

Known Substances - Regulatory Strategies in Europe, the Middle East and Russia/the EAEU

TOPICS

- Generic, bibliographic and hybrid applications in Europe
- Borderline products in Europe, the Middle East and Russia/the EAEU
- Food supplements, herbals, nutraceuticals - the possibilities
- Value added generics and OTCs in the Middle East
- Literature-based marketing authorisations outside the ICH region

*Regulatory affairs
for drugs, herbal
medicinal products,
food supplements,
borderline products,
etc.*

YOUR SPEAKERS

Markus Ambrosius

Sträter Lawyers, Bonn, GERMANY
Partner, Lawyer

Dr Edelgard Rehak

Dr Edelgard Rehak Consulting, GERMANY
Expert on registration in Russia and Central and Eastern Europe

Dr Mohammed Saleem

Boehmert & Boehmert, Representation Office
Middle East and North Africa, JORDAN
General Director of SIPS (Science Forum for
Research & Consultancy).

Known Substances - Regulatory Strategies

Aims and objectives

Do you want to evaluate the options available for launching your product containing a known substance in new markets? This seminar will cover the legal basis and marketing authorisation options in Europe, the Middle East and Russia/the EAEU. Three local experts will guide you in building the ideal strategy for your product in the respective market, be it a generic, OTC product, borderline product, food supplement or herbal medicinal product.

This seminar will give you a thorough understanding of the European, Russian and Middle Eastern markets, enabling you to develop your own strategy.

Who should attend?

This seminar addresses the needs of regulatory affairs managers dealing with known substances and working in the European, Middle Eastern or Russian/EAEU markets.

Medical affairs and business development managers aiming to enter one of these markets with their products will also find it helpful.

Limited number of attendees

This seminar is limited to 20 participants. This limitation, a feature of all FORUM seminars, enables participants to thoroughly discuss the complex issues covered by the programme.

Your speakers

Markus Ambrosius

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Additional meeting

May we also draw your attention to our seminar

- Electronic Regulatory Submissions in the Middle East on the 1 October 2019 in the same conference hotel.

You will find detailed information on www.forum-institut.com with webcode 1910235

By attending both courses, you will benefit from € 290.00 (+VAT) discount.

Your benefits

- Three local experts with extensive experience in the European, Middle Eastern and Russian/EAEU markets
- Comparison of the legal basis in three major markets
- Strategy expertise for successfully positioning borderline products in the respective markets.

in Europe, the Middle East and Russia/the EAEU

Your programme 09:00 - 17:00

Generic and hybrid application in Europe

Markus Ambrosius

- What is the reference medicinal product?
- Data protection schemes
- Special case: biosimilars

Bibliographic / well-established use in Europe

Markus Ambrosius

- Stringent requirements for well-established use
- Cases: What has worked so far and what has not?

Borderline: drugs, medical devices, food and food supplements in Europe

Markus Ambrosius

Generic, hybrid application and literature-based ('well-established use') marketing authorisations in the EAEU and Russia

Dr Edelgard Rehak

Marketing authorisation as a medicinal drug, medical device or food supplement: borderline products in the EAEU and Russia

Dr Edelgard Rehak

Generic and value added generic, OTC and new pharmaceutical product marketing authorisations in the Middle East

Dr Mohammed Saleem

Marketing authorisation as a drug, medical device, food supplement, herbal or nutraceutical: borderline products in Middle Eastern countries

Dr Mohammed Saleem

Discussion:

Literature-based marketing authorisation outside the ICH region. Is it possible?

All speakers

Known Substances - Regulatory Strategies

REGISTRATION UNDER

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REGISTRATION FORM

Yes, I will attend

- Known Substances - Regulatory Strategies in Europe, the Middle East and Russia/the EAEU (1910236)
- Electronic Regulatory Submissions in the Middle East (Details at our website and the webcode 1910235)
- Yes, I agree that FORUM Institut may inform me about events by:
 email; and/or telephone.
I may withdraw my consent at any time.

Name

Position, department

Company

Street

Post code, city, country

Tel. no./Fax no.

E-mail

Contact person at office

Date, signature

Date and venue

Wednesday, 2 October 2019 in Heidelberg
08:30 registration; 09:00 - 17:00 seminar
Heidelberg Marriott Hotel
Vangerowstr. 16 · 69115 Heidelberg
Tel. +49 6221 908-0 · Fax +49 6221 908-660

Fee

€ 1,090.00 (+ German VAT)

The fee includes course documentation (including free download) as well as refreshments, lunch and a certificate. You will receive an invoice as well as confirmation.

Fee for booking 2 courses

€ 1,890.00 (+VAT) for booking both courses:

- Known Substances - Regulatory Strategies in Europe, the Middle East and Russia/the EAEU (2 October 2019 - Webcode 1910236)
- and
- Electronic Regulatory Submissions in the Middle East (1 October 2019 - Webcode 1910235)

You will benefit from a € 290 (+VAT) discount.

CANCELLATION POLICY

Our general terms and conditions (as of 1 January 2016) apply and are available upon request. We can send them to you at any time. Alternatively, you can access them online at www.forum-institut.com/t&c

YOUR CONTACT



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