

**Update on GCC Region  
ICH-GCG Meeting,  
Yokohama, Japan  
9 June, 2009**

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# GCC

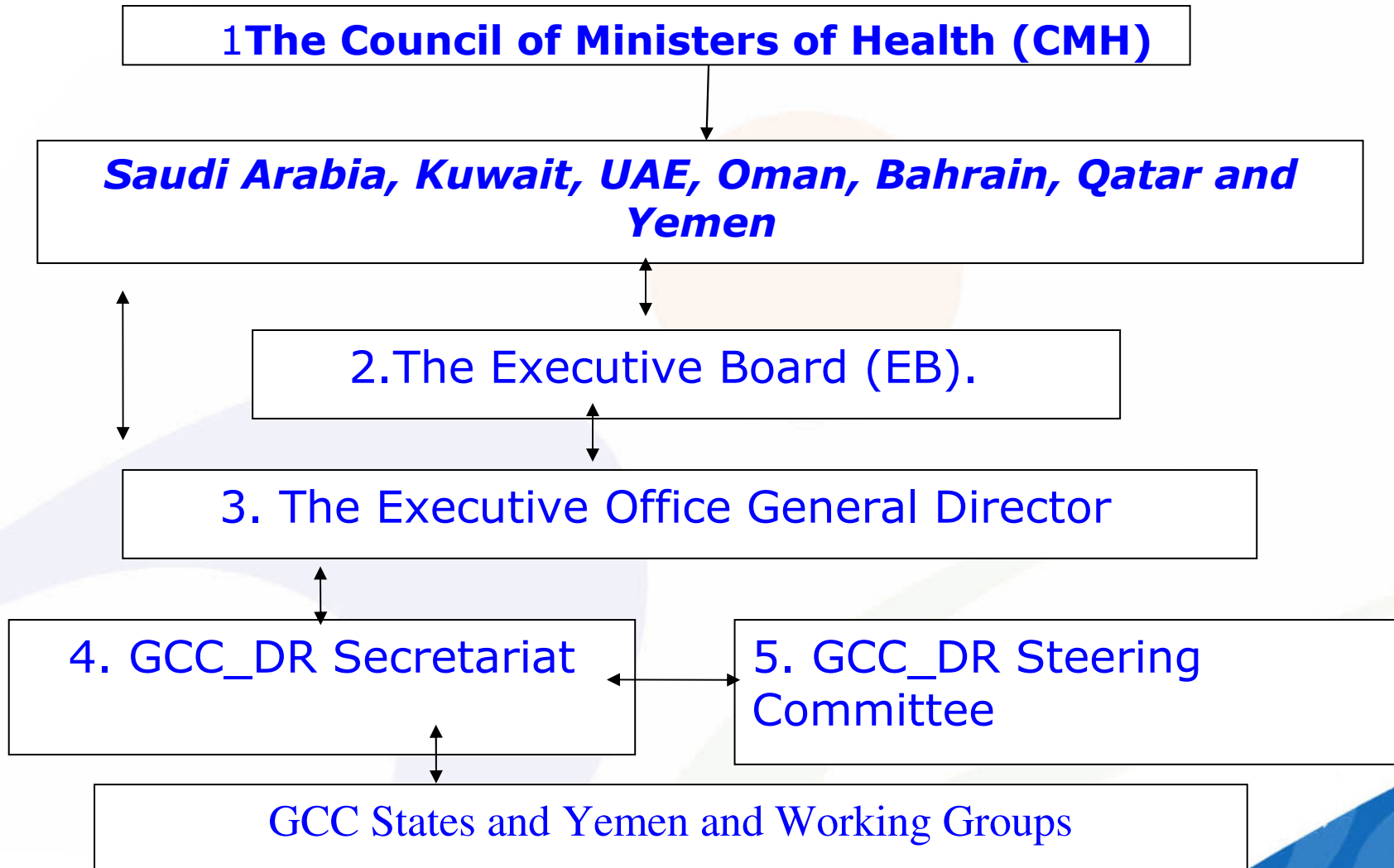
The Cooperation Council  
for the Arab States of the Gulf



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



# GCC RHI



# GCC Activities

- ❖ 8th Middle East Regulatory Conference MERC 2009. January 20-21, 2009. Bahrain.
- ❖ Participated in Webinar for S9 and Q8
- ❖ Towards Unified Arab CTD. Arab U Pharmaceuticals and Medical Supp Amman 30-31 May 2009. Jordan.
- ❖ GCC CTD. Dubai 30-31 May 2009,



# 8th Middle East Regulatory Conference MERC 2009. January 20-21, 2009. Bahrain.



# OPENING SESSION AND INTRODUCTORY REMARKS

reflected on the journey that had taken place since the first MERC in 1996, in particular:

- ❖ The rapid developments in health care and medical science
- ❖ The regulatory environment changes over that time
- ❖ The continuing partnership between industry and regulators in bringing safe, effective, and high quality medicines to patients in the Middle East region

The key topics of the conference were:

- Local regulatory authorities' views and key issues
- Pharmacovigilance
- Counterfeit medicines
- Innovation in the quality arena
- Common technical document and electronic submissions
- Evolving global legislation on medicines
- Health economics



➤ **ICH UPDATE**

– Dr. Yves Juillet,

➤ **PARTICIPATION OF REGIONAL  
HARMONIZATION INITIATIVES IN ICH-  
GCG**

– Professor Saleh Bawazir,

## Towards Unified Arab CTD.

AUPAM. Amman 30-31 May 2009 . Jordan.

- ❖ Arab Union of the Manufacturers of Pharmaceuticals and Medical Appliances (AUPAM) discussed problems facing manufacturers in registering pharmaceuticals.
- ❖ The two-day conference aims at drawing a draft on standardizing criteria affiliated with registering medicines in an attempt to establish a joint Arab pharmaceutical market.

# Harmonization of Drug Registration in the Arab Countries

## توحيد معايير التسجيل الدوائي في الدول العربية

**Prof Saleh A. Bawazir**

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Head of Drug Sector

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- Agreed to Adopt ICH CTD
- Agreed to use ICH guidelines as primary source when developing guidelines by AUPAM.
- Distributed booklet of E6 guideline translated in Arabic language

# GCC CTD. Dubai 30-31 May 2009

- Two days workshop on CTD and eCTD
- Discussed GCC Module 1.
- Future development towards eCTD.

THANKS

