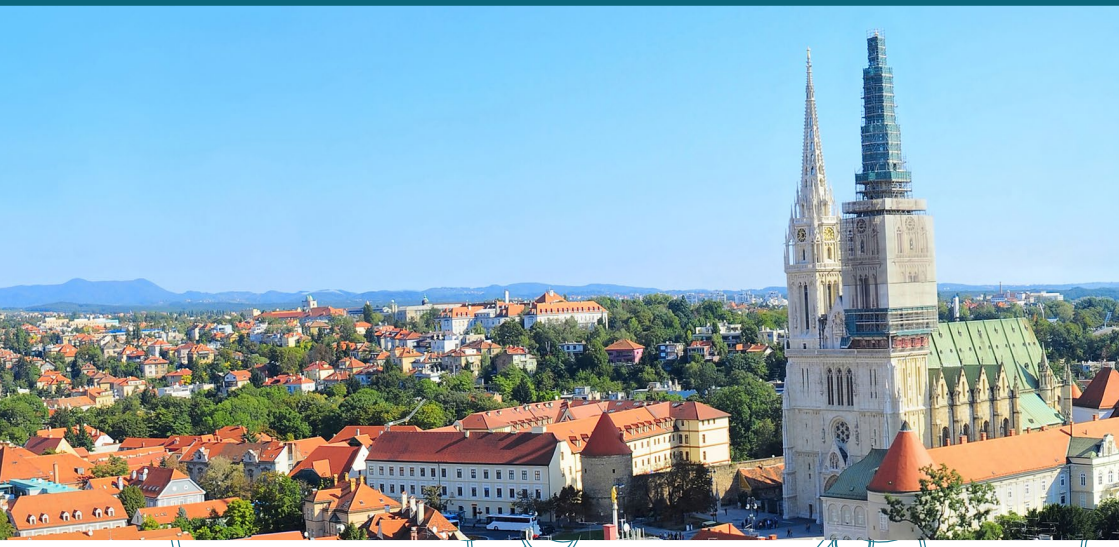
Medicademy®
The International Medical Academy

HALMED
Agency for Medicinal Products
and Medical Devices of Croatia

VARIATION WORKSHOP IN ZAGREB, CROATIA

In collaboration with HALMED and the Croatian Pharmaceutical Industry

May 4 – 5, 2017
Zagreb, Croatia



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JOIN US FOR A TWO-DAY VARIATION WORKSHOP IN CROATIA

Dialogue, explanations, clarification

The EU variation regulation went through a major revision in 2008 and was further amended in 2012. Now, almost 10 years later it can still be difficult for authorities and industry to have a common interpretation of the regulation. Therefore continuous dialogue and education is needed.

This workshop will address a number of the questions that marketing authorization holders (MAHs) may have on variation procedures and provide an overview of the EU legislation concerning the different types of variations. The main focus will be on the variation guideline, how to classify a variation according to the guideline, how and when to submit a variation and finally how to implement changes. Moreover, we will have a session on work-sharing and grouping as well as on when to use these submission pathways.

Meet Croatian and other National European Authorities and Industry Leaders

The workshop will have lecturers from different European authorities such as HALMED/Croatia and BfArM/Germany as well as the industry, and we will discuss challenges seen both from the perspectives of authorities and industry. We will mainly cover submissions via the MRP/DCP and national procedure. Panel sessions and group work will highlight different challenges and ensure that the audience can take an active part in the debate.

What Regulation and Guidelines will be Covered?

The workshop will take its off-spring in Regulation 1234/2008, amended with Regulation 712/2012 as the legal basis and also the guidelines on the Details of the Various Categories of Variations, on the Operation of the Procedures Laid Down in Chapters II, IIa, III and IV of Commission Regulation (EC) No 1234/2008 of 24 November 2008 Concerning the Examination of Variations to the Terms of Marketing Authorisations for Medicinal Products for Human Use and Veterinary Medicinal Products and on the Documentation to be Submitted Pursuant to Those Procedures.

