ABSTRACT

Regulatory problems in making opioid analgesics available and a series of policy and professional barriers often prevent proper treatment for people who suffer from severe pain. Over 40 experts from Bulgaria, Croatia, Hungary, Lithuania, Poland and Romania, along with experts from WHO and other organizations, attended the Workshop to evaluate national policies for opioid control and to develop action plans to improve the availability of these drugs for palliative care in their countries. The participants discussed the changes that might need to be made in laws and regulations or drug distribution to achieve this goal. They recognized the need to balance the regulatory requirements for control with the need to make opioids accessible for appropriate pain relief. The participants urged governments to ensure the accessibility of opioids for their population while complying with all international regulatory obligations.

Keywords

PAIN – drug therapy
NEOPLASMS – drug therapy
ANALGESICS, OPIOID – distribution and supply
PALLIATIVE CARE
EUROPE, CENTRAL
EUROPE, EASTERN
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1. **Background and introduction**

This is a report on a World Health Organization (WHO) workshop on opioid availability for palliative care for six central and eastern European countries that was held in Budapest, Hungary in February 2002.

Studies around the world have consistently shown that all types of pain (acute, cancer, and chronic non-cancer) are routinely under-treated. There are many reasons for this, including lack of knowledge about how to treat pain on the part of healthcare practitioners, patient fears and misunderstanding of the medications that are used to treat moderate to severe pain (opioid analgesics), and national regulatory barriers that restrict the availability of opioid analgesics.

In 1999, the World Health Organization Collaborating Center for Policy and Communications in Cancer Care (WHOCC) in the USA, under contract from the WHO Essential Medicines Department, prepared an initial draft of guidelines that could be used to evaluate national policy for its ability to ensure adequate availability of narcotic drugs while at the same time preventing their diversion to licit channels. An international expert workgroup reviewed the guidelines in late 1999, and in 2000, were published by the WHO. Titled “Achieving Balance in National Opioids Control Policy,” they were the basis of a PAHO workshop on opioid availability for palliative care for six Latin American countries in Quito, Ecuador in December 2000.

On that basis, a similar workshop was organized for six central and eastern European countries in Budapest, Hungary by the WHO Regional Office for Europe (EURO) together with the Essential Drugs and Medicines Policy department in WHO Geneva, in collaboration with the Open Society Institute (OSI) and the WHOCC.

2. **Objectives**

The desired outcomes were to provide participants with the knowledge necessary to evaluate their national opioids control policies, to encourage collaboration between representatives of national, government, and pain relief and palliative care organizations, and to formulate an action plan in each of the six participating countries to improve the availability of opioid medications for relief of pain and suffering of cancer and AIDS patients at the end of life.

3. **Workshop development**

Representatives of the WHO Regional Office for Europe, OSI, and WHOCC met in July 2001 to begin the planning process for the “Workshop on Assuring Availability of Opioid Analgesics for Palliative Care.” Following the meeting in Denver, the remainder of the workshop arrangements were accomplished via email and telephone communication. The workshop was funded by OSI; meeting arrangements were coordinated by the Regional Office, and the content of the meeting was prepared by WHOCC, in consultation with all partners involved. The workshop was held at the Central European University Centre in Budapest, Hungary on 25–27 February 2002.
The following countries participated in the meeting, taking into consideration their health care systems, and interest in pain management and palliative care: Bulgaria, Croatia, Hungary, Lithuania, Poland and Romania. It was planned that each country group consisted of representatives of the Ministry of Health for narcotics control, cancer control, and pain and palliative care, as well as several clinicians and non-governmental organizations working in the latter fields. Several observers and temporary advisers, including representatives of the International Association for the Study of Pain, European Association for Palliative Care, and Eastern and Central Europe Palliative Task Force, were invited to assist with the programme. The programme benefited from their participation (Annex 9).

Each country completed a country report about palliative care and opioid availability (Annex 1) prior to attending the workshop.

4. Programme

The mornings of the first and second day of the workshop (Annex 2) consisted of presentations by experts in pain management and opioid availability (Annex 3), and included statistics on the consumption of opioid analgesics in eastern and central Europe and the world (Annex 8). Country reports were presented to the group on the afternoon of the first day (Annex 4). For the remainder of the workshop, the country groups convened to discuss opioid availability in their own country, complete the country action packet (Annex 5), create their action plans (Annex 6), and present their plans to all participants.

