

**Update on GCC Region  
ICH-GCG Meeting, Brussels  
10 November, 2008**

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# GCC

The Cooperation Council  
for the Arab States of the Gulf



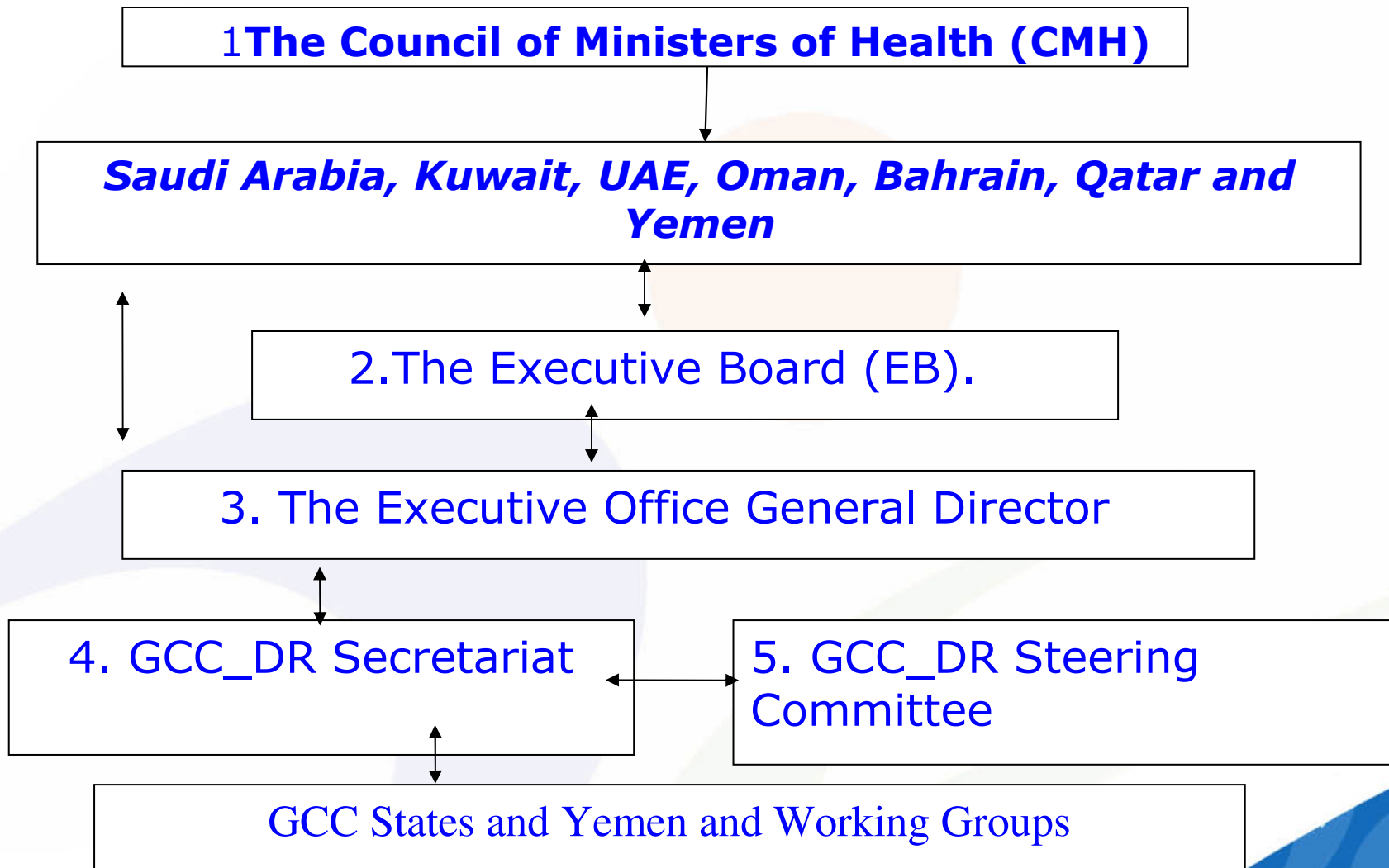
Bahrain  
Kuwait  
Oman  
Qatar  
Saudi Arabia  
United Arab Emirates  
and Yemen as  
member in Health  
Council.



# Mission of GCC\_DR

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

# GCC RHI



# GCC Activities

- ❖ The 39<sup>th</sup> Meeting for GCC\_DR

26-27 October 2008. Riyadh, Saudi Arabia.

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

# The 39<sup>th</sup> Meeting for GCC\_DR 26-27 October 2008. Riyadh, Saudi Arabia.

1. The GCC Stability Guideline.
  - ❖ The GCC\_DR will review the guideline based on the WHO Stability Guideline final version.
2. Under license, Contract Manufacturing and Technology Transfere.
  - ❖ Several suggestions and proposals were discussed.
  - ❖ A draft paper will be developed and discussed in the next meeting.
3. Update of GCC\_DR registration Requirements.
  - ❖ Package Insert translation
  - ❖ Time for appeal for rejected products.

# The 39<sup>th</sup> Meeting for GCC\_DR 26-27 October 2008. Riyadh, Saudi Arabia.

4. GMP Inspection
  - ❖ Review of inspection procedures
  - ❖ Nomination of inspectors
  
5. Requirements of Central Reregistration of manufacturers and Pharmaceutical products at
  - a. Manufacturing license and GMP certificate from DRA
  - b. Declaration form
  - c. Pay Re-registration Fee
  - d. Re-inspection if needed

# The 39<sup>th</sup> Meeting for GCC\_DR 26-27 October 2008. Riyadh, Saudi Arabia.

6. GCC National Drug Code and Barcoding.
  - ❖ Proposed by SFDA
  - ❖ A greed to discuss in special meeting.
  
7. CTD
  - ❖ Training for Staff
  - ❖ Proposed to enforce CTD starting January 2010.

# The 39<sup>th</sup> Meeting for GCC\_DR 26-27 October 2008. Riyadh, Saudi Arabia.

8. Single Entry Point for GCC.
  - ❖ Member States update the committee on preparation progress.
9. ICH Update
  - ❖ Prof. Bawazir present to the GCC\_DR an update of ICH and GCG.
10. Training Programs.
  - ❖ The committee approve the proposed training program on biotechnology products and biosimilars.

**8TH MIDDLE EAST**  
**REGULATORY CONFERENCE**  
**MERC 2009**  
**January 20-21, 2009 - Bahrain**

THANKS

