Understanding Medical Regulation

A guide to good practice

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Preface

Everyone has the right to medical care when they are ill (UN 1948) and it seems reasonable to expect that care to be provided by a good doctor. This simple assumption obscures the complexity of social and institutional mechanisms that must be in place before such a basic human right can be fulfilled. A number of questions arise:

- What is a good doctor?
- What is the necessary training and education for a person to become a good doctor?
- What is the necessary training for a doctor to become a specialist?
- Does a doctor once qualified and licensed to practice, always and automatically remain a good doctor without any further education or training?
- How does the public identify a good doctor?
- What happens when a doctor is not able to perform as a good doctor either because their knowledge and skills fall below accepted standards or because they themselves are ill?
- How should the public be protected when a doctor has committed an offence, which is not compatible with the standards of behaviour the public would normally expect of a doctor?

These questions converge on single issue: how to regulate the medical profession? Answering this question involves addressing the tension between the need for control to ensure adequate public protection and the need to allow doctors freedom from bureaucracy so that they can practise the art and science of sound medicine.

The aims of this guide are i) to promote understanding and stimulate discussion of the core functions of regulation of the medical profession ii) to present key issues in medical regulation iii) to bring together references and links to key source materials and relevant organisations in this field.

The guide does not prescribe any particular model for organising the various functions of medical regulation since each society has its own health system contexts and existing organisational structures. Doctors are actors within these complex interconnected systems and any review of medical professional regulation must bear in mind the wider regulatory frameworks within the health system in question.

Users of this guide

This guide is aimed at professionals who are interested in the development of high standards of medical care, particularly those working in middle-income countries where the health system has recently undergone, or is currently in the process of reform. The guide is primarily intended for a European context, where health policy makers are considering the implications for medical training of new or future membership of the European Union.

The guide is intended to be a practical guide, which presents the essential components of medical regulatory systems. It does **not** provide an in-depth analysis or critique of the pros and cons of different regulatory models.

The language is intended to be accessible to people whose first language may not be English and wherever possible technical terms are avoided. Definitions of the terms commonly found in the medical regulation literature are provided in the glossary together with a list of acronyms.

Layout of the guide

This guide consists of an introduction and eight chapters. The introduction gives an overview of the key issues that need to be considered in medical regulation and shows how these issues are both interconnected and in constant tension. Each subsequent chapter then describes an aspect of medical regulation, giving summary key points relevant to that issue at the end of the chapter. All the key points are collated in an appendix at the end of the document. The chapters are arranged into two sections: section one consists of four chapters addressing key functions and processes and section two comprises of four chapters addressing issues in the organisation of medical regulation. Finally a checklist of regulatory functions is given in the appendix. This checklist is aimed to serve as a focus for discussion for policy makers who are in the process of reviewing their own regulatory system.

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Acronyms

CCST   Certificate of Completion of Specialist Training
CPD   Continuing Professional Development
CRHP   Council for the Regulation of Healthcare Professionals (UK)
EBM   Evidence Based Medicine
GMC   General Medical Council (UK)
IAMRA   International Association of Medical Regulatory Authorities
PMQ   Primary Medical Qualification
PRHO   Pre-registration House Officer (UK): "The PRHO year provides new medical
        graduates an opportunity to put into practise as provisionally registered
        doctors the knowledge, skills and behaviour developed during undergraduate
        medicine. This period also allows new doctors to demonstrate that they are fit
        for full registration" – GMC, Quality assuring medical education,
        London July 2004.
UME   Undergraduate Medical Education
WFME   World Federation for Medical Education

Glossary

Acquis Communautaire: The entire body of legislation of the European Communities and Union, of which a significant body relates to justice and home affairs. Applicant countries must accept the *acquis* before they can join the EU.

Competent authority: A body or institution that has the authority to enforce Commission legislation.

Competency: *"Refers to the ability to apply knowledge, skills, and attitude by adding judgement. It refers to the potential. It could be referred to as 'can do'".* College of Physicians and Surgeons of British Columbia, Canada.

Performance: *"Refers to what is actually done. It could be referred to as 'does do'. The quality of the performance is a measure of the application of the competence. Performance could be thought of as being competence minus distraction".* College of Physicians and Surgeons of British Columbia, Canada.

Professional misconduct and poor performance: In general terms, poor performance may reflect a pattern of behaviour in which standards fall consistently below what is acceptable, whereas misconduct is more likely to refer to a one-off incident. Nevertheless the distinction may not always be clear because a pattern of poor performance may amount to misconduct if there are serious or potentially serious adverse outcomes for patients.

Self-regulation: *"Self regulation is the means by which members of a profession, trade or commercial activity are bound by a mutually agreed set of rules which govern their relationship with the citizen, client or customer. Such rules may be accepted voluntarily or may be compulsory. They will normally include a procedure for resolving complaints and for the application of sanctions against those who infringe the rules".* BRTF Self-regulation interim report, October 1999. www.brtf.gov.uk accessed 8/11/04.

Certification and recertification: *Certification* is the process of being *certified* or *qualified* as a doctor or a specialist. The word *qualified* may be used when talking about the *Primary Medical Qualification* (PMQ) and *certification* is used more commonly in the context of the specialist recognition. The phrase primary medical qualification refers to the basic certificate that a person has satisfactorily completed basic medical education in which the *"core of the medical curriculum consists of the fundamental theory and practice of medicine, specifically basic biomedical, behavioural and social sciences, general clinical skills, clinical decision skills, communication abilities and medical ethics".* WFME 2003.

Recertification is usually used to refer to the process (often following some continuing medical education) of re-establishing that someone has maintained a sufficient level of *knowledge and/or competency and/or performance* to continue to be recognised as a doctor or specialist. *Recertification* is sometimes used interchangeably with *revalidation* (see below).

Registration and re-registration: *Registration* is the mechanical process of placing a doctor's name and other details on the medical register. It involves several quality checks such as verification of identity, credentials and good standing. *Re-registration* is the process of replacing the person's details on the register after a period of absence (either voluntary or enforced). It may also be used to refer to a process of reconfirming registration after a certain period of time.

Licensing and re-licensing: *Licensing* is closely tied in with registering and in some jurisdictions it is the same thing. Some jurisdictions make a distinction on the basis of completion of continuing medical education requirements and provision of proof of continued adequate *competency* and *performance*. A doctor may have his or her details present on the medical register (i.e. be registered) but in order to gain a license to practice she or he must present this evidence. A license to practice may be granted for a limited period of time only, in which case it has to be periodically renewed: *re-licensing*.

Accreditation and re-accreditation: *Accreditation* is the term used to approve or certify the completion of a period of in-service training leading to achievement of agreed standards of *competency*. It can also be used in the context of the approval of courses or curricula. *Re-accreditation* refers to approval that an adequate refresher course has been undertaken and that levels of *competency* remain appropriate, it can be used as a condition for *re-licensing*.

Revalidation: *Revalidation* is the term used to refer to a process by which a doctor establishes that she or he remains up to date in medicine and is also continuing to participate in and contribute to quality assured medical practice (whether research, clinical or public health). *Revalidation* focuses on *performance* rather than *competency* and may be used as a condition for *re-licensing*.

Fitness to practice: Fitness to practise has different meanings in different jurisdictions. It may refer specifically to a doctor's health status for medical practice, for example, a regulator may regard an individual as unfit to practise because of impaired mental or physical health. The term may also be used to refer more broadly (e.g. the UK), to an individual's suitability for practice based on considerations of professional conduct, performance and health.

Acknowledgements

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BOX 1: Diagrammatic overview of medical regulation

Medical Register

S T A N D A R D S	
Who enters?	Registration and licensing
Who stays?	Recertification and revalidation
Who is removed?	Disciplinary procedures

An HLSP consulting toolkit

Introduction

Setting the context – key
issues in medical regulation

Setting the context – key issues in medical regulation

"The purpose of medical regulation is to ensure public confidence in the medical profession by endeavouring to guarantee that clinical care is of high quality"

Brian Salter 2000.

Key players
The public
Doctors take responsibility for people's lives and look after them before and when they are being born, when they are ill and when they are dying. It is therefore not surprising that people want to be able to trust their doctors.

The public has great and ever-growing expectations of the medical profession and increasingly they are insisting that these expectations should be met (Irvine 99). They want to be able to feel that their doctor:

- Is up to date with knowledge and best practice in medicine
- Is able and willing to communicate with them, to explain and to advise as appropriate, to help them make decisions on their own health care or to make the decisions for them if they prefer
- Will keep their secrets

Medical regulation concerns the development and maintenance of *public trust:*
"In sum, we want doctors to be happy and healthy, caring and competent, and good travel companions for people through the journey we call life". Rizo et al 2002.

The profession
Doctors collectively form a professional group. The term 'profession' has been defined in many different ways but in general a profession is:
"an occupation that is characterised by a strong commitment to the well-being of others, high moral standards, mastery of a body of knowledge and skills and a high level of autonomy; and the collectivity of individuals who practise that occupation". Canadian Medical Association.

Professional values
Members of the medical profession share a set of values described in a code of ethical conduct, which include compassion, dedication, respect for persons, probity and justice (see chapter one). These values are held by members of the profession individually and shared by the profession as a collective. Members of a profession are expected to behave with professionalism:

"Professionalism in medicine requires the physician to serve the interests of the patient above his or her self-interest. Professionalism aspires to altruism, accountability, excellence, duty, service, honor, integrity and respect for others". American Board of Internal Medicine, 1998.

Professionalism in medicine is currently being challenged both from inside and outside the profession. Whether these challenges (which include commercialisation, consumerism, bureacratisation and industrialisation) are seen as positive or negative is largely a matter of ideology. There is also an argument that as professional values become eroded, the effectiveness of internal or *self-regulation* is reduced and the need for external rules and regulation increases (see below external versus internal regulation).

Professional power
A profession has control of a particular body of knowledge that the public needs. Members of the profession control access to that knowledge. It is this control of medical knowledge, which is the basis of the power of the medical profession (Salter 1999). The implication of this control of medical knowledge is that since only members of the profession hold and control that knowledge, only they can judge whether another member of the professional group has used or is using that knowledge appropriately. This is the principle behind self-regulation.

Professional responsibilities
Membership of a profession confers rights and privileges of practice and status but also brings with it responsibilities and duties to use that knowledge ethically and responsibly for the public good. Traditionally medical ethics were founded on the Hippocratic Oath and though some argue that the ethics of Hippocrates are no longer applicable to modern medicine (Loefler 2002), others argue that these nevertheless still form the foundation of medical professional values (Roddy 2002).

Governance
"The governance of medicine, that is, the ways in which the profession is held accountable for its actions, is by no means synonymous with self-regulation". Salter 1999.

Although there are issues at the heart of the practice of medicine that only another professional with the same experience and training can judge on, doctors nevertheless are actors within a much wider organisational system – the health care system in which they work. Every health care system has its own specific *regulatory environment* which in turn depends on the wider societal and political system of which it forms a part (Groenewegen 2002). In addition to regulatory mechanisms in the health care system, regulation of the medical profession may also be dependent on the system of regulating further education in any given jurisdiction. In order for medical regulation to be effective and efficient, its regulatory mechanisms must complement the regulatory controls present in the wider health care and education systems.

Tension between the players

The extent to which any one of the players – public, profession or state – dominate within the regulatory environment depends on the power relations and tensions at play in any particular jurisdiction (Salter 1999). In section two we outline how different institutional arrangements may be developed in different jurisdictions to regulate the medical profession. The relationships and ownership of these institutions reflect the balance of power between government, the profession and the public.

Regulatory functions

Regulation involves three pillars or regulatory functions:
1)   Setting standards
2)   Monitoring activity against those standards
3)   Intervening to ensure that standards are maintained and where they are not, to apply sanctions

When applied to medical regulation these steps involve:
1)   Setting standards for:
   • Education
   • Ethical behaviour
   • Competency
   • Performance
   • Contractual behaviour

2)   Monitoring and evaluation activities include:
   • Examination and assessment
   • Peer review
   • Clinical audit
   • Management appraisal
   • Investigation of misconduct/poor performance

3) Interventions
- Registering, licensing, certification, validation
- Re-registering, re-licensing, recertification, re-validation
- Sanction decisions and application

Regulatory processes

Although these distinctions between standards, monitoring and interventions are conceptually tidy, the reality of modern medical regulation is that the mechanisms required to deliver these three key functions are becoming increasingly complex. As a result it is frequently difficult to separate standard setting from monitoring activities, or monitoring activities from intervention activities. It can therefore be more meaningful to talk about *regulatory processes*, each of which on the one hand *contribute* to the three basic regulatory functions of standard setting, monitoring and intervention, and yet on the other also *contains* the functions of standard setting, monitoring and intervention.

Regulatory processes:
- Education
- Registration and licensing (including re-certification and revalidation)
- Disciplinary procedures

Complexity of medical regulation

The lack of a clear conceptual demarcation between the three *regulatory functions* of medical regulation (standard setting, assessment and intervention) and the *regulatory processes* has contributed to a complex situation characterised by two features:

1) In most modern states, the medical regulatory system has grown up incrementally, adjusting and evolving in line with trends and forces in wider society. Where in the past a single regulatory body was able to encompass all the functions and processes, this is increasingly impossible as more players come into the regulatory picture. As a consequence there may be overlap and confusion *within the system*, resulting from power struggles between different organisations and interest groups. This can lead to a) unclear lines of *accountability* and b) regulatory processes that appear (and often are) obscure, complicated and impenetrable, rather than transparent and accessible.

2) Because of the incremental development of regulatory systems and because of differences in the balance of power between state, profession and public, the system in every jurisdiction is slightly, if not radically different. There are not only variations between systems in the way in which the regulatory functions are

undertaken and by whom, but also variations in the use of the terminology of regulation (not withstanding *actual* language differences). A bewildering set of terms including: registering (re-registering), licensing (re-licensing), accreditation (re-accreditation), certification (re-certification) and validation (re-validation) are used by different bodies, sometimes to refer to the same process and at other times to distinct processes. These terms are defined in the glossary according to the meaning with which we use them in this guide and while we aim for internal consistency and general application, we do not make any claim that these definitions will always apply in other settings. Differences between jurisdictions in the devolvement of functions and processes, makes comparison *between regulatory systems* complicated and can thwart efforts to seek international harmonisation and promote professional mobility.

External versus internal controls

" Regulation, in whatever form, can never substitute for a doctor's personal professionalism". Donald Irvine, former president UK GMC (Irvine 1999).

Because the standards at the heart of medical ethics are human *values* that are intrinsically subjective and unmeasurable, they involve *value judgements*. Traditionally it was felt that such judgements could and should only be made by the profession itself, but increasingly this assumption is being challenged as the public becomes more aware, more motivated and more capable (through increased knowledge) of being involved.

Regardless of who defines and monitors these professional standards, there remains an intangible element in the regulation of medicine which hinges on an individual doctor's own *personal* sense of integrity and ethics. This intangible ethic – or 'internal morality' (Paul 2000) creates a force for hidden control and regulation that is very difficult to identify or evaluate and impossible to quantify. This sense of professionalism forms part of the socialisation process which occurs in undergraduate medical education – the so-called 'hidden curriculum' (Lempp 2004). It can have both positive and negative sides – positive being the sense of responsibility and ethics of what a doctor 'should' do and negative being the arrogance and patronising behaviour that charactises the belief that doctors somehow occupy a superior position because of their knowledge and skills.

It has been argued that these hidden values and controls usually have a strong and predominantly positive regulatory effect provided that the profession is given the independence and trusted to behave well (Paul 2000).

"Complex regulations can disempower those enforced to observe them. If they accept they cannot be trusted there is a risk they will become less trustworthy and obey the letter of the law only".

Attempts to improve regulation (often following a high profile scandal) may become disproportionate, involving heavy handed external regulatory procedures that depend on complex organisational structures and rules at the expense of light handed regulation that depends on internal morality systems and the personal interpretation of professional ethics.

