least address one of the following topics:

- Fate and Transport - Data collection focused
- Exposure Modelling and Monitoring
- Use of data and models to generate predicted exposure concentrations
- Use of data developed during drug development for "read across" to environmental analyses
- Aquatic toxicity - data development and use
- Mixtures
- Regulatory aspects of environmental assessment of human medicines

Abstracts may not refer to specific brand names, and only one abstract per person should be submitted. Abstracts should follow a structured format including all of the following: objectives, methods, results and conclusions.

THE DEADLINE FOR SUBMITTING POSTERS IS MARCH 1, 2006.

All poster abstracts should be submitted with full details for identification (title, author's name, affiliation, address, phone number, e-mail) via e-mail to: diaeurope@diaeurope.org

Programme Committee

DR. ANDERS CRONLUND,

The Swedish Academy of Pharmaceutical Sciences, Sweden

DR. MICHAEL HOLSAPPLE,

ILSI Health and Environmental Sciences Institute (HESI), USA

MS ANNA-KARIN JOHANSSON,

Medical Products Agency, Sweden

MR. J. DAVID SANDLER,

ILSI Health and Environmental Sciences Institute (HESI), USA

MS ANNELIE SKAGERLIND,

The Swedish Association of the Pharmaceutical Industry, Sweden

DR. PER SPINDLER,

BioLogue, University of Copenhagen, Denmark (Chair) (DIA Advisory Council of Europe, member and European Co-Chairperson of the DIA Non-Clinical Special Interest Area Community)

DR. RICHARD T. WILLIAMS,

Pfizer, USA

Programme Advisors

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Uppsala University, Sweden

MR. DAVID J. COCKER,

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The Danish University of Pharmaceutical Sciences, Denmark

MR. JAN KOSCHORRECK,

UBA, Germany

PROF. KLAUS KÜMMERER,

University of Freiburg, Germany

DR. JOAKIM LARSSON,

Göteborg University, Sweden

DR. MARK MONTFORTS,

RIVM, The Netherlands

MR. MIKE MURRAY,

The Association of the British Pharmaceutical Industry, United Kingdom

DR. KLAUS OLEJNICZAK,

Federal Institute for Drugs and Medical Devices, Germany

DR. INES ROENNEFAHRT,

UBA, Germany

DR. HENRY STEMPLEWSKI,

MHRA, UK

PROF. DAVID TAYLOR,

AstraZeneca, UK

DR. JEAN-MARC VIDAL,

EMA, EU

DR. VIRPI VIRTANEN,

National Agency for Medicines, Finland

DR. KEITH WEBBER

FDA, USA

Conference Overview

The impact of chemical substances on human health and the environment is a subject that attracts increasing attention from society and policy makers. The new EU policies will affect the wider chemical industry. The pharmaceutical industry will also have to contend with specific and reinforced legislation for environmental risk assessment. Such policies not only place increasing responsibility on manufacturers/marketing authorisation holders to fully assess environmental risks, but also additional demands on the scientific comprehension to sustain plausible regulatory judgments.

This conference will explain the current understanding of environmental fate and effects of human medicines; it provides an update on the latest policy developments, highlights how to successfully manage data and clarifies how to achieve compliance. For the first time, key regulators from all major world regions will address their perspectives and expectations and will discuss scientific and regulatory needs. Attendance will provide you with both theoretical and practical guidance to facilitate the implementation of requirements for human pharmaceuticals Environmental Risk Assessment.

Target Audience

Regional and international academia, regulators, competent authorities, public affairs professionals, services laboratories professionals, environmental risk assessment consultants and EHS executives.

