2nd Joint DIA/EMA/CMD(h) Conference on Variations

Event #10109
23 November 2010
Radisson Edwardian New Providence Wharf Hotel, London, UK

Programme Committee

Truus Janse-de Hoog
Staff member MEB, Chair CMD(h), Medicines Evaluation Board, The Netherlands

Sandra Kruger-Peters
Secretary, Medicines Evaluation Board, The Netherlands

Sonia Ribeiro
Scientific Administrator,
European Medicines Agency, EU

Susanne A. Winterscheid
Project Management, BfArM, Germany,
CMD subgroup on variations

About the Drug Information Association (DIA)

DIA serves more than 30,000 biopharmaceutical professionals from industry, academia and regulatory agencies worldwide. Through its domestic and international meetings, training courses, workshops and webinars, DIA provides a neutral global forum for the exchange of information critical to the advancement of the drug discovery and lifecycle management processes.

Headquartered in Horsham, PA, USA, and with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India, and Beijing, China, the Association is led by its volunteer-based Board of Directors and executive management team. For more information, visit www.diahome.org or call DIA in Europe +41 61 225 51 51.

SwaPP and SGPM Credits

DIA meetings and training courses are approved by the SwAPP (Swiss Association of Pharmaceutical Professionals) Commission for Professional Development (CPD) and SGPM (Swiss Society of Pharmaceutical Medicine) and are honoured with credits for pharmaceutical medicine. All meeting and training course participants are eligible for these credits.

Overview

Since 1 January 2010 the new Variation Regulation for Human and Veterinary Marketing Authorisations granted through Mutual Recognition (MR) and Decentralised Procedure (DCP) as well as through Centralised Procedure (CP), apply.

In this conference different stakeholders present their experience with the new system in the first ten months after implementation. Speakers from the European Commission, the EMA, the CMDh, National Competent Authorities and pharmaceutical industry will give their opinion on successful and unsuccessful aspects of the revised Variation Regulation as well as the procedural and classification guidelines.

The nationally granted Marketing Authorisations are still outside of the scope of the Variation Regulation. The conference will give an update of the current status of the development of the 2nd Comitology procedure and the planned implementation timetable of the Variation Regulation for purely national licences.

Who Will Attend?

Representatives of pharmaceutical industry dealing with variations and Regulators/Assessors from National Competent Authorities and EMA involved in variation processes

Objectives

To discuss first experiences after implementation of the new variation regulation in MR/DCP and CP: Are the objectives “clearer, easier, more flexible” achieved?
A statistic overview about the use of the new procedures will be given in order to identify successful and unsuccessful aspects of the new variation regulation. The results should be considered for further updates of the regulation and the guidelines.
An update of the current status of the implementation of the regulation for purely national procedures will be given.

FEATURED SESSION INCLUDE:

- ARE THE OBJECTIVES OF THE NEW VARIATION REGULATION “SIMPLER, CLEARER AND MORE FLEXIBLE” ACHIEVED?
- HOW ARE THE NEW PROVISIONS WORKING IN PRACTICE?
- EXPERIENCE WITH THE USE OF THE CLASSIFICATION GUIDELINE & APPLICATION FORM
- QUESTIONS & ANSWERS PANEL DISCUSSION

For more information please contact
sandra.grass@diaeurope.org +41 61 225 51 63

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CMDh
Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

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www.diahome.org

TUESDAY | 23 NOVEMBER 2010

07:30 **Welcome Coffee and Registration**

09:00 **Session 1**

ARE THE OBJECTIVES OF THE NEW VARIATION REGULATION "SIMPLER, CLEARER AND MORE FLEXIBLE" ACHIEVED?

Session Chairperson:
Truus Janse-de Hoog, Staff member MEB, Chair CMD(h), Medicines Evaluation Board, The Netherlands

After one year of experience with the New Regulation representatives from the European Commission, European Medicines Agency and CMD(h) will present their views whether the objectives of the New Regulation have been met. A looking back on practical implementation, trends, general experiences and plans for the future.

Industry Perspective
Katie M. Harrison, EU Regulatory Intelligence Manager, Baxter Healthcare Ltd., UK

CMD(h) and European Medicines Agency Perspective
Truus Janse-de Hoog, Staff member MEB, Chair CMD(h), Medicines Evaluation Board, The Netherlands
Sonia Ribeiro, Scientific Administrator, European Medicines Agency, EU

10:30 **Coffee break**

11:00 **Session 2**

HOW ARE THE NEW PROVISIONS WORKING IN PRACTICE?

