

Access to Opioid Medication in Europe



Final report and Recommendations to the Ministries of Health

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Report and Recommendations to the Ministries of Health

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This report reflects only the views of the ATOME consortium members based on the available evidence as presented in this report.

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ATOME at a glance

- The World Health Organization (WHO) defines opioids as essential medicines for the treatment of severe pain and other symptoms, as well as for the treatment of opioid dependence. Access to opioid medicines is considered a human right.
- In the twelve European countries addressed by this project, strict regulations and inappropriate policies were found to have negative impact on adequate access to opioid medicines. Major barriers were found to exist in these countries in the field of legislation; national policies; knowledge and societal attitudes; and economic aspects, including affordability.
- Recommendations were developed for each country to address barriers to adequate opioid availability on different levels.
- In all participating countries, to some degree, action has already been taken to change policies and the legislation in order to improve access to opioid medicines. Factors enhancing change were committed opinion leaders and openness among relevant stakeholder groups towards a critical analysis of the national situation.
- It is recommended that governments implement the WHO policy guidelines *Ensuring Balance in National Policies on Controlled Substances, Guidance for Availability and Accessibility for Controlled Medicines* including the self-assessment checklist in order to analyse the situation in their country and initiate action towards improvement.

Executive Summary

The ATOME project

This report presents the outcomes of the Access To Opioid Medication in Europe (ATOME) project funded under the European Union's 7th Framework Programme. The project investigated why opioid medicines for moderate to severe pain and for the treatment of opioid dependence are not used adequately in twelve European countries, and developed tailor-made solutions for improved access to opioid medicines in these countries. The intended readership of this report is regulatory and law enforcement authorities, policy makers, opinion leaders, and healthcare professionals.

Background and problem statement

Opioid medicines are the mainstay of medical treatment of severe pain and breathlessness, and the treatment of opioid dependence. They are effective and cheap medicines to relieve unbearable suffering from physical symptoms in severe progressive illness, and to prevent unnecessary harm and deterioration of health in people suffering from opioid dependence. For these reasons, WHO defines opioid medications as essential medicines.

Due to their potentially harmful effects, opioids are defined as controlled substances and are controlled under the Single Convention on Narcotic drugs. The purpose of this treaty is to prevent the misuse of controlled substances while guaranteeing their availability for scientific and medical use. This implies a dual obligation for governments – that is, to implement regulations and policies that help to prevent potential harm resulting from opioids while ensuring that they are adequately available, accessible and affordable for those in need of them (the 'principle of balance'). However, in many countries the emphasis is on control and restriction, hereby unduly interfering with availability of opioid medicines.

ATOME goals and activities

The ATOME project was initiated by the Access to Controlled Medications Programme of WHO. It was a five-year project funded under the 7th Framework Programme of the European Community [FP7/2007-2013] under grant agreement n° 222994. The project consortium consisted of partners from the field of law, governance and public health, palliative care, and harm reduction.

A central feature of the ATOME work plan was close collaboration with national counterparts. In the beginning of the project, key stakeholders were invited to contribute to the project by becoming a member of the national country teams. These country teams comprised government officers, legal experts, palliative care and harm reduction specialists, and patient representatives. The national counterparts were key contacts for the ATOME consortium throughout the whole project. Collaboration with the national counterparts cumulated in a series of ATOME conferences in the 12 target countries.

The basic foundation of the project activities was the production of the revised WHO policy guidelines Ensuring Balance in National Policies on Controlled Substances, Guidance for Availability and Accessibility for Controlled Medicines using an expert consensus process. The resulting guidelines were the basis for all subsequent research and dissemination activities: both the legal and policy analysis were guided by the recommendations made in the

guidelines document; the self-assessment checklist was an important tool for the national problem analysis and development of strategic action plans towards improving access to opioid medication; and the barriers addressed in the guidelines built an important framework for the lectures and working groups during national conferences.

Building on this milestone, the ATOME project followed two tracks in parallel – one track of activities focused on legal analysis, the other on the analysis of national policies. The legal analysis looked at optimising the relevant legislation by identifying provisions that may impede access to controlled medicines and by making recommendations for improvement in consultation with the national counterparts. The policy analysis was related to an examination of national policies and circumstances affecting the accessibility and availability of opioid medicines. The goals were both to make professionals aware of problems arising from their professional practice, and to make recommendations to the governments.

ATOME key findings

Analysis of barriers

Scientific research undertaken within the ATOME project provided information on four areas relevant for access to opioid medicines: challenges concerning policy and guidance on access to opioids, legal and regulatory barriers, policy barriers, and the perception of barriers in different stakeholder groups.

A consensus process with experts from law and governance, public health, human rights, palliative care and pain treatment, and harm reduction revealed the difficulty of defining concepts such as ‘rational (medical) use’ versus ‘misuse’ of controlled substances, and reflected the challenge of outweighing the risks and benefits of certain substances. The consensus process underlined the complexity of political guidance in balancing between control and availability, between protection and harm.

An in-depth evaluation of the legislative and regulatory barriers in the participating countries found a wide range of potential barriers in the national legislation. The review identified potential legal and regulatory barriers in the following areas: prescribing, dispensing, and usage of opioid medicines; trade and distribution; manufacturing; affordability; penalties; and language. The outcomes of the legislation review resulted in detailed reports for each of the countries, describing the potential barriers, explaining the potential negative impact of the respective provisions on access to opioid medicines, and making a set of recommendations on how to lift these barriers and thereby improving the availability of opioids for those in need of them.

The findings of the review of national policies illustrate that beside barriers in the national legislation there are also several challenges concerning national policy strategies with regard to improved access to opioids and the use of these medicines for medical treatment. A detailed analysis of documents collected throughout the ATOME project and discussions with national stakeholders showed major challenges to opioid access in four areas; financial and economic aspects and governmental support, formularies, education and training, and societal attitudes. The analysis resulted in individual reports for each country, including recommendations on how to address the identified barriers and improve access to opioid medicines in relation to country specific backgrounds.

Several of the countries participating in the ATOME project are already in the process of revising legislation and policies, and implementing recommendations for improvement. As a result, several changes in legislation and policy have already come into force, lifting potential barriers to access to opioids.

Discussions with different stakeholders throughout the ATOME project revealed that perceptions may differ considerably with regard to what is seen as a 'barrier'. A questionnaire survey among different stakeholder groups provided insights into the different perceptions in a range of relevant stakeholder groups such as government officers, legal experts, healthcare professionals or advocacy workers. Government representatives often saw the impact of certain provisions on access to opioids less problematic than, for example, healthcare professionals. The outcomes of this survey underlined the importance of intensified dialogue between different stakeholder groups to facilitate a mutual understanding and establish a common ground for discussion on access to opioid medicines, and to develop effective solutions for improvement.

Achievements and societal impact

Next to the findings of the scientific research activities, achievements of the project are publication and dissemination activities that were targeted at providing guidance and having a societal impact.

- ▶ The publication of the WHO policy guidelines *Ensuring Balance in National Policies on Controlled Substances*, with 21 recommendations, as well as a checklist that can be used to survey legal and regulatory settings in each country.
- ▶ Implementation of several workshops and events with the aim of capacity building, sensitisation and awareness raising, education and training, and dissemination of knowledge regarding access to opioid medicines and findings from the project. In detail, these were two workshops directed at the legislation analysis – a lawyer's training workshop and a legislation review workshop; and two six-country workshops as well as a national follow-up conference in each of the twelve countries.

Key recommendations from the ATOME project

- Implement the WHO policy guidelines Ensuring Balance in National Policies on Controlled Substances, Guidance for Availability and Accessibility for Controlled Medicines;
- Identify potential legal and regulatory barriers to access to opioid medicines and working on changes with the aim to improve accessibility, availability and affordability.
- Ensure non-stigmatizing language in legal documents and language in official documents (e.g. by using the term 'Narcotic drug' only when referring to substances controlled under the Single Convention);
- Establish regular exchange opportunities (communication networks) between legal and governmental authorities, healthcare professionals and patients/families in order to raise awareness for practical impact and requirements of legal and policy decisions (target-performance comparison) regarding opioid availability and accessibility;
- Provide and support the implementation and development of national databases (including data on long-term outcomes and national fear of opioids) suitable for scientific research, evaluation of models of treatment with opioids and for monitoring the national demand on Essential Medicines;
- Ensure that treatment with opioids (knowledge, skills, attitudes) will be included in undergraduate and postgraduate education for relevant healthcare professionals (primarily physicians, nurses, pharmacists);
- Raise awareness and sensitisation for treatment with opioids among practicing healthcare professionals (e.g. via Continuing Medical Education, publication series on the rational use of opioids in highly-accessed national medical journals, a survey on knowledge and attitudes regarding opioid medicines);
- Raise awareness in the general public, e.g. via media campaigns or information, brochures for patients and relatives.

Conclusion

The impact of the different activities of ATOME has resulted in major improvements in access to essential controlled medicines in several of the participating countries. The ATOME project contributed to building a critical mass of interested parties, bringing together people from different fields such as pain therapy, palliative care, harm reduction, and from national governments. It is hoped that the activities initiated in ATOME will be sustained after the end of the project, improving accessibility, availability and affordability of essential medicines, including opioid analgesics and long-acting opioids used for the treatment of opioid dependence in the twelve participating European countries targeted in this project.

Improving Access to Opioid Medication in Europe

ATOME Final Report and recommendations to the Ministries of Health

Part I: General Part

1. Introduction

The WHO European region has a population of 881 million. Each year, 1.3 million people in the European Union die from cancer and approximately 5.7 million from non-cancer chronic diseases. In the 12 ATOME countries each year 300,000 people die from cancer (1). With the aging population, the pattern of mortality also changes (2). As more people live to older ages, and as chronic diseases become more common with older age, the numbers of people living with and suffering from these diseases will increase as well. With ongoing medical progress, patients will survive longer with chronic disabling disease, and in consequence suffer from pain or breathlessness over a longer period of time. A considerable percentage of these patients will require treatment with morphine or other opioids to achieve symptom control. However, many of them will not receive adequate treatment of their pain.

Opium has been used as an analgesic as long as 4000 years ago. Today, medicines derived from opium such as morphine are still the mainstay of analgesic therapies and most people will require their use at least once throughout their lifetime for acute or chronic pain. The World Health Organization has acknowledged the importance of opioid medicines in its Model List of Essential Medicines (3) and its Model List of Essential Medicines for Children (4). WHO considers fentanyl, hydromorphone, methadone, morphine and oxycodone essential medicines both for adults and children. The WHO Guidelines for the Pharmacological Treatment of Persisting Pain in Children with Medical Illnesses and the WHO guidelines on cancer pain management (5, 6) list a number of essential opioid analgesics equally.

The International Association for Hospice and Palliative Care lists not only codeine and morphine, but also tramadol, fentanyl, methadone and oxycodone as essential medicines for palliative care (7); and more recently the European Association for Palliative Care published new guidelines on the use of opioid medicines (8), reinforcing the value of these medicines as the mainstay of cancer pain management.

Opioids are also considered to be effective for the treatment of opioid dependence. Opioid maintenance treatment can interrupt the cycle of intoxication and withdrawal and reduces illicit opioid use and the risk of death through overdose and infection with hepatitis and HIV. In addition, it also reduces public nuisance and petty crime. The WHO Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence found opioid

agonist maintenance treatment, combined with psychosocial assistance, to be the most effective of all treatment options examined (9).

The United Nations Office on Drugs and Crime (UNODC) estimated that there are 15-39 million problem drug users in world, and 12 to 14 million heroin users (10). In Europe, it is estimated that between 3.1 and 3.5 million people use opioids illicitly.

In spite of the beneficial effects of opioid medicines, the fear of misuse has resulted in drug control regulations that have proven to be a major barrier against state-of-the-art medical use of opioids and other controlled medicines. In 1961, a number of treaties and protocols were merged into the Single Convention on Narcotic Drugs (11). In 1971 another convention, the Convention on Psychotropic Substances was agreed on (12). Together they cover about 120 substances and their medical preparations. Codeine, morphine and most other opioids are scheduled in the Single Convention and are subject to the measures of control detailed in this convention. This includes the estimation of medical needs for opioids, as well as rules concerning production, manufacture and distribution, and statistical reports. The Single Convention governs how opioids are shipped between countries, using a system of import and export permits, and also defines to some extent the requirements for safe distribution within a country. Governments that are party to the Single Convention have agreed to bring their laws and regulations in line with its requirements. The few countries that are not a party to the Single Convention often follow its basic procedures.

The broad purpose of the treaty is to prevent the misuse of 'narcotics' (a legal term referring to all substances regulated by this convention on 'narcotic drugs', but not a class of medicines) including opioids, while guaranteeing their availability for scientific and medical use. The preamble of the Single Convention recognizes that "the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering". However, the implementation of the treaty rules in national legislation and national policies are often much stricter than the treaties require. For this reason the availability of opioids for medical purposes is low in many countries, if not non-existent.

A survey on availability and accessibility of opioids for the management of cancer pain in 41 countries in Europe found substantial limitations of the opioid formularies in many of the 21 Eastern-European countries included in the survey (13). Regulatory restrictions such as requirements for patients for registration or physicians to hold a special licence for the prescription of opioids were much more common in Eastern-European countries than in the West.

There is currently a strong momentum worldwide to improve access to opioid medication with strong international initiatives advocating policy reform activities and supporting change towards more appropriate controlled substances policies and better public health outcomes. One important working group is the WHO Collaborating Centre for Pain and Palliative Care / Pain and Policy Studies Group (PPSG) in Wisconsin. The PPSG has developed methods and resources to assist governments and pain and palliative care groups to examine national policies and make regulatory changes – Romania, India, Italy are examples (14). The PPSG also developed an International Pain Policy Fellowship (IPPF) to expand leadership for change in more countries. Recognizing the requirement to balance the need to protect the population from harmful effects with the need to access controlled medicines for medical use, the World Health Organization (WHO) in 2007 established the Access to Controlled Medications Programme (ACMP) (15) in consultation with the International Narcotics Control Board

(INCB) in response to resolutions of the World Health Assembly (WHA) and the Economic and Social Council of the United Nations (ECOSOC) (WHA58.22 and ECOSOC 2005/25) (15,16). The programme aims at promoting the availability, affordability, accessibility and rational use of controlled medicines; it addresses all aspects that act as barriers in obtaining controlled medicines for medical treatment and furthermore, provides normative guidance, development and dissemination of internationally recognized standards for treatment, policy analysis, as well as training and support in drafting national action plans for improving access to opioid medicines. The ACMP, among others, collaborates with the WHO Collaborating Centre for Pain and Palliative Care, with the European Association for Palliative Care (EAPC), the International Association for Hospice and Palliative Care (IAHPC), the International Observatory on End of Life Care (IOELC), Human Rights Watch and Harm Reduction International (HRI).

The ACMP initiated the project Access to Opioid Medication in Europe (ATOME) with the aim to undertake applied research into the reasons why opioid medicines for moderate to severe pain and for the treatment of opioid dependence are not used adequately in 12 European countries. The ATOME project is embedded in these international activities; it was intended to address the inequality in access to opioid medicines in Europe and more specifically to implement activities in twelve Eastern European countries. Developed in 2006-2007 by WHO, it started in 2009 as a five-year project. It is funded by the European Community's Seventh Framework Programme [FP7/2007-2013] under grant agreement n° 222994, which has a section on cancer research. The project aimed to deliver a clear set of recommendations to governments on making controlled medicines accessible for the treatment of patients in need of them for medical reasons such as pain, including from cancer and opioid dependence, based on the *principle of balance* as enshrined in the preambles of the drug control conventions and promoted by the World Health Organization (WHO) (17) – ensuring that in parallel to a system of control in order to prevent misuse, controlled medicines will be sufficiently available for patient care.

Textbox 1 The principle of balance in the WHO policy guidelines (17)

The central principle of 'balance'

The central principle of 'balance' represents a dual obligation of governments to establish a system of control that ensures the adequate availability of controlled substances for medical and scientific purposes, while simultaneously preventing abuse, diversion and trafficking. Many controlled medicines are essential medicines and are absolutely necessary for the relief of pain, treatment of illness and the prevention of premature death. To ensure the rational use of these medicines, governments should both enable and empower healthcare professionals to prescribe, dispense and administer them according to the individual medical needs of patients, ensuring that a sufficient supply is available to meet those needs. While misuse of controlled substances poses a risk to society, the system of control is not intended to be a barrier to their availability for medical and scientific purposes, nor interfere in their legitimate medical use for patient care.

The ATOME Consortium aimed at helping to build a critical mass of interested parties, bringing people together from different fields such as pain therapy and palliative care, and from national governments. The work includes comprehensive legislative and policy reviews, in close cooperation with government officials and public health and medical experts in various countries. Specifically, the work entails:

- analysis of national policies and circumstances that affect the availability of opioid medicines
- proposing amendments to current law to better balance the need to prevent drug abuse, while allowing patients access to such medicines
- understanding the socio-cultural context of drug use and abuse in each country, and evaluating the impact of the activities of the ATOME project.

The ATOME project is also contributing to increasing awareness of the issues around opioid medicines. For example, the project has organised a series of workshops and conferences aimed at sensitising different stakeholder groups to the negative effects of too-tight restrictions on opioid medicines – for patients, their families, and also for healthcare professionals.

The concrete outcome are 12 country reports, offering recommendations for legislative changes. These reports are being presented to the relevant governments, national organisations and health-care professionals. In some countries, changes in legislation have already been prepared and even implemented, supported by the recommendations resulting from the ATOME legislation analysis.

2. Problem to be addressed

Opioid medicines are strictly controlled under the law because of their potential for harm and misuse. However, in some cases the controls are so restrictive that patients are denied access for medical use, including those who need treatment for pain or opioid dependence. Regulations to reduce substance misuse and to restrict the diversion of opioid medicines into illicit markets often unduly interfere with medical availability for the relief or pain and other symptoms, as well as for the treatment of opioid dependence. This has been identified as “the basis for the internationally recognized public health problem of overregulation” (13).

2.1. *Inequality in access to opioid medicines*

International health and regulatory authorities are increasingly concerned about wide disparities in access to opioid medicines (14). The problem has been highlighted by the Open Society Foundations International Palliative Care Initiative, the International Observatory on End of Life Care, the International Association for Hospice and Palliative Care (IAHPC), the International Narcotics Control Board (INCB), the WHO, the Council of Europe, Human Rights Watch, as well as by leading harm reduction organizations such as Harm Reduction International and the Eurasian Harm Reduction Network.

It is estimated that over 80% of the world's population, at one time or another, is denied treatment because the opioid medicines they need have been restricted as ‘controlled substances’ (18). In the European Union, for example, about 1.3 million people die from cancer each year, many in severe pain, even though effective pain medications are available. In six EU countries, medical consumption of opioids and similar medicines is low and in six others it is very low (19). Meanwhile, it was estimated that there are between 3.3 and 5.8 million injecting drug users in Europe (with absolute figures in Eastern Europe being three times as

high as in Western Europe) (20). However, only a minority has access to a methadone therapy that could help them to normalize their lives and re-integrate into society, prevent them from using and buying illegal drugs and reduce their risk of becoming infected with blood-borne diseases such as HIV.

While opioid consumption has significantly increased in Western European countries, the situation has hardly changed in Eastern Europe during the last 20 years (21). Although the European region in general is ‘performing best’ in the worldwide comparison, the consumption is far below average in Eastern Europe. In many European countries, particularly those in Eastern Europe, patient access to the opioid medicines recommended by the WHO to relieve pain is profoundly restricted due to inadequate formularies, excessive regulation and the attitudes and misconceptions by the administration, clinicians and patients (13, 21). WHO’s Access to Controlled Medicines Programme (ACMP) in its Briefing Note from 2012 stated that “The realization of the Millennium Development Goal ‘Provide access to affordable essential drugs in developing countries’ is likely to be further away for opioid analgesics than for any other class of medicines” (15).

2.2. *Reasons why opioids should be available*

There is scientific evidence for the benefits of opioid medicines for the treatment of specific symptoms and conditions, as well for the patients’ and families’ quality of life. The treatment is simple and inexpensive with at the same time good outcomes for the individual and public health (15).

Benefits for the treatment of pain

Pain management in palliative care follows the rules of cancer pain management, with analgesic medications according to the principles of the World Health Organisation (22) in the centre of the therapeutic approach. Opioids such as oral morphine are essential for pain management in palliative care, in acute pain as well as in many chronic pain conditions. They are relatively inexpensive and effective palliative care is not possible without the availability of a potent opioid. Whereas opioids are well established as the mainstay of pain management, it is less well known that opioids are also very effective for the treatment of breathlessness (dyspnea) in palliative care (22).

In 2013, the WHO Expert Committee on the Selection and Use of Medicines made important changes in the Model List of Essential Medicines and the Model List of Essential Medicines in Children. The most recent versions (18th Edition for adults and 4th Edition for children) have a separate section Medicines for Pain and Palliative Care (3, 4). The new section includes three subsections: non-opioids and non-steroidal anti-inflammatory medicines (NSAIDs); Opioid Analgesics; and Medicines for other symptoms common in palliative care.

Benefits for treatment of opioid dependence

Strong evidence suggests that methadone can reduce health risks for people with long-term opioid dependence, including a reduction of craving and drug-seeking behaviour, prevention of infection with Hepatitis C and HIV, improved psychosocial health, stability in people’s eve-

ryday lives, a better quality of life, as well as a reduction of criminal behaviour (19). In response to a resolution to the United Nations Economic and Social Council (ECOSOC), the WHO developed Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence (9). These guidelines are intended for policy makers and healthcare professionals.

The major benefit of methadone “is not only to reduce or stop opioid use, but also to improve health and social functioning” (9). Moreover, pharmacological treatment of drug dependence has the potential to provide psychological empowerment and give hope to a drug user by helping to see his or her problems from a different perspective (9). In addition, treatment can help to connect drug users with the main stream healthcare services, implying access to much wider health-care provision such as physical and psychiatric care, social assistance, and family support. Therefore, such long-term treatment should not be seen as treatment failure, but as an evidence-based way of protecting the drug users’ health.

Opioids are essential medicines

Due to their benefits for medical treatment, opioids – particularly orally administered morphine – are regarded as the treatment gold standard for moderate and severe pain, including pain associated with cancer, AIDS, and other diseases or conditions requiring palliative or end-of-life care, as well as pharmacological treatment of opioid dependence (23). For this reason, the WHO Expert Committee on the Selection and Use of Essential Medicines has designated morphine and other opioid analgesics as essential medicines (18). Essential medicines “satisfy the priority healthcare needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.” (3), p. 2.

Insufficient access to opioid medicines does have manifold and profound consequences for healthcare professionals, patients and their families. It also has severe negative impact on the public health that many patients in Europe do not receive adequate treatment for pain, dyspnea and opioid dependence because of inadequate regulations and deficiencies in public policy (13).

For an individual patient, it can cause serious and unnecessary suffering when opioid medicines – an essential, inexpensive and safe medication – are not adequately accessible. Numerous scandalous examples have illustrated the existential consequences of unnecessary and unspeakable suffering from pain and terminal dyspnea, as well as fatal consequences of illicit drug use like getting infected with HIV especially in low- and middle-income countries (23, 3). As a last resort, for some patients suicide appears the only way out. Family members’ distress associated with trying to support their loved ones in receiving opioid medicines and witnessing their suffering everyday can burden close relatives for years (3).

Access to opioid medicines as a human right

For the reasons highlighted above, health authorities are increasingly advocating for adequate access to opioid medicines as a human right. Because of their status as essential

medicines according to WHO, their availability for medical treatment is considered to be part of the right to the enjoyment of the highest attainable standard of health and well-being as defined in the International Covenant on Economic, Social and Cultural Rights (article 12, the Right to Health in conjunction with General Comment 14, paragraph 12) (15). WHA Resolution 67.19 *Strengthening of palliative care as a component of comprehensive care throughout the life course* affirms that access to palliative care and to essential medicines for medical and scientific purposes manufactured from controlled substances, including opioid analgesics such as morphine contributes to the realization of the right to the enjoyment of the highest attainable standard of health and well-being. The ACMP's recommendations are also taken on by those of Human Rights Watch, an international nongovernmental organization that has included opioid inaccessibility as a human right issue (3).

3. The principle of balance

A balance in national drug control policies needs to be ensured, allowing access to controlled medicines for the relief of pain and suffering in all cases while preventing their diversion and misuse. Therefore, a balanced strategy is needed to counter the problem, which not only focuses on law enforcement, but also includes a public health perspective (Textbox 2; (17)).

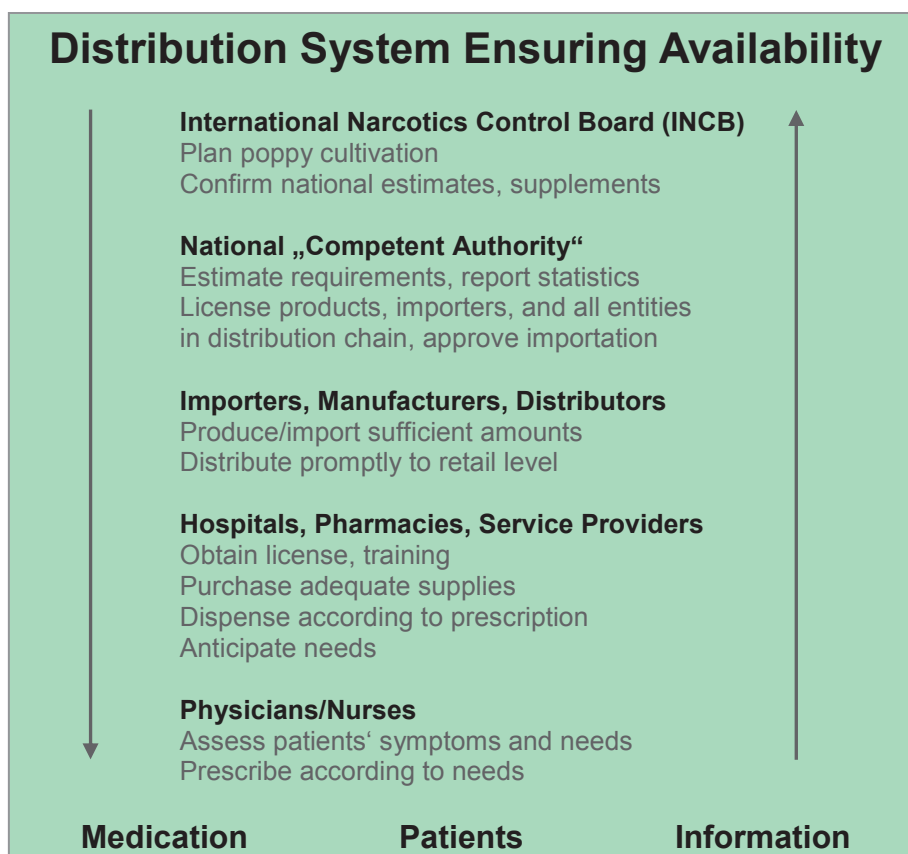
Textbox 2 Balanced public health outcome according to WHO

WHO considers the public health outcome to be at its maximum (or 'balanced') when the optimum is reached between maximizing access for rational medical use and minimizing substance abuse. All countries have a dual obligation with regard to these medicines based on legal, political, public health and moral grounds. The dual obligation is to ensure that these substances are available for medical purposes and to protect populations against abuse and dependence. Countries should aim at a policy that ultimately achieves both objectives; in other words, a 'balanced policy' (17).

Governments' obligation

The principle of balance implies a government's obligation to ensure their country's best public health outcome. One of the objectives of the Single Convention on Narcotic Drugs (11) is to ensure availability of opioids that are indispensable for the relief of pain and suffering. To accomplish this objective, the Single Convention requires that governments adopt laws, regulations and administrative procedures to implement mechanisms to ensure adequate availability of opioid medicines. Joranson et al. (14, 18) stated that "Any attempt to address adequate availability and accessibility of opioid analgesics should take a public health systems approach, the elements of which parallel those of patient care: examination of national and sometimes state-controlled drug policy and distribution systems; diagnosis of weaknesses and blockages; prescription of the necessary treatments; monitoring of outcomes; and re-treatment if necessary. The distribution system is only as strong as its weakest link. Figure 1 illustrates the basic elements of an opioid distribution system in which information about the requirement for opioids moves upward from the patient, and the adequate amount of medications move downward." (14, 18).

Figure 1 Distribution system that ensures patient access to opioids (modified from (14))



Guidance on government mechanisms to ensure adequate medicines availability is detailed in the WHO policy guidelines Ensuring Balance in National Policies on Controlled Substances, Guidance for Availability and Accessibility of Controlled Medicines (17). Annual estimates of the amount of opioids required for medical and scientific need to ensure sufficient import, reporting of consumption data, and dialogue with healthcare professionals to ensure appropriate procedures and sufficient supply of opioids in medical practice (18).

However, in many countries the focus of drug policies is on control at the cost of availability for medical purposes. Often governments have established control measures that are much stricter than required by the Single Convention, resulting in a disproportionate burden for healthcare professionals and patients compared to the potential public health outcome in terms of prevention of misuse and diversion. This includes excessive bureaucratic procedures such as complex prescription forms and prescription books, restrictions that limit the diagnoses of eligible patients, limitations on prescription amounts or on the daily dose, as well as complicated requirements for storage and dispensing of opioid medications (18). These unduly strict national laws have negative impact on the availability of opioid medications, resulting in a discrepancy between good medical practice and treatment reality, and eventually impeding relief of pain and suffering - an effect that was clearly not intended by the International Conventions (21).

4. Barriers to access to opioid medicines

Barriers to opioid availability are of multi-factorial nature; therefore tackling the problem from one side will not resolve it entirely. In a critical reflection on access to therapeutic opioid medications in Europe fifty years on from the Single Convention on Narcotic Drugs, James F. Cleary (Pain and Policy Studies Group) stated that “Implementation may be the hardest step as it would be false to state that the inadequate treatment of cancer pain is due entirely to regulatory restrictions. We know from experience that policy change alone does not bring about increased access. We need to address the low priority of pain with health care, inadequate education, exaggerated fear of opioids and addiction, and problems in the supply chain for the medications.” (21), p. 2. Next to legal and regulatory obstacles, barriers were identified in the following areas: national policies, knowledge and societal attitudes; and economic aspects, including affordability (17).

Legal and regulatory barriers include restrictive laws and regulatory barriers, resulting in burdensome bureaucratic procedures relating to the prescribing and dispensing of opioid medicines and in fear of legal sanctions and criminal prosecution due to unintended violations among healthcare professionals and pharmacists. But also restrictions regarding a patient’s eligibility for treatment with opioids, as well as professional restrictions such as specific license requirements for the prescribing and administering of opioid medicines can pose a barrier to access to opioids and interfere with clinical decision making.

Policy barriers refer to a country’s national policies related to availability of and access to opioids, such as the national health policy and infrastructure of service provision, reimbursement systems, but also the national priority for health problems requiring treatment with opioid medicines and how these factors can be barriers to the access of opioids.