Forces for change in medical regulation

Regulation of the medical profession takes place within a regulatory environment in constant flux and in which there are several forces at play (Southgate 1998). None of these forces is fixed. They include:

- Increasing *patient demand and expectation* and an increasing culture of litigation. This is contradicted simultaneously by a persistent tendency that people want to (and indeed probably largely still do – (Chantler 2002)), trust their doctors – because if they can't trust their doctors, who else can they trust in an uncertain world?
- Increasing *public knowledge* reducing the 'control' of the profession over the body of knowledge and therefore its 'power'.
- Increasing medical knowledge – the growth of *Evidence Based Medicine* (EBM) – bringing on the one hand knowledge about what works, but on the other hand showing more acutely the limits of medical knowledge.
- Disillusionment with conventional biomedicine with consequent increased demand for other 'alternative' and/or complementary types of treatment over which doctors as a group have little control or knowledge. This coupled with increased recognition of the roles of other conventional health professionals (nurses, therapists, psychologists etc) has led to the need for increased *team work* and sharing of bodies of knowledge, with a consequent reduction of medical supremacy.
- Needs for increased *cost-effectiveness* – increased need for management controls over inputs, outputs and resources. This need is in constant tension because of the reality that there is still little sound information on which to appropriately assess and compare clinical outcomes.
- Changes in the way health care is organised and financed, may lead to changes in the way governments influence the regulatory environment. Trends away from public funding and centrally planned care towards more *mixed models of financing care* means that more regulatory controls on the health care system may need to be imposed by governments so that they can ensure their objectives are met (Groenewegen 2002).

These forces for change can have unpredictable effects on the regulatory system and create a need for changes and reforms to traditional models. As changes occur within the system this can lead to increased complexity and the need for enhanced systems of governance.

Setting the context – key points

1 Medical regulation involves relationships between the public, the medical profession and government. These relationships are in constant tension.

2 Regulation of doctors should be seen against the backdrop of regulation of the wider health care and medical education systems in which the profession is embedded.

3 Regulation involves setting standards, monitoring against those standards and taking a course of action (intervention) dependent on the outcome of that monitoring. Regulatory processes include standard setting, education, registration and licensing, and disciplinary procedures.

4 Medical regulation is very complex and where historically one regulatory body could undertake everything there are now several players in the regulatory landscape.

5 The more players there are, the greater is the potential for duplication of activities between different organisations, nationally, regionally and locally. This can cause confusion, obscure lines of accountability and render the system inefficient.

6 Differences between regulatory systems in different jurisdictions can make international comparisons difficult.

7 Regulation can be external or internal. External regulation involves setting explicit standards, monitoring activities and imposing interventions. Internal regulation is based on individual interpretation of a set of values derived from professional ethics. If external regulation is too heavy-handed it may jeopardise the effectiveness of personal professionalism as a regulatory tool.

8 The medical regulatory environment is in constant flux. Forces for change include: increasing public expectations and knowledge, the growth of EBM, challenges to conventional (occidental) biomedicine, pressures for resource effectiveness and changes in the way the health care system is planned and financed.

Section one

The functions and processes
of medical regulation

→

Chapter one

Standards

Standards

A good doctor?

The quotation above from the editor of one of the world's leading medical journals shows that defining what makes a good doctor is probably impossible! Nevertheless if the public are to be protected from the incompetent and unscrupulous, we need some standards by which we can judge whether practice is acceptable or not, so that if it is not acceptable remedial action can be taken.

Standards are the cornerstone of regulation (box 1). Without standards against which to measure activity there can be no meaningful regulation and anybody, whether adequately qualified or not, could practice medicine without the need to be accountable for their actions. Medical regulation is the process by which the medical profession and its members are made publicly accountable for their actions. An effective system of regulation is necessary to safeguard the public against incompetent, unsafe or unethical medical practice and to encourage and support good practice amongst medical practitioners.

Ethical codes

(deontological code, "good medical practice")

Since the time of Hippocrates the medical profession has attempted to define professional values by developing a code of ethics intended to govern professional behaviour, attitudes and relationships. The dynamics between the medical profession and society, and between doctors and patients are constantly evolving and codes of medical ethics therefore need to be updated from time to time to reflect these changes (Fineschi 1997).

Codes of ethics (sometimes called 'deontological codes'), vary around the world and are by their very nature embedded in the prevailing cultural and religious values of the jurisdiction to which they belong. Codes also vary in whether they concentrate on promoting positive behaviours or conversely, outline behaviours that are deemed to be unacceptable. For instance until 1995, the UK GMC's approach was more one of identifying unacceptable behaviours and wrong-doing, as outlined in its publication: *Professional Conduct and Discipline: Fitness to Practice*. This was however revised in the 1990s with the publication of *Good Medical Practice* (GMC 2001) which shifted the emphasis towards describing positive behaviours and encouraging improvement through guidance.

Codes of medical ethics invariably run to several pages if not a large book. Some examples/extracts from codes of medical ethics are shown in boxes 2 and 3.

Issues typically addressed by a code of medical ethics include:
- *Behaviour of physician towards patients:* confidentiality, informed consent, appropriate behaviour and relationships, discrimination, accessibility, communication and patient rights.
- *Behaviour of physician towards colleagues:* communicating, referring, delegating, covering absence, fair treatment and respect.
- *Clinical practice issues:* this may vary between a general statement about negligent practice to a delineation of exactly what might be considered negligence – defined in more or less detail depending on the body concerned.
- *Physician behaviour as a member of civil society:* probity, conflicts of interest, role in research, commercial interests, exploitation of position and information for personal gain, infringements of common law.
- *Physician responsibility for his/her own health* and repercussions on patients, colleagues and public.

Although it is recognised that codes of ethics are very general and therefore difficult to enforce, they nevertheless have a very important value in setting general precepts of what is expected.

BOX 2: Spain – Extract from the Medical Ethics and Deontological code 1999, General Council of the College of Physicians.

Definición y ámbito de aplicación
Definition and field of application

Art. 1.

La Deontología médica es el conjunto de principios y reglas éticas que han de inspirar y guiar la conducta profesional del médico.
Medical deontology is the combination of principles and ethical rules which must inspire and guide a doctor's professional conduct.

Art. 2.

Los deberes que impone este código, en tanto que sancionados por una Entidad de Derecho Público, obligan a todos los médicos en el ejercio de su profesión, cualquiera que sea la modalidad en que la practiquen.
The duties imposed by this code, are sanctioned by an Official Public Law body and apply to all doctors in the exercise of their profession, whatever speciality they practice.

El incumplimiento de alguna de las normas de este Código supone incurrir en falta disciplinaria tipificada en los Estatutos Generales de la Organización Médica Colegial, cuya corrección se hará a través del procedimiento normativo en ellos establecido.
Failure to comply with any of the rules of this code will be regarded as a breach of discipline as set out in the General Statutes of the Organisation of Medical Colleges, and will require corrective action in accordance with the procedures established in those statutes.

Art. 3.

La Organización Médica Colegial asume como uno de sus objetivos primordiales la promoción y desarrollo de la Deontología profesional. Dedicará atención preferente a difundir los preceptos de este Código y se obliga a velar por su cumplimento.
The Organisation of Medical Colleges assumes as one of its primary objectives the promotion and development of professional Deontology.

It will pay special attention to promoting the precepts of this code and will undertake to ensure they are fulfilled.

CAPITULO II Principios generales
Chapter II General principles

Art. 4.

La profesión médica está al servicio del hombre y de la sociedad. En consecuencia, respetar la vida humana, la dignidad de la persona y el cuidado de la salud del individuo y de la comunidad, son los deberes primordiales del médico.
The medical profession exists to serve humankind and society. The primary duties of a doctor are therefore to respect human life, the dignity of the person and the care of both the individual's and the community's health.

BOX 3: Extract from Good Medical Practice – UK

UK

The duties of a doctor registered with the General Medical Council:

Patients must be able to trust doctors with their lives and well-being.
To justify that trust, we as a profession have a duty to maintain a good standard of practice and care and to show respect for human life. In particular as a doctor you must:

- *Make the care of your patient your first concern*
- *Treat every patient politely and considerately*
- *Respect patients' dignity and privacy*
- *Listen to patients and respect their views*
- *Give patients information in a way they can understand*
- *Respect the rights of patients to be fully involved in decisions about their care*
- *Keep your professional knowledge and skills up to date*
- *Recognise the limits of your professional competence*
- *Be honest and trustworthy*
- *Respect and protect confidential information*
- *Make sure that your personal beliefs do not prejudice your patients' care*
- *Act quickly to protect patients from risk if you have good reason to believe that you or a colleague may not be fit to practise*
- *Avoid abusing your position as a doctor*
- *Work with colleagues in the ways that best serve patients' interests*

In all these matters you must never discriminate unfairly against your patients or colleagues. And you must always be prepared to justify your actions to them.

Good Medical Practice. General Medical Council, London, UK September 2001.

Whose responsibility is it to develop a code of medical ethics?
The decision as to who is responsible for developing a code of medical ethics depends on the relationships between the profession, public and the government in the jurisdiction in question. In most Western European jurisdictions the responsibility is led predominantly by the medical profession, in consultation with the wider public. The extent of public consultation varies considerably from jurisdiction to jurisdiction, but there is an increasing trend towards more active public consultation as regulatory bodies modernise their systems (boxes 4, 5 & 6).

BOX 4: Public involvement in ethical code development – Ireland

Ireland
"It shall be a function of the Council to give guidance to the medical profession generally on all matters relating to ethical conduct and behaviour".
Medical Council of Ireland, Medical Practitioners Act, 1978, Section 69 (2)

BOX 5: Public involvement in ethical code development – France

France
"Le code de déontologie médicale n'est pas seulement établi par la profession. Si celle-ci, représentée en l'occurrence par l'Ordre national des médecins, est chargée de l'élaborer, le texte qui en découle est soumis à l'administration, au Conseil d'Etat et finalement au gouvernement, chacun ayant la charge de vérifier sa conformité avec les lois et autres règlements régissant la société où exercent les médecins et la possibilité d'y apporter des modifications. Enfin, le code est publié au Journal Officiel sous la signature du Premier ministre".
Introduction to the commentary on the French deontological code. The medical deontological code is not established only by the profession. Although the profession, represented by the National Order of Physicians, is in charge of developing it, the text is then submitted to the administration, to the State Council and finally to government, each of which is charged with verifying that the code conforms with the laws and other rules relevant to doctors' practice and each has the chance of making any appropriate changes. Finally the code is published in the Official Journal and signed by the Prime Minister.
www.conseil-national.medecin.fr

BOX 6: Public involvement in ethical code development – UK

UK

Development of Good Medical Practice document in the UK:
Process of consultation
The first draft Good Medical Practice was originally developed between 1993-95 within the GMC without outside consultation and then sent to all 200,000 registered doctors of whom about 100 responded with comments. Since then the GMC has consulted widely on re-drafts of the document with the most recent being sent for comment to over 1000 organisations and individuals including medical and patient organisations, government departments, charities etc. From this consultation around 400 responses were received and the final document, approved by the GMC in May 2001, was published in September 2001.

Competency and performance

The code of ethics can be understood as the core component or seed in what in most jurisdictions has now become a broad raft of standards, which govern good professional practice. Most if not all codes of ethics include requirements on doctors to provide good quality clinical care. In recent years understanding of what constitutes the ability to provide good clinical care has started to crystallise on ideas of *competency* and *performance*.

There are different understandings of what these terms mean (Diwarker 2002), but the following definitions, developed by the College of Physicians and Surgeons of British Columbia, Canada are helpful:
"Competency *refers to the ability to apply knowledge, skills, and attitude by adding judgement. It refers to the potential. It could be referred to as 'can do'. Performance refers to what is actually done. It could be referred to as 'does do'. The quality of the performance is a measure of the application of the competence. Performance could be thought of as being competence minus distraction"*.
http://www.cpsbc.ca/physician/education.htm. Accessed 20/10/04

Critics of the competency-based approach have argued that if competencies are narrowly defined and used inappropriately, the approach runs the risk of focusing on minimum acceptable standards by the use of checklists (Leung 2002). It is therefore important to be clear that a competency based approach to standard setting and assessment should focus on ability for *reflective practice* and not simply on the development and assessment of an exhaustive list of competencies (Diwarker 2002).

In this broader understanding of the term competencies, are sometimes referred to as 'higher' or *'meta-competencies'*.

Many professional bodies now recognise a four-stage hierarchy of professional competence as defined by Miller (Miller 1990): this starts with knowledge, progresses to "know how", then to "show how" (competence) and finally to "does" (box 7).

BOX 7: Definitions of competence and performance

La compétence se situe à un échelon différent de l'acquisition du savoir. Elle s'apprécie sur la capacité à mettre en oeuvre les notions acquises, à les adapter au cas particulier et à déterminer une attitude ou une décision. Plusieurs définitions ont été données à la significaction de "compétences". Celle qui a été retenue par la "Mission sur les modalités et les conditions d'évaluation des compétences professionnelles des métiers de Santé" fait état "d'un ensemble de caractéristiques individuelles (connaissances, aptitudes, attitudes) que permettent à une personne d'exercer son activité de manière autonome, de perfectionner sans cesse sa pratique et de s'adapter à un environnement en mutation rapide". Les pratiques professionnelles ne concernent pas l'acquisition ou la mise à jour du savoir, ni les capacités de mise en oeuvre des connaissances mais sont en rapport avec les comportements du médecin dans sa pratique quotidienne à savoir les modalités de son exercice, ses manières d'agir, ses habitudes, son respect du Code de Déontologie, en bref: son savoir faire. Evaluation de compétences et de pratiques professionnelles. Rapport adopté lors de la session su Conseil national de l'Ordre des Médecins du 2 juillet 2004. Pr. C.-F. DEGOS. Ordre National des Médecins, France.

Competency is on a different level from the acquisition of knowledge. Competency can be understood as the capacity to put into action concepts learnt, to adapt them to any particular case and to determine a course of action or take a decision. Several definitions have been given for the meaning of "competencies". The one agreed on by the "Mission on the modes and conditions for the evaluation of the professional competencies of health care workers" states "a collection of individual characteristics (knowledge, skills and attitudes) which enable a person to work autonomously, to continuously improve their practice and to adapt to a constantly changing environment". Professional performance does not concern the acquisition or the updating of knowledge, nor the capacity to put knowledge into practice but refers to the behaviour of a doctor in his or her daily practice in knowing how to go about their work, their way of behaving, their skills and respect for the Deontological code, in short, their savoir faire.

Expected standards of competency and performance change as a doctor progresses through his or her career path, so expectations of a newly qualified doctor are different from those of a middle grade doctor completing his or her specialist training and different again from those of an experienced specialist or general practitioner. As a result standards and the methods of assessing them also vary:
"Attempts to define competencies and meta-competencies across the scope of professional practice are likely to be impossible". Diwarker 2002.

Whose responsibility is it to develop standards of competency and performance?

"We think that the profession itself is best placed to lead on matters of professional competence: this is because professional input will always be required when specialised technical issues arise". Better Regulation Task Force: Alternatives to State Regulation: Case study General Practitioners. July 2000.

Until recently the process for regulating the medical profession in most Western European countries was relatively simple: the profession itself usually in the form of an autonomous self-regulated body, took responsibility for defining as well as monitoring and enforcing its code of ethics which included all the standards for professional practice that were deemed necessary.

In the last few decades a number of social phenomena (see Introduction) have combined to create a force for change on society and by implication, on the regulation of doctors. Different jurisdictions have responded (and are responding) to these forces for change in different ways and the body or bodies, responsible for developing standards of professional competency and performance differs accordingly. These bodies may also change throughout the course of a doctor's professional life, for instance from the medical school or university, to the professional colleges.

