



Glossary 2022

Project : Regulation of Narcotic Medicines

The terms and definitions in this document are based on the report of the Pompidou Group. (2018): *Opioid agonist treatment. Guiding principle for legislation and regulations*. Expert group on the regulatory framework for the treatment of opioid dependence syndrome and the prescription of opioid agonist medicines. Strasbourg.



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Agonist medicine used in opioid dependence treatment (OAM)	Medicine with marketing authorisation (MA) and whose active ingredient is an opioid. In a person diagnosed as having an opioid dependence syndrome, the main effects include: causing cessation or reduction of opioid consumption, minimising the risk of lethal intoxication and regulating the person in treatment's physiological and psychological state. The main OAMs are methadone, buprenorphine, morphine and diacetylmorphine. They are generally used as part of multimodal treatment, particularly in psychosocial and somatic care. In addition to their main effects, it has been demonstrated that the provision of these medicines affects public health and safety.
Controlled medicine(s)	Medicine which contains substances under control within the meaning of the Single Convention on Narcotic Drugs as amended by the Protocol of 1972, the Convention on Psychotropic Substances of 1971 and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988). The controlled medicines most commonly used as OAMs are methadone and buprenorphine.
Coverage rate	Proportion of a population eligible for assistance who actually obtain this assistance. For OAT, the coverage rate is defined as the number of OATs actually dispensed in a given geographical area compared to the number of persons in this area with opioid dependence syndrome.
Physicians' and pharmacists' basic training	University education including the entire course required for general professional qualification.
Equivalence of care	The principle according to which detained persons or those subject to other measures restricting their freedom must have access to healthcare which is equivalent to that made available to the general population.
Essential medecine	Medicine featuring on a list established by a government or intergovernmental agency setting out the minimum medical needs for a basic health system, listing the most efficient, safe and cost-effective medicines for priority states of health. Methadone and buprenorphine are OAMs included on WHO's Model List of Essential Medicines.
Indicator	Qualitative or quantitative data providing information on the conditions or performance of a public policy or programme.
International conventions on the control of psychoactive substances	A term referring to the Single Convention on Narcotic Drugs of 1961 as modified by the Protocol of 1972, the Convention on Psychotropic Substances of 1971 and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988).

Marketing authorisation (MA)	Marketing authorisation (MA) is a prerequisite for any possibility of marketing a medicinal product after an assessment of its quality, safety and effectiveness. In many countries it is also essential before any application for a substance to be included on the list of medicines reimbursed by the health insurance fund. MAs are generally issued by a national medicines agency, although they are also issued by the European Medicines Agency (EMA), which is an EU institution. MAs are official documents made up of a decision and appendices, including the Summary of Product Characteristics/Product Information (SPC/PI) and the person in treatment information leaflet.
Medicine	Any substance or composition that may be administered to a person with a view to establishing a medical diagnosis or restoring, correcting or modifying physiological functions.
Non-medical use	In this document, this term is defined as the use of controlled psychoactive substances outside the context of their prescription as medicines. Non-medical use covers use for recreational or ritual purposes and certain acts of self-medication with no medical justification.
Opioid(s)	Substance with a pharmacological activity similar to morphine.
Opioid agonist treatment (OAT)	Treatment of opioid dependence syndrome which is generally multimodal and multifocal and includes prescription of an OAM for an undetermined period (for the aims of OAT, see Section 3 of the Guiding Principles).
Opioid dependence syndrome	A cluster of physiological, cognitive and behavioural phenomena within the meaning of the WHO's international classification of diseases. According to the 10th edition of this classification (ICD 10) dependence syndrome exists when at least three of the following manifestations have occurred together for at least 1 month or, if persisting for periods of less than 1 month, have occurred together repeatedly within a 12-month period: (1) a strong desire or sense of compulsion to take the substance, (2) difficulties in controlling substance-taking behaviour, (3) existence of a withdrawal syndrome, (4) evidence of tolerance, (5) progressive neglect of alternative pleasures or interests and increased time spent in relation to consumption, (6) persisting with substance use despite emergence of overtly harmful consequences..
Primary care physician	A physician performing general medical activities in a community-based care facility, for example a private surgery or an out-patients' clinic. These physicians are sometimes also called "general practitioners" or "family physicians".

Prior authorization scheme	Term describing regulations on OAMs which require prior authorisation from an authority or a state medical body for a physician or pharmacist to be allowed to prescribe or continue prescribing and delivering such treatment. Such authorisation may be individual and hence attached to the person in treatment or the health professional, or more general, being linked to the place of care.
Psychoactive substance	A Chemical or natural substance which acts on the central nervous system bringing about changes in perception, feelings, mood and awareness. Psychoactive substances may be developed as medicines used to treat pain, act as anaesthetics or treat insomnia, various mental disorders and disorders linked to the use of such substances in a nonmedical context. The closely-related words “psychotropic” and “narcotic” have an essentially historic connotation although they are used in various national regulations and documents. “Psychotropic substances” refers on a legal level to the psychoactive substances listed in the Convention on Psychotropic Substances. “Narcotics” refers on a legal level to the psychoactive substances listed in the Single Convention on Narcotic Drugs of 1961, as amended by the Protocol of 1972.
Reduction/halt in consumption	Describes a therapeutic objective whose aim is to reduce consumption to a level below the criteria required for a diagnosis of dependence syndrome or use that is harmful to health (within the meaning of WHO’s classification of diseases) without necessarily eliminating all consumption.
Social costs	Social costs equate to all the adverse consequences for the community linked to a given condition, and the expenses incurred to prevent or remedy it. Accordingly, in the area of substance-related conditions, social costs include medical treatment, residential therapy, survival assistance, prevention and law enforcement costs (direct costs), current and future lost output (indirect costs) and the deterioration in the quality of the life of dependent persons and their families (human costs, also referred to as intangible costs).