LINKS TO REGULATION AND GUIDELINE

Integrated version of Regulation 1234/2008 with Regulation 712/2012

http://ec.europa.eu/health/files/eudralex/vol-1/reg_2008_1234_cons_2012-11-02/reg_2008_1234_cons_2012-11-02_en.pdf

Guidelines on the Details of the Various Categories of Variations, on the Operation of the Procedures Laid Down in Chapters II, IIa, III and IV of Commission Regulation (EC) No 1234/2008 of 24 November 2008 Concerning the Examination of Variations to the Terms of Marketing Authorisations for Medicinal Products for Human Use and Veterinary Medicinal Products and on the Documentation to be Submit-ted Pursuant to Those Procedures, 02-Aug-2013 (OJEU no. C 223, 02-Aug-2013, page 1.)

http://ec.europa.eu/health//sites/health/files/files/eudralex/vol-2/c_2013_2008/c_2013_2008_pdf/c_2013_2804_en.pdf

LEARNING AIMS/OUTCOME

At the end of the seminar you will have an overview and practical understanding of the variation regulation and the classification guideline. You will be familiar with the different types of variations and know how to use grouping and work-sharing. Moreover, you will have an understanding regarding what is important for a submission to get it right the first time.

TARGET AUDIENCE

The seminar is open to all with an interest in the variation regulation, but the target audience is professionals within:

- Competent Authorities
- Companies, HQ and Affiliate involved in Regulatory Affairs

DATE

May 4 – 5, 2017

LANGUAGE

The workshop is held in English

PRICE

• Authority/agency employee	EUR 160 ex VAT
• Industry employee	EUR 300 ex VAT

REGISTRATION

Please register at *www.medicademy.net*

Deadline for registration: March 15, 2017

VENUE

The workshop will take place at a hotel or conference center in Zagreb – yet to be decided.

WORKSHOP FACILITATORS

- Velimir Šimičevič, Regulatory Affairs Manager, Servier Pharma d.o.o., Croatia
- Inge Abildgaard, Regulatory Affairs Manager, Shire, Denmark
- Mette Schou-Hanssen, Project Leader, ALK Abelló A/S, Denmark

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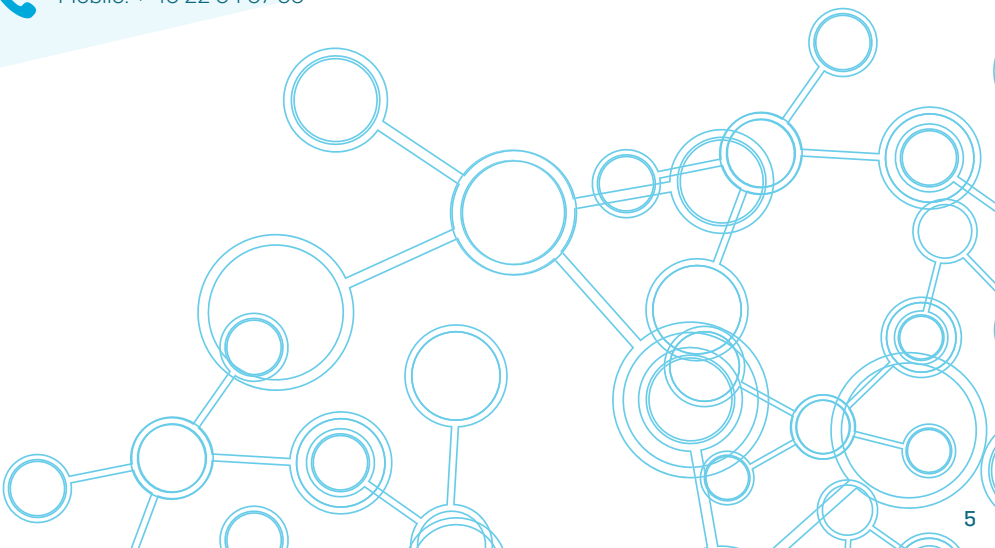