5. Conclusions and recommendations

- The workshop participants concluded that patients have the right to have their pain treated and their symptoms controlled, and opioid drugs should be available and accessible for that purpose when necessary.
- Governments should make pain relief and palliative care an institutional priority in the health care system, and adopt a national policy on cancer pain and palliative care.
- The patient’s need to have severe pain relieved and quality of life restored is at the heart of the need for availability of opioid pain medications.
- To maximize pain relief, the importance of education cannot be overlooked. Information and education campaigns are needed to stress the need for and ways to achieve appropriate pain treatment. These activities should be directed at both health professionals and the public in general.
- Participants recognized the need to balance the regulatory requirements for the control of narcotic drugs with the need for making opioids accessible for appropriate pain relief.
- The speakers stressed that governments should ensure accessibility of opioids to patient populations within their health care system, while complying with regulatory obligations. Accessibility to opioid analgesics should be ensured by national narcotics policies, their administration and an effective distribution system.
- Medical use, or consumption, of opioid analgesics varies widely among countries throughout Europe, as does the degree to which pain management and palliative care is developed. *Within* a single country, there may also be great differences in what is available between urban and rural settings, and between hospital and at-home settings. A country’s consumption can be used as an indicator of progress to improve pain treatment, but opioid consumption data do not provide a complete picture.

- The participants indicated that in some cases, the most cost-effective drugs are not being used for treating pain. Indeed, market conditions, dispensing practices and regulations are important factors that will affect the local availability.

- Countries indicated that national narcotic prescription and dispensing regulations should be reviewed, as they may be too restrictive, impeding accessibility of opioids. Some of the provisions for review include:
  1. limits on the quantity of drug prescribed at one time,
  2. limits on how long a patient may be treated with opioids,
  3. period of validity of the prescription,
  4. limits on the type of patient (i.e., only with cancer or “incurable”) that may be treated.
  5. limits on the type of physician who is authorized to prescribe opioids to the patient. In some cases, home-care team physicians are not authorized to prescribe, which may be an impediment to the patient receiving needed medications.

- Country representatives agreed to begin implementation of their action plans, recognizing that there will be needs for resources and technical assistance.

- The WHOCC will follow-up with the liaison person identified by the country groups, and will inform the workshop sponsors of progress.

- The participants determined that there is a need for collaboration among the national and international partners in this endeavour:
  - At the national level, among government policy makers and regulators with the health professionals.
  - At the international level, to include the INCB and WHO, especially on advocacy and policy, as well as through technical assistance.

6. **Workshop evaluations completed by the participants**

Thirty of the 36 participants completed workshop evaluations. The participants rated highly the quality and usefulness of the workshop, and made a number of useful suggestions for improvement (Annex 7).
Annex 1

OUTLINE FOR COUNTRY REPORT

A. Description

The country report is to be prepared by one or more individuals from the country team. It is recognized that some of the information may not be available. The report should be written and submitted on disk, and also summarized in slides or overheads for presentation in the early part of the workshop. Preparation and presentation may require two persons because there are two different areas of content and expertise: cancer/palliative care and narcotics control.

B. Purposes

1. To acquaint the participants of a country with information about the nature and extent of opioid availability or unavailability and potential resources to address the problem by asking them to obtain and present that information which is reasonably accessible;
2. To provide a starting point for a country delegation to develop a more refined statement of the problem and to develop preliminary objectives and action plans that are aimed at what is known about the problem and the resources that are available;
3. To provide a basis for comparison between countries.

C. Outline for the country report

1. Cancer, pain and palliative care (This information, to the extent that it is available, should be obtained from the WHO country or regional office, the national cancer program, institute or hospital, or national societies for cancer, pain relief and palliative care).
   a. What is the estimated prevalence and types of cancer in the country, and the prevalence of pain?
   b. Is there a national cancer control plan or program; if so, when did it start? Are pain relief and palliative care addressed? Is opioid availability addressed? What is the name of the office and person in charge?
   c. Has the government endorsed the WHO method for relief of cancer pain? Has the government sponsored or endorsed training programs in cancer pain relief and palliative care?
   d. Describe in brief terms the availability of pain relief and palliative care services in the country and comment on the extent to which the needy population has access to such services.
   e. Identify national associations (non-governmental organizations) that have a primary interest in pain relief and/or palliative care, and mention their relevant activities.
2. Opioid availability (This information, to the extent that it is available, should be obtained from the national office for narcotics control, i.e., the “Competent Authority,”1 and from pain and palliative care programs.)

