Pharmaceutical Medicine as a Specialised Discipline of Medicine

Gerfried K.H. Nell
Director, NPC Nell Pharma Connect
Austria
Pharmaceutical Medicine...

.....is a medical scientific discipline concerned with the discovery, development, evaluation, registration, monitoring and medical aspects of marketing of medicines for the benefit of patients and the public health.

(IFAPP, www.ifapp.org/pub/)
The Medical Discipline of Pharmaceutical Medicine

• Literature and science base
• Syllabus / curricula
• Evidence Base
• Own research methodologies
• Academic foundation
• Career structure
• Standards
• Curricula / training
• Examination system
• Accreditation of practitioners
• History
Does pharmaceutical medicine really exist?

- Is pharmaceutical medicine a genuine and autonomous *corpus* of medical and scientific knowledge?
- Or is it a mixture of components borrowed from various disciplines?
- Or a set of techniques and procedures used by physicians in pharmaceutical companies?

(Jean Marie Boeynaems, Brussels, Belgium)
Components of pharmaceutical medicine

**Intrinsic**
- Clinical research
- Pharmacoepidemiology
- Pharmacoeconomics
- Regulatory affairs
- Medical information

**Extrinsic**
- Pharmacology
- Pharmacokinetics
- Toxicology
- Galenic pharmacy
- Statistics
- Marketing
Syllabus for the Diploma in Pharmaceutical Medicine

**Intrinsic**
- Medicines regulation
- Clinical development
- Drug safety
- Healthcare Marketplace
- Role of the Medical Department

**Extrinsic**
- Clinical Pharmacology
- Statistics and Data Management
- Discovery of New Medicines
- Therapeutics
# The Textbook of Pharmaceutical Medicine

## Intrinsic

- **Part I**: Research and development
  - Exploratory development
  - Clinical trials and Good Clinical Practice
- **Part II**: Medical department issues
- **Part III**: Regulatory aspects
- **Part IV**: Pharmacoeconomic issues

## Exogenous

- **Part I**: Research and development
  - Discovery of new medicines
  - Pharmaceutical development
  - Toxicity testing
  - Clinical pharmacokinetics
  - Medical statistics
Where does Pharmaceutical Medicine sit?
Some Landmarks in Development of the Discipline of Pharmaceutical Medicine

- 1957 – AMAPI [later BrAPP] (UK) – first professional association
- 1972 – IFAPP formed – today, 30 national Member Associations
- 1976 – Diploma in Pharmaceutical Medicine RCPs UK
- 1978 – Postgraduate Course in Pharmaceutical Medicine, University of Cardiff
- 1987 – Society of Pharmaceutical Medicine
- 1989 – Faculty of Pharmaceutical Medicine
- 1992 – MSc in Pharmaceutical Medicine, University of Surrey
- 1993 – AAPP inaugurated in USA
- 1999 – Recognition of specialty - Mexico and Switzerland
- 2002 – Recognition of specialty - UK
- 2002 – IFAPP Council for Education in PM formed (CEPM)
- 2003 – Higher Medical Training introduced in UK
- 2005 – Recognition of specialty - Ireland
Evidence base
Clinical pharmacology: PK & PD. Procedures, processes, quality.

Own research methodology
Clinical trials, statistical methods, epidemiology, drug safety evaluation, pharmacoeconomic evaluation

Literature and science base
Journals devoted to pharmaceutical medicine, clinical pharmacology, clinical research, GCP, pharmacovigilance

Academic foundation
University Surrey UK; Faculty of Pharmaceutical Medicine, UK; College of Pharmaceutical Medicine, Belgium; France; Germany; Mexico; Spain; Serbia; Sweden; Switzerland

Standards
Knowledge & competency based, Continuing Professional Development, re-certification, ethics, codes of conduct

Examination system
Diplomas (local associations), Higher Medical Training, MSc degrees, PhD/MD theses
Syllabus in Pharmaceutical Medicine

• Medicines Regulation
• Clinical Pharmacology
• Statistics and Data Management
• Clinical Development
• Healthcare Marketplace
• Drug Safety
• Role of the Medical Department
• Discovery of New Medicines
• Therapeutics
Ethics and Pharmaceutical Medicine

- keynote document, published IJCP 2006
  - Ethical issues relevant to pharmaceutical physicians
    - Clinical research
    - Communications
    - Provision of Patient Services
Code of Conduct for Pharmaceutical Physicians

• Duties & responsibilities of pharmaceutical physicians – issued 2004
  – Good pharmaceutical medical practice
    • Providing a Good Standard of Practice
    • Maintaining Good Medical Practice
    • Teaching, training, appraising, assessing
    • Relationships with patients and research subjects
    • Good communication
    • Dealing with problems in professional practice
    • Working with Colleagues
    • Probity
    • Health
Physician Roles and the Pharmaceutical Industry

- Clinical Pharmacologist
- Clinical Research Physician
- Medical Adviser, Medical Affairs
- Medical Assessor, DRA
- Consultant
- Physician Scientist

