

The Sixth International Pharmaceutical Compliance Congress

Budapest – Hungary

MEA Annual Compliance Update

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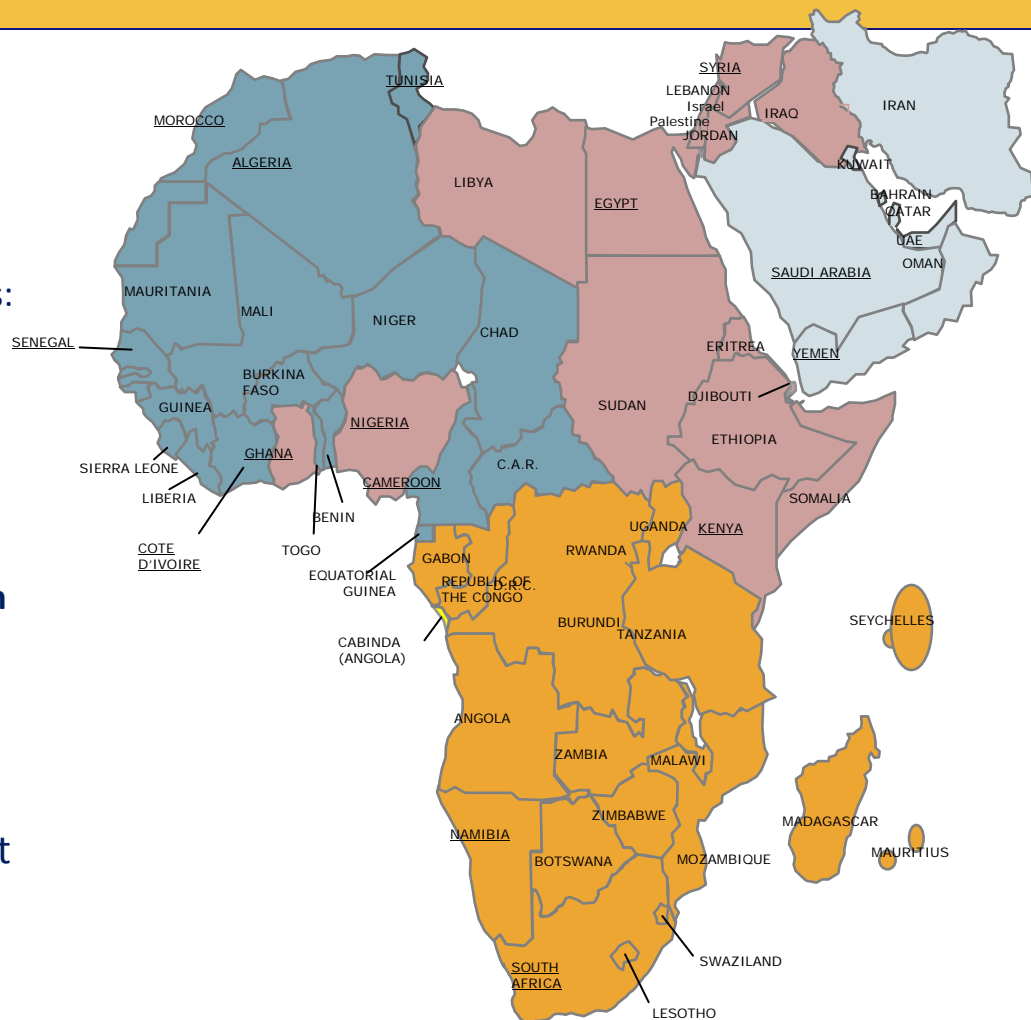
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Middle East Africa

- Middle East & Africa remains one of the pharmerging regions and continues to attract Pharma companies to actively operate and increase its presence in.
 - Growth resilience is supported by five drivers:
 - Significant **Government spending on healthcare systems and infrastructures**
 - Increasing **private investment flows as markets open up**
 - Increased coverage in **health insurance and profitable private-pay markets**
 - A very young and fast-growing population
 - Positive long term impact of “Arab springs” on healthcare expenditures
- The region has long-term growth potential since it includes some relatively wealthy but not-yet-saturated markets, fast-growing emerging, and undeveloped future ones





Corporate Compliance Initiatives

- Increased activities among Pharma Corporations to step up the compliance standards and understanding in the region, catching up with corporate environment
- Launching number of initiatives internally and rolling implementation externally
 - Fair Market Value
 - ✓ Consultants, Speakers, etc..
 - ✓ Methodology & benchmarking exercises
 - Anti-corruption Programs
 - ✓ FCPA
 - ✓ Interaction with Government Employees – an area of special interest for this region
 - Disclosure & Transparency
 - ✓ Preparing for the trend that will come our way in MEA



Corporate Compliance Initiatives - Reactions & Challenges

- Initial resistance – Internally & externally
- Education for HCP – protection for self and company
- Gradual positive evolvement and progress
- Reporting physician appreciation to these efforts by big Pharma

- Key challenges remain
 - Lack of Government enforcement
 - Unlevel playing field among companies and standards
 - Difficulty in forming and registering PhRMA associations – a legal frame could provide more legitimacy to enforce the code.
 - ✓ Positive progress was made in Tunisia only, while trend is going backward in others e.g. Lebanon (cancelled) UAE (declined to renew), and Saudi (rejected application)



Governments Initiatives

South Africa

- Governmental procurement will be centralized within the Department of Health and the policy will be articulated by a Ministerial Procurement Task Team (MPTT)
- MPTT will take over management of all financial applications by provinces; advice to provinces on the management of budgets; the facilitation of contracting with and payments to providers in accordance with a national procurement list. Assessments of the effectiveness of the supply chain, procurement processes and the supply of information will be also undertaken.
- Issues such as risk and corruption will be combated through a corruption hot line.