   a. Identify the national office that is the Competent Authority for narcotics control for the country. Who is in charge of the office, and who is in charge of submitting the annual estimate of medical requirements for narcotic drugs to the International Narcotics Control Board?

   b. What opioid analgesics are approved in the country, and in what dosage forms? List all licensed manufacturers for the needed opioids. What opioids are not available?

   c. For those opioids that are available, are they sufficiently available in the places where cancer patients are treated in the country, i.e., all hospitals with cancer units, hospices, pain clinics, palliative care programs, etc.?

   d. What are the national statistics for the consumption trends of strong opioid analgesics (morphine, pethidine, fentanyl, etc) for the last five years?2

   e. What are the basic requirements for a physician to prescribe an opioid such as morphine?

      i. What licenses are required?
      ii. Are special prescription forms required?
      iii. Is special training required?

   f. What are the other requirements for writing a prescription for an opioid such as morphine?

      i. Is there a maximum amount that can be prescribed at one time, for example a limitation on the number of dosage units or number of days?
      ii. Is there a maximum length of time that a patient can receive opioids?
      iii. What is the period of time that a prescription for an opioid such as morphine is valid?
      iv. Are there different legal requirements for prescribing, dispensing or purchasing different dosage forms of the same opioid, i.e., oral, transdermal, injectable?
      v. What is the minimum and maximum penalty for a physician or pharmacist who violates the prescribing laws or regulations?
      vi. Does the national law or regulation require reporting names of patients who receive opioid prescriptions to the government?

   g. What, if any, changes have been made in laws, regulations or commercialization to improve the medical use and availability of opioid analgesics?

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2 Statistics will also be provided by the WHOCC
Annex 2

AGENDA

Sunday, 24 February 2002 evening

18:00 – 19:00 Welcome and Reception, hotel

Monday, 25 February 2002

7:00 Breakfast – included in hotel

8:00 Opening of the workshop
   Welcome - Minister of Health, or his representative
   Kees de Joncheere, WHO Regional Office for Europe

8:15 Introduction of all participants/Warm-up exercise, Kees de Joncheere

9:15 Objectives of the workshop, Kees de Joncheere

9:30 Availability of opioid analgesics: One of the key components of the WHO
   Palliative Care Programme, by Cecilia Sepulveda, WHO-Geneva

9:45 Problem of pain in AIDS, by Kathleen Foley, OSI

10:00 Break

10:30 Undertreatment of pain, background and reasons.
   Assessment and management of pain; role of opioids, pharmacology and myths
   by Kathy Foley

11:30 Discussion

11:45 Opioid availability in Eastern Europe, by David Joranson

12:00 Role of various UN agencies in ensuring the availability of opioid analgesics
   by Dr Tokuo Yoshida, WHO-Geneva, EDM/QSM

12:30 Lunch

13:30 Dependence and control of drugs: Application of WHO terminology about dependence;
   medical use of opioid analgesics for pain relief from cancer
   by Tokuo Yoshida
13:45  Country reports on availability of opioids for palliative care:

Bulgaria
Croatia
Hungary

15:15  Break

15:45  Continuation of country reports:

Lithuania
Poland
Romania

17:15  Recess

19:00  Dinner

Tuesday, 26 February 2002

7:00  Breakfast

8:00  Overview of the new WHO Guidelines for evaluation of national narcotics control policy, by Tokuo Yoshida

8:15  Review and application of the Guidelines, Part I. Evaluation of national policy and administration

Guideline 1: Governments should review their drug control policies in order to identify excessive restrictions
Guideline 2: Opioids are necessary for palliative care
Guideline 3: Obligation of governments to ensure availability of opioids
Guideline 13: Establish a national cancer control program with a palliative care component
Guideline 14: Terminology related to pain, drug dependency and abuse
Guideline 15: Eliminate requirements that impede the practice of medicine and patient care
Guideline 16: Eliminate restrictive requirements of prescriptions by David Joranson

9:00  Discussion

9:15  Review and application of the Guidelines, Part II. Estimation of annual national opioids requirements according to the Single Convention of 1961

Guideline 5: Development of realistic estimates of medical needs for opioids
Guideline 6: Provision of annual estimates to the INCB
Guideline 7: Use of supplementary estimates if requirements increase
Guideline 8: Reporting statistics (production, manufacture, sale and stocks)
by Tokuo Yoshida

10:00 Discussion
10:15 Break

10:45 Review and application of the Guidelines, Part III
Obtaining and distributing opioids.

