Seminar

FORUM

Marketing Authorisation in North & South Africa

Regulatory Update - The Maghreb Countries & South Africa

Topics

- Marketing authorisation dossier requirements
- Key persons in the countries
- Communication with the national authorities
- Maintenance and product information duties - variations and labelling

Firsthand update on marketing authorisation application and maintenance duties

Your speakers

Tracy L. Burger
MC Pharma (Pty) Ltd.,
Pretoria, SOUTH AFRICA

Mieke Roels
UCB Pharma S.A.,
Brussels, BELGIUM

30 October 2013 in Frankfurt

Marketing Authorisation in North & South Africa

Aims and objectives

This course focuses on the regulatory environment in two interesting regions of the African continent - the Maghreb and South Africa. Participants will receive a broad overview of the opportunities and challenges that have to be faced when registering and during the lifecycle of a pharmaceutical product.

The seminar addresses the marketing authorisation procedures in detail as well as the maintenance of a granted authorisation. May we invite you to an intensive discussion with two local experts?

Who should attend?

This seminar will be of benefit to anyone working in the pharmaceutical industry who is interested in marketing pharmaceuticals in Africa. Especially those working in regulatory affairs and business development will profit from the seminar.

Limited number of attendees

This seminar is restricted to 20 participants. This limitation, a feature of all FORUM seminars, will give participants the opportunity for a thorough discussion of the complex issues to be covered by the programme.

Your speakers

Tracy L. Burger
MC Pharma (Pty) Ltd.,
Pretoria, SOUTH AFRICA

Director and Responsible Pharmacist

She deals with South African registration and regulatory matters on behalf of both national and international companies and represents clients to the regulatory authority.

Her experience covers clinical trials, pharmaceutical development, registration of new entities and generic medicines, and regulatory affairs management.

Mieke Roels
UCB Pharma S.A.,
Brussels, BELGIUM

Manager Global Regulatory Affairs - International

She deals with registrations in all international territories, with a focus on the Middle East - Africa region.

Her experience covers preclinical development, CMC, registration and lifecycle management of new chemical entities, biologicals and well-established use products.

Regulatory update - the Maghreb countries & South

South Africa

Your Expert:
Tracy L. Burger

Time table: 9.00 - 13.00,
including 15 min coffee break

The regulatory framework

- The current and proposed new South African Health Products Authority (former MCC)
- Registration procedure - timelines, terms & fees

Dossier requirements for South Africa

- From MBR1 and MRF1 (the old dossier formats) to the CTD
- National peculiarities in Module 1 and Module 3

Key person = the Responsible Pharmacist in South Africa

- Responsibilities
- Cooperation between the principal and manufacturer/s and the local RP
- Essential documents for the RP (dossier, master file, legal files, technical agreements...)

Maintenance of the marketing authorisation

- Updating the old MBR1 and MRF1 dossiers by 2016
- Variations, when Type A, B, C or D?

North Africa - The Maghreb

Your Expert:
Mieke Roels

Time table:14.00 - 17.00,
including 15 min coffee break

Update on the Maghreb region

Initial registrations in Tunisia, Algeria and Morocco

- Requirements for initial applications (NCE & Biologics)
- Specific national documentation (application forms, GMPs, ...) and required legalisation
- Samples and local laboratory testing

Maintenance and product information duties

- Variations
- Renewals
- Line extensions
- Labelling

Tender business in the Maghreb region

Marketing Authorisation in North & South Africa

Registration recommended 30 days in advance

Registration under
registration@forum-institut.com or
Fax +49 6221 500-555

Registration Form

Yes, I will attend the seminar
☐ Marketing Authorisation in North & South Africa

☐ I am interested in more information about FORUM events and I agree that this information is sent to me by e-mail.

Name

Position/Department

Company

Street

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at office

Date, Signature

How to register

- **Registration: +49 6221 500-501**
- **Conference-No. 13 10 232**

- **Internet:**
www.forum-institut.com

- **Date/Venue:**
Wednesday, 30 October 2013 in Frankfurt
8.30 registration; 9.00 - 17.00 seminar
InterContinental
Wilhelm-Leuschner-Str. 43 · 60329 Frankfurt
Tel. +49 69 2605-0 · Fax +49 69 252467

- **Fee:**
€ 990,00 (+ German VAT)
inklusive umfangreicher Dokumentation, Arbeitsessen, Erfrischungen und Kaffeepausen.

- **Hotel accommodation:**
A limited number of rooms have been reserved at the hotel and are subject to availability. Please book at least six weeks prior to the seminar to obtain a hotel room at the discounted rate. All bookings should be made directly with the hotel quoting Forum-Institut and the Seminar-No.

Any Further Questions?

Please feel free to contact me if you have any questions.

Dr. Henriette Wolf-Klein
Department Manager
Tel. +49 6221 500-680
h.wolf-klein@forum-institut.de

Cancellation Policy

Our general terms and conditions apply (as of 1 December 2011) 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