Co-operation Group to Combat Drug Abuse and Illicit Trafficking in Drugs

Expert Group on framework and support measures for opioid dependence treatment including the prescription of agonist medicines

DRAFT GUIDING PRINCIPLES
WORKING PAPER FOR CONSULTATION ONLY

Janvier 2016

In most countries, the prescription of opioid agonist medicines for the treatment of opioid-dependent persons is subject to restrictions which significantly impede access to care. Linked with the international system of control of psychoactive substances, these special regimes are based on the traditional – and scientifically and medically erroneous – understanding of this process as the "replacement of an illegal drug by a legal one".

Actually, through their pharmacological effects, the opiod agonist medicines prescribed for this indication have very different effects to illicit opioids. Used in an appropriate modality, these medicines stabilize the emotional state, reduce or eliminate the subjective reinforcing effects responsible for dependence and protect against overdose risks.

They are accordingly a central element of a wider, integrated medical and psychosocial treatment. Owing to their clinical effectiveness, the availability of these opioid medicines leads to a very significant reduction in mortality and comorbidities, particularly those related to intravenous heroin use (HIV, HCV). From this point of view, opiod medicines are also a key element of the public health approach to risk and harm reduction, in addition to their primary function of medical treatment. Two substances in particular, methadone and buprenorphine, appear on the WHO Model List of Essential Medicines.

To meet their obligations relating to healthcare and the prevention of discrimination, the States are therefore asked to review their regulations, based as far as possible on the ordinary provisions regulating the pharmaceutical market and the healthcare professions.

To assist administrative authorities in this process, the Pompidou Group's Permanent Correspondents mandated a group of health and legal experts to identify and detail criteria for the appropriate use of agonist medicines used in opioid dependence treatment, in line with ethical standards, international law, scientific knowledge and medical best practice.

The group comprises experts from the following countries: Algeria, Belgium, France, Greece, Lebanon, Lithuania, Morocco, Portugal, Slovenia, Switzerland, Tunisia and Turkey, and representatives of the EMCDDA and WHO. A scientific committee also brings together experts from Canada, Israel, Italy, the Netherlands, Poland, Spain and the United Kingdom.

At the first meeting of the group of experts on 7-8 September 2014, a Delphi approach was used to explore the similarities and differences between different pre-existing recommendations of international health authorities and gather additional information on the participating countries' practices.

At the second meeting on 27-28 August 2015, the Delphi approach was used to test the degree of consensus on some forty proposals. These were then brought together in a document provisionally entitled "guiding principles", whose key points are summarised below.

A third meeting is scheduled for 25-26 August 2016 to finalise the report.

The document should not be used for purposes other than placing it for consultation purposes. We request that any related communication is sent to the expert group coordinators **by May 15th, 2016**, by e-mail only, to the following two addresses Rene.Stamm@hotmail.com and Olivier.Simon@chuv.ch

Contents

Part I: DEFINITIONS & OBJECTIVES OF THE GUIDING PRINCIPLES

Section 1: Definitions

The terms used in these guiding principles are defined as follows[1]:

a. ***opioid dependence***: a set of physiological, cognitive and behavioural phenomena in accordance with the WHO international classification of diseases. The 10th edition (ICD-10) of this classification system defined dependency syndrome as the presence of at least three of six following criteria: (1) strong desire or sense of compulsion to take the substance, (2) difficulties in controlling substance-taking behaviour, (3) physiological withdrawal state when substance use has ceased or have been reduced, (4) evidence of tolerance, such that increased doses of the psychoactive substance are required in order to achieve effects originally produced by lower doses, (5) progressive neglect of alternative pleasures or interests because of psychoactive substance use, and increased amount of time necessary to obtain or take the substance or to recover from its effects, (6) Persisting with substance use despite clear evidence of overtly harmful consequences

b. **equivalence of healthcare**: the principle that persons held in detention should have access to healthcare equivalent to that provided to the general population.

c. ***basic training for physicians and pharmacists***: university training including the entire required curriculum for general professional qualification.

d. ***indicator***: quantitative or qualitative data providing information on the conditions or performance of a public policy or programme.

e. ***medicine(s)***: any substance or composition that can be administered to humans with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans.

