

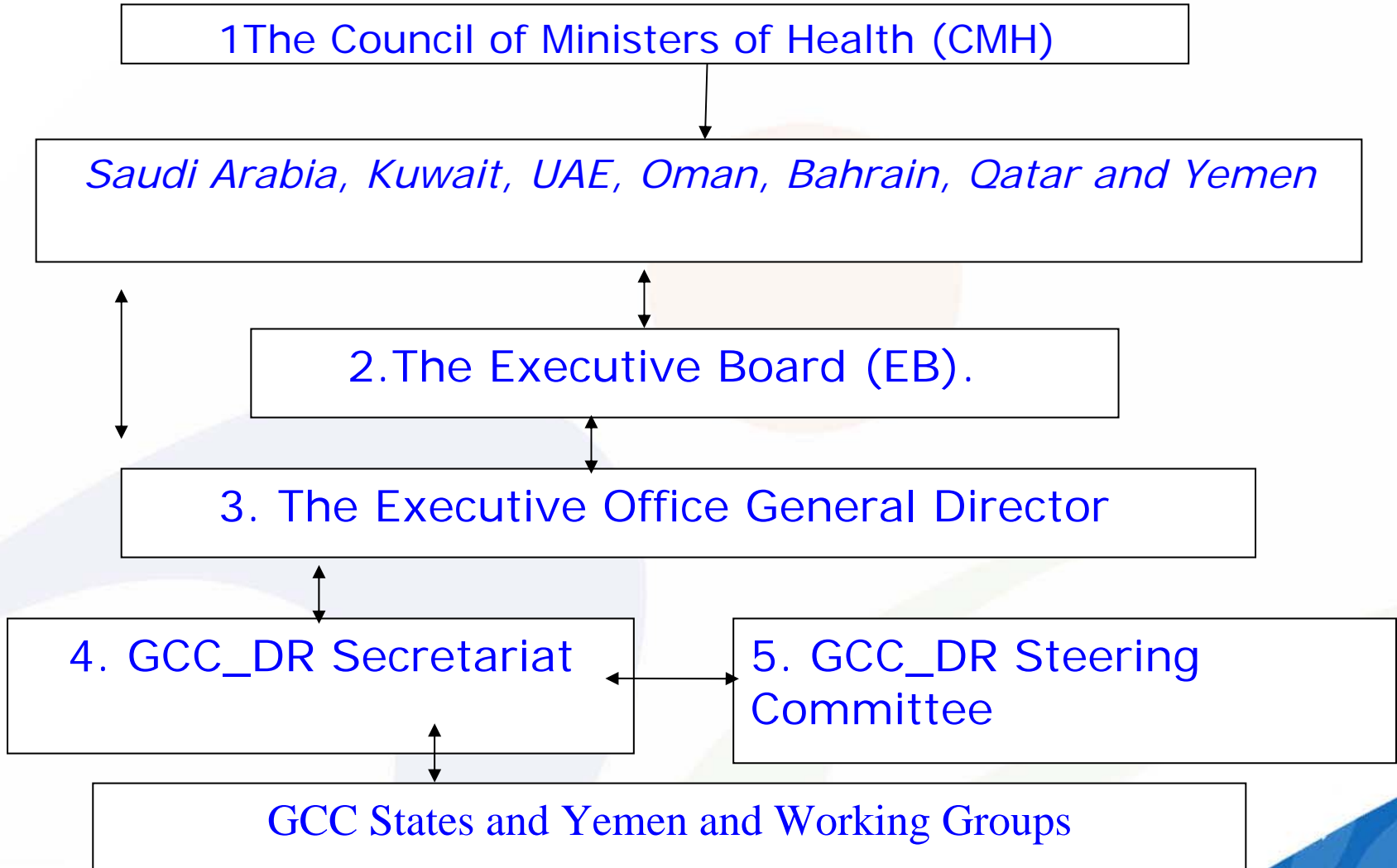
Mission of GCC_DR

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

Glossary

- ❖ CMH, Council of Ministers of Health
- ❖ EB, Executive Board
- ❖ GCC, Gulf Cooperation Council for Arab States on the Gulf.
- ❖ GCC-DR, Gulf Central Committee for Drug Registration.
- ❖ GCC_DR SC, GCC_DR Steering Committee
- ❖ GD, General Director

Organizational Structure



GCC-DR SC

- ❖ 2 members nominated by each state
- ❖ 2 consultants/advisors nominated by Executive Office (no voting rights) for total of 14 members
- ❖ Committee chairman nominated for period of one year.
- ❖ *Permanent, full-time secretariat*
- ❖ *Administration, coordination, communication.*
- ❖ Responsible for reviewing and approving of registration of pharmaceutical companies and their products, technical regulations and guidelines and administrative roles.

Three meetings are planned

- ❖ The GCC Adverse Event Reporting System Symposium (VAERS).
6-7 November 2007. Riyadh, Saudi Arabia.
- ❖ Bioequivalence Studies of Generic Pharmaceutical Products Workshop.
19-20 November 2007. Riyadh, Saudi Arabia.
- ❖ Stability Testing of Pharmaceutical Products Workshop.
2-3 December, 2007. Riyadh, Saudi Arabia

The GCC Adverse Event Reporting System Symposium (VAERS). 6-7 November 2007. Riyadh

- ❖ Prequalification of vaccines, WHO Perspective
- ❖ EU regulation for vaccines.
- ❖ Vaccine Safety, Immunogenicity, Efficacy, Monitoring.
- ❖ Vaccine quality control in GCC States.
- ❖ The need for vaccinevigilance.
- ❖ The vaccinevigilance from WHO and Industrial prospective
- ❖ Causality assessment tools.

Bioequivalence Studies of Generic Pharmaceutical Products Workshop. 19-20 November 2007.

- GCC guidelines.
- Bioanalytical methodology and validation
- Statistical analysis and acceptance criteria
- Special considerations for some drugs
- Biosimilars
- Inspections of bioequivalence centers and analytical laboratories

Bioequivalence Studies of Generic Pharmaceutical Products Workshop. 19-20 November 2007.

- A workshop on the evaluation of bioequivalence data and reports:
 - 1. Contents of bioequivalence data and reports
 - 2. How to evaluate bioequivalence reports submitted by pharmaceutical companies
 - 3. Evaluation forms and check list
 - 4. Examples of bioequivalence reports submitted for registration

Stability Testing of Pharmaceutical Products Workshop.

2-3 December, 2007. Riyadh

- ❖ GCC, WHO and ICH guidelines
- ❖ Methodology, specifications, and acceptance criteria
- ❖ Selection of batches/bracketing and matrixing for multiple strengths
- ❖ Stability testing of oral dosage forms
- ❖ Stability testing of parenteral products
- ❖ Stability testing of topical products
- ❖ Some major factors that may influence product stability

Stability Testing of Pharmaceutical Products Workshop.

2-3 December, 2007. Riyadh

- A workshop on the evaluation of stability data and reports:
- 1. Contents of stability reports
- 2. How to evaluate stability reports submitted by pharmaceutical companies
- 3. Evaluation forms and check list
- 4. Examples of stability reports submitted for registration

THANKS

