

**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



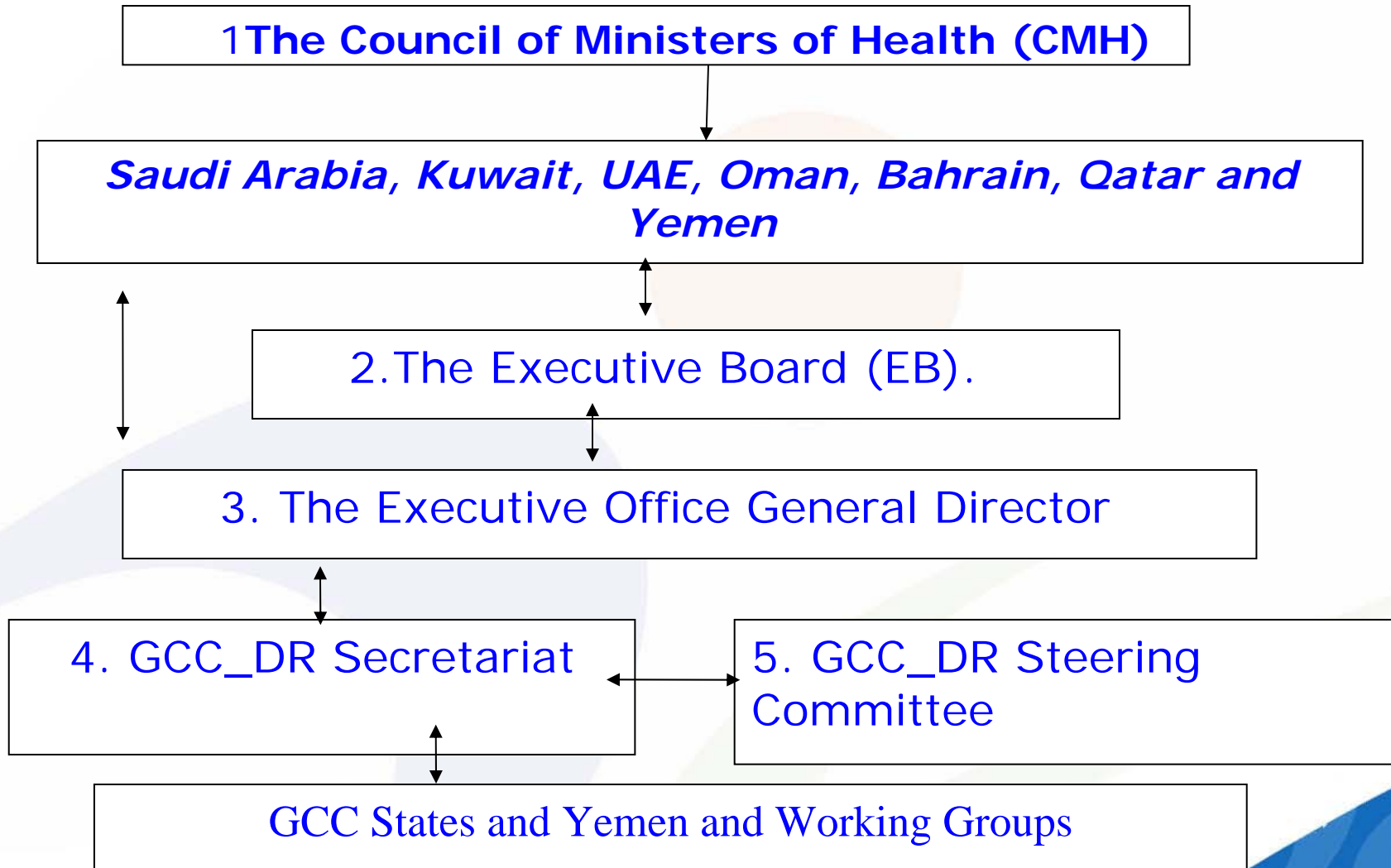
Bahrain
Kuwait
Oman
Qatar
Saudi Arabia
United Arab Emirates
and Yemen as
member in Health
Council.



Mission of GCC_DR

To provide Gulf States with safe and effective medicines with reasonable price.

