

WMA DECLARATION OF MADRID ON PROFESSIONALLY-LED REGULATION

Adopted by the 60th WMA General Assembly, New Delhi, India, October 2009 and revised by the 70th WMA General Assembly, Tbilisi, Georgia, October 2019

The WMA reaffirms the <u>Declaration of Seoul on professional autonomy and clinical independence of physicians</u>.

The medical profession must play a central role in regulating the conduct and professional activities of its members, ensuring that their professional practice is in the best interests of citizens.

The regulation of the medical profession plays an essential role in ensuring and maintaining public confidence in the standards of care and of behaviour that they can expect from medical professionals. That regulation requires very strong independent professional involvement.

Physicians aspire to the development or maintenance of systems of regulation that will best protect the highest possible standards of care for all patients. Professionally led models can provide an environment that enhances and assures the individual physician's right to treat patients without interference, based on his or her best clinical judgment. Therefore, the WMA urges its constituent members and all physicians to work with regulatory bodies and take appropriate actions to ensure effective systems are in place. These actions should be informed by the following principles:

- 1. Physicians are accorded a high degree of professional autonomy and clinical independence, whereby they are able to make recommendations based on their knowledge and experience, clinical evidence and their holistic understanding of the patient including his/her best interests without undue or inappropriate outside influence. This is expounded in more detail in the Declaration of Seoul.
- 2. The regulation of the profession must be proportionate and facilitative and not be burdensome, and be based on a model that applies to every physician equally and that protects and benefits patients and is based upon an ethical code. The planning and delivery of all types of health care is based upon an ethical model and current evidence-based medical knowledge by which all physicians are governed. This is a core element of professionalism and protects patients. Physicians are best qualified to judge the actions of their peers against such normative standards, bearing in mind relevant local circumstances.
- 3. The medical profession has a continuing responsibility to be strongly involved in regulation or self-regulating. Ultimate control and decision-making authority must include physicians, based on their specific medical training, knowledge, experience and expertise. In countries where Professionally led regulation is in place physicians must ensure that this retains the confidence of the public. In countries that have a mixed regulation system physicians must seek to ensure that it maintains professional and public confidence.
- 4. Physicians in each country are urged to consider establishing, maintaining and actively participating in a proportionate, fair, rigorous and transparent system of professionally-led regulation. Such systems are intended to balance physicians' rights to exercise medical judgment freely with the obligation to do so wisely and temperately.
- 5. National Medical Associations must do their utmost to promote and support the concept of well-informed and effective regulation amongst their membership and the public. To ensure that any potential conflicts of interest between their representative and regulatory roles are avoided they must ensure separation of the two processes and pay rigorous attention to a transparent and fair system of regulation that will assure the public of its independence and fairness.
- 6. Any system of professionally-led regulation must enhance and ensure:
 - the delivery of high quality safe and competent healthcare to patients
 - the competence of the physician providing that care the professional, including ethical, conduct of all physicians
 - the protection of society and the rights of patients

- the promotion of trust and confidence of patients, their families and the public
- the quality assurance of the regulation system
- o the maintenance of trust by patients and society
- the development of solutions to potential conflicts of interest
- o a commitment to wide professional responsibilities
- 7. To ensure that the patient is offered quality continuing care, physicians should participate actively in the process of Continuing Professional Development, including reflective practice, in order to update and maintain their clinical knowledge, skills and competence. Employers and management have a responsibility to enable physicians to meet this requirement.
- 8. The professional conduct of physicians must always be within the bounds of the Code of Ethics governing physicians in each country. National Medical Associations must promote professional and ethical conduct among physicians for the benefit of patients, and ethical violations must be promptly recognized, reported to the relevant regulatory authority and acted upon. Physicians are obligated to intervene in a timely manner to ensure that impaired colleagues do not put patients or colleagues at risk and receive appropriate assistance from a physician health program or appropriate training enabling a return to active practice.
- 9. The regulatory body should, when the judicial or quasi-judicial processes are complete, and assuming that a case is found against the physician, publish their findings and include details of the remedial action taken. Lessons learned from every case should, to the extent possible, be extracted and used in professional education processes.
- 10. The regulation process should ensure that the incorporation of such lessons is, as far as possible, seamless.
- 11. National Medical Associations are urged to assist each other in coping with new and developing challenges including potential threats to professionally-led regulation. The ongoing exchange of information and experiences between National Medical Associations is essential for the benefit of patients.
- 12. Whatever judicial or regulatory process a country has established, any judgment on a physician's professional conduct or performance must incorporate evaluation by the physician's professional peers who, by their training, knowledge and experience, understand the complexity of the medical issues involved.
- 13. An effective and responsible system of professionally-led regulation must not be self-serving or internally protective of the profession. National Medical Associations should assist their members in understanding that professionally-led regulation, in countries where that system exists, must maintain the safety, support and confidence of the general public, including their health-related rights, as well as the honour of the profession itself.