PROGRAMME

DAY 1: THURSDAY MAY 4, 2017

The EU Variation System

09.00 - 09:30 **Welcome and Introduction to the Workshop**

Medicademy/Facilitators/Participants

09.30 – 11.30 **The Variation Regulation – Setting the Scene for EU Regulators**

- Background for the Variation System
- Use of Best Practice Guideline
- Classification depending on Risk
- Impact on Quality, Safety and Efficacy

Jasna Ikić Komesar, Principal Advisor for Regulatory Affairs, HALMED – Agency for Medicinal Products and Medical Devices of Croatia

Peter Bachmann, Senior Expert, European Drug and Regulatory and International Affairs, German Federal Institute for Drugs and Medical Devices (BfArM), Germany

11.45 - 12.30 **Panel Session**

- How does this work for us?
- Which challenges do we have?
- Solutions?

Representatives from HALMED, Other National Agency, Innovator Company, Generic Company

13.30 - 15.00 **Classification in Practice**

- Administrative
- Quality
- Safety, Efficacy, Pharmacovigilance
- PMF/VAMF
- Unforseen Variations
- Other

Hanne Brokopp, Director, Regulatory Affairs Europe, Merck, Sharp & Dohme (Europe), Belgium

Industry Representative from Croatia

15.15 – 16.45 **Group Work**

Participants, Facilitators, Speakers

16.45 – 17.45 **Brain-storm Session and Closing Remarks**

Participants, Facilitators, Speakers

DAY 2: FRIDAY MAY 5, 2017

08.45 - 09:00	**Summary of day 1 and introduction to day 2**
	Facilitators
09.00 – 10.30	**Grouping and Worksharing**
	- Wrap-up on the Procedures
	- Examples from real-life
	Representative from Other National Agency
	Representative from Industry
10.45 - 12.45	**Preparation and Submission**
	• Focus on Examples from real-life and with and without Labelling Impact
	- Filling in the eAF: Practical Examples from different classifications
	- Prepare the Documentation Package
	- Product Information Changes
	- Variations with Labelling Impact
	- Translations, Submissions and Timelines
	- When do CTs occur?
	Representatives from the Industry
	Representatives from HALMED
13.45 - 14.30	**Panel Discussion on Submissions**
	- How does this work for us?
	- Which challenges do we have?
	- Solutions?
	Representatives from HALMED, Other National Agency, Innovator Company, Generic Company
14.30 – 15.30	**Procedures, Approvals and Implementation**
	- Timelines
	- Clock Stop
	- Responsibilities
	- End of Procedures Messages
	- Follow-up Measures
	Hanne Brokopp, Director, Regulatory Affairs Europe, Merck, Sharp & Dohme (Europe), Belgium
	Industry Representative from Croatia. Representative from HALMED
15.30 – 16.30	**Brain-storm Session and Closing Remarks**
	Participants, Facilitators, Speakers
16.30 – 17.00	**End of Workshop**
	Participants, Facilitators, Speakers

FACTS ABOUT MEDICADEMY

- Medicademy is a collaboration between the Danish Medicines Agency, University of Copenhagen and the Pharmaceutical Industry
- Medicademy is a module based training programme consisting of 15 regulatory and 8 pharmacovigilance modules
- Medicademy has welcomed students from 32 countries
- Medicademy is lectured by international speakers representing EMA, FDA, National Agencies, industry, organisations and academia
- The Medicademy programme can be followed as:
  - A Master Degree at the University of Copenhagen
    - *Master of Medicines Regulatory affairs (MRA http://mra.ku.dk/*
  - Diploma in Pharmaceutical Regulatory Affairs
  - Diploma in Pharmacovigilance
  - Individual modules

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