I) OBJECTIVES

1. To provide a broad training and in-depth experience at a level sufficient for trainees to acquire competence and professionalism required of a specialist in Clinical Pharmacology and Therapeutics, so as to be able:

   1.1. To provide a consultative and advisory service to general physicians and other specialists regarding drug therapy, particularly with respect to safe and cost-effective use of drugs, evidence-based therapeutics, adverse drug reactions, drug-drug interactions and therapeutic drug monitoring.

   1.2. To provide clinical toxicology services at local and regional levels, including poison treatment service for in-patients and out-patients, poison information service to health care professionals, consultative service for the management of poisoning and toxicovigilance.

   1.3. To provide an acute general medical service with responsibility for medical in-patients and input into specialist clinics that are relevant to Clinical Pharmacology and Therapeutics.

   1.4. To provide advice to local and regional hospitals and health authorities on drug- and clinical toxicology-related issues.

   1.5. To engage in diverse types of clinical activities that will contribute to new drug evaluation, clinical pharmacology, clinical toxicology, drug safety, pharmacovigilance, pharmacoepidemiology, pharmacoeconomics and pharmacogenetics.

   1.6. To lead a multidisciplinary team of health care professionals in promoting rational use of drugs and safe medication practices.

2. To develop skills, knowledge and competence in Clinical Pharmacology and Therapeutics at a specialist level.

3. To develop an interest in quality assurance, audits, cost-effectiveness and evidence-based medicine in relation to drug use and prescribing, with a view to the development and continued refinement of hospital formularies, drug policies, guidelines and shared care protocols.

4. To promote a commitment to continued medical education and to provide suitably
qualified teachers in Clinical Pharmacology and Therapeutics for undergraduates and postgraduates.

5. To develop an infrastructure for future commitment to clinical and laboratory research in Clinical Pharmacology and Therapeutics, with a view to promoting safe and cost-effective use of drugs and introducing and evaluating new drug therapy, poison prevention and control.

6. To acquire professional competence in training future trainees in Clinical Pharmacology and Therapeutics.

II) STRUCTURE

1. This period consists of three years of supervised and accredited training in Clinical Pharmacology and Therapeutics. The three-year training programme comprises two years of core training in Clinical Pharmacology and Therapeutics as described in paragraph 2 (with a minimum of 12 months of core training to be undertaken in training units that have been formally accredited by the College), plus one year of training in any of the following:

   1.1 The same specialty which may be accredited for a maximum of 12 months, AND/OR

   1.2 A broad-based specialty, defined as either Advanced Internal Medicine (AIM) or Geriatric Medicine, which may be accredited for a maximum of 12 months, AND/OR

   1.3 Overseas training in Clinical Pharmacology and Therapeutics, which may be accredited for a maximum of twelve months, with prior approval by the specialty board, AND/OR

   1.4 Research in Clinical Pharmacology and Therapeutics which may be accredited for a maximum of six months, with prior approval by the specialty board.

2. The core training in Clinical Pharmacology and Therapeutics includes a minimum of two years (cumulative) to be spent in a Clinical Pharmacology Service and Clinical Toxicology Service under the supervision of recognised trainer(s).

   2.1 The trainee should have primary responsibility for and adequate exposure to patient management and poison information and consultations within a Clinical Toxicology Services for a minimum of 12 months, including

      a) Resident emergency on-call duties, at least 4 times per month
b) Responsibility for patients with acute or chronic poisoning

c) Contribution to poison information service for hospitals and community doctors

3. To ensure the acquisition of a broad-based physician training for all Higher Physician Trainees undergoing Clinical Pharmacology and Therapeutics training, the College requires that all registered Higher Physician Trainees undergo dual training in a broad-based specialty, defined as either Advanced Internal Medicine (AIM) or Geriatric Medicine, together with training in Clinical Pharmacology and Therapeutics. Fellows who have been trained in Clinical Pharmacology and Therapeutics without a broad-based specialty will not be accepted as Trainer in any specialty in the future.

4. The structures of dual training programmes approved by the College include the following and Trainees must clearly indicate the programme chosen at the time of application to be registered as Higher Physician Trainee of the College:

4.1 Concurrent training: A minimum of four years of supervised training is required. The training programme comprises 24 months (cumulative) of core training in a broad-based specialty and 24 months (cumulative) of core training in Clinical Pharmacology and Therapeutics.

