INTERNATIONAL ASSOCIATION OF MEDICAL REGULATORY AUTHORITIES

STATEMENT
Independence of Regulation: The Primacy of Patient Safety

Purpose

1. One of IAMRA's strategic goals is *'creating a global community of medical regulators by expanding IAMRA's membership and influence, and increasing value to members.'* In support of this goal, IAMRA develops policy statements which may be of assistance to Members as they navigate the challenges of regulation in their own jurisdiction.

2. This statement addresses the principle of the independence of regulation and its importance in ensuring the primacy of patient safety in medical regulation. Regulation is complex and multifaceted and from time to time, Medical Regulatory Authorities (MRAs) may find themselves subject to pressures or competing demands that are in conflict with their role in ensuring the safety of individual patients or groups of patients.

3. While this statement focuses on the regulation of individual doctors, it is equally applicable to other aspects of regulation, such as the accreditation of medical education and training.

Background

4. Patient safety came into sharp focus in 1999, with the publication of the seminal report, *To Err Is Human*[1]. Around the world, there is considerable interest in patient safety and consumers of health care increasingly expect and demand safe, high quality care and treatment.

5. All doctors should aspire to providing excellent patient care, but regulators should expect, as a minimum, that patients' care will be safe, and patients will not be exposed to undue risk.

6. Health care systems are complex and patient safety requires robust and effective regulation, individual doctors to be fit to practise, teams to operate effectively, and the health care system to provide the necessary resources and infrastructure.

7. Not all of these factors are within the sphere of influence of MRAs, but it is a reasonable assumption that patient safety will be compromised if regulation is ineffective, as this may result in doctors who are not fit to practise adversely impacting patient safety.

[1] Kohn, L.T., Corrigan, J.M., Donaldson, M.S. (1999) *To err is human: Building a safer health system*. Washington, D.C.: National Academy Press.

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Models of Regulation

8. IAMRA does not promote a particular model of medical regulation, recognising that models are influenced by the structure of the health care system, the legal framework in which regulatory authorities operate and the resources available.

   Even within IAMRA's membership, a number of different models of regulation are represented, including:
   - Autonomous MRAs with different ways of appointing Council/Board members, including election and direct appointment;
   - MRAs responsible to a national or state government;
   - MRAs within a national or state government;
   - Hybrid models.

Nevertheless, member MRAs have a shared objective: to protect patients by employing effective regulatory tools to manage risk and ensure that doctors are fit to practise and contribute to the provision of high-quality health care.

9. What makes a doctor fit to practise?
   - They must possess a recognised and relevant qualification;
   - They must always practise in accordance with their training and competence;
   - They must demonstrate professionalism through their ongoing commitment to maintaining their competence throughout their working life;
   - Their personal health must not adversely impact their practice;
   - They must make safe and appropriate judgements, recognise when their performance is compromised and act accordingly;
   - They must always demonstrate professionalism in their interactions with patients and colleagues;
   - Their professional conduct and behaviour must always reflect the expectations of the community and the trust placed in them.

Note: this is not an exhaustive list.

10. No matter the model, regulation of the medical profession generally involves the following key processes, aimed at ensuring that doctors are fit to practise:

    i. setting and enforcing standards of practice
    ii. initial licensure – a process during which a doctor's qualifications and experience come under careful scrutiny, along with other fitness to practise considerations;
    iii. renewal of licensure – a process requiring consideration of a doctor's continuing competence and fitness to practise;
    iv. managing complaints – a process which may highlight fitness to practise concerns;
    v. managing impairment– a process whereby impaired doctors are able to continue in practice, if the impairment does not impede their ability to provide safe and effective care;
    vi. managing poor performance – a process generally focussed on remediation, but which may require restrictions on the doctor's practice or disciplinary action, if appropriate;

vii. managing unsatisfactory professional conduct/behaviour – a process that may result in disciplinary action as well as restrictions of the doctor's practice;
viii. reinstatement of licensure – a process whereby the reinstatement of a doctor's licence is considered, following a period of voluntary or imposed revocation;
ix. establishing and maintaining relationships with stakeholders.

11. Effective regulation makes a vital contribution to patient safety. MRAs are uniquely placed to manage all aspects of a doctor's fitness to practise, unlike, for example, employers that are only able to take action within the workplace and have no jurisdiction over a doctor who moves on to practise elsewhere.

Threats to the Independence of Regulation

12. From time to time, MRAs may find themselves subject to pressure in relation to any of their key regulatory processes, potentially compromising effective regulation. Individuals, organisations or governments may seek to exert their influence in relation to issues such as:

    i. the medical workforce – there can be considerable tension between maintaining standards and recruiting /licensing an expanded medical workforce;

    ii. institutional reputation – this may be an impediment to effective and collaborative oversight of doctors' practices;

    iii. the impact of medical practice on the economy – economic drivers, for example the promotion of medical tourism, can raise significant patient safety issues;

    iv. medical practice as a 'right' – individuals or groups may place higher value on a doctor's right to practise than the associated patient safety considerations;

    v. innovation and alternate modes of practice, in the absence of adequate evidence.

Statement

To the extent that it is possible within the structural and legal framework of the Medical Regulatory Authority, IAMRA supports and encourages all Medical Regulatory Authorities to maintain their independence and make patient safety their primary concern, especially when faced with pressure on the integrity of effective regulation.