Knowledge and societal attitudes include a lack of education in healthcare professionals resulting in inadequate medical practice, but also fears, misconceptions and stigma regarding opioids among patients, relatives, healthcare professionals, government officers, and the general public. For example, in the treatment of drug dependence there is a prevailing normative idea of ‘abstinence orientation’, i.e. the conviction that drug-freeness is the only possible therapeutic goal for people dependent on opioids. In pain treatment and palliative care, fear of dependence, side effects or even hastened death may prevent physicians from prescribing opioids but also patients from taking them. Lack of knowledge in healthcare professionals may lead to discomfort in physicians due to uncertainty in the appropriate assessment and treatment of pain or dyspnea, as well as insufficient knowledge in methadone maintenance treatment.

Economic aspects, including affordability refer both to a limited range of available formularies and to a gap in the supply of available opioids that would be required for medical treatment. A lack of available opioids can have different reasons such as problems in the storage, dispensing and distribution of opioids, gaps in the supply chain, inappropriate estimates and reporting of annual consumption data, or an inappropriate market of the necessary range of opioid formularies.

5. The ATOME project – an overview

The European Commission's 7th Framework programme funded the *Access to Opioid Medication in Europe* (ATOME) project from December 2009 for five years. Its objective is to improve access to opioids in 12 European countries (Figure 2) where there is statistical evidence of very low per capita morphine consumption: Estonia, Latvia, Lithuania, Poland, Slovakia, Hungary, Slovenia, Serbia, Bulgaria, Turkey, Greece and Cyprus.

Figure 2 Countries included in ATOME



The ATOME project was initiated and developed by the World Health Organization and coordinated by the University Hospital Bonn¹. The consortium consisted of 10 partners including members from the areas of palliative care, law and health policy as well as harm reduction (Table 1).

¹ From December 2009 until March 2011 by the University Hospital Aachen.

Table 1 Partners in the ATOME consortium

Palliative care	Law / health policy/ governance	Harm reduction
Department of Palliative Medicine, University Hospital Bonn, Germany	World Health Organization, Geneva, Switzerland	Eurasian Harm Reduction Network, Vilnius, Lithuania
Hospice Casa Sperantei, Brasov, Romania	Utrecht University, Utrecht, the Netherlands	Harm Reduction International, London, United Kingdom
Help the Hospices, London, UK	National Anti Drug Agency, Bucharest, Romania	
International Observatory on End of Life Care, Lancaster University, UK		
European Association for Palliative Care, Milan, Italy		

5.1. ATOME specific objectives and work plan

The partners of the ATOME project worked with country teams, including government officials and healthcare experts, to carry out applied legislative and policy research, leading to recommendations that would facilitate access for all patients requiring treatment with medicines controlled under the international drug conventions. The integration of palliative care and harm reduction was a key aim of the project. To accomplish its objectives, the ATOME project followed two tracks of activities in parallel (Figure 3).

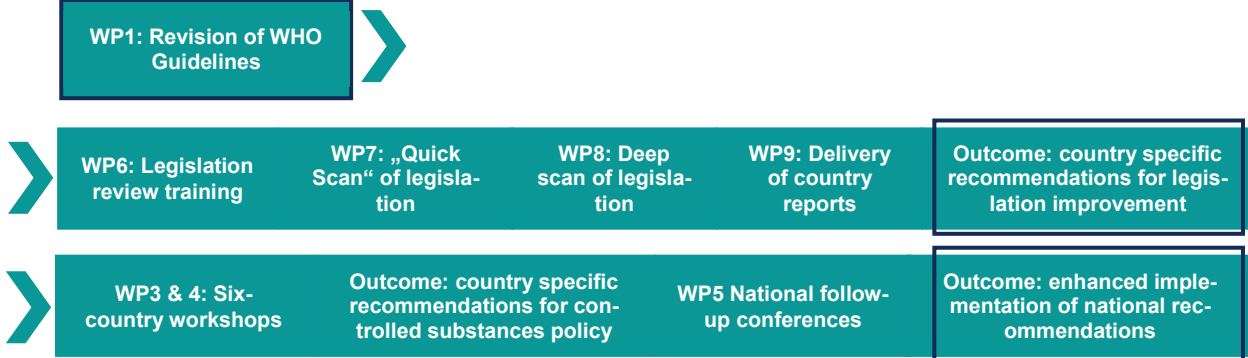
One track looked at optimising the relevant legislation in order to acknowledge both the prevention of misuse and dependence and the medical need for these medicines. The goal was to optimise relevant legislation by identifying provisions that may impede access to controlled medicines and to make recommendations for improvement in consultation with the national counterparts. Activities in this track started with a legislation review training for lawyers and national counterparts from the 12 target countries. This training focused on how to review national controlled substances legislation from the perspective of balancing availability and prevention of misuse and how to identify relevant legislation for the national legislation analysis. Based on this training, national counterparts selected legislation and provisions relevant for the access to opioid medicines in their country. A ‘quick scan’ of the pre-selected national legislation was undertaken followed by a deeper review of relevant legislation (for details on the methodology see Annex 2). The quality of final results, i.e. the identified legal barriers and appropriate recommendations for each country, was assured during a legislation review workshop with participants from the target countries and experts from relevant areas.

The other track was related to the analysis of national policies and national circumstances that affect the accessibility and availability of the medicines involved. The goals were both to make recommendations to the government and to make professionals aware of problems arising from their professional practice, by undertaking a national situational analysis with regard to controlled medicines, including their availability, rational use and reasons for underuse. Activities in this track were two six-country-workshops where the national delegations developed a national action plan for the improvement of the access to and availability of opioids in their country. The situation analysis, the identification of relevant challenges and appropriate proposals for solutions were elaborated by the national representatives themselves by using the value of an international exchange framework and by learning from mod-

els in other countries with similar problems. The national strategic action plans developed during these workshops were an important foundation for the subsequent activities of the country teams.

As a follow-up to the six-country workshops, national conferences were held in the respective countries. The aim of these one-day events was the sensitisation of key stakeholders towards opioid availability in their country, and dissemination of the results of the legislation analysis and the strategic action plan for improving access to opioids on a national level. The conferences also provided an opportunity for national experts to present their analysis and views and for national and international professionals from the fields of palliative care and harm reduction to network and engage in discussion about issues relating to opioid access. Building on the previously developed national strategic action plans, the conferences resulted in specific recommendations being developed in relation to improving opioid availability and accessibility at national level.

Figure 3 Two tracks of ATOME activities: legislation review and national situation analysis



Parallel to these two tracks, research and monitoring activities were undertaken in order to illuminate the background situation and the socio-cultural context in each country. Data were collected on the characteristics of each country such as demographic information, political and economic background, national healthcare system, public health context, prevalence of conditions associated with a potential need for opioid medicines, service provision and educational situation regarding controlled substances, as well as socio-cultural issues such as religion and spirituality, attitudes towards suffering, and public awareness regarding opioid medicines. The results of these research and monitoring activities were used to inform the ATOME database including country profiles for each of the countries addressed by this project.

5.2. ATOME strategic impact

The ATOME project was designed to have strategic impact on six levels: (1) developments of tools and standards; (2) national policy making processes and access to pain medication and substitution treatment; (3) national capacity building; (4) research collaboration and sharing of experiences in Europe; (5) contribution towards the implementation of European policies; and (6) impact on the patients and populations themselves – those in need of pain medication, people with opioid dependence, and related to the latter, populations at risk for HIV and HCV infections.

6. Key findings

Research conducted throughout the ATOME project provided insights and outcomes in four related areas relevant for access to opioid medicines: challenges in policy and guidance concerning access to opioids, legal barriers, policy barriers and the perception of barriers.

6.1. Challenges in policy and guidance concerning access to opioids

A substantial revision of the previous WHO Guidelines on national opioids control policy from 2000 (3) resulted in the WHO policy guidelines Ensuring Balance in National Policies on Controlled Substances, Guidance for Availability and Accessibility for Controlled Medicines (17). An expert consensus process reflected the challenges to the principle of balance inherent in the Single Convention on Narcotic Drugs (24). The expert panel consisted of experts from many countries and different work areas. The revision of the guidelines was developed through a three-stage Delphi process followed by a conference during which remaining differences of views were resolved. This consensus process reflected the difficulty of defining the ‘right’ balance between ‘rational use’ and ‘misuse’ of opioids. The definition of the concepts of ‘rational (medical) use’ vs. ‘misuse’ of controlled substances can be seen as pivotal for the principle of balance in controlled substances policies. However, it can also be questioned whether this distinction is an existing fact or a social construct in an attempt to cope with the challenge of outweighing the risks and benefits of certain substances. Disagreement emerging from the consensus process underlines the complexity of political guidance, which takes into account the delicate balance between control and easy availability, between necessary and unnecessary barriers, and between protection and harm. The resulting WHO policy guidelines provide guidance and recommendations on how to ensure balanced drug control policies (17).

6.2. Legal barriers

An external review of national legislation was undertaken to optimise relevant legislation by identifying provisions that may impede access to controlled medicines and by making recommendations for improvement in consultation with the national counterparts. The new WHO policy guidelines Ensuring Balance in National Policies on Controlled Substances provided the basis for the identification of potential barriers to access to opioids. The legislation review focused on nine different categories of potential legal and regulatory barriers, i.e. barriers

related to prescribing; dispensing; usage; trade and distribution; manufacturing; affordability; penalties; language; and other. A short summary of the most common potential legal and regulatory barriers identified in eleven of twelve European countries participating in the ATOME project is provided in this section.

The prescribing of opioids is subject to more or less strict administrative and non-administrative requirements. As an example, in several countries the authorisation to prescribe designated controlled medicines is restricted to a limited number of medical specialists (e.g. oncologists or psychiatrists). Some countries require a special permit, license or authorisation for prescribing controlled medicines. The procedures for prescribing opioid medicines can be complex and bureaucratic. Physicians are often obliged to use special prescription forms often in multiple copies. These forms are not always available free of charge. Complex reporting requirements can be applicable for physicians authorised to prescribe. In addition, limitations have been identified regarding the validity of medical prescriptions, the treatment period, the total amount of opioid medicines to be prescribed and some countries have lists with maximum daily dosages of opioid medicines in their legislation.

Similar to the prescribing of opioid medicines, most countries have complex administrative requirements regarding dispensing of opioids in their legislation. In some countries, only designated pharmacies are allowed to dispense these products or a license is required for dispensing. In addition, several countries require that opioid medicines are stored under overly strict and costly security conditions. Strict inclusion requirements can apply to accessing dependence treatment and the legislation in several countries contains administrative requirements and geographical restrictions to using opioid medicines.

The overly strict administrative requirements and the overly strict and costly storage requirements regarding the dispensing are also seen in the area of manufacturing, trade and distribution of opioid medicines. In some countries, intimidating language is used in punitive provisions and severe sanctions apply for patients, healthcare professionals or for persons involved in manufacturing, trade and distribution. In several countries treatment with necessary controlled medicines is not fully reimbursed or fees are applicable for receiving dependence treatment. In addition, all countries use language in their legislation that contributes to the stigmatisation of opioid medicines, for example by referring to opioid medicines as dangerous intoxicating drugs. Definitions are often absent or incorrectly used and patients with dependence syndrome are frequently referred to in a disrespectful manner.

The results of this external review of national legislation give rise to a critical internal review of national legislation and revision of provisions that might impede access to opioid medicines. This revision is recommended to take place in consultation with healthcare professionals to provide a legal framework that focuses on optimizing healthcare outcomes and preventing diversion and misuse. Several of the countries participating in the ATOME project are already in the process of revising legislation and implementing recommendations for improvement. As a result, several changes in legislation have already come into force, lifting potential barriers to access to opioids.

6.3. Policy barriers

To identify potential policy barriers to accessing opioid medication, documents developed during the project, such as protocols of national problem analyses, strategic action planning worksheets, and minutes of national ATOME conferences were systematically analysed. The identified policy barriers² and the resulting recommendations were sent to the respective national country teams for review and verification. For the twelve Eastern European countries participating in this project the major challenges to opioid access were identified in four main categories i.e. financial/ economic aspects and governmental support, formularies, education and training and societal attitudes. Based on material collected during several project events different provisions per category that have been considered to impede access to opioid medication in each country were also identified.

In terms of financial/economic aspects and governmental support, in most countries, the major provisions considered to impede opioid access were associated with insufficient funding for palliative care and harm reduction initiatives. The impact of economic recession currently experienced by a number of European countries as well as the lack of governmental support (of non-economic nature) were also identified as barriers to opioid access in almost half of the countries involved in this project. In some countries the governmental commitment/endorsement is more focused on prevention of diversion than on development, extension or promotion of effective standards for opioid treatment.

In terms of formularies in most countries, the major provisions considered to impede opioid access were associated with the high cost or the inadequate reimbursement of opioid treatment and palliative care services as well as the insufficient provision of such services or the conflicts observed between medical specialties during service provision. The shortage of palliative care experts and the lack of established multi-disciplinary palliative care networks were also identified as major barriers to opioid access in more than half of the countries involved in this project. In some countries, it was reported that there was a prevailing biomedical approach to illness and priority was given to causal treatment and cure of diseases, while the relief of pain and other symptoms, as well as psychosocial aspects were neglected. Moreover, provisions such as bureaucracy or overly restrictive regulations as well as geographical or age constraints were also identified as impeding access to opioid medication.

In terms of education and training, provisions related to absent, limited or fragmented post-graduate education and lack of training initiatives were identified in all countries whereas the absence or the inadequacy of continuing medical education was also observed in some of the participating countries. The impact of this type of barrier affects the implementation of legal changes in a country as well. Despite of formal changes such as facilitated requirements to use special prescription forms, physicians' prescribing activities do not change. As no formal barriers exist to obtain this type of prescription forms this is rather an effect of the lack of knowledge and inappropriate education or attitude towards opioid treatment of those physicians

² A barrier is reported for an individual country if it was identified to have an impact on access to opioid medicines in the respective country based on the collected data. Not for all countries was the similar amount of data (e.g. in the form of policy documents) available and therefore, the level to which access to opioids is impeded is not necessarily related to the number of barriers that was found. In countries where a particular barrier was not identified or directly reported, it can still be existent but may not have been focused or emphasised during the discussion with national stakeholders.

Related to societal attitudes, fears of opioids (fear of dependence, tolerance, diversion, and death), inadequate social dialogue and dissemination (of information and advice) as well as lack of awareness (misinformation and misconception) about the use of opioids in pain management, palliative care and harm reduction comprise barriers to opioid access identified in all twelve countries. In most countries stigma and discrimination was also considered to be one of the main barriers to impede access to opioid medication.

The findings of the review of national policies illustrate that beside barriers in the national legislation there are also several challenges concerning national policy strategies with regard to improved access to opioids and the use of these medicines for medical treatment. This outcome is based on problem analyses conducted by the country teams and on discussions with national stakeholders throughout the ATOME project. For several challenges recommendations have been made in relation to country specific backgrounds. Some of them have already been considered in national policies, some of them still are waiting for opportunities to be realized or to be completed. For that purpose the recommendations should be used in further exchange between authorities, stakeholders and the civil society.

6.4. Perception of barriers

Access to opioids can be hampered by barriers on different levels as described in chapters 6.2 and 6.3. Discussions within the ATOME project indicated that healthcare professionals and decision makers may have a different perception of barriers to opioid use. A questionnaire was compiled to compare the perception of barriers in different stakeholder groups in the field of pain management, palliative care and harm reduction.

A survey was conducted using a questionnaire partially constructed from already existing surveys, containing three sections: (1) knowledge and attitudes regarding medical use of opioids; (2) the perception of different types of barriers towards access to opioids; and (3) respondents' personal and professional details. The questionnaire was reviewed for content validity by four experts in pain management, palliative care, harm reduction and policy, and was pilot-tested in Latvia. Participants of the ATOME national conferences were invited to complete the questionnaire.

Data were collected from 233 stakeholders, among which 55% healthcare professionals, 17% government officers/ healthcare decision makers, 10% harm reduction professionals and 3% patient representatives during ATOME national conferences in seven countries (Estonia, Latvia, Lithuania, Poland, Slovakia, Hungary and Serbia).

The aspects that were most frequently perceived as a major barrier and as having major impact in practice were inadequate knowledge, skills and training in healthcare professionals; absence of a specific national policy on pain management/ palliative care; physicians' reluctance to prescribe opioids and lack of financial resources at an institutional level. Considerable differences were identified between groups; overall, government officers perceived issues less often as a major barrier compared to other stakeholder groups.

For example, a high proportion of healthcare professionals and patients reported that excessive regulation had a major impact on accessing opioids in practice, while this was seen less often as a problem by government officials. The regulatory burden perceived by healthcare

professionals could be one reason for the reported physicians' reluctance to prescribe opioids. The data do not allow to explain the reasons for the difference in perception between different stakeholder groups. Therefore, intensified dialogue will be necessary to facilitate a mutual understanding and develop effective solutions to improve access to opioid medicines.

6.5. General recommendations

Based on the analyses and the outcomes of the ATOME project general recommendations can be derived for all countries aiming to achieve and to ensure a balanced approach in national policies on controlled substances. A selection of them is presented in Textbox 3.

Textbox 3 Recommendations applicable to all countries

- Implement the WHO policy guidelines Ensuring Balance in National Policies on Controlled Substances, Guidance for Availability and Accessibility for Controlled Medicines;
- Identify potential legal and regulatory barriers to access to opioid medicines and working on changes with the aim to improve accessibility, availability and affordability;
- Ensure non-stigmatizing language in legal documents and language in official documents (e.g. by using the term 'Narcotic drug' only when referring to substances controlled under the Single Convention);
- Establish regular exchange opportunities (communication networks) between legal and governmental authorities, healthcare professionals and patients/families in order to raise awareness for practical impact and requirements of legal and policy decisions (target-performance comparison) regarding opioid availability and accessibility;
- Provide and support the implementation and development of national databases (including data on long-term outcomes and national fear of opioids) suitable for scientific research, evaluation of models of treatment with opioids and for monitoring the national demand on Essential Medicines;
- Ensure that treatment with opioids (knowledge, skills, attitudes) will be included in undergraduate and postgraduate education for relevant healthcare professionals (primarily physicians, nurses, pharmacists);
- Raise awareness and sensitisation for treatment with opioids among practicing healthcare professionals (e.g. via Continuing Medical Education, publication series on the rational use of opioids in highly-accessed national medical journals, a survey on knowledge and attitudes regarding opioid medicines);
- Raise awareness in the general public, e.g. via media campaigns or information, brochures for patients and relatives.

7. An outlook beyond ATOME

ATOME has produced some remarkable changes in the participating countries throughout the lifetime of the project. There are examples of the changes that may be directly attributable to the ATOME project. In Estonia validity of prescriptions for controlled medicines have been extended from 14 to 30 days, and digital prescription has been implemented in October 2012. Similarly, Turkey has started to implement an e-prescription system in July 2012. In Greece, legislation on controlled medicines was changed in March 2013, changing the designation from ‘narcotics law’ to ‘law on substances causing addiction’, introducing the principle of balance with mentioning of patients with chronic illnesses as potential users of controlled substances and an option for pharmacists to fill a prescription with a higher amount in emergency cases. In addition, a palliative care specialist was included in the Committee on Narcotics in the Ministry of Health. In Lithuania, the Department of Pharmacy in the Ministry of Health has prepared amendments to the regulations on opioid agonist therapy (OAT) which will allow to increase the amount of opioid medications to be stored in healthcare facilities from 7 to 60 days of supplies.

Some of these changes might have been triggered not only by ATOME activities, but also by other recent palliative care developments. The target countries of the ATOME project had been selected to include only countries where no major palliative care initiative had been reported, but parallel activities from other projects were evident in some countries. In Serbia, the project on ‘Development of Palliative Care Services in Serbia’ also looked at the legislation on controlled medicines and contributed to a change in legislation in December 2013 allowing non-governmental organizations to provide palliative care and prescribe medicines in the same way as public health institutions. However, feedback from the country teams suggested that ATOME activities had contributed significantly to these developments.

Even if not related directly to changes in legislation, ATOME activities resulted in more subtle changes, bringing together stakeholders from government, palliative care and pain management as well as harm reduction. This collaboration and networking has resulted in a change of atmosphere, and will produce more changes in legislation in the medium and long-term development that will overcome regulatory and legislative barriers.

ATOME has made an impact not only in the 12 participating countries, but also in other countries in Europe as well as in other regions of the world. The guidelines on ensuring balance in access to opioid medications of the World Health Organization have been used by government and non-government stakeholders, and the methodology with country teams and country workshops has also been used in other regions. National conferences with government representatives and palliative care experts from non-governmental organizations for example have been organized in Central and South American countries by the International Association for Hospice and Palliative Care.

ATOME results also have to be discussed in the context of recent advances in the global development of palliative care. Palliative Care has received considerable support from several international activities during the project time of ATOME. Foremost, a resolution on strengthening of palliative care at the World Health Assembly in May 2014 (25) has raised much attention on a global level. This was the first time that the highest global health authority published a statement on palliative care. The resolution urged member states to support access to essential medicines, and strengthen palliative care as a component of integrated

treatment throughout the life course, and stated that palliative care is an ethical responsibility of health systems.

Similarly, the inclusion of a palliative care indicator in the Action Plan for the Global Strategy for the Prevention and Control of Non communicable Diseases (26) (NCD) of the World Health Organization (WHO) has acknowledged pain relief and palliative care as among the top 12 issues on the global health agenda. The proposed indicator is: access to palliative care assessed by morphine-equivalent consumption of strong opioid analgesics (excluding methadone) per death from cancer. This indicator has some limitations and weaknesses, and morphine-equivalent consumption of strong opioid analgesics (excluding methadone) per capita has been suggested as an alternative (27).

Another important window of opportunity to put palliative care on the global health agenda: opens with the Sustainable Development Goals (SDGs) of the United Nations that will define global health priorities from 2015 to 2030 (28). The SDGs replace the eight millennium development goals (MDGs) that have been in place from 2000 until 2015. Palliative care is relevant to two of the targets related to the third goals in the SDGs. The target of achieving universal health coverage (UHC, target 3.8) includes access to essential health care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all. In addition target 3.9b aims to support research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, and provide access to affordable essential medicines and vaccines.

Results from the ATOME project such as the guidelines on ensuring balance (17) will be useful in the implementation of these global activities. The ultimate goal is to ensure access to adequate pain management, palliative care and harm reduction for every patient who needs it, no matter where he lives. Access to controlled medicines is needed for this goal.

8. Reference to the other chapters in this book

Part II of the ATOME final report provides twelve country reports including detailed findings and country specific recommendations to the Ministries of Health for each of the twelve European countries participating in the ATOME project. The country reports are presented according to the geographical order from North to South: Estonia, Latvia, Lithuania, Poland, Slovakia, Hungary, Slovenia, Serbia, Bulgaria, Turkey, Greece and Cyprus. Each country specific report starts with an introduction presenting the statistical evidence of very low per capita morphine consumption followed by a summary of identified legal and regulatory barriers and a selection of respective recommendations specific to each country. This section is followed by identified policy barriers and a selection of policy recommendations for the respective state. The fourth section of each country report presents citations of ATOME participants highlighting changes regarding access to opioid medicines in the country since the beginning of the project. Each report ends with a conclusion followed by a timescale presenting the ATOME activities and events in respective country during the five project years.

A further relevant element of the ATOME final report is the Annex collection. This collection includes four attachments:

- *Annex 1 Additional country information* contains selected parts of the respective country profile, a report of the national conference and an overview of national counterparts, i.e. the members of the ATOME national country team;
- *Annex 2 Legislation Review Reports* presents the original contents of eleven legislation review reports including a detailed description of methodology used for the lawyers' legislation review training, the 'quick scan' and the deep scan of legislation. These reports were prepared by the Utrecht Institute for Pharmaceutical Sciences, Division of Pharmacoepidemiology & Clinical Pharmacology, Utrecht University (Utrecht, the Netherlands) as this project partner was the responsible work package leader for the above mentioned activities;
- *Annex 3 ATOME publications* provides an overview on the ATOME articles in scientific journals and abstracts of international congresses as part of the dissemination activities;
- *Annex 4 Description of Consortium Members* presents organizations and staff members participating in the Consortium of the ATOME project.

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Report and recommendations to the Ministries of Health

Part II: Country Specific Part

November 2014



Access to Opioid Medication in Europe (ATOME)

Report and recommendations to the Ministry of Social Affairs

1. Country Report - Estonia

1.1. Introduction

Estonia is one of the countries with statistical evidence of inadequate morphine consumption per capita. In 2006, the adequacy of opioid analgesic consumption was only 11% - based on a per capita consumption of 24.63 morphine equivalents (mEq) while 216 mEq would have been adequate for treatment of all pain conditions³. Estonia was selected as one of the countries to participate in the ATOME project due to its low per capita morphine consumption. Four years later, in 2010, the adequacy of opioid analgesic consumption had even slightly decreased (both in absolute and in relative terms) – it was only 6%⁴ (based on a per capita consumption of opioid analgesics of 18.39 morphine equivalents (mEq) while 310.09 mEq in mg per capita would have been adequate). This report presents a summary of the results of the situational analysis that has been undertaken with regard to opioid availability and accessibility in Estonia. The results of the situational analysis are divided in two parts: the first part addresses legal and regulatory issues and the second part focuses on issues relating to policy. Both parts present the main barriers and recommendations for improving access to opioid medication in Estonia.

1.2. Identified legal and regulatory barriers

The results of the ATOME legislation review have been divided into nine different categories of potential legal and regulatory barriers, i.e. barriers related to prescribing; dispensing; usage; trade and distribution; manufacturing; affordability; penalties; language; and other. In Estonia, potential legal and regulatory barriers have been identified in eight of these nine categories: all except affordability (see Annex 2). A selection of these potential barriers is highlighted below according to category, followed by recommendations to remove these barriers. For a more detailed description of the methods and results, see Annex 2. Notably, in the course of the project – not least related to the continuing engagement of the legal experts in the ATOME Estonia country team – several changes to the legislation came into force. As a consequence, a number of major barriers were lifted before the end of the project and are not applicable anymore. For reasons of transparency, the original results of the external review of national legislation concerning controlled substances which was collected in the period March 2011 – February 2013 (legislative changes that were implemented after February 2013 have not been taken into account) are presented here; parts that were changed are

³ Seya MJ, Gelders SFAM, Achara UA, Milani B, Scholten WK. A First Comparison between the Consumption of and the Need for Opioid Analgesics at Country, Regional and Global Level. *Journal of Pain and Palliative Care Pharmacotherapy*, 2011; 25: 6-18. Accessible at:

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⁴ Duthey, B., Scholten, W. Adequacy of Opioid Analgesic Consumption at Country, Global, and Regional Levels in 2010, Its Relationship With Development Level, and Changes Compared With 2006. *Journal of Pain & Symptom Management* 47(2); 2014: 283-97 doi:10.1016/j.jpainsymman.2013.03.015; <http://www.sciencedirect.com/science/article/pii/S0885392413002728>

highlighted with an asterisk and the changes including the current situation are described in an amendment below the respective paragraph.

PRESCRIBING: The prescribing of opioids in Estonia is subject to many administrative and non-administrative requirements. For example, the total amount of controlled substance to be prescribed is limited to the quantity necessary for one month. In addition, the validity of a special medical prescription used for prescribing controlled substances is limited to 30 days from the date of issuance of the prescription⁵. These restrictions are potential barriers to access; patients who require medical treatment with controlled medicines for a longer period will need to visit the physician and pharmacy frequently.

Administrative requirements that apply to the prescribing of opioid medicines may deter healthcare professionals from prescribing these medicines. For example, special prescription forms - in three copies printed in green on red self-copying paper - must be used when prescribing controlled medicines classified as 'narcotic drugs'. A copy of the prescription form has to be stored for 5 years according to prescription date at the place of employment of the healthcare professional who prescribed the controlled medicine⁶.

In addition, medical practitioners are required to collect the remaining controlled medicines for destruction upon the death of a patient⁷. All these requirements may increase the administrative burden and potentially cause medical practitioners in Estonia to be reluctant to treat patients with controlled medicines.

DISPENSING: Additional requirements for the dispensing of controlled medicines may increase the administrative burden and may cause pharmacists to be reluctant to dispense controlled medicines. According to the Estonian legislation, a license is required to be authorised to dispense controlled medicines containing substances listed in Schedule II. In addition, only pharmacies that have obtained this license are authorised to receive unusable medicinal products classified as 'narcotic drugs' or 'psychotropic substances' from consumers. The requirement for a license to dispense controlled medicines in pharmacies is a potential barrier to access as it may deter pharmacist for applying for such a license⁸. The prohibition to receive unusable controlled substances without a license contributes to the stigma of controlled substances use.

TRADE AND DISTRIBUTION: Requirements regarding the trade and distribution (and also the manufacturing) of controlled medicines may increase the administrative burden and may delay or impede the availability of medicinal products on the market. According to the Estonian legislation, substances subject to special recording must be received in the presence of at least three members of the committee⁹. In addition, controlled substances have to be stored in a room without windows, separated from the surrounding rooms by partitions extending up

⁵ In October 2012 the prescription validity has been prolonged from 14 to 30 days and digital prescription has been implemented.

⁶ However, the digital prescription system, introduced in Estonia on 1st January 2010, ensures fast and paperless communication between the doctor, the pharmacist and the patient. Since 2010 more than 90% of all prescriptions were electronic (digital prescription). Drugs can also be bought from pharmacy for someone else (by family member, social worker etc.).

⁷ This specific requirement for collecting remaining controlled medicines was entirely repealed, entered into force on 23.09.2013 (*Regulation No. 73 of the Minister of Social Affairs of 18 May 2005 § 10. Gathering for destruction and destruction of narcotic drugs and psychotropic substances.*)

⁸ In July 2013, the requirement that an authorisation is needed to be allowed to dispense controlled medicines has been removed. Since 01.07.2013 all pharmacies can order and dispense controlled medicines.

⁹ This requirement/provision was repealed, entered into force on 23.09.2013, the whole paragraph was revised and paraphrased.

to the ceiling. The room must have a metal door and must be equipped with a separate alarm system connected to the security centre¹⁰. The costs of these security measures may be disproportional compared to the risk of misuse and diversion, and may therefore deter legal entities from trading in controlled medicines.

LANGUAGE: In the Estonian legislation, the distinction between medical use and abuse or illicit use is not always clear. In addition, the terms ‘addict(s)’, ‘addiction’ and ‘persons addicted’ are considered to be stigmatising, and are used in the reviewed Estonian legislation.

Textbox 4 Selection of recommendations specific to Estonia: legal and regulatory

- Reconsider the restrictions that apply to the amount to be prescribed and the validity of a medical prescription, in particular if these restrictions do not apply to other non-controlled medicinal products;
- Decrease the administrative burden for prescribing and dispensing opioid medicines;
- Remove the obligation for medical practitioners to collect the remaining controlled medicines for destruction upon the death of a patient¹¹;
- Remove the requirement for pharmacies to obtain a special license to be authorised to dispense (and receive unusable) controlled medicines¹¹;
- Ensure that the costs of security measures for the storage of controlled medicines are not disproportional compared to the risk of abuse and diversion;
- Provide clear language in legislation and avoid language that stigmatises the medical use of opioids or refers to patients with dependence in a disrespectful way.

1.3. Identified policy barriers

For Estonia, the main challenges concerning access to opioids were identified in financial/economic aspects, issues relating to formularies, education and training and social attitudes.

