TOP TRENDS, CHALLENGES FACED AND SOLUTIONS REQUIRED IN THE MIDDLE EAST PHARMACEUTICAL SECTOR

DID YOU KNOW?

Pharmaceutical regulations and guidelines are stricter and more numerous in Saudi Arabia and other Middle Eastern countries than almost anywhere else in the World.

Multinational pharmaceutical companies cite lengthy drug approval times, flimsy intellectual property protection and opaque government tender processes as some of the key regulatory challenges of working in the region.

Most Middle Eastern pharmaceutical legislation details are not accessible to the public, and legislation that is available is only available in the local language, making comprehension difficult for MNCs. [1]

TOP SOLUTIONS & TECHNOLOGIES REQUIRED

Engage with regulatory and health-system policies:

Regulatory and health-system policies are quickly changing in the GCC but few pharmaceutical companies actively engage in shaping them. Leading companies must hire senior government affairs managers who can provide appropriate support to policy makers. [8]

Greater adoption of RegTech:

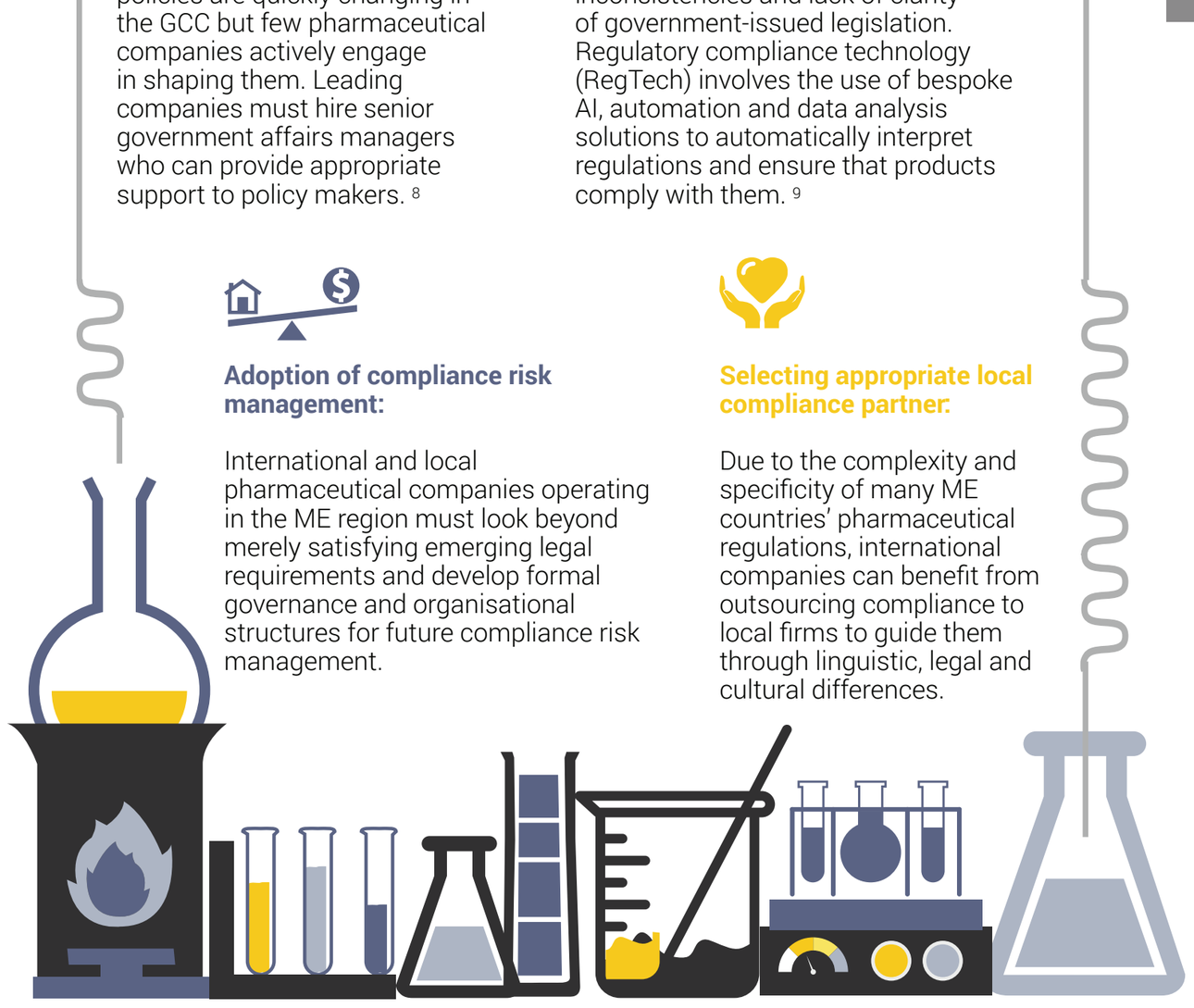
A technological approach to regulatory compliance can help overcome inconsistencies and lack of clarity of government-issued legislation. Regulatory compliance technology (RegTech) involves the use of bespoke AI, automation and data analysis solutions to automatically interpret regulations and ensure that products comply with them. [9]

