

**Update on GCC Region
ICH-GCG Meeting,
Tallinn, Estonia
8 June, 2010**

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GCC

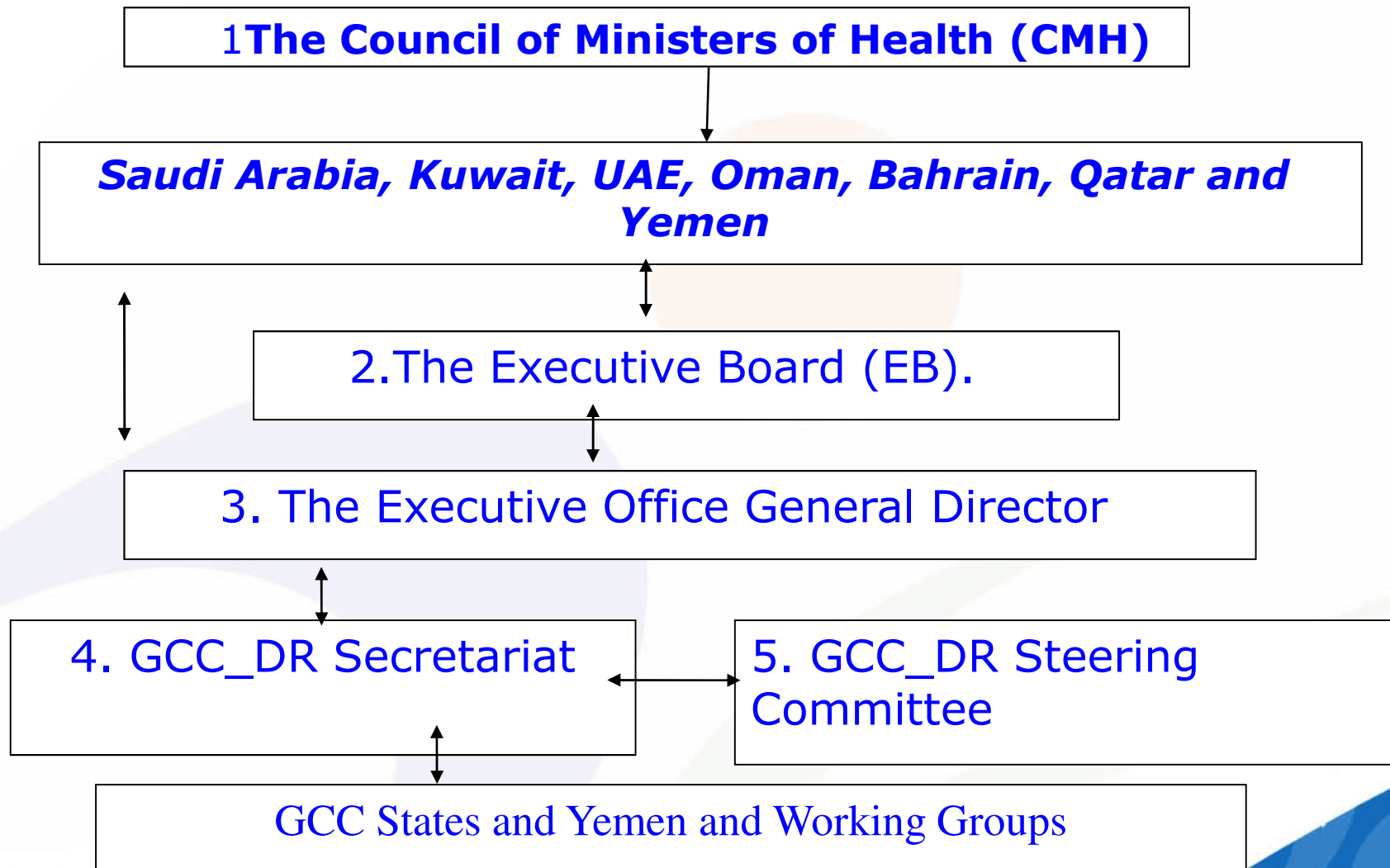
The Cooperation Council
for the Arab States of the Gulf



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



GCC RHI



GCC Activities

- ❖ First Arab Meeting- towards Advancing pharmaceutical Industry, Sharm Alshakh 21-23 February 2010.
- ❖ GCC_DR 48th Meeting, Kuwait 14-18 February, 2010
- ❖ GCC_DR 49th Meeting, Riyadh 30 May - 2 June, 2010
- ❖ GCC Biosimilars workshop.

First Arab Meeting- towards Advancing pharmaceutical Industry, Sharm Alshakh 21-23 February 2010.

- Organized by Arab institute for Administrative development, Arab League and GCC office
- Regulators and Industry representative
- Proposal for establishing Arab Forum for Harmonizing Drug registration

GCC_DR 48th Meeting, Kuwait 21-25 February, 2010

- Review and update Executive roles for GCC_DR
- Update Stability guideline
- Update bioequivalence guideline
- Assessment reports for stability and bioequivalence
- Requirements for products analysis
- Requirements for package inserts
- Proposal for establishing GCC NDC
- Preparation for GCC_DR meeting with industry representatives

GCC_DR 49th Meeting, Riyadh 30 May - 2 June, 2010

- Finalizing most of topics discussed in February meeting
- Contact industry on topics to be discussed in the proposed meeting

GCC Biosimilars workshop.

- To agree on dates
- To finalize the program
- Waiting for comments from EU colleagues.

THANKS