FINANCIAL/ ECONOMIC ASPECTS: Economic welfare appears to be the foremost priority in Estonia with more emphasis being placed on living rather than on how you are going to die. There is an evident lack of interest in pain management and palliative care with education and training on these fields being rarely available due to lack of sufficient funding. Hospitals do not have enough money to send their staff to attend refresher training although at least 60 hours per year of this kind of training is required for every healthcare worker. Given that refresher courses have to be paid for, most healthcare professionals abstain from attending since this is something they cannot afford. More money should be invested on palliative care opportunities and harm reduction initiatives. However, the financial crisis that Estonia suffers the last few years has resulted in the financial situation in healthcare being seriously affected.

FORMULARIES: Palliative care is not a medical specialty in Estonia and there is an overall lack of recognition leading to a shortage of experts. This lack of palliative care experts results

¹⁰ Storage conditions were revised and simplified, entered into force on 23.09.2013.

¹¹ These two recommendations have already been implemented. Entered into force 23rd of September 2012 and 1st of July 2013.

in physicians or nurses often ‘working alone’. The idea of the ‘multidisciplinary team’ is not common in Estonia as there is lack of awareness of certain professional roles (for example, the role of social workers is particularly ‘clouded’). This is mainly because biomedical approaches are given more priority than psychosocial or spiritual issues. In addition, the cost of receiving palliative care in a hospital or nursing home is reported as being ‘very expensive’ (partly-paid for by the patient/family).

For some patients living in areas with low prevalence the travel costs of getting Opioid Agonist Therapy (OAT) are extremely high. Some medications available in other EU countries or/and Estonia are either not listed as subsidized by healthcare funds or they are only subsidized by 50%. But Estonian Health Insurance reimburses all essential medicines listed in WHO Model Lists of Essential Medicines. Moreover, there is lack of experience in prescribing amongst family practitioners.

AVAILABILITY AND QUALITY OF OAT SERVICE PROVISION: Few healthcare professionals wish to become involved in OAT due to a lack of motivation and the fact that ‘additional competencies’ required by healthcare professionals working in this area (debt counselling, teaching skills, etc.) have not been identified. If a patient already starts working to get better and making progress but the attending healthcare professional does not have the qualifications or the competencies to offer as much as the person to be treated is actually able to take on, this will hamper the progress and the outcomes of the treatment. In many countries there are patient organisations that stand for the rights of this target group. The idea is to approach consultants in other countries where this experience already exists and to build up a group that could advise healthcare professionals in Estonia.

EDUCATION AND TRAINING: Education and training in pain management is rarely available in Estonia, mainly due to lack of priorities in this area. Undergraduate medical education does include pain management but this is quite fragmented. In addition, lecturers are not well informed about the contents of other programmes and, as a result, the curriculum on pain management is not well coordinated and not all important topics are sufficiently addressed. At universities or colleges, coordination within the faculty is necessary in order to agree on what exactly needs to be taught to the students. Training programmes are also weakly developed with few routes for accreditation/professional recognition. Training appears to focus heavily on oncology which makes it practically impossible for other medical specialties to be considered. Furthermore, there are no Continuing Medical Education (CME) opportunities in pain management. Continuing education or refresher courses should be made more obligatory or there should be more incentives for physicians to participate in refresher training courses. These could not only provide specific skills to physicians, nurses, social workers, and others healthcare professionals which were not acquired through their basic education but also address the outdated views of older colleagues by raising their awareness of the progress made in the field of pain treatment.

SOCIAL ATTITUDES: There is serious lack of awareness with respect to palliative care at all societal levels - politicians, healthcare professionals, and the general public. If people do not understand what palliative care is, the purpose, the potential benefits, and the long-term goals of this type of care provision. There is also ‘much negative’ media coverage relating to the use of opioids in pain management and palliative care. As a result, fear of opioids persists, mainly rooted in ‘not knowing’. Awareness and education is, therefore, important in order to break through the misunderstandings that opioids are dangerous, that someone will

become dependent on them straight away, or that an opioid prescription means that ‘you are ready for your grave’. It is extremely difficult to change the existing ‘mindset’ of people compounded by the societal perception that suffering/pain is normal, heroic and necessary. There is also a lot of scepticism surrounding OAT in Estonia. Therefore, a differentiated and professionally substantiated view of patients’ individual motivation and capability to change their situation in order to offer the adequate treatment approach. More resources will be needed to explore this appropriately and help patients and their families to achieve their goals more effectively. Moreover, it is important to work with families in order to support the patient’s treatment since their attitude towards OAT will have an impact on the patient’s compliance.

Textbox 5 Selection of recommendations specific to Estonia: policy

- Provide additional finance for palliative care opportunities and harm reduction initiatives;
- Invest more money on continuing education/refresher training;
- Reform education and training curricula on pain management and palliative care;
- Make continuing education/refresher training compulsory and offer more incentives to physicians in order to participate in such courses;
- Address traditional views (concerning attitudes towards opioids) in older colleagues and raise their awareness of the progress made in the field;
- Compile a list of essential medicines (based on WHO) to maintain supply chains;
- Improve the exchange of information between wholesalers, pharmacists, doctors and patients (enabled by the National Medicines Board);
- Liaise with public health institutions to contribute to the provision of OAT services;
- Identify ‘additional competencies’ required by healthcare professionals involved in OAT;
- Promote the concept of multi-disciplinary team work both in OAT and in pain management / palliative care;
- Involve patients and families in the process of developing OAT;
- Raise awareness of the general population with respect to opioid use for pain management and palliative care;
- Challenge the misunderstandings surrounding opioid use.

1.4. Voices from Estonia ATOME participants

In the summer of 2012 and of 2014, national key contacts and representatives of the national ATOME country teams were asked what had changed regarding access to opioid medicines in their country since the beginning of the project. Additionally, the national country team provided information concerning some changes in legislation in February 2014. These are examples of answers by representatives of the Estonia country team.

Textbox 6 Voices from Estonia ATOME participants

“Although there has been only one month since previously mentioned changes of legislation came into force [prescription for narcotic drugs valid for 30 days; new reimbursement possibilities for opioids etc.; entered into force 01.10.2012], feedback from doctors has been very positive. [...] Hopefully new less restrictive provisions in legislation will increase accessibility of opioids to patients who need them for pain treatment” (Ms Eda Lopato, 05.11.2012).

“By the time of and shortly after the ATOME Estonia National Symposium on Access to Opioid Medication in Tallinn (19.09.2013) we introduced some changes in legislative acts, e.g. ‘Act on Narcotic Drugs and Psychotropic Substances and Precursors thereof’ - sections 4 (6), 4 (7), 4 (8) and 4 (12) were repealed, entry into force 27.04.2013, in part 01.07.2013. Since then all pharmacies have been able to dispense controlled substances to patients.

We also introduced changes to the Regulation No. 73 of the Minister of Social Affairs of 18 May 2005, i.e. ‘Conditions and Procedure for Handling of Narcotic Drugs and Psychotropic Substances for Medical and Scientific Purposes, and Conditions and Procedure for Maintaining Records and Reporting in that Area and Schedules of Narcotic Drugs and Psychotropic Substances’ (entered into force on 23.09.2013).

Estonian legislation is in a continuous improvement process. There will be more changes (for example simplifying the requirements for travellers etc.) in the near future.

Furthermore, I am happy to let you know that according to the Estonian Health Insurance Fund 97% of all prescriptions were electronic (digital prescription) in 2013 in Estonia” (Ms Eda Lopato, 07.03.2014).

“The statistics on the consumption of opioids in Estonia (2008-2013) shows that the consumption of opioids increases. But we think that it takes more time to see the obvious impact of the ATOME project” (Ms Marta Mäe, 01.07.2014).


1.5. Conclusion

Potential barriers to accessing opioids in Estonia have been identified in the areas of legislation and policy. The ATOME project recommends that the Estonian legislation should be revised to provide a legal framework that focuses on optimizing healthcare outcomes while preventing diversion and misuse. The project also recommends that prescribing and dispensing should be facilitated (maximum amount of controlled medicines to be prescribed and the validity of a prescription should be reconsidered as well as special licenses for pharmacies). The costs of security measures for the storage of controlled medicines should not be disproportional compared to the risk of misuse and diversion. Clear language and non-stigmatizing terms in the Estonian legislation should be guaranteed. Considering the identified policy barriers in Estonia the ATOME project advises the provision of additional finance for palliative care and harm reduction initiatives; the reform of education and training curricula on pain management and palliative care; and identification of additional competencies required by healthcare professionals involved in OAT. Refresher training should become compulsory and at the same time accessible and affordable for healthcare professionals; a particular focus should be laid on awareness of the progress made in the field of opioid treatment as well as of the concept of multi-disciplinary team work. The reimbursement of essential medicines and of OAT treatment should be improved. Furthermore, the awareness of the general population with respect to opioid use should be raised – e.g. by improving the exchange of information between wholesalers, pharmacists, doctors and patients and by involving patients and families in the process of developing OAT.

Throughout the ATOME project, encouraging developments have been observed in terms of improved access to opioids in Estonia, supported by an extraordinary commitment of the Estonia country team. Some of the recommendations made in this report have already been implemented, but others remain as a barrier to access to opioids, and a balance between preventing misuse and ensuring availability still needs to be achieved.


The continuing efforts of the country team to implement the specific goals elaborated in the early stages of the ATOME project are expected to have facilitated improvements at different strategic levels.

Table 2 Timescale of ATOME activities and events in Estonia



Month Year	ATOME work activities	ATOME events	Activities Estonia country team	Important events in Estonia relevant for access to opioid medication	ATOME results/ achievements
Dec 2009		Start of the project			
Dec 2010	Identification of country team members and national counterparts				List of country team members and national counterparts available
Feb 2011		Lawyers' training workshop	Ms Eda Lopato attended the workshop		
Mar 2011	Quick scan of legislation started				
April 2011			Ms Eda Lopato sent legal documents on behalf of the ATOME Estonia country team	Meeting with pain experts	
May-June 2011			The Estonian country team completed the self-assessment checklist		
July 2011	Analysis of the completed self-assessment checklists				
Aug 2011	Preparation of the six-country workshops				
Sept 2011		First six-country workshop (Bulgaria, Cyprus, Greece, Serbia, Slovenia, Turkey)			
Nov 2011			The Estonian country team attended the workshop and worked on a national strategic action plan		National strategic action plan on improving access to opioids in Estonia
Jan 2012					Report on the results of the quick scan of legislation

Timescale of ATOME activities and events in Estonia	Month Year	ATOME work activities	ATOME events	Activities Estonia country team	Important events in Estonia relevant for access to opioid medication	ATOME results/ achievements
	Nov 2011 – May 2012	Preparation of ATOME national conference in Estonia		Collaboration between ATOME team and Estonian country team (co-ordinated by Ms Eda Lopato)	Changes in legislation 03.05.2012 entered into force 01.10.2012 (validity of prescription, amount of medicines prescribed)	
	June 2012			Ms Eda Lopato informed UU on revisions of legal documents and amendments, and sent additional legal documents on behalf of the ATOME Estonia country team		
	July-Nov 2012	In-depth analysis of national legislation				Draft overview of legal barriers to opioid availability in Estonia
	Oct 2012			Ms Eda Lopato sent additional legal documents on behalf of the ATOME Estonia country team	01.10.2012 abovementioned changes entered into force	
	Nov 2012	Preparation of legislation review workshop in Utrecht, the Netherlands		Ms Eda Lopato informed UU on further achievements and (foreseen) changes in legislation concerning opioid medicines		
	Jan 2013	Draft report on legal barriers in Estonia sent to the ATOME Estonia country team				Draft report on legal barriers in Estonia
	Jan-Feb 2013	Draft report on legal barriers in Estonia sent to the Estonian country team	Legislation review workshop in Utrecht, the Netherlands			Draft report on legal barriers in Estonia Report on legislation review workshop highlighting the important outcomes and topics of discussion
	Feb 2013			Ms Eda Lopato sent feedback to draft report		



Month Year	ATOME work activities	ATOME events	Activities Estonia country team	Important events in Estonia relevant for access to opioid medication	ATOME results/ achievements
Mar 2013			<p>Leading role of Estonia country team and experts at the national conference</p> <p>Ms Eda Lopato informed UU on further achievements and changes in legislation concerning opioid medicines</p>		
July 2013				Requirement for special license for pharmacies was repealed (legislational change entered into force 01.07.2013)	
Sept 2013	National follow-up conference implemented in Tallinn, Estonia			Legislational changes concerning storage, record keeping and reporting on Opioids (entered into force 23.09.2013)	
Feb 2014					Final report on legal barriers in Estonia sent to the ATOME Estonia country team

Access to Opioid Medication in Europe (ATOME)

Report and recommendations to the Ministry of Health

2. Country Report – Latvia

2.1. Introduction

Latvia is one of the countries with statistical evidence of inadequate morphine consumption per capita. In 2006, the adequacy of opioid analgesic consumption was only 9% - based on a per capita consumption of 21.31 morphine equivalents (mEq) while 233 mEq would have been adequate for treatment of all pain conditions¹². Latvia was selected as one of the countries to participate in the ATOME project due to this reason. Four years later, in 2010, the adequacy of opioid analgesic consumption had even slightly decreased (both in absolute and in relative terms) – it was only 6%¹³ (based on a per capita consumption of opioid analgesics of 19.64 morphine equivalents (mEq) while 332.56 mEq in mg per capita would have been adequate). This report presents a summary of the results of the situational analysis that has been undertaken with regard to opioid availability and accessibility in Latvia. The results of the situational analysis are divided in two parts: the first part addresses legal and regulatory issues and the second part focuses on issues relating to policy. Both parts present the main barriers and recommendations for improving access to opioid medication in Latvia.

2.2. Identified legal and regulatory barriers

The results of the ATOME legislation review have been divided into nine different categories of potential legal and regulatory barriers, i.e. barriers related to prescribing; dispensing; usage; trade and distribution; manufacturing; affordability; penalties; language; and other. In Latvia, potential legal and regulatory barriers have been identified in all nine categories (see Annex 2). A selection of these potential barriers is highlighted below according to category, followed by recommendations to remove these barriers. For a more detailed description of the methods and results, see Annex 2.

PRESCRIBING: The prescribing of opioids in Latvia is subject to many administrative and non-administrative requirements. For example, the authorisation to prescribe controlled medicines is restricted to physicians working in medical treatment institutions. In addition, only ‘narcologists’ are allowed to prescribe the controlled medicines methadone and buprenorphine. These restrictions can be a potential barrier to access, in particular if these physicians are not readily available to prescribe these medicines. Restrictions also apply to the amount of controlled medicines to be prescribed on a single prescription: physicians are not allowed

¹² Seya MJ, Gelders SFAM, Achara UA, Milani B, Scholten WK. A First Comparison between the Consumption of and the Need for Opioid Analgesics at Country, Regional and Global Level. *Journal of Pain and Palliative Care Pharmacotherapy*, 2011; 25: 6-18. Accessible at:

<http://apps.who.int/medicinedocs/documents/s17976en/s17976en.pdf>

¹³ Duthey, B., Scholten, W. Adequacy of Opioid Analgesic Consumption at Country, Global, and Regional Levels in 2010, Its Relationship With Development Level, and Changes Compared With 2006. *Journal of Pain & Symptom Management* 47(2); 2014: 283-97 doi:10.1016/j.jpainsymman.2013.03.015; <http://www.sciencedirect.com/science/article/pii/S0885392413002728>

to exceed the maximum amounts specified in regulations and for outpatient treatment 'narcologists' are not allowed to prescribe treatment with the controlled medicine buprenorphine more than once every two weeks. These restrictions can be potential barriers to access; patients who require medical treatment with controlled medicines for a longer period will need to visit the physician and pharmacy frequently.

Administrative requirements that apply to the prescribing of opioid medicines may deter healthcare professionals from prescribing these medicines. For example, special prescriptions with margins coloured in light red must be used when prescribing controlled medicines. The issuance of these prescription forms shall be ensured by a responsible official upon a request approved by the manager of a medical treatment institution. The requisites of the medical treatment institution, date of request, request number, number and type of prescription forms shall be indicated in the request, which will be valid for only seven days. In addition, the medical practitioner must - when prescribing controlled medicines - notify the patient that unused special prescriptions shall be turned in to the medical treatment institution in which they have been written out. All these requirements may increase the administrative burden and potentially cause medical practitioners in Latvia to be reluctant to treat patients with controlled medicines.

DISPENSING: Additional requirements for the dispensing of controlled medicines may increase the administrative burden and may cause pharmacists to be reluctant to dispense controlled medicines. According to the Latvian legislation, controlled substances have to be stored in a separate room or a safe, or in a metal cabinet, which is attached to a wall or to the floor and equipped with an alarm system. The costs of these security measures may be disproportional compared to the risk of misuse and diversion, and may therefore deter pharmacists from dispensing controlled medicines. In addition, pharmacies are obliged to provide many details to the State Agency of Medicines regarding medicinal products that have been ordered using the special prescription forms, including the prescription series and number; personal identity number of the patient; the name of the medical treatment institution; code of diagnosis; name of insurance company (if an insurance company compensates the patient for the purchase of medicinal products); code and quantity (number of packages) of the medicinal products dispensed. The recording of these details (in particular the code of diagnosis and personal identity number) may also unnecessarily violate the privacy of patients and may deter patients from entering or continuing treatment.

USAGE: Treatment with controlled medicines for patients with dependence should be available within a reasonable distance to ensure that all patients in need of treatment of dependence can have access to treatment. According to the Programme for Limiting the Spread of Human Immunodeficiency Virus for 2009–2013 pharmacological maintenance treatment for opioid dependence has only been available in Riga. Geographical restrictions to the availability of controlled substances can impede access, depending on the geographical spread of the places where the rehabilitation programs are running. According to the Latvian legislation, replacement treatment for opioid dependence will be terminated if patients use other controlled medicines without an order of the physician who prescribes treatment for opioid dependence. This provision can be a potential barrier to access to pain treatment for patients with dependence if this prohibition deters physicians from prescribing medicines for the treatment of pain when pain treatment is medically necessary.

AFFORDABILITY: High costs for controlled medicines can impede access to medicines. In Latvia, the controlled medicine buprenorphine used for the treatment of dependence is not reimbursed, which is considered to impede access to this specific controlled medicine.

LANGUAGE: In the Latvian legislation, the distinction between medical use and misuse or illicit use is not always clear. In addition, the terms ‘addict(s)’, ‘addiction’ and ‘persons addicted’ are considered to be stigmatising, and are frequently used in the reviewed Latvian legislation. This also applies to referring to controlled medicines as dangerous or addictive drugs.

Textbox 7 Selection of recommendations specific to Latvia: legal and regulatory

- Remove the restriction that only ‘narcologists’ are allowed to prescribe methadone and buprenorphine for the treatment of dependence, especially if the number of ‘narcologists’ available to treat dependence is too low or not well spread throughout the country, causing a delay in onset of treatment;
- Reconsider the restrictions that apply to the amount of controlled medicines to be prescribed on a single prescription;
- Decrease the administrative burden for prescribing and dispensing opioid medicines;
- Ensure that the costs of security measures for the storage of controlled medicines are not disproportional compared to the risk of misuse and diversion;
- Ensure that patients are able to receive treatment with controlled medicines within a reasonable time and distance, also in the situation that patients need controlled medicines for the treatment of dependence;
- Ensure that necessary controlled medicines are affordable for people in need of these medicines and medical institutions treating patients with these medicines, including buprenorphine for the treatment of patients with dependence;
- Provide clear language in legislation and avoid language that stigmatises the medical use of opioids or refers to patients with dependence in a disrespectful way.

2.3. Identified policy barriers

For Latvia, the main challenges concerning access to opioids were identified in governmental supports including financial/economic aspects, issues relating to formularies, education and training and social attitudes.

GOVERNMENTAL SUPPORT and FINANCIAL/ ECONOMIC ASPECTS: The importance of State/Governmental support needs to be emphasised since without their endorsement raising awareness about opioids in the general population is considered to be 'impossible'. Additional finance is also required. More money should be invested on harm reduction initiatives. However, politicians seem to be reluctant to support methadone treatment programmes in spite of strong evidence for the effectiveness of methadone maintenance programmes, which have various positive long-term effects both for the individual and for national public health (¹⁴). In addition, there is insufficient funding for palliative care services and the people who work in palliative care settings are underpaid. During the last few years, Latvia has been heavily hit by the financial crisis and, as a result, the financial situation in healthcare is currently worse than ever before.

FORMULARIES: Better access to opioids needs to be provided. Access needs to be improved for older people and for people living in rural areas of the country. This should also include reimbursement of the patients' travel costs. Moreover, opioids are reimbursed for HIV/AIDS patients but not for patients with other non-oncological diseases. This is an issue that needs to be addressed. In relation to harm reduction, Latvia ranks the lowest in Europe with respect to the coverage of long-term pharmacological treatment for opioid dependence compared to the estimated number of illicit opioid users. Further, it is estimated to have the lowest number of clients in methadone treatment programmes. Methadone treatment is very expensive (there are high fees for entering a treatment programme). Currently people have to spend half of their monthly salary to pay for treatment. General practitioners need to become more involved in order to improve access to harm reduction initiatives outside the central treatment centres. Finally, there is a lack of collaboration between the different parties involved to ensure the effectiveness of treatment. Social workers need to be also included in the multidisciplinary teams involved in the treatment of pain.

EDUCATION AND TRAINING: Human resources need to be considered as a top priority. The quality of education and training remains an important issue in Latvia. The amount of palliative care education opportunities currently available in the country is limited. There is a lack of certified teaching programmes on palliative care at both an undergraduate and post-graduate level. Sometimes general practitioners and specialists end up using different language which can be confusing and frustrating for patients and their families. Therefore, improvement of education is imperative. Definitions and language to be used needs to be agreed on for a better understanding between physicians themselves and between physicians and patients. Training in palliative care should be provided for physicians and nurses. Their knowledge about correct usage of opioids according to indications, prevention of side effects and substitution therapy with methadone seems to be quite restricted. Life-long learning and specialist courses should also be provided. Problems appear in the area of prescription with physicians not having the time for proper assessment of patients. Another important problem is measuring pain effectively as scales or other tools to measure pain are not used

¹⁴ World Health Organization. Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence. Geneva 2009. ISBN 978 92 4 154754 3. Accessible at: http://www.who.int/substance_abuse/publications/opioid_dependence_guidelines.pdf

on a regular basis. Every clinician should be familiar with pain management. It is therefore crucial to introduce pain assessment and pain management in general practice. There is also a lack of education/trained clinical pharmacists, especially in rural areas.

SOCIAL ATTITUDES: There are persistent misunderstandings surrounding opioid use amongst society and healthcare professionals (e.g. fear of dependence, diversion and death). Stigmatisation comprises a major problem (e.g. pain is seen a natural component of some diseases such as cancer and therefore needs to be accepted, suspicion of drug seeking behaviour) leading to resistance to the use of opioids for the treatment of pain. Communication and information exchange between physicians and patients needs to be facilitated. This way patients and families (which are often ignored) can get correct knowledge and accurate information (they have the right to get) concerning the use of opioids in pain management and palliative care.

Textbox 8 Selection of recommendations specific to Latvia: policy

- Encourage cooperation and collaboration between key stakeholders (Ministry of Health, Latvian Pharmacist Society, National Health Service, and Local Municipalities);
- Increase funding for palliative care and organise effective structures (including daycare centres and primary care services);
- Promote palliative care for non-oncological patients;
- Develop graded opioid education and training programs in collaboration with the Ministry of Health - especially the Pharmacy Division - and family doctor associations;
- Further develop palliative care education and training curricula;
- Provide additional finance for harm reduction initiatives (including reimbursement of buprenorphine);
- Improve cross-sectoral collaboration between different healthcare disciplines in relation to harm reduction initiatives;
- Amend unclear/stigmatizing terminology relating to opioids;
- Raise awareness of the general population with respect to opioid use;
- Challenge the stereotypes surrounding opioid use.

2.4. Voices from Latvia ATOME participants

In the summer of 2013, national key contacts and representatives of the national ATOME country teams were asked what had changed regarding access to opioid medicines in their country since the beginning of the project. This is an exemplary answer by one representative of the Latvia country team.

Textbox 9 Voices from Latvia ATOME participants

“This year, new formulations of Fentanyl tabs were included in the reimbursed system to treat the breakthrough pain in cancer. I see this as a direct impact of our work in the ATOME programme“
(Vilnis Sosars, 15.01.2014).


2.5. Conclusion

Potential barriers to accessing opioids in Latvia have been identified in the areas of legislation and policy. The ATOME project recommends that the Latvian legislation should be revised to provide a legal framework that focuses on optimizing healthcare outcomes while preventing diversion and misuse. The project also recommends that prescribing and dispensing should be facilitated (maximum amount of controlled medicines on a single prescription should be reconsidered as well as the restrictions on the authorisation to prescribe methadone and buprenorphine, the costs of security measures for the storage of controlled medicines should not be disproportional compared to the risk of misuse and diversion). Geographical availability of treatment for patients with dependence and the affordability of the controlled medicine buprenorphine should be improved. Clear language and non-stigmatizing terms in the Latvian legislation should be guaranteed. Considering the identified policy barriers in Latvia the ATOME project advises to encourage cooperations and collaborations between key stakeholders and between healthcare disciplines and to increase funding for palliative care and for harm reduction initiatives. Access to opioid treatment and reimbursement should be improved for specific population groups (older people, people living in rural areas, patients with other non-oncological diseases than HIV/AIDS, clients in methadone treatment programmes). Additional education opportunities and trainings, terminological work and introduction of pain measuring are necessary. Furthermore, the awareness of the general population should be raised – e.g. by providing correct knowledge and accurate information to patients and families.

Throughout the ATOME project, encouraging developments have been observed in terms of improved access to opioids in Latvia. Some of the recommendations made in this report may have already been implemented, but others remain to be a barrier to access to opioids and a balance of preventing misuse and ensuring availability still needs to be achieved.

The continuing efforts of the country team to implement the specific goals elaborated in the early stages of the ATOME project are expected to have facilitated improvements at different strategic levels.

Table 3 Timescale of ATOME activities and events in Latvia



Month Year	ATOME work activities	ATOME events	Activities Latvia country team	Important events in Latvia relevant for access to opioid medication	ATOME results/ achievements
Dec 2009		Start of the project			
Dec 2010	Identification of country team members and national counterparts				List of country team members and national counterparts available
Feb 2011		Lawyers' training workshop	Inguna Maca attended the workshop		
Mar 2011	Quick scan of legislation started				
April 2011			Inguna Maca sent legal documents on behalf of the ATOME Latvia country team		
May - June 2011			The Latvian country team completed the self-assessment checklist		
July 2011	Analysis of the completed self-assessment checklists				
Aug 2011	Preparation of the six-country workshops				
Sept 2011		First six-country workshop (Bulgaria, Cyprus, Greece, Serbia, Slovenia, Turkey)			

Timescale of ATOME activities and events in Latvia	Month Year	ATOME work activities	ATOME events	Activities Latvia country team	Important events in Latvia relevant for access to opioid medication	ATOME results/ achievements
	Nov 2011		Second six-country workshop (Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia, [Ukraine])	The Latvian country team attended the workshop and worked on a national strategic action plan	Regular country team meetings in the MoH analysing the situation in different aspects to optimize access to opioids	National strategic action plan on improving access to opioids in Latvia
	Jan 2012					Report on the results of the quick scan of legislation
	Nov 2011 – May 2012	Preparation of ATOME national conference in Latvia		Collaboration between ATOME team and Latvian country team (co-ordinated by Inguna Maca)		
	Jun - Nov 2012	In-depth analysis of national legislation				Draft overview of legal barriers to opioid availability in Latvia
	Nov 2012	Preparation of legislation review workshop in Utrecht, the Netherlands				
	Jan – Feb 2013		Legislation review workshop in Utrecht, the Netherlands			Report on legislation review workshop highlighting the important outcomes and topics of discussion
	Mar 2013	Draft report on legal barriers in Latvia sent to the ATOME Latvia country team National follow-up conference implemented in Riga, Latvia		Leading role of Latvia country team and experts at the national conference		Draft report on legal barriers in Latvia
	Feb 2014	Final report on legal barriers in Latvia sent to the Latvian country team				

Access to Opioid Medication in Europe (ATOME) Report and recommendations to the Ministry of Health

3. Country Report - Lithuania

3.1. Introduction

Lithuania is one of the countries with statistical evidence of inadequate morphine consumption per capita. In 2006, the adequacy of opioid analgesic consumption was only 12% - based on a per capita consumption of 24.62 morphine equivalents (mEq) while 208 mEq would have been adequate¹⁵. Lithuania was selected as one of the countries to participate in the ATOME project due to its low per capita morphine consumption. Four years later, in 2010, the adequacy of opioid analgesic consumption had even slightly decreased (in relative terms) – it was only 10%¹⁶ (based on a per capita consumption of opioid analgesics of 28.31 morphine equivalents (mEq) while 279 mEq in mg per capita would have been adequate). This report presents a summary of the results of the situational analysis that has been undertaken with regard to opioid availability and accessibility in Lithuania. The results of the situational analysis are divided in two parts: the first part addresses legal and regulatory issues and the second part focuses on issues relating to policy. Both parts present the main barriers and recommendations for improving access to opioid medication in Lithuania.

3.2. Identified legal and regulatory barriers

The results of the ATOME legislation review have been divided into nine different categories of potential legal and regulatory barriers, i.e. barriers related to prescribing; dispensing; usage; trade and distribution; manufacturing; affordability; penalties; language; and other. In Lithuania, potential legal and regulatory barriers have been identified in eight of these nine categories: all except penalties (see Annex 2). A selection of these potential barriers is highlighted below according to category, followed by recommendations to remove these barriers. For a more detailed description of the methods and results, see Annex 2.

PRESCRIBING: The prescribing of opioids in Lithuania is subject to many administrative and non-administrative requirements. For example, according to the Lithuanian legislation the total amount of controlled substance to be prescribed is limited to the quantity necessary for a 7 day treatment course. This requirement is applicable until the individual and effective maintenance dose per day for pain relief has been determined. Then all oral unmodified-release forms, all injection forms allowed for outpatients, sublingual tablets and suppositories of opioid medicines may be prescribed for a maximum treatment course of 15 days. Oral modified-release medicine and transdermal therapy systems of opioid medicines may be prescribed for a maximum treatment course of 30 days. Methadone can be prescribed for

¹⁵ Seya MJ, Gelders SFAM, Achara UA, Milani B, Scholten WK. A First Comparison between the Consumption of and the Need for Opioid Analgesics at Country, Regional and Global Level. *Journal of Pain and Palliative Care Pharmacotherapy*, 2011; 25: 6-18. Accessible at: <http://apps.who.int/medicinedocs/documents/s17976en/s17976en.pdf>

¹⁶ Duthey, B., Scholten, W. Adequacy of Opioid Analgesic Consumption at Country, Global, and Regional Levels in 2010, Its Relationship With Development Level, and Changes Compared With 2006. *Journal of Pain & Symptom Management* 47(2); 2014: 283-97 doi:10.1016/j.jpainsymman.2013.03.015; <http://www.sciencedirect.com/science/article/pii/S0885392413002728>

pain relief for a maximum of 45 days. In addition, the validity of a special medical prescription used for prescribing controlled substances is limited to 5 days including the day of issuing of the prescription. These restrictions are potential barriers to access; patients who require medical treatment with controlled medicines for a longer period will need to visit the physician and pharmacy frequently.