Guideline 4: Designation of an administrative authority
Guideline 9: Dialogue with health professionals
Guideline 10: Cooperation between regulators and health professionals
Guideline 11: Eliminate shortage and interruption of supply
Guideline 12: Maximize access and prevent abuse and diversion
by David Joranson

11:30 Discussion
12:00 Lunch

13:00 Developing national action plans: Objectives for the country groups
by David Joranson

13:30 Country groups, first session
15:00 Break
15:30 Country groups, second session
18:00 Recess *
19:00 Dinner

*Optional continuation of country group meetings
Group facilitator(s) may meet with individual country coordinators
Wednesday, 27 February 2002

7:00  Breakfast

8:00  Country groups, third session
      Country reports – Action plans
      Each country presents for 15 minutes, followed by a 15-minute discussion

11:30 Discussion

12:30 Lunch

13:30 Closing remarks by Kathleen Foley, David Joranson and Kees de Joncheere

14:00 Meeting adjourns
Annex 3

FACULTY PRESENTATIONS

1) DR KATHLEEN M. FOLEY
   - HIV/AIDS
   - PAIN

2) MR TOKUO YOSHIDA
   - TERMINOLOGY
   - UN AGENCIES

3) DR DAVID JORANSON

4) DR CECILIA SEPULVEDA
   - CANCER
WHO Meeting
Budapest, Hungary
February 25 – 27
Dr. Kathleen M. Foley
Director, PDIA

UN AIDS DATA
2001
Eastern Europe, Central Asia
Adults & Children living with HIV/AIDS 1,000,000

Adult Prevalence Rate 0.5%
  women - 20%
  men - 80%

Intravenous Drug Users 90%
Prevalence of Pain in AIDS

PREVALENCE:
Ranges from 40% – 60%
Increases as Disease Progresses

PAIN INTENSITY:
Comparable to Cancer Pain

PAIN NUMBER:
Average of 2–3 pains at a time

Pain in AIDS
Relationship to Disease Progression
Prevalence of Pain Increases as HIV Disease Progresses (P<.01)

Pain Syndromes In HIV/AIDS Patients

Pain related to HIV/AIDS
HIV Neuropathy
HIV Myelopathy
Kaposi’s Sarcoma
Secondary Infections (intestines, skin)
Gonorenomalgia
Arthritis/Vasculitis
Myopathy/myositis

Pain related to HIV/AIDS therapy
Anti-retrovirals, Anti-virals
Anti-mycobacterials, FCP Prophylaxis
Chemotherapy (vincristine)
Radiation/Surgery
Procedures (bronchoscopy, biopsies)

Pain unrelated to HIV/AIDS
Intervertebral disc disease
Diabetic neuropathy
Slide 6

**Pain In Women with HIV Disease**
- Pain in women with HIV disease is undertreated
- Women with HIV disease have higher prevalence rates for pain than men with HIV disease
- Women with HIV have unique pain syndromes
  - Pelvic
  - Gynecologic
- Causes
  - Infection
  - Tumors

Slide 7

**WHO Analgesic Ladder**
Management of Pain in AIDS

- **1 Mild Pain**
  - Non-opioid + Adjunct
- **2 Moderate Pain**
  - Weak Opioid + Non-opioid + Adjunct
  - Pain persisting or increasing
- **3 Severe Pain**
  - Strong Opioid + Non-opioid + Adjunct
  - Pain persisting or increasing

*Adapted from Cancer Pain Relief WHO, 1990*

Slide 8

**Analgesics Prescribed for “Severe” Pain (BPI- NRS 8–10) in Ambulatory AIDS Patients (N=114)**

<table>
<thead>
<tr>
<th>Analgesic Class</th>
<th>% of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-opioid</td>
<td>25%</td>
</tr>
<tr>
<td>Opioid</td>
<td>25%</td>
</tr>
<tr>
<td>Adjunct</td>
<td>25%</td>
</tr>
<tr>
<td>Total</td>
<td>50%</td>
</tr>
</tbody>
</table>

N.H.O. Analgesic Ladder would suggest that 100% of patients with “severe” pain receive a strong opioid.
Slide 9

**Undertreatment of Pain in AIDS and Cancer**

- Adequate Analgesic Medication (P.M.I. > 4) - 59%
- Inadequate Analgesic Medication (P.M.I. = 1, 2, 3) - 5%

