Current trends in generic medicines in the Middle East: challenges and opportunities

Mazen Darwazah
Vice Chairman, Hikma Pharmaceuticals PLC
Middle East and North African pharmaceutical markets

- Middle East and North Africa, MENA region, spans 18 countries - from Morocco to Iran
- MENA pharmaceutical market began to develop in 1970’s
- More than 140 pharmaceutical factories operating across the region today
- Local production dominated by generic manufacturers
- Strong dependence on imported finished products, raw materials and packaging
- Licensing by domestic producers has helped to accelerate the adoption of good manufacturing practices across the region
MENA markets represent nearly 2% of world market

Source: IMS data, Scrip reports, Hikma estimate, Espicom Business Intelligence report.
MENA markets offer significant growth opportunities for generics

- **Opportunities**
  - Growing populations
  - Increasing affluence
  - Increasing government health expenditure
  - Stable pricing environment
  - Developing health insurance industry
  - Lower manufacturing costs

- **Challenges**
  - Brand promotion
  - Fragmented regulatory procedures
  - Preferential treatment for local producers
  - Lower quality perception limiting generic penetration
Significant scope to increase per capita pharmaceutical spend

Per capita drug spending (1)

(US $)

USA 841
France 370
Germany 299
Czech Republic 216
Hungary 208
Poland 94
Slovakia 78
Russia 33
Romania 32
UAE 133
Kuwait 118
Saudi Arabia 45
Jordan 21
Algeria 20
Egypt 14

(1) Source: Merrill Lynch Estimates
Population growth and higher health standards are key drivers of pharmaceutical spend

- Population growing at approximately 2.7% per annum
  - Increasing life expectancy
    - Now 70 versus 60 a decade ago
  - Reduction of still births

- Improving standard of living
  - Wealth created by increasing oil prices
  - Rising GDP
  - Better awareness of health issues

- Increase in chronic diseases of developed countries
  - Diabetes, heart disease and cancer incidence increasing

2006 private market size and market growth
Governments are increasing spend and modernising healthcare systems

- Governments are promoting the development of the private healthcare market
- Health insurers are entering the market
- GCC countries are making private health insurance for expatriates mandatory
- Jordan
  - Three public hospitals recently constructed
  - Four more hospitals underway as well as 50 healthcare centres
- Saudi Arabia actively encouraging expansion of health services in the private sector
  - Approved loans for the construction of private hospitals and multi-disciplinary health facilities
MENA’s competitive landscape

■ Multinationals operating across the region

■ Local producers split between public and private sector

■ Few local manufacturers have a regional presence

■ High dependency on imports

■ Domestic production accounts for approximately 45% of drug consumption in the region
### Leading manufacturers

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<tr>
<th>Company</th>
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= Generic manufacturers

Source: IMS Health MAT Dec 2006.
Note: Saudi Arabia and Jordan data available on an aggregate group basis, while Algeria data is available on a company basis.
GCC pharma markets are most attractive in region

- The favorable economic environment, limited political risk, falling regulatory barriers and strong market growth potential of the GCC countries make them some of the most attractive markets in the MENA region

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Source: Business Monitor International, June 2007
Relatively low generic penetration means scope for growth

- Largely Branded market
  - Patented, generic and OTC products marketed under specific brand names

- Relative wealth of population, particularly in the GCC, drives demand for branded drugs

- Generic penetration is fairly low across the region, especially in the GCC

- BMI estimates that generic drugs account for less than 10% of the GCC pharmaceutical market

- Markets like Egypt and Tunisia have higher generic penetration
Relatively stable pricing environment protects local manufacturers

- Prices are controlled by health authorities

- First generic priced at 25-30% discount to the originator

- Further reductions determined by ministries of health

- Subsequent generics priced at a 5% discount to the preceding registered generic

- Number of registrations for each generic limited in some markets

- Price determinants:
  - added value of product to health services
  - price in neighboring countries
  - price in country of origin
  - price of competitors in the market
Local manufacturers benefiting from relatively low cost base

- Labor costs lower in Middle East relative to western pharmaceutical markets

- Governments encouraging private sector investment in pharmaceuticals
  - Saudi Arabia:
    - Incentives: free land, interest free loans, subsidised utility costs
    - Disbursing 10% subsidy on production cost of pharmaceutical products

- Limited regulation of API supply
Brand promotion required to build strong market position

- Relatively affluent market prefers branded products, particularly in the GCC

- Quality reputation critical for local manufacturers

- Indian competition limited to leading firms and brands
Intellectual property protection still developing in the MENA region

- **TRIPS**
  - Intellectual property rights are increasingly being implemented and adhered to across the region

- **FTA**
  - Some Arab countries have also signed the Free Trade Agreement with the US (Jordan, Bahrain, Oman)
  - Adoption of data exclusivity rights

- **WTO**
  - Pending entry into the WTO should accelerate the adoption of intellectual property rights in countries like Algeria, Sudan and Lebanon

- IP violations still remain due to lack of transparency and/or access to patent linkage systems in countries like Saudi Arabia and Egypt
Registration poses barriers to entry

- Each country in the region has its own registration procedures
  - Mutual recognition developing in the GCC
  - Certain health authorities are considered as “standards” for other authorities which will expedite their approving the product

- Stringent regulation requirements represent a significant barrier to entry in countries like Saudi Arabia, Egypt and Morocco

- Registration times stretch from six months up to 3-4 years

- Most markets favor local manufacturers by a variety of methods
  - faster registration times
  - preferential pricing
  - prohibition of importation of generic versions of locally manufactured products
New therapeutic areas are key growth drivers

- Four of the five countries with the highest prevalence of diabetes in the world are in the Middle East*

- More than half of the population of UAE is classified as at risk of contracting diabetes

- Demand for diabetes-related pharmaceuticals grew by 22% in the UAE in 2004

- Coronary heart disease has been rising in the region and is expected to increase in incidence

* Business Monitor International, Middle East & Africa Pharma & Healthcare Insight, June 2007
Hikma is well-positioned in the MENA generic market

- Operations span 18 countries in MENA
- Strong brand recognition, developed over nearly 30 years
- 500-strong sales force with strong customer relationships
- Large product portfolio and significant pipeline
- Market leader in key therapeutic categories
- Excellent relationships with MNCs as licensing partner
THANK YOU