In Lithuania, the authorisation to prescribe opioid agonist maintenance therapy for the treatment of dependence is restricted to a consulting panel of physicians. If there is 'a serious somatic condition', substitution maintenance therapy can also be delivered by a practicing psychiatrist, provided that this decision is approved within two weeks by the consulting panel of physicians. These restrictions regarding the authorisation to prescribe medicines for the treatment of dependence can be a potential barrier to access. This is especially the case if the 'consulting panel of physicians' is not readily available to deliver substitution maintenance therapy.

Administrative requirements for medical practitioners in the Lithuanian legislation regarding the treatment of patients with controlled medicines can be considered disproportional. Special prescription blanks used for prescribing opioid medicines have to be stored in a designated safe and may not exceed a six-month demand. Physicians are not allowed to receive more than 10 special prescription blanks¹⁷. These requirements may increase the administrative burden and may cause medical practitioners to be unable (no prescription forms available) or reluctant to treat patients with controlled medicines.

The storage of controlled medicines in pharmacies is subject to many strict requirements. For example, the amount of controlled medicines to be stored shall not exceed a 7-day supply in healthcare institutions without a pharmacy, a 5-day supply in separate healthcare institution departments and a 30 day supply in the hospital pharmacy¹⁸. Premises in hospital pharmacies where controlled medicines are kept must have a steel door or a solid wood door, covered with steel plate, fastened with nails no shorter than 35cm. Many other storage requirements are applicable. The costs of these storage measures may be disproportional compared to the risk of misuse and diversion, and may therefore deter healthcare institutions from storing controlled medicines.

TRADE AND DISTRIBUTION: Requirements regarding the trade and distribution of controlled medicines may increase the administrative burden and may delay or impede the availability of medicinal products on the market. According to the Lithuanian legislation, controlled substances have to be stored in premises with external walls made from reinforced concrete 250 mm brick walls or made from other material with the same strength. The external walls that do not meet these requirements shall be reinforced with protective grilles. Additional requirements apply, the costs of which may be disproportional compared to the risk of

¹⁷ These requirements have been changed. Since 12. 05. 2014 physicians are allowed to have 20 blank prescriptions for narcotic medications (instead of 10).

¹⁸ These requirements have been changed first in 2011 by new annex in the law which set out the requirements for storage and accounting of narcotic medicinal products in the Healthcare institutions. Since that the amount of controlled medicines to be stored shall not exceed a 30 day supply in healthcare institutions without a pharmacy, a 30 day supply in the hospital pharmacy, a 5-day supply in separate healthcare institution departments and a 15 day supply in emergency medical service departments. In 2014 the legal requirements related to the quantity of opioids that is allowed to be stored in Healthcare Institutions providing service of Opioid Agonist Therapy (OAT) have been changed from 7 days of demand to 60 days in healthcare Institutions which do not have their own hospital pharmacies; in hospital pharmacies it has been changed from 14 days of demand to 60 days and in departments of Health Care Institution from 5 days to 7 days.

misuse and diversion, and may therefore deter legal entities from trading in controlled medicines.

LANGUAGE: The distinction between medical use and misuse or illicit use is not always clear. In the reviewed Lithuanian legislation, death, intoxication and dependence are referred to as a result of the use of 'narcotic drugs' and 'psychotropic substances'. This may cause fear and confusion and may deter healthcare professionals from prescribing or dispensing opioid medicines or may deter patients from using controlled medicines for legitimate purposes. This is particularly the case if severe sanctions are involved for unintended violations. In addition, the terms 'addict(s)', 'addiction' and 'persons addicted' are considered to be stigmatising, and are used in the reviewed Lithuanian legislation.

Textbox 10 Selection of recommendations specific to Lithuania: legal and regulatory

- Remove limitation of the validity of 7 days for prescriptions for medicines containing controlled substances;
- Remove restrictions that apply to the amount to be prescribed, in particular if these restrictions do not apply to other non-controlled medicinal products;
- Remove the restriction that opioid agonist therapy for the treatment of dependence can only be assigned by a panel of physicians;
- Remove the limitations regarding the total amount of controlled medicine to be stored;
- Remove the storage requirements for special prescription blanks, and remove the limitation that physicians are not allowed to receive more than 10 special prescription blanks;
- Decrease the administrative burden for prescribing and dispensing opioid medicines;
- Remove the obligation for public pharmacies to collect unused controlled medicines for destruction;
- Ensure that the costs of security measures for the storage of controlled medicines are not disproportional compared to the risk of misuse and diversion;
- Provide clear language in legislation and avoid language that stigmatises the medical use of opioids or refers to patients with dependence in a disrespectful way.

3.3. Identified policy barriers

For Lithuania, the main challenges concerning access to opioids were identified in financial/economic aspects, issues relating to formularies, education and training and social attitudes.

FINANCIAL/ ECONOMIC ASPECTS: The Lithuanian association for the support of cancer patients, established in 2011, together with the Lithuanian Palliative Medicine Association put pressure on the government and policy-makers to ensure the development, appropriate funding and recognition of palliative care. A national Hospice Support Fund, whose council includes a member of the Lithuanian parliament, was created in 2013 to try to alleviate funding issues. However, the current model of funding does not promote more service provision - incentives are lacking since pharmacotherapy with opioids requires a heavy workload (e.g. managing prescription blanks, urine tests, involvement of other social services etc.).

Healthcare institutions need to invest when they plan to offer such treatment (storage, equipment, safe doors, etc.). The Ministry of Health only finances two to four palliative care beds in smaller regions and this insufficient funding precludes team-work. In addition, there is no funding basis and no system of incentives for healthcare organizations to offer opioid agonist therapy. Centres for dependency disorders have to supply medicines to prisons; they also have the responsibility for storage, recording, and control. This means that a series of additional activities need to be undertaken with no additional funding provided to cover the cost of such activities or even support any efforts made towards this direction.

FORMULARIES: The treatment of breakthrough pain becomes more difficult since medicines are not reimbursed. As a result, this treatment is not applied even when appropriate. The prescription of analgesics for non-cancer patients is also a problem that needs to be addressed, as well as treatment for neuropathic pain and the possibility to reimburse this treatment. Another problem regarding service provision is that guidelines or recommendations are often not implemented. No equal service provision is ensured in different healthcare institutions. In addition, the services available are not always provided in a good professional manner. Although a standardised methodology and evaluation procedure have been developed, it cannot be guaranteed that all institutions implement these recommendations properly. Finally, the special requirements regarding the prescription of narcotics make physicians reluctant to use opioid medicines for the treatment of pain. Also, the assessment of pain is not always adequately performed. When monitoring the patient and correcting or adapting treatment options, it is important to explore the reasons which generate the pain and to measure the level of pain. The aetiology and the nature of the pain need to be assessed properly and various other factors that may increase the level of pain need to be addressed in order to be able to provide the necessary treatment which is not always the case in Lithuania.

EDUCATION AND TRAINING: Education and training are a very important and essential requirement for palliative care provision. Palliative care in Lithuania is taught in some universities. Since 2009 there have been programmes on palliative care but they are mostly linked to geriatric medicine. Several scientific articles on palliative care are published every year and it is not uncommon for students to write their bachelor's or master's theses on topics related to palliative care. However, the concept of palliative care seems to be not clear considering that palliative care is often perceived merely as end-of-life care. Training for specialists is essential in order to change attitudes in healthcare professionals and improve the approach in medical staff. The approach of pain by many older physicians sometimes does not meet modern standards. They often support the opinion that opioids should only be prescribed in patients with stage 4 cancer. In addition, the teams offering palliative care at home are not well educated and equipped for this type of care provision. Finally, there is a lack of inter-institutional collaboration not only to promote research on palliative care and the use of opioids for pain management (in cancer patients and others), but also to ensure best practice and optimal quality of the services provided.

SOCIAL ATTITUDES: In Lithuania, the use of opioids is affected by a range of attitudinal barriers. A couple of years ago even talking about opioid medicines was a taboo. Stigma still persists not only in patients and their families but also among medical staff, stakeholders and the general public. Some politicians think they can resolve issues that professionals should resolve instead, which gives rise to stereotype notions in the society. Fear of dependence/tolerance comprises a major issue regarding pain treatment in Lithuania. Dependence

is not understood as a disease but as a moral deviation from the norm. Many physicians are reluctant to prescribe opioid medicines in young people for fear of unsafe situations in people's everyday life (work, driving, etc.). Another issue that deserves attention is what a physician should do if a patient is in his dying phase but his family/relatives do not want them to use opioids. Another problem is 'demonisation' of patients who are treated with certain medication (e.g. tramadol). To this end, peer-to-peer education (e.g. in nursing staff) should be implemented in order to eliminate misunderstandings considering that the message received from peers is always different. In addition, drug users are frequently 'demonised'. For example a patient suffering from withdrawal syndrome, and therefore being in unbearable pain might be treated like a 'drug addict' in a pharmacy and may have to confront barriers before getting any help. The majority of healthcare centres have negative attitudes towards people who are addicted to drugs. Even traffickers spread misunderstandings since it is in their interest that people continue using illicit drugs. Articles in the press often show a biased picture. Case stories and real life stories should help to promote understanding and respect towards people who are addicted to drugs. Decreasing the stigma in society and also the stigma among patients to reduce fear about treatment is imperative. An analysis of the societal mechanisms underlying the various misunderstandings around opioids and the reasons that generate fear of opioids should be conducted. The social media and other interactive ways should be used to promote education and raise awareness of the general public, patients, families, physicians and other stakeholders concerning the benefits of opioid use for pain management and palliative care in Lithuania.

Textbox 11 Selection of recommendations specific to Lithuania: policy

- Minimize the bureaucratic burden surrounding the prescription of opioids;
- Address the issue of opioid prescription for non-cancer patients and those with neuropathic pain;
- Reimburse costs and minimise bureaucracy regarding OAT;
- Provide healthcare institutions with incentives to offer OAT;
- Revise the prescription procedures of opioids in hospitals to make sure that patients will have sufficient medication available after discharge home;
- Provide outpatient treatment for withdrawal symptoms;
- Promote inter-institutional collaboration;
- Implement training courses for healthcare professionals to improve the quality of the services provided;
- Monitor the process of pain treatment to ensure quality;
- Enhance doctor-patient communication;
- Inform (educate) the general public and other stakeholders about the usefulness of opioids in pain treatment and palliative care;
- Use the social media and other interactive ways to raise awareness of opioid use;
- Implement peer education to eliminate misunderstandings over opioid use.

3.4. Voices from Lithuanian ATOME participants

In the summer of 2013, national key contacts and representatives of the national ATOME country teams were asked what had changed regarding access to opioid medicines in their country since the beginning of the ATOME project. These are examples of answers by one representative of the Lithuania country team. These quotations show that some of the legal and policy barriers identified during the ATOME legal and policy analysis have already been lifted towards the end of the project.

Textbox 12 Voices from Lithuanian ATOME participants

- *“After the discussion at the ATOME national follow-up conference a representative of the Department of Pharmacy in the Ministry of Health has prepared amendments on the Order Nr V-653 from August 6, 2007 (about Opioid Agonist Therapy (OAT)) and suggested to significantly increase the amounts of opioid medications that will be allowed to be stored in healthcare facilities (from 7 to 60 days of supplies). This was requested by healthcare facilities, mainly because of significant interruptions of funding for OAT and to reduce frequent travel for supplies.*
- *Also the proposal was made to change order Nr. V-1051 from May 13, 2006 (about the general requirements on the control of narcotic medications). A new specification allows for a physician to have 20 blank prescriptions for narcotic medications (instead of 10).*
- *Proposed changes to the orders V-653 and V-1051 have been introduced accordingly with the orders V-557 and V-556 of the Minister of Health on 12 May 2014.*
- *In addition one more barrier to access OAT programmes has been lifted – the order V-819 of the Minister of Health of 16 July 2014 allows for one psychiatrist to initiate OAT (before that the decision to initiate OAT for a patient had to be made by the Consultative Commission of Doctors.” (Marija Subataite, Program Manager of the Eurasian Harm Reduction Network (EHRN), 06.04.2014).*

3.5. Conclusion

Potential barriers to accessing opioids in Lithuania have been identified in the areas of legislation and policy. The ATOME project recommends that the Lithuanian legislation should be revised to provide a legal framework that focuses on optimizing healthcare outcomes while preventing diversion and misuse. The project also recommends that prescribing should be facilitated (maximum amount of controlled medicines to be prescribed and the limited prescription validity should be removed as well as the administrative requirements regarding the used prescription blanks; the restrictions on the authorisation to prescribe opioid agonist maintenance therapy should be reconsidered). The administrative burden for dispensing opioid medicines should be decreased (total amount of controlled medicines to be stored). The costs of security measures for the storage of controlled medicines should not be disproportional compared to the risk of misuse and diversion. Clear language and non-stigmatizing terms in the Lithuanian legislation should be guaranteed. Considering the identified policy barriers in Lithuania the ATOME project advises to enhance the financial support for palliative care and to ensure funding and incentives to offer Opioid Agonist Therapy. The reimbursement of particular medicines (e.g. for breakthrough pain as well as for neuropathic pain; analgesics for non-cancer patients) should be guaranteed. Training courses for healthcare professionals should be implemented to improve the quality of services provided, and in order to enhance the communication between physicians and patients. Furthermore, the awareness concerning the usefulness of opioids in pain treatment and palliative care amongst the general public and stakeholders should be raised; misunderstandings about opioid use should be challenged – e.g. by implementing peer education, by using social media and other interactive ways.

Throughout the ATOME project, encouraging developments have been observed in terms of improved access to opioids in Lithuania. Some of the recommendations made in this report may have already been implemented, but others remain as barriers to access to opioids and a balance of preventing misuse and ensuring availability still needs to be achieved.

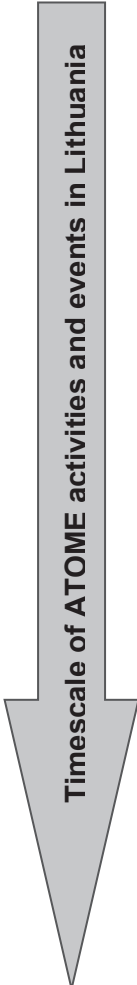
The continuing efforts of the country team to implement the specific goals elaborated in the early stages of the ATOME project are expected to have facilitated improvements at different strategic levels.

Table 4 Timescale of ATOME activities and events in Lithuania

Timescale of ATOME activities and events in Lithuania	Month Year	ATOME work activities	ATOME events	Activities Lithuania country team	Important events in Lithuania relevant for access to opioid medication	ATOME results/ achievements
	Dec 2009		Start of the project			
	Dec 2010	Identification of country team members and national counterparts				List of country team members and national counterparts available
	Feb 2011		Lawyers' training workshop	Jolanta Strazdienė attended the workshop		
	Mar 2011	Quick scan of legislation started				
	May - June 2011			Jolanta Strazdienė sent legal documents on behalf of the ATOME Lithuania country team The Lithuania country team completed the self-assessment checklist		
	July 2011	Analysis of the completed self-assessment checklists				
	Aug 2011	Preparation of the six-country workshops				

Timescale of ATOME activities and events in Lithuania

Month Year	ATOME work activities	ATOME events	Activities Lithuania country team	Important events in Lithuania relevant for access to opioid medication	ATOME results/ achievements
Sept 2011		First six-country workshop (Bulgaria, Cyprus, Greece, Serbia, Slovenia, Turkey)			
Nov 2011		Second six-country workshop (Lithuania, Hungary, Latvia, Estonia, Poland, Slovakia, [Ukraine])	The Lithuania country team attended the workshop and worked on a national strategic action plan Gražina Bobelienė sent information regarding amendments in legislation		National strategic action plan on improving access to opioids in Lithuania
Jan 2012					Report on the results of the quick scan of legislation
Nov 2011 – May 2012	Preparation of ATOME national conference in Lithuania		Collaboration between ATOME team and Lithuania country team (co-ordinated by Audronė Astrauskienė)		
July 2012	In-depth analysis of national legislation		Gražina Bobelienė sent additional legislation on behalf of the Lithuania country team		Draft overview of legal barriers to opioid availability in Lithuania
Nov 2012					
Nov 2012	Preparation of legislation review workshop in Utrecht, the Netherlands				



ATOME work activities	ATOME events	Activities Lithuania country team	Important events in Lithuania relevant for access to opioid medication	ATOME results/ achievements	Month Year
Jan – Feb 2013		Legislation review workshop in Utrecht, the Netherlands	Gražina Bobelienė and Audronė Astrauskienė attended the workshop on behalf of Lithuania		Report on legislation review workshop highlighting the important outcomes and topics of discussion
May 2013	Draft report on legal barriers in Lithuania sent to the Lithuania country team				Draft report on legal barriers in Lithuania
June 2013	Marija Subataite sent feedback to the draft report on legal barriers in Lithuania				
Feb 2014	National follow-up conference implemented in Vilnius, Lithuania		ATOME Lithuania country team participated in the organisation of the conference and informed the preparation of the programme		Final report on legal barriers in Lithuania sent to the Lithuania ATOME country team

Access to Opioid Medication in Europe (ATOME) Report and recommendations to the Ministry of Health

4. Country Report – Poland

4.1. Introduction

Poland is one of the countries with statistical evidence of inadequate morphine consumption per capita. In 2006, the adequacy of opioid analgesic consumption was 19% - based on a per capita consumption of 42.8 morphine equivalents (mEq) while 230 mg would have been adequate for treatment of all pain conditions¹⁹. Poland was selected as one of the countries to participate in the ATOME project due its low per capita consumption. Four years later, in 2010, the adequacy of opioid analgesic consumption had even decreased (both in absolute and in relative terms) – it was only 12%²⁰ (based on a per capita consumption of opioid analgesics of 35.76 morphine equivalents (mEq) while 232 mEq in mg per capita would have been adequate)²¹. This report presents a summary of the results of the situational analysis that has been undertaken with regard to opioid availability and accessibility in Poland. The results of the situational analysis are divided in two parts: the first part addresses legal and regulatory issues and the second part focuses on issues relating to policy. Both parts present the main barriers and recommendations for improving access to opioid medication in Poland.

4.2. Identified legal and regulatory barriers

For Poland no legislative analysis has been applied because no legal documents were provided.

4.3. Identified policy barriers

For Poland, the main challenges concerning access to opioids that were identified are financial/economic issues and issues relating to formularies, education, training and social attitudes.

FINANCIAL/ ECONOMIC ASPECTS: There is not an equal geographical distribution of pain clinics due to financial reasons in Poland. Moreover, financing of procedures provided by pain clinics is not sufficient for some new procedures to be introduced in order to encourage pain clinic staff to engage more actively in the assessment and treatment of pain. In addition,

¹⁹ Seya MJ, Gelders SFAM, Acharya UA, Milani B, Scholten WK. A First Comparison between the Consumption of and the Need for Opioid Analgesics at Country, Regional and Global Level. *Journal of Pain and Palliative Care Pharmacotherapy*, 2011; 25: 6-18. Accessible at:

<http://apps.who.int/medicinedocs/documents/s17976en/s17976en.pdf>

²⁰ Duthey, B., Scholten, W. Adequacy of Opioid Analgesic Consumption at Country, Global, and Regional Levels in 2010, Its Relationship With Development Level, and Changes Compared With 2006. *Journal of Pain & Symptom Management* 47(2); 2014: 283-97 doi:10.1016/j.jpainsymman.2013.03.015; <http://www.sciencedirect.com/science/article/pii/S0885392413002728>

inadequate financing appears to be allocated to palliative care and harm reduction initiatives. The results of the economic recession that the country has recently experienced have considerably affected such initiatives. More specifically, general budget constraints seem to pose a serious challenge to the wider availability of palliative care and the implementation of opioid agonist therapy (OAT) in Poland. As a result, changes in the allocation of financial resources by the National Health Fund (NHF) are deemed necessary.

FORMULARIES: One of the most important barriers to opioid access in Poland relates to the reimbursement of opioid treatment and palliative care services²². On the one hand, although opioid medication is available free of charge or at a low basic price for cancer patients, patients with other diseases can only get a 30% reimbursement²³. Moreover, in the case of really expensive formulations even cancer patients are forced to pay partial costs. Also, if physicians want to prescribe fentanyl for nasal application, it is necessary to prove that other formulations of short term application did not work, as the health system does not want to be burdened with the cost of fentanyl nasal applications. This is probably why fentanyl consumption appears to have strongly decreased in the country. Regarding other strong opioids an equally significant decrease is observed in morphine consumption whereas methadone consumption has also slightly decreased. However, methadone appears to be available on the black market which means that the legal supply of methadone for patients in Poland is not satisfactory²⁴. On the other hand, palliative and end of life care consultations appear to be used rather informally; as a result, they cannot be properly reimbursed. Such consultations are also restricted to cancer patients whereas palliative care should be broader and cover a bigger spectrum of patients with chronic and advanced diseases.

Reimbursed medicines have defined levels of payment and reimbursement limit. In Poland, four levels of payment have been established: free of charge, lump sum, 30% and 50%. If the retail price of the medicine is higher than the reimbursement limit, a patient has to pay the difference between the retail price and the reimbursement limit. About 73% of reimbursed opioids (in different indications) are available at max. 2€.

EDUCATION AND TRAINING: Daily experience shows that inadequate education comprises one of the main barriers to opioid access in Poland. There is lack of knowledge about opioids as medicines and their role in pain management and palliative care. Training on pain treatment to provide at least basic knowledge and familiarize physicians with the use of opioids is also insufficient at postgraduate level. Therefore, changes in the postgraduate curricula for physicians should be implemented and the course on psychiatry and dependence treatment should be revised. This is a responsibility of the Ministry of Health and the Medical Centre for Postgraduate Education. Because physicians need to be able to effectively cope with the fears and concerns expressed patients and families, their knowledge needs to be up-to-date, focusing particularly on communication skills. Although a platform for best practices has been established in Poland in an attempt to relieve physicians' concerns, inconsistent pain treatment situations are still observed in the country and should comprise the reason for further

²² This has been changed. Since the 1st of May 2014 tramadol in combination with paracetamol is being reimbursed. Oxycodone in combination with naloxone will be reimbursed from the 1st of November 2014. Moreover, the reimbursement procedure of medicines containing tapentadol is in progress.

²³ The situation concerning this matter has changed. Cancer patients have to pay 0-6 € (there are different levels of payment). Patients with other indications (all registered indications) have to pay 0,2-7€ (different levels of payment). For most medicines there are less expensive generics available. Medicines that are being reimbursed in Poland are: buprenorphine (5 products with unique EAN code), dihydrocodeine (2), fentanyl (32), methadone (3), morphine (17), oxycodone (10), tramadol (51), tramadol in combination with paracetamol (22).

²⁴ Methadone is being reimbursed for cancer patients at max.1,5€.

education and training initiatives to be developed and implemented. Such initiatives should not only include physicians (providing educational credits for professional development), but also regional/local decision-makers and specialists in psychiatry (raising awareness of the regional needs) and employees of the NHF (analysing the regional situation and revising policy for appropriate allocation of funds). This is to ensure further support from regional and local authorities which is currently lacking. Finally, education and training in relation to palliative care needs to be improved including promoting active team work and multi-disciplinary collaborations.

SOCIAL ATTITUDES: Fear of opioids comprises another major barrier to opioid access in Poland. This fear can be observed not only amongst patients and their families but also amongst healthcare professionals and the general public. More specifically, the main fears of patients and families relate to dependency, tolerance and death. Such fears are much more common in patients taking strong opioids. Moreover, there are cases where patients and families feel hopeless because many physicians seem to believe that pain does not need to be assessed and treated. Also, although physicians should know that at the early stages of palliative care treatment they need to sit down and talk to patients and families about opioid use and the benefits of opioid treatment, they do not provide adequate information about risks and side-effects so that fear of opioids can be averted. In addition, reluctance to prescribe opioids in many GPs results in patients being frequently referred to a pain clinic. Finally, there is still prejudice against opioids in the Polish society. Harm reduction is seen as a controversial area which is currently highly stigmatized. For example, employment for patients involved in an OAT programme is a serious problem; they have to hide their therapy or stay away from work to get methadone treatment. Although there have been several initiatives to raise public awareness, prejudice against opioids remains a major issue that needs to be addressed and resolved.

Textbox 13 Selection of recommendations specific to Poland: policy

- Ensure better reimbursement of opioid treatment;
- Expand palliative care to include a wider spectrum of patients (e.g. non cancer patients);
- Formally arrange and properly reimburse palliative care consultations;
- Change the knowledge and attitudes of medical staff with respect to the treatment of pain;
- Encourage the collaboration amongst healthcare professionals and palliative care specialists;
- Implement more practical pain management education (training initiatives, workshops);
- Monitor the process of pain treatment to ensure quality and patient safety;
- Lower the threshold (entry barriers, restrictive rules) for people to join harm reduction programs;
- Improve OAT availability and reduce the stigma on people receiving OAT but also integrate it into the range of treatment approaches of opioid dependence;
- Provide more information on OAT, e.g. via the media;
- Educate patients and families about the usefulness of opioids in pain relief and palliative care;
- Educate patients, families and the public about the impact of fear of opioids.

4.4. Voices from Poland ATOME participants

In the summer of 2013 and of 2014, national key contacts and representatives of the national ATOME country teams were asked what had changed regarding access to opioid medicines in their country since the beginning of the project. These are exemplary answers by two representatives of the Poland country team.

Textbox 14 Voices from Poland ATOME participants

“According to amendments from the 21st of December 2012 regulation of Minister of Health on prescriptions there is no need to issue a copy of prescription for drugs containing substances like morphine, methadone, oxycodone or fentanyl. It’s possible to prescribe those medicines for a longer period of time (up to 90 days instead of 30 days). Those prescriptions are valid longer (30 instead of 14 days).

As for the drugs containing tramadol, tramadol with paracetamol, buprenorphine or dihydrocodeine – they can be prescribed now on common prescriptions. In addition to that, in 2014 there was a change of law which allowed to prescribe those medicines for a longer period, up to 360 days” (Agata Krupa, 21.10.2014).

“There were several changes regarding opioid availability. Despite of formal changes however some physicians still do not have prescription forms for opioids. As no formal barriers exist to obtain this type of prescription forms this is rather an effect of the lack of education and inappropriate knowledge or attitude towards pain management of those physicians.

Recently, a National Medical Council (Naczelna Rada Lekarska) has published an appeal on appropriate treatment of pain in Poland to physicians. The Vice Minister of Health Igor Winnicki promised to implement the obligatory program on pain management for all medical students at all medical universities.”

An active role apart from physicians’ associations (the Polish Association for Palliative Medicine – Polskie Towarzystwo Medycyny Paliatywnej and the Polish Association for the Study of Pain – Polskie Towarzystwo Badania Bólu) a patient organization take part in campaigning for appropriate pain management in Poland. For example the foundation ‘Let’s Win with Pain’ (Wygrajmy z Bólem) is an active in campaigning through the voice of patients. A recent press conference took place on 9th October 2014 to inform journalists from public TV and main newspapers about developments and still existing barriers in appropriate pain management” (Wojciech Leppert, 24.10.2014).

4.5. Conclusion

Potential policy barriers to accessing opioids in Poland have been identified. The ATOME project recommends the revision of the allocation of financial resources by the National Health Fund in order to improve the geographical availability of pain clinics, the availability of palliative care services and to widen the availability of Opioid Agonist Therapy (OAT). The reimbursement of opioid treatment for non-cancer patients as well as of palliative care consultations should be enhanced. Specific opioids (e.g. fentanyl nasal applications) should be refunded and sufficient legal supply of methadone should be ensured²⁵. The postgraduate curricula for healthcare professionals should be revised in order to provide sufficient knowledge about the use of opioid analgesics in pain treatment and palliative care. Training opportunities should be developed and implemented to ensure consistent quality in pain treatment; to promote multi-disciplinary collaborations; and to improve the communication and information exchange between physicians and patients. Furthermore, the fear of opioids within the general public should be challenged as well as the stigmatization on people receiving OAT – e.g. by providing education initiatives for patients and their families; or by providing more information on OAT via media.


Some of the recommendations made in this report may have already been implemented, but others remain to be as barriers to access to opioids and a balance of preventing misuse and ensuring availability still needs to be achieved.

The continuing efforts of the country team to implement the specific goals elaborated in the early stages of the ATOME project are expected to have facilitated improvements at different strategic levels.

²⁵ Fentanyl nasal applications are refunded for the following indications: Breakthrough pain in adult patients with cancer who are in the treatment of chronic cancer pain with opioid maintenance therapy, with documented contraindications while using other short-term working opioids or ineffectiveness of these drugs. Patients have to pay less than 1€.

Table 5 Timescale of ATOME activities and events in Poland

Timescale of ATOME activities and events in Poland	Month Year	ATOME work activities	ATOME events	Activities Poland country team	Important events in Poland relevant for access to opioid medication	ATOME results/ achievements
	Dec 2009		Start of the project			
	Dec 2010	Identification of country team members and national counterparts				List of country team members and national counterparts available
	Feb 2011		Lawyers' training workshop	Mr Kuba Sękowski attended the workshop		
	March 2011	Quick scan of legislation started				
	June 2011				Third Congress of the Polish Association for Palliative Medicine in Lodz	
	July 2011	Analysis of the completed self-assessment checklists				
	Aug 2011	Preparation of the six-country workshops				
	Sept 2011		First six-country workshop (Bulgaria, Cyprus, Greece, Serbia, Slovenia, Turkey)			
	Nov 2011		Second six-country workshop (Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia, [Ukraine])	The Poland country team attended the workshop and worked on a national strategic action plan		National strategic action plan on improving access to opioids in Poland
	Nov – May 2012	Preparation of ATOME national conference in Poland				



Month Year	ATOME work activities	ATOME events	Activities Poland country team	Important events in Poland relevant for access to opioid medication	ATOME results/ achievements
Dec 2012				A decree of the Ministry of Health allowed to prescribe opioids on a white instead of a stigmatized 'pink' prescription form.	
Jan - Feb 2013		Legislation review workshop in Utrecht, the Netherlands	No legal documents were sent on behalf of Poland		Report on legislation review workshop highlighting the important outcomes and topics of discussion
Mar 2013			Leading role of Poland country team and experts at the national conference		
July 2013	Date set for the ATOME national follow-up conference in Poland				
Oct 2013 - April 2014	National follow-up conference implemented in Warsaw, Poland		Collaboration between ATOME team and Poland country team (co-ordinated by Agata Krupa)		
Sept 2014				Decree of the Ministry of Health decreased the number of requirements for prescription of opioid e.g. a larger amount of opioid prescribed for 90 days instead of 30 days of treatment was allowed	

Access to Opioid Medication in Europe (ATOME) Report and recommendations to the Ministry of Health

5. Country Report - Slovakia

5.1. Introduction

Slovakia is one of the countries with statistical evidence of inadequate morphine consumption per capita. In 2006, the adequacy of opioid analgesic consumption was 58% - based on a per capita consumption of 120.98 morphine equivalents (mEq) while 210 mg would have been adequate for treatment of all pain conditions²⁶. Slovakia was selected as one of the countries to participate in the ATOME project due to this reason. Four years later, in 2010, the adequacy of opioid analgesic consumption had even decreased (both in absolute and in relative terms) – it was only 27%²⁷ (based on a per capita consumption of opioid analgesics of 74.28 morphine equivalents (mEq) while 275.76 mEq in mg per capita would have been adequate). This report presents a summary of the results of the situational analysis that has been undertaken with regard to opioid availability and accessibility in Slovakia. The results of the situational analysis are divided in two parts: the first part addresses legal and regulatory issues and the second part focuses on issues relating to policy. Both parts present the main barriers and recommendations for improving access to opioid medication in Slovakia.