JOIN THE DIA NOW: WWW.DIAHOME.ORG/DOCS/MEMBERSHIP

Monday, May 22, 2006 - Scientific Perspective

08:00 - 09:00	REGISTRATION & WELCOME COFFEE
09:00 - 09:30	WELCOME ADDRESS <hr/> Brigitte Franke-Bray, Director, DIA European Branch Office, Switzerland Michael Holsapple, ILSI Health and Environmental Sciences Institute, USA Anders Cronlund, The Swedish Academy of Pharmaceutical Sciences, Sweden
09:30 - 10:45	KEYNOTE PRESENTATIONS <hr/> Co-Chairpersons: David J. Cocker, Ecotrac N.V., Belgium, Annelie Skagerlind, The Swedish Association of the Pharmaceutical Industry, Sweden <p>These keynote presentations delivered by two eminent scientists set out the history and challenges in the evolution of pharmaceuticals in the environment as a scientific regulatory issue.</p> <ul style="list-style-type: none">• What do we know and what are the challenges? What do we need to know and what are the roadblocks to knowing the details?• What are the data that have resulted in the evolution of pharmaceuticals in the environment as an issue?• What do we know about the acute and chronic eco-toxicity potential from human pharmaceuticals and is it clear what contribution pharmaceuticals make?• Is it possible to prioritize areas of research to maximize chances of telling us what we need to know? Environmental Exposure Richard T. Williams, Pfizer, USA Environmental Effects John Sumpter, Brunel University, United Kingdom
10:45 - 11:15	COFFEE BREAK
11:15 - 13:00	PARALLEL WORKSHOPS ON CONTEMPORARY SCIENTIFIC ISSUES <hr/> Co-Chairpersons: Richard T. Williams, Pfizer, USA Klaus Olejniczak, BfArM, Germany
13:00 - 14:00	LUNCH BREAK
14:00 - 16:00	PARALLEL WORKSHOPS A / B / C / D / E CONTINUED <hr/>
16:00 - 16:30	COFFEE BREAK
16:30 - 17:30	SCIENTIFIC WORKSHOP SUMMARIES & CONCLUSIONS <hr/> Co-Chairpersons: Richard T. Williams, Pfizer, USA Klaus Olejniczak, BfArM, Germany
17:30 - 19:30	Conference Reception: SCIENTIFIC POSTER SESSION AND TABLE TOP EXHIBITION Co-Chairpersons: Joakim Larsson, Göteborg University, Sweden Bent Halling-Sørensen, The Danish University of Pharmaceutical Sciences, Denmark
19:30	END OF DAY 1

PARALLEL WORKSHOP A

Co-Chairpersons:

**Virginia Cunningham,
GlaxoSmithKline, UK**

**Klaus Kuemmerer,
University of Freiburg, Germany**

FATE AND TRANSPORT - DATA COLLECTION FOCUSED

Pharmaceutical compounds, as a class, generally possess characteristics that make them different than conventional industrial chemicals for which standardised environmental fate and transport testing protocols were developed. They have comparatively large, chemically complex molecular structures and are often ionizable, with multiple ionisation sites spread throughout the molecule. Some molecules possess both acidic and basic functions within the same molecule. In consequence, their behaviour in the environment depends strongly on pH. In addition, human pharmaceuticals are introduced into the environment from use by patients, and may be transformed by various human metabolic processes before excretion. These characteristics need to be kept in mind when establishing the environmental form to be evaluated (parent, metabolite(s), other), designing fate and effects testing strategies, interpreting test results, predicting environmental fate, and carrying out environmental risk assessments. In particular, since most pharmaceuticals are charged, polar and hydrophilic, the sorption of these compounds to particles in municipal wastewater treatment plants (WWTPs), surface waters and sediments cannot be predicted from parameters such as the octanol/water partition coefficient that are often used for predicting partitioning of hydrophobic compounds.

The purpose of this workshop is to identify the best available experimental or estimation methods for collecting or calculating environmental fate and transport data on human pharmaceuticals and to describe the research needed to improve existing methods.

PARALLEL WORKSHOP B

Co-Chairpersons:

**Richard Murray-Smith,
AstraZeneca, UK**

**Maria Ramil,
BAFG, Germany**

EXPOSURE MODELLING AND MONITORING - USE OF DATA AND MODELS

The purpose of this parallel workshop is to explore the roles of exposure modelling and monitoring in the context of environmental risk assessment of human pharmaceuticals. Modelling is effectively the only option for new pharmaceuticals prior to marketing approval, but for established products it may be possible to measure actual concentrations in the environment and to utilise more sophisticated exposure modelling techniques. The question is when and how should such 'higher tier' assessment methods be applied - and how should the results be interpreted in a risk assessment context?

This workshop will attempt to summarise current thinking from both scientific and regulatory perspectives, highlight common principles and practice, and identify research and development needs to ensure that future application of monitoring and modelling techniques can effectively support the environmental risk assessment of human medicines.

