




European Association for Palliative Care
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Non Governamental Organisation (NGO) recognised by the Council of Europe
Association Européenne pour les Soins Palliatifs
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Form for EAPC web platform about EU supported projects

Project Title:	Access To Opioid Medication in Europe		
Project Acronym:	ATOME	Logo: 	YES
Funding programme: (e.g 7 th framework...)	Seventh Framework Programme		
Funding programme web page:	http://cordis.europa.eu/fp7/home_en.html		
Project type:	Collaborative Project (Small of medium-scale focused research projects)		
Project number:	222994		
Coordinator:	RWTH Aachen University, Germany (Prof. Dr. Lukas Radbruch)		
Partner countries:	Switzerland, Lithuania, Romania, United Kingdom, The Netherlands, Italy		
Project web-site:	www.atome-project.eu		
Keywords:	Better use of medicines; opioid medication; access to pain medication; drug availability; harm reduction		
Summary of the project:	<p>Medicines derived from opium are very valuable in the medicine practice and therefore regarded as essential medicines. However, they are generally not readily available for patients who are in need of them for medical reasons. It is estimated that over 80% of the world's population is inadequately treated, because opioid (pain relieving) medicines have been categorized as "controlled substances", due to concerns about their possible abuse. These medicines are therefore subject to strong international control, and rendered accessible. Severe under-treatment of pain is reported in more than 150 countries. In 15 countries of the EU-25, medical consumption of opioids (and other medications that are controlled under these conventions) is close to non-existent, consequently a large number of patients are not treated appropriately for moderate to severe pain. The overall goal of this project is 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 and to elaborate and disseminate tailor-made recommendations to each country for improving accessibility, availability and affordability of controlled medicines, and disseminate these to governments, health-care professionals, other key decision-making bodies as well as to the general public. The outcome of the research will serve to underpin</p>		



EAPC Head Office: Istituto Nazionale dei Tumori, Via Venezian 1, 20133 Milano, ITALIA
EAPC Sede: Tel: +39-02-23903390 Fax: +39-02-23903393

Fiscal Code
Codice Fiscale
 97100170154



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	informed policy decisions on health systems and more effective and efficient evidence-based strategies for health therapies (pain management) in 12 European countries, thereby contributing to the realisation of the activity area that frames the specific call to which this project responds, optimising the delivery of health care to European citizens and the overarching EU values of "universality, access to good health care, equity and solidarity, aiming to make provision that is patient-centered and responsive to individual need".
Aims (research questions) :	<p>Specific objective 1: To undertake a national situational analysis in 12 European countries with regard to access to controlled medicines, including their availability, rational use, and causes for underuse; and to make recommendations to their national governments for improvements.</p> <p>Specific objective 2: To undertake an external review of relevant national legislation in 12 European countries and recommend, in compliance with the international drug conventions, appropriate amendments to governments in order to improve access for legitimate and rational use of controlled medicines.</p> <p>Specific objective 3: To elaborate and introduce a research and monitoring tool for tracking and comparing the extent of per capita opioid availability in countries, regions and continents.</p>
Expected Results:	Elaboration and dissemination of tailor-made recommendations to each of the 12 target countries for improving the accessibility, availability and affordability of controlled medicines, and dissemination of these recommendations to governments, health-care professionals, other key decision-making bodies as well as to the general public.
Date of application:	18.9.2007
Date of approval:	14.3.2008
Starting date:	01.12.2009
Duration (in months):	60
Amount of contribution:	The total budget of the ATOME project is €2 801 930. The core resources needed for its implementation will through this proposal be sought from the European Commission (total requested is €2 449 801).
Methods:	Revision of WHO Policy Guidelines (two round Delphi survey); identification of national participants for workshops and national counterparts for legislation review; two six-countries workshops in target countries; 12 national follow-up conferences; review training of lawyers and national counterparts; quick scan of national legislations; review of legislation from 9 selected countries and drafting of recommendations; creation of an international Opioid Consumption Database
Deliverables:	1. Revised WHO Guidelines Achieving Balance in National Opioids Control Policy: Guidelines for Assessment (Month 13)





