DIA/EMEA/CMD(h) Joint Conference on Variations

DRUG INFORMATION ASSOCIATION

October 26, 2009 - Hotel Radisson Edwardian New Providence Wharf, London, UK

Overview

The new variation regulation (EC) 1234/2008 has entered into force on January 01, 2009 and will apply from January 01, 2010. It applies for human and veterinary marketing authorisations granted through a mutual recognition process (MRP), decentralised procedure (DCP) or centralised procedure (CP). National marketing authorisations will be integrated in a later step.

In this conference different stakeholders will give an overview of the content of the variation regulation, the Commission guidelines on the procedures and the categorisation details, as well as further practical implementation guidance.

Speakers from the European Commission, the EMEA, CMD and different working groups will give an overview of the new procedures, and the industry expectations and views will be presented.

Who Should Attend?

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

Objectives

To provide detailed information on the implementation of the new variation regulation in MRP, DCP and CP and to discuss the resulting expected simplifications for the handling of variation procedures. The influence on the maintenance of marketing authorisations will be explained. Furthermore, the participants will get information about the new tools such as grouping and worksharing and practical submission details.

AUTHORIZED IACET PROVIDER

The Drug Information Association (DIA) has been approved as an 'Authorized Provider' by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102.

DIA is authorised by IACET to offer **0.6 CEUs** for this programme.

If you would like to receive a statement of credit, you must attend the programme, return your evaluation form and complete the online credit request process through My Transcript at www.diahome.org. Participants will be able to download a statement of credit upon successful submission of the credit request.

Disclosure Policy
It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabelled or unapproved uses of drugs or medical devices. Faculty disclosures will be included in the course materials.

Programme Committee

Hilde Boone
Scientific Administrator – Regulatory Affairs, EMEA, EU, Chair EU variation task force

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

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

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Monday, October 26, 2009

09:00 **Session 1**

THE NEW VARIATION REGULATION AND IMPLEMENTING GUIDELINES

Session Chairperson:
Hilde Boone, Scientific Administrator – Regulatory Affairs, EMEA, EU, Chair EU variation task force

The new Variation Regulation (EC) 1234/2008 entered into force on January 01, 2009. The guidelines for the implementation of the Variation Regulation were released for consultation of the different stakeholders in March 2009 and publication of the final guidelines is expected for the 4th quarter of 2009. Further practical operational guidance documents by EMEA and CMD are in preparation.

In this section an overview of the key principles of the new variation regulation will be given, as well as an update on the status and content of the implementing guidelines.

Key Principles of the Regulation and Guidelines Development
Hilde Boone, Scientific Administrator – Regulatory Affairs, EMEA, EU, Chair EU variation task force

Status Update and Content of the Implementing Guidelines, including outcome of the external consultation
María Angeles Figuerola Santos, Administrator, European Commission, EU

CMD Update of the Best Practice Guidance
MHRA representative invited

10:30 **Coffee Break**

11:00 **Session 2**

INTRODUCTION OF THE NEW PROCEDURES – PROCEDURAL ANNEX OF THE GUIDELINE

Session Chairperson:
Susanne Winterscheid, Head of Project Management of Licensing Division 4, BfArM, Germany and Chair CMD(h) and (v) subgroup on variations

There are new procedures according to the new variation regulation; for example worksharing procedures, grouping, Type IA "Annual Reports", CMD-referrals, etc. This session gives an overview of the implementation of the new procedures.

Grouping and Annual Reporting
- Zahra Hanaizi, Scientific Administrator, Post-Authorisation Safety/Efficacy, EMEA, EU
- Sandra Kruger-Peters, Staff member, Medicines Evaluation Board, The Netherlands

Work Sharing
- Sandra Kruger-Peters, Staff member, Medicines Evaluation Board, The Netherlands
- Tania Teixeira, Scientific Administrator, Post-Authorisation Safety/Efficacy, EMEA, EU

Panel discussion with representatives from Industry Associations:
- Paloma de Miguel, VP Global Regulatory Affairs, Baxter, UK, representing EFPIA
- Beata Stepniewska, Director of Regulatory Affairs, European Generic medicines Association (EGA), Belgium
- Kate Stockman, Regulatory Manager UK & Ireland, Wyeth Consumer Healthcare, UK representing AESGP

12:30 **Lunch Break**

14:00 **Session 3**

INTRODUCTION OF THE CLASSIFICATION ANNEX OF THE GUIDELINE

Session Chairperson:
Evdokia Korakianiti, Scientific Administrator, Quality of Medicines, EMEA, EU

Most changes in the categorisation annex of the guideline concern changes in the quality dossier. Furthermore, safety/efficacy and changes to pharmacovigilance system will be introduced.

This session will deal with the novelties in the classification annex, especially the impact of the revision on quality variations, explain the background for decisions on the procedure type and inform about special provisions for biological products.