*Fromhart et al., Pain 52 (1992) 243-249
**Cleveland et al., 1994

Slide 10

**Factors Predicting Undertreatment of Pain in AIDS and Cancer**

<table>
<thead>
<tr>
<th>AIDS</th>
<th>Cancer**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender - females</td>
<td>Gender - females</td>
</tr>
<tr>
<td>Education - less</td>
<td>Race, age, Karnofsky</td>
</tr>
<tr>
<td>IDU as HIV risk factor</td>
<td>Cause of pain (non-cancer)</td>
</tr>
<tr>
<td>Patient-related barriers</td>
<td>Patient-related barriers</td>
</tr>
<tr>
<td>Physician-patient discrepancy</td>
<td>in judging pain interference</td>
</tr>
</tbody>
</table>

*Cleveland et al., 1994
**Fromhart et al., Pain 52 (1992) 243-249

Slide 11

**Patient-related Barriers to Pain Management in AIDS (N = 199)**

Under treatment of pain (P.M.I.) is significantly correlated (r = 0.27; P < .0001) with total scores on the Barriers Questionnaire (BQ — Ward, et al., 1993), and the following BQ factors:
- Desire to be a “good” patient (p < .01)
- Fear of distracting physician from treating the disease (p < .01)

BQ factors most commonly endorsed:
- Addiction — 75%
- Fear of Injection — 61%
- Tolerance — 71%
- Disease Progression — 55%
- Side Effects — 66%
**Slide 12**

AIDS-Specific Patient Related Barriers to Pain Management

<table>
<thead>
<tr>
<th>Item</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>I prefer to manage my pain through (non-medication) holistic approaches</td>
<td>90%</td>
</tr>
<tr>
<td>I try to limit my overall intake of medicine</td>
<td>40%</td>
</tr>
<tr>
<td>Pain medicines, like morphine, are not available in my neighborhood drug store</td>
<td>40%</td>
</tr>
<tr>
<td>I'm afraid pain medication will hurt my immune system</td>
<td>30%</td>
</tr>
<tr>
<td>Pain medication might interfere with my sexual interest or activity</td>
<td>30%</td>
</tr>
<tr>
<td>I can't afford to fill a prescription for pain medicine</td>
<td>40%</td>
</tr>
<tr>
<td>If I use pain medicines, my family/friends will think I'm getting high again</td>
<td>45%</td>
</tr>
<tr>
<td>I don't talk to the doctor about pain because I'm afraid habits will think I'm just trying to get drugs</td>
<td>40%</td>
</tr>
</tbody>
</table>

**Slide 13**

Health Professionals (N=492) Ranking of Barriers to Pain Management in AIDS

<table>
<thead>
<tr>
<th>Barriers</th>
<th>Rank in AIDS</th>
<th>Rank in Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of knowledge regarding pain management</td>
<td>1 (92%)</td>
<td>5 (52%)</td>
</tr>
<tr>
<td>Reluctance to prescribe opioids</td>
<td>2 (92%)</td>
<td>4 (91%)</td>
</tr>
<tr>
<td>Lack of access to professional methods</td>
<td>3 (91%)</td>
<td>7 (12%)</td>
</tr>
<tr>
<td>Concern regarding drug addiction/abuse</td>
<td>4 (92%)</td>
<td>—</td>
</tr>
<tr>
<td>Lack of psychological support services</td>
<td>5 (43%)</td>
<td>3 (11%)</td>
</tr>
<tr>
<td>Inadequate pain assessment</td>
<td>6 (38%)</td>
<td>1 (79%)</td>
</tr>
<tr>
<td>Focus of care on care not comfort</td>
<td>7 (38%)</td>
<td>—</td>
</tr>
<tr>
<td>Concern regarding opioid side effects</td>
<td>8 (33%)</td>
<td>—</td>
</tr>
</tbody>
</table>

*Involving strongly * 
**involving or et al. 1983

**Slide 14**

Pain Management and Substance Abuse in AIDS

- Substance abusers with AIDS are the fastest-growing segment of the epidemic in urban centers
- Substance abusers with AIDS are most undertreated for pain
- Fears of contributing to drug abuse behavior or causing re-addiction contribute to physician reluctance to prescribe opioids

