Combination Products Workshop

Regulatory Landscape for Drug/Device Combinations and Companion Diagnostics

Event #13106
17 October 2013
Hotel Dorint, Basel, Switzerland

Programme Co-Chairs

Shayesteh Fürst-Ladani
Managing Director, SFL Regulatory Affairs & Scientific Communication Ltd, Switzerland

Cordula Landgraf
Head of Networking, Swissmedic, Swiss Agency for Therapeutic Products, Switzerland

Continuing Education

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

About DIA

DIA is a neutral, global, professional and member-driven association of nearly 18,000 professionals involved in the discovery, development and life cycle management of pharmaceuticals, biotechnology, medical devices and related health care products. Through our international educational offerings and myriad networking opportunities, DIA is an independent non-profit organisation who provides a global forum for knowledge exchange that fosters the innovation of products, technologies and services to improve health and well-being worldwide. Headquarters are in Horsham, PA, USA, with offices in Basel, Switzerland; Tokyo, Japan; Mumbai, India; Beijing, China; Washington, D.C.; and Latin America.

For more information, visit www.diahome.org or call DIA Europe +41 61 225 51 51.

Overview

This one-day workshop will provide delegates with an understanding of the current regulatory framework for drug/device combinations and companion diagnostics, and of the anticipated impact of the revision of the European medical device and In-Vitro Diagnostics (IVD) legislation.

The meeting will focus on the differences between device and pharma regulations and highlight challenges faced by manufacturers who need to comply with elements of both regulatory structures. It will give guidance to those who operate on the drug/device borderline where it is not immediately obvious which regulatory framework applies.

Key Topics

- Overview of the current regulatory framework for combination products in the EU, and outline of the situation in the US
- Overview of anticipated changes to the EU's medical device and IVD legislation and the likely impact on the combination products
- Competent authority and notified body views on their roles in regulating drug/device combinations and companion diagnostics
- Regulatory challenges in developing combination products and companion diagnostics, with case studies

Who Will Attend

- Pharma, medical device and diagnostic industry professionals
- Health authority representatives
- Notified body representatives
- Regulatory, clinical and other professionals responsible for developing drug/device combinations and companion diagnostics

Objectives

- Highlight regulatory options and routes that are available to manufacturers developing drug/device combinations and companion diagnostics
- Give an overview on how the latest EU regulatory developments impact drug/device combinations and companion diagnostics
- Provide an open forum to discuss the relative merits and drawbacks between the different regulatory frameworks

For regular programme updates, please visit www.diahome.org/CombinationsWS
If you have any questions, please contact Junes Babay, Planning and Development, at DIA Europe on +41 61 225 51 54 or email junes.babay@diaeurope.org

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THURSDAY | 17 OCTOBER 2013

08:45 REGISTRATION AND WELCOME COFFEE

09:30 Session 1

OVERVIEW OF CHANGING THE REGULATORY FRAMEWORK FOR COMBINATION PRODUCTS, MDD AND IVD

Session Chair:
Cordula Landgraf, Head Networking, Swissmedic, Switzerland

This session will provide an overview of the revision of the Medical Device Directives, including the In Vitro Diagnostics Directive and of how the changes are likely to impact the regulation of drug/device combinations and companion diagnostics.

Overview of Latest Development on the Proposed Revision of Medtech Legislation and Impact on Regulatory Framework for Combination Products
Shayesteh Fürst-Ladani, Managing Director, SFL Regulatory Affairs & Scientific Communication Ltd, Switzerland

Regulator View of European Legislation for Combination Products
Waldo Weijers, Coordinator Consultation Procedures Medicated Medical Devices, Medicines Evaluation Board, the Netherlands

Notified Body View on Revision of European Medtech Law Impacting Combination Products
Theresa Jeary, Technical Manager, LRQA, UK

Panel Discussion

11:00 COFFEE BREAK

11:30 Session 2

REGULATORY REQUIREMENTS FOR COMPANION DIAGNOSTICS IN THE EU

Session Chair:
Shuna Mason, Partner, Head of Regulatory, CMS Cameron McKenna LLP, UK

Overview of Current and Future Regulatory Requirements for Companion Diagnostics
Shuna Mason, Partner, Head of Regulatory, CMS Cameron McKenna LLP, UK

Case Study: Development of a Companion Diagnostic with Drug
Bruce Jordan, International Business Leader, Roche Diagnostics International Ltd., Switzerland

Regulatory and Reimbursement Challenges in Patients' Access to High-Quality Diagnostics
Rebecca Jungwirth, Government Affairs Manager, Roche, Switzerland

13:00 LUNCH BREAK

14:00 Session 3

CONSIDERATIONS IN DEVELOPMENT OF COMBINATION PRODUCTS

Session Chair:
Manfred Maeder, Global Head Quality Assurance in Technical Research & Development, Novartis, Switzerland

Manufacturing and Quality Aspects
Manfred Maeder, Global Head Quality Assurance in Technical Research & Development, Novartis, Switzerland

Clinical Development Considerations
Blake Green, Regulatory Affairs Senior Manager, Amgen, UK

Assessing Classification of Borderline Products
Shayesteh Fürst-Ladani, Managing Director, SFL Regulatory Affairs & Scientific Communication Ltd, Switzerland

15:30 COFFEE BREAK

16:00 Session 4

ACHIEVING REGULATORY APPROVAL OF COMBINATION PRODUCTS

Session Chair:
Shayesteh Fürst-Ladani, Managing Director, SFL Regulatory Affairs & Scientific Communication Ltd, Switzerland

National Competent Authorities' Role in Assessing Drug/Device Combinations
Waldo Weijers, Coordinator Consultation Procedures Medicated Medical Devices, Medicines Evaluation Board, the Netherlands

Notified Body's Role in Assessing Device/Drug Combinations
Theresa Jeary, Technical Manager, LRQA, UK

Case Study: Drug Device Combination Product– Regulated as a device
Toni Joergensen, Founder and President of MDRAC, Switzerland

17:30 END OF WORKSHOP

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 DIA. Speakers and agenda are subject to change without notice. Recording of any DIA tutorial/workshop information in any type of media is prohibited without prior written consent from DIA.