PARALLEL WORKSHOP C

Co-Chairpersons:

**Klaus Olejniczak,
BfArM, Germany**

**Per Spindler,
University of Copenhagen, Denmark**

**Richard T. Williams,
Pfizer, USA**

USE OF DATA DEVELOPED DURING DRUG DEVELOPMENT FOR "READ ACROSS" TO ENVIRONMENTAL ANALYSES

The chemistry, primary and secondary pharmacodynamics (e.g., mechanism of action and pharmacological actions unrelated to the therapeutic effect), pharmacokinetics (absorption, distribution, metabolism, and excretion) and in vitro and animal toxicology of human pharmaceuticals are extensively studied during pre-registration discovery and development. Effectively utilizing data that support the medical use of a pharmaceutical to answer environmental questions, or guide the development of environmental data, has potential benefits that include minimizing (e.g., duplicating) animal testing and enhancing the focus and effectiveness of the environmental risk assessment.

This workshop is designed to highlight the state of the science and identify opportunities and research needs for mechanistic ecotoxicology and 'reading across' taxonomic lines to support environmental risk assessment of human pharmaceuticals.

PARALLEL WORKSHOP D

Co-Chairpersons:

**Ingvar Brandt,
Uppsala University, Sweden**

**Tom Hutchinson,
AstraZeneca, Sweden**

**Mark Montforts,
RIVM, The Netherlands**

AQUATIC TOXICITY - DATA DEVELOPMENT AND USE

This workshop will evaluate current approaches to generate and interpret ecotoxicological effect data in aquatic organisms. Both the applicability of the base set testing (algae, daphnids, fish) and the potential of other standardised chronic test guidelines are discussed. Ideas to develop improved testing methods for chronic pharmacological and toxic effects will be addressed, particularly with regard to the primary pharmacological mechanism in humans and mammals and the concept of evolutionary conservation of target molecules. The usefulness of data obtained in test systems on the molecular, cellular, organ-organismal and population level of biological organisation for environmental risk assessment need to be evaluated, also taking into account animal (vertebrate) welfare considerations.

PARALLEL WORKSHOP E

Co-Chairpersons:

**Bent Halling Sørensen,
The Danish University of
Pharmaceutical Sciences, Denmark**

**Reinhard Laenge,
Schering AG, Germany**

MIXTURES

Pharmaceuticals individually occur at concentrations mostly below any known environmental effect levels. In order to determine the potential environmental risks of pharmaceuticals, it is necessary to evaluate whether mixtures of different compounds with different or similar activity/structure have environmental relevance. Particularly, appropriate methods and models are required to determine whether mixtures represent a risk below concentrations of their individual effects thresholds. In a regulatory context, adequate guidance is needed for methods to evaluate the environmental risks related to mixtures of pharmaceutical compounds.

Tuesday, May 23, 2006 - Regulatory Perspective

08:30 -09:00

OVERVIEW OF DAY 1

Co-Chairpersons:

Richard T. Williams, Pfizer, USA

Klaus Olejniczak, BfArM, Germany

REGULATORY PERSPECTIVE

The evaluation of environmental risks of medicinal products for human use is regulated, but regional differences exist. In the following sessions regulatory aspects on environmental risk assessment from a global perspective will be presented by representatives from USA, Japan, EU and Canada. What are the requirements for marketing approval of a medicinal product? What are the principles of environmental risk assessment and what is stated in current and emerging guidelines? What kind of risk mitigation is possible within the authorisation process and what kind of risk mitigation/risk management is possible in general? The sessions will end with some reflections on experience from harmonisation of guidelines on environmental risk assessment of veterinary medicinal products and an example of possible risk mitigation/risk management.