- Target identification
- Early studies in humans
- Protocol design & review
- Regulatory Affairs
- Pharmacovigilance & risk management
- Interface with key clinicians
- Interface with senior management
- Commercial issues
- Legal accountabilities
Pharmaceutical Medicine: a continuously developing discipline

• New Science: Genomic medicine - Gene therapy - Stem cell therapy - Tissue engineering

• New Regulations: EU CT Directive - EU GCP Directive - New regulatory paths - Paediatric studies - Orphan drugs - Academic medicine now works under the same regulations

• New Standards: Need for training recognised everywhere - CCST in Pharmaceutical Medicine established in UK 2002 - Republic of Ireland has now recognised speciality of Pharmaceutical Medicine
Royal College of Physicians
Founded in 1518
Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK
(founded 1989)

To advance the science and practice of pharmaceutical medicine by working to develop and maintain competency, ethics and integrity and the highest professional standards in the specialty for the benefit of the public.
The Faculty – Role

- Examinations & qualifications in pharmaceutical medicine
- Higher Medical Training programme (CCT-UK)
- Promotion and protection of professional standards and practices in pharmaceutical medicine
- Specialty recognition & listing for pharmaceutical medicine
- Continuing education & professional development
- A focus for all practitioners of pharmaceutical medicine, regardless of membership status
Specialist Training in Medicine

- European Medical Directive 93/16/EEC
- Free movement of doctors between member states, mutual recognition of formal qualifications, grant of certificate of completion of training (CCT)
- Recognised, structured training programme which is supervised, monitored, assessed, flexible, deliverable
- Defined competitive entry criteria, minimum period of specialist training, defined exit criteria
- To accredit the competency of specialists, capable of independent (unsupervised) practice
- Maintained by Continuing Professional Development (CPD)
Specialist training in pharmaceutical medicine in UK

- Registered with General Medical Council
- Post in pharmaceutical medicine
- Clinical training – 4 years post-qualification (from 2007)
- Higher Medical Training – 4 years workplace-centred programme
- Specialty knowledge base (Diploma in Pharmaceutical Medicine)
- Competency-base in 6 areas of practice:
  - Medicines regulation
  - Clinical pharmacology
  - Statistics & data management
  - Clinical development
  - Healthcare marketplace
  - Drug safety surveillance

  - plus Generic module
    - Interpersonal & management skills;
    - Good Pharmaceutical Medical Practice
HMT in UK 2003-06

- 280 pharmaceutical physicians have enrolled or are in the process of enrolling into HMT
- 50 Certificates of Completion of Training have been awarded to date
- 55 companies and organisations are participating
- 70% of programme has been completed in work
- Aim for 80% of physicians joining industry to participate

First CCTs presented May 2005
MISSION

To foster education and training in Pharmaceutical Medicine

CEPM established by IFAPP 2002
CEPM: 5 Objectives

• To assist national Member Associations of IFAPP to establish appropriate educational and training programmes in PM, and provide a global perspective of needs, developments and opportunities in this discipline.

• To support the development of continuing medical education and continuing professional development (CME/CPD) in PM.

• To contribute to the international harmonisation of educational programmes in PM.

• To aid in the mutual recognition of equivalent educational qualifications and CME/CPD requirements between countries.

• To promote, through IFAPP, the recognition of PM as a distinct medical discipline grounded in a body of knowledge, skills and attitudes acquired through education, training and practice.
Progress in Courses/Diplomas

- Barcelona (Spain) – CEPM approved
- Basel (Switzerland) – CEPM approved *
- Belgrade (Serbia) – CEPM approved
- Brussels (Belgium) – CEPM approved *
- Cardiff (UK) – CEPM approved
- Dublin (Ireland, Trinity College) – CEPM approved
- Dublin (Ireland., Hibernia College)
- Essen (Germany)
- Lyon (France)
- Madrid (Spain) – CEPM approved
- Mexico City (Mexico) – CEPM approved
- Stockholm (Sweden) – CEPM approved
- Surrey (UK) – CEPM approved
- Sydney (Australia)

* Diploma recognised by Faculty
Status of Pharmaceutical Medicine as a specialised discipline of medicine

- PM a listed medical specialty in Switzerland, Mexico, UK and Ireland

- Official recognition as a medical specialty underlined by accredited education & training of specialists, establishment and maintenance of standards of practice & professionalism in the competency, care and conduct applied to their work

- PM has growing public recognition and accountability
Conclusion

• Pharmaceutical Medicine, the discipline of pharmaceutical and regulatory physicians, has a discrete programme of education and training, which is able to meet international standards of work and medical professionalism, for example in Europe

• Establishing courses with accredited diplomas is a slow but persistent process

• Establishing Pharmaceutical Medicine as a listed medical specialty remains a process beset with significant hurdles and challenges in most countries

• All professional associations of pharmaceutical physicians espouse development of education & training as their top objective

• There is a link between the education & training and specialty recognition for Pharmaceutical Medicine which must be fostered, reinforced and communicated
For further reading….

- http://www.fpm.org.uk/
- http://www.sgpm.ch/
- http://www.ifapp.org/