

Removing regulatory barriers to opioid availability in Serbia: A step forward

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Overly restrictive drug control policies block opioid availability and patient access to essential pain relief medicines. One health professional from Serbia was awarded an International Pain Policy Fellowship (IPPF) Grant to learn how to evaluate national policy and work with government to remove regulatory barriers. As a part of IPPF, a preliminary evaluation of national drug control laws and regulations was undertaken using WHO Guidelines for Achieving Balance in National Opioids Control Policy.

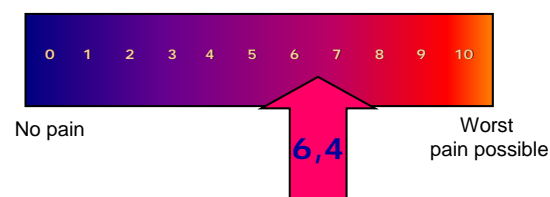


Population:
8,153,000 (2004)

“There is a gap between the need to relieve severe pain and the unavailability of opioids with which to do it.”

(Un)available opioids

Average severity of cancer pain (N=1169)



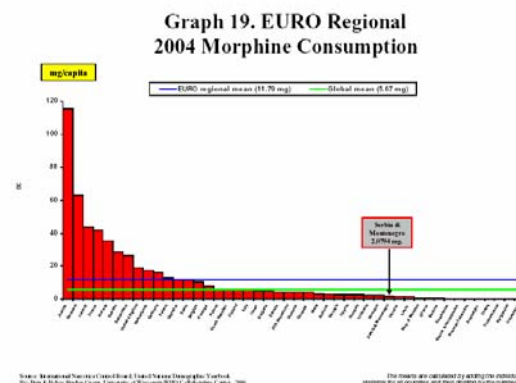
Drug	Dosage Form		
	Oral/Rectal	Parenteral	Transdermal
Tramadol	50 mg caps. 10 ml drops (100 mg / 1 ml) 100 mg tbl. SR 100 mg supp	50 mg IV 100 mg IV	x
Methadone	IR 10 ml drops (10 mg / 1 ml)	Not available	x
Morphine	NOT AVAILABLE	20 mg vial	x
Pethidine		100 mg vial	
Fentanyl TDS			25-100 ugr/h

“Serbian opioids control policy is NOT balanced!”



- Government has not conducted an examination of the narcotics control policies
- No recognition in law that opioids are indispensable for the relief of pain & suffering
- No recognition in law that it is government's obligation under international narcotic conventions to ensure adequate availability of opioids while preventing abuse and diversion
- Outdated terminology that describes opioid analgesics only in relation to addiction and health impairment
- Restrictions to opioid dose or duration of therapy, depending on the diagnosis (cancer vs. other diseases)
- Prescription (Rx) related barriers (restricted amount and number of opioids per Rx, unduly short validity of Rx, use of a duplicate Rx form)
- No cooperation between the government and health care professionals to ensure the availability of opioid analgesics for medical and scientific purposes
- Serbia does not have a national cancer control/ cancer pain relief programme; National Strategy for HIV/AIDS control was formulated in 2005

“In 2004, consumption of morphine in Serbia was 2.08 mg per person”



Conclusion: In adhering to international drug treaties, governments often concentrate on drug control to the exclusion of their obligation to ensure opioid availability for medical and scientific purposes. An Action Plan was developed to facilitate acknowledgement of the medical value and necessity of opioids and to remove regulatory barriers to their availability and accessibility in Serbia.

Any Qs
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