4.2 Sequential training: A minimum of five years of supervised training is required. The training programme comprises 36 months training in either Clinical Pharmacology and Therapeutics or the broad-based specialty followed by 24 months of core training in remaining specialty.

III) CONTENTS

1. Knowledge and practical skills:

1.1 Knowledge and understanding of the principles of basic and clinical pharmacology and toxicology.

1.2 The principles and specialised techniques essential to the assessment of drug pharmacokinetics and pharmacodynamics.

1.3 The principles and methods to promote rational and cost-effective use of drugs at all levels, e.g. developing and maintaining drug formularies and participating in drug and therapeutics committee.

1.4 The management, investigation and prevention of drug-related problems,
including adverse drug reactions, drug-drug, food-drug and herb-drug
interactions, therapeutic failure and drug non-compliance.

1.5 The key actions required to improve medication safety and the key components
of a safe medication-use system

1.6 The principles and applications of pharmacovigilance, pharmacoepidemiology,
pharmacogenetics, pharmacoeconomics and outcomes research.

1.7 The management, investigation and prevention of acute poisoning from drugs,
chemicals and natural toxins and other toxicological problems.

1.8 Drug and poison consultative and advisory service to health care professionals.

1.9 Laboratory methods of measurement of drugs, chemicals and their metabolites in
biological fluids and data interpretation for the purposes of therapeutic drug
monitoring, clinical toxicology, pharmacokinetic and other studies.

1.10 Analysis of bioavailability and pharmacokinetic data with a view to advising on
the choice of appropriate pharmaceutical preparations and drug dosage regimens,
and on problems encountered in special patient groups such as the elderly or
those with renal impairment.

1.11 Audits, quality assurance, cost-effectiveness, epidemiological studies and applied
statistics in Clinical Pharmacology and Clinical Toxicology.

1.12 Research methodology and evaluation in clinical trials, including design,
execution, data interpretation and analysis of adverse events.

1.13 Investigation skills required for pharmacological studies in accordance with
Good Clinical Practice.

1.14 The principles and role of pre-marketing studies of drugs and postmarketing
surveillance.

1.15 An understanding of the potential problems associated with the use of herbal
medicines, including toxicological problems and herb-drug interactions.

1.16 An understanding of the ethical and regulatory aspects of drug prescribing,
clinical trials and research.

2. **Attitudes**

2.1 The basic requirements are the same as Advanced Internal Medicine (AIM) and
the general attitudes required of a doctor regardless of specialty.
2.2 An impartial attitude in the interactions between the Clinical Pharmacologist and the pharmaceutical industry.

2.3 A good understanding of the role of Pharmacists both in hospital and in the community.

2.4 An appropriate attitude, demonstrating an awareness and understanding of the ethical issues in relation to the use of drugs in the management of patients and conduction of clinical trial.

IV) INSTITUTIONAL REQUIREMENTS

1. Sufficient number of general medical beds to admit patients of both genders and with a variety of medical disease, with consultations from a broad range of surgical disciplines, and where consultations in Clinical Pharmacology and Clinical Toxicology are called upon on a regular basis.

2. An acute hospital with medical subspecialties and multidisciplinary teams, where interspecialty and interdisciplinary liaison with clinical pharmacologists is important in patient care.

3. Organised ambulatory care, specialist outpatient follow-up clinics in Medicine and Clinical Pharmacology and Clinical Toxicology, and linking with extended care facilities for rehabilitation and chronic care.

4. An Intensive Care Unit where full cardiorespiratory support is provided for critically ill patients including those suffering from drug overdose.

5. A sufficient number of fully trained staff with specialist accreditation and trainer status in Clinical Pharmacology and Therapeutics, to provide a minimum trainer to trainee ratio of 1:2 at any one time. The trainee should have the opportunity of experiencing all aspects of patient management in Clinical Pharmacology and Clinical Toxicology, including ward rounds, emergency calls and consultations and out-patient services.

6. General laboratory and diagnostic facilities including chemical pathology, haematology, microbiology, histopathology, diagnostic radiology, and access to laboratory facilities for assays of plasma drug concentrations and toxicological analysis.

7. Regular medical audit procedures and quality assurance programmes.

8. A structured continuing educational programme including attendance and participation in seminars, journal clubs and grand rounds in General Internal Medicine, Clinical Pharmacology and Clinical Toxicology.

9. Adequate educational facilities including access to medical libraries with computerized
search systems and specialised databases for information on drugs and poisons.