Within the profession itself, in addition to the self-regulatory body, other organisations such as medical colleges, associations and societies play important roles in the definition of standards of professional knowledge, competency and performance (chapter 6). These bodies may also play a role (either leading or in partnership) in monitoring and enforcing these standards. Different professional bodies may represent the interests of doctors in the negotiation of their contractual rights and obligations (many of which also encroach on the ethical code). And yet other organisations protect the interests of doctors in cases of complaint or litigation. In some jurisdictions all of these functions are performed by separate bodies whereas in others they are undertaken by different departments under one umbrella body.

In addition to the myriad of players within the profession, new players from outside the profession have recently either entered the regulatory picture or have increased their powers, especially through contractual relationships with doctors: these include health care managers, health care purchasers and policy makers, health insurance fund managers and of increasing importance, the general public – see box 15 (chapter 6).

Accountability – the way marker through the system

The forces for change and the incremental changes which most societies have made in response, have led to a *complexity* in regulatory environments which can make it difficult to see who or what body is responsible for the setting, monitoring and enforcement of standards. Where there are several professional colleges, different associations and regulatory bodies involved, it is extremely important that there are *clear lines of accountability* between: i) the bodies which set the standards for the different processes (education, competency, contractual duties etc) ii) those who are charged with monitoring and assessing against those standards and iii) those with the responsibility for taking action based on the outcome of those assessments.

Ultimately regulation of doctors is about controlling the license or right to practice. It is therefore important that whichever body holds the power to give or withhold this right, is also *involved* in setting and monitoring educational standards. In a complex system in which there are many players and standards flexible, lines of accountability need to be simplified as much as possible to ensure *maximum public transparency* and engender *public trust* in the system (chapter 8).

Standards – key points

1   Although an exact definition of a good doctor is impossible, it is important to have standards of ethics and practice as these form the cornerstone of a regulatory system which protects the public from incompetent and unscrupulous practitioners.

2   Codes of ethics vary around the world and although their development is usually led by the medical profession, increasingly the public is becoming involved.

3   Standards of practice now differentiate knowledge, from competency and performance. Competency can by understood as 'can do', and performance as 'does do'.

4   Standards and types of expected competencies change as the professional moves through their career and are a measure of a doctor's ability to engage in reflective practice.

5   Recent forces for change in medical regulation have led many jurisdictions to alter the organisation of their system. The increase in the number of organisations involved in regulation can make the system appear confusing to the outsider. Given this complexity, it is essential that the lines of accountability between standard setting, monitoring and intervention are clear.

6   The ultimate sanction in medical regulation is removal of the right to practice (or refusal to grant this right in the first place). The body charged with this statutory responsibility is therefore the key player in the regulatory system. All regulatory processes within the system, must link up explicitly with the process of licensing or removal of licensure.

Chapter two

Education

Education

"An education isn't how much you have committed to memory, or even how much you know. It's being able to differentiate between what you do know and what you don't".

Anatole France, novelist. 1824-1924

Education is the process by which practitioners are enabled to meet standards of practice. An inadequate or inappropriate education means that medical practice will in turn be substandard. It is therefore intrinsically relevant to the set up and maintenance of an effective medical regulatory system to ensure that the *process of medical education* is of a standard which can enable professionals to meet the required standards of ethics and practice. For this reason, medical education itself must undergo a process of quality assurance, to ensure that the desired outcome – competent and caring doctors – is achieved.

Standards in education

The World Federation of Medical Education (WFME) is the global organisation concerned with the education and training of doctors. In 2003 the WFME formally endorsed its "Global standards in medical education – for better health care" (http://www.wfme.org/). This document consists of a trilogy of global standards covering basic, postgraduate and continuing medical education. The WFME acknowledges that the role of accrediting medical education courses and programmes rests with the responsible authority in each respective country but advises that these global standards can be used as a template by national accrediting bodies. The standards, which should not be confused with an attempt at a core curriculum, offer an opportunity for developing international quality assurance in medical education through a process of organisational self-evaluation and peer review. Intended primarily as a lever for change, WFME standards are in two groups:

Basic standards – or minimum standards that must be met if a minimally acceptable level of education is to be achieved. These standards are defined by a 'must'.

Quality development standards – standards that are in accordance with international consensus about best practice in education at the particular level of interest (basic, postgraduate or continuing). These standards are defined by a 'should'.

The WFME standards are intended to be:

- A lever for change and reform
- Concerned with the process rather than the specific content of medical education
- Used for self evaluation to meet minimum standard and direct quality improvements
- Flexible in their use to help aid compliance and accreditation
- A stimulus to promote discussion and develop consensus about aims, objectives and the development of quality improvement programmes

The main areas or components of the WFME global standards for undergraduate, postgraduate and continuing professional development are shown in box 8.

BOX 8: World Federation for Medical Education global standards, main components

Undergraduate	Postgraduate	Continuing Professional Development
Mission and Outcome	Mission and Outcome	Mission and Outcome
Educational Programme	Training Process	Learning Methods
Assessment of Students	Assessment of Trainees	Planning and Documentation
Students	Trainees	The Individual Doctor
Academic staff/Faculty	Staffing	CPD Providers
Educational Resources	Training Settings and Educational Resources	Educational Context and Resources
Programme Evaluation	Evaluation of Training Process	Evaluation Methods and Competencies
Governance and Administration	Governance and Administration	Organisation
Continuous Renewal	Continuous Renewal	Continuous Renewal

Maintaining the standards
Undergraduate medical education

A good education is fundamental to becoming a good doctor. Although the basic ingredients of the education that make a good doctor start long before university, the first stage in formal education is the general medical training, usually undertaken at a university. Undergraduate education of new doctors is the first step in ensuring that agreed standards of good medical practice are achieved and for this reason these standards should be central to both student selection and curriculum planning.

Responsibility for selecting students and educating them to become doctors normally rests with a recognised university or medical school. At the end of the training period the student undergoes an assessment, usually in the form of an examination known as the primary medical qualification (PMQ), which may be either a university degree examination and/or a national qualifying examination.

In order to ensure that the standards of knowledge and competency attained by graduating medical students are sufficient to allow them to practise as doctors, the process of quality assuring undergraduate medical education should tie in with the process of granting a legal licence to practice. This implies the need for a clear line of accountability between the organisation that grants the PMQ and the body that grants the licence to practice. Sometimes this may be through a process of accreditation of the curriculum, educational process and assessment mechanisms. An example is that the UK GMC (by way of its Education Committee), has a statutory duty to set standards for basic medical education and to ensure that they are met. To this end a document entitled "Tomorrow's doctors" (GMC 2003) sets out standards of knowledge, skills, attitudes and behaviour, which the GMC expects of new medical graduates (box 9).

BOX 9: Linking regulation with undergraduate education – the UK example

"Our statutory responsibilities…

5. *The GMC's Education Committee has a statutory duty (Medical Act 1983) to set and maintain the standards of basic medical education (undergraduate education and the PRHO year).*

6. *The Education Committee has the power to visit universities to make sure that undergraduate teaching is appropriate and to inspect examinations to make sure that the standards expected at qualifying examinations are maintained and improved. We make recommendations to the Privy Council about whether a university should:*
a) Be added to the list of institutions that can award a registrable UK medical degree (Section 8 of the Act).
b) Be removed from the list of institutions that can award a registrable UK medical degree (Section 9 of the Act).

7. *Our requirements for undergraduate medical education (UME) are set out in Tomorrow's Doctors (2003). This can be found on our website at http://www.gmc-uk.org/.*
Extract from: Quality Assuring Undergraduate Medical Education – An Overview. General Medical Council, 6th July 2004.

Postgraduate medical education

"The competent authorities must define, in consultation with the professional organisations, the mission and outcome objectives for the various types of postgraduate medical training and make them known".
WFME Postgraduate Medical Education. WFME Global Standards for Quality Improvement, 2003.

In most industrialised countries, if a doctor wishes to specialise in any particular branch of medicine, she or he will need to undergo further post-graduate, specialist training. There are differences between countries as to when a qualified practitioner is given the title of 'doctor', and exactly what constitutes a 'specialist' – and therefore what exactly is necessary for specialist training (Nicholas 2003).

In spite of these differences there is general agreement about the nature of postgraduate education, captured by this definition from the World Federation for Medical Education (WFME 2003b):

"…the phase in which doctors train under supervision towards independent practice after completion of their basic medical qualification. It comprises pre-registration training, vocational/professional training, specialist and sub-specialist training and other formalised training programmes. Upon completion of a formal postgraduate training programme a degree, diploma or certificate is usually granted". WFME Postgraduate Medical Education. WFME Global Standards for Quality Improvement.

With respect to qualification and registration as a specialist, there may be a variety of organisations involved, depending on the speciality concerned and the jurisdiction in question. Unlike the PMQ, qualification as a specialist is not usually covered by legal statute and does not therefore need to be directly tied in with the process of issuing a license to practice i.e. the right to practice as a doctor does not usually *depend* on having a specialist qualification. Nevertheless, whether any particular doctor is accredited or qualified as a specialist is information which is directly relevant to the way in which they represent themselves both to the public and any employer. It is therefore important that this information is properly registered and publicly accessible along with information regarding the PMQ and record of good standing (see below).

Responsibility for specialist training is often held by organisations which are independent from the competent *registration* authority. For instance this role is currently undertaken in the UK by the Specialist Training Authority of the Royal Colleges (soon to be replaced by the Postgraduate Medical Education and Training Board).

Where different bodies are involved in standard setting and accreditation of postgraduate medical training, efforts must be taken to ensure clarity to the public over who is responsible for what. This clarity needs to translated into clear lines of responsibility and good communication as well as a clear definition of the components of training required to become a specialist.

Continuing professional development
"…mastering the reality of today does not prepare students for the challenges of tomorrow". Gro Harlem Brundtland, former Director-General, World Health Organisation, Opening Address, WFME, Copenhagen 2003.

Knowledge in medicine is expanding rapidly and every doctor, if they are to remain able to provide the best care for their patients, must try to keep abreast with the developments which are relevant to their professional practice. Continuing

professional development (CPD) is the on-going process of education and training that a doctor follows from the time of completing their basic or specialist training until they finish practising as a medical professional. CPD is a process of continuous professional life-long learning, which includes formal and informal learning activities and which is essential to ensure high quality health care.

As the WFME points out, CPD differs from undergraduate and postgraduate education in that there is no educational institution overseeing its delivery and it may be undertaken by any number of agents varying from individual professionals to multi-national organisations such as pharmaceutical companies. Because of this range of possible providers the WFME has identified the medical professional organisations as being mainly responsible for planning and coordinating CPD activities (WFME 2003c). In addition the individual doctor takes a leading role in designing and following their own professional education and development programme. In CPD independent self-directed learning is encouraged and supervised training for any extended period of time is unusual. There is wide variation in the way in which CPD is organised, delivered and monitored around the world but the WFME's Global Standards for CPD can form a quality assurance framework for doctors and the profession as well as for CPD providers.

Recertification and revalidation

Increasing public concern over processes of continuing education and updating has led some countries to consider procedures for formalising the monitoring of CPD activities. Such processes, known as recertification or revalidation (see glossary) are currently at the forefront of medical regulatory activity but few bodies have as yet developed fully-fledged programmes.

A recent analysis of international models of recertification (SHM 2003) found that there where jurisdictions have introduced or are introducing recertification programmes, there is great variation in the models adopted:

"No single system recurs worldwide. Instead systems are carefully designed to be sensitive to widely varying contextual factors. There is a considerable amount of sophistication and intelligence in the way that these systems have been designed to respond to local needs". Report prepared by SHM for the General Medical Council: Analysis of international medical recertification models, October 2003.

This research found that it is difficult to compare different models of recertification because of differences in their purpose. In general, purpose varies along a spectrum from programmes designed primarily to *protect patients and avoid harm* (to avoid a negative), to those designed to support professional development and

promote improved clinical care (to promote a positive). Purpose is driven by the regulatory and professional environments (see chapter 7) of the programme in question and also by any social imperatives such as high profile medical scandals.

Programmes of recertification and revalidation may be considered to be either *"light touch"*: centralised, carried out irregularly, based on sampling or *"high touch"*: local, regular and ongoing, carried out on all doctors. In general regulators seem to prefer light touch approaches that create more confidence in doctors and rely more on professional trust and values (SHM 2003).

A full system of revalidation, rooted in the widespread devolution of clinical governance and appraisal to local level, is currently being established in the UK (box 10). Although few regulatory bodies have to date established a comparable programme to that in the UK, others have programmes in place for screening physician's performance and instituting measures to enhance their performance where this is considered at risk.

BOX 10: Revalidation in the UK

Overview and key features of revalidation procedures in the UK
- All registered doctors to be included
- System tied in closely with local clinical governance and appraisal procedures
- Doctors will need to i) show the GMC that they are participating in an appraisal scheme based on Good Medical Practice ii) provide local certification about their fitness to practice
- Lay participation in the process will be secured at local and GMC levels
- Revalidation to be based on what doctors actually do, rather than what they can or could do
- Doctors who fail to participate in revalidation, or whose standard of practice is found to be unacceptable, will lose their licence to practice
- All aspects of revalidation process subject to effective quality assurance arrangements

GMC: The Policy Framework for Revalidation: a position paper. July 2004

Approaches to improving the quality of medical education

Introducing change to improve medical education can be challenging and there is no one right method for doing so. Nevertheless the WFME standards can be a useful tool in helping to bring about change. Recent work in developing medical education in Kosovo has used these standards as a template for introducing change into the system. A user's manual published as a result of this work published a seven-point action plan which summarises the main activities which have to be undertaken to bring about change (see box 11).

BOX 11: Creating change in medical education

The following seven-point plan summarises the main activities that have to be undertaken to bring about change, but not necessarily in the order presented.

- *Gain commitment from the top management to the need for change. The process should be managed from the top with a clear statement of the goals and expected benefits. Improving the quality of medical education is a complex process that needs to be managed in a planned and measured way.*
- *Develop a group of individuals who are committed to improving the quality of medical education and who can explain how the WFME global standards can be used as a lever for change.*
- *Involve key stakeholders from the beginning and establish teams to review the current situation, compare the current situation with the WFME global standards, prepare strategies and implementation plans and take action to improve the quality of medical education.*
- *Communicate widely the goals of reforming medical education and explain why change is necessary and what benefits are likely to accrue. Undoubtedly there will be resistance to change from some quarters. These concerns need to be addressed. Early successes in implementing improvements should be widely communicated.*
- *If necessary use external change agents and identify best practice from elsewhere and use these to stimulate change.*

- *Adopt a **planned approach** to introducing change that addresses all the deficiencies of the existing situation as compared with the global standards and builds on the strengths of the current structures and systems.*
- ***Retain flexibility** to respond to the challenges that will inevitably occur as changes are introduced. Deliver and publicise early successes so that people can see from the start that medical education is going to improve. Learn from experience.*

A user's manual to improve quality in medical education: integrating the global standards of the World Federation for Medical Education (WFME). HLSP Consulting (Europe) SL. Barcelona 2003.

Education – key points

1 The medical education system must be of a sufficient standard to ensure that competent and caring doctors are trained.

2 The World Federation for Medical Education has published a trilogy of standards for i) undergraduate, ii) postgraduate and iii) continuing medical education. These standards are basic or minimum standards and quality development standards.

3 To ensure effective regulation of practitioners entering the profession, the process of assuring quality of medical education at undergraduate level should be tied in with the process of granting a legal licence to practice.

4 A variety of organisations may be involved in setting standards, assessing and accrediting specialist practice. It is important that lines of accountability are established and clear to the public. Mechanisms for ensuring proper registration of this data should also be put in place.

5 The medical profession takes the lead in the development of continuing professional development programmes but the individual doctor also assumes personal responsibility for their own programme.

6 CPD programmes which are tied into conditions of re-issuing of a license to practice are currently being developed and implemented in a number of countries as a further quality assurance mechanism.

