ONLINE CONFERENCE

FORUM

ExpertFORUM Labelling

Digital, patient-friendly and safety labelling

TOPICS

- Impact of EU pharmaceutical legislation on drug labelling
- Patient information in the digital age: Latest achievements in ePI and the use of AI
- How to achieve patient-friendly package leaflets
- Labelling compliance during product lifecycle: National and global perspectives
- Pharmacovigilance: Current requirements and trends for labelling and educational material

YOUR SPEAKERS

Dr Peter Bachmann
Senior Expert Regulatory Affairs, GERMANY

Robert Begnett
Kyowa Kirin International plc, GREAT BRITAIN

Dr Rüdiger Faust
UCB BIOSCIENCES GmbH, GERMANY

Dr Jörg Fuchs
PAINT-Consult®, GERMANY

Dr Thomas Grüger
Senior Expert in Pharmacovigilance, GERMANY

Olga Kolcak
Bayer Consumer Care AG, SWITZERLAND

Nina Malvik
Norwegian Medicines Agency, NORWAY

Kim Sherwood
Medical Products Agency, SWEDEN

16–17 OCTOBER 2023 – ONLINE

SPEAKERS, DAY 1

Dr Peter Bachmann
Bonn, GERMANY

Senior Expert Regulatory Affairs

Kim Sherwood
Medical Products Agency (MPA),
Uppsala, SWEDEN

Regulatory Administration Department,
QRD member

Nina Malvik
Norwegian Medicines Agency,
Oslo, NORWAY

Senior Adviser Product Information,
QRD member, CMDh alternate

Dr Rüdiger Faust
UCB BIOSCIENCES GmbH,
Monheim, GERMANY

EU Regulatory Policy and Intelligence Lead
Regulatory Affairs Europe

Dr Jörg Fuchs
PAINT-Consult®,
Jena, GERMANY

Managing Director, User Testing Consultant

PROGRAMME, DAY 1

EU pharmaceutical legislation: Impact on drug labelling

- The specific impact of EU pharmaceutical legislation on drug labelling requirements

Updates on ePI: Enhancing patient information in the digital age

- Latest developments and advancements in electronic product information (ePI)
- Use of AI at the Swedish Medical Products Agency

Beyond the box: Exploring innovative channels for delivering digital package leaflets to patients

- Digital delivery platforms and regulatory landscape
- Sharing insights on compliance and current practices from the Norwegian Medicines Agency's perspective

Challenge of achieving data and a label for women of childbearing/ breastfeeding age

- The need to improve existing labelling guidance
- Case study

Readability testing, alternatives and the way forward for patient-friendly package leaflets

- Readability testing and its importance in patient-friendly package leaflets
- Simplification techniques for improving readability of package leaflets

PROGRAMME, DAY 2

Labelling compliance as a key factor for product compliance

- Implementation of CCDS changes in local labelling
- Management of PV signals, PRAC recommendations and PSUSAs
- Challenges in labelling end-to-end process

Pharmacovigilance: Current requirements and trends for labelling and educational materials

- Impact of EU pharmaceutical legislation
- Recommendations for implementation following PSUSA procedures

Global labelling compliance throughout the product lifecycle

- Managing labelling compliance – Global consistency and local flexibility
- Addressing labelling changes and updates during key phases of the product lifecycle
- Understanding the drivers that effect labelling
- Upcoming changes in regulatory and technology landscapes that will impact labelling

SPEAKERS, DAY 2

Olga Kolcak
Bayer Consumer Care AG, Basel, SWITZERLAND

Head of Labelling Consumer Health

Dr Thomas Grüger
Bonn, GERMANY

Senior Expert in Pharmacovigilance

Robert Begnett
Kyowa Kirin International plc, Marlow, GREAT BRITAIN

Global Labelling Lead Associate Director

AIMS AND OBJECTIVES

This ExpertFORUM focuses on labelling digitalisation, patient-friendly labelling and safety labelling.

European authority and industry experts will provide the latest on the impact of EU pharmaceutical legislation on labelling, the future of the digital package leaflet and all you need to know about fulfilling the requirements of product information, patient empowerment and safety labelling.

WHO SHOULD ATTEND

This online conference addresses the needs of individuals in regulatory affairs, medical affairs and pharmacovigilance involved in product information.

It provides useful updates on the relevant trends in digitalisation, patient-friendly labelling and safety labelling. A working knowledge of product information and labelling is required.

YOUR BENEFITS

This ExpertFORUM will give you the opportunity to:

- meet leading authority and industry experts.
- get the latest on the impact of EU pharmaceutical legislation on labelling.
- obtain first-hand insights into recent developments on ePI and patient-friendly package leaflets.
- learn about trends in labelling compliance and pharmacovigilance.

REGISTRATION FORM

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Date
16 - 17 October 2023
Day 1: 09:00 - 16:30
Day 2: 09:00 - 13:00
You may dial in 30 min. before the session.

Fee
1,690.00 (+German VAT)

CANCELLATION POLICY

Our general terms and conditions apply (as of 1. November 2021) and are available upon request. We can send them to you anytime or you can find them on the internet at www.forum-institut.de/agb_en

ANY FURTHER QUESTIONS?

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