Changes to the Pharmaceutical Dossier
MHRA representative invited

Particularities for Biological Products
Peter Richardson, Scientific Administrator, Quality of Medicines, EMEA, EU

Safety/Efficacy and Pharmacovigilance System Changes
Helena Matos, Scientific Administrator, Post-Authorisation Safety/Efficacy, EMEA, EU

Panel discussion with representatives from Industry Associations:
- Michael J. James, Head of CMC Regulatory Advocacy and Intelligence, Global Regulatory Affairs GlaxoSmithKline, UK, representing EFPIA
- Julie Marechal-Jamil, Senior Manager Regulatory Affairs, European Generic medicines Association (EGA), Belgium
- Merete Schmiegelow, Director, Regulatory Intelligence, Novo Nordisk A/S, Denmark, representing Europabio
- Kate Stockman, Regulatory Manager UK & Ireland, Wyeth Consumer Healthcare, UK, representing AESGP

15:30 **Coffee Break**

16:00 **Session 4**

QUESTIONS & ANSWERS - PANEL DISCUSSION

Session Co-Chairs:
Truus Janse de Hoog, Staff member MEB, Chair CMD(h), Medicines Evaluation Board, The Netherlands and
Anu Tummavuori, Associate Director European Regulatory Liaison, Celgene International Sarl, Switzerland

This session will give the opportunity to the participants to discuss special issues with the panel consisting of speakers from the European Commission, EMEA, CMD, Variation Task Force and Industry Associations.

17:30 **End of Conference**

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the Drug Information Association.

HOTEL INFORMATION

The DIA has blocked a number of rooms at the:

Radisson Edwardian New Providence Wharf Hotel
5 Fairmont Avenue, Canary Wharf
London E14 9PQ, UK

Tel: +44 (20) 7987 2050
Fax: +44 (20) 7987 8424

at the special rate of:
£115.00 (approx. EUR 135.00) per single room inclusive of VAT and breakfast

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Please quote the booking reference: **1026DIA**

Important:
Please complete your reservations by **September 30, 2009**

Cancellation Policy:
Free cancellation can be made up to 16.00 PM (UK time) on the day of arrival. The full accommodation will be charged when cancellations are received after this deadline or in case of no show.

TRAVEL INFORMATION

East India Station on Docklands Light Railway (which is connected to the underground) is a 5 minute walk from the Radisson Edwardian New Providence Wharf Hotel. From London City Airport the DLR takes 10 minutes to reach the East India Station.

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

Register for upcoming DIA conferences

Workshop on Biosimilars
September 28, 2009 | London, UK

3rd Annual Clinical Forum
Improving Clinical Development Together
October 19-21, 2009 | Nice, FRANCE

3rd Paediatrics Forum
EFGCP Children's Medicines Working Party 5th Annual Conference
Integrating Paediatrics into Drug Development –
From Concept towards Reality
October 27-28, 2009 | London, UK

Pharmaceutical Quality Forum
November 9-10, 2009 | Prague, CZECH REPUBLIC

Health Technology Assessment (HTA) Forum
November 25-26 | Paris, FRANCE

10th Conference on European Electronic Document Management
BEFORE YOU ASK: "WHAT CAN EDM DO FOR ME?"
ASK: "WHAT HAVE I DONE FOR EDM?"
December 2-4 | Vienna, AUSTRIA

22nd Annual EuroMeeting
March 8-10, 2010 | MONACO

Register for upcoming DIA training courses

European Regulatory Affairs Training Course
September 10-11, 2009 | Frankfurt, Germany

Essentials of Clinical Study Management Training Course
September 16-18, 2009 | Copenhagen, Denmark

Building the eCTD
September 17-18, 2009 | Copenhagen, Denmark

Medical Approach in Diagnosis and Management
of ADRs Training Course
September 17-18, 2009 | Paris, France

Practical GCP Compliance Auditing of Trials
and Systems Training Course
October 7-9, 2009 | London, United Kingdom

Clinical Statistics for Nonstatisticians Training Course
October 8-9, 2009 | London, United Kingdom

Excellence in Pharmacovigilance:
Clinical Trials and Post Marketing Training Course
October 12-16, 2009 | Berlin, Germany

An Introduction to Product Information Management (PIM)
Training Course
October 15-16, 2009 | Berlin, Germany

US Regulatory Affairs Training Course
October 19-22, 2009 | Basel, Switzerland

REGISTRATION FORM

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ID# 09113

DIA Drug Information Association

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

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

CATEGORY	NON-MEMBER FEE
Industry	**€ 965.00** ❑
Charitable/Non-profit/Academia (Full-Time)	**€ 752.00** ❑
Government (Full-Time)	**€ 540.00** ❑

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TOTAL AMOUNT DUE: € _____

NOTE: Payment due 30 days after registration and must be paid in full by commencement of the event

STUDENT AND GROUP DISCOUNTS RATES ARE AVAILABLE! PLEASE CONTACT DIA FOR MORE INFORMATION. 09113DIAWEB

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PAYMENT METHODS

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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# 09113 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 October 19, 2009

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