Chapter three

Registration and licensing

Registration and licensing

3

"The maintenance of a register of the competent is fundamental to the regulation of a profession".

Committee of Inquiry into the Regulation of the Medical Profession.
Merrison Committee report.

What is a medical register?

A medical register is an official list containing details of people who hold a recognised qualification in medicine and who *in accordance with the regulations of the jurisdiction* in question, enjoy a right to practice the profession within that jurisdiction.

The purpose of a medical register

A medical register that records details of the right to practice medicine exists for three reasons:

- To distinguish the qualified from the unqualified
- To assure the public of an individual's good standing
- To assure the public and the profession of an individual's continuing competence

Controlling entry to and exit from this register is therefore the *core medical regulatory activity* and all other regulatory activities must link in clearly with the control of the right to practice.

The registration and licensing process

Registration and licensing is a process that incorporates aspects of the two regulatory functions: i) monitoring or assessment against standards and ii) intervention (see box 1).

Control of entry to and exit from the medical register consists of two component activities:

1. *Holding the register* and administering its day to day management
2. *Decision-making* as to who enters, stays and is removed

In this chapter we focus mainly on the key activities and issues involved in the process of holding and administering the register. The body that holds the register may be but is not necessarily the same as the body (or bodies) responsible for deciding who goes on, stays on and is removed from the register. The complexity around these decision-making procedures is described in chapters 5 and 6.

Verification and assessment of standards

The verification and assessment aspect of medical registration and licensing includes:

- Verification of identity
- Verification of credentials
- Where it is not possible to verify competency by checking credentials of educational and professional achievement, a process of independent assessment of competence may be necessary
- Verification of good standing

Intervention to control entry to and exit from the medical register

Control of access to the register includes:

- Mechanisms for registration (including type of data held and accessibility to that data)
- Mechanisms for conditional registration under strictly observed conditions
- Mechanisms for voluntary removal from the register
- Mechanisms for enforced removal or suspension from the register

The key features of these activities are described below. To ensure high quality in the medical register, a quality assurance programme needs to address standards and practice within each of these registration activities.

Verification of identity

Until recently name, address, place and date of birth and place and date of qualification were regarded as sufficient 'proof' of identity of a doctor. Because improvements in information technology have made falsification of documents relatively simple, many regulatory registration authorities now ask for more firm proof such as a passport or national identity cards, especially for applicants from outside of their jurisdiction. To increase security, regulators may communicate directly with each other to help them establish doctors' credentials and/or identity.

Verification of credentials
i)   Graduates from universities within the same jurisdiction as the registering body

Before entering a doctor on the register the competent authority must satisfy itself that the doctor's qualifications are in order. If the degree has been awarded by a university within the jurisdiction of the registering body, this should be a straightforward procedure, provided that there is a clear line of accountability between the registration body and the body responsible for monitoring and accrediting the curricula and examination procedures of the universities within its jurisdiction. In practice these two responsibilities may be held by the same body (see chapter 2).

ii)   Graduates from another jurisdiction

The competent authority must have a procedure for assessing the credentials of doctors presenting with a PMQ outside of their jurisdiction. In some countries (e.g. members of the EEA), there is reciprocal agreement based on *mutual trust* between governments that doctors who hold a primary medical qualification awarded by a recognised body in one member state should automatically be recognised in any other member state on production of a certificate, diploma or other evidence of PMQ (Nicholas 2004). Although this system of mutual recognition is based on the achievement of a set of minimum common training standards, in reality these standards are light on detail (see chapter 7). In the case of doctors from EEA member states, language testing is not a condition of registration, indeed regulators are specifically precluded by EC law from language testing incoming EEA nationals as a requirement for registration. Instead the responsibility is placed with the host Member State (in practice often delegated down to prospective employers) to ensure that doctors have the necessary linguistic skills.

Where the applicant for registration has come from a jurisdiction with which there is no mutual recognition of qualifications, the authority may decide that the only fair and robust method of evaluating an individual's current capability for practice is to undertake an objective assessment of that person's competency and language proficiency. Examples of objective assessments include the Professional and Linguistic Assessment Board (PLAB) test in the UK and the United States Medical Licensing Examination (USMLE).

Verification of good standing

Verification of credentials does not necessarily imply fitness to practice. In addition to verifying that the qualifications a doctor holds are valid for registration, the registration authority must also satisfy itself that the doctor is in good standing with respect to both professional and performance standards, in all the jurisdictions in which she/he has practised. For recent graduates this involves ensuring that there is an adequate system,

involving both educational and regulatory bodies, for monitoring and communicating about personal and professional probity of medical students.

For professionals moving into the jurisdiction from elsewhere, procedures need to be in place for establishing that a doctor remains in good standing in the country in which they obtained their PMQ *and/or* in the country in which they have most recently been practising.

Most competent authorities therefore ask candidates for a certificate of good standing from the competent authority of origin as well as from the country in which the doctor most recently practiced. Even with current international agreements there are still potential loopholes because of differences between countries in interpretation of what constitutes good standing, and the legal protection and data protection granted to doctors who may be undergoing investigation of their character and/or conduct. This issue is currently being reviewed by members of the International Association of Medical Registration Authorities (IAMRA) (See chapter 7).

Mechanisms for registration

Once identity and credentials have been verified satisfactorily, the competent authority can register the doctor:

Unique identifier

The registering authority must ensure that there is no possibility of anyone else either fraudulently or mistakenly assuming any individual's professional identity. For this reason each individual placed on the register must be uniquely identifiable, a process usually achieved by assigning a unique number or identifier which is never re-used even after the doctor has died.

Data held

In addition to holding identifying information, the competent authority may wish to record other data on the doctor such as details of specialist qualifications, posts held and other personal details such as civil status. This minimum dataset also needs to conform to the data protection laws of the state in which the register is held and organisational systems must be in place for ensuring that these regulations are complied with.

Accessibility of data

A key issue in assuring the quality of a register is to establish accessibility to the data held. Concerns over data protection and privacy need to be addressed and weighed up against the rights of the public and potential employers to essential information about doctors. Currently there is variation around the world in the amount of data

which jurisdictions makes publicly available. This may vary between two extremes: i) all the data is publicly available and accessible in a published register (on paper and/or electronically via the internet) ii) data availability is restricted to members of the profession only and perhaps on special written request only to members of the public. Accessibility to the register is largely determined by the defined purpose of the register. Where the need to assure the public of doctors' probity is paramount, public access to the relevant information on qualifications and probity is also likely to be a priority.

Normally all doctors who are registered will receive some paper documentation of their entry on the register which the individual can use to verify their good standing to anyone (e.g. a prospective employer) who requests it. In addition some authorities may issue more firm identifying documentation such as photo identity cards. Although such paper documentation can be useful, it is important to bear in mind that this can be unreliable, partly because of the ease of fraudulent copying but also because of the need for being up-to-date. A doctor may be in good standing at the time of issue of the document but there needs to be in place a robust system for recalling such documents in the case of disciplinary proceedings, otherwise it will soon be out of date. Provision of information about an individual's current status either electronically or by phone directly to enquirers is therefore more reliable.

Re-registering and re-licensing

In chapter 2 we discussed how some regulatory bodies have or are introducing systems of continuing professional development which are directly tied in through certification and professional appraisal schemes, to the registration process. In some jurisdictions, all doctors have to apply to be re-registered after a certain amount of time and a variable degree of evidence concerning on-going competency and performance is required of them. This evidence may vary from the production of certificates of attendance at approved CPD courses to a fully detailed peer-reviewed appraisal and performance ratification (see chapter 2).

Mechanisms for voluntary removal from the register

Under certain circumstances, doctors may wish to be removed from the register. Such circumstances include: removal for family or other personal reasons, removal because of move abroad or removal on retirement. The competent registration authority must ensure that it has procedures in place that allow for the voluntary removal of doctor from the register, either permanently or temporarily. Where removals are temporary, procedures for re-verifying character and competence for re-entry to the register are also necessary.

Mechanisms for enforced removal or suspension from the register

Membership of the medical profession brings both privileges and obligations. The obligations implied by being recognised as a medical doctor require that the individual meets agreed standards of personal and professional conduct as well as standards of professional competence and performance (see chapter 1).

Unfortunately there are occasions when the regulatory body has to take action in the public interest, to prevent an individual doctor from practising either because of poor professional performance or because of misconduct (see glossary for definition of these terms). The ultimate professional sanction is to remove the right to practice by removing (or suspending temporarily) a doctor from the medical register – and/or removing their licence to practice. Because of the extreme weight of this sanction, which has far-reaching implications on the personal and professional life of the doctor concerned, it is essential that disciplinary mechanisms are transparent, accountable and effective. The general principles involved in instituting mechanisms for investigating and managing poor performance and/or professional misconduct are outlined in chapter 4.

Registration and licensing – key points

1   A medical register records details of the right to practice medicine distinguishes the qualified from the unqualified and provides evidence of a doctor's good standing and continuing competence.

2   The control of entry to, maintenance on and exit from the medical register is at the core of medical regulatory activities and consists of a) holding the register and b) decision-making about who enters, stays and is removed from it.

3   The registration and licensing process (holding the register) involves verification activities as well as activities concerned with the mechanisms of registering, re-registering and de-registering doctors.

4   Quality assurance of the registration process must pay attention to the type, quality and validity of the information it holds on doctors, liability to fraud and issues of public accessibility to the database.

5   Liability to fraud can be reduced by increasing reliance on electronic records, unique identifiers, photo-ID and improved communication between regulators in different jurisdictions.

Chapter four

Disciplinary procedures

Disciplinary procedures

4

"Regulation is a word that usually brings doctors out in a rash".

Professor Ian Kennedy, Chairman, UK Healthcare Commission.

Regulation of the medical profession is primarily about protecting the public by ensuring that those individuals who hold a licence to practice medicine *have met and continue* to *meet* standards of conduct and performance (see box 1). The effectiveness of a regulatory system hinges on its power to take appropriate action to protect the public when doctors fail to meet the standards expected of them.

Professional misconduct and poor performance

Broadly speaking a doctor can be called to account for his or her actions for two possible underlying reasons:

- *Professional misconduct*
- *Poor performance*

The distinction between these two concepts is not always easy to define and not all jurisdictions make the distinction. In general terms, poor performance may reflect a pattern of behaviour in which standards fall consistently below what is acceptable, whereas misconduct is more likely to refer to a one-off incident. Whether or not this distinction is made, coming to a common understanding of what constitutes either poor professional performance or misconduct is not easy and meaning varies not only from country to country but even among doctors themselves. In this section when we use the term poor performance we also include professional misconduct unless otherwise stated.

An assessment of professional performance will inevitably involve value judgements, but it is nonetheless essential to have a commonly agreed yardstick of what constitutes good medical practice. In chapter 1 we discussed how a code of ethics, deontological code or standards of good medical practice, must form the essential underpinning of every aspect of a medical regulatory function, and nowhere is this more the case than in the area of performance assessment. A code of good practice

may detail unacceptable practices or it may be more general, outlining instead positive behaviours. Regardless of its form, the code is the essential cornerstone of disciplinary procedures and must be closely tied in with them.

What is acceptable behaviour, what constitutes a disciplinary offence and the degrees of severity with which such offences should be judged currently varies considerably around the world (Brearley 1999). While much of this variation can be understood in terms of different culture, education, tradition, history and politics, the fact of increasing medical mobility means that such variation in standards may increasingly jeopardise public confidence in the medical profession. The need to reach some internationally agreed standards is therefore becoming increasingly urgent and this is being addressed by the International Association of Medical Regulation Authorities (IAMRA).

What are the reasons for poor performance?

There are many possible reasons for a doctor to perform below the standards of accepted good practice. These include:
- Ill-health (most frequently substance misuse and/or mental health problems – and therefore potentially amenable to treatment).
- Inadequate knowledge, skills or experience – and therefore potentially amenable to educational intervention.
- Structural, organisational or resource problems with the health system, service or institution.
- Personal problems underlying misconduct or behaviour and/or a criminal offence.

An understanding of the reasons for the performance problem is essential in order to be able to decide how to deal with the doctor concerned (i.e. medical treatment, education, organisational/system intervention or a disciplinary sanction). Nevertheless, regardless of the underlying reason(s) the principles that underlie the investigation of a complaint are identical.

Cases of poor performance may be brought to light by two mechanisms:
- An on-going, pro-active 'surveillance' of competency and professional performance – clinical audit, clinical governance programmes and peer review.
- As a result of a complaint.

Although a system of prevention of poor performance seems intuitively more desirable than one based on investigation of complaint once a problem has occurred, in fact few jurisdictions have a fully developed pro-active system for the surveillance of clinical performance. This is the objective of the revalidation programme that is currently being introduced in the UK, a programme that is at the forefront of modernising medical self-regulation procedures (see chapter 2).

It is beyond the scope of this guide to give an in-depth description of clinical governance programmes. The essential components of a complaints system is described below:

Complaints procedures – essential components

Open and clear process for making complaints
The public needs to know not only that they may make complaints about the treatment they have received but also *how* and *to whom* to make those complaints. They need to know that once they have made a complaint that the issue will be dealt with fairly and transparently and that an investigation, proportionate to the issue of concern, will be undertaken. To ensure that the public is aware of their rights, there needs to be sufficient information, which is highly accessible and can be clearly understood by everyone regardless of their educational level or the languages they speak.

Screening of complaints
Complaints vary in severity and in the level of investigation that is necessary to deal with them. Some issues can be dealt with easily with minimal levels of investigation whereas others need more attention. Usually a screening procedure is put in place so that those complaints of a less serious nature are dealt with at local level and/or by more simple mechanisms. This screening may be undertaken by a medically qualified individual and/or someone else appropriately trained for the task.

Investigation procedures
Other complaints need a fuller investigation and may involve the need for legal representation, witness accounts and if necessary a full hearing in which all the evidence is presented and considered. A decision will normally be taken at the screening stage as to the *level* (national, regional or local) that is appropriate for these investigations to occur, although this also depends on the organisational arrangements in the jurisdiction in question.

In cases of serious misconduct or crime, there may also be a need to impose a temporary restriction on practice of the doctor concerned and there needs to be a mechanism by which such a restriction can be formalised.

Adjudication procedures

In all but the most trivial cases, there needs to be a system for deciding whether a complaint requires some action to be taken. Again the seriousness of the complaint and the organisational arrangements of regulation will determine how such adjudication takes place. Decisions regarding the composition of adjudication panels, methods of selection of members of such panels, representation from professions (medical and legal), government and the public and whether proceedings are open or closed to the public are all necessary. In general terms adjudication procedures that involve the public, are open and transparent and are timely in their decision making are more likely to be trusted both by the profession and by the public.

Sanctions

Where some degree of fault or blame is determined, sanctions may be imposed on the doctor. The type and severity of sanctions usually depends on the nature of the misdemeanour as well as the specific circumstances in which it occurred (although in a minority of EEA countries there is little room for discretion in the type of sanction imposed for particular offences (Brearley 1999)). Sanctions can vary from a warning or a fine to either a temporary removal from the register 'suspension' or a permanent removal or 'erasure'. The purpose of the sanction may also vary from one jurisdiction to another. In many jurisdictions sanctions are seen as primarily about protecting the public and the punitive element is a secondary effect (although probably not in the eyes of the doctor concerned).

Remediation

In many cases where disciplinary action is taken, in addition to the imposition of sanctions, there are also remedial actions that may help the doctor and prevent such events occurring again. Remedial action may involve medical or psychological treatment in the case of sick doctors or special education or training programmes in cases of poor performance. All such remedial actions need to be structured and organised appropriately and mechanisms put in place for ensuring that the desired outcomes have been achieved. This may involve the need for independent medical examinations for sick doctors and assessments of competence where there has been poor performance.