Governments Initiatives

Saudi Arabia

- The Launch of the New Saudi Promotional Code by the Saudi FDA

Saudi Code

of Pharmaceutical Promotional Practices
in the Kingdom of Saudi Arabia



Drug Sector
Executive Directorate of communication and education



The Saudi Code

➤ Intro By CEO & Exec. VP of SFDA

The aim of this Code is to ensure the access of health care providers to the correct and Reliable information, as well as creating a healthy environment for competition between the different pharmaceutical companies, and, more importantly, develop and regulate the relationship between pharmaceutical companies and the health care providers and to eliminate negative factors at this relationship.

We hope that all pharmaceutical companies, agents, and health care providers follow (committed to) the terms of this Code to get benefits for the kingdom and its citizens through cooperation between SFDA and private sector according to this code.

The Saudi Code for the ethics of pharmaceutical products marketing in the Kingdom has been issued after conducting many meetings with the representatives of private sector and review the successful pharmaceutical experiences. This code was a result from the productive meetings with the

The responsibility of providing the balanced and tendentious information to healthcare providers is on the pharmaceutical companies and manufactures. All activates and marketing operations must follow the standards and regulations that mentioned in the Code.



The Saudi Code

➤ Objectives

Introduction :

This Code is considered as an ethical code for the practicing of pharmaceutical promotion in the Kingdom of Saudi Arabia. All pharmaceutical companies/plants working in the Kingdom of Saudi Arabia and how working in health sector , physician , and Pharmacists either working at private or Governmental sectors and should adhere to this code.

Objectives :

1. Organizing the marketing practices in line with ethics profession of medicines and Pharmacy.
2. Provide accurate, fair, and objective information about the pharmaceutical products to the health care providers, In order to reach the correct decisions about the usage .
3. Create suitable and healthy environment for virtuous competition between the pharmaceutical companies.
4. Developing and organizing the pharmaceutical companies/plants relationships with health sectors professionals through providing accurate and reliable information about the pharmaceutical products for patient benefit.



The Saudi Code

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The Saudi Code

Enforcement

Article (11)

Enforcement roles :

11-1 Each company must have a specified procedures to monitor and observe any infringements to this codes.

11-2 The chambers of commerce and industry will form a committee, in cooperation with SFDA, which include the company's representative, in order to ensure their commitment to this Code in the Kingdom of Saudi Arabia.

11-3 Any complains about the implementation of this code should be presented to the committee , so it can study It and take a decision about the company and inform it about its infringement.

11-4 If the company didn't comply to committee decision, the committee must inform the Saudi Food and Drug Authority to take an appropriate action to the company's infringements.



Local Associations

General

- Functioning and registered associations are
 - ✓ Morocco,
 - ✓ South Africa
 - ✓ Egypt
 - ✓ Tunisia

- In other countries is a struggle to register local associations which will be able to drive a better industry self regulation



Local Associations

Tunisia

- The new association representing the innovative medicines sector in Tunisia, SEPHIRE (le Syndicate des Entreprises Pharmaceutiques Innovantes de Recherche) held its launch meeting and reception on Friday, March 3, in the capital, Tunis.
- Approximately 150 participants were there representing the innovative and generics industry, academia, various government ministries and agencies, and the media.
- The SEPHIRE launch featured the signing of a new code of promotion practices, and presentations emphasizing the important role of clinical research conducted under high ethical standards.
- The launch is the culmination of almost one year's intensive organizational efforts; SEPHIRE starts off with 14 globally leading biotechnology and research based pharmaceutical member companies.



Local Associations

South Africa

- Organized by Innovative Medicines SA (IMSA), an IP Training Seminar was launched in partnership with the Anti-counterfeiting unit of the National Department of Trade and Industry, Adams and Adams Attorneys and the University of Pretoria.
- The focus was on balancing intellectual property rights with access to medicines and enforcement efforts to control counterfeit medicines and effectively manage the threat to public health and safety



Local Associations

Egypt

- PhRMA Egypt Chair and two board members were elected on Sunday, March 18.
- Anticipation for resuming activities and addressing pending issues in Egypt

Algeria

- PhRMA Chairman & 2 Vice Chairs have been elected for the LAWG in Algeria
- PhRMA-LEEM taskforce will meet to establish future working framework and agenda



MEA Code of Promotional Practices





MEA Code - Progress so Far...

MEA Code Update

- Finalized in 2011
- Copies printed and distributed to different LAWG chairs in different countries

Toolkit Rollout

- Completed in UAE, Jordan, Lebanon and Saudi Arabia
- Egypt and Kuwait are in the pipeline

Member Companies Rollout

- Completed: UAE and Saudi Arabia
- Next steps: Jordan, Lebanon, Kuwait and Egypt

Government Rollout

- In progress. LAWG Chairs will be responsible in leading the campaign with stakeholders in respective countries



MEA Code – Enforcement Updates

- LERB is expanding to include members from all multinational companies
- 8 companies represented so far and all companies encouraged to have their Compliance Officers as members
- One call every 2 months to discuss hot topics and issue some guidance to be shared with all companies via steering committee
- Enforcement Procedure of the code was updated to make it more understandable and easier to implement



Emerging Topics in the Middle East

- Reinforcement of Hospitality / location of meetings with HCPs
– Independent Meeting organized by Associations
- Promotion of EU/US product at MEA tender institutions prior to the local approval
- Interaction with Pharmacists / Pharmacy staff in the pharmacies: where to draw the line and what should be the boundaries. Update the Code to include some guidance on Pharma companies interaction with Pharmacies?
- More discussions on Patient education (when we cross the lines)