JOIN THE DIA DEVICES AND DIAGNOSTICS COMMUNITY

You can now join the Devices and Diagnostics Community (formerly SIAC) and maximise the benefits of your DIA Membership!

The Devices and Diagnostics Community aims to increase awareness and contribute actively to shaping global legislation of medical devices, in-vitro diagnostics and drug/device combination products.

Joining the Community will offer you a wide range of benefits and enable you to:

- Better understand the most beneficial regulatory routes for your company
- Network with colleagues and specialists around the world
- Exchange vital information
- Stay on the pulse of hot new topics
- Be aware of speaking opportunities
- Help DIA identify your professional development needs

To join a Community, go to www.diahome.org, log in to My DIA, click on **Manage My Communities** and join the communities of your choice.

For more information about DIA Communities, go to www.diahome.org > Networking and Communities > Communities, or contact Kaija Kurki-Suonio on kaija.kurki-suonio@diaeurope.org or +41 61 225 51 51

HOTEL INFORMATION

DIA has blocked a limited number of rooms at the following hotel:

Dorint an der Messe Basel Hotel
Schönaustrasse 10
4058 Basel
Switzerland

Email: info.basel@dorint.com
Tel: 0041 61 695 70 00
Fax: 0041 61 695 71 00
Website: www.dorint.com/basel

at the rate of:
CHF 230.00 per standard room, single occupancy inclusive of breakfast buffet, VAT & mobility ticket, exclusive of city tax of CHF 3.50 per guest and day.

To make your reservation please use the hotel booking form on the DIA website.

Important: Please complete your reservation by 13.09.2013. Reservations received after this date will be subject to hotel availability and room rate may vary.

Cancellation: Cancellations of reservations are possible up to 31 days prior to arrival. No shows will be billed for the entire stay.

26TH ANNUAL
EUROMEETING
VIENNA 2014
25-27 March 2014
ACV, Vienna, Austria
Preliminary programme available at www.diahome.org/EM2013
REGISTRATION OPEN!

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DIA EUROPE CONFERENCES AND WORKSHOPS 2013-2014

- **7th Joint DIA/EFGCP/EMA Medicines for Children Conference**
  24-25 September 2013 | London, United Kingdom | ID 13115
- **10th Middle East Regulatory Conference (MERC 2013)**
  24-25 September 2013 I Muscat, Oman | ID 13102
- **Joint DIA/MHRA Statistics Workshop**
  2-4 October 2013 I London, United Kingdom | ID 13107
- **7th Annual Clinical Forum and Exhibition**
  8-9 October 2013 I Dublin, Ireland | ID 13103
- **Combination Products Workshop**
  17 October 2013 I Basel, Switzerland | ID 13106
- **14th Conference on European Electronic Document Management (eDM) and Exhibition**
  20-22 November 2013 I Dublin, Ireland | ID 13110
- **Joint DIA/IMB Common European Submission Platform (CESP) Information Day**
  20 November 2013 I Dublin, Ireland | ID 13111
- **European Healthcare Deciders' Forum**
  January 2014 I Paris, France I ID 13108
- **26th Annual EuroMeeting and Exhibition**
  25-27 March 2014 | Vienna, Austria | ID 14101
- **7th European Conference on Rare Diseases & Orphan Products (ECRD 2014)**
  8-10 May 2014 I Berlin, Germany I ID 14106
- **8th European Forum for Qualified Person for Pharmacovigilance (QPPV)**
  13-15 May 2014 I London, United Kingdom

For more information and a complete listing of all DIA conferences, please visit: www.diahome.org > click on Meetings & Training

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REGISTRATION FORM

Combination Products Workshop

17 October 2013 | Hotel Dorint, Basel, Switzerland

DIA www.diahome.org

ID #13106

Early-bird rates available for members: Register by 5 September 2013

Join DIA now to qualify for the Early-bird member fee! The Early-bird registration form and accompanying payment must be received by the date above.
Early-bird fee applies to industry members only. *(www.diahome.org/membership)*

€ 700.00 ❑

FEES (after 5 September 2013)

	Member	Non-Member
Industry	€ 900.00 ❑	€ 1'015.00 ❑
Academia/Charitable/Government/Non-profit (Full-time)	€ 450.00 ❑	€ 565.00 ❑
Join DIA now to qualify for the member rate	€ 115.00 ❑	

*All fees are subject to local Swiss VAT of 8%

TOTAL AMOUNT DUE: _____

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

Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility – please contact DIA Europe for more information.

Registration fee includes: refreshments, lunches and meeting material.

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

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

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Exp. Date /

Cardholder's Name

❑ **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." Please include your name, company, Event ID #13106 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. **If you have not received your confirmation within five working days, please contact DIA Europe.**

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking. These are available from the office or on http://www.diahome.org/EUTerms

Date	Signature

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All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00
- Tutorial cancellation € 50.00

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The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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