Communication of disciplinary findings and actions taken

One of the most sensitive areas to consider when setting up a disciplinary mechanism, is how, when, how much and to whom to communicate the fact that a doctor is either subject to an on-going investigative procedure or has been sanctioned. As outlined above there is variation among jurisdictions in a) what constitutes a sanctionable offence (including an offence requiring removal of license to practice) and also in b) whether information on disciplinary processes is communicated either to the public

or to other jurisdictions. In some jurisdictions the fact that disciplinary actions are taken in public and information about them is publicly available is seen as crucial to the public having confidence in the integrity and accountability of the regulatory system. Within the EEA only France, Ireland and the UK routinely send information on disciplinary outcomes to other countries in the area, whereas others will do so on request but for others data protection legislation prevents this (Nicholas 2004).

Disciplinary procedures – key points

1 Professional misconduct and poor performance are the reasons for instituting disciplinary procedures, but definitions vary between jurisdictions and involve value judgements.

2 Many factors may contribute to poor performance, including ill health, inappropriate or inadequate education, structural or health system problems and personal problems. An understanding of the underlying reasons is vital to deciding on the most appropriate intervention – remediation and/or sanction.

3 Poor performance can be brought to light either through a pro-active monitoring programme or as a result of a complaint.

4 Key features of a sound complaints system include: transparency, screening and investigation system, fair adjudication, and intervention and communication to the public and other regulators about action taken.

Section two

The organisation and governance
of medical regulation

Chapter five

The profession, the regulatory body
and self-regulation

The profession, the regulatory body and self-regulation

5

"Medicine may not be the world's oldest profession, but it has long been the prototypical one. It has exhibited, to the highest degree, the principal features of professionalism, including a systematic body of theory, authority to define problems and their treatment, community sanctions to admit and train its members, ethical codes that stress an ideal of service to others and a culture that includes the institutions necessary to carry out all of its functions".

Canadian Medical Association.

Origins of medical regulation

Regulation of doctors has its roots in the concept of the profession and the conservation and promotion of professional values (see Introduction). The notion of a professional association or Order that formed the focus of medical ethics has its origins in the Ancient Greece of Hippocrates. Later in the middle ages, the world's first medical school founded in Montpellier, France (1220) assumed a role of overseeing the profession, its honour and independence and its monopoly of practice by doctors of medicine and surgeons who were grouped into "corporations". In 1845, 2000 doctors meeting in Paris agreed to the creation of a "Conseil de Discipline" (Disciplinary Council) for the medical profession and to the establishment by law of a "Conseil Médical" (Medical Council) and a "Chambre Disciplinaire des Médecins" (Medical Disciplinary Chamber) in each department (province) in the country. With the establishment in 1858 of the General Council on Medical Education and Registration in London (abbreviated to the General Medical Council), following the Medical Act of the same year, the journey towards modern day medical regulation had begun.

In its first century of existence the modes of working of the UK General Medical Council scarcely changed, there was little interest from Government and though legally there was provision for public involvement, in reality the Council was dominated by doctors. The regulatory body embodied the principles of a self-regulating profession, operating under a collegial system in which protection of its members and relations between them were considered more important than issues of protecting patients:

"Professionalism in medicine involved the organization of an elite college of equals, and in this collegial culture detailed control over the professional judgement of the doctor, once admitted to the collegial community, was inappropriate". Moran 2003.

With its Royal Colleges, ancient universities and societies of elite members, the medical profession was defined in the past more as a social group than one characterised by special skills (Moran 2003). But with the arrival of industrialisation, medical knowledge and practice were gradually transformed, by a series of technological, social and market forces into the blend of science and art that is recognised as occidental biomedicine now in the 21st century.

In spite of modernisation and in some states the removal of considerable institutional power from the profession, in most jurisdictions the regulation of medicine remains grounded in the principle of self-regulation.

The professional regulatory body or "Order"

"From the profession's perspective, the institutional expression of medical regulation is the measure of its professional power, or lack of it, as the case may be".
Salter B. Medical regulation and public trust, an international review.
Kings Fund Publishing, London, 2000.

Many (but not all) modern states have some form of professional representative organisation which aims to ensure that all members of the profession behave with probity and practice ethical medicine. These professional bodies emphasise in their mission statements the importance of the independence and integrity of the profession, and the need to observe the highest standards of morality, probity, competence and duty (boxes 12 and 13).

BOX 12: Extract from mission statement, Order of Physicians, France

France

"L'Ordre des Médecins veille au maintien des principes de moralité, de probité, de compétence et de dévouement indispensables à l'exercice de la médecine et à l'observation, par tous ses membres, des devoirs professionnels ainsi que des règles édictées par le Code de Déontologie prévu à l'Article L. 4127-1 du présent titre.

"Il assure la défense de l'honneur et de l'indépendance de la profession médicale".

"Il peut organiser toutes oeuvres d'entraide et de retraite au bénéfice de ses membres et de leurs ayants droit.

"Il accomplit sa mission par l'intermédiaire des Conseils départementaux, des Conseils régionaux et du Conseil National de l'Ordre".

http://conseil-national.medecin.fe Accessed 8/11/04

The Order of Physicians looks after the principles of morality, probity, competence and commitment in the practice of medicine and the observation by all its members of both their professional duties and the rules set out in the Deontological Code as per Article L.4127-1.

"It assures the defence of the honour and the independence of the medical profession".

"It can organise mutual support and early retirement for the benefit of its members and their dependents".

"It undertakes its missions by way of the Departmental Councils, Regional Councils and the National Council of the Order".

BOX 13: Extract from mission statement, the Official Medical Association of Barcelona.

Barcelona

"The Official Medical Association of Barcelona (COMB) was founded in 1894 to defend the collective interest of the medical profession, and to assure that it offers the best healthcare services to the public. In the last one hundred years, the organization has defended these objectives, maintaining a watchful eye on professional and ethical principles, but also adapting it's Code of Ethics to health and social changes that have transformed the face of the country in the last century."

http://www.comb.es/eng/home.htm Accessed 11/11/04

The exact roles and responsibilities of professional regulatory bodies differ considerably from jurisdiction depending on various contextual factors. We describe some of these variations in chapter 6. In spite of these differences the basic principle on which they operate is one of professional self-regulation:

Self-regulation

"Self regulation is the means by which members of a profession, trade or commercial activity are bound by a mutually agreed set of rules which govern their relationship with the citizen, client or customer. Such rules may be accepted voluntarily or may be compulsory. They will normally include a procedure for resolving complaints and for the application of sanctions against those who infringe the rules".
BRTF Self-regulation interim report, October 1999. www.brtf.gov.uk Accessed 8/11/04

There are both advantages and disadvantages with self-regulation in general but with respect to the medical profession these include:

Advantages

- Control of knowledge: only doctors have specialist knowledge of medicine. This makes it difficult for anyone else to understand in-depth the issues at stake.
- Because standards for practice are defined by the profession, these standards should best define the key issues in the practice of medicine.
- If the profession self-regulates, then the profession as a whole has an interest in maintaining its reputation. Adherence to the values and standards that make a good doctor is better secured since they are owned by the profession, rather than being imposed from outside.
- Governments may prefer the public to place blame for medical mistakes and malpractice on the profession rather than on politicians.

Disadvantages

- Competing interest: there may be public suspicion that the profession protects the interests of its members before the interests of the public. Lack of transparency in procedures may create a real or apparent lack of public accountability and trust.
- Not all doctors may appreciate the need to operate within the standards of practice expected of them.
- There may be public confusion as to how the system operates and to whom they can complain.

In effect, the need for specialist knowledge and expertise to understand the detail of many medical practice and performance issues makes at least some peer involvement

in medical regulation almost inevitable. It is difficult to imagine any fair, in-depth investigation of alleged medical malpractice without significant input from professional colleagues who have similar knowledge and experience in the field of interest. Whether or not such colleagues are involved as judge and jury as well as witnesses for defence and prosecution, remains however a matter for individual jurisdictions to determine.

Generally speaking in most European states, the machinery of the state and/or medical management are more concerned with the regulation of the health care *systems* than the regulation of medical decisions themselves. Even in states where some regulatory functions, such as holding and administering the medical register are undertaken by an arm of the Ministry of Health as in the Netherlands (box 19), the profession remains an important player in the disciplinary courts and in the recognition, certification and recertification of specialists (Swinkels 1999). It is of note however that outside Europe, in states where the market plays a dominant role, mechanisms may be introduced which attempt to take at least some control of medical decision making, as experience with the introduction of diagnostic related groups (DRGs) in the US has shown (Salter 2000).

Professionally led regulation

"Medicine is far too important a subject simply to be left to doctors. Self-regulation has been shown in the past to be a flawed model, which can lead to professions becoming increasingly isolated and losing touch with society. I know that self-regulation contributes to a loss of the public's trust in professions. A cosy club, I think, is the least of its shortcomings."
Professor Sir Graeme Catto MD, President GMC, speech to Social Market Foundation. London, 2004.

Since the 1960s several strong social trends have combined to create a force for reform of medical regulation of almost earthquake proportions in many jurisdictions. Central to this reform has been a focus on the main disadvantage of self-regulation highlighted above: the dangers of protectionism and lack of public accountability. Increasingly modern states are experiencing demand from the public for a medical regulatory system that protects the public (and is seen to protect the public) and which ensures *greater public involvement* in the processes of regulation. This has led to changes not only in the mission statement of some professional regulatory bodies, but also in the make up of their governing bodies (box 14). The term *"professionally led regulation in partnership with the public"* is sometimes used to refer to this more publicly involved form of self-regulation.

BOX 14: UK GMC – Representation on new governing body

The new streamlined Council

The Council is the GMC's governing body. Until 2003 it had 104 members and delegated much of its work, including the consideration of complaints against doctors, to numerous committees.

The new streamlined Council, which was established on 1 July 2003, consists of 35 members, 40% of whom are lay people. There are 19 elected medical members; two appointed medical members and 14 lay members appointed by the Government. The make-up of the new Council reflects the principle of professionally led regulation in partnership with the public. It will meet seven times a year, more frequently than its predecessor.

The main reasons for the change are that the smaller Council will be able to act more quickly and effectively. It includes a higher proportion of lay members than before, giving the public a stronger voice. Under the new complaints procedure, Council members will no longer be responsible for casework, as in the past, but will be able to focus on governance of the GMC.

General Medical Council – Protecting patients, guiding doctors – Annual Review 2003/4

The profession, the regulatory body and self-regulation – key points

1   The regulation of medicine is rooted in the origins of the profession and professional values.

2   Professional regulatory bodies have their origins in traditional ideas of professional values. Many have modernised their mission statements and some are increasingly involving the public in their governance.

3   There are advantages and disadvantages of self-regulation. The main advantages are that only doctors have the necessary knowledge and experience to understand medical practice issues in depth and there is professional ownership of values. The main disadvantage is that it may or may be seen to protect its members more than it protects the public.

4   Most modern medical regulatory systems either rely on self-regulation or at least incorporate self-regulation into the system, but not all have a professional regulatory body.

Chapter six

Professional and regulatory environments

Professional and regulatory environments

"Professional self-regulation is one element in the complicated relationship between the medical profession and society. For example, doctors working for the NHS are also accountable as employees and contractors. In a web of complex regulatory arrangements some tension is not only inevitable but healthy".

Sir Donald Irvine. 1997

The professional body or Order recognised internationally as a medical regulatory body (e.g. the GMC in the UK, the Ordre des Médecins in France and the Colegio de Médicos in Spain) is by definition an institution that regulates doctors. In practice however the roles and responsibilities of medical regulatory bodies are not the same from one jurisdiction to another because of variations in two wider environments: i) the medical professional environment and ii) the regulatory environment.

The medical professional environment

"Division, rivalry and, on occasions, internecine conflict are more common features of the internal organisation of medicine than are harmony, sweetness and light".
Salter B. Medical regulation and public trust. King's Fund, 2000.

The regulation of the quality of medical practice is not the only purpose of organised groups in the medical profession. Five basic or 'ideal' types of professional organisation have been described (Burrage 1990):
*   The learned society (preservation and advancement of knowledge base)
*   The certifying association (transmission and accreditation of knowledge)
*   The licensing association (professional suitability or 'fitness' to practice
    – competence and performance)
*   The representative association (lobbying)
*   The trade union association (economic negotiation)

These functions frequently overlap between different organisations, associations, societies and bodies within any given jurisdiction and add to the complexity of the regulatory system. Membership of these associations may be voluntary or obligatory, usually depending on whether the body concerned has a role in registration and licensing of practice – either as a physician or as a specialist. Lack of clarity over

demarcation lines of responsibility and power may lead to conflict within the profession and public confusion and suspicion over accountability:

The regulatory environment

The extent to which any professional regulatory body controls the different functions and processes of medical regulation is heavily influenced by the nature and forces at play in the wider regulatory environment. The regulatory environment is formed by the health care regulatory system and medical education regulatory system in each jurisdiction. For any given jurisdiction the roles of each of the players in regulation can be understood by looking at the core activity that controls medical activity: *the control of entry to and exit from the register* that grants a right to practice. This core activity is supported by the three regulatory functions of standard setting, monitoring and evaluation, and intervention, realised through the regulatory processes of standard setting, education, registration and licensing, and disciplinary procedures.

Control of entry and exit from the medical register consists of two components:
1. ***Holding the register*** and administering its day to day management (see chapter 3)
2. ***Decision-making*** as to who enters, stays and is removed

Whilst the day to day management of the register requires attention to a number of important quality assurance issues, not least of which is fraud (chapter 3), it is the control of the decision making processes around who is registered that is the most complex.

Box 15 shows some of the different bodies that may be involved in each of the two steps in controlling entry and removal from the medical register (see also box one).

BOX 15: Core regulatory processes, activities and involved players

Key process	Activities	Who is/may be responsible &/or involved*?
Holding the register	Database management including verification of identity and credentials	Competent authority** for recognition and registration of medical qualifications
Decision-making: Who enters?	Certification, registration and licensing	Competent authority for recognition and registration of medical qualifications, universities medical schools &/or national examination bodies. Competent authority for training and issuing CCSTs. Professional associations. The public
Decision-making Who stays?	Recertification reaccreditation	Competent authority for recognition and regsitration of medical qualifications; CME organisations, peer group and professional associations, health care providers, healthcare providers, health authorities/purchasers.
Decision-making: Who is removed?	Disciplinary procedures	Competent authority for recognition and registration of medical qualifications; Public law or disciplinary courts; Peer group and professional associations; health care providers; health authorities/purchasers; professional defense bodies. The public.

*where there is more than one organisation involved, the lead or responsible body varies from jurisdiction to jurisdiction
** the competent authority is determined by national legislation in EU States as being the body designated to enforce Commission legislation

In the past it was common for a professional regulatory body to be responsible for all of these functions, but with the increasing complexity in modern health care systems this is no longer practical in most societies and a variety of organisational models now exist. The model adopted by a nation state depends on historical, political and forces as well as on geography and medical demography.

Regulatory body – models of organisation
Single national body

In some jurisdictions (e.g.UK, Ireland) a professional body (or a professionally led body) remains the lynch pin in medical regulation in that it is the designated 'competent authority' for registration and licensing and in addition has responsibility for, or contributes to, all of the processes and activities in the table. Nevertheless the forces for change in regulation that we discussed in the Introduction have led to some regulatory functions being carried out by other bodies. This means there are sometimes overlaps in responsibilities between bodies and lines of demarcation between them may not always be clear (see below under comparisons and complexity).

Single national organisation, geographical devolvement of responsibilities

In some jurisdictions (e.g. France) there are national, regional and departmental (provincial) bodies with separate responsibilities for different aspects of regulation (box 16). The division of responsibilities (for registration and discipline) on the basis of administrative level has the advantage of enabling a degree of independence between these functions whilst maintaining them all within the same overall organisation.