5.2. Identified legal and regulatory barriers

The results of the ATOME legislation review have been divided into nine different categories of potential legal and regulatory barriers, i.e. barriers related to prescribing; dispensing; usage; trade and distribution; manufacturing; affordability; penalties; language; and other. In Slovakia, potential legal and regulatory barriers have been identified in seven of these nine categories: all except affordability and penalties (see Annex 2). A selection of these potential barriers is highlighted below according to category, followed by recommendations to remove these barriers. For a more detailed description of the methods and results, see Annex 2.

PRESCRIBING: The prescribing of opioids in Slovakia is subject to many overly strict administrative and non-administrative requirements. For example, according to the Slovak legislation the total amount of controlled medicines to be prescribed is limited to the quantity necessary for a 30 day treatment course. In addition, the validity of a special medical prescription used for prescribing controlled medicines is limited to 5 days. These restrictions are potential barriers to access; patients who require medical treatment with controlled medicines for a longer period will need to visit the physician and pharmacy frequently.

²⁶ Seya MJ, Gelders SFAM, Achara UA, Milani B, Scholten WK. A First Comparison between the Consumption of and the Need for Opioid Analgesics at Country, Regional and Global Level. *Journal of Pain and Palliative Care Pharmacotherapy*, 2011; 25: 6-18. Accessible at: <http://apps.who.int/medicinedocs/documents/s17976en/s17976en.pdf>

²⁷ Duthey, B., Scholten, W. Adequacy of Opioid Analgesic Consumption at Country, Global, and Regional Levels in 2010, Its Relationship With Development Level, and Changes Compared With 2006. *Journal of Pain & Symptom Management* 47(2); 2014: 283-97 doi:10.1016/j.jpainsymman.2013.03.015; <http://www.sciencedirect.com/science/article/pii/S0885392413002728>

Administrative requirements for medical practitioners in the Slovak legislation regarding the treatment of patients with controlled medicines can be considered disproportional. Special prescription forms marked with a diagonal blue stripe have to be used and persons authorised to prescribe controlled medicines are obliged to keep records of these special prescription forms. The special prescription forms may be sold to medical practitioners authorised to prescribe controlled medicines after verification of his/her identity and production of the letter of assignment of his/her code from the Health Care Surveillance Authority. These requirements may increase the administrative burden and may have the effect that medical practitioners are unable (no prescription forms available) or reluctant to treat patients with controlled medicines.

DISPENSING: Additional requirements for the dispensing of controlled medicines may increase the administrative burden and may cause pharmacists to be reluctant to dispense controlled medicines. In Slovakia, the procedures for dispensing controlled medicines are complex and bureaucratic. For example, a special record book has to be kept to record the dispensing of controlled medicines without any delay. Upon dispensing, a special document which contains information regarding the dispensing has to be filed to demonstrate the dispensing. This document has to be signed by the person who personally dispensed the controlled medicine. Additional requirements apply, all increasing the administrative burden and potentially deterring pharmacists from dispensing controlled medicines.

OTHER: Other requirements in legislation may limit access to opioid medicines to patients in need of medical treatment with these medicines. For example, according to the Slovak legislation methadone maintenance treatment can only be provided by a psychiatrist in specialised outpatient programmes or in drug dependence outpatient facilities. In addition, patients who live too far from the dispensary and clinic and patients with a pending unconditional imprisonment without the possibility of providing methadone in prison are excluded from receiving methadone maintenance treatment. During transportation, like by airline companies, it is allowed to have a first aid kit on board containing small amounts of controlled medicines provided that the Ministry grants permission based on an application submitted by the international transporter. This application should contain data about the person responsible for manipulation with medicines including a declaration of his/her good health condition and professional capacity. These complex application requirements may deter the international transporter from applying for permission.

LANGUAGE: The distinction between medical use and misuse or illicit use is not always clear. In the reviewed Slovak legislation, narcotic and psychotropic substances are referred to as a 'problem'. This may cause fear and confusion and may deter healthcare professionals from prescribing or dispensing opioid medicines or may deter patients from using controlled medicines for legitimate purposes. This is particular the case if severe sanctions are involved for unintended violations. In addition, the terms 'addict(s)', 'addiction' and 'persons addicted' are considered to be stigmatising, and are used in the reviewed Slovak legislation.

Textbox 15 Selection of recommendations specific to Slovakia: legal and regulatory

- Reconsider the prescription validity of 5 days that applies to prescriptions for medicines containing controlled substances;
- Remove restrictions that apply to the amount to be prescribed, in particular if these restrictions do not apply to other non-controlled medicinal products,
- Remove the administrative requirements for receiving special prescription forms,
- Decrease the administrative burden for dispensing opioid medicines;
- Ensure that patients in prison or patients living in a remote area are able to access controlled medicines if medically needed;
- Allow for controlled medicines to be on board in small amounts in first aid kits during international transportation without complex application requirements;
- Provide clear language in legislation and avoid language that stigmatises the medical use of opioids or refers to patients with dependence in a disrespectful way.

5.3. identified policy barriers

For Slovakia, the main challenges concerning access to opioids were identified in financial/economic aspects, issues relating to formularies, education and training and social attitudes.

GOVERNMENTAL SUPPORT and FINANCIAL/ ECONOMIC ASPECTS: There is lack of financial resources available for palliative care in Slovakia whereas funding of centres offering palliative care services in specific regions of the country needs to be further facilitated. Political/ Governmental support is needed as well as improved communication between healthcare professionals and stakeholders. For example, the Ministry of Health should work closely with the Ministry of Finance and the National Health Insurance Funds to provide the necessary economic support. Moreover, the Ministry of Health should be actively involved in promoting education and training on pain management, pain medicine and palliative care in Slovakia. For this purpose, collaboration is recommended with other regional authorities, as well as national and international specialist associations such as the Association of Hospice and Palliative Care in Slovakia (AHPS), the Slovak Society for the Study and Treatment of Pain (SSSLB), or the European Association for Palliative Care (EAPC).

FORMULARIES: Palliative care is currently not recognized as a specialty in Slovakia. The major barrier identified relates to reimbursement of palliative care services and opioid treatment. There is lack of a basic palliative care network which means that insurance companies can provide no contracts and there are no government-reimbursed palliative care services offered at outpatient clinics. Similarly, patients in home-based palliative care services need to pay out of their pocket for any prescriptions signed by hospice or palliative care physicians, the cost of which is as high as a monthly pension. Only pain physicians are allowed to provide strong opioids that are reimbursed by insurance companies. Moreover, there is no reimbursement of mobility costs which can exacerbate the problem of access to opioids in Slovakia. In addition, the process of pain treatment needs to be further monitored and pain guidelines need to be developed and implemented. Finally, the meaning of strong opioids

needs to be reassessed and pre- and post- treatments need to be extended, emphasizing the importance of specialist input to ensure optimal quality of the services provided.

EDUCATION AND TRAINING: There is lack of basic education and training opportunities regarding palliative medicine and the use of opioid analgesics in undergraduate and post-graduate curricula for physicians and other healthcare professionals. A good illustration of the gap in existing knowledge is the fact that the two-week detoxification procedure necessary before a patient can enter an opioid dependence treatment program is not something that all physicians seem to be aware of. In addition, most physicians are reluctant to prescribe due to the lack of adequate education leading to insufficient knowledge. To improve this situation, education and training of healthcare professionals need to be facilitated. More regional / community courses and workshops on pain management, opioid treatment and palliative care should be designed and implemented. To achieve this, the Ministry of Health, the Ministry of Education, regional authorities and specialist associations such as the AHAPS, the SSSLB or the EAPC should be involved. Finally, more networks need to be developed in order to effectively handle the barrier of insufficient knowledge about how to work with palliative care patients or how to establish palliative care centres.

SOCIAL ATTITUDES: Although treatment principles and attitudes towards opioids have changed in Slovakia the stigma of morphine has not retreated. Still, this stigma seems to be diminishing considering that there is no word for 'addiction' in Slovak language and the word frequently used in such situations is 'abuse'. However, there are still negative cultural stereotypes about opioids (fear of opioids) mainly related to fear of dependence, fear of tolerance and fear of side effects. There is a misunderstanding and misinformation about opioids in the sense that morphine therapy is inevitably associated with impending death or that pain is necessary and needs to be endured. As a result, it would be essential to raise public awareness and change their attitudes towards the use of opioids for pain management and palliative care through continuous education. Moreover, doctor patient communication needs to be improved. Patients and their families should be adequately informed about the temporary side effects which might be experienced when using opioids such as breathlessness, headache, tiredness, immunity problems, and insomnia. In the same way, patients should be informed about physical tolerance (higher dosage to the same level of pain), dependence as well as the effects of rapid discontinuation. Finally, there appears to be lack of trust towards the knowledge and expertise of palliative care professionals in Slovakia which is a serious issue that needs to be addressed and can only be resolved through education and sustainability in palliative care services.

Textbox 16 Selection of recommendations specific to Slovakia: policy

- Increase the number of palliative care beds around the country;
- Support outpatient clinics;
- Reimburse home-based palliative care services;
- Reimburse prescriptions written by palliative care and hospice physicians;
- Introduce 'opioid treatment' as a subject in the Faculty of Medicine;
- Undertake further research on non-cancer patients to examine the use of opioids in clinical practice;
- Raise the status of palliative care from sub-specialty to specialty;
- Set-up undergraduate and postgraduate palliative care training in medical schools;
- Provide opportunities for continuous education/ training for healthcare professionals involved in pain management, palliative care, and treatment of opioid dependence;
- Monitor the process of pain treatment to ensure quality;
- Educate the public about appropriate opioid use.

5.4. Voices from Slovak ATOME participants

In the summer of 2013 and of 2014, national key contacts and representatives of the national ATOME country teams were asked what had changed regarding access to opioid medicines in their country since the beginning of the project. This is an exemplary answer by one representative of the Slovakia country team.

Textbox 17 Voice from a Slovak ATOME participant

“There was an increase of co-payment for the patients receiving some strong opioids (oxycodone in slow-release tablets, rapid release fentanyl in sublingual tablets)” (Kristina Križanová, Department of Palliative Care, National Oncologic Institute, 13.10.2014).

5.5. Conclusion

Potential barriers to accessing opioids in Slovakia have been identified in the areas of legislation and policy. The ATOME project recommends that the Slovak legislation should be revised to provide a legal framework that focuses on optimizing healthcare outcomes while preventing diversion and misuse. The project also recommends that prescribing and dispensing should be facilitated (limited prescription validity and the maximum amount of controlled medicines to be prescribed should be removed as well as the administrative requirements regarding the receipt of special prescription forms). The restrictions on the authorization to provide methadone maintenance treatment should be reconsidered and access to controlled medicines should be ensured for specific patient groups (patients in prison and patients in remote areas). Clear language and non-stigmatizing terms in the Slovak legislation should be guaranteed. Considering the identified policy barriers in Slovakia the ATOME project advises to improve the communication and collaboration between authorities, stakeholders and healthcare professionals in order to enhance financial support for palliative care. Basic palliative care networks should be established to provide contracts with insurance companies and to ensure the reimbursement for palliative care services. Access to opioid treatment should be improved by reimbursing mobility costs and by extending the authorisation to prescribe strong opioids that are reimbursed. Palliative medicine should be recognized as a medical speciality. Basic education and training opportunities in palliative care and the use of opioids analgesics as well as the treatment of opioid dependence should be included in under- and postgraduate curricula for healthcare professionals. Continuous training courses and further research should be developed in order to guarantee sufficient knowledge about the use of opioids in medical treatment. Furthermore, misunderstandings and misinformation about opioids within the general public should be challenged as well as the lack of trust towards the expertise of palliative care professionals – e.g. by enhancing the communication and the information exchange between physicians and patients.


Throughout the ATOME project, encouraging developments have been observed in terms of improved access to opioids in Slovakia. Some of the recommendations made in this report may have already been implemented, but others remain to be as barriers to access to opioids and a balance of preventing misuse and ensuring availability still needs to be achieved.

The continuing efforts of the country team to implement the specific goals elaborated in the early stages of the ATOME project are expected to have facilitated improvements at different strategic levels.

Table 6 Timescale of ATOME activities and events in Slovakia

Timescale of ATOME activities and events in Slovakia	Month Year	ATOME work activities	ATOME events	Activities Slovakia country team	Important events in Slovakia relevant for access to opioid medication	ATOME results/ achievements
	Dec 2009		Start of the project			
	Dec 2010	Identification of country team members and national counterparts				List of country team members and national counterparts available
	Feb 2011		Lawyers' training workshop	Dr Viera Kološtová attended the workshop		
	Mar 2011	Quick scan of legislation started				
	Apr 2011			Viera Kološtová sent legal documents on behalf of the ATOME Slovakia country team		
	July 2011	Analysis of the completed self-assessment checklists		Viera Jakubovová sent additional information on behalf of the ATOME Slovakia country team		
	Aug 2011	Preparation of the six-country workshops				
	Sept 2011		First six-country workshop (Bulgaria, Cyprus, Greece, Serbia, Slovenia, Turkey)			
	Nov 2011		Second six-country workshop (Estonia, Latvia, Lithuania, Poland, Slovakia, Hungary, [Ukraine])	The Slovakia country team attended the workshop and worked on a national strategic action plan		National strategic action plan on improving access to opioids in Slovakia
	Jan 2012					Report on the results of the quick scan of legislation

Timescale of ATOME activities and events in Slovakia	Month Year	ATOME work activities	ATOME events	Activities Slovakia country team	Important events in Slovakia relevant for access to opioid medication	ATOME results/ achievements
	Nov 2011 – May 2012	Preparation of ATOME national conference in Slovakia		Collaboration between ATOME team and Slovakia country team (co-ordinated by Dr Barbora Muraňyiova)		
	Oct 2012			Barbora Muraňyiova sent additional information regarding amendments in legislation on behalf of the ATOME Slovakia country team		
	July - Nov 2012	In-depth analysis of national legislation				Draft overview of legal barriers to opioid availability in Slovakia
	Nov 2012	Preparation of legislation review workshop in Utrecht, the Netherlands		Barbora Muraňyiova sent additional legal documents on behalf of the ATOME Slovakia country team		
	Dec 2012			Barbora Muraňyiova sent additional legal documents on behalf of the ATOME Slovakia country team		
	Jan - Feb 2013		Legislation review workshop in Utrecht, the Netherlands	Barbora Muraňyiova attended the legislation review workshop in Utrecht on behalf of the Slovakia country team		Report on legislation review workshop highlighting the important outcomes and topics of discussion



Month Year	ATOME work activities	ATOME events	Activities Slovakia country team	Important events in Slovakia relevant for access to opioid medication	ATOME results/ achievements
March 2013			Barbora Muranyiova sent additional legal documents on behalf of the ATOME Slovakia country team Leading role of Slovakia country team and experts at the national conference		
July 2013	Draft report on legal barriers in Slovakia sent to the Slovak country team				Draft report on legal barriers in Slovakia
Feb 2014	Final report on legal barriers in Slovakia sent to the ATOME Slovakia country team		Martina Hromadkova supported the preparation of the National follow-up conference on behalf of the Slovakia country team		Final report on legal barriers in Slovakia
Mar 2014	National follow-up conference implemented in Bratislava, Slovakia				

Access to Opioid Medication in Europe (ATOME)

Report and recommendations to the Ministry of Human Capacities

6. Country Report - Hungary

6.1. Introduction

Hungary is one of the countries with statistical evidence of inadequate morphine consumption per capita. In 2006, the adequacy of opioid analgesic consumption was 28% - based on a per capita consumption of 69.14 morphine equivalents (mEq) while 250 mEq would have been adequate for treatment of all pain conditions²⁸. Hungary was selected as one of the countries to participate in the ATOME project for this reason. Four years later, in 2010, the adequacy of opioid analgesic consumption had slightly decreased (both in absolute and in relative terms) – it was 23%²⁹ (based on a per capita consumption of opioid analgesics of 76.31 morphine equivalents (mEq) while 325.96 mEq in mg per capita would have been adequate). This report presents a summary of the results of the situational analysis that has been undertaken with regard to opioid availability and accessibility in Hungary. The results of the situational analysis are divided in two parts: the first part addresses legal and regulatory issues and the second part focuses on issues relating to policy. Both parts present the main barriers and recommendations for improving access to opioid medication in Hungary.

6.2. Identified legal and regulatory barriers

The results of the ATOME legislation review have been divided into nine different categories of potential legal and regulatory barriers: i.e. barriers related to prescribing; dispensing; usage; trade and distribution; manufacturing; affordability; penalties; language; and other. In Hungary, potential legal and regulatory barriers have been identified in eight of these nine areas: all areas except affordability (see Annex 2). A selection of these potential barriers is highlighted below according to category, followed by recommendations on how to remove these barriers. For a more detailed description of the methods and results, see Annex 2.

PRESCRIBING: The prescribing of opioid medicines in Hungary is subject to many administrative and non-administrative requirements. For example, the competence to prescribe controlled medicines for a period that exceeds 30 days is restricted to the family practitioner. In addition, the total quantity of controlled substances to be prescribed is limited to complete package units or dosage units that equal the number of package units. Only specialist physicians are allowed to prescribe those controlled substances whose prescription is subject to

²⁸ Seya MJ, Gelders SFAM, Achara UA, Milani B, Scholten WK. A First Comparison between the Consumption of and the Need for Opioid Analgesics at Country, Regional and Global Level. *Journal of Pain and Palliative Care Pharmacotherapy*, 2011; 25: 6-18. Accessible at: <http://apps.who.int/medicinedocs/documents/s17976en/s17976en.pdf>

²⁹ Duthey, B., Scholten, W. Adequacy of Opioid Analgesic Consumption at Country, Global, and Regional Levels in 2010, Its Relationship With Development Level, and Changes Compared With 2006. *Journal of Pain & Symptom Management* 47(2); 2014: 283-97 doi:10.1016/j.jpainsymman.2013.03.015; <http://www.sciencedirect.com/science/article/pii/S0885392413002728>

the possession of a specialist board examination. These restrictions can be a potential barrier to access, in particular if the family practitioner or specialist physicians are not readily available to prescribe these medicines for patients in medical need. Administrative requirements that apply to the prescribing of opioid medicines may deter health care professionals from prescribing these medicines. For example, the family practitioner is required to fill in a notification form and is required to notify the pharmacy chosen by the patient. A new notification has to be filled in if the patient requires a larger quantity, a different controlled substance or requires treatment for a period exceeding three months.

DISPENSING: Additional requirements for the dispensing of controlled medicines may increase the administrative burden and may cause pharmacists to be reluctant to dispense controlled medicines. According to the Hungarian legislation, controlled medicines are not allowed to be dispensed if the prescription was issued more than five working days ago. In addition, only a designated pharmacy, appointed in consultation with the patient, is authorised to dispense continuous or repeated prescriptions for controlled substances. These legal restrictions can be a potential barrier to access, in particular if patients require medical treatment with controlled medicines for a long period and are not able to visit the physician and pharmacy frequently (e.g. when living in a remote area and having to travel far to visit the physician and pharmacy or when patients rely on the help of family members and friends living in a different area due to worsening of the illness). Pharmacies are allowed to dispense controlled substances provided that an activity license has been issued by the National Chief Medical Officer Authority or the sub-region public health institute of the metropolitan or county government office. If unused controlled medicines are returned to the pharmacy, the pharmacist is obliged to provide a written record of the return of the controlled substance using a five-copy printed document. Many other administrative dispensing requirements can be found in the Hungarian legislation, all increasing the administrative burden and potentially causing pharmacists to be reluctant to dispense controlled medicines.

USAGE: Patients requiring continuous or repeated treatment with controlled medicines are obliged to visit the same designated pharmacy every time a prescription is issued (see also: **PRESCRIBING** and **DISPENSING**). Patients with dependence syndrome should be able to receive treatment for dependence within a reasonable amount of time. According to the Hungarian legislation, the dependence treatment can commence within six months of the issuance of the opinion without early status assessment. This can be a potential barrier to access if this implies that patients might have to wait six months or more (depending on the time needed for the 'issuance of the opinion') to be able to receive treatment. In case of an issuance during a criminal procedure, drug dependence needs to be established by a forensic medical expert additionally. This can also be a potential barrier to accessing treatment if the total number of forensic medical experts is too low to establish drug dependence within a reasonable time.

TRADE AND DISTRIBUTION: Requirements regarding the trade and distribution (and also the manufacturing) of controlled medicines may increase the administrative burden and may delay or impede the availability of medicinal products on the market. According to Hungarian legislation, the application for an activity license should be accompanied by many documents. For example, the applicant has to submit an overview of the mechanical and/or electronic security devices, as well as a description of the system for guarding, records, and movement within the site, together with an expert opinion certifying the operability of the security system. An application for a modification of the license is required even when there

has been a change in for example the security or security technology installations required for law-enforcement purposes. In addition, the license holder is obliged to reclaim unused stocks from its own customers every year, and a police representative has to be present to witness the destruction of these controlled substances.

Textbox 18 Selection of recommendations specific to Hungary: legal and regulatory

- Remove the restriction that only the family practitioner is authorised to prescribe controlled medicines for a period longer than 15 days. Remove the limited prescription validity of five working days and the restrictions that apply to the authorisation to prescribe controlled substances whose prescription is subject to the possession of a specialist board examination;
- Decrease the administrative burden for prescribing and dispensing opioid medicines;
- Remove the obligation for patients requiring continuous or repeated treatment with controlled medicines to visit one designated pharmacy;
- Ensure that patients are able to receive treatment with controlled medicines within a reasonable time, also in the situation that patients are arrested or imprisoned and need controlled medicines for the treatment of dependence;
- Remove the restriction that only forensic medical experts are allowed to establish dependence, during a criminal procedure, especially if the number of forensic medical experts available to establish dependence is too low, causing a delay in onset of treatment;
- Decrease the administrative burden for legal entities involved in the trade and distribution (and also manufacturing) of opioid medicines.

6.3. Identified policy barriers

For Hungary, the main challenges concerning access to opioids were identified in financial/economic aspects, issues relating to formularies, education and training and social attitudes.

FINANCIAL/ ECONOMIC ASPECTS: A key policy barrier to opioid access in Hungary relates to funding coming from the Health and Social Insurance Fund and the way this funding is allocated to support pain management, harm reduction and palliative care. The standard of palliative care in the country appears to be 'variable' with paediatric palliative care not being financed and home-based care being only financed to provide one visit per day. Institutions should be able to set up palliative care units which cannot be achieved unless funding allocation is reconsidered. For instance, if 1% of the costs of oncology care would be invested in palliative care, this would considerably improve the patients' quality of life. Research funding has also decreased considerably. As a result, forms of financed care should be expanded and the Hungarian finance system and the way funds are allocated should be re-thought.

FORMULARIES: Registration for treatment costs a lot. The cost for advanced formulations is also too high. In addition, not all pain medication is fully reimbursed. This discourages patients from getting the treatment necessary for pain relief. All forms of OAT medication for the required dose on an individual basis as well as new forms of palliative care services should be reimbursed. Reimbursement is also not sufficient for practitioners providing palliative care. Financial incentives should be offered to physicians for good practice and responsible prescribing and administering of opioid medication.

EDUCATION AND TRAINING: Palliative care is not recognised as a medical specialty in Hungary. Chronic pain management is not included in the programmes implemented by the Ministry of Human Resources and there is a lack of recognition, knowledge and training in this area. There is no palliative care specialist education for doctors. Many GP's lack experience in prescribing due to limited education (they usually refer this responsibility to oncologists). As a result, specialists should advise GPs on opioid regimens and how to apply the pharmacotherapy of pain (practical skills). Education programmes for undergraduate and postgraduate education levels must be developed, as well as subspecialty training for palliative care specialists. Palliative medicine needs to be established as a subspecialty. Mandatory pain management training needs to be provided for doctors during their specialisation and Continuing Medical Education (CME) organised (physicians should be required to pass a regular exam). Pharmacists should also be taught in pain relief, and both pharmacists and physicians should be trained in communication with patients since certain communication has been observed to scare patients away from opioids. In addition, physicians need to be taught to recognise drug dependence. OAT education initiatives must be increased and more practical skills should be provided to this direction. Special training programmes relating to OAT within the prison system need to be developed and implemented. Finally, protocols and directives need to be issued and included in education.

SOCIAL ATTITUDES: Health care professionals generally suffer from fear of opioids. Physicians discourage patients from using opioids for pain relief due to fear of dependence. Similar fears persist between patients and their families. This is mainly because of the lack of awareness of opioid use for pain management and palliative care within the society. For example, a patient once injected with morphine felt very relieved and said to her physician: "You must have given me a magic substance, a miracle has happened!" But when she told him that she had been given morphine, she turned all pale and said „Oh no - now I will become addicted!". Moreover, if a patient finally accepts that strong opioids should be used to treat his or her pain effectively, the people in their environment may disapprove (family, friends, etc.). There is also a legal uncertainty regarding needle exchange programmes and providing sterile syringes is still considered to be a crime. Drug users receiving OAT are often marginalised and treated as "criminals". Taboos in relation to opioids still prevail amongst physicians, patients, families as well as the general public. A change in perceptions must be achieved involving campaigns, advertisement and patient organisations to raise awareness and inform the population about the benefits and the risks of opioid use.

Textbox 19 Selection of recommendations specific to Hungary: policy

- Increase financing for harm reduction programmes and palliative care physician reimbursement;
- Reimburse new forms of palliative care services;
- Reimburse all forms of OAT medication for the required dose on an individual basis;
- Broaden the range of OAT medication;
- Offer financial incentives to physicians for good practice and responsible prescribing and administering of opioids;
- Establish more palliative and outpatient care units;
- Establish palliative care as a medical specialty;
- Provide mandatory pain management training for doctors during their specialisation;
- Train pharmacists and physicians in communication with patients;
- Educate physicians to recognise drug dependence;
- Increase OAT education initiatives;
- Implement special training programmes relating to OAT with the prison system;
- Issue protocols and directives and include them in education;
- Raise awareness of the general population with respect to opioid use;
- Challenge the stereotypes surrounding opioid use.

6.4. Voices from Hungary ATOME participants

In the summer of 2013 and of 2014, national key contacts and representatives of the national ATOME country teams were asked what had changed regarding access to opioid medicines in their country since the beginning of the project. These are exemplary answers by two representatives of the Hungary country team.

Textbox 20 Voices from Hungary ATOME participants

“The basic decree which defines the rules of prescribing and retail dispensing of controlled substances has been changed twice during the last two years in the direction of facilitation and simplification. Two examples: A family practitioner may prescribe a controlled substance in the amount which shall not exceed a 90-day supply. Before the amendment of the decree the amount was only 30 days supply. Furthermore, prescriptions for controlled substances do not have to be written in duplicate any longer.

As a result of the ATOME legislation review country report further simplifications are under preparation these days. Hopefully they will come into force on the 1st of July. (Returning of unused controlled substances to the pharmacy, changing the terminology of narcotic drugs to controlled substance etc.)” (Dr Éva Geecső Luxné, 10.06.2013).

“A new ministerial decree came into force on 14th of September in 2012, and the new provision requires that all doctors have the basic knowledge of pain killing and palliative care before obtaining a specialist qualification” (Dr Éva Geecső Luxné, 07.07.2014).

“As of 2014, physicians in Hungary will be able to take a one-year course to qualify for a license in palliative medicine. The licensure program supersedes the previous 40-hour training requirement for physicians wishing to qualify for a hospice-palliative position and will be offered through the four participating Hungarian medical schools in Pecs, Debrecen, Szeged, and Budapest. The program will produce better trained physicians, and result in more desperately needed palliative care programmes across the country. The curriculum has been designed, and further work remains to be done to finalize the logistics and coordination, so the programme should be up and running by late 2014” (Dr Ágnes Csikós, 17.12.2013).

6.5. Conclusion

Potential barriers to accessing opioids in Hungary have been identified in the areas of legislation and policy. The ATOME project recommends that the Hungarian legislation should be revised to provide a legal framework that focuses on optimizing healthcare outcomes while preventing diversion and misuse. The project also recommends that prescribing and dispensing should be facilitated (limited prescription validity and the restrictions on the authorisation to prescribe and to dispense controlled medicines should be removed), in order to ensure sufficient treatment for patients with dependence syndrome access to treatment should be guaranteed within a reasonable time as well as sufficient capacities to establish drug dependence and the administrative burden for legal entities involved in trade, distribution, and manufacturing of opioid medicines should be decreased. Considering the identified policy barriers in Hungary the ATOME project advises to reimburse new forms of palliative care services and harm reduction programmes, to expand the reimbursement for all pain medications and all forms of opioid agonist therapy (OAT) and to broaden the range of OAT medication; ensure an adequate level of professional knowledge and competence by improving education and training in the field of palliative care and harm reduction. Furthermore, the awareness and the acceptance of the effectiveness and risks of opioid use should be raised within the general society – i.e. within healthcare professionals as well as within patients and their families – by involving campaigns, advertisement and patient organisations.

Throughout the ATOME project, encouraging developments have been observed in terms of improved access to opioids in Hungary. Some of the recommendations made in this report may have already been implemented, but others remain to be a barrier to access to opioids and a balance of preventing misuse and ensuring availability still needs to be achieved.

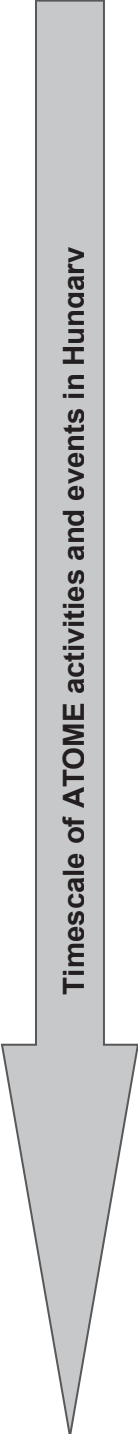
The continuing efforts of the country team to implement the specific goals elaborated in the early stages of the ATOME project are expected to have facilitated improvements at different strategic levels.

