



## SCAN OF NATIONAL LEGISLATION

### Results of the ‘quick’ scan of national legislation of twelve European countries (Work Package 7)

Marjolein Vranken (LLB, PharmD), Aukje Mantel-Teeuwisse (PhD, PharmD), Prof. Marie-Hélène Schutjens (PhD, LLM)

Utrecht Institute for Pharmaceutical Sciences, Division of Pharmacoepidemiology & Clinical Pharmacology, Utrecht University, the Netherlands

The research leading to these results has received funding from the European Community's Seventh Framework Programme [FP7/2007-2013] under grant agreement n° 222994 with the overall aim to improve the access to opioid medication in Europe.



**Universiteit Utrecht**



# ATOME scan of national legislation

## Background

The main objective of ATOME is to improve the access to opioid medication in Europe. This overall aim will be implemented through several aims, including a legislation review of nine Eastern European countries to identify barriers to access and make recommendations for improvement. In order to select the nine countries with the most impeding legislation all 12 ATOME target countries (Bulgaria, Cyprus, Estonia, Greece, Hungary, Latvia, Lithuania, Poland, Serbia, Slovakia, Slovenia and Turkey) have been approached for a scan of their legislation. This report presents the methods, results and the conclusions (selection of nine countries that will be further reviewed) of the quick scan of national legislation of the ATOME target countries.

## Methods

A 'quick scan method' to identify legal and regulatory barriers to opioid medication was developed focusing on six different categories of barriers (import/export, manufacture, prescribing, storage, dispensing and registration). Legislation intended or used in regulating opioid substances and opioid medicines (case law excluded) was obtained from key experts in each country. Key experts were selected based on their expertise in the field of pharmaceutical law and health policy in the twelve target-countries. All key experts were trained in identifying and selecting relevant information during a two-day workshop (WP 6). Additionally, a guidance document was created to help identify and select relevant information. Relevant information only available in the national language was translated into English by a professional translation agency (NOVA Language

Services). The legislation was analyzed ('quick scanned') using WHO criteria<sup>1</sup> and overly restrictive provisions were identified. Provisions that contain stigmatizing language and incorrect use of terminology and definitions were also identified. Selected provisions were independently scored by two reviewers into two categories: 1) probable barriers and 2) potential barriers. A barrier was recorded if both reviewers concurred with each other. In addition, the quantity of the obtained legislation (number of documents (partly) reviewed excluding amendments) was scored by one reviewer in order to get insight into the number of identified barriers in relation to the quantity of legislation received (incomplete data may have caused a lower number of identified barriers). The nine countries with the highest total number of barriers have been selected for further review. If a selection solely based on the total number of barriers could not be made, the countries with the highest number of barriers in relation to the quantity of legislation received, following the highest number of different categories where barriers can be identified, were selected.

## Results

Legislation intended or used in regulating opioid substances and opioid medicines was obtained from eleven Eastern European countries (all countries with the exception of Poland; see Table 1).

Table 1: Number of relevant documents (partly) reviewed (excluding amendments)

Country	Number of documents (partly) reviewed	Country	Number of documents (partly) reviewed
Bulgaria	4-10	Lithuania	4-10
Cyprus	1-3	Poland	0
Estonia	4-10	Serbia	1-3
Greece	1-3	Slovakia	1-3
Hungary	4-10	Slovenia	4-10
Latvia	4-10	Turkey	4-10

0	1-3	4-10	> 10
---	-----	------	------

<sup>1</sup> World Health Organization (2011), *WHO Policy Guidelines Ensuring Balance in National Policies on Controlled Substances, Guidance for Availability and Accessibility for Controlled Medicines* (Geneva).