BOX 16: Division of responsibilities between national, regional and departmental bodies, France

In France the Conseils Départementaux (Departmental councils) are administrative bodies which take responsibility for holding and maintaining the medical register, including the conditions for entry to the register and therefore the right to free medical practice. The Departmental councils fall under the direct responsibility of the Conseil National and have no disciplinary powers but scrutinise the decisions made by the disciplinary jurisdictions. The main responsibility of the Conseils Régionaux is disciplinary: for the investigation of complaints and decisions regarding sanctions where necessary. The Regional councils are the Chambers of first instance – that is, the first levels at which disciplinary decisions are taken. The Regional councils also have a role in cases of appeal against registration decisions made by the Departmental councils. The Conseil National de l'Ordre de Médecins has the responsibility for dealing with appeals against disciplinary decisions made by the Regional councils – Appeal Chamber. The National Council is the consultative body for government and represents French doctors at national and international levels.

Locally devolved jurisdiction, national coordinating body

In other jurisdictions the regulatory functions are devolved 'en bloc' to regional or provincial levels and the national bodies are umbrella-coordinating bodies (Germany, Spain). In effect each of the regional or provincial bodies form separate regulatory jurisdictions. In Spain there is a representative professional organisation, Official Medical College or Association, in each of the 52 provinces. A national umbrella organisation, the Organisation of Medical Colleges of Spain (Organización Médica Colegial de España – OMC), is a body made up by the Official Colleges, which represents registered doctors in Spain, ensuring the safeguard of basic professional values: the deontological and ethical code (box 17). The OMC comprises the General Council of the Official Medical Colleges (Consejo General de Colegios Oficiales de Médicos – CGCOM), which is made up of representatives of the 52 Official Colleges and is responsible for coordinating and representing the Colleges at national and international levels. Each of the 52 Official Colleges, regardless of the size of its membership, has one vote on the Consejo General.

BOX 17: Functions of the Official Colleges of Physicians – Spain

"Los Colegios Oficiales de Médicos son entidades provinciales que agrupan a todos los médicos que, de acuerdo con las leyes vigentes, ejerzan su profesión en cualquiera de sus modalidades públicas o privadas. Entre sus cometidos está la ordenación, representación, promoción y defensa de la profesión médica, así como la salvaguarda de sus principios deontológicos y ético-sociales, siempre en beneficio de la sociedad general y de los ciudadanos en particular.

The Official Colleges of Physicians are provincial bodies made up of all doctors who, in accordance with current legislation, are engaged in professional practice in any public or private setting. Included in their functions are the organisation, representation, promotion and defence of the medical profession, as well as the safeguard of its deontological and ethico-social principles, always for the benefit of society in general and of citizens in particular."
http://www.cgcom.org/colegios/index.htm
Accessed 12/11/04.

In Germany the self-regulatory bodies are at Regional or Länder level and there is an overarching umbrella organisation (box 18):

BOX 18: Structure and functions of the German Medical Association

Germany

"The Bundesärztekammer (BÄK) is the central organisation in the system of medical self-administration in Germany. It represents the interests of the 388,201 doctors (as at 31.12.2003) in matters relating to professional policy. As the joint association of the 17 Länder Medical Associations in Germany, the German Medical Association plays an active role in the opinion-forming process in relation to health policy in society, and in legislative procedures.

The German Medical Association arose from the Working Group of West German Medical Associations, which was founded in 1947. Today, it is the joint association of the 17 Länder Medical Associations and thus an organisational combination of public-law corporations. The individual doctor is only indirectly a member of the BÄK via compulsory membership of his or her local medical association.

The German Medical Assembly is the "parliament of the medical profession" in Germany. The Regional Medical Associations (Ärztekammern) send a total of 250 delegates to the German Medical Assembly, which is held once per year. The tasks of the German Medical Assembly include elaborating and adopting professional regulations valid for all Länder (e.g. the model professional code and the model post-graduate training regulations), as well as formulating the standpoints of the medical profession in topical health-related and socio-political debates in society, and communicating these to the public". **http://www.bundesaerztekammer.de/05/90Englisch/01_ baekbrief.html** Accessed 12/11/04

No single regulatory body

In some jurisdictions, some or all of the functions have been separated and although the profession remains a key player (particularly in disciplinary matters and specialist recognition and training), the functions of the competent authority for registration and licensing are assumed by a government department. In the Netherlands a branch of the Ministry of Health known as the BIG register takes responsibility for holding and assuring the quality of the register of all registered health professionals (box 19). Applicants to the register must fulfil (and provide sound documentation of) the legal

requirements for assuming the title of their profession, especially the training requirements. The BIG register department is the competent authority for registration and licensing of physicians, but although it works closely with other bodies it does not play a role in *decision-making* regarding training standards (responsibility of education and training bodies), specialist recognition and registration (responsibility of professional associations) or disciplinary sanctions (the Disciplinary Board, the Health Care Inspectorate and the law courts).

BOX 19: Overview of the Health Care Professions (BIG) Act – Netherlands

In The Netherlands, eight health care professional groups (doctors, dentists, pharmaceutical chemists, clinical psychologists, psychotherapists, physiotherapists, midwives and nurses) are all regulated under a single Act of Parliament the Individual Health Care Professions Act known by the acronym of the Dutch words as the BIG Act (Wet BIG). This Act was introduced in 1993 and replaced twelve previously existing statutory regulations governing these health care professions. The principle of this Act was to lift the ban on the unauthorised practice of medicine, which was seen as out of date. The Act focuses on the quality of professional practice and patient protection and although it lifts the ban on the unauthorised practice of medicine, it restricts the performance of certain procedures and protects the use of titles such as "Doctor":

"A person is who needs health care is free to go to the health provider of his or her choice. This may be a 'mainstream' care provider or an 'alternative' care provider. The basic principle behind the BIG Act is that the practice of medicine is open to all. However, some procedures, the so-called reserved procedures, may only be carried out under specified circumstances. It is also a serious criminal offence to harm a patient's health. Furthermore, there are restrictions on the use of titles associated with a small number of professions that are additionally covered by professional disciplinary rules".
Het Register van Beroepen in de Individuele Gezondheidszorg, Ministry of Health, Welfare and Sport, The Netherlands.

Comparisons and complexity

There is an argument that separating the different regulatory functions (especially registration and disciplinary procedures) and indeed separating some aspects of disciplinary procedures from others (e.g. investigation from sanctioning) may lead to greater accountability.

As the examples show, separation of function can occur either 'vertically' – different organisations at the same administrative level of the jurisdiction undertake different functions, or 'horizontally' in that the jurisdiction divides the functions according to administrative level (national, regional, provincial) but maintains all within a single national organisation.

Comparisons of medical regulation between one nation State and another are difficult because there may be differences in both of these kinds of separation in function: For instance in the UK the professional regulatory body is a single, unified, national organisation whereas in Spain there are 52 provincial regulatory bodies – a difference in horizontal organisation. But there also is a vertical difference: whereas in the UK the GMC has control over all decision-making regarding entry to, maintenance on and erasure from the medical register, in Spain the professional bodies in each of the 52 jurisdictions do not have as many powers. The Spanish medical colleges are the competent authorities for registration and licensing, as well as the bodies that set ethical standards and take disciplinary action when physicians are in breach of these standards. Complaints seeking financial compensation for health damage are more likely however to be dealt with by the law courts (civil, criminal and administrative etc). The criminal courts have powers (independent from the medical colleges), to suspend doctors from the medical register, whereas the medical colleges can suspend doctors and are the only bodies with powers to permanently erase a doctor from the register. Additionally in some jurisdictions (e.g. Barcelona) these bodies may also have a role in defending doctors in cases of litigation and assume a variety of other professional control and representative functions.

A subject of current debate in Spain is whether registration with the medical college is obligatory for medical practice, when a doctor is employed by the public health service and is therefore a funcionario or civil servant. Because Spain is divided into geographical and political territories (Autonomous Communities), laws regarding registration vary from one Region to another: in some Regions (e.g. Andalucia, Cantabria and Extremadura) doctors employed by the public health sector do not have to be registered with the college, even if they have direct clinical responsibilities. In other regions (Galicia, Castilla-La Mancha, Canaries) doctors must register if they have direct clinical duties, but doctors whose work is entirely administrative, managerial or in preventive or forensic medicine do not need to be registered.

In the remaining regions (e.g. Madrid, Valencia or Catalonia to date) registration with the college is obligatory for all doctors who represent themselves to the public in any way as a doctor, regardless of whether their responsibilities are clinical or non-clinical. These differences between Regions have created a situation of heterogeneity within Spain although this does not seem to have had implications on mobility of doctors within the country. Since this issue is tied in with the politics of devolution of power, it is a topic that is likely to remain contested for some time.

Whatever organisational model a jurisdiction adopts, there is potential for confusion, because of the multiple overlapping regulatory functions that may be performed by other players in the regulatory environment. The following statement reflecting on complexity in the regulatory environment in the UK is not an uncommon situation in other jurisdictions:

"While conducting this review, we found it very difficult to identify a clear overview of the system of regulation. This was true of not only the self-regulatory arrangements, but also the state's controls and provisions: The confusing array of bodies with difficult to define responsibilities creates several problems. For example, we felt that it was difficult for a patient to know where and to whom to address complaints about their family doctor… We also thought that confusion about the roles and powers of different bodies contributes to dissatisfaction with (and increasing mistrust of) the system". Better Regulation Task Force: Alternatives to State Regulation: Case study General Practitioners. July 2000.

This quotation from a review of regulation of UK general medical practitioners by an independent advisory Task Force set up to advise the British Government on improving regulation shows that maintaining clarity in a complex and constantly changing environment can be very challenging.

The Task Force set out a series of principles or criteria to guide a good regulatory system and we describe these in chapter 8.

Professional and regulatory environments – key points

1   The roles and responsibilities of professional regulatory bodies (where they exist) differ from jurisdiction to jurisdiction and depend on the medical professional and the regulatory environments in which they are embedded.

2   Functions of medical professional organisations include the preservation and advancement of knowledge, the transmission and accreditation of knowledge, accreditation and licensing, lobbying and economic negotiation. Only some of these are regulatory functions and there may be duplication and overlap between different associations, creating confusion and conflict.

3   The regulatory environment is formed by the health care system and medical education regulation in each jurisdiction. Regulation of medical professionals centres on the core activities controlling entry to, maintenance on and erasure from the medical register.

4   Regulatory functions can be separated horizontally – by administrative level, or vertically – different organisations or a mixture of the two. The exact model adopted varies between nation States and depends on historical, political and demographic forces.

5   The number of organisations involved in these regulatory functions and the degree of control the medical profession has over them is varies from jurisdiction to jurisdiction.

Chapter seven

The international environment

The international environment

7

"We found that hospital practice in the NHS has become increasingly dependent on doctors who trained overseas: they represent 15% of consultants appointed during 1964-91 and 24% of those appointed since 1991. These doctors comprise a particularly high percentage of consultants in geriatric medicine, psychiatry, learning disability, and genitourinary medicine."

Goldacre et al 2004.

Globalisation and medical mobility

The advent of globalisation has brought with it increased mobility of individuals and medical professionals are no exception to this trend. There are several reasons why a doctor may move to practice medicine in another country:

- Improved pay and conditions
- Improved employment opportunities
- Improved training opportunities
- Force of circumstance (refugees)
- Personal reasons

Counterbalanced against these pressures for migration are barriers that include language, culture, problems with recognition of qualifications and bureaucracy.

Medical mobility in Europe

European legislation allows for the free movement of professionals within the European Economic Area (EU Member States plus Norway, Iceland and Liechtenstein). The system which is based on *mutual trust* was established as a matter of principle in the signing of the Treaty of Rome in 1957, and adopted as legislation following a Directive in 1975 and supplement in 1986. In 1993 this legislation was amalgamated into a single Council Directive 93/16/EEC to *"facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications".* (http://europa.eu.int/scadplus/leg/en/lvb/l23021.htm). In February 2004 the European Parliament agreed with the European Commission's proposal of 2002 to replace the original sectoral directives by a single general system – this means that it is likely that in future the mobility of doctors will be covered by the same legislation as the mobility of all other professionals i.e. there will be no separate 'Doctors' Directive'.

Challenges of increased mobility

Although there is limited information on the extent of movement of professionals around the world, this is nevertheless an area of increasing concern to both the public and medical profession as it is clear that some countries can be considered as net 'importers' of doctors whereas others 'export' doctors. Within Europe, the UK has in recent years been the biggest importer of doctors following a widespread (and somewhat criticised) recruitment campaign overseas.

Mobility of doctors creates tensions in which governments, regulatory bodies, health care professions and the public must balance potentially conflicting imperatives:

- To maintain standards and protect the public when doctors change regulatory jurisdiction
- To avoid a brain drain of valuable human resources from countries of origin
- To facilitate mobility and exchange of professionals

Definitions

Before considering the specific regulatory issues involved in medical mobility, it is important to be aware of problems of definition:

Definitions of title

a) Doctors

Although most countries have a more or less common understanding of what is meant in general terms by a medical doctor, there is variation between States as to when a person trained in conventional medicine (as opposed to complementary or alternative therapies) can call themselves a doctor. For instance in the UK as soon as a medical student has passed their university qualifying examination they are entitled to assume the title of 'Dr', whereas in Germany doctors cannot assume the title of Dr.Med. until they have written a thesis (Nicholas 2004). In addition differences in the licensing systems means that in some states (e.g. the Czech Republic and Slovenia) there is no primary medical qualification (PMQ) and doctors are only granted a licence to the free exercise of medicine after they have completed specialist or general medical practice training (Brettenhaler 2001).

b) Specialists

The picture is even more complicated for definitions of a specialist. Currently 52 medical specialities are recognised by the EU medical Directive but only 17 of these are common to all Member states and 26 common to 2/5 of the 25 (i.e. 10 countries). Even where the definition of a specialist coincides between Member states there is still wide variation in the qualifications and accreditation procedures required to be registered as a specialist.

Definitions in regulatory terms

As we described in the introduction, differences in the meaning and use of various terms used in medical regulation (e.g: qualification, certification, registration, accreditation and validation) between (and often within) jurisdictions makes comparisons and attempts to find equivalents challenging.

Mobility and medical regulation
Standards
a)   Ethics

Ethical and professional codes for the practice of medicine are common in many countries as a study of applicant countries to the EU found (Brettenhaler 2001). Rules of conduct usually cover issues such as conscientious patient care, confidentiality and adequate documentation. As we discussed in chapter 1 these codes of conduct nevertheless tend to be rather vague and as a result lead to wide variations in interpretation. Add to this differences in cultural and social norms and it is easy to understand why there is a wide variation between countries in what are considered to be a sanctionable offences (Brearley 1999).

b)   Competency and performance

Although the distinction between the concepts of knowledge, competency and performance are also generally agreed upon, it is much more difficult to decide on what are acceptable standards for these at the different stages of the medical career. We have seen that there can be many conflicting interests, both inside and outside the profession, involved in setting and monitoring these standards even within a single jurisdiction, so finding common ground between jurisdictions is even more challenging (see below).

Education

"Faced, therefore, with earnest speculation about whether the accession countries meet the standards of the Directives, one might be tempted to ask 'What standards?' The danger is that, until these is greater transparency and more support for work to fill in the gaps, the trust on which the sectoral system is supposed to operate will not be there". Nicholas 2004.

As described in chapter 2, the World Federation for Medical Education has set standards for the processes of medical education, but as the WFME themselves state these are guidelines rather than prescriptive. It is difficult to agree minimum standards for the training required to meet minimum standards of knowledge, competency and performance – since these have not been set in many single jurisdictions. The current training requirements for recognition as a medical professional in an EU member state are shown in box 20. Training requirements for specialities and general practice detail

only the length of time that should be spent in training and the types of educational establishment in which such training should occur.