*NETWORK PROJECT*
Slide 15

Pain in Substance Abusers with AIDS
Comparison of IDUs and Non-IDU's
Prevalence of Pain
IDU's (N=266)  Non-IDU's (N=239)
Pain (N=179)    Pain (N=142)
67%            59%
33%            41%
No Pain (N=87) No Pain (N=97)

chi-square=3.4, DF=1, p=NS

Slide 16

Pain in Substance Abusers with AIDS
Comparison of IDUs and Non-IDU's
Number of Pains per Subject
IDU's (N=266)  Non-IDU's (N=239)
2 Pains (N=85) 2 Pains (N=65)
36.0%          36.0%
1 Pain (N=41)  1 Pain (N=35)
17.5%          17.6%
3 Pains (N=41) 3 Pains (N=42)
15.0%          16.0%
4 Pains (N=21) 4 Pains (N=20)
8.1%           8.9%
5 Pains (6)    5 Pains (6)
63.0%          60.0%

mean # of pains = 2.5  mean # of pains = 2.5
t=0.63, DF=321, P=NS

Slide 17

PAIN IN SUBSTANCE ABUSERS WITH AIDS
Comparison of IDUs and Non-IDUs

<table>
<thead>
<tr>
<th>Pain Variables</th>
<th>IDUs</th>
<th>Non-IDUs</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain intensity at its worst (BPI-VASPI of primary pain)</td>
<td>7.5</td>
<td>7.2</td>
<td>1.0</td>
<td>NS</td>
</tr>
<tr>
<td>Pain intensity on average (BPI-VASPI of primary pain)</td>
<td>5.5</td>
<td>5.6</td>
<td>-0.3</td>
<td>NS</td>
</tr>
<tr>
<td>Pain relief (BPI-VASPR of primary pain)</td>
<td>56.9</td>
<td>64.7</td>
<td>-2.0</td>
<td>.005</td>
</tr>
<tr>
<td>Pain interference (BPI-Interference subscale)</td>
<td>42.1</td>
<td>39.9</td>
<td>1.1</td>
<td>NS</td>
</tr>
</tbody>
</table>

Slide 21

**Pain in Substance Abusers with AIDS**

**Relationship of Current Drug Use to Psychological Variables**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (SD)</th>
<th>Active</th>
<th>Inactive</th>
<th>Methadone</th>
<th>Nonscored</th>
<th>P&lt;sup&gt;1&lt;/sup&gt;</th>
<th>P&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>SDI total score</td>
<td>22.10 (18.6)</td>
<td>12.51 (9.2)</td>
<td>21.06 (18.7)</td>
<td>0.0001</td>
<td>N.S.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SDI DFI mean score</td>
<td>1.36 (0.7)</td>
<td>1.05 (0.7)</td>
<td>1.27 (0.8)</td>
<td>0.02</td>
<td>N.S.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SDI total score</td>
<td>9.03 (5.5)</td>
<td>5.46 (4.0)</td>
<td>6.22 (5.1)</td>
<td>0.0001</td>
<td>N.S.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FLIC total score</td>
<td>94.52 (20.1)</td>
<td>106.03 (22.5)</td>
<td>97.17 (20.9)</td>
<td>0.0002</td>
<td>N.S.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. social supports</td>
<td>5.03 (1.1)</td>
<td>5.03 (1.1)</td>
<td>5.03 (1.1)</td>
<td>0.002</td>
<td>N.S.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social support quality</td>
<td>5.20 (1.1)</td>
<td>5.20 (1.1)</td>
<td>5.20 (1.1)</td>
<td>N.S.</td>
<td>N.S.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

P<sup>1</sup> = Probability of equal group means between active and inactive/methadone subjects
P<sup>2</sup> = Probability of equal group means between active and methadone subjets

W. Breitbart et al., Pain 72 (1997) 235-240

Slide 22

**An Approach to Pain Management in Substance Abusers with HIV Disease:**

1. Substance abusers with HIV disease deserve pain control; We have an obligation to treat pain and suffering in all of our patients.
2. Accept and respect the report of pain.
3. Be careful about the label “substance abuse”; Distinguish between tolerance, physical dependence, and “addiction” (psychological dependence or drug abuse).
4. Not all “substance abusers” are the same; Distinguish between active users, individuals in methadone maintenance, and those in recovery.

