Availability of Opioid Analgesics in Romania, Europe, and the World

Prepared by:

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About the Pain & Policy Studies Group

The Pain & Policy Studies Group mission is to promote “balance” in international, national and state pain policies to ensure adequate availability of opioid analgesics and their appropriate medical use for patient care while addressing diversion and abuse. The PPSG is designated the World Health Organization Collaborating Center for Policy and Communications in Cancer Care. Much of the PPSG’s work, including new WHO Guidelines that are discussed later in this document, are available on their website at www.medsch.wisc.edu/painpolicy. As a WHO Collaborating Center, the PPSG provides technical assistance to governments in Africa, Asia, Europe, and Latin America, and established a WHO Demonstration Project in Calicut, India.

The PPSG also supports a global communications program to improve access to information about pain relief, palliative care, and pain policy, and publishes a WHO newsletter *Cancer Pain Release* (http://www.medsch.wisc.edu/WHOcancerpain/).

Citation:

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Opioid Availability Initiative in Romania

In January 2003, the Pain & Policy Studies Group/World Health Organization Collaborating Center for Policy and Communications in Cancer Care launched a new initiative to improve the availability of opioid pain medications in Romania. The project is in collaboration with Dr. Elena Copaciu of the University Hospital of Bucharest, Dr. Daniela Mosoiu of the Hospice Casa Sperantei in Braşov, and a new Ministry of Health Working Group for Palliative Care and Pain Control. The project entails a study of the acquisition, consumption and distribution systems for opioid pain medications within Romania, with the goal of identifying and then addressing provisions in national narcotics control policy and its implementation that may impede patient access to these important medications.

This work is based on the World Health Organization (WHO) Guidelines "Achieving Balance in National Opioids Control Policy: Guidelines for Assessment" (http://www.medsch.wisc.edu/painpolicy/publicat/00whoabi/00whoabi.htm). The Guidelines were discussed at a regional workshop on opioid availability in February 2002 in Budapest, Hungary for six Eastern European countries: Bulgaria, Croatia, Hungary, Lithuania, Poland, and Romania (http://www.euro.who.int/document/e76503.pdf). Workshop participants used the WHO Guidelines to evaluate national drug control policies for interference with medical practice and patient care. Following the Budapest workshop, Romania was selected for this project. In addition, there will be follow-up with the regional teams from Bulgaria, Croatia, Hungary, Lithuania and Poland, and information will be made available to highlight the importance of improving patient access to opioid analgesics in the region.

WORKSHOP ON ASSURING AVAILABILITY OF OPIOID ANALGESICS FOR PALLIATIVE CARE

Budapest, Hungary
25-27 February 2002

This project is jointly funded by the United States Cancer Pain Relief Committee and the Open Society Institute. Additional information about the work in Eastern Europe, as well as in Africa, Asia and Latin America, is available at http://www.medsch.wisc.edu/painpolicy/publicat/monograp/globaltrends.htm.

SECTION I - CANCER PAIN RELIEF AND OPIOID AVAILABILITY IN THE WORLD

Relieving cancer pain

In 1986, the WHO said that implementation of currently available medical knowledge could relieve most pain due to cancer.[1] WHO recommended that health professionals use a three-step Analgesic Ladder to treat cancer pain and that governments make the drugs available. The successful implementation of the WHO Analgesic Ladder depends on the availability of drugs that are safe and effective in relieving chronic severe pain, such as morphine or other strong opioids including fentanyl, hydromorphone, methadone and oxycodone. However, the availability of these drugs varies greatly from country to country.

Monitoring progress

The WHO monitors countries' consumption of opioids as one indicator of national progress to improve cancer pain relief. Morphine is the principal indicator because it is the most widely available opioid analgesic for moderate to severe pain. Consumption trends for pethidine are included in this monograph because, although pethidine is not recommended for chronic pain, it is an opioid with the same control status as morphine, and its medical use is extensive. If governments can make pethidine available, they can also make morphine available.

Prior to 1986, the consumption of morphine throughout the world was low and stable. After 1986, the total global consumption of morphine began to increase substantially as some national governments and health professionals adopted the WHO Analgesic Ladder and as new opioid products became available more widely. It should be noted that medical use of morphine in some countries is mainly for cancer pain, but morphine and other opioids can be used for acute post-operative pain, AIDS pain, and chronic non-cancer pain.

Morphine consumption in the world

Only ten industrialized countries account for the vast majority (69%) of global morphine consumption: Australia, Austria, Brazil, Canada, France, Germany, Japan, Portugal, the United Kingdom, and the United States. These ten countries represent less than 10% of the world's population. The remaining countries of the world (a number of developed countries and all developing countries) consumed 31% of the morphine in 2000, compared to only 13% in 1999. In some countries, the lack of palliative care and opioids is particularly serious because, by the time most patients are diagnosed with cancer, they have late-stage cancer that is often accompanied by severe pain.

Inadequate opioid availability

Although many countries have experienced little change in morphine consumption since 1986, some have recently begun to increase their use of opioids for cancer pain relief. Nevertheless, global consumption remains extremely low in comparison to the medical need, and many national governments have yet to address this important health priority. According to a 1996 survey of governments by the International Narcotics Control Board (INCB),[2] injectable forms of morphine were more available than oral forms recommended by WHO, and approximately one-half of governments reported that morphine is not available in all hospitals that treat cancer patients. In addition, only 60% of governments surveyed had endorsed the WHO Analgesic

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[1] World Health Organization. *Cancer Pain Relief.* Geneva, Switzerland: World Health Organization; 1986.

[2] International Narcotics Control Board. *Report of the International Narcotics Control Board for 1995: Availability of Opiates for Medical Needs*. Vienna, Austria: United Nations; 1996. *Available at* http://www.incb.org/e/ar/1995/suppl1en.pdf

Ladder. Success in implementing the WHO Analgesic Ladder has been limited by the lack of opioid analgesics, exaggerated fear of addiction, and excessively strict regulation of narcotic drugs; future success will depend on governmental efforts to address regulatory barriers and make opioids more available.

Impediments to availability

The INCB and the WHO have concluded that there are a number of impediments to the availability and use of opioid analgesics for cancer pain relief. Many government policies limit the quantity and duration of opioid prescriptions and impose special requirements for physicians who prescribe. National health priorities may not include cancer pain relief, as was evident in about half of the governments responding to the survey. In addition, health professionals, narcotic regulators and legislators may not realize there is a need for pain relief; they may be mainly concerned about narcotic addiction and diversion. In fact, 43% of governments that responded to the INCB survey said that they require physicians to report to the government those patients who are prescribed opioid analgesics.

SECTION II - EFFORTS TO IMPROVE OPIOID AVAILABILITY IN THE WORLD

The WHO and the INCB are addressing the unmet need for opioid analgesics, as well as the impediments to their adequate availability.