BOX 20: Extract from European Union Council Directive on medical training

Title III Coordination of provisions laid down by Law, Regulation or Administrative Action in respect of activities of doctors
Article 23
1. The Member States shall require persons wishing to take up and pursue a medical profession to hold a diploma, certificate or other evidence of formal qualifications in medicine referred to in Article 3 which guarantees that during his complete training period the person concerned has acquired:
a) Adequate knowledge of the sciences on which medicine is based and a good understanding of the scientific methods including the principles of measuring biological functions, the evaluation of scientifically established facts and the analysis of data.
b) Sufficient understanding of the structure, functions and behaviour of healthy and sick persons, as well as relations between the state of health and physical and social surroundings of the human being.
c) Adequate knowledge of clinical disciplines and practices, providing him with a coherent picture of mental and physical diseases, of medicine from the points of view of prophylaxis, diagnosis and therapy and of human reproduction.
d) Suitable clinical experience in hospitals under appropriate supervision.

2. A complete period of medical training of this kind shall comprise at least a six-year course or 5 500 hours of theoretical and practical instruction given in a university or under the supervision of a university.
http://europa.eu.int/scadplus/leg/en/lvb/l23021.htm

Envisaged changes to EU legislation intended to simplify processes around mobility in the enlarged Union may have serious implications for the extent of professional involvement in future standard setting for medical training in Europe: When the Directives regarding medical mobility were initially adopted by the EU, expert advisory committees (for medicine, the Advisory Committee on Medical Training – ACMT) were

also established to ensure that comparable standards were maintained in different member states. In addition, a Committee of Senior Officials in Public Health (CSOPH) was established to oversee the implementation of the medical Directives. It has long been recognised the ACMT has become largely defunct (Nicholas 2004) and with the proposed replacement of the 'sectoral' Directives with one single general Directive, all expert advisory committees are to be abolished. Concern has been raised by the profession that their voice should continue to be heard in standard setting procedures. Resolutions proposed by the European Parliament may go some of the way to meet these concerns (European Union of Medical Specialists website Accessed 9/11/04).

Registration and licensing

Registration and licensing of doctors is the key regulatory process and it is therefore important that a competent authority for purposes of registration and licensing is visible in every country. EU legislation requires Member states to designate *"authorities and bodies competent to issue or receive the diplomas and certificates and other evidence of formal qualifications"*.

Transparency of the registration process is very important and a clear delineation of procedures to ensure the quality of registration (e.g. reducing fraud, ensuring validity of qualification etc – see chapter 3) will enhance trust between jurisdictions.

The extent to which a competent registration authority gets involved in wider regulatory purposes is a matter for the social and political forces within the medical profession, health care system and medical education regulatory environments in each country.

It is important for countries that are or who are likely to be net importers of doctors, to provide accessible information for incomers on requirements and procedures for registration and licensing in the country, indeed this is part of current EU legislation. Induction training and orientation to the system for the incoming doctors is also an important consideration for countries interested in recruiting doctors from overseas. Some complementary awareness and sensitivity training for host health institutions to the needs of outsiders may also be useful. Finally it is important that incoming doctors are informed of the standards of ethics and practice in the host (receiving) country (see below).

Disciplinary matters

When a doctor moves from one medical regulation jurisdiction to another it is important that the host (receiving) competent authority is aware of all relevant information regarding that individual's right to practice. Although all host authorities currently ask for certificates of good standing from the competent authority of origin, because of variations in data protection legislation in different states, there is still

potential for problems, of which fraudulent documentation is only one. For instance a doctor may be undergoing investigation in an authority of origin where national laws forbid the publication of such investigations before a decision is reached. Equally an individual may have been subject to a sanction (or even temporary removal from the register) in the past but has now been reinstated. The law in some jurisdictions does not allow for publication or transmission of information about past offences. It is important that enthusiasm to promote free mobility is matched by a similar enthusiasm to protect patients by ensuring that information about individuals who are unfit to practice is transmitted effectively and efficiently.

Another issue that may lead to debate involves the issuing of sanctions for acts which are considered to be offences in some states but not in others (e.g. termination of pregnancy, euthanasia). In these cases the issue at stake is not the nature of the act or offence, but the fact that the doctors contravened a state law or professional code, knowing that such an act was illegal or considered unethical in that state.

In addition to certificates of good standing, information sharing may be facilitated by electronic mail and telephone since these guarantee up to date information. A recent pilot initiative by the GMC and Medical Council of New Zealand found this gave a number of advantages compared with the traditional system, including enhanced speed, security of data and improved communication between regulators. A second pilot scheme in which regulators from Australia, Egypt, USA, South Africa and the UK are participating, involves the development of a web-based, encrypted database for the proactive exchange of information on problem doctors, but this scheme also has a number of problems which will need to be overcome before it can be more widely used.

Standards and the brain drain

"Despite his cheerful manner Lithuania's health minister Juozas Olekas faces a serious problem—how to keep doctors in the country. According to the ministry's own research, 61% of doctors in training and 27% of practising doctors said they wanted to work abroad once the Baltic country joins the European Union this May, along with nine other states. Of those, 15% of doctors in training and 5% of practising doctors firmly intend not to return". Krosnar 2004

It is natural that countries who are net importers of physicians from other states should also be at the forefront of setting standards in medical regulation to assure and enhance public safety. But it is salutary to remember that policies of active recruitment from other countries and of pressure on those countries to improve standards of training can lead to unintended knock-on effects. Given that the countries with shortages of doctors are invariably those which offer higher salaries than those who

have a surplus of doctors, this has created a tension in countries which potentially face the loss of some of their most highly skilled and valuable personnel:

"The risk of brain drain could be the most important disadvantage of enlargement for the Polish health care system. Moreover, the group of potential emigrants most likely to leave would be the youngest and the best qualified nurses and doctors".
Zajac 2004.

The International Association of Medical Regulatory Authorities (IAMRA)

"IAMRA strives to be responsive to the needs and future direction of medical regulatory authorities worldwide. Communication, participation and interaction by all are deemed paramount to the true success of this international collaboration.
Purpose: To support medical regulatory authorities worldwide in protecting the public interest by promoting high standards for physician education, licensure and regulation, and facilitating the ongoing exchange of information among medical regulatory authorities".
http://www.iamra.com/ Accessed 12/11/04

With international mobility of physicians now a reality, the importance of endeavouring to reach international agreement on what constitutes minimum and preferred standards in education, registration and licensure and communication of relevant information on status is becoming increasingly urgent. The work of IAMRA is of central importance to this goal as is the work of other international professional bodies some of which are listed in the appendix.

Work is currently underway by members of IAMRA to develop a 'Fast Track Credentialing System' to facilitate international mobility between some countries, but the universal meeting of common international standards on education and training is a long way off.

International recruitment drives by wealthier countries has raised thorny issues of international workforce planning as some developing countries are currently contemplating lowering their standards in order to prevent developed nations from poaching all their professionals! Such an array of challenges to the development of a fair and just regulatory system in *all* jurisdictions can only be met through fruitful international collaboration and cooperation.

The international environment – key points

1 EU legislation allows for free movement of professionals within the EEA and mutual recognition of qualifications based on trust

2 Differences in definitions of title and specialist can make international comparisons difficult

3 Although all jurisdictions have ethical codes, sanctionable offences may be different standards of competency and performance have not been agreed inter nationally

4 All EU Member states are required to identify a competent authority for registration and licensing. Quality assurance of registration procedures will enhance trust between States

5 Current mechanisms for ensure good standing of doctors moving jurisdictions have loopholes. Initiatives to improve communications between competent authorities include the use of electronic mail and web-based, encrypted databases.

6 Recruitment by richer countries of the best qualified doctors from poorer countries can drain the poorer countries of valuable human resources

7 IAMRA is a key player in working towards harmonising medical regulation internationally and developing mechanisms for the exchange of information between regulators.

Understanding Medical Regulation – A guide to good practice

Chapter eight

Developing a sound and sustainable medical
regulatory system

Developing a sound and sustainable medical regulatory system

8

"Medicine used to be simple, ineffective and relatively safe. Now it is complex, effective and potentially dangerous"

Professor Sir Cyril Chantler 1999.

It is not easy to create a good medical regulatory system that is capable of responding flexibly to the constant pressures placed on it by evolving social and technological demands. Faced with pressures from the public for more and better health care, from the profession for control of traditional power bases and from the market for increased liberalisation, governments seeking to establish or improve their regulatory system may find themselves steering through a minefield of vested interests.

In section one we outlined the functions and processes of a regulatory system and in chapters 5 and 6 we described the traditional institutions and systems in society that may deliver these.

We have seen that:
- Regulation of medicine is embedded in professional values
- Self-regulation usually forms a component of a fair system
- A professional regulatory body of some form is commonplace in modern states but the extent of its responsibilities varies depending on the professional and regulatory environments
- Increasing public demand for transparency and accountability is leading to new models of the governance of regulation including increased public involvement in decisions about who enters, stays and is removed from the medical register
- New methods of ensuring quality of regulation incorporate a proactive system of surveillance of medical practice standards rather than relying on complaints to identify problems

There will always be wide variation in opinion as to how much a government should seek to impose external rules for regulating the medical profession, but whatever system is chosen it is important that it enjoys public confidence.

Five basic principles of good regulation have been identified by the UK's Better Regulation Task Force and these are a useful tool for assessing the quality of a regulatory system:
- Accountability
- Transparency
- Targeting
- Consistency
- Proportionality

Accountability

In a theoretical and ideal system of regulation there would be a clear line of accountability from the setting of standards, to monitoring and assessment of performance against those standards through to taking action according to the results of the assessment of standards. In practice there are many processes and functions involved in medical education and clinical and research practice (see box 16) so more than one line of accountability is necessary.

Since control of the register – and the decisions about who enters, stays and is removed from it – is the central activity of medical regulation, it is important that lines of accountability can be traced to this control from *any point* within the regulatory system. For instance, whoever is responsible for determining standards of basic medical practice should also be responsible for assessing whether medical education processes are adequate to prepare students to meet those standards and if they are not adequate, that body should have powers to require improvements in the education processes and/or refuse access to the register to those students not meeting the standards.

A review of regulation of general medical practitioners in the UK highlighted that lines of accountability for professional competence and performance should be clearly differentiated from lines of accountability for contractual duties.

Transparency

"Currently, we think that the range of different bodies having responsibility for overlapping areas may be resulting in confusion and inaction". Better Regulation Task Force: Alternatives to State Regulation: Case study General Practitioners. July 2000.

Since there may be any number of professional bodies, educational institutions, and health care providers and purchasers at local, regional and national levels involved in the different regulatory functions (see table), there is great scope for duplication, obfuscation and confusion.

A transparent system will make clear to all (public and profession) the different regulatory standards, the methods of assessing them, the bodies responsibly for their assessment and the outcomes of any assessments – whether positive or negative. A good regulatory system will ensure that responsibilities for the different regulatory functions and processes are clearly demarcated between different organisations – mission statements of organisations participating in the regulatory system should be explicit and openly communicated to all – including the general public.

In addition to having a well-developed communications strategy (box 22), a regulatory body should also make clear to the public the way in which it is governed (box 14) and financed (box 21):

BOX 21: Funding of the General Medical Council – Ireland

Funding
"The Medical Council is funded exclusively by the annual payments of registered doctors; no funds are received from government or other sources. The annual retention fee for a fully registered doctor has been set at Euros 340 since 2003.

On 6th June 2003 there were, in total 16,060 doctors, of the various registration categories, registered with the Medical Council."
Medical Council of Ireland: http://www.medicalcouncil.ie/
Accessed 3/9/04.

BOX 22: Key components in a communications strategy – Albania

Communication strategies
Key components of a communications strategy are:
• Clear identification and articulation of mission and functions of the regulatory organisation
• Identification of key interested parties "audiences"
• Key messages to be communicated
• Most effective methods of communicating the messages

Zahir K, Smith G. Communication Strategy for the Order of Physicians of Albania, HLSP Consulting, 2003.

Targeting

A good regulatory system will be clear about who and what it is regulating, it will have defined goals and objectives and indicators to assess the extent to which those goals are achieved. As we have described in the relevant chapters, standard setting, education and disciplinary procedures themselves involve the establishment and maintenance of quality assurance (QA) systems: a sound regulatory system will have in-built procedures for QA of educational processes, certification and re-certification processes, as well as QA of competency and performance validation and revalidation.

Consistency

It is important that a regulatory system sets standards that dovetail with other rules and regulations within the wider environment – for instance other professions, government bodies and other similar bodies in other states. There should also be procedures in place for ensuring that decisions made for one problem are consistent with other similar problems dealt with by the system.

Proportionality

A system will be respected by both public and profession alike if it is seen to give due credence to the concerns of the public, to deliver fair sanctions that are in proportion to the nature of the offence and not to overburden the profession with unnecessary bureaucracy.

Developing a sound and sustainable medical regulatory system – key points

1   Five principles of good regulation are: accountability, transparency, targeting, consistency and proportionality.

2   Accountability and transparency are particular problems in the self-regulation of doctors, but external rules should not be so heavy as to reduce trust in doctors' personal professionalism.

3   Whatever system of regulation is adopted its key aim should be to enjoy public confidence.

Conclusion

Conclusion

There can be no one right way of organising a high quality medical regulatory capacity. Any system must operate in the context of rapidly changing and highly politicised environments in which relations between public, profession and governments are in constant flux. We have seen that one of the main challenges is to develop and govern a system in which key responsibilities and lines of accountability are clear to all players. The table in Appendix one may help as a focal point for considering key issues in medical regulation, for harnessing discussions and for finding a workable route through the web of complexity. External regulatory systems undoubtedly have an important role, but adopting a light-handed approach can foster greater internal control by capitalising on doctors' sense of individual professionalism.

No medical regulatory capacity will ever be perfect, but the dialogue and relationships that govern its development will determine its success in meeting the overriding objective of a good system: that it enjoys a **sustained public confidence.**

References

References

Brearley S. Regulation of doctors in the European Economic Area – types of misconduct, disciplinary machinary and exchange of information. Report to the Conference Internationale des Ordres. November 1999.

Brettenhaler R, Wallner F, Pruckner MM. Analysis of the health care systems of the accession countries and the possible consequences for the accession negotiations. Standing Committee of European Doctors, 2001 http://www.cpme.be/

Burrage M, Jarausch K, Siegrist H. An actor based framework for the study of professions. In: Burrage M, Torstendahl R, eds. Professions in theory and history: rethinking the study of professions. London: Sage, 1990.

Canadian Medical Association. Professionalism in Medicine. CMA series of health care discussion papers.

Chantler C, The second greatest benefit to mankind. Clin Med 2002;2:544-53.

Chantler C, The role and education of doctors in the delivery of care. Lancet 1999;353:1178-81.

Committee of Inquiry into the Regulation of the Medical Profession. Report. London:HMSO,1975. (Cmnd 6018; Merrison Committee report).

Diwarker V. Commentary: The baby is thrown out with the bathwater. BMJ 2002;325:695-696.

European Union of Medical Specialists. D 0416. Professional recognition directive – vote of the European Parliament. www.uems.net (accessed November 9th 2004).

Fineschi V, Turillazzi E, Cateni C. The new Italian code of medical ethics. J Med Ethics 1997; 23:239-44.

General Medical Council. Good Medical Practice. GMC, London 2001.

General Medical Council. Tomorrow's doctors. GMC, London 2003.

Goldacre MJ, Davidson JM, Lambert TW. Country of training and ethnic origin of UK doctors: database and survey studies. BMJ 2004;329:597-600.

Groenewegen PP, Dixon J, Boerma WGW. The regulatory environment of general practice: an international perspective. In: Saltman Rb, Busse R, Mossialos E. Regulating entrepreneurial behaviour in European health care systems. European Observatory on Health Systems and Policies series, World Health Organisation. Open University Press, 2002.

Irvine D. The performance of doctors: i:professionalism and self-regulation in a changing world. BMJ 1997;314:1540.