Session Chairperson:
Sonia Ribeiro, Scientific Administrator, European Medicines Agency, EU

Speakers from the European Medicines Agency, CMD(h) and Industry will share their practical experience with the use of the new provisions of the Variations Regulation and address successful and unsuccessful aspects of these new provisions.
This session will provide an opportunity to exchange views on the practical implementation of the new provisions and on some of the aspects to be considered for further updates of the Regulation and Commission guidelines.

CMD(h) and European Medicines Agency Perspective covering:
- **Grouping/work sharing**
- **Article 5 & IB by default**
- **Type IA & Annual Reports**

Susanne A. Winterscheid, Project Management, BfArM, Germany, CMD subgroup on variations
Heidi Janssen, Scientific Administrator, European Medicines Agency, EU

Industry Perspective on any of the new Provisions with Implementation of Variations
Caroline Kleinjan, Head of Regulatory Competence Centre Europe, Sandoz B.V., The Netherlands

12:30 **Lunch**

13:30 **Session 3**

EXPERIENCE WITH THE USE OF THE CLASSIFICATION GUIDELINE & APPLICATION FORM

Session Chairperson:
Sandra Kruger-Peters, Secretary, Medicines Evaluation Board, The Netherlands

Speakers both from industry and competent authorities will share their experience with the changes introduced in the classification of variations and the new elaborated application form. Issues for which a lot of questions were raised over the last months will be presented. After this session it will be absolutely clear for you what is the difference between an unforeseen and foreseen type IB variation and how the 'z' variations should be used.

CMD(h) Perspective
Peter Bachmann, European Drug and International Affairs, BfArM, Germany

European Medicines Agency Perspective
Evdokia Korakianiti, Scientific Administrator, European Medicines Agency, EU
Catherine Drai, European Medicines Agency, EU

Industry Perspective
Fiona Reekie, Director, Global Regulatory Affairs Strategic Policy & Support, Policy & Intelligence EMEA
Johnson & Johnson Pharmaceuticals Group, UK

15.00 **Coffee break**

15:30 **Session 4**

QUESTIONS & ANSWERS PANEL DISCUSSION

Session Chairperson:
Susanne A. Winterscheid, Project Management, BfArM, Germany, CMD subgroup on variations

This session will give the opportunity to the participants to discuss special issues with the panel with speakers from the European Commission, EMA, CMDh, CMDv, experts from the national competent authorities and members of the Variation Task Force. Furthermore, questions submitted in advance of the meeting will be answered and may be considered in future updates of the Guidelines and Best Practice Guides.

Panel:
- **Joan Boye**, Head of Regulatory Unit, Danish Medicines Agency, Denmark, Member of the CMD(h) group
- **Heidi Janssen**, Scientific Administrator, European Medicines Agency, EU
- **Evdokia Korakianiti**, Scientific Administrator, European Medicines Agency, EU
- **Sandra Kruger-Peters**, Secretary, Medicines Evaluation Board, The Netherlands
- **Keith Pugh**, Assessor, MHRA, UK
- **Sonia Ribeiro**, Scientific Administrator, European Medicines Agency, EU
- **Esther Werner**, Head of Section "Bacterial Vaccines and Immune Sera", Department of Veterinary Medicine, Paul-Ehrlich-Institute, Germany

Questions on topics:
- Grouping
- Worksharing
- Article 5
- Classification guideline
- Procedural guideline
- Revision of Variation Regulation & extension to purely nationally authorised products
- Others

17:00 **End of Conference**

TRAVEL INFORMATION

East India Station on Docklands Light Railway (which is connected to the underground) is a 5 minute walk to the hotel. From London City Airport the DLR takes 10 minutes to East India Station.

For more details on the DLR Train click here:
http://www.tfl.gov.uk/assets/downloads/dlr-route-map.pdf

HOTEL INFORMATION

The Radisson Edwardian New Providence Wharf Hotel is already fully booked; therefore we recommend to visit the following website for hotels in the area:

http://canary-wharf.hotels-london.co.uk/

VENUE INFORMATION

Radisson Edwardian New Providence Wharf Hotel
5 Fairmont Avenue, Canary Wharf
London E14 9PQ, UK
Tel: +44 (0)20 7987 2050 Fax: +44 (0)20 7987 8424
http://www.radissonedwardian.com/newprovidencewharf

For directions please click here:
http://www.radissondestinationguide.com/locationMap.process/OID_EB39EA2D/?hotelCode=GBCANARY

Register for upcoming DIA events in Europe

2nd Joint DIA/European Medicines Agency Innovation Forum: Is the EU Regulatory Framework Ready?
29-30 November 2010 | London, UK