WHO activities to improve availability

The WHO recommends that national governments implement a three-part strategy to make cancer pain relief and palliative care a priority: (1) establish a national policy that supports pain relief and palliative care; (2) develop educational programs for the public and health professionals; and (3) ensure the availability of needed drugs for the treatment of pain and other symptoms. The WHO Collaborating Center for Policy and Communications in Cancer Care provides technical assistance to governments and health professionals to evaluate impediments to opioid availability and to monitor the progress to improve opioid availability while preventing diversion. In 2000, the WHO published guidelines for evaluating national opioids control policy for "balance."

INCB activities to improve availability

The INCB is the international narcotics regulatory authority for the United Nations. The INCB monitors national governments' implementation of the 1961 Single Convention on Narcotic Drugs, as amended, a treaty that governs availability of narcotic drugs in the world.

According to the Single Convention, opioids (narcotic drugs) are indispensable for the treatment of pain and suffering, and governments should ensure their adequate availability for all medical and scientific purposes while preventing addiction and diversion. Thus, it is the responsibility of national governments (because most governments are parties to this treaty) not only to prevent misuse and diversion but also to ensure availability of opioids for medical needs. The INCB reports that, despite the large number of transactions of narcotic drugs, there was no diversion reported in 1999.[3] The INCB and other United Nations organizations, such as the Commission on Narcotic Drugs, have recognized that opioids are not sufficiently available in the world. The INCB has requested all national governments to (a) re-evaluate their medical needs for opioids,

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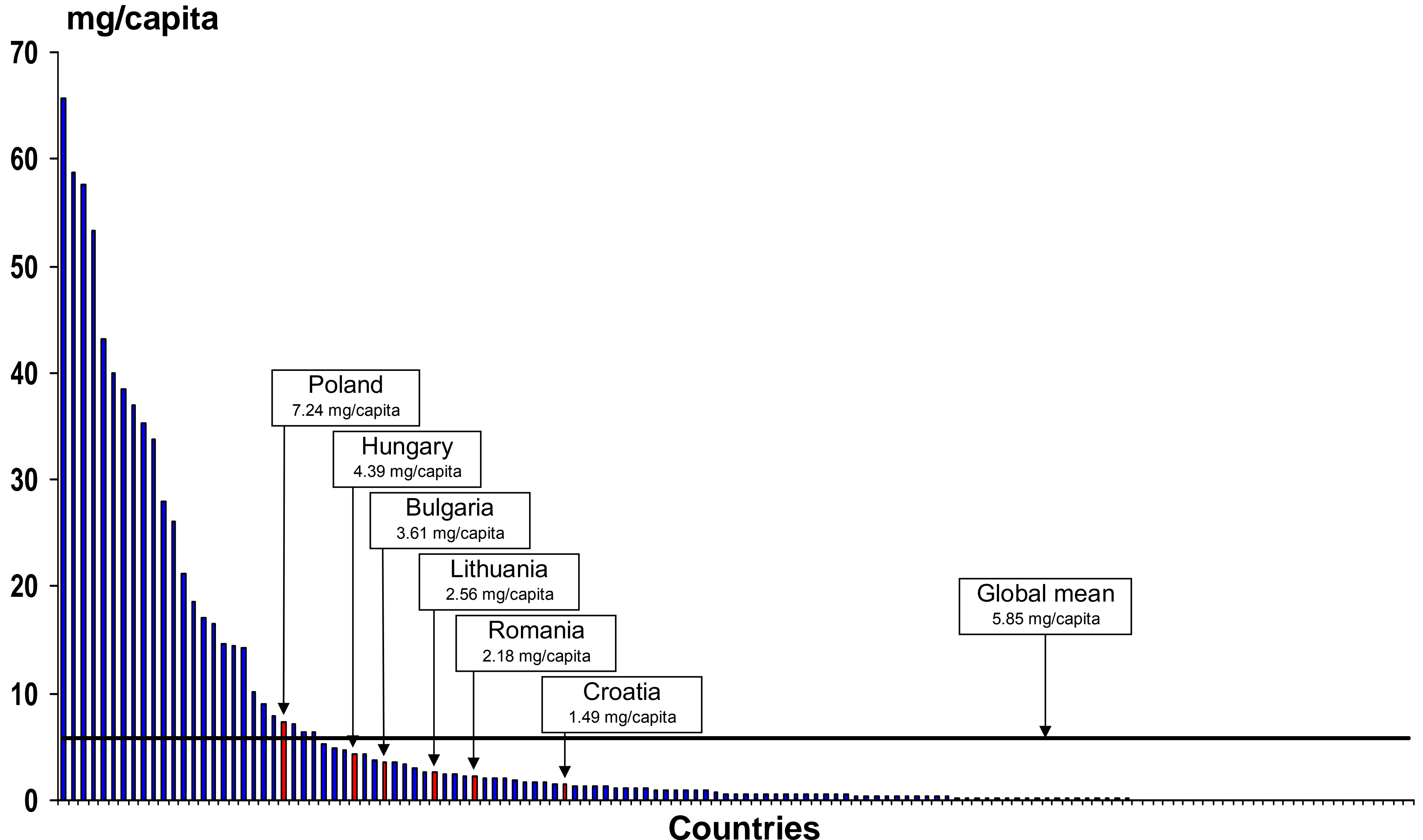
[3] International Narcotics Control Board. *Report of the International Narcotics Control Board for 1999*. New York, NY: United Nations; 2000. *Available at* http://www.incb.org/e/ar/1999/

(b) identify and address impediments, and (c) communicate with health professionals to determine the unmet medical need for opioid analgesics.