f. ***agonist medicine(s) used in opioid dependence treatment (AMODT(s))***: medicine with a marketing authorisation and whose active ingredient is an opioid, with the primary effect, in a person diagnosed as opioid dependent, of causing cessation or reduction of opioid consumption, minimising the risk of overdose and regulating his or her physiological and psychological state. The main AMODTs are methadone, buprenorphine, morphine, and diacetylmorphine.

g. ***essential medicine(s)***: medicine on a list established by a governmental or intergovernmental agency, defining the minimum medical needs for a basic healthcare system, listing the most efficacious, safest and best value for priority *health* conditions. In terms of AMODT, methadone and buprenorphine are on the WHO Model List of Essential Medicines.

h. ***controlled medicine(s)***: medicine containing controlled substances according to the 1961 Single Convention on Narcotic Drugs, the 1971 Convention on Psychotropic Substances and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988). The controlled medicines most commonly used as AMODT are methadone and buprenorphine.

i. ***opioid(s)***: substance having a similar pharmacological effect to morphine.

j. ***cessation/reduction of problematic consumption***: a therapeutic goal to reduce consumption to a level that falls short of the criteria required for a diagnosis of dependence, or use harmful to health (according to the WHO classification of diseases), without necessarily suppressing all consumption.

[1] A more comprehensive glossary will be included in the project`s final report, accompanied by detailed explanatory notes on the selected terms and terms to avoid; this glossary is available from the project coordinators on request.

Section 2: Objectives of the guiding principles

The objectives of the guiding principles are:

- **a.** to strengthen the fundamental right to access to care for people diagnosed with opioid dependence;
- **b.** to eliminate and reduce barriers, especially those of a regulatory nature, which limit access to healthcare and to AMODTs;
- **c.** to permit the use of AMODTs based on the best medical and scientific evidence[2];
- **d.** to define the role of physicians and pharmacists, as well as the necessary framework conditions to deliver healthcare services and AMODTs in an optimal way to people diagnosed with an opioid dependence (see Section 9);
- **e.** to support and encourage countries introducing AMODTs to develop a legislative and administrative framework which takes into account both the following guiding principles and available resources with a view to continuous improvement (see Section 14);
- **f.** to ensure the monitoring and the adaptation of regulation of AMODTs, including through structural, process and outcome indicators (see Section 17).

Section 3: Primary and secondary objectives of AMODTs

3.1. The objectives of using AMODTs are first and foremost *person-centred* (primary aim) i.e.:

- **a.** to improve the clinical state of persons diagnosed with opioid dependence:
  - to reduce the symptoms of the disease that has been diagnosed;
  - to reduce the risks associated with acute intoxication and fatal overdose;
  - to improve quality of life;
  - to maintain and support social integration (particularly at a family, social and professional level).
- **b.** to reduce the occurrence of somatic (especially HIV and HCV) and psychological (especially anxious-depressive disorders and suicidal ideation) comorbidities associated with opioid dependence.

3.2. A treatment which achieves the above objectives also has a positive impact on society (secondary objectives), whether in terms of public health or public safety:

- **a.** public health: reduction in mortality, morbidity and psychiatric and somatic comorbidities, reduction in the incidence of injection-related transmissible diseases (among persons with dependence but also in the general population) and reduction in mortality attributable to these diseases.
- **b.** public safety: reduction in the illicit trafficking of controlled substances and related crime; improvement in both the objective and subjective perception of safety in public and social spaces.
- **c.** conjointly:
  - reduction of healthcare costs by means of early treatment and regular monitoring;
  - reduction of social costs through maintaining appropriate integration of persons with dependence into occupational and social spheres, and by the discharge of judicial and prison apparatus;
  - reduction of indirect costs relating to negative repercussions for those in close contact with people with dependence (work, school and family environment, particularly with regard to development of the children of persons in treatment).

[2] For further scientific information, we suggest to report to the WHO guidelines: http://www.who.int/substance_abuse/publications/opioid_dependence_guidelines.pdf

Part II: RIGHT TO HAVE ACCESS TO AGONIST MEDICINES FOR ODT AND TO RELATED CARE

Section 4: Right to healthcare

Any person presenting with a potential diagnosis of opioid dependence should have access:

- **a.** to a healthcare professional capable of diagnosing opioid dependence, as defined by the medical classification criteria, and to a functional and multi-dimensional assessment of related needs (medical and social) of the person and those in close contact with him or her (with regard to the training of healthcare professionals, see Sections 10 and 11);
- **b.** to medical care and medicines, including AMODTs, adapted to their health situation and in line with the most recent scientific knowledge (with regard to the medicines approval process, see Section 13);
- **c.** to medico-psycho-social advice adapted to their situation.