11th Conference and Exhibition on European Electronic Document Management - The New Frontiers
1-3 December 2010 | Nice, France

DIA/EMA/IFAH Global Animal Health Conference
23-24 March 2011 | London, UK

9th Middle East Regulatory Conference MERC 2011
1-2 February 2011 | Amman, Jordan
Register on or before 21 December 2010 and save EUR 200

23rd Annual EuroMeeting
28-30 March 2011 | Geneva, Switzerland
Register on or before 29 January 2011 and save EUR 150

5th European Forum for Qualified Person for Pharmacovigilance (QPPV)
2011 | London, UK

5th Annual Clinical Forum
10-12 October 2011 | Basel, Switzerland

Register for upcoming DIA Training Courses in Europe

Clinical Research

Advanced GCP Study Monitoring
19 November 2010 | Paris, France | ID 10561

Essentials of Clinical Study Management
10-12 November 2010 | Lisbon, Portugal | ID 10528

Regulatory Affairs

An Introduction to Product Information Management (PIM)
28-29 October 2010 | Geneva, Switzerland | ID 10539

CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3
5-7 December 2010 | Dubai, United Arab Emirates | ID 10530

European Regulatory Affairs: Review of Current Registration Procedures in the EU
18-19 November 2010 | Paris, France | ID 10540

Good Management of Medical Devices
10-12 November 2010 | Zurich, Switzerland | ID 10547

Quality by Design: A Hands-on Short Course for Pharma
4-5 November 2010 | Graz, Austria | ID 10565

Training Course for eCTD Submissions in Switzerland
9 December 2010 | Zurich, Switzerland | ID 10572

US Regulatory Affairs
18-21 October 2010 | Prague, Czech Republic | ID 10552

Safety and Pharmacovigilance

Excellence in Pharmacovigilance: Clinical Trials and Post Marketing
25-29 October 2010 | Vienna, Austria | ID 10533

Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing
1-3 December 2010 | Paris, France | ID 10526

EudraVigilance (EV) and EudraVigilance Medicinal Product Dictionary (EVMPD)
Courses throughout the year | European Medicines Agency, London, UK and selected European cities
For course details on EV, please visit www.diahome.org > Training > EudraVigilance > Click on Related Courses

Non-Clinical Sciences

Non-Clinical Safety Sciences and Their Regulatory Aspects
22-26 November 2010 | Lisbon, Portugal | ID 10562

REGISTRATION FORM

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ID# 10109

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Category	Member Fee FEE
Industry	**€ 850.00** ❑
Charitable/Non-profit/Academia (Full-Time)	**€ 637.00** ❑
Government (Full-Time)	**€ 425.00** ❑

Category	Non-Member Fee FEE
Industry	**€ 965.00** ❑
Charitable/Non-profit/Academia (Full-Time)	**€ 752.00** ❑
Government (Full-Time)	**€ 540.00** ❑

A one-year membership to DIA is available to those paying a non-member registration. If paying a non-member fee, please indicate if you do, or do not wish to become a member: YES___ NO___

TOTAL AMOUNT DUE: € _____ **NOTE:** Payment due 30 days after registration and must be paid in full by commencement of the event

STUDENT RATES AND GROUP DISCOUNTS ARE AVAILABLE! PLEASE CONTACT DIA FOR MORE INFORMATION. 10109DIAWEB

REGISTRANT

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE REGISTRANT'S BUSINESS CARD HERE

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Please indicate your professional category: ❑ **Academia** ❑ **Government** ❑ **Industry** ❑ **Contract Service Organisation**

PAYMENT METHODS - Credit cards are our preferred payment method.

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

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D.I.A., Elisabethenanlage 25, Postfach, 4002 Basel, Switzerland

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." including your name, company, Meeting ID# 10109 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer.

Persons under 18 are not allowed to attend DIA meetings.

CANCELLATION POLICY

All cancellations must be in writing and received at the DIA office by 17:00 CET on 15 November, 2010

Cancellations received by the date above are subject to an administrative fee:
Full Meeting Cancellation: Industry (Member/non-member) = € 200.00 Government/Academia/Non-profit (Member/non-member) = € 100.00. Tutorial cancellation: € 50.00. 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 hotel reservations. DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA is not responsible for airfare, hotel or other costs incurred by registrants.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute registrants will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

IMPORTANT: Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA. If you have not received your confirmation within five working days, please contact DIA.

HOW TO REGISTER

The DIA Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

Online	Fax	Email	Mail
www.diahome.org	+41 61 225 51 52	diaeurope@diaeurope.org	DIA European Office Postfach, 4002 Basel, Switzerland