Adoption of compliance risk management:

International and local pharmaceutical companies operating in the ME region must look beyond merely satisfying emerging legal requirements and develop formal governance and organisational structures for future compliance risk management.

Selecting appropriate local compliance partner:

Due to the complexity and specificity of many ME countries' pharmaceutical regulations, international companies can benefit from outsourcing compliance to local firms to guide them through linguistic, legal and cultural differences.



TOP REGIONAL REGULATIONS TRENDS

PHARMACEUTICAL

The unified pricing system for pharmaceuticals, adopted by all GCC states in 2014, is close to being implemented. The agreement prohibits both global and domestic companies from increasing prices for pharmaceutical products. [2]

Better IP protection regulations are being refined across the Middle East in order to comply with Trade-Related Aspects of the Intellectual Property Rights (TRIPS) agreement of 2012. [3]

New drug application waiting times are being reduced to encourage more international pharma involvement. [4]

The Saudi Arabian Government has started issuing 100% ownership trading licences to global firms. In mid 2016, Pfizer was the first pharmaceutical company to win a license. [5]

Strengthened Pharmacovigilance (PV) systems and initiatives are emerging in GCC countries to allow for the more effective reporting and prevention of Adverse Drug Reactions (ADRs). [6]

MEDICAL DEVICES

The Global Harmonization Task Force (GHTF) is currently working with ME governments to simplify their regulatory relationship with international medical device companies.

CHALLENGES FACED IN THE INDUSTRY

Keeping up with emerging legislation

As healthcare demands in the ME region skyrocket, regulators are introducing wider and more numerous regulatory changes in order to protect the public and the industry's long-term security.

Siloed approach to regulatory compliance

Regulatory compliance is made harder by siloed nature of pharma companies' data, leading to missed details, deadlines and processes.

Disconnect between regulators and international pharmas

Development of new regulations often occurs in isolation without international pharmaceutical companies developing sufficiently deep connections with regulators of their target audience's host country.

[1] Decision Resources Group, *Middle Eastern Medical Device Markets: A Region of Opportunities*, 11/01/2017

[2] Arabian Business, *Is this the right prescription for Saudi Arabia?*, 07/11/2016

[3] Ibid

[4] Arabian Business, *Is this the right prescription for Saudi Arabia?*, 07/11/2016

[5] Ibid

[6] Saudi Pharmaceutical Journal, *Pharmacovigilance system in Saudi Arabia*, 08/09/2016

[7] SABA, *Intellectual Property, UAE: New regulations for cosmetics and perfumes*, 24/01/2017

[8] McKinsey and Company, *Pharma's Next Challenge*, July 2015

[9] Financial Times, *Market grows for 'regtech', or AI for regulation*, 4/10/2016

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