All eleven countries showed legal and regulatory barriers in the area of prescribing opioid medication (most frequently observed barrier; see Table 2). Several (but not all) countries showed barriers in the area of dispensing of opioid medication. No barriers concerning the manufacture of opioid medicines were identified in the reviewed legislation. Identified barriers that can be classified in the category ‘other’, concerned among others the possession, reimbursement or pricing of opioid medicines. Ten countries showed stigmatizing language<sup>2</sup> and incorrect use of definitions in their legislation.<sup>3</sup>

Table 2: identified provisions per category that have been considered to impede access to opioids

	import/ export	manufacture	prescribing	Storage	dispensing	registration	language	other	total
Bulgaria	1-2	0	> 5	1-2	1-2	1-2	1-2	1-2	≥ 25
Cyprus	0	0	1-2	0	0	0	0	1-2	< 15
Estonia	0	0	> 5	1-2	1-2	1-2	0	0	≥20 - 25
Greece	0	0	> 5	0	> 5	1-2	> 5	1-2	≥ 25
Hungary	0	0	> 5	1-2	1-2	1-2	0	0	≥15 - 20
Latvia	0	0	> 5	1-2	0	1-2	1-2	1-2	≥15 - 20
Lithuania	0	0	> 5	1-2	1-2	1-2	1-2	1-2	≥ 25
Poland	0	0	0	0	0	0	0	0	
Serbia	1-2	0	> 5	1-2	1-2	1-2	1-2	1-2	≥ 25
Slovakia	0	0	> 5	1-2	0	1-2	1-2	0	≥15 - 20
Slovenia	0	0	> 5	0	> 5	1-2	0	1-2	≥ 25
Turkey	1-2	0	> 5	1-2	1-2	1-2	1-2	1-2	≥20 - 25

0	1-2	3-5	> 5
---	-----	-----	-----

In total, five countries showed twenty-five or more barriers in their legislation; see Table 2. As the current research has to be considered as a quick scan of impediments for the use of opioid medication and not as a complete analysis of all possible restrictions detailed qualitative aspects of the barriers have not been taken into account at this

<sup>2</sup> In this report we consider the use of terminology such as “addictive drugs” and “dangerous drugs” as stigmatizing which is in line with the WHO Guidelines. The consequence of using such terminology is that it may cause healthcare professionals and patients to be reluctant to prescribe, dispense and use opioid medicines.

<sup>3</sup> In this report we consider the incorrect use of definitions as a barrier if it is considered to impede access to opioid medicines.

## ATOME - scan of national legislation

---

point in time. We still feel it possible to rank the concerned countries on the basis of the number of impediments because our judgment is that this number is representative for the level of impairment. The number of identified barriers was the lowest for Cyprus (<15). Hungary, Latvia and Slovakia showed in total fifteen to twenty barriers in their legislation. Cyprus showed the lowest number of barriers and will therefore not be selected for further review. Latvia, Hungary and Slovakia showed the second lowest number of barriers. Considering the quantity of relevant legislation received (relatively more barriers can be identified in the Slovakian legislation) and the number of categories where barriers were found (highest for Hungary), Latvia is not selected for further review.

This scan of legislation deals with some limitations. Firstly, barriers were identified on the basis of legislation selected by key experts. Incomplete data may have caused incomplete reporting of barriers. By careful selection, training and guidance of the key experts the omission of data has been reduced as much as possible. Secondly, although most of the translations were made by a professional translation agency specialized in the area of health and law, some inconsistencies may have occurred. Thirdly, the assessment of barriers is subject to differences in scoring depending on the reviewer. However, the variation in scoring between the two independent reviewers was minimal. Finally, although barriers can be identified in all eleven countries, additional research is needed to assess the extent of the barriers and their impact on the availability and accessibility of opioid medicines.

---

## Conclusions

All eleven scanned countries showed barriers in multiple categories of legislation. Based on the total number of identified barriers, the quantity of obtained legislation and the number of categories in which barriers were identified the following nine countries have been selected for further review:

- Bulgaria;
- Estonia;
- Greece;
- Hungary;
- Lithuania;
- Serbia;
- Slovakia;
- Slovenia;
- Turkey.

## Acknowledgements

We would like to express our gratitude to the key experts in the ATOME target counties and to the members of the ATOME consortium. Special thanks to the ATOME Project Management Team and John Lisman for their feedback on this report.