Slide 23

**An Approach to Pain Management in Substance Abusers with HIV Disease:**

5. Individualize pain treatment plan.
6. Utilize the principles of pain management outlined for all patients with HIV disease and pain (WHO Ladder).
7. Set clear goals and conditions for opioid therapy: set limits, recognize drug abuse behaviors, make consequences clear, use written contracts, establish a single prescriber.
8. Use a multidimensional approach: pharmacologic and nonpharmacologic interventions, attention to psychosocial issues, team approach.
Pain Management Issues in Patients with HIV Disease: Summary

- Pain must be a focus of care in persons with HIV/AIDS
- Pain in patient with HIV disease is often undertreated
- Principles guiding the management of pain in AIDS are similar to those developed in cancer
- Pain contributes greatly to psychological and functional morbidity in patients with HIV disease
- A multidisciplinary approach to pain management in HIV/AIDS is optimal
Slide 1

WHO Meeting

Budapest, Hungary
February 25 – 27
Dr. Kathleen M. Foley
Director, PDIA

Slide 2

Pain Defined

The International Association for the Study of Pain:
An unpleasant sensory or emotional experience
associated with actual or potential tissue damage
or described in terms of such damage

Pearl: Caring for patients with pain requires a
comprehensive physical and emotional assessment
by definition. Localize the lesion!

Slide 3

Epidemiology of Cancer Pain

- Five million patients with cancer experience pain
every day
- 33% of patients receiving active treatment
- 60-90% of patients with advanced cancer
 experience moderate to severe pain
- 25% of patients worldwide die at home or in the
 hospital with severe pain

World Health Organization, 1996
Eastern Cooperative Oncology Group
Physician Study (n=897)

- 86% reported that the majority of their patients with pain were under-medicated
- Only 51% believed that pain control in their practices was good or very good
- 31% would wait until their patient’s prognosis was six months or less before starting maximum-tolerated analgesia

Van Roenn et al., Ann Intern Med 1993;119:121-6

Clinician-Related Barriers

- Lack of pain assessment skills
- Lack of knowledge of current therapeutic approaches
- Uncertainty about the role of opioid therapy
- Deficiencies in knowledge of opioid therapy
- Overestimation of risks of addiction
- Concern about tolerance
- Concern about managing side effects
- Concern about regulation of controlled prescription drugs

The Network Project, MSKCC 1996
Slide 7

Patient-Related Barriers

- Prefer to focus on treatment of tumor
- Stoicism
- Desire to please the staff
- Fear that pain signals disease progression
- Fear of becoming addicted
- Confusion about the role of tolerance, physical dependence, and psychological dependence
- Fear of experiencing side-effects

The Network Project, MSKCC 1996

Slide 8

Healthcare System Related Barriers

- Focus on prolonging life and cure
- Low priority given to pain and symptom control
- Unavailability of opioid analgesics
- Inaccessibility to specialized care
- Medical insurance coverage
- Cost of pain management

The Network Project, MSKCC 1996

Slide 9

Opioid Primer: Myths vs. Facts

Myth # 1: Opioids cause addiction.

Fact #1: The medical use of opioids does not cause addiction in the absence of a history of substance abuse.
Myth #2: Opioids hasten death

Fact #2: Opioids have never been demonstrated to hasten death and may prolong life

- Wilson WC et al., JAMA 1992; 267:949-953
- Brescia FJ et al., J Clin Oncol 1992; 10:149-155
- Portenoy RK, J Pall Care 1996; 12:44-46
- Bercovitch M et al., Cancer 1999
- Sykes et al., Lancet 2000; 356:398-399

Myth #3: “I’m afraid to use the medication now because it won’t work later when I really need it.”

Fact #3: Opioids may be safely and effectively used at all stages of disease.

Foley KM. Changing concepts of tolerance to opioids: What the cancer patient has taught us, Raven Press Ltd., NY 1993
Opioid Pharmacotherapy

- Tolerance
- Physical Dependence
- Psychological Dependence
- Pseudoaddiction

Opioid Analgesics: Tolerance

Definition: A change in the dose-response relationship induced by exposure to the drug and manifest as a need for a higher dose to maintain an effect.

Key points:
- Opioids should never be reserved only for patients with advanced disease.
- Tolerance rapidly develops to all opioid side-effects except constipation.
- Analgesic tolerance is rarely a problem; in the absence of worsening pathology, opioid doses usually remain stable.

Modified from The Network Project, MSKCC 1996.

Opioid Analgesics: Physical Dependence

Definition: The development of an abstinence (withdrawal) syndrome following dose reduction or administration of an antagonist.