WHOCC activities to improve availability

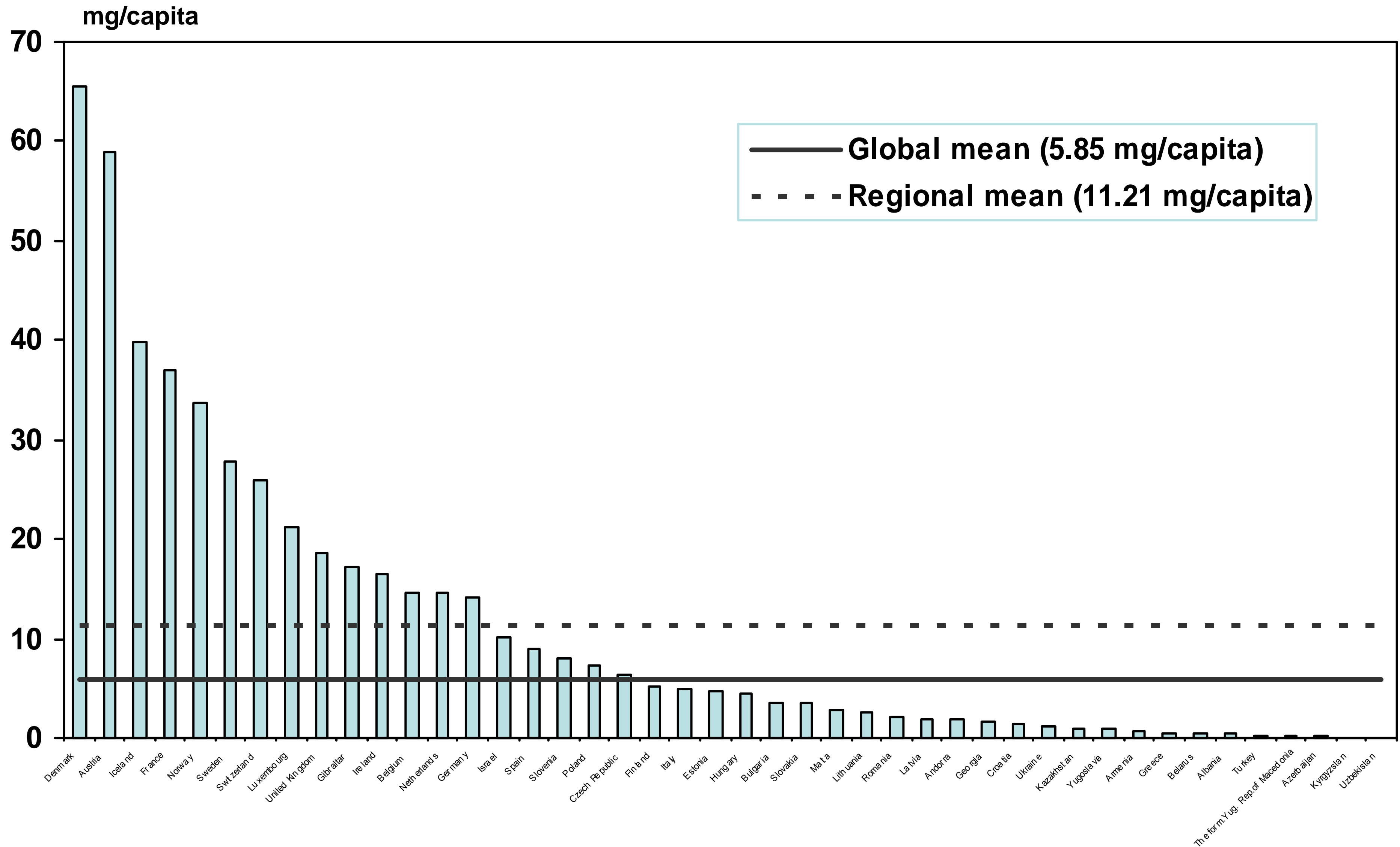
As a WHO Collaborating Center, the Pain and Policy Studies Group (PPSG) provides technical assistance to governments in Africa, Asia, Europe, and Latin America, and established a WHO Demonstration Project in Calicut, India. The World Health Organization Collaborating Center efforts to improve opioid availability are summarized in annual reports available at http://www.medsch.wisc.edu/painpolicy/publicat/annrepts.htm.

Morphine Consumed Per Capita by Country (2001)



Sources: International Narcotics Control Board; United Nations "Demographic Yearbook, 2000"
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2003

Per Capita Consumption of Morphine: Europe 2001



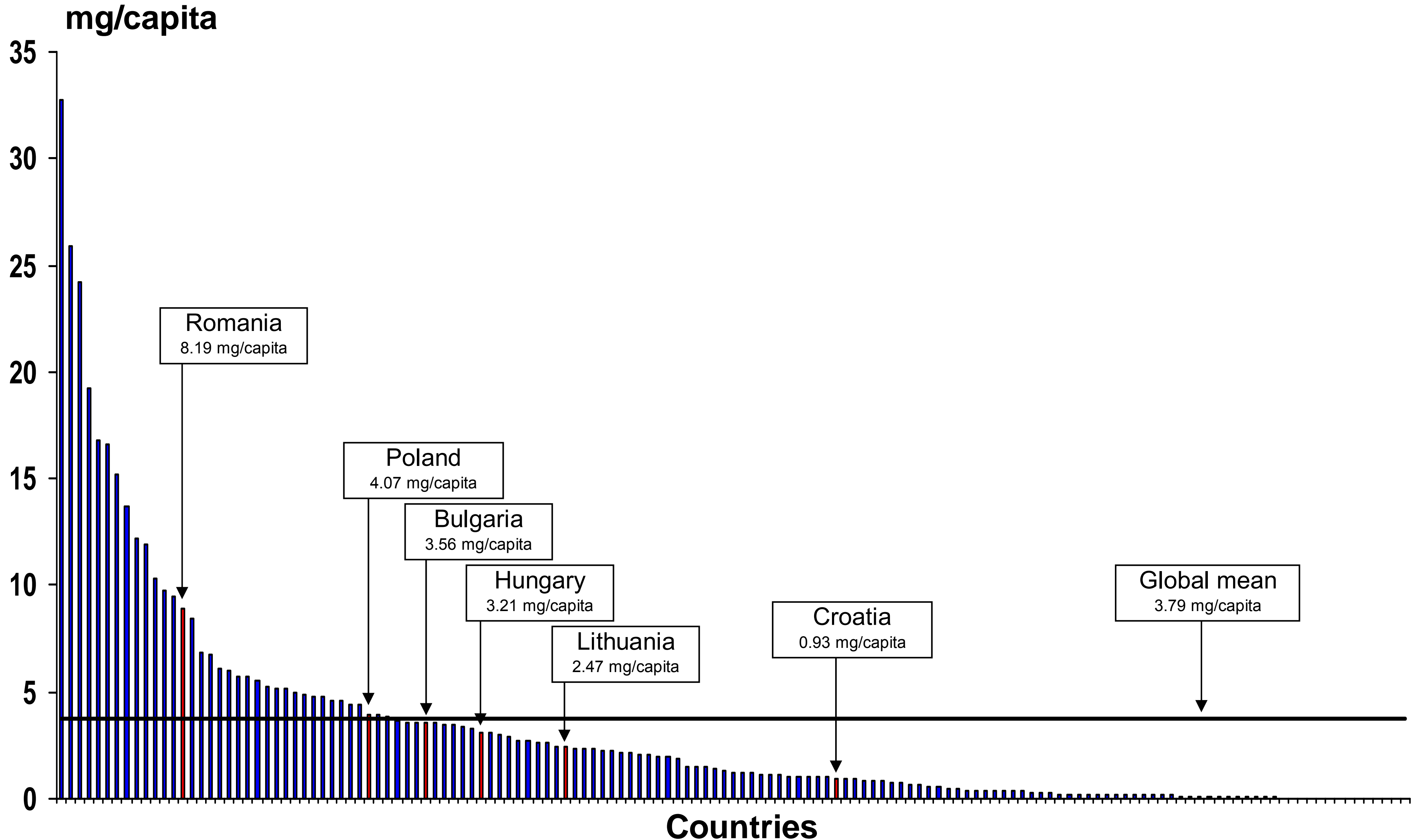
Sources: International Narcotics Control Board; United Nations “Demographic Yearbook, 2000”
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2003

Morphine Consumed, milligrams per capita by country (2001)

