



## **DRUG CONTROL AUTHORITY**

### **MINISTRY OF HEALTH**

#### **TERMS OF REFERENCE**

The Control of Drugs and Cosmetics Regulation 1984 was gazetted in June 1984. As provided for by the Regulation, the Drug Control Authority (DCA) was established in June 1985 with the National Pharmaceutical Regulatory Agency (NPRA) serving as its Secretariat.

The DCA is a eleven-member executive committee chaired by the Director-General of Health and comprises of the Senior Director of Pharmaceutical Services, the Director of NPRA plus eight other appointed members including a consultant physician in public service, a pharmacist in public service, three persons from any local universities with expertise in pharmaceutical sciences and two fully registered medical practitioners and a veterinary practitioner in the public service. The Secretary is a pharmacist from the public service.

Members are appointed by the Minister of Health for a period of three years but they are eligible for re-appointment. Any appointment or suspension or termination of membership shall be published in the *Gazette*.

The main objective of the DCA is to ensure that pharmaceuticals, marketed in Malaysia are safe, efficacious and of quality and that the traditional medicines, health and personal care products are safe and of quality.

## **TERMS OF REFERENCE**

The Drug Control Authority (DCA) is a body set up under the Control of Drugs and Cosmetics Regulation 1984 and as such its responsibility, role and mandate are defined by law. DCA provides the general principles of safety, quality and efficacy that form the basis for the evaluation and eventual registration of products.

### **1.0 ROLE AND MANDATE OF THE DCA**

The DCA is empowered by law to:

- (i) review matters related to PRODUCT REGISTRATION
- (ii) consider recommendations proposed by Secretariat and
  - register any product subject to such conditions as it may impose
  - reject any application for the registration of any product
  - grant exemptions
  - issue such certification required by any country importing such a product
  - suspend or cancel registration of any product
  - make decisions related to REGULATORY POLICIES
- (iii) maintain a register of the products registered
- (iv) impose REQUIREMENTS for registration of products

### **2.0 MEMBERSHIP**

#### **I. Members:**

The DCA shall consist of the following members:

1. The Director-General of Health as chairman
2. The Senior Director of Pharmaceutical Services as alternate chairman
3. The Director of the National Pharmaceutical Regulatory Agency and

4. 8 other members to be appointed by the Minister. The members shall be the following person:

- A consultant physician in the public service;
- A pharmacist in the public service;
- 3 persons from any local universities with expertise in pharmaceutical sciences; and
- 2 fully registered medical practitioners;
- A veterinary practitioner in the public service.

**II. Alternate members:**

- An alternate member who shall be similarly qualified as the substantive member in respect of each member appointed under no. 4 may appointed by The Minister.
- An alternate member may attend meetings of the DCA or otherwise act for the substantive member when the substantive member is unable to act.
- An alternate member attending any meeting of DCA or acting for the substantive member shall be deemed for all purposes to be a member of the DCA.

**III. A secretary appointed by the Minister after consultation with the DCA.**

- The Secretary is a pharmacist in the public service.
- The Secretary shall not be a member of the DCA

**IV. Advisors**

- The DCA may appoint a person or persons as it may think necessary as advisors for the purpose of giving it advice when discharging any of its functions.

### 3.0 CURRENT MEMBERSHIP OF THE DCA

#### Ex-officio members:

YBhg. Datuk Dr. Muhammad Radzi bin Abu Hassan  
Director General of Health

YBrs. Puan Norhaliza binti A. Halim  
Senior Director of Pharmaceutical Services

YBrs. Puan Rosilawati binti Ahmad  
Director National Pharmaceutical Regulatory Agency (NPRA)

#### Secretary:

YBrs. Dr. Azuana binti Ramli  
Deputy Director, Centre of Product & Cosmetic Evaluation, NPRA

No.	Appointed Members	Appointed Alternate Members
1.	Dr. Mithra a/p C. Seganathirajah Hospital Kuala Lumpur, Kuala Lumpur	Dr. Zamri bin Mohamed Hospital Sultanah Nur Zahirah, Terengganu
2.	Puan Wan Noraimi binti Wan Ibrahim Pharmaceutical Services Programme, Ministry of Health	Puan Noraini binti Mohamad Pharmacy Department, Hospital Kuala Lumpur
3.	Dr. Nur Hidayah Kaz binti Abdul Aziz Universiti Sains Malaysia, Pulau Pinang.	Prof. Madya Dr. Balamurugan a/l Tangiisuran Universiti Sains Malaysia, Pulau Pinang.
4.	Prof. Dr. Hasniza binti Zaman Huri Universiti Malaya, Kuala Lumpur	Prof. Madya Dr. Baharudin bin Ibrahim Universiti Malaya, Kuala Lumpur
5.	Prof. Dr. Mohd bin Makmor Bakry Universiti Kebangsaan Malaysia, Kuala Lumpur.	Prof. Madya Dr. Norazrina binti Azmi Universiti Kebangsaan Malaysia, Kuala Lumpur.
6.	Dr. Nor Hayati binti Ali Hospital Selayang, Selangor	Dr. Choong Swee Hsia Hospital Pulau Pinang, Pulau Pinang
7.	Datuk Dr. Thirunavukarasu Rajoo Malaysian Medical Association	Dr. Sivanaesan a/l Letchumanan Malaysian Medical Association
8.	Dr. Rohaya binti Mohd. Ali Division of Veterinary Public Health Ministry of Agriculture & Food Industries	Dr. Alifah binti Ismail Division of Veterinary Public Health Ministry of Agriculture & Food Industries

#### **4.0 MEETINGS**

1. The Director-General of Health shall be the Chairman of the DCA and shall preside at all meetings of the DCA.
2. The Senior Director of Pharmaceutical Services shall be the alternate Chairman and shall preside at meetings of the DCA in the absence of the Chairman.
3. The chairman of meeting shall have an original vote and, in the event of an equality of votes, a second or casting vote.
4. Four members of the DCA including the chairman shall form a quorum.
5. The DCA shall meet at such times and places as the Chairman may determine. This includes the use of any virtual communication platform to hold the meeting when necessary.
6. The DCA may invite any person who is appointed as Advisor or any other person to attend any meeting of the DCA, but such person shall not have the right to vote at the meeting.
7. The DCA shall regulate its own procedure. No action or proceeding of the DCA shall be questioned on the ground:
  - (a) of the existence of any vacancy in the membership, or any defect in the constitution of the DCA, or
  - (b) of any omission, defect or irregularity in procedure not affecting the merits of the case; or
  - (c) of any tabling of paper(s) and/or product(s) that requires urgent decisions carried out via circulation among DCA members, where the decision is made when a quorum is formed.

8. Members of the DCA, the Secretary and advisors invited under sub regulation (6) of CDCR to attend any meeting of the DCA may be paid such allowances and other expenses as may be approved by the Government from time to time. Such allowances and expenses shall be payable out of the general revenues of the Government.

## **5.0 SECRETARIAT**

The National Pharmaceutical Regulatory Agency (NPRA) shall function as the secretariat and shall coordinate all meetings.