Section 5: Non-discriminatory access

5.1. Access to AMODTs must be non-discriminatory, whether in terms of age, gender, sexual orientation, ethnicity/race, migratory status, insurance status, health status (e.g. persons with HIV, pregnant or breastfeeding women), type of substances consumed, or any situation of detention (persons pending judgment, serving a sentence or those held in administrative detention). There must be non-discrimination both in the legal and regulatory texts (*de jure*) and in practice (*de facto*).

5.2. A person in treatment who is a minor (according to the civil legislation of the country concerned), but capable of discernment, must benefit from the same access and medical secrecy, like any adult in treatment who is capable of discernment (for medical secrecy, see Section 7.2)

5.3. Detained persons must be able to continue with existing treatment in the healthcare facility of their place of detention; they must also be able to start such treatment if they wish to (principle of equivalence of healthcare).

5.4. This access cannot be withdrawn for reasons of behaviour, from the person in treatment, that is judged to be inadequate, including in the case of:

- violence or threats to others;
- trafficking in substances (licit or illicit);
- concurrent consumption of other substances (licit or illicit).

The sanctions for violation of the rules of the healthcare setting must be strictly necessary and proportionate; under no circumstances should such sanctions interfere with the continuation or the quality of the treatment. However, in cases where the treatment can no longer be administered under circumstances in which the security of the care setting can be ensured, as a last resort, referral of the person receiving treatment to another care setting must be offered. When no other care setting is available and no other alternative can be identified, a transfer to a hospital or residential establishment - in all cases with the continuation of AMODTs – should be considered (see Section 8).

5.5. If a person in treatment sells or hands over his or her prescribed AMODTs to another person this may constitute a criminal offence; however, the penalty imposed must remain proportionate; it should take into account of circumstances (mitigating or aggravating) specific to the case and more generally, the principle of discretionary prosecution. The commission of such an offence should not be in itself a justifiable reason for the cessation or suspension of the treatment.

Section 6: Free and informed consent

6.1. In order to exercise their free choice of treatment (AMODTs and related healthcare), the person in treatment must be given clear and comprehensible, written and oral information, provided in the language that they currently use most (e.g. giving the person an information leaflet translated into this language).

6.2. Under no circumstances may AMODTs and related healthcare services be imposed against the wishes of the person in treatment, including against the wishes of a person being held in detention.

Section 7: Non-discrimination related to being in treatment

7.1. The fact of using AMODTs, in itself, should not give rise to any judicial or administrative penalties, or to any negative consequences from a civil rights point of view. Undertaking treatment cannot in any case constitute an offense or indication of committing a crime.

7.2. Medical confidentiality must be maintained, particularly in relation to the employer, the family. or the.penitenciary authorities. Exceptions to medical confidentiality must be based on the consent of the person in treatment. This principle also applies to minors who are capable of discernment.

Section 8: Organisation of healthcare for AMODTs

8.1. Access to AMODTs (see Section 5) and to related healthcare services must be long-term, without interruption (including in the event of imprisonment or geographical displacement), and from an integrated healthcare perspective.

8.2. This access must be established immediately, once the medical indication is applied/confirmed by the physician and the consent from the person in treatment is obtained.

8.3. This access and its continuation may not be refused on account of:

- the lack of *prior* agreement from another medico-psycho-social professional;
- the lack of agreement from a required judicial or administrative authority *prior* to the commencement of treatment or *after* the commencement of treatment.

In contrast, there may be a requirement for a *declaration* by the healthcare professional to the health authority in order to avoid any duplication of medical prescriptions. This declaration should be submitted *after* the commencement of treatment (see Section 14).