09:00 -10:30

REGULATORY PERSPECTIVE I

Co-Chairperson:

Anders Cronlund, The Swedish Academy of Pharmaceutical Sciences, Sweden

Jean-Marc Vidal, EMEA, EU

Regulations and Guidelines in the USA

Keith Webber, FDA, USA

Regulations and Guidelines in Japan

Yoshitada Yoshioka, Ohito University, Japan

10:30 - 11:00

COFFEE BREAK

11:00 - 12:00

REGULATORY PERSPECTIVE II

Co-Chairperson:

Michael Holsapple, ILSI Health and Environmental Sciences Institute (HESI), USA

Anna-Karin Johansson, Medical Products Agency, Sweden

Regulations and Guidelines in the EU

Klaus Olejniczak, BfArM, Germany

Per Spindler, BioLogue, University of Copenhagen, Denmark

Regulations and Guidelines in Canada

Andrew Beck, Healthy Environments & Consumer Safety Branch, Health Canada, Canada

12:00 - 13:30

LUNCH

13:30 - 15:15

REGULATORY PERSPECTIVE III

(COFFEE AVAILABLE IN THE AFTERNOON)

Co-Chairperson:

Keith Webber, FDA; USA

Henry Stemplewski, MHRA, UK

Experiences from VICH

Joe Robinson, Pfizer, USA

Risk Management and Labelling – a Voluntary Classification System

Bengt Mattson, The Swedish Association of the Pharmaceutical Industry, Sweden

Challenges of Meeting Global Standards and a Short Notion on Environmental Assessment of Human Medicines as Possible ICH Topic?

David Taylor, Astra Zeneca, United Kingdom

15:15 - 16:15

CONFERENCE DISCUSSION & SUMMARY

Moderators:

Jean-Marc Vidal, EMEA, EU

Richard T. Williams, Pfizer, USA

Bent Halling-Sørensen, The Danish University of Pharmaceutical Sciences, Denmark

David Taylor, AstraZeneca, United Kingdom

Per Spindler, BioLogue, University of Copenhagen, Denmark

Mark Montforts, RIVM, The Netherlands

Panellists:

All speakers and chairpersons

16:15

END OF CONFERENCE

Hotel & Travel Information

The DIA has blocked a limited amount of rooms at the:



Scandic Infra City
Kanalvägen 10
SE-194 61 Upplands Väsby, Sweden
Tel: +46 8 517 344 00
Email : Infracity@scandic-hotels.com

At the special rate of:

Single Room SEK 1550
Double Room SEK 1675

The above rates are per room per night, inclusive of breakfast, service charge and VAT.

Attendees must make their own hotel reservation by

Telephone: ++46 8 517 344 10 or
email: infracity@scandic-hotels.com
referring to the reservation code **DIA 210506**

A deposit payment for one night must be made to secure the reservation by providing your name, number, expiry date of your credit card and signature.

Reservation Conditions:

- The hotel should receive the reservation three weeks before your arrival at the latest
- All changes should be made in writing
- All cancellations must be made in writing
- Check in 15:00 / Check out 12:00

In case of cancellation: Cancellation must be in writing. One night deposit will be kept as cancellation fee. All no shows will be billed for the entire stay.

IMPORTANT: To be assured of accommodation in the Scandic Infra City, the registrants are recommended to complete their reservation, if possible, by April 24, 2006.

The hotel is strategically located to the north of Stockholm between Arlanda airport and the city.
If you are arriving by plane you have easy access to the Scandic Infra City by taxi. The Journey will take about 15 minutes.
If arriving by train to Stockholm Central station, take the commuter train leaving from the Central station in the direction of Märsta and get off at the station Upplands Väsby. Take bus no. 536, 533 or 566 and get off at the stop of Infra City. If you prefer to take a taxi from the Stockholm Central station, it takes about 20 minutes to the Scandic Infra City.
If you are arriving by car, you can park in the hotel garage. There are also public parking facilities within the near vicinity of the Scandic Infra City.

ACCOMMODATION BOOKING FORM

1 FORM PER RESERVATION

WS06103 - May 22-23, 2006
Joint DIA/HESI/SAPS Conference on
Environmental Assessment of Human Medicines
Please send your completed form to the
Scandic Infra City referring to the reservation code DIA210506
by April 24, 2006
Telephone: +46 8 517 344 10 or
email: Infracity@scandic-hotels.com

GUEST

Prof. Dr. Ms. Mr.