Country	mg per capita	Country	mg per capita	Country	mg per capita
Denmark	65.6257	Latvia	1.7867	Philippines	0.2392
Austria	58.8158	Andorra	1.7769	Tonga	0.2323
Canada	57.6875	Botswana	1.7247	Wallis and Futuna Islands	0.2143
Australia	53.2361	Georgia	1.6043	Vanuatu	0.2081
New Zealand	43.1993	Argentina	1.5725	Turkey	0.1995
Iceland	39.9390	Croatia	1.4921	Dem. Peop. Rep. of Korea	0.1963
Falkland Islands	38.5000	Ukraine	1.2840	Peru	0.1939
France	36.9054	Tunisia	1.2597	Iran (Islamic Republic of)	0.1720
United States of America	35.3263	Cuba	1.2471	China	0.1656
Norway	33.7318	Netherlands Antilles	1.2279	The form.Yug. Rep.of Macedonia	0.1475
Sweden	27.9286	Bahamas	1.1194	Zimbabwe	0.1418
Switzerland	26.0317	United Arab Emirates	1.0668	Antigua and Barbuda	0.1385
Luxembourg	21.2532	Kazakhstan	1.0452	Azerbaijan	0.1367
United Kingdom	18.5585	Lebanon	1.0438	Venezuela	0.1269
Gibraltar	17.1481	Singapore	1.0026	Qatar	0.1257
Ireland	16.4664	Colombia	0.9382	Kyrgyzstan	0.0983
Belgium	14.6433	Seychelles	0.9121	Uzbekistan	0.0959
Netherlands	14.5021	Malaysia	0.8773	Nicaragua	0.0883
Germany	14.2364	Macao	0.8636	United Republic of Tanzania	0.0854
Israel	10.0671	Yugoslavia	0.8521	India	0.0781
Spain	8.9664	Paraguay	0.7455	Syrian Arab Republic	0.0749
Slovenia	7.9527	Republic of Palau	0.6316	Morocco	0.0736
Poland	7.2405	Cook Islands	0.6145	Grenada	0.0690
Japan	7.0610	Bahrain	0.6123	Algeria	0.0516
Czech Republic	6.4698	Armenia	0.5935	Saint Kitts and Nevis	0.0495
New Caledonia	6.4134	Mauritius	0.5793	Viet Nam	0.0469
Finland	5.2005	Oman	0.5604	Uganda	0.0442
ItalyF	4.8382	Jordan	0.5485	Zambia	0.0326
Estonia	4.7383	Greece	0.5474	Bolivia	0.0286
Hungary	4.3850	Turks and Caicos Islands	0.5294	Maldives	0.0221
Barbados	4.2693	Panama	0.5249	Libyan Arab Jamahiriya	0.0170
South Africa	3.7157	Belarus	0.5074	Iraq	0.0137
Bulgaria	3.6122	Dominican Republic	0.4856	Senegal	0.0129
Slovakia	3.5167	Albania	0.4802	Nepal	0.0121
Hong Kong SAR	3.3812	Cambodia	0.4681	Mozambique	0.0116
Malta	2.9202	Sierra Leone	0.4540	Sudan	0.0092
Costa Rica	2.6782	Sri Lanka	0.4523	Bhutan	0.0091
Lithuania	2.5619	Brunei Darussalam	0.4167	Benin	0.0078
Namibia	2.5129	Fiji	0.3919	Cape Verde	0.0047
Uruguay	2.4567	Kiribati	0.3855	Myanmar	0.0038
Cyprus	2.3395	Suriname	0.3671	Eritrea	0.0030
Romania	2.1764	Kuwait	0.3402	Kenya	0.0029
Chile	2.0889	Jamaica	0.3293	Côte d'Ivoire	0.0016
Brazil	2.0249	Thailand	0.3235	Ethiopia	0.0002
Republic of Korea	2.0182	Saudi Arabia	0.2427	Dem. Rep. of the Congo	0.0001

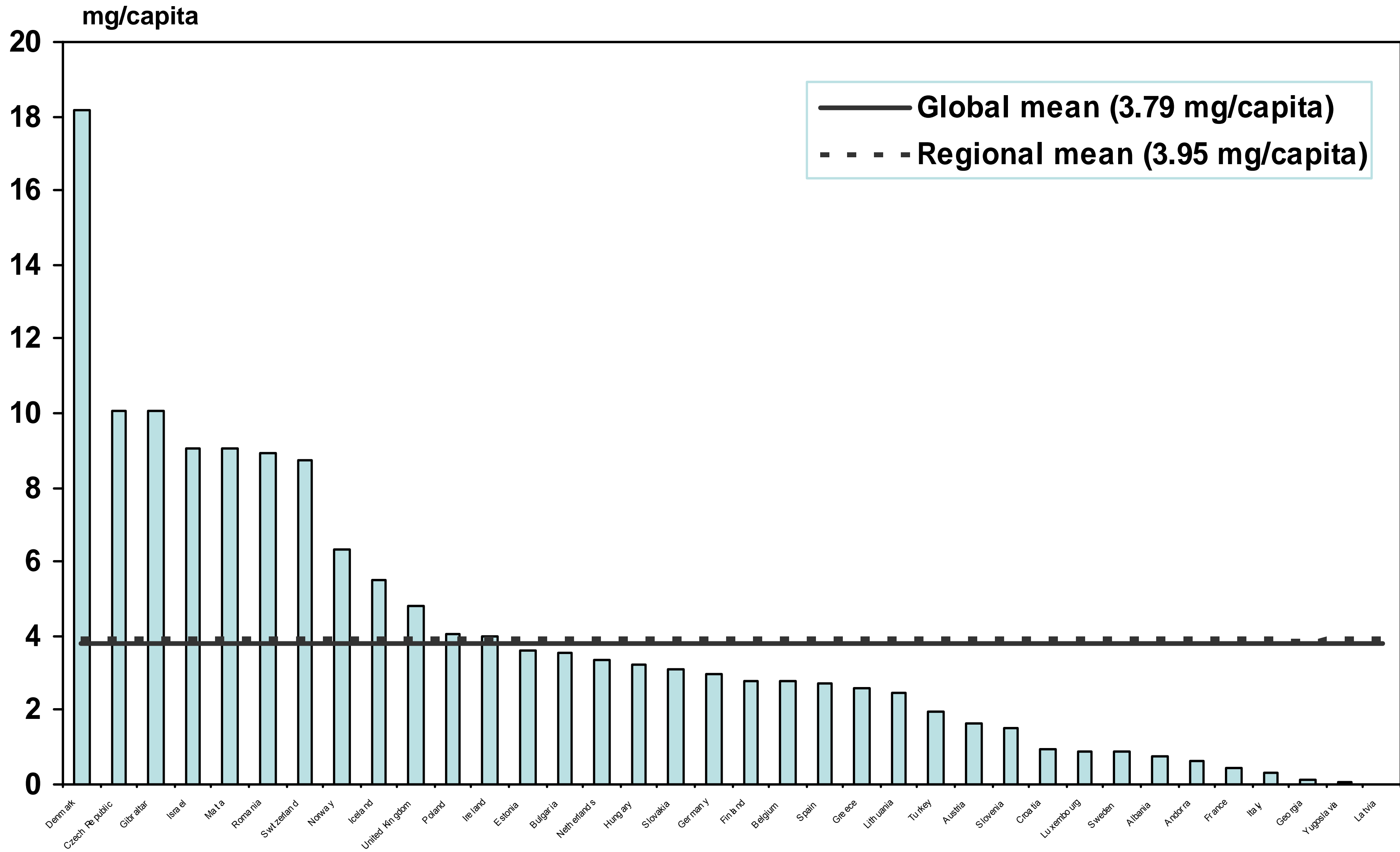
Notes: Countries not represented on this list did not report consumption statistics to the INCB for 2001
Milligrams per capita data are computed using population data from 2000, which is the most recent data available from the United Nations.