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	<ol style="list-style-type: none"> 2. Report on workshop for six European countries, including national country analyses (country group I) (Month 30) 3. Report on workshop for six European countries, including national country analyses (country group II) (Month 30) 4. Report on 12 national follow-up conferences (Month 60) 5. Legislation review reports with recommendations for 9 selected countries (in English) (Month 40) 6. Report of the delivery of 9 country review reports and recommendations to the Ministers of Health (Month 60) 7. Publicly accessible web-based interactive database International Opioid Consumption Database (Month 13) 8. Initiation of project website presenting information about the project (Month 13) 9. Report from the scientific session on the ATOME Project during the EAPC congress in Lissabon, June 2011 (Month 30) 10. Media package with information about project developments and results (Month 48)
<p>Time lines (milestones):</p>	<p>Milestone 1: WHO Guidelines revised - publication of text (Month 13)</p> <p>Milestone 2: Responsible civil servants in Ministries of Health (MoHs) identified - List available internally (and on request to EC) (Month 13)</p> <p>Milestone 3: Country Team participants identified - List available internally (and on request to EC) (Month 13)</p> <p>Milestone 4: Six-country workshop undertaken (country group I) - Workshop report (Month 20)</p> <p>Milestone 5: Six-country workshop undertaken (country group II) - Workshop report (Month 20)</p> <p>Milestone 6: 12 National follow-up conferences management undertaken - Conference reports (Months 21-55)</p> <p>Milestone 7: ???</p> <p>Milestone 8: Review training undertaken - Training report (Month 19)</p> <p>Milestone 9: Quick scan of legislation performed - country review list (Month 19)</p> <p>Milestone 10: Legislation review undertaken - Text of reports (Month 40)</p> <p>Milestone 11: Legislation review reports presented to a MoH (multiple milestones) - Report on the delivery (Month 60)</p>





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	Milestone 12: International Opioid Consumption Database posted online - Internet availability (Month 13)
Work package leaders (name and affiliation):	<p>WP1: Dr. Willem Scholten (WHO)</p> <p>WP2: Dr. Willem Scholten (WHO)</p> <p>WP3: Asta Minkeviciene (Eurasian Harm Reduction Network, EHRN)</p> <p>WP4: Dr. Daniela Mosoiu (Hospice Casa Sperantei)</p> <p>WP5: Mr. David Prail (Help the Hospices)</p> <p>WP6: Dr. Daniela Mosoiu (Hospice Casa Sperantei)</p> <p>WP7: Dr. Aukje Mantel-Teeuwisse (Utrecht University)</p> <p>WP8: Dr. Aukje Mantel-Teeuwisse (Utrecht University)</p> <p>WP9: Dr. Aukje Mantel-Teeuwisse (Utrecht University)</p> <p>WP10: Prof. Sheila Payne (University of Lancaster)</p> <p>WP11: Prof. Lukas Radbruch (RWTH Aachen University Hospital)</p>
Other partners (name and affiliation):	Advisory board members? (awaiting confirmation)
Work package goals:	<p>WP1: 1) To identify gaps and deficits in the current version of the WHO Guidelines Achieving Balance in National Opioids Control Policy: Guidelines for Assessment that are relevant from an expert point of view. 2) To identify relevant barriers to adequate use of controlled drugs. 3) To identify current public health issues relevant to controlled drug use. 4) To revise the WHO Guidelines Achieving Balance in National Opioids Control Policy: Guidelines for Assessment to include public health arguments and all medicines controlled under the international drug conventions currently on the WHO Model List of Essential Medicines, using an acknowledged consensus procedure (Delphi procedure).</p> <p>WP2: 1. To identify counterparts for the legislation reviewers who are responsible in the Ministry of Health for controlled substance legislation in each target country. 2. To identify participants in each country who will form a Country Team and will participate in one of the workshops (WPs 3 - 4). 3. To describe the professional backgrounds and experience of the country stakeholders included in the country teams, with a focus on the differences between countries.</p> <p>WP3: 1. To undertake a national situational analysis in six European countries with regard to controlled medicines, including their</p>





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availability, rational use and causes for underuse. 2. To make recommendations to the national governments for improvement. 3. To plan how the implementation of these recommendations can be promoted at country level. Intentionally, the countries for this workshop are: Estonia, Hungary, Latvia, Lithuania, Poland and Slovakia ("Country group I").