Table 7 Timescale of ATOME activities and events in Hungary

Timescale of ATOME activities and events in Hungary	Month Year	ATOME work activities	ATOME events	Activities Hungarian country team	Important events in Hungary relevant for access to opioid medication	ATOME results/ achievements
	Dec 2009		Start of the project			
	Dec 2010	Identification of country team members and national counterparts				List of country team members and national counterparts available
	Feb 2011		Lawyers' training workshop	Dr Éva Geecső Luxné and Dr Hedvig Boruzs Zajzonne attended the workshop		
	Mar 2011	Quick scan of legislation started				
	Apr 2011			Dr Éva Geecső Luxné sent legal documents on behalf of the ATOME Hungary country team		
	May - June 2011			The Hungarian country team completed the self-assessment checklist		
	July 2011	Analysis of the completed self-assessment checklists				
	Aug 2011	Preparation of the six-country workshops				

Timescale of ATOME activities and events in Hungary

Month Year	ATOME work activities	ATOME events	Activities Hungarian country team	Important events in Hungary relevant for access to opioid medication	ATOME results/ achievements
Sept 2011		First six-country workshop (Bulgaria, Cyprus, Greece, Serbia, Slovenia, Turkey)			
Oct 2011			On the 3 rd of October the Hungarian team sent the completed self-assessment checklist		
Nov 2011		Second six-country workshop (Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia, [Ukraine])	The Hungarian country team attended the workshop and worked on a national strategic action plan	Follow-up discussion in the Ministry of Health with the participation of the members of the Hungarian country team on 8th of December	National strategic action plan on improving access to opioids in Hungary
Jan 2012					Report on the results of the quick scan of legislation
Nov 2011 – May 2012	Preparation of ATOME national conference in Hungary		Collaboration between ATOME team and Hungarian country team (co-ordinated Dr Eva Gecsó Luxné)	The documentary film: 'Life before death' was screened in the Ministry of Health in the circle of health professionals on 18th of May	
June - Nov 2012	In-depth analysis of national legislation		Dr Éva Gecsó Luxné sent additional legal documents on behalf of the ATOME Hungary country team	1 st Symposium of Hospice-Palliative Care in Pécs on 4 th of October	Draft overview of legal barriers to opioid availability in Hungary



Month Year	ATOME work activities	ATOME events	Activities Hungarian country team	Important events in Hungary relevant for access to opioid medication	ATOME results/ achievements
Jan - Feb 2013	Draft report on legal barriers in Hungary sent to the ATOME Hungary country team Final report on legal barriers in Hungary sent to the ATOME Hungary country team	Legislation review workshop in Utrecht, the Netherlands	Dr Éva Geecső Luxné sent feedback to draft report		Draft report on legal barriers in Hungary Report on legislation review workshop highlighting the important outcomes and topics of discussion Final report on legal barriers in Hungary
Apr 2013	National follow-up conference implemented in Athens, Hungary and Preparation of legislation review workshop in Utrecht, the Netherlands		Leading role of Hungarian country team and experts at the national conference		
Feb 2014					Final report on legal barriers in Hungary sent to the ATOME Hungary country team
Apr 2014			Dr Eva Gecso Luxné sent additional feedback to final report		
May 2014				On 14 th of May a summarizing discussion was organized with the participation of Country Team members in order to identify the next steps needed	

Access to Opioid Medication in Europe (ATOME)

Report and recommendations to the Ministry of Health

7. Country Report - Slovenia

7.1. Introduction

Slovenia is one of the countries with statistical evidence of inadequate morphine consumption per capita. In 2006, the adequacy of opioid analgesic consumption was only 51% (based on a per capita consumption of 104.09 morphine equivalents (mEq) while 205.78 mEq would have been adequate for treatment of all pain conditions³⁰). Slovenia was selected as one of the countries to participate in the ATOME project due to this reason. Four years later, in 2010, the adequacy of opioid analgesic consumption had even decreased (both in absolute and in relative terms) – it was only 41%³¹ (based on a per capita consumption of opioid analgesics of 112.63 morphine equivalents (mEq) while 271.88 mEq per capita would have been adequate). This report presents a summary of the results of the situational analysis that has been undertaken with regard to opioid availability and accessibility in Slovenia. The results of the situational analysis are divided in two parts: the first part addresses legal and regulatory issues and the second part focuses on issues relating to policy. Both parts present the main barriers and recommendations for improving access to opioid medication in Slovenia.

7.2. Identified legal and regulatory barriers

The results of the ATOME legislation review are presented into nine different categories of potential legal and regulatory barriers, i.e. barriers related to prescribing; dispensing; usage; trade and distribution; manufacturing; affordability; penalties; language; and other. In Slovenia, potential legal and regulatory barriers have been identified in six of these nine categories: all except affordability (see Annex 2). A selection of these potential barriers is highlighted below according to category, and followed by recommendations to remove these barriers. For a more detailed description of the methods and results, see Annex 2.

PRESCRIBING: The prescribing of opioids in Slovenia is subject to administrative and non-administrative requirements. For example, physicians are obliged to use special forms when prescribing opioids and these forms have to be issued in duplicate. Examples of non-administrative requirements are the limitations that apply to the treatment period (which is limited in some cases), the maximum amount of medicines per prescription (based on the approved dosing regimen in the SPC) and the duration of the prescription validity. Although some requirements may not be recognised as 'barriers to access', they may limit access to opioids in practice; when multiple barriers are identified in the same category (for example

³⁰Seya MJ, Gelders SFAM, Achara UA, Milani B, Scholten WK. A First Comparison between the Consumption of and the Need for Opioid Analgesics at Country, Regional and Global Level. *Journal of Pain and Palliative Care Pharmacotherapy*, 2011; 25: 6-18. Accessible at: <http://apps.who.int/medicinedocs/documents/s17976en/s17976en.pdf>

³¹Duthey, B., Scholten, W. Adequacy of Opioid Analgesic Consumption at Country, Global, and Regional Levels in 2010, Its Relationship With Development Level, and Changes Compared With 2006. *Journal of Pain & Symptom Management* 2013; <http://www.sciencedirect.com/science/article/pii/S0885392413002728>

prescribing), the problem is substantially compounded. For example, the limited prescription validity of five days in combination with both a maximum amount per prescription and a maximum treatment period of 30 days may result in limited access to opioids for medical purposes.

DISPENSING: In Slovenia, the authorisation to dispense controlled medicines is restricted to pharmacists, whereas other medicinal products not containing controlled substances can also be dispensed by pharmacy technicians. For this reason, opioids cannot be dispensed if the pharmacist is (temporarily) unavailable; this can delay the onset of therapy. When dispensing opioids, pharmacists are required to keep special officially sealed books to record the statistics of the dispensing. These books must be kept and signed by the person that dispensed the controlled medicine, which increases the administrative burden and may deter pharmacists from dispensing such medicines.

USAGE: Opioid medicines can only be dispensed to patients who are 18 years of age or older and are able to produce a valid identity card; this may delay or impede access for patients in medical need of opioids (see also par. 6.6.4, Annex 2).

TRADE AND DISTRIBUTION: Incomplete applications for a license to import or export controlled medicines must be supplemented within eight days. This restrictive timescale can delay the availability of opioids if a completely new application is required.

PENALTIES: The Slovenian legislation contains severe, disproportional sanctions for legal entities and individual persons for the violation of administrative requirements, such as the requirements related to storage of controlled medicines and substances. These severe sanctions may cause fear of unintended violations and may deter legal entities and individual persons from producing, trading or storing opioids.

LANGUAGE: In the Slovenian legislation, the distinction between medical use and misuse or illicit use is not always clear. In addition, the definition used for controlled substances is may contribute to the stigmatization of opioids. This also applies to the use of stigmatising terms such as 'addicts' and 'addiction' in the Slovenian legislation.

Textbox 21 Selection of recommendations specific to Slovenia: legal and regulatory

- Remove the limited prescription validity of five days;
- Allow for appropriately trained pharmacy technicians to dispense opioid medicines;
- Decrease the administrative burden for prescribing, dispensing and receiving opioid medicines;
- Ensure that applying for a license to import or export opioid medicines is not unnecessarily complicated;
- Ensure that sanctions for unintended violation of administrative rules are not disproportionate in relation to the risk of misuse and diversion;
- Provide clear language in legislation, use correct definitions and avoid language that stigmatises the medical use of opioids or refers to patients with dependence in a disrespectful way.

7.3. Identified policy barriers

For Slovenia, the main challenges concerning access to opioids were identified in financial/economic aspects, issues relating to formularies, education and training, social attitudes.

FINANCIAL/ ECONOMIC ASPECTS: One of the major barriers to opioid access in Slovenia is lack of funding allocated to harm reduction and palliative care initiatives. There are two main forms of dependency treatment currently available in the country - specialized treatment in hospitals (in accordance with Slovenian healthcare provision) and outpatient treatment provided from mobile units by an association of non-governmental organizations (NGOs) which are co-financed by various State Ministries only under certain circumstances., The Ministry of Health is the competent body to finance social prevention programmes. The right to harm reduction treatment is afforded to any dependent person and there is 100% coverage of funding by the National Insurance Company. Moreover, funding for palliative care is provided through general agreements for each contractual year; a team structure was defined in 2010, but currently funding for palliative care is not included in the agreement between the Ministry of Health and the National Insurance Company.

FORMULARIES: The prescription procedure of opioids in Slovenia is too liberal; there are no guidelines for indications and no control regarding the increase of dose. The average time frame of seven minutes that are granted for home visits is yet another problem. Therefore, this timeframe should be extended. In addition, the consultation time should be documented in the patient charts (codes for documenting can be found on the website of insurance companies). Relevant associations should be addressed to put this into practice. Prescribing should also follow guideline recommendations. However, given that existing guidelines in Slovenia appear to be not sufficient the guidelines from the US Pain Society relating to the use of opioids in chronic non-cancer pain and the WHO Guidelines for the Pharmacological Treatment of Persisting Pain in Children with Medical Illnesses could be used as a template or for guidance. Still, it is difficult to enforce the use of treatment guidelines in Slovenia since certain substances are not being imported. Moreover, a standard legal definition needs to be established for measuring pain in all medical settings where pain can occur. Although pain medication is widely available, physicians must acknowledge that pain is an acute symptom that requires urgent treatment. Many emergency medicines do not have suitable instructions for use; therefore those should be drafted and distributed by pharmacies. Not all emergency medications are free of charge for patients; therefore, those should be added to the list of medicines that are free of charge. Finally, not all pharmacists have sufficient equipment/ staff to provide PCAs (Patient-Controlled Analgesia) elastomeric pumps. Although not all pharmacies need such provisions, there should be a clear list of pharmacists where these are available to make sure that the patient does not need to travel to another pharmacy; instead, the equipment should be delivered to the pharmacy closest to the patient's home via an established network.

EDUCATION AND TRAINING: There is a lack of education/competencies amongst healthcare professionals in palliative care and pain treatment. Although there is some education and training in pain management, it is described as only a few hours duration and limited to certain specialties (for example, anaesthesiology, and emergency physicians). Better education for healthcare professionals is therefore required in Slovenia. There is a need to increase the qualifications required of post-graduate and practicing healthcare professionals to work with opioid medications (based on EAPC recommendations) and change the Laws of Medical Practice to enable only healthcare professionals with this specific education to pre-

scribe opioids. In addition, palliative care should be included in the undergraduate education of healthcare professionals. Although this action plan was already prepared, the changes in the government (the Minister of Health changed at least 3 times during the ATOME project) did not allow for this plan to be realised. There is no specialized training in palliative care for healthcare professionals in Slovenia³². The requirement for interns to spend two months studying palliative care has already been included. A curriculum for postgraduate study programmes (including pain management and palliative care) should be developed. A network is also needed to educate and support GPs given that guidelines on paper are not sufficient. This issue must be discussed with physicians' associations and medical faculties. A more structured approach towards education needs to be developed that will include multidisciplinary. Specialists for drug dependence and pain management do not know each other's fields of competence and as a result they should cooperate more closely. Finally, training/education should be established for measuring pain in all medical settings where pain can occur. This initiative should involve physician societies, professional associations and other healthcare professionals.

SOCIAL ATTITUDES: There is a lack of awareness amongst the general population (patients, relatives) about the accessibility of pain management/opioid medication in Slovenia. Not enough information is provided to the public. In addition, the knowledge health care professionals receive on palliative care is also insufficient considering that this topic is not adequately addressed during medical education. A case study of successful use of opioid medication for pain management demonstrated a fear of using strong opioids on the part of physicians and patients. Physicians are reluctant to prescribe opioids for pain relief due to fear of dependence/tolerance or unexpected side effects. Moreover, patients often live in fear that their dosage will be reduced and they might suffer relapse. Gaps in harm reduction strategy include lack of treatment of dependence for prescribed medications and issues of stigma and discrimination. Patients receiving opioid agonist therapy are often stigmatised leading to social and professional isolation. The issue of fear of opioids needs to be addressed and resolved. This may be achieved by expanding public knowledge about pain management/opioid medication, using different social media (TV, newspapers, etc.) and professional knowledge by developing and implementing training initiatives for health care providers involved in pain management and palliative care.

³² Since March 2011 there is a 50 hour course on palliative care.

Textbox 22 Selection of recommendations specific to Slovenia: policy

- Provide additional funding for pain management and harm reduction initiatives and palliative care services (for example, mobile teams to provide coverage in rural areas) via the National Insurance Company;
- Improve marketing authorization procedures;
- Develop a list of pharmacies that possess sufficient and appropriate equipment/staff to provide opioids;
- Provide harm reduction in relation to treatment of dependence for prescribed medications;
- Ensure that opioid education is included in undergraduate and postgraduate curricula for relevant healthcare professionals (to include all members of the multidisciplinary team);
- Raise awareness and sensitisation about pain management among practicing health-care professionals (e.g. via Continued Medical Education; a series of publications about the rational use of opioids in highly-accessed national medical journals; a survey on knowledge and attitudes regarding opioid medicines);
- Develop initiatives to reduce stigma and discrimination associated with harm reduction;
- Raise awareness among the general public via media campaigns, patient information (e.g. leaflets/brochures about fear of opioids).

7.4. Voices from Slovenian ATOME participants

In the summer of 2013, national key contacts and representatives of the national ATOME country teams were asked what had changed regarding access to opioid medicines in their country since the beginning of the project. These are examples of answers by one representative of the Slovenian country team.

Textbox 23 Voices from Slovenian ATOME participants

“The most important contribution of the ATOME project was the adoption of the Essential drug list and inclusion of most of the drugs from that list to our essential drug list. So, now we have again the prolonged release morphine in different oral formulations and many other drugs, and that makes our work easier.

We have developed a more structured approach towards education that will include all profession from the multiprofessional team. It is foreseen to cover Slovenia with mobile palliative units who will connect intra and extramural territory.

There has been a much better cooperation with the MoH. Regular reports of palliative care development are included in the meetings of National programme for cancer control.

There has been a special meeting dedicated to the problem of abusing the prescribed drugs at the Slovenian Society for Pain Medicine“ (Mateja Lopuh, 06.06.2013).


7.5. Conclusion

Potential barriers to accessing opioids in Slovenia have been identified in the areas of legislation and policy. The ATOME project recommends that the Slovenian legislation should be revised (in consultation with healthcare professionals) to provide a legal framework that focuses on optimizing health care outcomes while preventing diversion and misuse. The project also recommends that education on palliative care and pain treatment (at both undergraduate and postgraduate level) be expanded, that funding in these areas be increased (in addition to harm reduction) and that awareness-raising initiatives in all these areas be promoted.


Throughout the ATOME project, encouraging developments have been observed in terms of improved access to opioids in Slovenia. Some of the recommendations made in this report may have already been implemented (or are in the process of implementation). For example, the WHO Model List of Essential Medicines has been adopted and most of the medicines from that list were included in the national Slovenian essential medicines list. There is improved cooperation and collaboration with the Ministry of Health, regular reports of palliative care development are included in National Programme for Cancer Control meetings, and there has been a special meeting at the Slovenian Society for Pain Medicine relating to the misuse of prescribed medicines.

The continuing efforts of the country team to implement the specific goals elaborated in the early stages of the ATOME project can be assumed to have facilitated improvements at different strategic levels; this steady progress has enabled them to continue improving access to opioid medicines in Slovenia in alignment with specific recommendations provided in this report.

Table 8 Timescale of ATOME activities and events in Slovenia



Month Year	ATOME work activities	ATOME events	Activities Slovenia country team	Important events in Slovenia relevant for access to opioid medication	ATOME results/ achievements
Dec 2009		Start of the project			
Dec 2010	Identification of country team members and national counterparts				List of country team members and national counterparts available
Feb 2011		Lawyers' training workshop	Mrs Doroteja Novak Gosaric attended the workshop		
Mar 2011	Quick scan of legislation started				
May 2011			The Slovenian country team completed the self-assessment checklist		
June 2011					
July 2011	Analysis of the completed self-assessment checklists				
Aug 2011	Preparation of the six-country workshops				
Sept 2011		First six-country workshop (Bulgaria, Cyprus, Greece, Serbia, Slovenia, Turkey)	The Slovenian country team attended the workshop and worked on a national strategic action plan	Adoption of essential medicines list and inclusion of most of the medicines into Slovenian essential medicines list	National strategic action plan on improving access to opioids in Slovenia
Nov 2011		Second six-country workshop (Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia, [Ukraine])			



Month Year	ATOME work activities	ATOME events	Activities Slovenia country team	Important events in Slovenia relevant for access to opioid medication	ATOME results/ achievements
Nov 2011 – Mar 2012	Preparation of first ATOME national conference in Slovenia		Collaboration between ATOME team and Slovenia country team (co-ordinated by Dr Mateja Lopuh)	Special meeting dedicated to misuse of prescribed medicines at Slovenian Society for Pain Medicine	
Jan 2012					Report on the results of the quick scan of legislation
Mar 2012	First national follow-up conference implemented in Slovenia		Leading role of Slovenian country team and experts at the national conference		
Nov 2012	Preparation of legislation review workshop in Utrecht, the Netherlands				
Jan - Feb 2013		Legislation review workshop in Utrecht, the Netherlands	Representatives from the Slovenian ATOME country team attended the legislation review workshop in Utrecht, the Netherlands		

Access to Opioid Medication in Europe (ATOME) Report and recommendations to the Ministry of Health

8. Country Report - Serbia

8.1. Introduction

Serbia is one of the countries with statistical evidence of inadequate morphine consumption per capita. In 2006, the adequacy of opioid analgesic consumption was only 8% - based on a per capita consumption of 12.81 morphine equivalents (mEq) while 166mEq would have been adequate for treatment of all pain conditions (Data for Serbia and Montenegro)³³. Serbia was selected as one of the countries to participate in the ATOME project due to its low per capita morphine consumption. Four years later, in 2010, the adequacy of opioid analgesic consumption had slightly increased (both in absolute and in relative terms) – it was 14%³⁴ (based on a per capita consumption of opioid analgesics of 40.06morphine equivalents (mEq) while 285.61mEq in mg per capita would have been adequate). This report presents a summary of the results of the situational analysis that has been undertaken with regard to opioid availability and accessibility in Serbia. The results of the situational analysis are divided in two parts: the first part addresses legal and regulatory issues and the second part focuses on issues relating to policy. Both parts present the main barriers and recommendations for improving access to opioid medication in Serbia.

8.2. Identified legal and regulatory barriers

The results of the ATOME legislation review have been divided into nine different categories of potential legal and regulatory barriers: i.e. barriers related to prescribing; dispensing; usage; trade and distribution; manufacturing; affordability; penalties; language; and other. In Serbia, potential legal and regulatory barriers have been identified in seven of these nine areas: all areas except affordability and other (see Annex 2). A selection of these potential barriers is highlighted below according to category, followed by recommendations to remove these barriers. For a more detailed description of the methods and results, see Annex 2.

PRESCRIBING: The prescribing of opioid medicines in Serbia is subject to many administrative and non-administrative requirements. For example, according to the Serbian legislation the authorisation to prescribe controlled medicines for the treatment of patients with dependence is restricted to medical practitioners working in healthcare institutions, private practices and other designated legal entities performing healthcare activities. This restriction can be a potential barrier to access, in particular if the total number of healthcare professionals availa-

³³ Seya MJ, Gelders SFAM, Achara UA, Milani B, Scholten WK. A First Comparison between the Consumption of and the Need for Opioid Analgesics at Country, Regional and Global Level. *Journal of Pain and Palliative Care Pharmacotherapy*, 2011; 25: 6-18. Accessible at: <http://apps.who.int/medicinedocs/documents/s17976en/s17976en.pdf>

³⁴ Duthey, B., Scholten, W. Adequacy of Opioid Analgesic Consumption at Country, Global, and Regional Levels in 2010, Its Relationship With Development Level, and Changes Compared With 2006. *Journal of Pain & Symptom Management* 47(2); 2014: 283-97 doi:10.1016/j.jpainsymman.2013.03.015; <http://www.sciencedirect.com/science/article/pii/S0885392413002728>

ble (and allowed) to prescribe controlled medicines is (too) low or healthcare institutions do not meet the needs of patients needing controlled medicines (e.g. palliative patients).

According to the Serbian legislation, the total amount of controlled medicine to be prescribed is limited. For example, a physician may prescribe a maximum amount of 0.2 g morphine or 0.2 g methadone. For the treatment of malignant diseases, the total amount to be prescribed is limited to a treatment duration of 14 days per prescription. For other conditions, medicines containing controlled substances can be prescribed for a maximum treatment period of 30 days per prescription. In addition, the validity of a special medical prescription (used for prescribing controlled substances) is limited to seven days from the date of issue. These restrictions are potential barriers to access; patients who require medical treatment with controlled medicines for a longer period will need to visit the physician and pharmacy frequently.

TRADE AND DISTRIBUTION: Requirements regarding the trade and distribution of controlled medicines may increase the administrative burden and may delay or impede the availability of medicinal products on the market. According to Serbian legislation, legal entities must have open-ended employment contracts with any employee responsible for controlled substances and with a deputy officer in charge to be able to submit an application for a production or trading license. This requirement may have financial consequences for the legal entity and may also increase the administrative burden, which can cause legal entities to be reluctant to produce or trade controlled substances. In addition, controlled substances may only be transported in metal containers with security locks, in specially constructed luggage compartments equipped with a locking mechanism, or in an enclosed compartment of a vehicle that must be adapted in such a way that controlled substances cannot be removed. In addition, for the storage of controlled substances legal entities are obliged to ensure the permanent presence of a security service and appropriate technical installations. The cost of these safety measures may be disproportionate to the actual risk of diversion and may therefore deter legal entities from trading in controlled medicines.

PENALTIES: Provisions containing intimidating language or severe sanctions for unintended violations may deter legal entities from manufacturing or distributing controlled medicines. According to the Serbian legislation, severe sanctions apply for violation of provisions concerning controlled medicines. In particular provisions containing very high penalties for private persons and provisions with high minimum sanctions and high maximum sanctions (e.g. 3-12 years imprisonment for the unlawfully purchasing, keeping or transporting for sale of narcotics) can be considered intimidating.

LANGUAGE: In the Serbian legislation, the distinction between medical use and misuse or illicit use is not always clear. The misuse of controlled medicines is often referred to as the use of controlled medicines. The phrase 'reduction of demand for psychoactive controlled substances' is often used to indicate that there should be a reduction of misuse. This language may cause fear and confusion and may deter healthcare professionals from prescribing or dispensing opioid medicines or may deter patients from using controlled medicines for legitimate purposes, in particular if severe sanctions are involved for unintended violations. In addition, the terms 'addict(s)', 'addiction' and 'persons addicted' are considered to be stigmatising, but are used in the reviewed Serbian legislation. This also applies to referring to controlled medicines as dangerous or harmful drugs.

Textbox 24 Selection of recommendations specific to Serbia: legal and regulatory

- Remove the prescription validity of 7 days that applies to prescriptions for medicines containing controlled substances;
- Remove restrictions that apply to the amount to be prescribed, in particular if these restrictions do not apply to other non-controlled medicinal products;
- Decrease the administrative burden for prescribing and dispensing opioid medicines;
- Remove the overly strict requirements regarding the storage of controlled medicines in premises;
- Ensure that the costs of security measures for the storage of controlled medicines are not disproportional compared to the risk of misuse and diversion;
- Revise provisions containing punitive sanctions, in particular provisions containing severe penalties for natural persons and provisions with high minimum sanctions;
- Ensure that punitive provisions contain exceptions for unintended violations; unintended errors that do not result in diversion of controlled medicines or serious health consequences should not be subject to criminal penalties;
- Provide clear language in legislation and avoid language that stigmatises the medical use of opioids or refers to patients with dependence in a disrespectful way.

8.3. Identified policy barriers

For Serbia, the main challenges concerning access to opioids were identified in financial/economic aspects, issues relating to formularies, education and training and social attitudes.

FINANCIAL/ ECONOMIC ASPECTS: In 2004, the Serbian Government implemented the National Health Accounts (NHA) in an attempt to produce evidence to help policy makers and health managers better understand the way the health system operates and inform action to improve performance. As a result, the increased transparency of financial flows in the health sector could enable a more reliable distribution of funds. In 2007 twenty-six centres for harm reduction offering opioid agonist therapy (OAT) were established in Serbia with the financial support offered by the Global Fund. However, there is still no underlying systematic approach and the funding provided by the Global Fund will run out 2014, leaving the centres with an unclear future. There are also evident difficulties in the funding of opioids by the National Health Insurance Fund (NHIF) since prescription requires authorization from the prescribing institution.

FORMULARIES: There is an urgent need to establish palliative medicine as a medical specialty in Serbia³⁵. Although palliative care is being increasingly recognized as a medical discipline, a disease-oriented (cure) vs. patient oriented holistic approach (care) dichotomy still exists in the country. Several hospitals have started pain clinics but holistic palliative care has yet to be introduced in these settings. Another important policy barrier relates to the 'overly restrictive regulations for the prescribing, dispensing and reimbursement of opioids' in

³⁵ This need has already been fulfilled. Since 2009 palliative care is part of the curriculum for some specializations and sub specializations such as oncology, radiology, vascular surgery and general practitioners. According to the Serbian rulebook on specialization and sub specialization of healthcare professionals and associates, palliative medicine is a sub specialization accompanied by pain treatment since October 2013.

Serbia. Some palliative care medicines are available free of charge through the public healthcare service but some medicines used in palliative care are not covered when used specifically for symptom management rather than disease-specific applications. In addition, general practitioners (GPs) are not allowed to prescribe opioids independently but must have an official recommendation from a hospital doctor who usually does not see palliative care patients. This policy often results in a situation where doctors must recommend opioids without seeing the patient. A number of reforms have been introduced to address such issues in the healthcare system; however, these reforms have failed to implement a basic level of healthcare provision for all members of the Serbian population and, as a result, there are varying levels of standards in the healthcare services provided throughout the country.

EDUCATION AND TRAINING: Although some medical training and education relating to pain management was included in the manual of palliative care issued in 2013, there are currently no modules relating to 'pain medicine' in the medical undergraduate curriculum. There have been some courses and presentations on palliative care topics (mostly on symptom control) and several nursing schools have introduced modules on palliative care. There is some training and education available. However, since palliative care is not a medical specialty, there are only a few palliative care specialists in Serbia who had opportunities to access international specialist training³⁶. Although approximately 1500 healthcare professionals have received some palliative care training, education initiatives in this area are considered to be insufficient. Palliative care education and training needs to be included in the programmes of Continuing Medical Education as well as the curricula of medical schools and nursing colleges. It is imperative that healthcare professionals receive further education and training in areas such as pain management, pain medicine and palliative care and as a result such initiatives need to be encouraged and supported.

SOCIAL ATTITUDES: Besides any legal and regulatory barriers, the low morphine consumption in Serbia is related to a range of attitudinal barriers including barriers in knowledge about the use of opioids for pain management and palliative care i.e. 'much misinformation and misunderstanding' (e.g. outdated terminology in relation to opioids, use of stigmatizing/ unclear language) resulting in strong fear of opioid use. In a 2013 survey on fear of opioids, 88% of physicians were found to be reluctant to prescribe opioids and only 7% of patients did not object when morphine was suggested for pain relief. Physicians' reluctance was mostly linked to fear of respiratory depression while patients' fears related to concerns about tolerance, dependence and adverse effects as well as the association of morphine with imminent death (the prescription of morphine being considered as a death sentence). In addition, some patients did not want to appear as a weakling and stated that they would not need morphine but rather bear the pain, holding on to a cultural belief that it is better not to say that opioids are helpful. Beyond physicians and patients, policy makers need to be convinced that prescribing opioids does not automatically result in opioid dependence or hastened death. Brochures about fear of opioids addressing the concerns / misunderstandings about misuse, dependence, tolerance and withdrawal need to be produced and distributed throughout the country³⁷.

³⁶ This has been changed in 2009 and 2013 (see ³⁶).

³⁷ This request change has already been achieved. Serbian palliative care guidelines have been disseminated (Milicevic, 2004). A book on pharmacotherapy of cancer pain has been published (Bosnjak, 2007). Educational brochures on fear of opioids for healthcare professionals and patients/ families have been produced (Bosnjak, 2009). Lectures about cancer pain management, the principle of balance and fear from opioids have been held. Educational posters on fear of opioids (for healthcare professionals and patients) and patients' rights to pain relief

Textbox 25 Selection of recommendations specific to Serbia: policy

- Provide a clear statement that opioid use is legal (with or without mandatory authority);
- Ensure reimbursement of opioids from the MOH/NHIF;
- Increase the number and type of available opioids (particularly for breakthrough pain)³⁸;
- Develop a provision that allows for 'off-label' use of opioids under strict circumstances;
- Enhance prescription of opioids for non-cancer pain;
- Enable physicians to prescribe more than one opioid at on one prescription form;
- Enable pharmacies to dispense opioids at the local level;
- Include pharmacists in the National Strategy of Palliative Care and provide them with special training courses;
- Establish palliative medicine as a medical specialty;
- Include palliative care education and training in the programmes of Continuing Medical Education as well as the curricula of medical schools and nursing colleges;
- Promote education/training initiatives in areas such as pain management, pain medicine and palliative care;
- Collect and share information about OAT between different groups interested in receiving treatment (i.e. HIV/AIDS groups);
- Raise awareness of opioids amongst healthcare professionals and the general public;
- Produce and distribute brochures on fear of opioids to patients and families throughout the country.

have been presented. A palliative care network with professional associations, NGOs and the WHO country office has been established in Serbia.

³⁸ Since 26th of December 2006 immediate release (IR) and slow release (SR) morphine can be imported to Serbia. The pharmacy of the Institute for Oncology and Radiology of Serbia started to produce oral morphine solution in May 2007. In June 2008 the central pharmacy in Belgrade imported oral morphine and IR morphine has been registered in Serbia for the first time. SR hydromorphone has been registered in October 2007. Since 2012 methadone can be reimbursed for cancer pain treatment. In 2014 lactulosis has been accepted by the Health Insurance Fund for prevention and treatment of opioid induced constipation.

8.4. Voices from Serbia ATOME participants

In the summer of 2013, national key contacts and representatives of the national ATOME country teams were asked what had changed regarding access to opioid medicines in their country since the beginning of the project. These are examples of answers by two representatives of the Serbian country team.

Textbox 26 Voices from Serbia ATOME participants

“The ATOME project certainly has raised the Government’s level of awareness about the need to make opioids available and accessible. The WHO guidelines translated to Serbian are a valuable educational tool and the ATOME analysis of the presence of legislative barriers provides an excellent platform to start changing regulations and practice” (Dr Snezana Bosnjak, 16.06.2013).

“Our project ‘Development of Palliative Care Services in Serbia’ paid a lot of attention to legislation. It is my pleasure to inform you that at the end of December 2013 the Government adopted a new law on healthcare that officially enables NGOs to provide palliative care and to prescribe all medications in the same way as public or private institutions (RE article 64:6.2.1.). This law must be approved by the Parliament, too” (Dr Natasa Milicevic, 18.02.2014).