Pethidine Consumed Per Capita by Country (2001)



Sources: International Narcotics Control Board; United Nations “Demographic Yearbook, 2000”
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2003

Per Capita Consumption of Pethidine: Europe 2001



Sources: International Narcotics Control Board; United Nations “Demographic Yearbook, 2000”
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2003

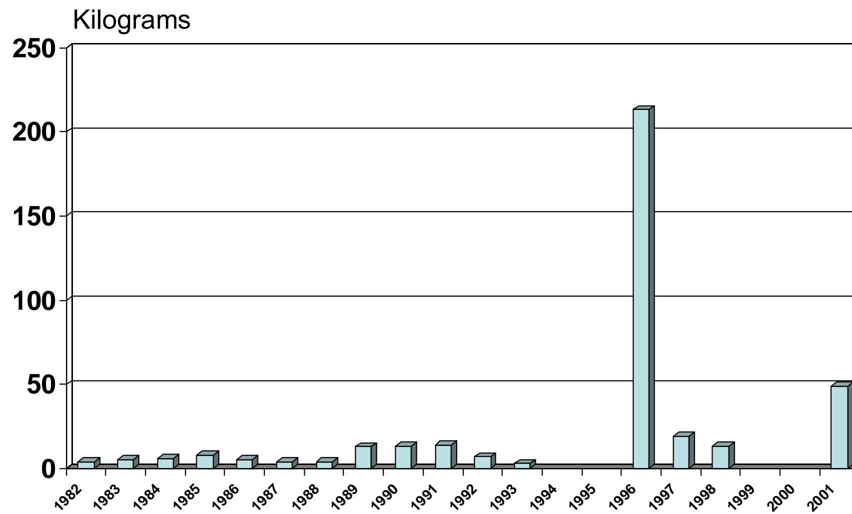
Pethidine Consumed, milligrams per capita by country (2001)

Country	mg per capita	Country	mg per capita	Country	mg per capita
Barbados	48.3383	Anguilla	3.1818	Andorra	0.6531
Canada	35.9465	Libyan Arab Jamahiriya	3.1380	Uruguay	0.6518
United States of America	22.4081	Slovakia	3.1275	Suriname	0.6494
Bahamas	21.6850	Botswana	3.0410	Guatemala	0.6148
Denmark	18.1525	Malaysia	2.9906	Costa Rica	0.5530
Australia	15.9588	Germany	2.9701	Cape Verde	0.5363
Cook Islands	15.5307	United Arab Emirates	2.7897	Iraq	0.4796
New Zealand	12.8694	Finland	2.7655	Venezuela	0.4679
Republic of Palau	12.3158	Belgium	2.7642	Tunisia	0.4644
Czech Republic	10.0930	Spain	2.7385	Lao Peop. Dem. Rep.	0.4501
Gibraltar	10.0370	Saudi Arabia	2.6606	Uganda	0.4483
Israel	9.0800	Greece	2.6093	Morocco	0.4392
Malta	9.0364	Falkland Islands	2.5000	Peru	0.4317
Romania	8.9146	Lithuania	2.4742	France	0.4236
Antigua and Barbuda	8.9077	Cuba	2.3332	Japan	0.3600
Switzerland	8.7480	Kiribati	2.2892	Italy	0.2944
Cyprus	8.5667	Lebanon	2.2457	Nepal	0.2906
Mauritius	8.1247	Macao	1.9946	Sudan	0.2180
Turks and Caicos Islands	7.5882	Turkey	1.9862	Philippines	0.1741
South Africa	7.4773	Netherlands Antilles	1.9721	Indonesia	0.1739
Norway	6.3185	China	1.9187	Dominican Republic	0.1535
Iceland	5.4881	Brunei Darussalam	1.8735	India	0.1519
Jamaica	5.2596	Fiji	1.8686	Benin	0.1473
Saint Kitts and Nevis	5.0235	Tonga	1.8485	Togo	0.1398
Brazil	4.9608	Austria	1.6550	Georgia	0.1114
Jordan	4.9542	Slovenia	1.4945	Maldives	0.1068
Bahrain	4.8493	Sri Lanka	1.3044	Burundi	0.1043
United Kingdom	4.7924	Vanuatu	1.2843	Bhutan	0.0935
Qatar	4.7788	Thailand	1.2320	Paraguay	0.0819
Grenada	4.2801	Argentina	1.2142	New Caledonia	0.0758
Zimbabwe	4.2418	Panama	1.1650	Viet Nam	0.0725
Kuwait	4.1632	Iran (Islamic Republic of)	1.1498	Eritrea	0.0691
Poland	4.0687	United Republic of Tanzania	1.0772	Mozambique	0.0626
Ireland	3.9988	Colombia	0.9780	Ethiopia	0.0620
Hong Kong SAR	3.9122	Croatia	0.9324	Yugoslavia	0.0616
Seychelles	3.7100	Luxembourg	0.8951	Senegal	0.0394
Estonia	3.6318	Kenya	0.8943	Bolivia	0.0192
Oman	3.5616	Sweden	0.8845	Dem. Rep. of the Congo	0.0188
Bulgaria	3.5569	Chile	0.8452	Myanmar	0.0186
Singapore	3.4932	Albania	0.7827	Sao Tome and Principe	0.0145
Netherlands	3.3403	Zambia	0.7229	Côte d'Ivoire	0.0126
Hungary	3.2096	Republic of Korea	0.7177	Cambodia	0.0053
Namibia	3.1840	Syrian Arab Republic	0.7012	Latvia	0.0004

Notes: Countries not represented on this list did not report consumption statistics to the INCB for 2001
Milligrams per capita data are computed using population data from 2000, which is the most recent data available from the United Nations.

