Middle East Regional Report

"The Patient is (Still) Waiting": But the Middle East Has Plans

11th Middle East Regulatory Conference (MERC)

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Biosimilars, pharmacovigilance, regulatory innovation and best practices, quality and counterfeits, and the eCTD are "hot topics" in the Middle East. Suprising?

At the *11th Middle East Regulatory Conference (MERC)* in Riyadh, Saudi Arabia (November 17-18), Conference Chairperson Professor Trevor M. Jones, CBE, King's College, London (and former Director General, Association of the British Pharmaceutical Industry [ABPI], UK) began the conference celebration of its twenty year history and introduced this two-day program jointly developed by leadership from industry and health/regulatory authorities by sharing his thoughts on how far regulatory practices, and this regulatory conference, have developed in the region over the past two decades.

As the "genetic revolution" has changed our understanding of disease, new regulatory models such as adaptive pathways and accelerated reviews have emerged, bringing together common interests amongst regulators and industry in safeguarding the public while maintaining access to innovative medicines. "More than ever we need to work together to bring advances in medical research to the benefit of our people," he explained. "The patient is waiting!"

DIA co-hosted the *11th Middle East Regulatory Conference* with the SFDA and European Federation of Pharmaceutical Industries & Associations (EFPIA) Middle East Regulatory Network (MERN). It brought regulators from different countries together to share best practices; industry representatives included both local and multi-national pharmaceutical companies. The conference was opened by Saudi Food & Drug Authority (SFDA) Chief Executive Officer, His Excellency Dr. Mohammed Al-Meshal, who welcomed its more than 400 attendees from nearly 30 different countries.

Key messages from the remaining topical sessions:

LOCAL REGULATORY ENVIRONMENT

- Improve transparency with industry stakeholders
- Establish pharmacovigilance centres
- Move towards implementing serialization / track and trace in their markets
- Continually improve the regulatory framework, including accelerated review pathways, to improve patient access to innovative medicines (Egypt, Jordan, Kuwait, and Saudi Arabia).

REGULATORY INNOVATION & CHALLENGES

- The WHO encourages work-sharing among health authorities
- Harmonization/convergence can help form the basis for evolving new regulatory paradigms
- Industry calls for enhanced regulatory assessment processes, unified registration mechanism, and optimal use of the Certificate of Pharmaceutical Product (CPP)
- SFDA may optimize resources use by stratifying review efforts, using stringent regulatory authority reviews as a basis for approval, and improving transparency by publishing summary basis for approval
- The Universal Benefit Risk Assessment Framework, a structured approach to the benefit-risk assessment of medicines developed by the Centre for Innovation in Regulatory Science consultancy, may enable improved decision making during the review process.

QUALITY THROUGH COMPLIANCE: COUNTERFEITS

- SFDA has controlled counterfeiting by introducing hand-held Raman spectroscopy scanners to aid detection, and by reducing points of entry into the country
- Supply chain complexity and lack of control enable criminal activities which lead to medication errors, harming patients and health care systems
- Industry and health authorities working together to implement scalable solutions based on international standards (e.g., GS1) would enhance supply chain integrity.

QUALITY THROUGH COMPLIANCE: POST-APPROVAL CHANGES (PACS)

- Approving PACs globally can take years
- The fragmented global regulatory landscape inhibits implementing innovation via PACs
- Global harmonization/ convergence of PAC regulations would be a "win-win" for patients, regulators, and industry
- Proposed ICH Q12 guideline represents a paradigm shift in managing post-approval CMC changes across the product lifecycle: Established Conditions for Manufacture and Control present binding information concerning the manufacture and control of a pharmaceutical product, proposed by the applicant in a new submission and approved by the appropriate regulatory authority.

REGULATORY PRACTICES ADDRESSING SCIENTIFIC & REGULATORY INNOVATION

- Advances in understanding the molecular basis of disease must correspondingly change drug development and regulation models
- EMA adaptive pathways model simultaneously allows for faster access to treatment and continuing benefit-risk oversight
- Stem cell therapies raise new benefit-risk challenges for regulators; well-regulated therapies can provide significant benefit
- Stem-cell tourism is a significant health risk
- Global data sharing between regulatory agencies, especially those in countries where regulation is still developing, will benefit patients
- Companion diagnostics to detect oncology biomarkers, which can guide treatment, need regulation
- Regulatory oversight of companion diagnostics and their therapeutic products

requires strong collaboration between regulators, industry, and academia.