8.5. Conclusion

Potential barriers to accessing opioids in Serbia have been identified in the areas of legislation and policy. The ATOME project recommends that the Serbian legislation should be revised to provide a legal framework that focuses on optimizing healthcare outcomes while preventing diversion and misuse. The project also recommends that prescribing should be facilitated (maximum amount of controlled medicines to be prescribed and the limited prescription validity should be removed; the restrictions on the authorisation to prescribe controlled medicines for the treatment of patients with dependence should be reconsidered). The administrative burden for legal entities involved in trade and distribution of opioid medicines should be decreased. It should be ensured that punitive provisions contain exceptions for unintended violations. Clear language and non-stigmatizing terms in the Serbian legislation should be guaranteed. Considering the identified policy barriers in Serbia the ATOME project advises to develop a systematic analysis of financial flows in the health sector, and to ensure financial support for harm reduction initiatives. The number and type of available opioids should be increased (e.g. for breakthrough pain) and the reimbursement of opioids should be improved. Palliative medicine should be established as a medical speciality in Serbia; education and training in palliative care and pain management should be included in the programmes of Continuing Medical Education as well as the curricula of medical schools and nursing colleges. Furthermore, the awareness concerning opioid treatment amongst healthcare professionals and the general population should be raised – e.g. by producing and distributing brochures on fear of opioids addressing the misunderstandings about misuse, dependence, and tolerance throughout the country.


Throughout the ATOME project, encouraging developments have been observed in terms of improved access to opioids in Serbia. Some of the recommendations made in this report may have already been implemented, but others remain to be a barrier to access to opioids and a balance of preventing misuse and ensuring availability still needs to be achieved.

The continuing efforts of the country team to implement the specific goals elaborated in the early stages of the ATOME project are expected to have facilitated improvements at different strategic levels.

Table 9 Timescale of ATOME activities and events in Serbia



Month Year	ATOME work activities	ATOME events	Activities Serbia country team	Important events in Serbia relevant for access to opioid medication	ATOME results/ achievements
Dec 2009		Start of the project			
Dec 2010	Identification of country team members and national counterparts				List of country team members and national counterparts available
Feb 2011		Lawyers' training workshop	Ms Dragana Kosic and Dr Snezana Bosnjak attended the workshop		
Mar 2011	Quick scan of legislation started		Dr Snezana Bosnjak sent legal documents on behalf of the ATOME Serbia country team		
April 2011			Dr Snezana Bosnjak sent legal documents on behalf of the ATOME Serbia country team		
May - June 2011			Dr Snezana Bosnjak sent legal documents on behalf of the ATOME Serbia country team The Serbian country team completed the self-assessment checklist		
July 2011	Analysis of the completed self-assessment checklists				
Aug 2011	Preparation of the six-country workshops				



Month Year	ATOME work activities	ATOME events	Activities Serbia country team	Important events in Serbia relevant for access to opioid medication	ATOME results/ achievements
Sept 2011		First six-country workshop (Bulgaria, Cyprus, Greece, Serbia, Slovenia, Turkey)	The Serbian country team attended the workshop and worked on a national strategic action plan		National strategic action plan on improving access to opioids in Serbia
Oct 2011			Dr Snezana Bosnjak sent legal documents on behalf of the ATOME Serbia country team		
Nov 2011		Second six-country workshop (Estonia, Latvia, Lithuania, Poland, Slovakia, Hungary, [Ukraine])			
Jan 2012					Report on the results of the quick scan of legislation
June 2012			Dr Snezana Bosnjak sent additional legal documents on behalf of the ATOME Serbia country team		
July 2012	In-depth analysis of national legislation				Draft overview of legal barriers to opioid availability in Serbia
Oct 2012			Ms Ljubica Pakovic sent additional legal documents on behalf of the ATOME Serbia country team		
Aug 2012	Preparation of legislation review workshop in Utrecht, the Netherlands				

Timescale of ATOME activities and events in Serbia

Month Year	ATOME work activities	ATOME events	Activities Serbia country team	Important events in Serbia relevant for access to opioid medication	ATOME results/ achievements
Nov 2012	Preparation of legislation review workshop in Utrecht, the Netherlands				
Dec 2012			Ms Ljubica Pakovic sent additional legal documents on behalf of the ATOME Serbia country team		
Jan 2013	Draft report on legal barriers in Serbia sent to the Serbian country team		Dr Snezana Bosnjak sent feedback to draft report on legal barriers in Serbia		Draft report on legal barriers in Serbia
Jan - Feb 2013		Legislation review workshop in Utrecht, the Netherlands	Representatives from the Serbian ATOME country team attended the legislation review workshop in Utrecht, the Netherlands		Report on legislation review workshop highlighting the important outcomes and topics of discussion
Feb 2013			Dr Natasa Mili-cevic sent feedback to draft report on legal barriers in Serbia		
Mar 2013			Ms Ljubica Pakovic sent feedback to draft report on legal barriers in Serbia		
Mar - Oct 2013	Preparation of ATOME national conference in Serbia		Collaboration between ATOME team and Serbian country team (co-ordinated by Ms Dragana Kosic)		
Oct 2013	National follow-up conference implemented in Belgrade, Serbia		Leading role of Serbia country team and experts at the national conference		
Feb 2014	Final report on legal barriers in Serbia sent to the Serbian country team		Dr Snezana Bosnjak sent additional feedback to Final report on legal barriers in Serbia		Final report on legal barriers in Serbia sent to the ATOME Serbia country team

Access to Opioid Medication in Europe (ATOME) Report and recommendations to the Ministry of Health

9. Country Report - Bulgaria

9.1. Introduction

Bulgaria is one of the countries with statistical evidence of inadequate morphine consumption per capita. In 2006, the adequacy of opioid analgesic consumption was 8% - based on a per capita consumption of 12.20 morphine equivalents (mEq) while 156 mg would have been adequate for treatment of all pain conditions³⁹. Bulgaria was selected as one of the countries to participate in the ATOME project due its low per capita consumption. Four years later, in 2010, the adequacy of opioid analgesic consumption had decreased even further in relative terms – it was only 6%⁴⁰ (based on a per capita consumption of opioid analgesics of 13.27 morphine equivalents (mEq) while 236 mEq in mg per capita would have been adequate). This report presents a summary of the results of the situational analysis that has been undertaken with regard to opioid availability and accessibility in Bulgaria. The results of the situational analysis are divided in two parts: the first part addresses legal and regulatory issues and the second part focuses on issues relating to policy. Both parts present the main barriers and recommendations for improving access to opioid medication in Bulgaria.

9.2. Identified legal and regulatory barriers

The results of the ATOME legislation review have been divided into nine different categories of potential legal and regulatory barriers, i.e. barriers related to prescribing; dispensing; usage; trade and distribution; manufacturing; affordability; penalties; language; and other. In Bulgaria, potential legal and regulatory barriers have been identified in all nine categories (see Annex 2). A selection of these potential barriers is highlighted below according to category, followed by recommendations to remove these barriers. For a more detailed description of the methods and results, see Annex 2.

PRESCRIBING: The prescribing of opioids in Bulgaria is subject to many overly strict administrative and non-administrative requirements. For example, according to the Bulgarian legislation the authorisation to provide treatment for dependence (including the prescribing of medicinal products containing controlled medicines) is subject to a license issued by the Ministry of Health. In addition, for cancer patients opioid analgesics can in certain cases only be prescribed by physicians appointed by the director of the medical institution. These restrictions interfere with the professional autonomy of adequately trained healthcare professionals. In

³⁹ Seya MJ, Gelders SFAM, Achara UA, Milani B, Scholten WK. A First Comparison between the Consumption of and the Need for Opioid Analgesics at Country, Regional and Global Level. *Journal of Pain and Palliative Care Pharmacotherapy*, 2011; 25: 6-18. Accessible at: <http://apps.who.int/medicinedocs/documents/s17976en/s17976en.pdf>

⁴⁰ Duthey, B., Scholten, W. Adequacy of Opioid Analgesic Consumption at Country, Global, and Regional Levels in 2010, Its Relationship With Development Level, and Changes Compared With 2006. *Journal of Pain & Symptom Management* 47(2); 2014: 283-97 doi:10.1016/j.jpainsymman.2013.03.015; <http://www.sciencedirect.com/science/article/pii/S0885392413002728>

addition, the total amount of controlled medicine to be prescribed is limited to the quantity necessary for a 30 day treatment course. Moreover, the validity of a special medical prescription used for prescribing controlled medicines is limited to 7 days from the day of issuance of the prescription. These restrictions are potential barriers to access; patients who require medical treatment with controlled medicines for a longer period will need to visit the physician and pharmacy frequently.

Administrative requirements for medical practitioners in the Bulgarian legislation regarding the treatment of patients with controlled medicines can be considered disproportional. In Bulgaria, medicinal products that contain controlled substances must be prescribed using a prescription form for such substances. These special forms in three copies in yellow and green colour can be purchased from the regional healthcare centres. The third copy must be stored by the physician or dentist for one year. After this year, the prescription forms must be submitted together with an acceptance certificate to the Regional Healthcare Centre inspectors. These (and many other) requirements may increase the administrative burden and may have the effect that medical practitioners are unable (in case that no prescription forms are available) or reluctant to treat patients with controlled medicines.

DISPENSING: Additional requirements for the dispensing of controlled medicines may increase the administrative burden and may cause pharmacists to be reluctant or unable to dispense controlled medicines. In Bulgaria, the procedures for dispensing controlled medicines are complex and bureaucratic. For example, the pharmacist is obliged to note on the first copy of every prescription for controlled medicines the full name and information from the ID document of the person bringing the prescription. It is unclear whether the Bulgarian legislation allows this task to be delegated to for example pharmacy technicians. In addition, many administrative requirements concerning the record keeping should be followed with strict reporting timelines. These administrative requirements increase the burden and potentially cause pharmacists to be reluctant to dispense controlled medicines, which may impede availability and accessibility. In addition, in Bulgaria only pharmacies that have been awarded a license for retail trade and storage of controlled substances are allowed to dispense medicinal products containing such substances. Moreover, these licensed pharmacies can only dispense medicinal products containing controlled substances if they are located in the region where the prescription was issued. This can be a potential barrier to accessing controlled medicines, especially when patients are not or no longer able to visit the pharmacy - for example due to worsening of the illness – and rely on the help of family members and friends living in a different (remote) area.

USAGE: Similar to the requirements for dispensing (see above), patients requiring treatment with controlled medicines are continuously or repeatedly obliged to visit the pharmacy located in the territory of the region where the prescription was issued. In addition, the Bulgarian legislation limits access to substitution and maintenance programmes for the treatment of dependence to persons who are at least 18 years of age and have previously attended at least three formally documented treatment programs, but have not ceased to misuse controlled substances. These requirements are potential barriers to access; patients, including adolescents and children when indicated, should be able to receive necessary controlled medicines based on an authorised medical prescription when needed within a reasonable time.

LANGUAGE: The absence or the incorrect use of definitions may cause confusion relating to terminology used in legislation and can cause fear for the use of opioid medicines in medical practice, in particular if stigmatising language is used. In the reviewed Bulgarian legislation, controlled substances are referred to as intoxicating substances. In addition, the language used in the Bulgarian legislation and the distinction between medical use and misuse or illicit use are not always clear. Moreover, the terms ‘addict(s)’, ‘addiction’, ‘persons addicted’ and the reference to controlled medicines as ‘dangerous/intoxicating drugs’ are considered to be stigmatising, and are frequently used in the reviewed Bulgarian legislation.

Textbox 27 Selection of recommendations specific to Bulgaria: legal and regulatory

- Ensure that competent medical practitioners are authorised to prescribe controlled medicines, without further license requirements that only apply to the prescribing of controlled medicines;
- Reconsider the prescription validity of 7 days that applies to prescriptions for medicines containing controlled substances;
- Remove restrictions that apply to the amount to be prescribed, in particular if these restrictions do not apply to other non-controlled medicinal products;
- Decrease the administrative burden for prescribing and dispensing controlled medicines;
- Remove the requirement for pharmacies to obtain a special license and the geographical restriction that applies to the dispensing of controlled medicines issued by physicians of other regions;
- Ensure that all patients are able to receive treatment for dependence with controlled medicines when needed within a reasonable time;
- Provide clear language in legislation and avoid language that stigmatises the medical use of opioids or refers to patients with dependence in a disrespectful way.

9.3. Identified policy barriers⁴¹

For Bulgaria, the main challenges concerning access to opioids were identified in governmental support including financial/economic aspects, issues relating to formularies, education and training and social attitudes.

Although the availability of opioids in Bulgaria is described as ‘good’ as both oral morphine and fentanyl are currently available in the country, the affordability is very limited as this medication is very expensive and the cost is not always covered by government funding. An enormous sum of money is being blocked; as a result opioid treatment cannot be adequately reimbursed. Enlarging the list of opioids financed or reimbursed by the National Health Care Cash could be one possible way to overcome this barrier. It is deemed necessary, that the

⁴¹ This information was retrieved from a report on the ATOME six-country workshop (29th September – 1st October 2011), as well as the action plan and the strategy planning work sheet submitted by the national counterparts. To follow-up on these outcomes, the ATOME work plan intended implementation of a national ATOME conference, as well as continuing exchange with the national country team. This would have allowed for providing more accurate information, identifying any changes or improvements in relation to policy barriers from 2011 to date, and ensuring that the recommendations made in this final report are accurate and up-to-date. However, after the initial workshops, no further contact has been possible with the national counterparts and for this reason, the final ATOME national conference could not be organized in Bulgaria.

European Commission formulates concrete suggestions to put pressure upon the government and professional organizations, trade unions and patient organizations to achieve this.

Palliative care appears to be widely discussed in Bulgaria due to the huge impact it appears to have on society. However, the Ministry of Finance shows little interest in providing financial support for palliative care in the country. In addition, no good network of palliative care facilities is established and this poses a 'very serious problem' for the country. Although healthcare in Bulgaria is organised in 'clinical pathways', palliative care is not included in these pathways. There are some training and education initiatives in palliative medicine within other medical specialties; for example, in neurology and anaesthesiology.

Rehabilitation programmes for opioid dependence are not well developed; geographical coverage of treatment is described as 'not good' and there is a lack of financing for harm reduction initiatives. There are rehabilitation programmes currently operating in the country (204 treatment slots, half of them free of charge). Treatment places are also available for 3,100 patients but only 1/3 of these are free of charge. In addition to treatment in specialized centres, patients are also treated for dependence in psychiatry.

In Bulgaria it is rather uncommon for a doctor to refer either a patient or a family member to someone who can provide psychological support. This poses serious challenges to treatment of pain with opioids in Bulgaria considering that major psycho-somatic problems (fear of pain, dependence and death) have been identified being directly associated with patients being unaware of their diagnosis and prognosis.

Textbox 28 Selection of recommendations specific to Bulgaria: policy


- Enlarge the list of opioids financed or reimbursed by the National Health Care Cash;
- Increase the funding allocated to palliative care and harm reduction initiatives;
- Include palliative care in the 'pathways' based on which healthcare is organised;
- Provide incentives to increase interest in palliative care;
- Establish a network of palliative care facilities;
- Ensure more free-of-charge treatment places on rehabilitation programmes;
- Promote education and training in opioid treatment;
- Encourage and support patients and families to seek for psychological help to address major psycho-somatic problems identified in relation to opioid treatment and end of life care.

9.4. Conclusion


Potential barriers to accessing opioids in Bulgaria have been identified in the areas of legislation and policy. The ATOME project recommends that the Bulgarian legislation should be revised to provide a legal framework that focuses on optimizing healthcare outcomes while preventing diversion and misuse. The project also recommends that prescribing and dispensing should be facilitated (license requirements for practitioners, limited prescription validity and the maximum amount of controlled medicines to be prescribed should be removed as well as the administrative requirements regarding the receipt of special prescription forms and the limitation of regional dispensing). The restrictions on the authorization to provide methadone maintenance treatment should be reconsidered and access to controlled medicines should be ensured for all patients who require it in a reasonable timeframe (also patients under 18 years). Clear language and non-stigmatizing terms in the Bulgarian legislation should be guaranteed. Considering the identified policy barriers in Bulgaria the ATOME project advises to enlarge the list of medicines that are reimbursed and to enhance financial support and integrate palliative care provision into existing clinical pathways. Palliative care networks should be established to negotiate contracts with insurance companies, to provide incentives for palliative care provision and to increase healthcare professionals' engagement in palliative care. More free-of-charge treatment should be provided in rehabilitation programmes for patients with opioid dependence syndrome. Basic education and training opportunities in the use of opioid analgesics should be included in the curricula for healthcare professionals. Furthermore, psychological support for patients receiving opioid treatment and their families should be established in the Bulgarian healthcare system.

Some of the recommendations made in this report may have already been implemented, but others remain to be barriers to access to opioids and a balance of preventing misuse and ensuring availability still needs to be achieved.

Table 10 Timescale of ATOME activities and events in Bulgaria



Month Year	ATOME work activities	ATOME events	Activities Bulgaria country team	Important events in Bulgaria relevant for access to opioid medication	ATOME results/ achievements
Dec 2009		Start of the project			
Dec 2010	Identification of country team members and national counterparts				List of country team members and national counterparts available
Feb 2011		Lawyers' training workshop	Mrs Venda Zidarova and Fani Mihaylova attended the workshop		
Mar 2011	Quick scan of legislation started				
May 2011 - June 2011			Fani Mihaylova and Venda Zidarova sent legal documents on behalf of the ATOME Bulgaria country team		
July 2011	Analysis of the completed self-assessment checklists				
Aug 2011	Preparation of the six-country workshops		The Bulgarian country team completed the self-assessment checklist		
Sept 2011		First six-country workshop (Bulgaria, Cyprus, Greece, Serbia, Slovenia, Turkey)	The Bulgarian country team attended the workshop and worked on a national strategic action plan		
Nov 2011		Second six-country workshop (Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia, [Ukraine])			National strategic action plan on improving access to opioids in Bulgaria



Month Year	ATOME work activities	ATOME events	Activities Bulgaria country team	Important events in Bulgaria relevant for access to opioid medication	ATOME results/ achievements
Jan 2012					Report on the results of the quick scan of legislation
Nov 2011 – May 2012	Preparation of ATOME national conferences				
July 2012 - Nov 2012	In-depth analysis of national legislation				Draft overview of legal barriers to opioid availability in Bulgaria
Nov 2012	Preparation of legislation review workshop in Utrecht, the Netherlands				
Jan - Feb 2013		Legislation review workshop in Utrecht, the Netherlands	Communication between ATOME team and Bulgarian country team / WHO Country Office in an endeavour to organise the national ATOME conference		Report on legislation review workshop highlighting the important outcomes and topics of discussion
Mar 2013					
May 2013	Draft report on legal barriers in Bulgaria sent to the Bulgarian country team				Draft report on legal barriers in Bulgaria
Feb 2014	Final report on legal barriers in Bulgaria sent to the ATOME Bulgaria country team				Final report on legal barriers in Bulgaria

Access to Opioid Medication in Europe (ATOME) Report and recommendations to the Ministry of Health

10. Country Report - Turkey

10.1. Introduction

Turkey is one of the countries with statistical evidence of inadequate morphine consumption per capita. In 2006, the adequacy of opioid analgesic consumption was only 6% - based on a per capita consumption of 6.76 morphine equivalents (mEq) while 118 mg would have been adequate⁴². Turkey was selected as one of the countries to participate in the ATOME project due to this factor. Four years later, in 2010, the adequacy of opioid analgesic consumption had slightly increased (both in absolute and in relative terms) – but was still only 7%⁴³ (based on a per capita consumption of opioid analgesics of 14.31 morphine equivalents (mEq) while 196.50 mEq in mg per capita would have been adequate). This report presents a summary of the results of the situational analysis that has been undertaken with regard to opioid availability and accessibility in Turkey. The results of the situational analysis are divided in two parts: the first part addresses legal and regulatory issues and the second part focuses on issues relating to policy. Both parts present the main barriers and recommendations for improving access to opioid medication in Turkey.

10.2. Identified legal and regulatory barriers

The results of the ATOME legislation review are presented into nine different categories of potential legal and regulatory barriers, i.e. barriers related to prescribing; dispensing; usage; trade and distribution; manufacturing; affordability; penalties; language; and other. In Turkey, potential legal and regulatory barriers have been identified in eight of these nine categories: all except affordability (see Annex 2). A selection of these potential barriers is highlighted below according to category, and followed by recommendations to remove these barriers. For a more detailed description of the methods and results, see Annex 2.

PRESCRIBING: The prescribing of opioids in Turkey is subject to many administrative and non-administrative requirements. For example, physicians are obliged to use special forms with serial numbers when prescribing opioids. The special forms have to be issued in triplicate and are not available free of charge for physicians; they have to be purchased. Examples of non-administrative requirements are the limitations that apply to the maximum amount of controlled medicine per prescription (predefined maximum dosages). Although some requirements may not be recognised immediately as ‘barriers to access’, they may limit

42 Seya MJ, Gelders SFAM, Achara UA, Milani B, Scholten WK. A First Comparison between the Consumption of and the Need for Opioid Analgesics at Country, Regional and Global Level. *Journal of Pain and Palliative Care Pharmacotherapy*, 2011; 25: 6-18. Accessible at:

<http://apps.who.int/medicinedocs/documents/s17976en/s17976en.pdf>

43 Duthey, B., Scholten, W. Adequacy of Opioid Analgesic Consumption at Country, Global, and Regional Levels in 2010, Its Relationship With Development Level, and Changes Compared With 2006. *Journal of Pain & Symptom Management* 47(2); 2014: 283-97 doi:10.1016/j.jpainsymman.2013.03.015; <http://www.sciencedirect.com/science/article/pii/S0885392413002728>

access to opioids in practice; multiple barriers identified in the same category (e.g. prescribing) can substantially exacerbate the problem. The complex prescribing procedures in combination with the predefined maximum dosages and the fact that prescription forms have to be purchased may for instance result in limited access to opioids for medical purposes.

DISPENSING: In Turkey, a special license is required for pharmacies where controlled medicines are dispensed. When dispensing opioids, pharmacists are required to complete an indicated part of all copies of the prescription form, which increases the administrative burden and may deter pharmacists from dispensing such medicines. If an incorrect prescription form is used (for example the use of a green prescription form instead of a red form to dispense 'narcotic drugs'), the pharmacist is not allowed to dispense the controlled medicine under any circumstances, which can impede access to necessary medicines in the situation of an emergency.

TRADE AND DISTRIBUTION: In Turkey, the authorisation to apply for an export license is limited to pharmacists and laboratory owners. Incomplete applications for a license to import or export controlled medicines must be supplemented within eight days. This restrictive time-scale can delay the availability of opioids if a completely new application is required.

LANGUAGE: The language used in the Turkish legislation is not always clear and may cause confusion, in particular if legitimate use is confused with misuse or illicit use. In addition, the definition used for 'substance misuse' and 'intoxication' may contribute to the stigmatisation of opioids used in medical practice. This also applies to the use of stigmatising terms such as 'addicts' and 'addiction' and to referring to controlled substances as 'toxic substances'.

OTHER: Educational programs for healthcare professionals on controlled substance misuse appear not to be easily accessible; an application is required which will be evaluated by the Ministry and approved if the request is found to be appropriate. In addition, only designated institutions are allowed to provide these educational services. Public institutions and organisations and private legal entities or natural persons are not allowed to provide educational services, unless permission has been granted by the Ministry.

Physicians are required to indicate personal information regarding the employment of the patient on the prescription. Although this information may be required for the reimbursement of these medicines, it potentially violates the privacy of patients and may cause them to be reluctant to initiate or continue treatment with controlled medicines.

Textbox 29 Selection of recommendations specific to Turkey: legal and regulatory

- Remove the limitations that apply to the maximum amount of controlled medicine allowed per prescription;
- Allow the dispensing of opioid medicines in all pharmacies without additional license requirements;
- Decrease the administrative burden for prescribing, dispensing and receiving opioid medicines;
- Ensure that applying for a license to import or export opioid medicines is not unnecessarily complicated;
- Provide clear language in legislation, use correct definitions and avoid language that stigmatises the medical use of opioids or refers to patients with dependence in a disrespectful way;
- Ensure that all healthcare professionals can easily access educational programmes on controlled substances misuse.

10.3. Identified policy barriers

For Turkey, the main challenges concerning access to opioids were identified in financial/economic aspects, issues relating to formularies, education and training and social attitudes.

FINANCIAL/ECONOMIC ASPECTS: Although treatment centres (currently 28 in Turkey) are funded by the government and treatment is provided free of charge, more money needs to be invested on supporting further education and training of physicians, pharmacists, nurses and lawyers, the lack of which is seen to pose barriers to the use of opioids in the country.

FORMULARIES: The lack of access to treatment comprises a major issue in Turkey at the moment. Service provision is administered by the Ministry of Health and some treatment hospitals but, outside these settings, treatment cannot be provided. The Department of Cancer runs a National Cancer Control Program (2009-2015) including breast, colorectal and cervical cancer scanning but pain management is not included. In addition, chronic pain is not recognised as a condition. The lack of regulations for the pharmacists' provision of pharmaceutical care issues and the lack of an appropriate location for a provision of health service to patients exacerbate the problem. There are overly bureaucratic procedures (high levels of paper work and excessive admission criteria) and stringent controls, especially in relation to drug prescription and distribution. There are also severe punitive provisions for errors or problems in the prescription and dispensing of opioids. The prescription period is too restrictive while the use of strong opioids is restricted only to certain conditions such as cancer pain or terminal cancer pain. Therefore it is requested to extend the prescription period from one week to one month. All these restrictions pose barriers to the availability and accessibility of opioids while at the same time do not contribute to the prevention of misuse or diversion.

EDUCATION AND TRAINING: There is some education and training in opioids in Turkey but training in pain management and palliative care is 'virtually non-existent'. An education enhancing the knowledge about opioid medicines and reducing fear of using opioids is necessary for physicians, pharmacists, nurses and lawyers. This needs to be addressed and overcome by good training and awareness rising. Issues of misuse or diversion are also not in-

cluded in the existing education and training programmes. In addition, the correct diagnosis of pain needs to be taught and to this end lectures at medical faculties shall be initiated.

SOCIAL ATTITUDES: A key ethical issue relating to palliative and end-of-life care in Turkey is the fear about the use of opioids ('fear of opioids'). This may result in low usage and potentially increased suffering at the end of life. Morphine is associated with impeding death which deters people from wanting to use opioids. Moreover, opioids are frequently associated with drug dependence and misuse. As a result, some people are reluctant to apply for treatment because they feel stigmatised.

Textbox 30 Selection of recommendations specific to Turkey: policy

- Introduce oral morphine and other immediate-release opioids to the market;
- Reduce bureaucracy in prescribing practices;
- Increase awareness of pain relief and reduce fear of opioids embedded in an understanding of religious and cultural differences;
- Education on appropriate pain assessment and evidence based approaches of pain relief needs to be provided, for example through lectures at Universities;
- Increase awareness about opioid medicines (and that pain can be alleviated) amongst the general public through media initiatives;
- Provide more palliative care services and additional education and training.

10.4. Voices from Turkey ATOME participants

In the summer of 2013, national key contacts and representatives of the national ATOME country teams were asked what had changed regarding access to opioid medicines in their country since the beginning of the project. These are exemplary answers by one representative of the Turkey country team.

Textbox 31 Voices from Turkey ATOME participants

"ATOME's aim is to create awareness about opioids in governments. Currently legislation and laws are still improving. They have started to use correct language, prescriptions and new terminology.

As of 01.07.2012, Turkey has started to implement an e-prescription system. However, the red, green, purple and orange e-prescriptions/prescriptions – will continue to have to be created on paper as well because of controls on the storage of copies in the pharmacies. Then they should be sent to the Provincial Health Directorates. In reality, electronic prescriptions extended the bureaucratic process of prescribing" (Dr Serpil Özsezgin, 13.06.2013).


10.5. Conclusion

Potential barriers to accessing opioids in Turkey have been identified in the areas of legislation and policy. The ATOME project recommends that the Turkish legislation should be revised to provide a legal framework that focuses on optimizing healthcare outcomes while preventing diversion and misuse. The project also recommends that prescribing and dispensing should be facilitated (maximum dosages should be removed and special licenses for pharmacies should be approachable), clear language in legislation should be guaranteed and education on opioid medicines should be available for all healthcare professionals in order to ensure appropriate use of controlled substances – including opioids - and to counteract fear of opioids. Considering the identified policy barriers in Turkey the ATOME project advises to introduce additional opioids (especially immediate-release opioids) in the country, reduce bureaucracy in the prescription procedure and increase the awareness of the importance of pain therapy in society.


Throughout the ATOME project, encouraging developments have been observed in terms of improved access to opioids in Turkey. Some of the recommendations made in this report may have already been implemented but others remain to be a barrier to access to opioids and a balance of preventing misuse and ensuring availability still needs to be achieved.

The continuing efforts of the country team to implement the specific goals elaborated in the early stages of the ATOME project can be assumed to have facilitated improvements at different strategic levels.

Table 11 Timescale of ATOME activities and events in Turkey



Month Year	ATOME work activities	ATOME events	Activities Turkey country team	Important events in Turkey relevant for access to opioid medication	ATOME results/ achievements
Dec 2009		Start of the project			
Dec 2010	Identification of country team members and national counterparts				List of country team members and national counterparts available
Feb 2011		Lawyers' training workshop	Dr Öznur Sevim Evranosoğlu attended the workshop		
Mar 2011	Quick scan of legislation started				
April 2011			Dr Öznur Sevim Evranosoğlu sent legal documents on behalf of the ATOME Turkey country team		
May 2011			The Turkey country team completed the self-assessment checklist		
June 2011					
July 2011	Analysis of the completed self-assessment checklists				
Aug 2011	Preparation of the six-country workshops				



Month Year	ATOME work activities	ATOME events	Activities Turkey country team	Important events in Turkey relevant for access to opioid medication	ATOME results/ achievements
Sept 2011		First six-country workshop (Bulgaria, Cyprus, Greece, Serbia, Slovenia, Turkey)	The Turkey country team attended the workshop and worked on a national strategic action plan		National strategic action plan on improving access to opioids in Turkey
Nov 2011		Second six-country workshop (Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia, [Ukraine])			
Nov 2011 – May 2012	Preparation of ATOME national conference in Turkey		Collaboration between ATOME team and Turkey country team (co-ordinated by Dr Murat Gultekin)		
May 2012	National follow-up conference implemented in Ankara, Turkey		Leading role of Turkey country team and experts at the national conference		
July - Aug 2012	In-depth analysis of national legislation				Draft overview of legal barriers to opioid availability in Turkey
Nov 2012	Preparation of legislation review workshop in Utrecht, the Netherlands				
Jan - Feb 2013		Legislation review workshop in Utrecht, the Netherlands	Demet Aydin sent additional legal documents on behalf of Turkey		Report on legislation review workshop highlighting the important outcomes and topics of discussion
July 2013	Draft report on legal barriers in Turkey sent to the Turkey country team				Draft report on legal barriers in Turkey
Feb 2014					Final report on legal barriers in Turkey sent to the Turkey ATOME country team

Access to Opioid Medication in Europe (ATOME) Report and recommendations to the Ministry of Health

11. Country Report - Greece

11.1. Introduction

Greece is one of the countries with statistical evidence of inadequate morphine consumption per capita. In 2006, the adequacy of opioid analgesic consumption was 54% - based on a per capita consumption of 92.49 morphine equivalents (mEq) while 171 mg would have been adequate for treatment of all pain conditions⁴⁴. Greece was selected as one of the countries to participate in the ATOME project due to this factor. Four years later, in 2010, the adequacy of opioid analgesic consumption had slightly decreased (both in absolute and in relative terms) – it was 46%⁴⁵ (based on a per capita consumption of opioid analgesics of 98.32 morphine equivalents (mEq) while 214.42 mEq in mg per capita would have been adequate). This report presents a summary of the results of the situational analysis that has been undertaken with regard to opioid availability and accessibility in Greece. The results of the situational analysis are divided in two parts: the first part addresses legal and regulatory issues and the second part focuses on issues relating to policy. Both parts present the main barriers and recommendations for improving access to opioid medication in Greece.

