Update on GCC Region
ICH-GCG Meeting, Brussels
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Three meetings were conducted since November 2006


- The Arab Union for Pharmaceuticals Manufacturers (AUPAM) meeting on 19-20 February 2007. Jeddah, Saudi Arabia.

The 31 GCC_DR meeting – the Policy meeting on 28-30 November 2006.

- Stability Guidelines
- Requirements for biosimilar products.
- Requirements for Blood products.
- Requirements for Vaccine and sera products.
- Pharmaceutical Product Study Report
- API
- Contract manufacturing.
Updating GCC Stability Guidelines

- Update the guidelines with the following:
  1. Stability testing of Active Drug Substances
  2. Annex for Testing Parameters
  3. In use stability (Multi-dose Products)
  4. Post registration variations
Updating GCC Stability Guidelines

- Use standard form for stability assessment
- Dossier should include a summary sheet
- Guideline was revised and approved
- GCC countries are categorized in climatic zones III & IVa.
The GCC Guidelines on Stability Testing of Pharmaceutical Products

Ramadan 1424 H / Nov 2003 G
The Arab Union for Pharmaceuticals Manufacturers (AUPAM) meeting on 19-20 February 2007

- Towards a unified CTD for drug registration in the Arab world.

- The ICH CTD was recommended as the format to be adopted.
The GCC Drug Quality Symposium on 26-27 February 2007
Declaration Of Riyadh

1. The office of the Executive Board of Health Ministers Council for Gulf Cooperation Council States should initiate action so as to actively engage themselves with worldwide activities like IMPACT (International Medicinal Products Anti-Counterfeit Task Force). The office of the Executive Board of Health Ministers Council for Gulf Cooperation Council States should take the lead to address this problem at the next meeting of Arab Health Ministers.

2. National pharmacovigilance infrastructure and implementation needs to be established and/or strengthened in the GCC member countries. The concept of pharmacovigilance is a broader concept than just ADR reporting and should be operationalized in this sense.

3. Develop network of Single Points of Contact (SPOC) per sector e.g. DRA, inspection, police, customs, industry to allow for communication and immediate action

4. Develop network of Official Medicines Control Laboratories (OMCL) and specific anti-counterfeit expertise.
5. Make an inventory of needs for Training and Education of officials e.g.; police, customs, prosecutors, as to the specifics of medicine counterfeiting.

6. Define Regional and National priorities based on risk analysis.

7. A multi-stakeholder national level committee should be formed involving at least MOH, customs department and law enforcement agencies to develop specific national strategies and operations to combat counterfeit problems.

8. A national level study should be launched to assess the situation with regard to counterfeit medicines

9. A three level approach should be adopted for collaborating with other countries in terms of joint action and information sharing
   a. At GCC level
   b. At EMRO level
   c. At global level
Drug Quality Reporting System

1. Each state should establish a drug quality reporting system as a part of post-marketing surveillance programme.

2. Encourage the Health Professionals (pharmacists, nurses, physicians) and patients to report any irregularity in drug quality.

3. Each country should establish a recalling system that responds to the needs of protecting the public from defective pharmaceutical products.
Quality of Active Pharmaceutical Ingredient (API)

- Drug regulatory authorities must ensure that drug master file (DMF) must be submitted along with registration file of the Pharmaceutical product.

- Drug regulatory authorities should request GMP certificate of API manufacturers and that certificate of suitability (COS) is submitted along with registration file.

- Drug regulatory authorities are encouraged to train their staff in process validation and laboratory analysis.
Good Manufacturing Practices (GMP)

- Drug regulatory authorities should develop experienced inspectors in sufficient numbers that will meet the high demand for conducting Good Manufacturing Practice Inspection to ensure compliance of manufacturers of pharmaceutical products.

- Drug regulatory authority should inspect pharmaceutical manufacturers at regular intervals to ensure their compliance with GMP regulations.
Storage and Transportation

- Each GCC country should develop and enforce a system that ensures the proper storage and transportation of pharmaceutical products.
THANKS...