Total Consumption of Morphine - Romania-

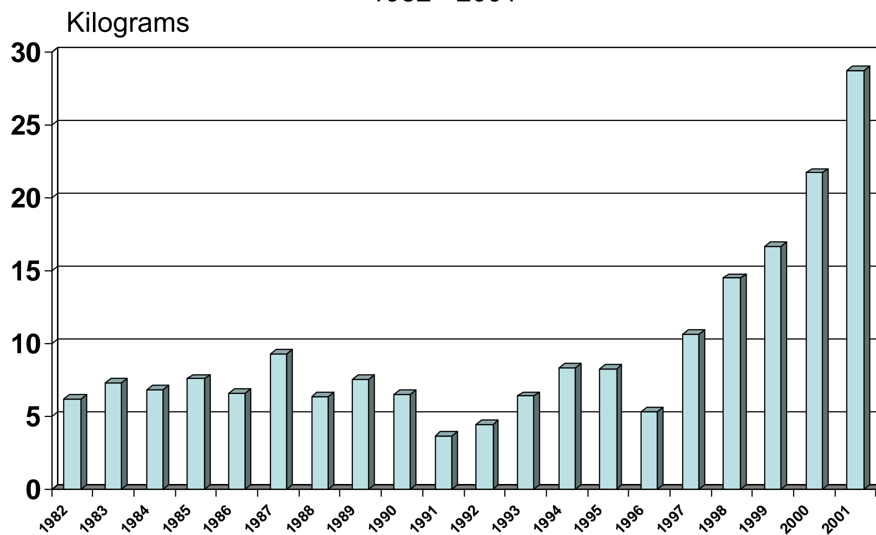
1982- 2001



Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 2001
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2003

Total Consumption of Morphine - Bulgaria -

1982 - 2001



Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 2001
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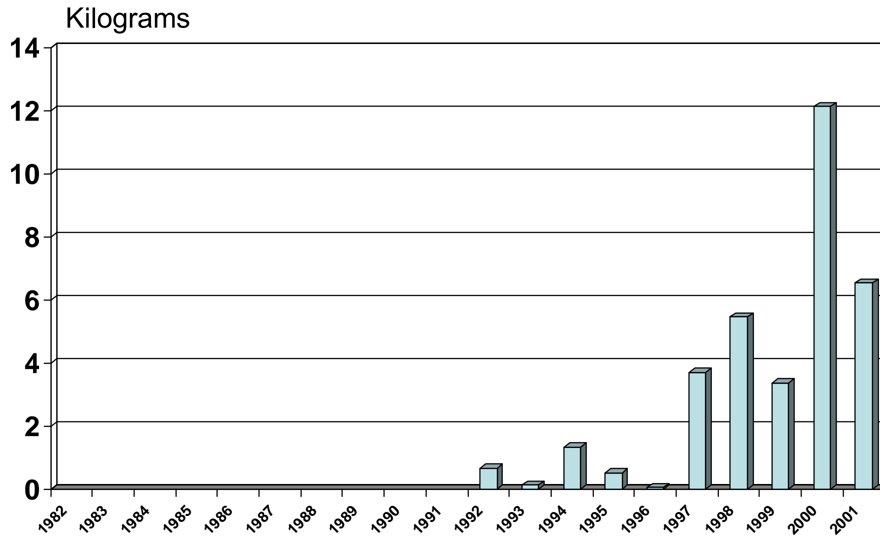
Total Consumption of Morphine
- Croatia -
1982 - 2001
Kilograms
14
12
10
8
6
4
2
0
1982
1983
1984
1985
1986
1987
1988
1989
1990
1991
1992
1993
1994
1995
1996
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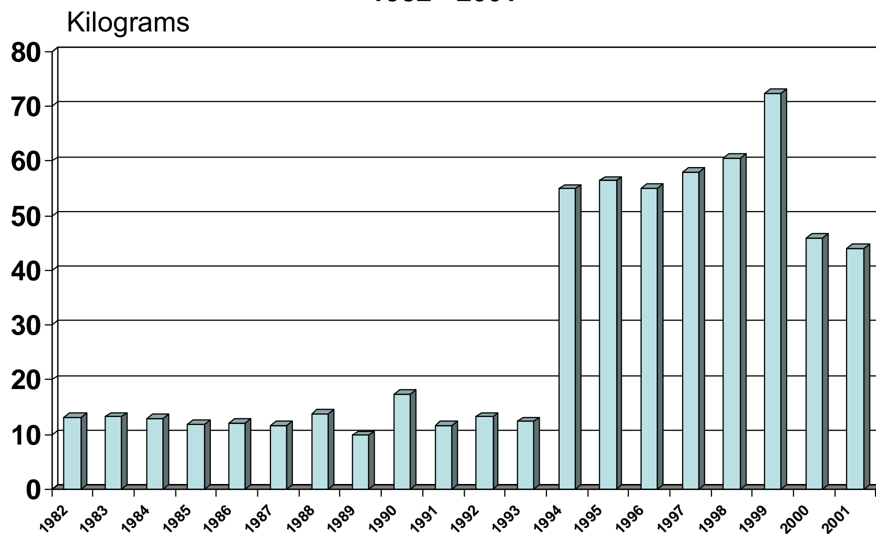
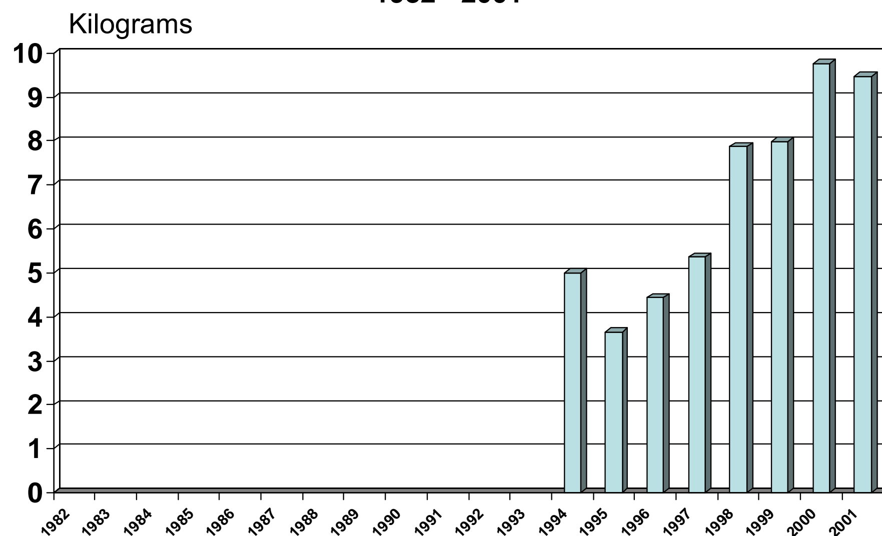
1998
1999
2000
2001
Source: International Narcotics Control Board; United Nations “Demographic Yearbook,” 2001
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2003


Total Consumption of Morphine
- Hungary -
1982 - 2001
Kilograms
80
70
60
50
40
30
20
10
0
1982
1983
1984
1985
1986
1987
1988
1989
1990
1991
1992
1993
1994
1995
1996
1997
1998
1999
2000
2001
Source: International Narcotics Control Board; United Nations “Demographic Yearbook,” 2001
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2003

