INTERNATIONAL ASSOCIATION OF MEDICAL REGULATORY AUTHORITIES

MANAGEMENT COMMITTEE STATEMENT
Prescribing Drugs of Dependence:
Role of Medical Regulatory Authorities

Background

1. IAMRA's Purpose is to promote effective medical regulation worldwide by supporting best practice, innovation, collaboration and knowledge sharing in the interest of public safety and in support of the medical profession.

2. IAMRA does not promote a particular model of medical regulation, recognizing that models are influenced by the structure of the health care system, the legal framework in which regulatory authorities operate and the resources available. Nevertheless, member Medical Regulatory Authorities (MRAs) have shared objectives: to protect patients by employing effective regulatory tools to manage risk and to ensure that doctors are fit to practice and contribute to the provision of high-quality health care.

3. One of IAMRA's strategic goals is, *'creating a global community of medical regulators by expanding IAMRA's membership, partnerships and impact, 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 and competing priorities of regulating the medical profession in their own jurisdiction.

Purpose

4. This statement addresses the development of effective regulatory approaches related to doctors who manage pain by prescribing drugs of dependence (also known as drugs of addiction), to mitigate the unintended risk of direct harm to patients and indirect harm to society.

   Drugs of dependence, such as opioids and benzodiazepines, have important therapeutic uses in the management of pain, and clinically appropriate prescribing of them is a legitimate component of medical practice. However, in collaboration with medical regulation as needed, measures may be required to minimize harm from inappropriate and unsanctioned drug use. Inappropriate prescribing, which may include indiscriminate, excessive or reckless prescribing, is clinically and ethically unacceptable and harmful to patients, the medical profession and society.

5. Recognizing the different regulatory frameworks in which MRAs work, MRAs may wish to consider establishing or disseminating best practice principles related to the responsible prescribing of drugs of dependence in the setting of pain management, so as to mitigate the risk of harm to patients. This statement provides MRAs with a framework for an effective regulatory approach.

Principles

6. IAMRA recommends that if MRAs develop principles, best practice, recommendations and/or policies and related communications materials, they should:

i. address the appropriate assessment and management of patients living with acute and chronic pain, and/or a drug use disorder;
ii. reflect an expectation for doctors to balance the needs of the patient with the potential risks of prescribing. The decision to prescribe drugs of dependence, like other aspects of clinical practice, should be made with the patient, and require their informed consent, recognizing, however, that doctors should not be pressured into prescribing;
iii. are regularly reviewed and updated to ensure they remain clinically appropriate and are in the best interest of patients;
iv. highlight the pitfalls of doctors prescribing for themselves, their family members and those with whom they are close;
v. remind doctors that their prescribing patterns/behaviours could be influenced by their interactions with the pharmaceutical industry including through any gifts or incentives they receive and any sponsored educational activity they attend.

Ideally, such materials should provide recommendations for all doctors who prescribe or may need to prescribe drugs of dependence. They should clearly state the MRA's expectations for appropriate prescribing practices, with the secondary purpose of assisting the MRA to determine whether individual doctors' prescribing practices are problematic.

Standards framework

7. IAMRA recommends that if MRAs are to provide guidance that sets out the MRA's standards of practice for doctors who prescribe drugs of dependence, such standards should include, but need not be limited to:

i. performing and documenting a relevant and appropriate clinical assessment based on the patient's history and presentation, to ensure that prescribing is in the patient's best interest.
ii. explaining that prior to prescribing, sufficient information about the patient's health is required, including relevant information from other healthcare providers involved in the patient's care;
iii. considering if the patient is seeking drugs of dependence for non-therapeutic purposes, to supply other individuals or has legally/contractually restricted access to such drugs. The doctor should take note of prescription monitoring and surveillance services where available;
iv. directing new patients who may already be on an established treatment plan to their regular prescriber and, if unavoidable, only providing a small quantity of drugs of dependence;
v. considering alternative treatments, including non-pharmaceutical interventions;
vi. ensuring that patients understand how to take or use drugs of dependence;
vii. informing patients of the potential risks of drugs of dependence, including physical dependence, tolerance, withdrawal, the consequences of diversion to other individuals, overdose and death;
viii. prescribing according to all relevant laws;
ix. collaborating and communicating with the patient's health care team and consulting with other providers including other prescribers, pharmacists and pain management/addiction experts and services, where available;
x. making evidence-informed decisions, ensuring that prescribing is in accordance with accepted practice and any recognized best practice guidelines and documenting the justification for varying from evidence-based guidelines and best practice;
xi. assisting the patient to access other doctors/services in circumstances where the doctor is unwilling or unable to prescribe drugs of dependence.

Statement

Where medical regulatory authorities decide to develop and implement policies and guidance on prescribing drugs of dependence for pain management, these should be informed by evidence and/or best practice and emphasize:

i. **doctors' ethical, professional and legal obligations; and**
ii. **a patient-centered; and**
iii. **an expectation that doctors will adhere to relevant legislation, regulatory policies and guidance when prescribing drugs of dependence.**

POLICY STATUS:	***Prescribing Drugs of Dependence***
Governing Authority	Management Committee
Approval Authority	Management Committee
Responsible Officer	Executive Director
Approval Date	October 2020
Effective Date	October 2020
Review Date*	Approval date + 4 years (maximum)
Date of Last Revision	
Related Policies	

* Unless otherwise indicated, this policy will still apply beyond the review date.