Last Name _____

First Name & Middle Initial _____

Company _____

Job Title _____

Street Address / P.O. Box _____

Postal Code _____

City _____

Country _____

Telephone _____

Telefax _____

E-Mail _____

Room:

Single 1550 SEK Double 1675 SEK

The above rates are per room per night, inclusive of breakfast, service charge and VAT

non smoking smoking

Arrival date: _____ Expected Time of Arrival: _____

Departure Date: _____ Number of Nights: _____

In case of cancellation: Cancellation must be in writing. One night deposit will be kept as cancellation fee. All no shows will be billed for the entire stay.

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I hereby authorize the Scandic Infra City to charge my credit card according to the conditions mentioned above.

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Cardholder's Name: _____

Date: _____

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JOINT DIA/HESI/SAPS CONFERENCE ON ENVIRONMENTAL ASSESSMENT OF HUMAN MEDICINES
MAY 22-23, 2006 - SCANDIC INFRA CITY HOTEL, STOCKHOLM UPPLANDS VÄSBY, SWEDEN



Registration will be accepted by
mail, fax, or online
www.lakemedelsakademien.se

Swedish Academy of Pharmaceutical Sciences
Box 1136, SE-111 81, SWEDEN
annica.flodin@lakemedelsakademien.se

	MEMBER			NONMEMBER		
	FEE	VAT 25%	TOTAL	FEE	VAT 25%	TOTAL
Industry	€ 1'200.00	€ 300.00	€ 1'500.00 <input type="checkbox"/>	€ 1'330.00	€ 332.50	€ 1'662.50 <input type="checkbox"/>
Discount Registration Fees						
Charitable Nonprofit/ Academia or Government (Full Time)	€ 600.00	€ 150.00	€ 750.00 <input type="checkbox"/>	€ 730.00	€ 182.50	€ 912.50 <input type="checkbox"/>
Student (proof of student status must be provided)	€ 300.00	€ 75.00	€ 375.00 <input type="checkbox"/>	€ 332.50	€ 83.13	€ 415.63 <input type="checkbox"/>

TOTAL AMOUNT DUE: € _____

VAT NUMBER IF APPLICABLE _____

Registration includes conference material, coffee-breaks,
luncheons and reception.

NOTE: Payment of registration fees must be received before commencement of the meeting.

Group Discount Available! Send 3, the 4th is FREE

Register 3 individuals from the same company and receive complimentary registration for a 4th! **All 4 individuals must be registered and prepaid at the same time.** SAPS will apply the value of the lowest applicable fee to this complimentary registration. Substitutions of enrolled delegates of similar membership may be made at any time. Group registration is not available online. To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company and return them together to SAPS.

Please indicate that this form is part of a group registration by ticking this box. Please indicate the full names of the other three registrants from your company.

2. Name _____

3. Name _____

4. Name _____

REGISTRANT

Prof. Dr. Ms. Mr.

Last Name _____

First Name _____

Company _____

Job Title _____

Street Address / P.O. Box _____

Postal Code _____

City _____

Country _____

Telephone _____

Telefax (Required for confirmation) _____

Email (Required for confirmation) _____

PAYMENT METHODS

Please charge my credit card - Credit card payments by VISA or Mastercard can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

VISA MC

Card Number _____

Exp. Date _____

Cardholder's Name _____

Date _____ Cardholder's Signature _____

Invoice - After registration an invoice will be sent to the address on the registration form with instructions on how to complete the bank transfer.

Persons under 18 are not allowed to attend DIA meetings.

CONFERENCE CANCELLATION POLICY All cancellations must be in writing and be received at the SAPS office by 17:00 on May 15, 2006.

Cancellations received in writing on or before May 15, 2006 – Administrative fee that will be deducted from fee paid:

Full Meeting Cancellation: Industry Member/Nonmember = EUR 200.00. Government/Academia/Nonprofit (Member/Nonmember) = EUR 100.00

Registrants who do not cancel by the date above and do not attend, will be responsible for the full registration fee. Registrants are responsible for cancelling their own airline and hotel reservations. You may transfer your registration to a colleague at any time. Please notify SAPS of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable. DIA reserves the right to alter the venue, if necessary. **If an event is cancelled, DIA/SAPS is not responsible for airfare, hotel or other costs incurred by registrants.**

Confirmation will be received via fax or email within five working days after the registration has reached SAPS.
Hotel and travel reservation is not handled by SAPS and should be made ONLY after receipt of written registration confirmation.