DIA **VIRTUAL EVENT**

Workshop on Optimising Variations Regulatory Framework

Towards EU Accession

29-30 October 2020 | Timing displayed in CEST

PROGRAMME ADVISORS

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Overview

Periodic safety surveillance and continuous improvement of quality and manufacturing controls of products are requiring marketing authorization holders to frequently engage with regulators and update their initial product licenses to the state of the art. However, coordinating regulatory activities with global manufacturing operations and supply of medicines have made appropriate change control a challenging task, specifically when differing requirements, processes and timelines are applied in different countries and regions. These divergent practices bear potentially unintended consequences and unnecessary supply disruption risks for products that are essential to patients.

Considering closer alignment with EU regulatory frameworks, this workshop will discuss the opportunities for convergence and streamlined regulatory management, assessment and approval of post-approval changes, which in turn will facilitate the efficient management of change control and better planning of global supply by manufacturers. In addition, opportunities for more collaboration and reliance on regulatory marketing authorization assessments and renewals performed in national Health Authorities across countries and regions might have further positive impact on capacity and resources at regulator level and speed up the implementation of quality and safety changes for products on the market. This workshop will also allow participants to learn from best practices examples and share those learnings across boundaries.

Objectives

What will you get from this event?

- Update on the EU variation legislation and expected developments under ICH Q12
- Insights into managing variations in South East Europe and EU accession countries
- Discussion on how to optimize the post-approval framework for variations to facilitate uninterrupted product supply to patients
- Meet Health Authorities and Industry Leaders from EU countries and South Eastern Europe non-EU countries

Who will attend?

Professionals involved in:

- Regulatory Affairs
- Regional Regulatory Development
- Regulatory Compliance
- Regulatory Submissions
- ICH Guidelines implementation and development
- CMC Lifecycle Management
- CMC Project Management
- Market Access
- Patient Advocates
- Policy
- Supply chain
- Pharmacovigilance
- Manufacturing
- Health Authorities
- EU Integration office

DAY ONE | THURSDAY, 29 OCTOBER 2020

13:30 LOG-IN

13:40 WELCOME AND INTRODUCTION TO THE WORKSHOP - HOW TO NAVIGATE THE PLATFORM

Sara Torgal, Scientific Programmes Manager, DIA EMEA

14:00 SESSION 1

LEARNINGS AND BEST PRACTICES FOR VARIATIONS: THE INTERNATIONAL PERSPECTIVE

Session Chair:
Susanne A. Winterscheid, Head of Project Management of Licensing Division 3, BfArM, Germany

Post-Approval Change systems have a big impact on the management of the global supply chain of medicines and vaccines and are a major part of regulatory maintenance work. This session will highlight the experience gained from the European Variation Legislation and provide an outlook on the future development and evolution as part of the implementation of newly adopted ICH Quality guidelines (Q12). It will further provide insights into the concept of regulatory Reliance as a tool for implementing smart regulation to facilitate regulatory activities.

Experience with the EU Variation Legislation, Current Discussions and Outlook
Susanne A. Winterscheid**,** Head of Project Management of Licensing Division 3, BfArM, Germany

Post-Approval Change Management from a Manufacturing/Supply Chain Perspective: Including Regulatory Reliance as a New Concept
Melly Lin**,** Regulatory Policy, F. Hoffmann-La Roche Ltd, Switzerland

Outlook on new ICH Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management Guideline
Frank Montgomery, Global Head Regulatory CMC, GRAPSQA, AstraZeneca, UK

Reliance as a Facilitator of Regulatory Activities
Samvel Azatyan, Team Lead, Regulatory Convergence and Networks (RCN/REG), World Health Organization (WHO)

Post-Approval Changes to Marketing Authorisations Courses
Ana Holt, Senior Health Specialist, The World Bank
Loubna Djemame, Consultant, Health, Nutrition and Population, The World Bank

Panel Discussion with Q&A

15:35 BREAK

15:50 SESSION 2

TOWARDS EU ACCESSION

Session Chair:
Riccardo Luigetti, Senior Scientific Administrator, European Medicines Agency (EMA), EU

This session will provide information from Regulators in South East Europe regarding their experience with the variation system. It will shine a light on the activities that are currently under way to align their local systems in preparation for EU accession. The panel discussion will take Q&A from the audience.

