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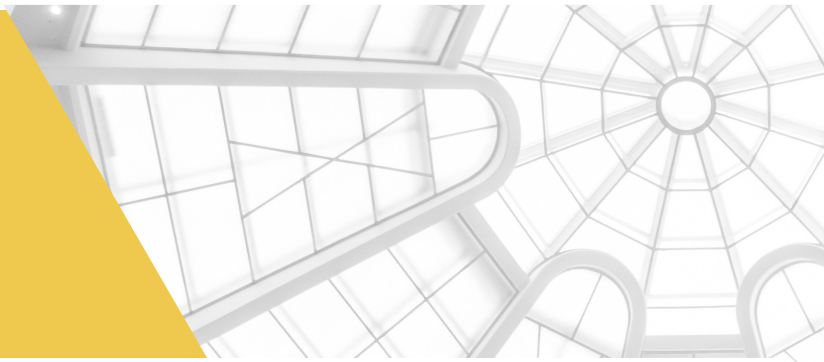
MENA

REGULATORY OVERVIEW



MENA Requirements

MENA countries are mainly secondary review countries for **innovative, Biologic & Biosimilars products**. (i.e Reference country approvals are necessary). For locally manufactured generics, MENA countries act as primary reviewers.

- Main reference Regulatory bodies: USFDA, EMA, MHRA, TGA, HC, Swiss Med, Sweden, Germany, France, Belgium.
- CPP from COO with marketing status is condition for the application
- Lab testing is a challenging part of registration [Iraq, Algeria, Egypt, Morocco & Jordan are the most challenging countries]
- Stability: Gulf, Iraq, Iran & Egypt require Zone 4 for one year for innovative products [except Kuwait- requiring full shelf life]

Breakthroughs & Fast Track

- UAE, KSA, Egypt, Jordan provide fast track registration pathways for Breakthrough medicines and unavailable medicines for unmet needs.
- KSA provides an exclusivity marketing scheme for Essential medicines with no availabilities [up to 2 companies]

Biologics & Biosimilars

- Most MENA Regulatory Authorities request a reference country for approval
- Some local manufacturers try to bypass the reference. country approval by local filings of foreign produced API concentrate.
- Blood products & vaccines need batch release certificates for each consignment from a recognized reference lab

Labelling

Follows the CPP country strictly. However, regulatory authorities request safety updates issued by reference authorities other than the CPP country to be included.

MENA

GENERAL REGULATORY GUIDE

*only applies to pharmacuetical products classified as Drug/Medicinal products subject for pricing (innovative & generics)

Pricing

- IRP is the basis for pricing across MENA, where GCC countries prices, UAE known to be the least restrictive.
- COO price is the ceiling price as per laws in MENA
- KSA takes prices of other products within same TA in consideration

Concept of COO

Different definitions across MENA and in the same country. Definition is dependent on the purpose.

- **Pricing:** COO is the release country
- **Marketing approval** & CPP the COO is the CPP (MAH) country
- **Tenders:** COO is the country of bulk manufacturing

Pack & Artworks

- Serialization & 2 data metric coding: a must in Gulf & Levant countries up to Egypt
- In GCC & Gulf mandate specific conditions (fonts & additional info on the outer pack)
- English is a must for ME, French for NWA

Formulary/insurance **Enlisting**

- Pre-registration Listing: Iraq, Iran, Algeria & Egypt (Box) request prior enlisting of the molecule/strength/dosage form within their national formulary as a condition for submission of registration application
- This process is time consuming and subject to budget limitations of these countries
- Other markets: enlisting at different government institutions should happen before procuring or reimbursement
- UAE, KSA, Qatar & Bahrain allow enlisting at government institutions for none registred products if justified

Imports

- For unregistered with no available alternatives: allowed in most MENA (other than Algeria, Morocco, Iraq)
- Parallel Imports: common in Qatar, Bahrain, Egypt, Iraq, Iran
- Lab testing for batches upon import is a must in many countries (Eqypt for 1st 3 batches then 1 every 10 batches. Iraq for 1st batch then at random. Kuwait for every batch (not biologics)