SHARING eCTD PRACTICAL EXPERIENCE GLOBALLY, REGIONALLY & LOCALLY

- eCTD has been implemented by over 30 health authorities globally; Oman will launch an online submission portal as its Ministry of Health implements eCTD in 2016
- Version 4 will allow questions and answers to be managed within the dossier
- Mature products without full eCTD can be evaluated on a case-by-case basis
- Debate continues over the requirement for baselines; industry and health authority collaboration is essential in establishing the path forward.

ASSESSING BIOSIMILARS

- WHO has been mandated to assist health authorities in developing expertise and guidance to review dossiers for similar biotherapeutic products (SBPs)
- SBPs are not generics and require rigorous assessment to ensure similarity to the reference biological product
- Distinguishing between biotherapeutic products in adverse event reporting is important; the WHO proposal for adding a biological qualifier to the International Nonproprietary Naming (INN) would enable such distinction
- Regional health authorities want to deliver the benefits of appropriately reviewed biosimilars to their patients, and are building their review expertise and developing guidance in line with international standards
- Local regulators will re-evaluate previously approved biosimilars/ non-comparable biologics when new guidelines are implemented
- Where interchangeability has not been demonstrated, avoid substitution without informed physician consent.

ENSURING COMPLIANCE WITH NEW PHARMACOVIGILANCE REGULATIONS

- Numerous countries – including KSA, Egypt, and Jordan – are implementing the Pan Arab Good Pharmacovigilance Guideline
- Oman, Kuwait and UAE will soon implement some, or all, of the Pan Arab GVP
- The Saudi Qualified Person must be a Saudi national by the end of 2016
- In 2016, SFDA will issue guidance for graphic design of medication packaging to minimize prescription errors.

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"Harmonization…but also Innovation"

DIA 11th Middle East Regulatory Conference 2015

Middle East and Africa Regional Report

Continued Strengthening of Regulatory Efficiencies & Effectiveness in Africa

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The *2015 PhRMA Middle East & Africa Annual Meeting* was held in Dubai, UAE, on December 9. Its agenda focused on regulatory trends, including a discussion panel on "How to Achieve Efficiencies and Effectiveness in Regulatory Systems in the Middle East and Africa," where participants highlighted key regulatory initiatives supported by the pharmaceutical industry.

Further discussions on potential future synergies with the non-PhRMA Regional Harmonization of Regulatory Systems programs in Africa are planned. To this end, representatives from PhRMA Middle East & Africa and the African Medicines Regulatory Harmonization (AMRH) initiative have scheduled a meeting to explore their areas of common interest.

Under the theme "Regulatory Systems Strengthening for Advancing Research, Innovation and Local Pharmaceutical Production in Africa," the *2nd Biennial Scientific Conference on Medicines Regulation on Africa*, presented in Addis Ababa from November 30 – December 1, brought together representatives from the WHO, African Union Commission, Pan African Parliament, NEPAD-Agency, multinational and local pharmaceutical companies and trade associations, regulatory authorities from inside and outside Africa, donor organizations, NGOs, and the public and private sectors. Highlights of session topics include:

- Keynote review of local manufacturing status in Africa by the current President of the Federation of African Pharmaceutical Manufacturers' Associations, who eloquently advocated for African herbal medicine research
- The Pharmaceutical Manufacturing Plan for Africa, an AU initiative anchored upon regulatory strengthening, raising GMP standards for local manufacturers, and building a regional bio-equivalence center of excellence for new public-private partners (initially for generic products)
- Review of regulatory system building initiatives led by the WHO, alone or in collaboration with global partners, which promote regional harmonization that leverages the technical competence of high-income country regulators; promising early results from these initiatives were discussed, as were ways to attract the interest of innovator pharmaceutical companies
- Lessons from Ebola virus disease intervention efforts were presented from the perspectives of affected countries – Guinea, Liberia, Sierra Leone, and neighboring Ghana – in an effort to increase speed and efficiency in responding to future regional epidemics.