Towards EU Accession – the EMA role and contribution
Riccardo Luigetti, Senior Scientific Administrator, European Medicines Agency (EMA), EU

Sharing post EU Accession Experience – The Croatian Regulator Perspective
Ivana Zadro, Senior Advisor - Specialist II for Validation of Applications, Agency for Medicinal Products and Medical Devices (HALMED), Croatia

SEE Road to EU Accession and Alignment of Current Framework – The North Macedonia's Health Authority Perspective
Elona Chilku, Agency for Medicines and Medical Devices of Macedonia (MALMED), North Macedonia

SEE Road to EU Accession and Alignment of Current Framework – The Bosnia and Herzegovina's Health Authority Perspective
Biljana Tubic, Head of Department of Medicinal Products, Agency for Medicinal Products and Medical Devices (ALMBiH), Bosnia and Herzegovina

Panel discussion with Q&A, with the additional participation of:
Susanne A. Winterscheid, Head of Project Management of Licensing Division 3, BfArM, Germany

17:05 WRAP-UP

17:20 NETWORKING ACTIVITY

18:20 END OF DAY ONE

Disclosure Policy

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 DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

DAY TWO | FRIDAY, 30 OCTOBER 2020

13:30 WELCOME NOTE

Sara Torgal, Scientific Programmes Manager, DIA EMEA

13:45 SESSION 3, PART I

WHERE ARE WE NOW WITH POST-APPROVAL CHANGES?

Session Chair:
CMDh representative

This session will focus on the experience from the users of the system. First from the trade associations who will provide some general reflections on the national user experience and the impact on patients. This is followed by some concrete case study examples from companies to better illustrate the broader impact of national rules in the global operational context.

Comparing Requirements and Systems across Countries and with the EU **(Serbia, North Macedonia, Bosnia and Herzegovina):**
Overview of common Challenges and Opportunities for the Region - Ivana Ferber, Regulatory Affairs Lead Croatia & BiH, MSD, Croatia
Bosnia and Herzegovina - Lejla Rizvanbegovic-Taletovic, Regulatory Affairs Manager, Sanofi, Bosnia and Herzegovina & Amra Hadziabdic Deljkovic, Regulatory Affairs Manager, Novartis, Bosnia and Herzegovina
Serbia - Bojan Trkulja, Managing Director, The Association of the Manufacturers of Innovative Drugs – INOVIA, Serbia
North Macedonia - Mirjana Ipsha-Koceva, Regulatory Coordinator, Merck Sharp & Dohme (MSD), North Macedonia

Post-approval Changes in the SEE: Industry Perspective **- Case Studies within the Global Context**
MSD - Sylvie Meillerais, Director, Global CMC Policy, MSD (Europe) Inc., Belgium
Sanofi - Winona Bolislis, Regulatory Science and Policy Associate, Sanofi, France
Roche - Gordon Patrick Byrne**,** Technical Regulatory Lead – Innovation, F. Hoffmann-La Roche Ltd, Switzerland

Panel discussion with Q&A

15:00 BREAK

15:05 KEYNOTE

WHAT DO PATIENTS EXPECT?

Veronica Popa, MCT8-AHDS Foundation, Romania

Q&A

15:30 BREAK

15:40 SESSION 3, PART II

ROUNDTABLE ON OPPORTUNITIES TO OPTIMISE THE POST-APPROVAL SYSTEM

Session Chair:
Lina Cacic, Senior Advisor - Specialist I for Validation of Applications, Agency for Medicinal Products and Medical Devices (HALMED), Croatia

The panel discussion will focus on the future outlook and opportunities for the evolution of variation system to benefit of patients and regulatory operations.

Panel Discussion with the participation of:
AKBPM - Ranela Ceci, Specialist, Marketing Authorisation and Regulatory Affairs Department, National Agency for Medicinal Products and Medical Devices, Albania
AKPPM - Sulltane Havolli, Department for Marketing Authorisation, Kosovo Medicines Agency, Kosovo
ALMBiH - Biljana Tubic, Head of Department of Medicinal Products, Agency for Medicinal Products and Medical Devices, Bosnia and Herzegovina
CALIMS - Milena Lješkovic, Head of Department for Marketing Authorisation, Agency for Medicines and Medical Devices of Montenegro, Montenegro
MALMED - Elona Chilku, Agency for Medicines and Medical Devices of Macedonia, North Macedonia
WHO - Samvel Azatyan, Team Lead, Regulatory Convergence and Networks (RCN/REG), World Health Organization (WHO)

16:45 WRAP-UP AND CLOSING REMARKS

17:00 END OF THE WORKSHOP

About DIA

DIA is the global connector in the life sciences product development process. Our association of thousands of members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation that has its Global Center in Washington, DC, USA and the Europe, Middle East and Africa office in Basel, Switzerland. DIA has additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China. For more information, visit www.DIAglobal.org or call DIA EMEA: +41 61 225 51 51.