GCC RHI



GCC Activities

- ❖ The First GCC Food & Drug Conference. 31 March – 2 April 2008. Kuwait.
- ❖ Workshop on Pharmaceutical Pricing. May 20-21, 2008. Riyadh, Saudi Arabia.
- ❖ 8th Middle East Regulatory Conference MERC 2009. January 20-21, 2009. Bahrain.

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



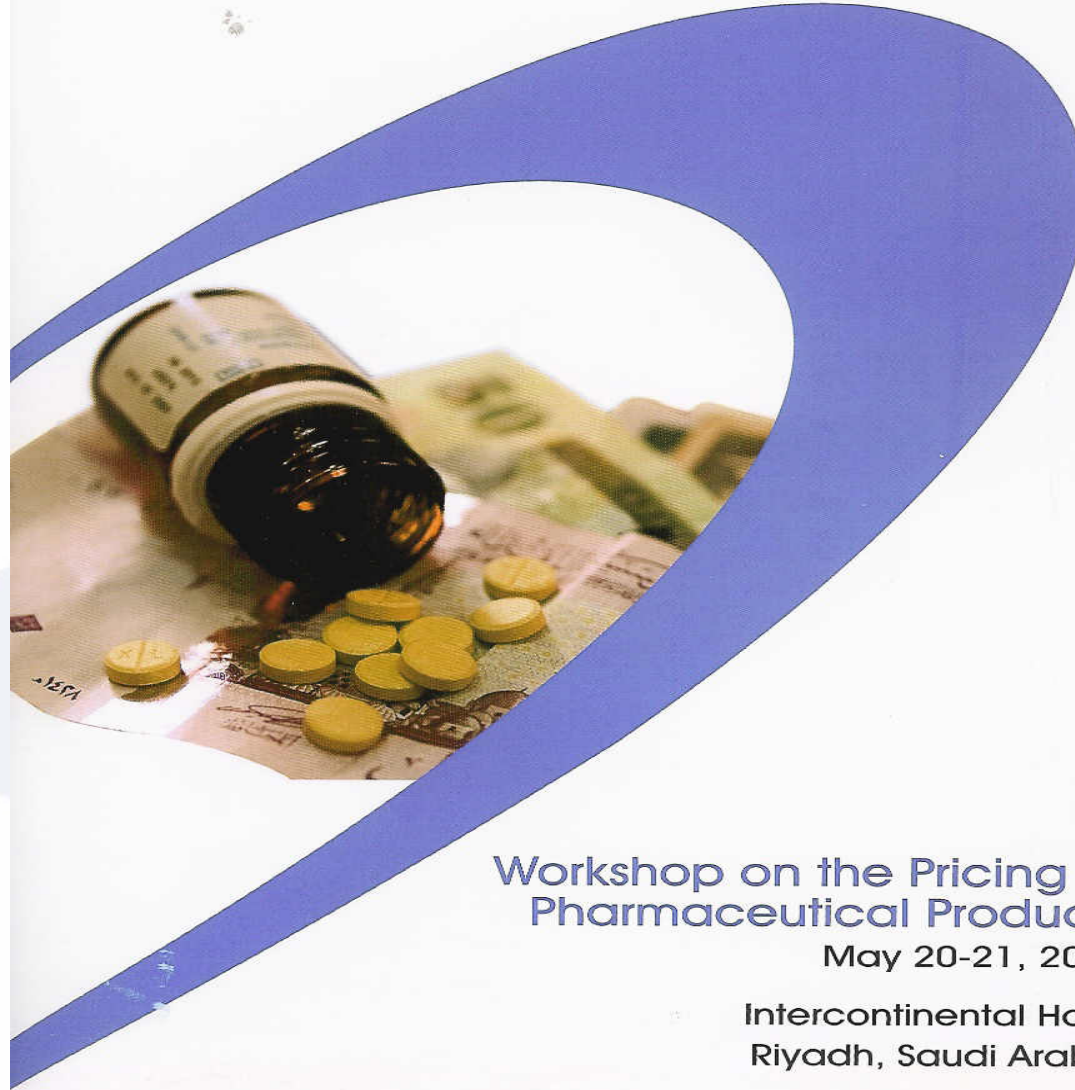
Conference Themes

- ❖ 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

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority



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

Middle East Regulatory Conference 2009

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

Middle East Regulatory Conference 2009

Quality by Design

➤ 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