WP4: 1. To undertake a national situational analysis in six European countries with regard to controlled medicines, including their availability, rational use and causes for underuse. 2. To make recommendations to the national governments for improvement. 3. To plan how the implementation of these recommendations can be promoted at country level. Intentionally, the countries for this workshop are: (Bulgaria, Cyprus, Greece, Turkey, Serbia and Slovenia ("Country group II").

WP5: To organize 12 national follow-up conferences, one in each of the countries at which the proposal is directed at , each with approximately 60 - 100 participants and the following aims:

1. To enable information sharing, knowledge exchange and networking between international, regional and national treatment experts and advocates, and relevant national health-care professional associations, government officials and policy makers, health-care professionals and main educational institutions;
2. To discuss how relevant health-care workers can be trained in adequate pain treatment and in the provision of substitution treatment, including how to incorporate it into the curricula of schools of medicine, schools of pharmacy and nurses schools;
3. To develop and disseminate tailor-made recommendations for the target country for improving the accessibility, availability and affordability of opioid analgesics and substitution treatment, including specific recommendations to governments for improvement of pain management and substitution therapy in the target country;
4. To organize the dissemination of pain management information, the evidence-base for pain management and the workshop recommendations to national health-care professionals and the general public (including pain patients and their families) thus promoting the acceptance of good pain management in the target country; and
5. To organize the dissemination of substitution treatment information, the evidence-base for substitution treatment and the workshop recommendations to national health-care professionals and the general public (including people who use drugs and their families) thus promoting the acceptance of substitution treatment in the target country; and
6. To organize the dissemination of workshop recommendations to national health-care professionals and the general public.
7. To evaluate the level of impact, dissemination and coverage of





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the guidelines in each of the countries.

8. To investigate the setting and overlapping areas of work for pain management and for substitution therapy experts,

9. To describe the commonalities and differences between pain management and substitution therapy in barriers to acceptance and implementation and in perceived priorities for strategic planning.

WP6: 1. To train three lawyers and their 12 national counterparts on how to review national controlled substance legislation from the perspective of balancing availability and prevention of abuse. 2. To familiarize the translations coordinator with the issues. 3. To develop and describe the method for training of lawyers, 4. To evaluate suitability and efficacy of the training (with feedback from the participants), 5. To describe the curriculum for training, 6. To prepare a series of case vignettes for use in future interventions

WP7: 1. To identify which regulations are relevant for control of opioid medicines in each participating country. 2. Translation of legislation into English for reviewing. 3. To select the 9 legislations from the 12 countries that qualify most for a complete legislation review.

WP8: 1. To identify any rules in the legislations under review that limit or impede patients' access, availability and affordability to opioid medicines in cases where a patient qualifies for treatment with these medicines according to the state-of-the-art in medicine. 2. To make recommendations for lifting these barriers in such a way that prevention of drug abuse is warranted. 3. Translation of the nine legislation review reports into the national language of the target country, in order to make the reports accessible for policy makers and to make the recommendations simple to implement. 4. To identify barriers in the legislation that limit or impede patients' access to controlled drugs. 5. To compare barriers in the countries.

WP9: To bring the reports and recommendations under the attention of the Ministers of Health of the countries involved in order to increase the probability that the recommendations will be seriously considered.

