Iran, the Middle East and Turkey: Marketing Authorisation & Market Access

Meet the Experts

Dr Mahmoud Alebouyeh
Ministry of Health, Iran
Food and Drug Control and Research Laboratory (FDCRL)

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Seda Kadioglu Consulting, Turkey

Dr Abdolazim Behfar
Ministry of Health, Iran
Food & Drug Administration (IR-FDA)

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Food & Drug Administration (IR-FDA)

Dr Mohammed Saleem
Boehmert & Boehmert Representation Office Middle East and North Africa, Jordan

28th – 29th September 2016 in Frankfurt

Your experts

Dr Mahmoud Alebouyeh
Ministry of Health, IRAN
Food and Drug Control and Research Laboratory (FDCRL)
Deputy of FDCRL and head of the biological control department

Dr Abdolazim Behfar
Ministry of Health, IRAN
Food & Drug Administration (IR-FDA)
Deputy Head of the Halal Research National Center

Dr Manouchehr Dadgarnejad
Ministry of Health, IRAN
Food & Drug Administration (IR-FDA)
Deputy Director for programming of food and cosmetic; Vice Chairman of the Codex Committee on food import and export inspection and certification systems

Dr Mostafa Esmaeili
Ministry of Health, IRAN
Food & Drug Administration (IR-FDA)
Head of the cosmetic and hygienic department

Seda Kadioglu
Independent consultant on drug development, clinical trials and regulatory affairs, TURKEY
Since 2010 she has been helping international companies to register and maintain their pharmaceutical products in Turkey.

Dr Mohammed Saleem
Boehmert & Boehmert
Representation Office Middle East and North Africa, JORDAN
General Director of SIPS (Science forum for Research & Consultancy)

Day one 10.00 - 17.00

Iran

Chaired by Dr Mohammed Saleem

IR-FDA structure and policy
- IR-FDA structure
- Market access and product importation
- Local manufacturing requirements

Who can be an agent, distributor or authorised representative for international companies?

Company registration
- Related regulations and requirements
- Forms, procedures, fees and time frames

Pharmaceutical product types in Iran
- Biopharmaceuticals, ethical drugs, OTC, GSL and medical devices
- Herbal, vitamin and nutritional supplements
- Cosmetics, functional foods, etc.

Related regulations for each product type at a glance
- Product approval process diagram
- Forms, procedures, fees and time frames

Interaction between the relevant bodies for the registration of products with the IR-FDA
- Company registration department, product registration department, laboratory control, Iranian pharmacopoeia and industrial property organisations
- Intellectual property

Day two 9.00 - 12.30

The Middle East/GCC

Dr Mohammed Saleem

National marketing authorisation vs. GCC marketing authorisation

- Pros and cons
- Market access strategies
- Current legislative changes

Essential documents for the national marketing authorisation application in the key markets

- Company registration
- Application forms, document lists and required legalisation
- Material provider requirements
- CTD/eCTD – current status and regional requirements

GCC: necessary documents and approval process

Maintenance/pharmacovigilance obligations

- Vigilance duties in the marketing authorisation procedure
- Risk management, system description and risk management plan
- Maintenance duties – variations

Product pricing and tender business in the region

Day two 13.30 - 17.00

Turkey

Seda Kadioglu

Access to the Turkish market

- Company registration in Turkey
- Turkish legal representative

The national marketing authorisation

- The marketing authorisation procedures for different products – fees, time frames and prerequisites
- GMP audit obligation

Dossier requirements

- CTD/eCTD according to EU requirements?
- Originator applications
- Generics applications (incl. biosimilars)

Maintenance of the marketing authorisation

- Variations – similar requirements to the EU Variations Regulation?
- Renewals
- Pharmacovigilance

Product pricing and reimbursement

Your benefits

- First-hand expertise of IR-FDA members on regulatory challenges and possibilities in Iran
- Practical advice from industry experts from Jordan – also with regard to the GCC (Gulf Cooperation Council) countries – and Turkey
- English translations of Iranian key regulations (not usually available; translated only for participants in this seminar)

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Invitation

Please join us for a unique meeting with experts from the Iranian Food and Drug Administration (IR-FDA) as well as industry experts from Jordan and Turkey. I invite you to take this opportunity to get a thorough update in only two days on:

- Marketing authorisation
- Company registration
- Product importation and market access
- Product maintenance

I look forward to welcoming you in Frankfurt.

Kind regards

Dr. Henriette Wolf-Klein
Department Manager Pharma & Healthcare

Who should attend

This unique conference addresses the needs of employees in the healthcare industry who intend to register/export pharmaceuticals to Iran, the Middle East or Turkey.

Those involved in:

- Business development
- Regulatory affairs
- Market access
- Export

will particularly benefit from the speakers' first-hand expertise.

Registration service@forum-institut.de or fax +49 6221 500 555

Yes, I will attend the conference

☐ Iran, the Middle East and Turkey: Marketing Authorisation & Market Access

Name

Position/Department

Company

Street

Postal Code/City/Country

Tel. No.

E-Mail

Date/Signature

- **Registration: +49 6221 500-500**
- **Conference-No. 16 09 234**

- **Date/Venue:**
28 – 29 September 2016
NH Frankfurt Airport West
Kelsterbacher Str. 19-21 · 65479 Raunheim
Tel. +49 6142 9900

- **Fee:**
€ 1,890.00 (+German VAT) incl. course documentation (incl. free download) as well as mid-session refreshments, lunch and certificate.

- **Questions and information:**
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- **Cancellation Policy:**
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