Part III: ROLE OF HEALTHCARE PROFESSIONALS

Section 9: Indication, prescription, dispensation et coordination

9.1. It is the physician's responsibility to decide whether AMODTs are indicated and to stipulate how the treatment is to be administered, in relation to the individual situation of person in treatment, and under the reserve of their free and informed consent (see Section 6). This includes the choice of medicines, dosage, specified strength and length of treatment. It also includes any associated measures, such as psycho-social support and screening for transmissible diseases[3].

9.2. Any physician who has completed his or her basic training, regardless of his or her subsequent specialisation, must be able to initiate AMODTs. The physician may need to be assisted by other healthcare professionals, including a pharmacist.

9.3. Following medical prescription, a pharmacist must be able to deliver AMODTs following completion of his or her basic training, in his or her role as manager or employee of a pharmacy, regardless of the type of pharmacy (private or public dispensing pharmacy, pharmacy in a hospital or health centre).

9.4. Healthcare (in the broad sense) must be co-ordinated between physicians, pharmacists and, depending on the clinical needs, other healthcare or social professionals, from a multidisciplinary perspective. This care, including the delivery of medicines, can be administered in private physicians` practices, dispensing pharmacies, specialist health centres (outpatient or residential), public or private hospitals and also via healthcare facilities in detention centres.

9.5. As part of an integrated treatment system, primary care physicians and pharmacists must have recourse to dependence specialists in the different professions involved (medicine, pharmacy, social work, nursing, psychiatric and psychological care) and/or ad hoc networks.

9.6. When the medicines are dispensed by another healthcare professional working in a medico-social centre, a public hospital, private clinic, medical facility in a place of detention, the rules as mentioned below apply by analogy.

Section 10: Physicians` training

10.1. To provide treatment of good quality, special attention must be paid to the training of healthcare professionals concerned, particularly physicians and pharmacists. Subject to the structure of medical and pharmaceutical studies, the body of necessary skills and knowledge will be transmitted during pre-graduate, postgraduate and / or continuing education.

10.2. The training of all physicians, whatever their specialisation, should include basic training in the treatment of substance dependence with special attention for:

- diagnosis of opioid dependence;
- multi-dimensional functional diagnosis in relation to dependent behaviour;
- knowledge of the different treatment options for opioid dependence, in particular the different AMODTs indicated and their respective benefit/risk profiles;
- the ability to arrange for medical care and to initiate the prescription of an AMODT;
- the ability to incorporate the treatment in a broader public health context offering a range of prevention, therapy and risk and harm reduction measures; knowledge of the legislative and regulatory framework in a broad sense (in particular the administrative formalities and specific financial conditions) for the administration of AMODTs.

[3] For further scientific information, we suggest to report to the WHO guidelines: http://www.who.int/substance_abuse/publications/opioid_dependence_guidelines.pdf

10.3. The training must be based on the latest medical and psycho-social knowledge.

10.4. At the end of the basic training, the physician should also know with which medical specialties, other healthcare professionals (particularly pharmacists, nurses, psychologists and social workers) and which institutions it is necessary or useful to collaborate when treating a person with opioid dependence.

10.5. This basic training will be kept up-to-date throughout the professional career by continuing education to integrate changes, at all levels. For this, service-related training and/or a specialist training (academic and/or professional) in the field of dependence in general and AMODTs in particular should be available for each physician and each pharmacist.

Section 11: Pharmacists' training

11.1 The basic training for all pharmacists should include basic training in the treatment of substance dependence, which specifically includes:

- knowledge of the different medicine options, in particular the benefits/risk profiles of the different medicines, including their pharmacodynamic and pharmacokinetic effects, the desired clinical effects as well as adverse effects and interactions with other medicines;
- assessment of the state of general health for persons in treatment, and state of intoxication, in particular;
- knowledge of the legislative and regulatory framework in the broad sense (in particular the administrative formalities and specific financial conditions) for the introduction and administration of AMODTs.

11.2. Following their basic training, pharmacists must also know how to collaborate effectively with the prescribing physician, other healthcare professionals (e.g. social workers) and the different institutions and programmes which may be involved in the treatment.

11.3 The training given should be based on the latest medical and pharmacological knowledge.

Section 12: Supervision of healthcare professionals

12.1. In the same way as all physicians and pharmacists, those involved in giving AMODTs shall be subject to ordinary monitoring and auditing exercised by professional bodies (disciplinary or professional law). This monitoring is above all to ensure compliance with ethical codes and good practice (including informed consent of the person in treatment, regular updating of knowledge, exercise of evidence-based medicine). Disciplinary supervision is in the interests of healthcare professionals, the persons in treatment and those who are close to them, and of society in general.