11.2. Identified legal and regulatory barriers

The results of the ATOME legislation review have been divided into nine different categories of potential legal and regulatory barriers, i.e. barriers related to prescribing; dispensing; usage; trade and distribution; manufacturing; affordability; penalties; language; and other. In Greece, potential legal and regulatory barriers have been identified in eight of these nine categories: all except trade and distribution (see Annex 2). A selection of these potential barriers is highlighted below according to category, followed by recommendations to remove these barriers. For a more detailed description of the methods and results, see Annex 2.

PRESCRIBING: The prescribing of opioid medicines in Greece is subject to administrative and non-administrative requirements. For example, special forms, available to doctors by their local medical associations upon request, must be used in duplicate to prescribe opioids. The special forms must contain a double red line on the top right side, a serial number and the text 'special narcotic drug prescription' and full details of the patient, including the patient's symptoms and disease. When prescribing opioids, it is prohibited to prescribe an amount that exceeds the daily dose allowed by the Greek pharmacopoeia, while each prescription form should be issued for only a five-day treatment. This results in the need for repeated prescriptions on a weekly basis. Exceptions are made only in specified cases provid-

⁴⁴ Seya MJ, Gelders SFAM, Achara UA, Milani B, Scholten WK. A First Comparison between the Consumption of and the Need for Opioid Analgesics at Country, Regional and Global Level. *Journal of Pain and Palliative Care Pharmacotherapy*, 2011; 25: 6-18. Accessible at: <http://apps.who.int/medicinedocs/documents/s17976en/s17976en.pdf>

⁴⁵ Duthey, B., Scholten, W. Adequacy of Opioid Analgesic Consumption at Country, Global, and Regional Levels in 2010, Its Relationship With Development Level, and Changes Compared With 2006. *Journal of Pain & Symptom Management* 47(2); 2014: 283-97 doi:10.1016/j.jpainsymman.2013.03.015; <http://www.sciencedirect.com/science/article/pii/S0885392413002728>

ed that special permission has been granted. In addition, restrictions apply to the total amount of controlled medicine to be dispensed on a single prescription. In the case of cancer patients, the physician is allowed to prescribe an amount that exceeds the maximum daily dose for a five-day treatment, provided that a permit has been granted by the health department of the local prefectural administration. This permit is only valid for one month. This legal restriction on the daily dosage - especially in combination with a limited treatment period and additional administrative requirements - of controlled medicines can be a potential barrier to access. This is in particular the case if the maximum daily dosage allowed is lower than the dosage advised by evidence based medical treatment guidelines. Individual patient needs may require higher dosages than allowed by Greek legislation, which may result in inadequate treatment with controlled medicines of individual patients.

DISPENSING: Additional requirements for the dispensing of controlled medicines may increase the administrative burden and may cause pharmacists to be reluctant to dispense controlled medicines. According to the Greek legislation, pharmacists are required to use special books for recording the statistics concerning the dispensing of opioid medicines. In addition special prescriptions must be signed by the pharmacist and patient and these forms must be appropriately stamped by the authorities.

USAGE: In Greece, opioid substitution therapy for patients who are held in detention by the police or prosecution authorities is only provided in the places where the rehabilitation program is running. This geographical restriction to the availability of controlled substances can impede access, depending on the geographical spread of the places where the rehabilitation programs are running. The Greek legislation limits the treatment period of patients that have been arrested and need controlled medicines for the treatment of dependence syndrome to twelve days.

PENALTIES: The Greek legislation contains severe punitive sanctions for violation of provisions concerning the prescribing and dispensing of controlled medicines. These severe sanctions, even for unintended violations, may deter healthcare workers from legitimate prescribing and dispensing of controlled substances and may deter patients from using controlled medicines when medically needed. For example, it is forbidden for pharmacists to provide narcotic drugs for daily use in amounts greater than the daily dose allowed by the Greek pharmacopoeia even when a greater dose is prescribed by a physician, unless a special permission has been granted. According to the Greek legislation, pharmacists who provide narcotic drugs in violation of this article shall be punished and two-time offenders shall be prosecuted and punished with a prison term of up to two years. In addition, pharmacists who do not submit the annual statements before the deadline stipulated shall be penalized in accordance with the provisions of the act on pharmacy inspections in force at that time. Moreover, a penalty shall be imposed in accordance with the same provisions, to any pharmacist or pharmacy manager who does not consistently maintain the special book for recording the statistics concerning the dispensing of opioid medicines or does not store medical prescriptions used to dispense narcotics. Punitive provisions should contain exceptions for unintended violations; unintended errors that do not result in diversion of controlled medicines or serious health consequences should not be subject to criminal penalties.

LANGUAGE: In the Greek legislation, the distinction between medical use and misuse or illicit use is not always clear. In addition, the definition used for 'narcotic drugs' can cause fear for the use of opioid medicines in medical practice and may contribute to the stigmatiza-

tion of patients in need of opioids. This also applies to the use of stigmatising terms such as ‘addicts’ and ‘addiction’ in the Greek legislation.

Textbox 32 Selection of recommendations specific to Greece: legal and regulatory

- Remove the limitations that apply to the amount of controlled medicine to be prescribed (the maximum daily dose and the limited duration of treatment per prescription form) and remove the requirement for a permit or special license to prescribe a higher daily dose than provided by the Greek pharmacopoeia;
- Decrease the administrative burden for prescribing, dispensing and receiving opioid medicines;
- Ensure that patients are able to continue their treatment with controlled medicines when they are hospitalized in health facilities or when they are arrested or imprisoned, regardless of whether they need pain treatment, treatment for dependence syndrome or for other diseases;
- Ensure that sanctions for unintended violation of administrative rules are not disproportionate in relation to the risk of misuse and diversion;
- Provide clear language in legislation, use correct definitions and avoid language that stigmatises the medical use of opioids or refers to patients with dependence in a disrespectful way.

11.3. Identified policy barriers

For Greece, the main challenges concerning access to opioids were identified in governmental support, issues relating to formularies, education and training and social attitudes.

GOVERNMENTAL SUPPORT: There is little support from the government to develop harm reduction initiatives, promote opioid use for the treatment of pain and expand palliative care in Greece. This is reinforced by a lack of interest on behalf of politicians in these topics considering that, for the last 30 years, they have kept prioritising other health subjects on their political agenda. The financial crisis has currently placed plans at a standstill; still the Greek government has made a commitment to provide funding for the development of twenty eight new centres to provide opioid substitution therapy to patients with drug dependence problems.

FORMULARIES: Prescribed medicines provided for those with the diagnosis of cancer are free of charge but patients suffering from chronic pain have to pay a low percentage of the medicines’ cost. However, there is a high number of people without access to the healthcare system (e.g. the unemployed) which means that no matter how low the cost of a prescription they may not be able to afford it. Consumption of opioids is very low and the cost for withdrawing and destroying the medicines that are not used is extremely high. Patients often have limited access to opioids due to bureaucratic difficulties while most of the hospitals treating patients with life threatening diseases are insufficiently staffed.

EDUCATION AND TRAINING: Knowledge deficits in all those involved comprise the major barrier to the use of opioids in Greece. Limited knowledge and reluctance regarding the use of opioids exist amongst physicians due to the lack of adequate education and training initiatives. This often results in the under-treatment of patients. Currently, education initiatives in Greece are at a low level and provided in a fragmented fashion. There is also no standard training in opioid analgesia in the basic curriculum of physicians and other healthcare professionals as well as no comprehensive continuing education and training in this area. Many

physicians are afraid to prescribe opioids due to a fear of ‘criminal involvement’, in the event that the patient dies. Moreover, in most cases very low doses of strong opioids are being used which are much lower than would be necessary to relieve the pain experienced by the patient. Training is therefore essential to overcome fear of opioids, understand the medical use of opioids and learn how to handle opioid use, dependence and tolerance. Besides opioid management, it is important that palliative care is also included in the basic training of physicians and other healthcare professionals. Promising initiatives have been the availability of a Greek translation of WHO guidelines regarding pain relief in adults as well as the recent translation of WHO guidelines on persisting pain in children⁴⁶ and the WHO Policy Guidelines on *Ensuring balance in national policies on controlled substances*.⁴⁷

SOCIAL ATTITUDES: Fear of opioids comprises a key ethical issue relating to the use of opioids in Greece for patients, families, healthcare professionals and the general public. There are many misunderstandings, fears and negative cultural stereotypes associated with the use and misuse of opioids (e.g. the stigmatised status of dependence). No family would ever like to have a treatment centre in their neighbourhood even if that same family had a member with a drug dependence problem. Furthermore, suffering is often regarded as a normal state of affairs and, as a result, pain does not get the attention and the respect it deserves. Patients think that taking opioids for pain relief means they are going to die soon. Many physicians are also sceptical about the prescribing of opioids for pain management leading to a significant amount of cases being under-treated. Opioid use and dependence are strongly correlated in the public opinion. The need to raise public awareness, reinforce civil society dialogue and readdress public attitudes towards opioids remains a critical issue in Greece.

⁴⁶ The Greek translation is available at:
http://apps.who.int/iris/bitstream/10665/44540/29/9789608630772_Guidelines_gre.pdf?ua=1

⁴⁷ The Greek translation is available at:
http://www.who.int/medicines/areas/quality_safety/GLs_Ens_Balance_NOCP_sanend_GRK.pdf

Textbox 33 Selection of recommendations specific to Greece: policy

- Raise awareness of government officials regarding the importance of pain management;
- Educate healthcare and other professionals about the importance of opioid use in pain management and the ways to overcome fear of opioids;
- Establish palliative care as a specialty or at least as a specialisation for doctors and nurses;
- Include palliative care and opioid management in basic university curricula for all healthcare professionals;
- Expand training programs in palliative care and opioid management for healthcare professionals and medical students;
- Establish mandatory courses for continued education of all healthcare professionals involved with patients suffering from life threatening diseases;
- Establish academic centres to promote research and education in palliative care;
- Promote interconnection and collaboration of palliative care centres;
- Develop and implement guidelines for opioid maintenance therapy (translate theory into practice);
- Introduce more measures for the prevention of harm reduction;
- Educate the public about the usefulness of opioids for the treatment of pain;
- Disseminate brochures to overcome the ‘misunderstandings and cultural attitudes’ surrounding opioid use.

11.4. Voices from Greece ATOME participants

In the summer of 2013, national key contacts and representatives of the national ATOME country teams were asked what had changed regarding access to opioid medicines in their country since the beginning of the project. These are exemplary answers by one representative of the Greek country team.

Textbox 34 Voices from Greece ATOME participants

“During the workshop at the national follow-up conference in November 2012, participants agreed on the necessary changes that needed to be submitted in the form of a memorandum to the Ministry of Justice, in relation to the new ‘Narcotics Law’. A number of appropriate suggestions were taken into consideration and included in the law. The New Law was passed on 20 March 2013 (Law number 4139/ 2013).

In summary:

- 1. Terminology: Previously the law was named ‘Code of Narcotics’. Our suggestion was ‘Law on controlled substances’. Even though the term narcotic is still widely used in the law to describe controlled substances, the law is now characterized as ‘Law about substances causing addiction’.*
- 2. Before the law referred only to ‘drug addicts’. Now the law mentions also patients with chronic illnesses, in its 1st article, as potential users of these substances.*
- 3. Most of the issues regarding controlled substances are being decided in the Committee of Narcotics, in the Ministry of Health. Previously, the Committee had 7 members, now it has 13, one of them being a doctor specialized in palliative medicine. This Committee is now also responsible for the availability of controlled substances throughout the country.*
- 4. Regarding the dose and duration of treatment, previously the Committee of Narcotics was responsible to approve the doctor’s application for overcoming the maximum dose. An addition in the new law states that pharmacists can execute a doctors’ prescription with a higher than the approved dose, on emergency cases.*

There were more changes in the new law regarding substitution therapy and diversion initiated by the Ministry of Justice (for example de-penalization of cannabis) or the Substitution Therapy Program Teams (OKANA, etc.)” (Dr Aiki Tserkezoglou, Director of Palliative Care Team Gallilee, 12.06.2013).


11.5. Conclusion

Potential barriers to accessing opioids in Greece have been identified in the areas of legislation and policy. The ATOME project recommends that the Greek legislation should be revised to provide a legal framework that focuses on optimizing healthcare outcomes while preventing diversion and misuse. The project also recommends that prescribing and dispensing should be facilitated (maximum daily dosage per prescription and the maximum treatment period per prescription should be removed as well as the requirement for a permit, approved by the authorities, to prescribe a higher daily dose), the treatment continuation of specific patient groups (hospitalized, arrested or imprisoned) should be ensured, sanctions for unintended violation of administrative rules should be revised and clear language and correct definitions in legislation should be guaranteed to avoid stigmatisation. Considering the identified policy barriers in Greece, the ATOME project recommends that there is an increase in the awareness of governmental officials regarding the importance of pain management, to extend governmental support to develop harm reduction initiatives and to ensure better access to treatment for patients suffering from chronic pain and for unemployed people. Furthermore, education and training for healthcare professionals concerning medical use of opioids are necessary to avoid under-treatment and the reinforcement of the civil society dialogue should be ensured to handle the critical public attitudes towards opioids.

Throughout the ATOME project, encouraging developments have been observed in terms of improved access to opioids in Greece. Some of the recommendations made in this report may have already been implemented, but others remain to be a barrier to access to opioids and a balance of preventing misuse and ensuring availability still needs to be achieved.

The continuing efforts of the country team to implement the specific goals elaborated in the early stages of the ATOME project are expected to have facilitated improvements at different strategic levels.


Table 12 Timescale of ATOME activities and events in Greece



Month Year	ATOME work activities	ATOME events	Activities Greek country team	Important events in Greece relevant for access to opioid medication	ATOME results/ achievements
Dec 2009		Start of the project			
Dec 2010	Identification of country team members and national counterparts				List of country team members and national counterparts available
Feb 2011		Lawyers' training workshop	Dr Spyros Karanikolas attended the workshop		
Mar 2011	Quick scan of legislation started				
April 2011			Dr Spyros Karanikolas sent legal documents on behalf of the ATOME Greece country team		
July 2011	Analysis of the completed self-assessment checklists				
Aug 2011	Preparation of the six-country workshops				
Sept 2011		First six-country workshop (Bulgaria, Cyprus, Greece, Serbia, Slovenia, Turkey)	The Greek country team completed the self-assessment checklist The Greek country team attended the workshop and worked on a national strategic action plan		National strategic action plan on improving access to opioids in Greece

Timescale of ATOME activities and events in Greece

Month Year	ATOME work activities	ATOME events	Activities Greek country team	Important events in Greece relevant for access to opioid medication	ATOME results/ achievements
Oct 2011			Dr Spyros Karanikolas sent legal documents on behalf of the ATOME Greece country team		Preliminary results of quick scan of Greek legislation sent to Dr Spyros Karanikolas
Nov 2011		Second six-country workshop (Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia, [Ukraine])			
Nov 2011 – May 2012	Preparation of ATOME national conference in Greece		Collaboration between ATOME team and Greek country team (co-ordinated by Dr Aliko Tserkezoglou)		
May 2012					
June 2012			Dr Spyros Karanikolas sent confirmation that legislation is still up to date		
July - Aug 2012	In-depth analysis of national legislation				Draft overview of legal barriers to opioid availability in Greece
Nov 2012	National follow-up conference implemented in Athens, Greece and Preparation of legislation review workshop in Utrecht, the Netherlands Preparation of legislation review workshop in Utrecht, the Netherlands		Leading role of Greek country team and experts at the national conference		
Jan 2013				'ATOME legislation review – country report' feedback document submitted by the Greek group	



Month Year	ATOME work activities	ATOME events	Activities Greek country team	Important events in Greece relevant for access to opioid medication	ATOME results/ achievements
Feb 2013		Legislation review workshop in Utrecht, the Netherlands		Letter to Minister of Justice and the Members of the relevant Committee highlighting the suggestions regarding law revision and the outcomes of the national conference	Report on legislation review workshop highlighting the important outcomes and topics of discussion
July 2013	Draft report on legal barriers in Greece sent to the Greek country team			Dr Tserkezoglou presented to the Greek Parliament's Department responsible for Narcotics Law revision, the outcomes of the national conference	Draft report on legal barriers in Greece
Sept 2013				ATOME conference report/ executive summary for Greece	
Feb 2014			Greece ATOME country team sent feedback that was prepared January 2013 to draft report		Final report on legal barriers in Greece sent to the Greek country team

Access to Opioid Medication in Europe (ATOME) Report and recommendations to the Ministry of Health

12. Country Report - Cyprus

12.1. Introduction

Cyprus is one of the countries with statistical evidence of inadequate morphine consumption per capita. In 2006, the adequacy of opioid analgesic consumption was only 12% - based on a per capita consumption of 13.89 morphine equivalents (mEq) while 116 mg would have been adequate⁴⁸. Cyprus was selected as one of the countries to participate in the ATOME project due to its low per capita morphine consumption. Four years later, in 2010, the adequacy of opioid analgesic consumption had even slightly decreased (both in absolute and in relative terms) – it was only 10%⁴⁹ (based on a per capita consumption of opioid analgesics of 13.61 morphine equivalents (mEq) while 138.35 mEq in mg per capita would have been adequate). This report presents a summary of the results of the situational analysis that has been undertaken with regard to opioid availability and accessibility in Cyprus. The results of the situational analysis are divided in two parts: the first part addresses legal and regulatory issues and the second part focuses on issues relating to policy. Both parts present the main barriers and recommendations for improving access to opioid medication in Cyprus.

12.2. Identified legal and regulatory barriers

The results of the ATOME legislation review have been divided into nine different categories of potential legal and regulatory barriers, i.e. barriers related to prescribing; dispensing; usage; trade and distribution; manufacturing; affordability; penalties; language; and other. In Cyprus, potential legal and regulatory barriers have been identified in seven of these nine categories: all except manufacturing and affordability (see Annex 2). A selection of these potential barriers is highlighted below according to category, followed by recommendations to remove these barriers. For a more detailed description of the methods and results, see Annex 2.

PRESCRIBING: The prescribing of opioids in Cyprus is subject to administrative and non-administrative requirements. For example, the total amount of controlled medicine to be prescribed and the validity of medical prescriptions used for prescribing opioid medicines are limited to 13 weeks. Although these limitations do not seem to be very strict, they can be a potential barrier to access for patients who require long term treatment with opioid medicines. In addition, a license is required for medical practitioners to be authorised to prescribe or

⁴⁸ Seya MJ, Gelders SFAM, Achara UA, Milani B, Scholten WK. A First Comparison between the Consumption of and the Need for Opioid Analgesics at Country, Regional and Global Level. *Journal of Pain and Palliative Care Pharmacotherapy*, 2011; 25: 6-18. Accessible at:

<http://apps.who.int/medicinedocs/documents/s17976en/s17976en.pdf>

⁴⁹ Duthey, B., Scholten, W. Adequacy of Opioid Analgesic Consumption at Country, Global, and Regional Levels in 2010, Its Relationship With Development Level, and Changes Compared With 2006. *Journal of Pain & Symptom Management* 47(2); 2014: 283-97 doi:10.1016/j.jpainsymman.2013.03.015; <http://www.sciencedirect.com/science/article/pii/S0885392413002728>

administer methadone for the treatment of patients with dependence. This restriction can be a potential barrier to access, in particular if the total number of medical practitioners available to prescribe controlled medicines for patients with dependence syndrome is too low. Other administrative requirements include the obligation for medical practitioners treating persons “whom he considers or has reasonable grounds to consider to be addicted to any controlled drug” to send detailed patient information to a medical officer designated by the Minister of Health within seven days from the first visit of the patient. These requirements may increase the administrative burden of medical practitioners and may deter patients from visiting a medical practitioner due to privacy reasons.

USAGE: In Cyprus, it is prohibited to possess or use utensils that have been used or can be used in connection with the smoking, taking, or preparation of – amongst other – cannabis. An exception has been made for the procurement of syringes and needles, provided that they are contained in their original packaging. The prohibition regarding the possession or usage of utensils in Cyprus may contribute to the stigmatisation of legitimate use of controlled medicines.

PENALTIES: The Cypriot legislation contains punitive provisions that can be considered disproportionate and may contribute to the stigma of the use of controlled medicines. For example, printed photographs of controlled drugs are considered to promote the illegal use of controlled drugs. This implicates that it is an offence to for example show pictures of controlled drugs in educational text books.

LANGUAGE: The Cypriot legislation is written in Old Greek, which makes it difficult to read and understand these legal texts. In addition, many definitions are missing in the Cypriot legislation and stigmatising language is used. Unclear and stigmatising language may deter healthcare providers from prescribing or dispensing opioid medicines and may deter patients from using medically needed controlled medicines, in particular if violation of these unclear provisions may lead to (severe) sanctions for healthcare providers or patients.

Textbox 35 Selection of recommendations specific to Cyprus: legal and regulatory

- Reconsider limitations that apply to the maximum amount of opioid medicine allowed per prescription and the validity of a medical prescription for opioid medicines if they are stricter than the limitations that apply to non-controlled medicines;
- Decrease the administrative burden and remove the license requirement for prescribing opioid medicines used for the treatment of dependence;
- Remove provisions regarding the possession of utensils that contribute to the stigmatisation of legitimate opioid use while having no or limited impact on the prevention of misuse and diversion;
- Revise punitive provisions that are considered to be disproportional and ensure that language used in punitive sanctions does not cause fear for the use of opioid medicines in medical practice;
- Ensure clear language in legislation by rewriting the Old Greek language in all Cypriot legal documents and by providing clear and consistent definitions of terms used in legal documents;
- Avoid language that stigmatises the medical use of opioids or refers to patients with dependence in a disrespectful way.

12.3. Identified policy barriers

For Cyprus, the main challenges concerning access to opioids were identified in financial/economic aspects, issues relating to formularies, education and training and social attitudes.

FINANCIAL/ ECONOMIC ASPECTS: There are no governmental organisations currently supporting palliative care in Cyprus which means that palliative care provision needs to rely mostly on charity funds. The Ministry of Health only provides a 'very small amount funding'. Without governmental funding it is practically not possible to develop effective standards or policies, which leads to lack or ineffective quality control over the services provided. Governmental support has been requested to enable medical staff to participate in more education and training initiatives. An international pharmaceutical company, a branch of which currently operates in Cyprus, has offered sponsoring the development of a leaflet to inform patients and healthcare professionals on the use of opioids, including on unjustified fears for opioid medicines. However, funding for reliable information material independent from commercial sponsoring would be clearly preferable in order to provide unbiased information to patients and professionals. Unfortunately, the economic crisis the country is currently experiencing has put everything at a standstill.

FORMULARIES: Controlled substances are available only in 40 private pharmacies which only stock oxycodone for which patients have to pay. The only oral immediate release opioid available free in government pharmacies (e.g. for breakthrough pain) is morphine but there is no provision for patients with a morphine allergy. In addition, there is no high dose of immediate-release morphine available in Cyprus. There is also a major difficulty in prescribing opioids for non-cancer patients. There is suboptimal communication between the government and healthcare professionals. Availability in rural centres is more problematic since there are normally only general practitioners (GPs) who are not specialised in treatment with opioids.

EDUCATION AND TRAINING: Although there is expertise in palliative care available in Cyprus, there is 'very little' education and training in relation to pain control. This needs to be focused on both an undergraduate and postgraduate level and be based on a multi-level approach and not viewed as a 'luxury' in relation to palliative medicine. Physicians and nurses are often trained overseas due to the lack of courses in the country. Currently healthcare professionals wait for the National Cancer Control Strategy to be implemented in order to support education and multi-professional teams (including physicians, nurses, social workers and psychologists). Training in harm reduction for healthcare providers needs to be developed.

SOCIAL ATTITUDES: Fear of opioids (unjustified and exaggerated fear for opioid medicines) and ignorance comprise key ethical issues relating to opioid use and palliative care in Cyprus for both patients and healthcare professionals. Pain does not get the attention and the respect it deserves. Patients are not trained in order to be able to assess their own pain (both physical and spiritual). There are also sceptical attitudes towards pain assessment amongst many physicians. Statements such as 'you have already got your medication so you should not have pain' indicate the problematic nature of such attitudes. In addition, no control seems to exist over the advice and information that is provided to patients and families about the use of opioids for pain treatment and palliative care. The need to reinforce civil society dialogue and readdress public and healthcare providers attitude towards opioids remains a critical issue in Cyprus.

Textbox 36 Selection of recommendations specific to Cyprus: policy

- Develop national treatment guidelines for opioid use in pain management;
- Develop systems of policy and organisation of pain management (e.g. pain guidelines, use of protocols) for both cancer and non-cancer patients;
- Integrate an inter-disciplinary approach to pain management;
- Encourage pharmaceutical companies to register and place new opioids on the market;
- Improve communication between government, healthcare professionals, users of the healthcare system and pharmaceutical companies;
- Increase the number and scope of out-of-hours outlets (e.g. pharmacies, clinics) to ensure availability of emergency supplies of opioids;
- Invest on education and training initiatives;
- Increase education and training relating to opioid use amongst healthcare professionals;
- Reinforce civil society dialogue and readdress public attitude towards opioids;
- Generate two separate fear of opioids leaflets one to be distributed to patients and the other to health professionals;
- Train patients to be able to assess their own pain.

12.4. Voices from Cyprus ATOME participants

In the summer of 2013 ATOME participants were asked what had changed regarding access to opioid medicines in their country since the beginning of the project. These are the answers of three participants from Cyprus.

Textbox 37 Voices from Cyprus ATOME participants

“The country team of the ATOME Project made some recommendations on the Cyprus' legislation, which were discussed with the involved partners, but no actual changes in legislation have been made. The legislation is under study and hopefully the given recommendations will be taken under serious consideration for future revision” (Nasia Fotsiou, Cyprus Antidrug Council 06.06.2013).

“ATOME suggestions have been presented to the Antinarcotics Council¹. As soon as the recommendations have been considered by the Legal Services a project of adjusting the legislation and issuing guidelines for healthcare professionals will be undertaken. Unfortunately the current economic crisis in Cyprus has shifted the focus of the political leaders so the review will not be made very soon” (Ioannis Kkolos, Pharmacist Pharmaceutical Services, Ministry of Health, 06. 06.2013).

“At the first ATOME project meeting we learned that methadone could be prescribed by doctors other than psychiatrists. We now prescribe methadone with strict records kept for the Ministry of Health. The use of methadone shows very good results in patients whose pain was otherwise not well controlled and who suffered from severe side effects.

Recently some networking of different groups happened. For example, through organising the ATOME project nurses working at the MoH and universities have included pain management as a core subject and palliative care as an extra (elective) option - in nursing education” (Barbara Pitsilides, 06.06.2013).

¹The Antinarcotics Council is the formal body for the determination of the state's policy on narcotics and psychotropics.

12.5. Conclusion


Potential barriers to accessing opioids in Cyprus have been identified in the areas of legislation and policy. The ATOME project recommends that the Cypriot legislation should be revised to provide a legal framework that focuses on optimizing healthcare outcomes while preventing diversion and misuse. The project also recommends that prescribing should be facilitated (maximum treatment period and validity of a prescription should be reconsidered if they are stricter than the limitations that apply to non-controlled medicines and special licenses for prescribing opioid medicines for treatment of patients with dependence syndrome should be reconsidered). Clear language in legislation should be guaranteed by rewriting legal documents using modern Greek language. To avoid stigmatisation, language used in punitive sanctions should be revised as well as provisions regarding the possession of specific utensils. Considering the identified policy barriers in Cyprus the ATOME project advises to extend governmental funding to ensure education and training in the country and the development of effective quality standards. Furthermore, additional opioids (especially immediate-release opioids and medication for non-cancer patients), better availability in rural areas, introduce patients' training with regard to pain assessment and increase the awareness of the importance of pain therapy in society are important changes which are needed in Cyprus.

Throughout the ATOME project, encouraging developments have been observed in terms of improved access to opioids in Cyprus. Some of the recommendations made in this report may have already been implemented, but others remain to be a barrier to access to opioids and a balance of preventing misuse and ensuring availability still needs to be achieved.

The continuing efforts of the country team to implement the specific goals elaborated in the early stages of the ATOME project can be assumed to have facilitated improvements at different strategic levels.

Table 13 Timescale of ATOME activities and events in Cyprus

Timescale of ATOME activities and events in Cyprus	Month Year	ATOME work activities	ATOME events	Activities Cyprus country team	Important events in Cyprus relevant for access to opioid medication	ATOME results/ achievements
	Dec 2009		Start of the project			
	Dec 2010	Identification of country team members and national counterparts				List of country team members and national counterparts available
	Feb 2011		Lawyers' training workshop	Mr Ioannis Kkolos attended the workshop		
	Mar 2011	Quick scan of legislation started		Mr Ioannis Kkolos sent legal documents on behalf of the ATOME Cyprus country team		
	May 2011			The Cyprus country team completed the self-assessment checklist		
	June 2011					
	July 2011	Analysis of the completed self-assessment checklists				
	Aug 2011	Preparation of the six-country workshops				
	Sept 2011		First six-country workshop (Bulgaria, Cyprus, Greece, Serbia, Slovenia, Turkey)	The Cyprus country team attended the workshop and worked on a national strategic action plan		National strategic action plan on improving access to opioids in Cyprus
	Nov 2011		Second six-country workshop (Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia, [Ukraine])			



Month Year	ATOME work activities	ATOME events	Activities Cyprus country team	Important events in Cyprus relevant for access to opioid medication	ATOME results/ achievements
Nov 2011 – May 2012	Preparation of ATOME national conference in Cyprus		Collaboration between ATOME team and Cyprus country team (co-ordinated by Mr Ioannis Kkolos)		
May 2012	National follow-up conference implemented in Nicosia, Cyprus		Leading role of Cyprus country team and experts at the national conference		
July - Aug 2012	In-depth analysis of national legislation				Draft overview of legal barriers to opioid availability in Cyprus
Oct 2012			Mr Ioannis Kkolos sent confirmation that legislation is still up to date		
Nov 2012	Preparation of legislation review workshop in Utrecht, the Netherlands				
Jan - Feb 2013	Draft report on legal barriers in Cyprus sent to the Cyprus country team	Legislation review workshop in Utrecht, the Netherlands	Mr Ioannis Kkolos sent feedback on the draft report on legal barriers		Draft report on legal barriers in Cyprus Report on legislation review workshop highlighting the important outcomes and topics of discussion
Feb 2014	Final report on legal barriers in Cyprus sent to the Cyprus country team				

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