WP10: 1. To provide a first international research and monitoring tool for the extent of opioid availability (standardized per capita medical opioid consumption) in EU Member States and the world; allowing for the analysis, monitoring and comparison of worldwide use of controlled medicines between countries, regions and continents. 2. To enable the assessment of the progress and impact of implementation of the ATOME project and the WHO Access to Controlled Medicines Programme, in addition to individual efforts taken at national level to improve opioid availability. 3. To provide a first international research and monitoring tool, for researchers,





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	<p>policy makers and others. 4. To publish an annual access report from the database for each year of the project.</p> <p>WP11: The key objective of this work package is efficient project management and coordination. This includes monitoring of the timelines of the work packages and continued effective and efficient communication, exchange of ideas and suggestions and collaboration between the 10 Project Consortium members during the whole duration of the project. Coordination and communication between partners with vastly different professional background will require considerable effort, as medical, legal and political language has to be integrated and different information and communication styles have to be considered. The Project Management Team will develop tools and mechanisms for regular monitoring and evaluation of progress in the different work packages. Project Management Team members will share information on the technical, managerial and financial situation of the project, and on project successes and constraints. They will archive this with regular communication through meetings, video or teleconference, at least on a bimonthly basis. Project Management Team members will also participate in the workshops and conferences organized in the other work packages. The Project Management Team will also coordinate the publication of reports, scientific papers and other material from the project in close collaboration with the work package leaders.</p>
<p>Dissemination (publications - articles):</p>	<p>The updated WHO Guidelines Achieving Balance in National Opioids Control Policy: Guidelines for Assessment will be published and disseminated worldwide by the WHO in print. The WHO Guidelines will furthermore be forwarded directly by the Project Management Team to relevant government ministries, public health institutes and NGOs. The current version is available in 22 languages (from all over the world) and the revised version will be made available in 11 European languages initially, but WHO will strive for more translations, into French and Spanish and into non-European languages.</p> <p>WP 9 (delivery of Country Reports) is the dissemination of the outcomes of the training of lawyers and national counterparts, whereby a representative of the ATOME Project Consortium will present the Country Reports and recommendations to the Ministers of Health in the targeted 12 European Countries, if not personally, to their representatives.</p> <p>In addition to dissemination of project results to the targeted audience specified in the work packages, the project coordinator (EAPC) will coordinate the publication and dissemination of scientific papers that will be produced by the project, develop a media package with information about the project and disseminate project results to professional societies as relevant.</p>
<p>Dissemination online</p>	<ul style="list-style-type: none"> • ATOME Website



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	<ul style="list-style-type: none"> • WHO and EAPC websites • WHO and EAPC mailing lists and newsletters • The websites and contact networks of other ATOME members, where relevant <p>The updated WHO Guidelines Achieving Balance in National Opioids Control Policy: Guidelines for Assessment will be published and disseminated worldwide on WHO and EAPC's websites, which include a large mailing list to all relevant experts and public health institutions in Europe.</p> <p>The International Opioid Consumption Database will be designed, hosted and maintained by the International Observatory for End of Life Care, and will be available for public use and will as such be an excellent tool for the dissemination of information on the nature, extent and trends in opioid use across EU members states, and beyond (the database is global). The introduction of the database will be widely announced on the websites of WHO, EAPC and other relevant organizations working on these issues in Europe, in the margins of international events mentioned above, and evidently in relevant technical and scientific meetings in Europe.</p>
<p>Dissemination (Conferences)</p>	<p>The 12 national follow-up conferences will convene 60-100 national participants from all relevant public health bodies in the 12 countries targeted by the project. These conferences will serve as excellent dissemination channels for the results and recommendations as analysed in the six-countries workshops by Country Teams. These conferences will by their nature draw a lot of publicity, both in the countries where they will take place, as well as in the European region.</p> <p>Activities under work packages 6-8 will undertake training of lawyers and national counterparts, scan national legislation and review legislation of 9 selected countries and draft recommendations.</p> <p>For efficiency reasons, the Country Reports and recommendations will also be presented in the margin of international events attended by ministers, such as the annual World Health Assembly, the European Council of Ministers, as well as to the 12 targets countries' ambassador to the United Nations in Geneva and to the World Health Organization's Office at the European Union who liaises with technical focal points in the various EC Directorates-Generals in Brussels. Widest targeted dissemination will hereby be ensured.</p>