12.2. Disciplinary sanctions for healthcare professionals involved in AMODTs are the same as those which apply to other healthcare professionals.

12.3. Regular professional monitoring is, above all, designed to prevent the risks of healthcare professionals inappropriate conduct which otherwise could lead to administrative or criminal penalties.

12.4 Physicians, pharmacists and other healthcare professionals shall be subject to *administrative sanctions* (at State level) only if the healthcare professional's conduct presents or presented a risk to public health or to the health of the persons receiving treatment and their relatives; the administrative measure considered must be deemed appropriate, necessary and proportionate to preclude this risk. These measures may include (notably) restrictions on the right of the professional in question to practice his or her profession.

12.5. The administrative framework must, moreover, be designed to *prevent* the risks of inappropriate conduct; support measures in place of or combined with sanctions must also have been considered (e.g. coaching, participation in exchange groups, supervision/peer supervision).

12.6. Physicians, pharmacists and other healthcare professionals shall be subject to criminal sanctions only if their conduct – deliberately or through negligence – has endangered public health or safety or if it has endangered the health of persons who have been physically and individually identified and/or people who are close to them.

12.7. The penal framework must, moreover, be designed to prevent the risks of behaviours that are dangerous for public health and security.

Part IV: ROLE OF THE PUBLIC AUTHORITIES

The State is responsible for ensuring a consistent framework to ensure access to medicines and treatments, as well as their quality.

Section 13: Availability and quality of AMODTs

13.1. The State must ensure that:

- **a.** the necessary and useful AMODTs are available on the national market; these medicines shall include as a minimum the AMODTs on the WHO list of essential medicines (and therefore, at present, at least methadone and buprenorphine);
- **b.** these medicines have been duly registered in their territory by one/several specialised agency/agencies (e.g. medicine agency);
- **c.** the conditions for granting the approval are based on current medical knowledge with regard to the safety and effectiveness of the treatment;
- **d.** the information leaflets (label/professional information also called "Summary of Product Characteristics") for approved medicines reflect current medical knowledge, particularly with regard to the permitted therapeutic indications, dosage, form, length of treatment;
    - these leaflets should provide all the necessary clinical, pharmacological and dosage information for correctly giving AMODT treatment;
    - these leaflets should be regularly updated by, and at the initiative of, the authority, and take into account the best international practices.

13.2. Only in specific cases where the State is unable to ensure a sufficient supply in the country (in accordance with paragraph 13.1 above), it must ensure that:

- **a.** it is, in practice, possible to import medicines that have been approved in other countries (being admitted to the market by the medicines agency of the exporting country);
- **b.** there is the possibility of off-label use of medicines when this is clinically justified in the case of a person receiving an individual treatment;
- **c.** it is possible to use non-authorised medicines, including extemporaneous or officinal preparations.

13.3. The State, in principle via its medicines agency, must *monitor* the medicines market so as to ensure that the abovementioned objectives are guaranteed in the long-term.

Section 14: Proportionality of framework measures

14.1. When the State at any level, establishes the legal and administrative framework for the use of AMODTs, it will pay attention to the a priori evaluation of its impact upon access to healthcare and medicines, as well as on the availability of physicians and pharmacists involved in this form of treatment.

14.2. The *administrative obligations* (State rules) incumbent upon physicians and pharmacists should be limited to what is strictly necessary and proportionate in order to ensure safe and effective treatment for the treated person as well as for third parties (in particular the children of persons in treatment).