Total Consumption of Morphine - Lithuania -

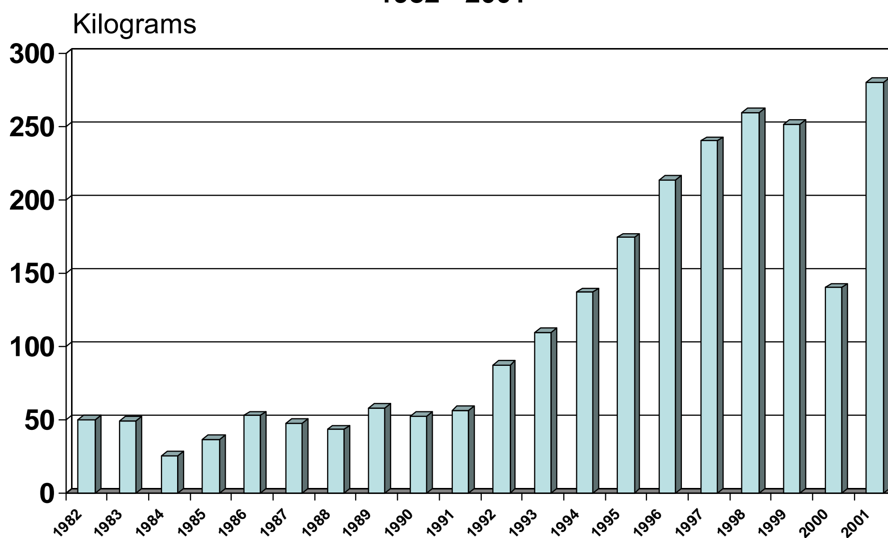
1982 - 2001



Source: International Narcotics Control Board; United Nations “Demographic Yearbook,” 2001
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2003

Total Consumption of Morphine - Poland -

1982 - 2001



Source: International Narcotics Control Board; United Nations “Demographic Yearbook,” 2001
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Status of adherence to conventions, Receipt of statistics, and estimates

	ADHERENCE			
	Single Convention 1961	As amended 1961/72	Consumption statistics for 2001	Estimated requirements for 2003
BULGARIA			●	●
CROATIA	●	●	●	●
HUNGARY	●	●	●	●
LITHUANIA	●	●		
POLAND	●	●	●	●
ROMANIA	●	●	●	

Source: International Narcotics Control Board. *Narcotic Drugs: Estimated World Requirements for 2003- Statistics for 2001*. New York, NY: United Nations, 2003.

Consumption of Selected Opioid Analgesics, 2001 (mg/capita)

	FENTANYL	METHADONE	MORPHINE	OXYCODONE	PETHIDINE
Global mean	0.08	7.51	5.85	4.22	3.79
Europe Regional mean	0.17	10.51	11.21	2.67	3.95
Bulgaria	0.01	0.94	3.61	--	3.56
Croatia	0.02	14.65	1.49	--	0.93
Hungary	0.13	0.23	4.39	0.01	3.21
Lithuania	0.03	1.82	2.56	--	2.47
Poland	0.08	0.48	7.24	--	4.07
Romania	0.03	--	2.18	--	8.91

Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 2000
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2003
-- means that the INCB did not receive data

Estimated requirements for selected opioids, 2002 and 2003 (in grams)

Country & Population	Year	Fentanyl	Methadone	Morphine	Oxycodone	Pethidine
Bulgaria 7,949,000	**2002**	300	14,000	50,000	500	35,000
	2003	350	15,000	50.000	2,000	35,000
Croatia 4,381,000	**2002**	1,800	120,000	10,000		12,000
	2003	1,800	120,000	10,000		12000
Hungary 10,024,000	**2002**	1,850	10,000	5,770,000	3,000	53,000
	2003	1,800	5,000	3,230,000	3,000	19,001
Lithuania 3,696,000	**2002**	75	10,000	13,000	1,000	11,000
	2003	150	10,000	13,000		11,000
Poland 38,646,000	**2002**	3,000	30,000	1,200,014	2,000	300,000
	2003	8,000	30,000	600,000	1,500	250,000
Romania 22,435,000	**2002**	188	938	11,250		187,500
	2003	296	3,000	63,500		200,000

Source: International Narcotics Control Board
Quarterly Supplement, International Narcotics Control Board Estimated World Requirements of Narcotic Drugs for 2002
Advance Copy, International Narcotics Control Board Estimated World Requirements of Narcotic Drugs for 2003
United Nations “Demographic Yearbook,” 2003
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2003

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ANNEX 1. ACHIEVING BALANCE IN NATIONAL OPIOIDS CONTROL POLICY (Verbatim to Executive Summary and Sections I and X)[4]

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ENGLISH ONLY
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NARCOTIC & PSYCHOTROPIC DRUGS

ACHIEVING BALANCE IN NATIONAL OPIOIDS CONTROL POLICY

GUIDELINES FOR ASSESSMENT

WORLD HEALTH ORGANIZATION

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[4] World Health Organization. *Achieving Balance in National Opioids Control Policy: Guidelines for Assessment*. Geneva, Switzerland: World Health Organization; 2000. (Available at http://www.who.int/medicines/library/qsm/who-edm-qsm-2000-4/who-edm-qsm-2000-4.htm).

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EXECUTIVE SUMMARY

The World Health Organization (WHO) has determined that the inadequate management of pain due to cancer is a serious public health problem in the world. Worldwide, there are 10 million new cases of cancer and 6 million deaths annually from this noncommunicable disease *(1)*. Twenty years from now, the global burden of cancer will double. The incidence of cancer, presently greatest in developed countries, will shift to developing countries, reflecting better prevention strategies in the developed world. The WHO Programme on Cancer Control has estimated that by the year 2020, approximately 70% of the annual 20 million new cancer cases will occur in developing countries *(1)*, where most patients are diagnosed when the disease is already in the late stages. Pain is prevalent in cancer, but especially in the late stages, near the end of life.

Tragically, cancer pain frequently goes untreated; when it is treated, relief is often inadequate. Yet, the WHO has demonstrated that most, if not all, pain due to cancer *could* be relieved if we implemented *existing* medical knowledge and treatments. There is a treatment gap: it is the difference between what can be done, and what *is* done about cancer pain. The treatment gap can be narrowed by educating and training health care workers, and by increasing access to pain relief and palliative care services. However, much of the treatment gap, especially in developing countries, is defined by the inadequate availability and use of pain medications, in particular the opioid analgesics.

Although there are many drug and non-drug pain treatments, the opioid analgesics such as codeine and morphine are *absolutely necessary* for the management of pain due to cancer. When cancer pain is moderate to severe, there is no substitute for opioids in the therapeutic group of morphine. The International Narcotics Control Board (INCB)[1], the international body that monitors, inter alia, global availability of narcotic drugs, emphasizes that these drugs must be available for pain relief.

Opioids are classified as narcotic drugs because they have a potential for abuse. As a consequence, they are regulated by international treaties and national drug control policies. The INCB, the WHO and national governments report that opioids are not sufficiently available for medical purposes. There are a number of reasons, including the low priority for pain management in health care systems, greatly exaggerated fears of addiction, overly restrictive national drug control policies, and problems in procurement, manufacture and distribution of opioids.

