Annex J

Proposed Organization of the Dedicated Office on Drugs

Head

(+1) Personal Secretary I

Pharmacovigilance, Risk Communication and Quality Management Division (Principal Medical and Health Officer)

(+1) Personal Secretary II

Administration, Information Technology and Quality Management Unit

(+1) Chief Executive Officer,
(+3) Senior Pharmacists/
Senior Medical and Health Officers

1. Internal Administration Team
2. Internation Liaison & Training Team
3. Drug Safety Website and Information Technology Support Team
4. Quality Management Team

(+6) Pharmacists
(+1) Senior Information Officer
(+2) Information Officers
(+1) Scientific Officer
(+1) System Manager
1 System Analyst
2(+1) Information Technology Assistants
1 Senior Executive Officer
(+1) Executive Officer I
(+1) Executive Officer II
(+1) Personal Secretary II
Clerical support

Risk Analysis, Management and Communication Unit

2(+7) Senior Pharmacists/
Senior Medical and Health Officers

1. Pharmacovigilance Team
2. Risk Analysis, Management and Communication Team
3. Undesirable Medical Advertisements Team (Surveillance, Intelligence and Investigations Branch)

15(+20) Pharmacists
(+9) Medical Officers
(+2) Scientific Officers
(+1) Executive Officer II
(+2) Personal Secretaries II
Clerical support

Inspection and Licensing Division Chief Pharmacist 1

(+1) Personal Secretary II

Licensing and Compliance InspectionUnit

1(+4) Senior Pharmacists/
Senior Medical and Health Officers

1. Importer/exporter RegulatoryTeam
2. Wholesalers Regulatory Team (Poisons and Non-poisons Branch)
3. Retailers Regulatory Team (ASPs, LSPs and Non-poisons Branch)

6(+24) Pharmacists
(+1) Executive Officer II
(+2) Personal Secretaries II
Clerical support

PIC/S Unit

1(+3) Senior Pharmacists/
Senior Medical and Health Officers,
(+1) Senior Engineer

1. PIC/S Membership Team
2. Manufacturing Quality Assurance Team (Local, Mainland and Overseas Branch)

6(+12) Pharmacists
(+3) Medical Officers
(+8) Scientific Officers - Chemistry
(+4) Scientific Officers - Microbiology
(+2) Engineers
(+2) Veterinary Officers
(+2)Environmental Hygienists
(+1) Executive Officer II
(+2) Personal Secretaries II
Clerical support

Pharmaceuticals Registration and Business Development Division (Chief Pharmacist 2)

(+1) Personal Secretary II

Pharmaceuticals Registration and Import/Export Control Unit

2(+4) Senior Pharmacists/
Senior Medical and Health Officers

1. Pharmaceuticals Registration Team (Pre-market Assessment, Renewal and Change of registered particulars Branch)
2. Clinical Trials Team (Application Evaluation and Site Inspection Branch)
3. Import and Export Control Team (Licensing and Entry Point Control Branch)

10(+26) Pharmacists
(+1) Medical Officers
(+3) Scientific Officers
(+1) Executive Officer II
(+2) Personal Secretaries II
Clerical support

Clinic Service and Business Development Unit

1(+2) Senior Pharmacists/
Senior Medical and Health Officers

1. Clinic service Team
2. Procurement & Manufacturing Team
3. Drug Information Management System Team
4. Public Education and Training Team

4(+6) Pharmacists
(+1) Medical Officers
(+2) Scientific Officers
(+1) System Manager
(+1) System Analyst
(+6) Information Technology Assistants
(+1) Executive Officer II
(+1) Personal Secretary II
Clerical support

( ) Additional manpower