14.3. As examples, the following administrative provisions are generally considered disproportionate:

- **a.** the requirement to obtain authorisation prior to the start of treatment (excluding prescription by the physician);
- **b.** the obligation to have the treatment, which has been indicated by the physician, subsequently validated by a state authority[4]
- **c.** a predetermined waiting time before initiating AMODTs;
- **d.** the obligation to receive special training, as a physician, for prescribing AMODTs (see Section 10);
- **e.** the obligation to receive special training, as a pharmacist, to provide AMODTs;
- **f.** the obligation to have the person in treatment assessed by two or more different healthcare professionals;
- **g.** the imposition of a specific medicine, a specific dosage, a specific administration form and strength, or a minimum or maximum duration of treatment;
- **h.** discriminatory conditions for specific persons in treatment, particularly with regard to the criteria stipulated above (see Section 5);
- **i.** a ban on all off-label use of medicines;
- **j.** security arrangements for the storage of AMODTs by healthcare professionals where these generate costs that are incompatible with effective access to AMODTs via primary medical care (for example safety lockers complying with standards that make them prohibitively expensive).
- **k.** the requirement to include in the physician`s prescription information which may impede delivery of the medicine, unless there is a clearly established need based on the clinical state of the person being treated.
- **l.** a regime of AMODTs delivery that would not fall under the sole responsibility of the healthcare professional tasked with implementing the treatment (with regard to the training of healthcare professionals, see Sections 10 and 11)[5].

14.4. Countries that are introducing AMODTs may need, for a transitional period, to adopt exceptional measures in order to evaluate the feasibility, effectiveness, accessibility and funding while duly taking into account accessibility to healthcare.

Non-discriminatory access, free and informed consent of the person in treatment and data protection must be guaranteed.

Exceptional measures should be designed as an explicitly transitional device that the State regularly re-evaluates regarding:

- its necessity;
- its consequences (effects) on access to healthcare;
- its funding;
- the difficulties encountered.

The results of this re-evaluation should be made public.

[4] In contrast, the physician may be required to declare the treatment in order to avoid any duplication of medical prescriptions or to collect epidemiological data.

[5] In this respect, the professional must take account of the safety of the person receiving treatment, in particular the risk of non-compliance, and trafficking, in addition to the risks to the people they are close to (e.g. accidental access by others, particularly children). Supervised administration is generally necessary at the beginning of the treatment in order to verify the security and effectiveness for the person in treatment. Following this, supervised administration is only justified if the healthcare professional considers, based on an individual assessment of the person in treatment, that this is the only possible way of minimising the security risk. For further scientific information, we suggest to report to the WHO guidelines:
http://www.who.int/substance_abuse/publications/opioid_dependence_guidelines.pdf

Section 15: Funding and remuneration of healthcare services

15.1. The State must ensure that the care delivered by healthcare professionals, the AMODT that have received market authorization in the country and the psychosocial support are *affordable* for the persons in treatment in its territory.

15.2. If the cost of the care/support is not already fully covered by a public health insurance scheme, it should be covered by a specific scheme (state-run) which guarantees that those on low incomes have full access to such care and support (see Section 5).

15.3. The services provided by physicians, pharmacists and other healthcare professionals must be adequately *remunerated*, taking into account the workload, the difficulty of delivering the service and the liability incurred. The remuneration must be at a level that ensures the availability of a sufficient number of physicians, pharmacists and healthcare professionals.

Section 16: Promotion of training, research and innovation

16.1. Within the limits of its financial resources, the State shall encourage innovation, particularly by assuring the promotion of:

- **a.** basic, postgraduate and continuing training for professionals working in the opioid dependence domain, including awareness-raising for those professions involved on an occasional basis;
- **b.** supervision of healthcare professionals by medical societies (disciplinary bodies);
- **c.** healthcare organisations related to opioid dependence;
- **d.** research into medicines, care processes and the organisation of care;
- **e.** research into comorbidities related to opioid dependence;
- **f.** research into the epidemiology and mechanisms related to opioid dependence;
- **g.** the activities of national authority for coordination and monitoring (see Section 18).

In doing so, the State shall encourage a *global approach* to all dependent behaviours, and not limited solely to illegal drugs.

16.2. The State shall ensure that the legislative framework contains no provision particularly likely to restrict the initiation or completion of the innovative projects or research mentioned above.

Section 17: Monitoring and indicators

17.1. Each State must evaluate its healthcare system responsible for treating dependencies (healthcare system, healthcare provision and outcomes). Such evaluation comprises a routine monitoring through:

- structural indicators regarding the regulatory measures and the availability of healthcare structures, necessary medicines and trained professionals needed to provide treatment;
- process and coverage indicators for meeting the needs for access to care (non-discriminatory access, prompt and uninterrupted for anyone within the territory with a diagnosis of opioid dependence, who has consented to treatment); and relating to the quality of healthcare, and professional knowledge (whether they are specialists or involved on a timely and occasional basis);
- outcome indicators on treatment retention and completion, mortality, morbidity and comorbidity, as well as quality of life.

