

GCC RHI

Gulf Central Committee for Drug Registration.

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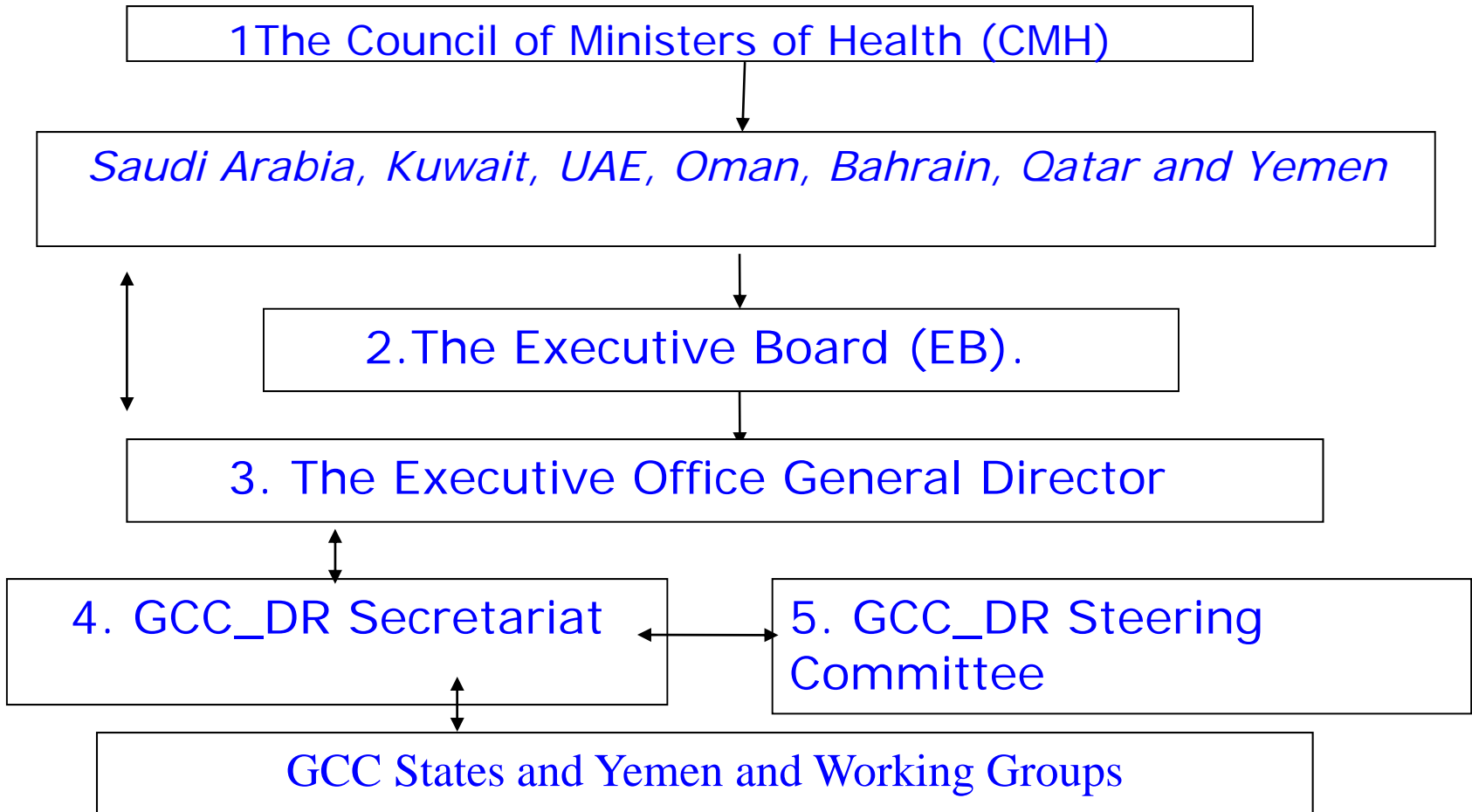
Glossary

- 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

Mission

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

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.

Norms and Procedures

- *Description of file flow.*
- *Description of policy and procedures of each step of registration for products and companies.*
- *Selection prioritisation of topics*
- *Solicitation of comments from stakeholders*
- *Approval/implementation of technical guidelines*
- *Responsibilities of decision-making body, working groups and secretariat*
- *Funding*

Harmonisation Process

GCC Executive Office – GCC_DR SC

Prioritization and selection of topics to be addressed by GCC_DR SC

SC selects expert WG's to meet and monitors performance

WG's analyze topics and develop proposals or adapt int'l standards

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GCC_DR SC lead implementation & adoption of documents in jurisdictions

Technical Documents

- GMP standard
- Bioequivalence guidelines
- Stability guidelines
- GLP guidelines
- Postmarket surveillance guidelines

Topics under discussion

- Pharmacovigilance
- Biosimilars
- Sera and Antivenum
- Vaccines
- Blood products
- Radiopharmaceuticals
- Clinical trials



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Events

10 December 2006

**the 4th Saudi
Conference on Food and
Nutrition**



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SFDA News

Participants in the Symposium on Food Regulation Call For a Lawful Base That Covers All Sectors of the Food Authority

Participants in the Symposium on Food and
Drug Regulation (Present and Outlook)
assured the importance of developing a
lawful base that covers all sectors of the





- Vision and Mission
- Technical and consultant committees
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- Human Drugs
- Veterinary Medicines
- Cosmetic Products
- Drug and Poison Information Center
- Pharmacovigilance Center
- Related Links

- Quick Links
- [About drug](#)
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Drug News

French health authorities ban cosmetics containing vitamin K1 (phytonadione)

The French Health Products Safety Agency (AFSSAPS) has announced a temporary ban on all cosmetic products containing vitamin K1 (INCI name: phytonadione; common name: phylloquinone; CAS: 84-80-0)...[more](#)

FDA Warns Consumers About Dangerous Ingredients in "Dietary Supplements" Promoted for Sexual Enhancement

The U.S. Food and Drug Administration (FDA) is warning consumers not to purchase or consume Zimaxx, Libidus, Neophase, Nasutra, Vigor-25, Actra-Rx, or 4EVERON. These products are promoted and sold on web sites as "dietary

Drug and Poison Information Center

Pharmacovigilance Center (Saudi Watch)

Symposium On Food and Drugs Regulation
((Present & Outlook))
Symposium Lectures

Poll

Do you have any knowledge about the tasks of the Food and Drug Authority?

Yes

Somewhat



**Executive Board
of the
Health Ministers' Council
for
GCC States**



Executive Board

**Group Purchasing
Program**

**The Most Achievements
of the Council**

Central Drug Registration

Computer Department

**Mass Media & Public
Relations**

Address

Arabic

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Thank you





**Executive Board
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Health Ministers' Council
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