

Marketing Authorisation for Human Medicines in Latin America

Topics

- Legal framework and national authorities
- National marketing authorisation procedures
- Dossier requirements - NCEs and generics
- Maintenance of the marketing authorisation
- National specialities in Brazil, Mexico, Argentina, Chile, Peru, Colombia and Venezuela

Brazil, Mexico, Argentina, Chile,
Peru, Venezuela and Colombia

Your speakers



Esther Gil López
PAREXEL Consulting,
Madrid, ESPAÑA



Ana Amélia Padua
Latin America
Regulatory Affairs Expert,
São Paulo, BRAZIL

Marketing Authorisation in Latin America

Aims and objectives

Brazil, Mexico, Argentina, Chile, Peru, Colombia, Venezuela etc are lucrative countries for marketing pharmaceuticals. The essential precondition is of course a national marketing authorisation.

What are the local requirements for these marketing authorisations? Which data, concepts etc can be used from a European point of view? These are the key questions to be answered during this seminar.

May we invite you for a thorough discussion with two experts on

- dossier requirements
- marketing authorisation procedures, and
- maintenance duties?

You are welcome to join this meeting for a successful entry on the Latin American market.

Who should attend?

This seminar will be of benefit to all those working in the pharmaceutical industry who are interested in marketing pharmaceuticals in Latin America. Especially those working in regulatory affairs and business development will benefit from the seminar.

The seminar will focus on human medicinal products (chemicals and biologics; herbals will not be addressed).

Limited number of attendees

This seminar is restricted to 25 participants. This limitation will give participants the opportunity for a thorough discussion.

Your speakers



Esther Gil López
PAREXEL Consulting,
Madrid, ESPAÑA

Director



Ana Amélia Padua
São Paulo,
BRAZIL

Latin America

Regulatory Affairs Expert

Further international events

- Marketing Authorisation in the CIS Countries/Russia
22 - 23 August 2013 in Berlin
- Marketing Authorisation in the Balkan States
3 September 2013 in Frankfurt
- 10th Conference on Marketing Authorisation
30 September - 1 October 2013 in Cologne
- Marketing Authorisation in ASIA, Australia & New Zealand
15 - 18 October 2013 in Frankfurt
- Marketing Authorisation in North & South Africa
30 October 2013 in Frankfurt

Your programme 10.00 - 18.00

> 10.00

The pharmaceutical market and marketing authorisation in Latin America

- The local pharmaceutical market - success strategies
- Factors to push drug development and registration for emerging markets

> 11.00 Coffee break

> 11.15

Marketing authorisation & maintenance in Brazil

- National procedures
- Dossier requirements for NCEs and generics
- Maintenance: variation & renewal

> 12.30

Marketing authorisation & maintenance in Argentina

- National procedures
- Dossier requirements for NCEs and generics
- Maintenance: variation & renewal

> 13.15 Lunch

> 14.30

Marketing authorisation & maintenance in Chile and Peru

- National procedures
- Dossier requirements for NCEs and generics
- Maintenance: variation & renewal

> 15.15

Marketing authorisation & maintenance in Mexico

- National procedures
- Dossier requirements for NCEs and generics
- Maintenance: variation & renewal

> 16.00 Coffee break

> 16.15

Marketing authorisation & maintenance in Venezuela

- National procedures
- Dossier requirements for NCEs and generics
- Maintenance: variation & renewal

> 17.00

Marketing authorisation & maintenance in Colombia

- National procedures
- Dossier requirements for NCEs and generics
- Maintenance: variation & renewal

> 17.45

Final discussion and future trends in Latin America

> 18.00 Seminar end

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

Registration Form

Yes, I will attend the seminar

☐ Marketing Authorisation for
Human Medicines in Latin America

☐ 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 10 236**

■ **Internet:**

www.forum-institut.com

■ **Date/Venue:**

Monday, 14 October 2013 in Frankfurt/Offenbach
9.30 registration, 10.00 - 18.00 seminar
Sheraton Offenbach
Berliner Straße 111 · 63065 Frankfurt/Offenbach
Tel. +49 69 82999-0 · Fax +49 69 82999-810

■ **Fee:**

€ 990,00 (+ German VAT)

The fee includes course documentation as well as
mid-session refreshments and lunch. Invoice and
confirmation will be forwarded to you.

■ **Hotel accommodation:**

A limited number of rooms have been reserved at the
hotel and are subject to availability.

Any Further Questions?



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

Dr. Henriette Wolf-Klein

Head of Department

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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