17.2. In this regard, each State must ensure it has the means to regularly obtain data on structural, process and outcome indicators. It is recommended that these indicators are standardised and in line with the EMCDDA epidemiological and treatment system indicator protocols in order to assure reliability and comparability of the data collected (see Section 17.3).

17.3. The indicators to be collected and the corresponding data must be made public. The data collected should also be made available to researchers, according to the common ethical standards related to consent and the protection of personal data.

17.4. These indicators should then be analysed by the State and other stakeholders in order to optimise treatment and their regulatory frameworks, both nationally and internationally (see Sections 18 and 19). The designated national consultative body referred to in Section 18 will support these efforts.

17.5. Each State makes the list of indicators that it collects on AMODT easily accessible, for example by publishing the list online.

Part V: NATIONAL COORDINATION AND INTERNATIONAL COLLABORATION

Section 18: National authority for coordination and monitoring

18.1. In order to coordinate the monitoring and implementation of AMODTs, the State shall appoint a national body bringing together representatives of the concerned professionals and representatives of the different state domains involved, particularly representatives responsible for the authorisation of medicines, reimbursement of healthcare and medicine costs, supervision of healthcare professionals, public health policies and social insurance supervisory authorities.

18.2. This body shall be responsible for the regular tasks of:

- **a.** identifying obstacles to access to care;
- **b.** identifying the international directives issued on the matter of AMODTs and assessing their relevance for the country;
- **c.** evaluating the pertinence of selected indicators, the data collected and the results obtained (see Section 17);
- **d.** supporting the efforts to exploit these indicators in order to improve treatments and their regulatory framework;
- **e.** track the results of research and make recommendations to ensure their implementation;
- **f.** on the basis of the above, formulate recommendations to prevent discrimination and improve access to treatment and quality of healthcare;
- **g.** coordinate the efforts of various concerned partners.

18.3. The State provides this body sufficient means to perform the above tasks as well as stable funding over time.

Section 19: International collaboration

19.1. In order to facilitate the implementation of AMODTs by the concerned professionals, the States collaborate to update common international guidelines.

19.2. The States as well as their competent internal bodies on the matter of AMODTs make explicit reference to international guidelines considered to be current references in light of the state of science.

The State remains free to specify these directives in order to concretely apply them in its territory. It is equally free to introduce more favourable framework conditions for access to AMODTs.

19.3. In order to ensure the comparability of collected data, permitting its use for scientific ends, the States shall agree on the minimum common indicators which they will collect (see Section 17.2). To this end, they shall designate and provide funding for an inter-governmental body which has adequate skills to perform or coordinate data collection.

19.4. If a State intends to collect supplementary indicators (beyond a common minimum list) it shall notify the other States in order to ensure, as far as possible, the international comparability of data.

19.5. At an internal level, the tasks of collaboration and communication are ensured, in principle by the body mentioned in Section 18.

Appendix 1: LIST OF THE EXPERT GROUP MEMBERS

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Appendix 2: STATEMENT OF LINKS OF INTERESTS OF THE EXPERT GROUP

When collecting data to establish their profile, the experts were asked whether, in the past, they had filed, individually or through the organisation to which they are affiliated, mandates for a laboratory involved in the development or marketing of products for use in the treatment of addicted persons (medicines, laboratory tests, specific medical equipment, etc.).

Marc Auriacombe reports no connected interests ad personam but mentions partnerships with the University of Bordeaux and/or its Foundation with pharmaceutical companies RBPharma, Mundipharma, Lundbeck, and DAPharma Ferrer.

Laurent Michel declares no connected interests within the past two years. Previously, he reports having performed services on behalf of pharmaceutical companies Bouchara, Reckitt and Etypharm.

Willem Scholten provides consulting services on issues related to controlled substances, including access to opioid analgesics. He received funding from Mundipharma and Grünenthal for speaking on accessibility of analgesia at conferences and meetings.

Didier Touzeau reports interventions on behalf of pharmaceutical companies Lundbeck France and RB Pharmaceuticals France.