In some countries, governments and health care professionals have been working together to improve cancer pain management and palliative care; some have begun to identify and correct overly restrictive regulatory control over the medical use of opioid analgesics. Other countries have yet to address these matters. These Guidelines can be used by governments to determine whether their national drug control policies have established the legal and administrative framework to ensure the medical availability of opioid analgesics, according to international treaties and the recommendations of the INCB and the WHO.

A 1995 INCB report *(3)* stated:
"...an efficient national drug control regime must involve not only a programme to prevent illicit trafficking and diversion, but also a programme to ensure the adequate availability of narcotic drugs for medical and scientific purposes" (p.14).

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[1] The International Narcotics Control Board is an independent treaty-based body that monitors implementation of the Single Convention on Narcotic Drugs, 1961, and other related treaties. For a description of the Board and its activities see: INCB, 1999 *(2)*.

SECTION I
PURPOSE AND AUDIENCE

The purpose of these self-assessment Guidelines is to encourage governments to achieve better pain management by identifying and overcoming regulatory barriers to opioid availability.[2] These Guidelines may also be used to develop balanced national (including state, provincial or territorial authorities where relevant) drug control policies where none already exist. (See Annex 1 for definition of "national policy.") "Balance" refers to the dual purpose of preventing illegal trafficking and diversion, while ensuring their availability for medical and scientific purposes, in particular for the treatment of pain and suffering (see Section VII for further discussion).

This document is intended for those who make national drug control policy, as well as those who implement it. It may also be used by health care professionals and their organizations to encourage cooperation with governments and to facilitate further education.

This document accomplishes its purpose in several ways:

I. Background information is presented about the global problem of inadequate cancer pain relief (Section II);
II. Information is provided about why opioids (i.e., narcotic drugs, opiates[3]) are needed for the medical management of pain (Section III);
III. Information is given about the inadequate availability of opioid analgesics in most countries (Section IV);
IV. The reasons for inadequate availability are given, with specific reference to the overly restrictive regulation of pain medications under some national drug control policies (Section V);
V. A rationale is presented for governments to assess national policies for balance (Section VI);
VI. The method that was used to develop guidelines for conducting a self-assessment is described (Section VII);
VII. The Guidelines are presented to encourage consensus in the adoption of balanced national drug control policy. They are based on international medical and regulatory consensus that national drug control policy should be balanced (Section IX);
VIII. A checklist of questions is provided to guide the self-assessment (Section X);
IX. Reference information is provided on page 28-29;
X. Ordering information for key resources is provided in Annex 2; and
XI. A directory of the government offices responsible for narcotic regulation (National Competent Authorities) is available from the INCB at the following:

website http://www.incb.org
telephone +43-1-26060-4277, facsimile +43-1-26060-5867/5868

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[2] There are three levels of barriers to adequate pain management: economic, medical and regulatory. While these Guidelines focus solely on regulatory issues, it is well understood that economic and medical barriers play major roles in the inadequate treatment of pain. For example, in some countries, for economic reasons, health care professionals are encouraged to use more expensive and less effective pharmaceutical products. This may exacerbate inadequate availability, both for the health care system in general, and for the individual patient. In some countries, scarce medical resources are spent on expensive curative treatments that are futile for patients with late-stage cancer *(4)*. Such policies preclude the provision of palliative care. Finally, medical education that does not address pain management contributes to inadequate pain management.

[3] See Annex 1 for an explanation of "opiate" and "opioids," and other key terms used in this publication.

SECTION X
SELF-ASSESSMENT CHECKLIST

Governments or other interested groups, including health care professionals, may use the following checklist to guide their analysis of national drug control policies. Please note that some inquiry may be needed prior to answering the questions contained on this checklist.

1. Has the government conducted an examination to determine if there are overly restrictive provisions in national (and state, if applicable) drug control policies that impede prescribing, dispensing or needed medical treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and made the necessary adjustments?

• Yes • No • Information not available

2. Is there a provision in national drug control policies that recognizes that narcotic drugs are absolutely necessary for the relief of pain and suffering?

• Yes • No • Information not available

3. Is there a provision in national drug control policies that establishes that it is the government's obligation to make adequate provision to ensure the availability of narcotic drugs for medical and scientific purposes, including for the relief of pain and suffering?

• Yes • No • Information not available

4a. Has the government established administrative authority for implementing the obligation to ensure adequate availability of narcotic drugs for medical and scientific purposes, including licensing, estimates and statistics?[11]

• Yes • No • Information not available

4b. Are adequate personnel (employees) available for the implementation of this responsibility?

• Yes • No • Information not available

5a. Does the government have a method to estimate realistically the medical and scientific needs for narcotic drugs, including for the opioid analgesics which are needed for pain relief and palliative care?

• Yes • No • Information not available

[11] **In some cases, the government's policy may be found in either the law or administrative policies, or in both.**

5b. Has the government critically examined its method for assessing medical needs for narcotic drugs, as requested by the INCB?

• Yes • No • Information not available

5c. Has the government established a satisfactory system to collect information about medical need for opioid analgesics from relevant facilities?

• Yes • No • Information not available

6. Does the government furnish annual estimates to the INCB of need for narcotic drugs for the next year in a timely way?

• Yes • No • Information not available

7. If it appears that the medical need for opioid analgesics will exceed the estimated amount which has been approved and confirmed by the INCB, is it government policy to furnish a request for a supplementary estimate?

• Yes • No • Information not available

8. Does the government submit to the INCB in a timely way the required annual statistical reports respecting production, manufacture, trade, use and stocks of narcotic drugs?

• Yes • No • Information not available

9a. Has the government informed health professionals about the legal requirements for the use of narcotic drugs, and provided an opportunity to discuss mutual concerns?

• Yes • No • Information not available

9b. Has the government identified and addressed concerns of health care professionals about being investigated for prescribing opioids?

• Yes • No • Information not available

10. Is there cooperation between the government and health care professionals to ensure the availability of opioid analgesics for medical and scientific purposes?

• Yes • No • Information not available

11. Has the government taken steps, in cooperation with licensees, to ensure that there are no shortages of supply of opioid medications caused by inadequate procurement, manufacture and distribution systems?

• Yes • No • Information not available

12. Do national drug control policies provide for the licensing of an adequate number of individuals and entities to support a distribution system that will maximize physical access of patients to pain relief medications?

•Yes • No • Information not available

13a. Has the government established a national cancer control programme to which it allocates health care resources?

• Yes • No • Information not available

13b. Has the government taken steps to ensure the practice of the WHO Analgesic Method for cancer pain relief by continuing education programmes and by its inclusion in medical, pharmacy and nursing curriculum?

• Yes • No • Information not available

14. Is there terminology in national drug control policy that has the potential to confuse the medical use of opioids for pain with drug dependence?

• Yes • No • Information not available

15. Are there provisions in national drug control policy that restrict the amount of drug prescribed or the duration of treatment?

• Yes • No • Information not available

16. Are there prescription requirements in national drug control policy that may unduly restrict physician and patient access to pain relief?

• Yes • No • Information not available

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