Irvine D. The performance of doctors: the new professionalism. Lancet 1999; 353:1174-77.

Krosner K. Could joining the EU club spell disaster for the new members? BMJ 2004; 328:310

Lempp H, Seale C. The hidden curriculum in undergraduate medical education: qualitative study of medical students' perceptions of teaching. BMJ 2004;329: 770-773.

Leung W-C. Competency based medical training:review. BMJ 2002; 325:693-5.

Loefler I. Why the Hippocratic ideals are dead. BMJ 2002; 324:1463.

Miller GE. The assessment of clinical skills/competence/performance. Acad Med1990;65:563-7.

Moran M. The British Regulatory State. Oxford University Press. Oxford, 2003.

Nicholas S. The challenges of the free movement of health professionals. In: McKee M, MacLehose L, Nolte E, eds. Health policy and European Union enlargement. European Observatory on Health Systems and Policies series, World Health Organisation. Open University Press, 2004.

Paul C. Internal and external morality of medicine: lessons from New Zealand. BMJ 2000;320:499-50.

Rizo CA, Jadad AR, Enkin M. Doctors should be good companions for people? BMJ 2002;325:711.

Roddy E, Jones E, Yeager AL. On Hippocrates. BMJ 2002; 325:496.

Salter B. Change in the governance of medicine: the politics of self-regulation. Policy and Politics, 1999,27:144-45

Salter B. Medical Regulation and Public Trust. An International Review. King's Fund Publishing, London 2000.

SHM. An analysis of international medical recertification models, Research report submitted to the General Medical Council. October 2003.

Southgate L. Dauphinee D. Maintaining standards in British and Canadian medicine: the developing role of the regulatory body. BMJ 1998;316:697-700.

Stone J. Professional codes of ethics. In: Allsop J and Saks M, Eds. Regulating the health professions. London; Sage 2002.

Swinkels JA. Reregistration of medical specialists in the Netherlands. BMJ 1999;319:1191-2.

United Nations. Universal Declaration of Human Rights. 1948. www.un.org/Overview/rights/ (accessed 16th November 2004).

World Federation for Medical Education. Basic Medical Education, WFME Global Standards for Quality Improvement. WFME Office: University of Copenhagen, Denmark 2003.

World Federation for Medical Education. Postgraduate Medical Education, WFME Global Standards for Quality Improvement. WFME Office: University of Copenhagen, Denmark 2003.

World Federation for Medical Education. Continuing Professional Development (CPD) of Medical Doctors. WFME Global Standards for Quality Improvement. WFME Office: University of Copenhagen, Denmark 2003.

Zajac M. Free movement of health professionals: The Polish experience. In : Health policy and European Union enlargement. McKee M, MacLehose L, Nolte E. European Observatory on Health Systems and Policies World Health Organisation 2004.

Websites

Websites

International organisations

Foundation for Advancement of Medical Education and Research (FAIMER)
http://imed.ecfmg.org/

International Association of Medical Regulatory Authorties (contact details of
70 organisations in 29 countries). www.iamra.com

United Nations Declaration of Human Rights. http://www.un.org/Overview/rights

World Federation for Medical Education www.wfme.org

World Health Organisation Directory of Medical Schools
http://www.who.int/hrh/wdms/en/

European organisations

European Federation of Salaried Doctors http://www.fems.net/index.htm

European Union legislation on mutual recognition of qualifications
http://europa.eu.int/scadplus/leg/e

European Union of Medical Specialists http://www.uems.net

Standing Committee of European Doctors http://www.cpme.be/

National organisations

Accreditation Council for Graduate Medical Education (USA)
http://www.acgme.org/acWebsite/home/home.asp

Barcelona Medical Association www.comb.es

British Medical Association http://bma.org

Canadian Medical Association http://www.cma.ca

College of Physicians and Surgeons of British Columbia
https://www.cpsbc.ca/cps

Federation of State Medical Boards (USA) http://www.fsmb.org/
General Medical Council www.gmc-uk.org

German Medical Association http://www.bundesaerztekammer.de/

Medical Council of Ireland http://www.medicalcouncil.ie/

Netherlands Ministry of Health, Welfare and Sports
http://www.minvws.nl/en/themes/individual_health_care_professionals/

Order of Physicians, France
http://www.conseilnational.medecin.fr/?url=mission/index.php#
Accessed 8/11/04

Organisation of Medical Associations, Spain
http://www.cgcom.org/cgcom/que_hacemos/index.htm

Professional and Linguistic Assessment Board test (PLAB – UK entry exam for overseas
qualified doctors) http://www.gmc-uk.org/register/plab.htm

Specialist Training Authority UK http://www.sta-mrc.org.uk/index.html

UK Department of Health information on professional appraisal in the National
Health Service
http://www.dh.gov.uk/PolicyAndGuidance/HumanResourcesAndTraining/
LearningAndPersonalDevelopment/Appraisals/fs/en

UK Better Regulation Task Force http://www.brtf.gov.uk/

Public inquiries into medical scandals

The Bristol Royal Infirmary Inquiry: http://www.bristol-inquiry.org.uk/
(Inquiry into the care of children receiving complex heart surgery at the Bristol Royal
Infirmary, Bristol, UK).

The Shipman Inquiry: http://www.the-shipman-inquiry.org.uk/home.asp
(Inquiry set up to investigate what changes should be made to current systems to
safeguard the public in the future, following the conviction of the former British
general practitioner Dr Harold Shipman for the murder of 15 of his patients).

The Cartwright Inquiry: http://www.womens-health.org.nz/cartwright/
cartsummary.htm
(Inquiry into the case of a doctor in a New Zealand Hospital alleged to have
withheld treatment on about 40 women with cervical cancer so that he could study
the natural history of the disease).

The Lourdes Inquiry: http://www.womenshealth.org.nz/cartwright/
cartsummary.htm
(Inquiry set up to investigate the high rate of peripartum hysterectomy in the
Maternity Unit of Our Lady of Lourdes Hospital, Drogheda, Ireland. The Inquiry
will report its findings to the Minister for Health and Children with a view to
preventing a recurrence of such events).

Appendices

Appendix one
Appendix two

Appendices

Appendix one: Understanding medical regulation – key points

Setting the context

1. Medical regulation involves relationships between the public, the medical profession and government. These relationships are in constant tension.

2. Regulation of doctors should be seen against the backdrop of regulation of the wider health care and medical education systems in which the profession is embedded.

3. Regulation involves setting standards, monitoring against those standards and taking a course of action (intervention) dependent on the outcome of that monitoring.

4. Regulatory processes include standard setting, education, registration and licensing, and disciplinary procedures.

5. Medical regulation is very complex and where historically one regulatory body could undertake everything there are now several players in the regulatory landscape.

6. The more players there are, the greater is the potential for duplication of activities between different organisations, nationally, regionally and locally. This can cause confusion, obscure lines of accountability and render the system inefficient.

7. Differences between regulatory systems in different jurisdictions can make international comparisons difficult.

8. Regulation can be external or internal or a combination of these. External regulation involves setting explicit standards, monitoring activities and imposing interventions. Internal regulation is based on individual interpretation of a set of values derived from professional ethics. If external regulation is too heavy-handed it may jeopardise the effectiveness of personal professionalism as a regulatory tool.

9. The medical regulatory environment is in constant flux. Forces for change include: increasing public expectations and knowledge, the growth of EBM, challenges to conventional (occidental) biomedicine, pressures for resource effectiveness and changes in the way the health care system is planned and financed.

Standards

10 Although an exact definition of a good doctor is impossible, it is important to have standards of ethics and practice as these form the cornerstone of a regulatory system that protects the public from incompetent and unscrupulous practitioners.

11 Codes of ethics vary around the world and although their development is usually led by the medical profession, increasingly the public is becoming involved.

12 Standards of practice now differentiate knowledge, from competency and performance. Competency can by understood as 'can do, and performance as 'does do'.

13 Standards and types of expected competencies change as the professional moves through their career and are a measure of a doctor's ability to engage in reflective practice.

14 Given the complexity of medical regulation systems, it is important that lines of accountability between standard setting, monitoring and intervention are very clear.

15 The ultimate sanction in medical regulation is removal of the right to practice (or refusal to grant this right in the first place). The body charged with this statutory responsibility is therefore the key player in the regulatory system. All regulatory processes within the system, must link up explicitly with the process of licensing or removal of licensure.

Education

16 The medical education system must be of a sufficient standard to ensure that competent and caring doctors are trained.

17 The World Federation for Medical Education has published a trilogy of standards for i) undergraduate, ii) postgraduate and iii) continuing medical education. These standards are basic or minimum standards and quality development standards.

18 To ensure effective regulation of practitioners entering the profession, the process of assuring quality of medical education at undergraduate level should be tied in with the process of granting a legal licence to practice.

19 A variety of organisations may be involved in setting standards, assessing and accrediting specialist practice. It is important that lines of accountability are established and clear to the public. Mechanisms for ensuring proper registration of this data should also be put in place.

20 The medical profession takes the lead in the development of continuing professional development programmes but the individual doctor also assumes personal responsibility for their own programme.

21 CPD programmes which are tied into conditions of re-issuing of a license to practice are currently being developed and implemented in a number of countries as a further quality assurance mechanism.

Registration and licensing

22 A medical register records the right to practice medicine, distinguishes the qualified from the unqualified and provides evidence of a doctor's good standing and continuing competence.

23 The control of entry to, maintenance on and exit from the medical register is at the core of medical regulatory activities and consists of a) holding the register and b) decision-making about who enters, stays and is removed from it.

24 The registration and licensing process (holding the register) involves verification activities as well as activities concerned with the mechanisms of registering, re-registering and de-registering doctors.

25 Quality assurance of the registration process must pay attention to the type, quality and validity of the information it holds on doctors, liability to fraud and issues of public accessibility to the database.

26 Liability to fraud can be reduced by increasing reliance on electronic records, unique identifiers, photo-ID and improved communication between regulators in different jurisdictions.

Disciplinary procedures

27 Professional misconduct and poor performance are the reasons for instituting disciplinary procedures, but definitions vary between jurisdictions and involve value judgements.

28　Many factors may contribute to poor performance, including ill health, inappropriate or inadequate education, structural or health system problems and personal problems. An understanding of the underlying reasons is vital to deciding on the most appropriate intervention – remediation and/or sanction.

29　Poor performance can be brought to light either through a pro-active monitoring and CPD programme or as a result of a complaint.

30　Key features of a sound complaints system include: transparency, screening and investigation system, fair adjudication, and intervention and communication to the public and other regulators about action taken.

The profession, self-regulation and the regulatory body

31　The regulation of medicine is rooted in the origins and development of the profession.

32　There are advantages and disadvantages of self-regulation. The main advantages are that only doctors have the necessary knowledge and experience to understand medical practice issues in depth and there is professional ownership of values. The main disadvantage is that it may be or may be seen to protect its members more than it protects the public.

33　Most modern medical regulatory systems either rely on self-regulation or at least incorporate self-regulation into the system, but not all have a professional regulatory body.

34　Professional regulatory bodies have their origins in traditional ideas of professional values. Many have modernised their mission statements and some are increasingly involving the public in their governance.

Professional and regulatory environments

35　The roles and responsibilities of professional regulatory bodies (where they exist) differ from jurisdiction to jurisdiction and depend on the medical professional and the regulatory environments in which they are embedded.

36　Functions of medical professional organisations include the preservation and advancement of knowledge, the transmission and accreditation of knowledge, accreditation and licensing, lobbying and economic negotiation. Only some of these are regulatory functions and there may be duplication and overlap between different associations, creating confusion and conflict.

37　The regulatory environment is formed by the health care system and medical education regulation in each jurisdiction. Regulation of medical professionals centres on the core activities controlling entry to, maintenance on and erasure from the medical register.

38　Regulatory functions can be separated horizontally – by administrative level, or vertically – different organisations, or a mixture of the two. The exact model adopted varies between nation States and depends on historical, political and demographic forces.

39　The number of organisations involved in these regulatory functions and the degree of control the medical profession has over them varies from jurisdiction to jurisdiction.

The international environment

40　EU legislation allows for free movement of professionals within the EEA and mutual recognition of qualifications based on trust.

41　Differences in definitions of title and specialist can make international comparisons difficult.

42　Although all jurisdictions have ethical codes, sanctionable offences may be different.

43　Standards of competency and performance have not been agreed internationally.

44　All EU Member states are required to identify a competent authority for registration and licensing. Quality assurance of registration procedures will enhance trust between states.

45　Current mechanisms for ensuring good standing of doctors moving jurisdictions have loopholes. Initiatives to improve communications between competent authorities include the use of electronic mail and web-based, encrypted databases.

46 Recruitment by richer countries of the best qualified doctors from poorer countries can drain the poorer countries of valuable human resources.

47 IAMRA is a key player in working towards harmonising medical regulation internationally and developing mechanisms for the exchange of information between regulators.

Developing a sound and sustainable medical regulatory system

48 Five principles of good regulation are: accountability, transparency, targeting, consistency and proportionality.

49 Accountability and transparency are particular problems in the self-regulation of doctors, but external rules should not be so heavy as to reduce trust in doctors' personal professionalism.

50 Whatever system of regulation is adopted its key aim should be to enjoy public confidence.

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Appendix two: Checklist of regulatory functions

Function	Is this done? Yes/no/partial	Who does it? Responsible vs delivery	Where is it done Local/regional/national
Standards setting/definition			
A1. Professional behaviour standards Good doctor – ethical code/ professional values			
A2. Competency standards Clinical/professional knowledge, skills & abilities (competencies – PMQ, post-graduate/specialist)			
A3. Performance standards Performance standards: (ability to apply knowledge & skills – junior, middle grade, senior, GP)			
A4. Educational process standards a) Pre-entry standards for medical school b) Medical school curriculum standards c) Medical school teaching quality d) Post-graduate education curriculum standards e) Post-graduate education teaching/ training quality f) CME 'curriculum'/ content standards g) CME quality of process standards			

Function	Is this done? Yes/no/partial	Who does it? Responsible vs delivery	Where is it done Local/regional /national
B. Monitoring/evaluation activity (against above standards)			
B1. Primary assessment of individual professionalism, knowledge, competence and performance. Certification for primary qualification as a doctor (PMQ) Specialist accreditation &/or certification			
B2. Verification of knowledge, competence and performance certificates			
B3. On-going assessment of knowledge, competence and performance Recertification or revalidation of competency and performance Adherence to contractual agreements			

Function	Is this done? Yes/no/partial	Who does it? Responsible vs delivery	Where is it done Local/regional /national
B4. Investigation of complaint of professional misconduct, for presumed: Breach of ethical/professional code Insufficient competency Inadequate/inappropriate performance Ill-health, personal issue System failure – local System failure – regional/national Combined reasons			
B5. Investigation of complaint of poor professional performance, for presumed: Breach of ethical/professional code Insufficient competency Inadequate/inappropriate performance Ill-health, personal issue System failure – local System failure – regional/national Combined reasons			
B6. Assessment of educational processes /curricula Undergraduate Postgraduate Continuing medical education			

Function	Is this done? Yes/no/partial	Who does it? Responsible vs delivery	Where is it done Local/regional /national
C. Regulatory intervention (once monitoring activity completed)			
C1. Satisfactory primary competency & performance Registration and/or licensing			
C2. Satisfactory on-going competency & performance Re-licensing and recertification			
C3. Sanction decision for misconduct or poor performance. In cases of: Beach of ethical/professional code Insufficient competency Inadequate/inappropriate performance Ill-health, personal issue System failure – local System failure – regional/national Combined reasons			
C4. Sanction application Warning Remediation – education, medical treatment, limited or supervised practice. Temporary removal of license/from register. Permanent removal of license/ from register			
C5. Satisfactory educational intervention/ process. Accreditation of course or institution			

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