Update on GCC Region
ICH-GCG Meeting, Portland
3 June, 2008

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GCC
The Cooperation Council for the Arab States of the Gulf

Bahrain
Kuwait
Oman
Qatar
Saudi Arabia
United Arab Emirates
and Yemen as member in Health Council.
Mission of GCC_DR

To provide Gulf Sates with safe and effective medicines with reasonable price.
GCC RHI

1. The Council of Ministers of Health (CMH)

Saudi Arabia, Kuwait, UAE, Oman, Bahrain, Qatar and Yemen

2. The Executive Board (EB).

3. The Executive Office General Director

4. GCC_DR Secretariat

5. GCC_DR Steering Committee

GCC States and Yemen and Working Groups
GCC Activities

- The First GCC Food & Drug Conference. 31 March – 2 April 2008. Kuwait.
The First GCC Food & Drug Conference
Kuwait, 31 March – 2 April 2008
Conference Themes

- The role of the GCC executive office to obtain a safe and effective Drug
- The pharmacovigilance in the GCC
- Future perspective of drug regulation in GCC
- National drug policy
- Central drug registration an update
- GCC drug Manufacturing:
  - Counterfeit medicines
- Group purchasing for pharmaceuticals
recommendations

- GCC States are encouraged to prepare and implement a national drug policies.
- Each GCC State should establish their national pharmacovigilance center.
- GCC States are encouraged to establish independent national authorities for Food and Drug.
- Explore the possibility to establish a single Authority for Food and Drug for the GCC States.
- The second conference should be organized in 2010.
Workshop on the Pricing of Pharmaceutical Products
May 20-21, 2008
Intercontinental Hotel
Riyadh, Saudi Arabia
Objectives

- Overview on the regional and international regulatory agencies pricing policies.

- Industrial perspective on pricing policies.

- Applications of pharmacoeconomics.

- Current and proposed changes on the Saudi Pricing Guidelines.
8TH MIDDLE EAST
REGULATORY CONFERENCE
MERC 2009
January 20-21, 2009 - Bahrain
Proposed Topics – Priority Listing

1. Local Authority Views and Key Issues
2. Pharmacovigilance
3. Pharmacoeconomics
4. Counterfeits
5. Quality by Design
6. GMP and PIC/S
7. Biologics-Medicines for the future
8. Biosimilars
9. Variations Future Trends
10. CTD and eSubmissions

*Ranking code: 1st Red 2nd Blue 3rd Green 4th Black
Objective:
To enhance awareness on Quality by Design
What is Quality by Design?
New approach for establishing specifications and manufacturing controls
Impact of these initiatives on EU/US regulations:
  More flexible regulatory process
  Allows timely manufacturing process improvements while mitigating risk
Applications
Focus of the session ICH Guidelines

Q8 Pharmaceutical development, current step4 version
Q9 Quality risk management, current step4 version
Q10 Pharmaceutical quality system, current step2 version

Description of Quality by Design

Process understanding
Progress
Quality Risk Management

Practical examples
THANKS...