Conference Committee

Truus Janse-de Hoog
Staff member MEB, European cluster, Chair CMD(h),
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Head of Medical Information Sector, Chair of Quality Review of Documents (QRD), EMEA, EU

Alexios Skarlatos
Quality Review of Documents (QRD), EMEA, EU

Overview

In this joint workshop EMEA and Member States representatives will discuss their experiences in the assessment of user tests and give recommendations how the test can contribute to improve the quality of a package leaflet. Industry and Member States representatives will present their experiences on bridging studies and justifications for exemption from user consultation.
What are the lessons learned so far? Representatives from European Commission, Patient Organisations and Academia will give their views on possibilities to improve the quality of the package leaflet.

Who will attend?

- Regulators / Assessors from National -/ Competent Authorities involved in the evaluation of User Testing (UT) reports
- Representatives of pharmaceutical industry creating package leaflets
- Representatives of pharmaceutical industry responsible for user consultation
- Representatives of CROs directly involved in conducting User Testing
- EMEA representatives

Objectives

To provide updates and experiences with the assessment of user consultation tests of package leaflets three years after the implementation of the New Medicines Legislation. Discuss with all stakeholders (Regulators, Industry, Clinical Research Organisations (CROs), Academia and Patient Representatives) how to achieve good quality package leaflets.

Hotel Information

DIA Europe has blocked a number of rooms at the:

Devonport House
King William Walk, Greenwich,
London, SE10 9JW
United Kingdom
http://www.deverevenues.co.uk/find-venue/devonport-house.html

Booking details
Rooms: Single rooms
Rates: £119.00 per night
Details: Rate includes breakfast and 17.5% VAT

To reserve a room please contact the Devonport House
Tel.: +44 208 269 5400
Fax: +44 208 269 5401
Email: devonport@deverevenues.co.uk

To receive this special rate please mention the DIA Reservation code:
500 723 10

Important
To ensure accommodation at the Devonport House please complete your reservation by **October 17, 2008**

For further information, please visit: www.diahome.org > Select **Educational Offerings** > Keyword: **08112.** To secure your place at the workshop, please complete and fax back the enclosed registration form or register online. The DIA Europe Customer Services Team will be pleased to answer your questions and assist you with the registration process. Call us on +41 61 225 51 51 from Monday to Friday, 08:00-17:00 CET, or email: diaeurope@diaeurope.org

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DRUG INFORMATION ASSOCIATION

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

emea

Joint DIA – EMEA – CMD(h) Workshop on

USER TESTING

December 5, 2008
Devonport House, London, UK

PROGRAMME

ID# 08112

Programme

08.00-09.00 Registration and Welcome Coffee

09.00-10.30 **Session 1**

USER CONSULTATION – THREE YEARS OF EXPERIENCE IN CONDUCTING AND REVIEWING USER TESTS

Session Chairperson:
Alexios Skarlatos, Quality Review of Documents (QRD), EMEA, EU

EMEA has carried out an analysis of the User Testing reports submitted by applicants / Marketing Authorisation Holders (MAHs) for the period 2005-2008 and the way these were handled by the member states assessors. During this session key stakeholders will share their experiences of the first three years following the implementation of the User Testing requirement.

EMEA Experience
Alexios Skarlatos, Quality Review of Documents (QRD), EMEA, EU
- Summary of findings / recommendations drawn from all User Testing reports submitted to the EMEA for the period 2005-2008
- Handling of assessment by Rapporteur / Co-Rapporteur

Pharmaceutical Industry Experience
Petra Baddack, GRA - Head of Europe, Regulatory Affairs Coordination, Solvay Pharmaceuticals GmbH, Germany

Member State Experience
MHRA representative invited

Clinical Research Organisation Experience
Theo Raynor, Chairman, Luto Research Ltd., UK

10.30-11.00 Coffee break

11.00-12.30 **Session 2**

BRIDGING STUDIES – JUSTIFICATIONS FOR EXEMPTION FROM USER TESTING REQUIREMENT – DESIGN AND LAYOUT

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

CMD(h) has published a guidance paper on bridging studies. The QRD group of EMEA also has ongoing discussions for which applications exemptions from user consultation can be granted. In this session representatives from National Agencies and generic industry will present their experiences.

Bridging Data: Guidance Documents and Experience at National Level
Klaus Menges, Head of Scientific Quality Assurance, BfArM, Germany

The Case of Generic Products
Susan De Stasio, Head EU Regulatory Affairs, Arrow Generics Ltd., Chair European Generic Medicines Association (EGA) Regulatory and Scientific Affairs Committee, UK

Member States Experience
Anna Wachnik-Swiecicka, Office for Registration of Medicinal Products, Medical Devices and Biocides, Poland

12.30-13.30 Lunch

13.30-15.00 **Session 3**

HEALTH LITERACY - IS IT POSSIBLE TO WRITE LEAFLETS THAT ARE UNDERSTANDABLE FOR ALL PATIENTS?

Session Chairperson:
Ilaria Passarani, Health Policy Officer, BEUC, The European Consumers' Organisation and EMEA Patient & Consumer Working Party (EMEA PCWP), , Belgium

Inadequate health literacy may result in difficulty following instructions and taking the medicine properly. Can a single package leaflet answer the needs of all the patients irrespective of their background? This session will look at the extent of the problem and possible ways to address the diversity of the package leaflet audience.

Health Literacy in EU
European Commission representative invited

The Academic Perspective
Leo Lentz, Director Education Dutch Language, University of Utrecht, The Netherlands

Patient's Views
Ilaria Passarani, Health Policy Officer, BEUC, The European Consumers' Organisation and EMEA Patient & Consumer Working Party (EMEA PCWP), , Belgium

15.00-15.30 Coffee break

15.30-17.00 **Session 4**

LESSONS LEARNED: THE WAY FORWARD

Co-Session Chairpersons:
Truus Janse-de Hoog, Staff member MEB, European cluster, Chair CMD(h), Medicines Evaluation Board, The Netherlands
Isabelle Moulon, Head of Medical Information Sector, Chair of Quality Review of Documents (QRD), EMEA, EU

Design and Layout – Key for a Successful Package Leaflet
Helen Darracott, Director of Legal and Regulatory Affairs, PAGB, UK

Lessons Learned: The Way Forward – CRO's Perspective
Joerg Fuchs, PAINT – Consult, Germany

Lessons Learned: The Way Forward – Member State Perspective
Kim Sherwood, Regulatory Administration Department, Medical Products Agency (MPA), Sweden

Panel Discussion

17:00 End of Workshop