Key points:
- Should always be assumed to exist following repeated dosing of opioids for more than three days.
- Not a clinical problem if abstinence is avoided and the patient is reassured.
- Should not be confused with “addiction”.

Modified from The Network Project, MSKCC 1996.
Slide 16

Psychological Dependence (i.e., addiction)

- Usage out of control
- Obsession with obtaining a supply
- Use causes personal and legal difficulties
- Use continues despite problems
- User denies taking the substance
- Quality of life is NOT improved

The World Health Organization

Slide 17

Pseudoaddiction

Patient behaviors that are reminiscent of addiction, but are driven by undertreatment of pain and disappear with adequate analgesia.

Weissman et al., Pain 1989;36:363-6

Slide 18

Concept of “Pseudoaddiction”

Inadequate pain management

Patient Health Care Team

Avoidance behaviors
- Anger
- Isolation of patient
- No “benefit of doubt”

Self-fulfilling prophecy

Loss of confidence

Specific drug
- Specific doses/route of administration
- Impatience

Anger/demanding behaviors
Pain Evaluation Essentials

- Believe the patient’s complaint
- Take a careful history focusing on pain characteristics and underlying disease
- Perform a careful medical and neurological examination
  - Localize the lesion!
- Order and personally review appropriate diagnostic tests
- Evaluate the extent of disease
- Perform a thorough psychological and social assessment
- Understand what the pain means to the patient
- Manage the pain during the assessment
- Reassess early and often

Pain Characteristics

Clinician should assess:
- Pain intensity
- Pain quality
- Pain distribution
- Factors that increase or decrease the pain
- Temporal characteristics

Inferred pathophysiology

The Network Project, MSKCC 1996
Impact of a Comprehensive Pain Evaluation

In 276 consecutive consultations:
64% identified a new lesion and of these more than 50% were neurologic
18% received radiation, surgery, or chemotherapy as a result of the consultation

Gonzales et al., Pain 1991;47:141-144

Pain Management Strategies

Primary treatment of etiology
• Radiotherapy
• Surgery
• Chemotherapy
• Antibiotics

Analgesic Approaches
• Pharmacotherapy
• Anesthetic Techniques
• Surgery
• Rehabilitation
• Psychological interventions

Sedation for refractory symptoms at the end of life

The Network Project, MSKCC, 1996
Slide 25

WHO Ladder: Step One

For the treatment of mild pain:
- Acetaminophen, NSAIDS

Benefits:
- No tolerance or physical dependence
- Additive analgesia when combined with an opioid

Caution:
- Ceiling effect for analgesia

Slide 26

Slide 27

WHO Ladder: Step Two

For the management of moderate pain:
- Codeine
- Hydrocodone
- Propoxyphene
- Oxycodone (in combination with a non-opioid)
- Tramadol
WHO Ladder Step Three:
For the management of severe pain:
Morphine
Hydromorphone
Fentanyl
Methadone
Oxycodone
Meperidine (parenteral)

Morphine is the Gold Standard
In the management of severe pain morphine should be used first except:
• In elderly populations
• In the setting of renal or hepatic insufficiency
• When contraindicated due to allergy or other adverse consequences from past exposure

Meperidine
Not recommended for acute or chronic pain due to its toxic metabolite, normeperidine
Normeperidine:
• A convulsant and weak analgesic
• Long half life, accumulation after repetitive dosing
• CNS excitability, mood effects, tremor, myoclonus, seizures.
• Naloxone does not reverse normeperidine-induced seizures
• Administration with MAO inhibitors may lead to hyperpyrexia and death

Adapted from The Network Project, MSKCC 1996
Opioid Dosing Guidelines 1

- Opioids have no ceiling effect. The right dose is the dose that provides maximal pain relief with minimal adverse effects.
- Individualization of analgesic therapy is a critical guiding principle.

Opioid Dosing Guidelines 2

- Avoid the common error of providing only long-acting or short-acting analgesic medication.
- Adjust the controlled release medicine based upon the patient’s usage of the immediate release drug.
- The dose of the immediate release drug should represent 15-20% of the 24 hr. long-acting dosage.
- e.g., MS Contin 30mg TID, MSIR 15-30mg po q 3hrs. prn.
Slide 34

**Breakthrough Pain**

Definition: A transitory exacerbation of severe pain over a baseline of moderate to mild pain

Incidence: 2/3 of cancer patients with controlled baseline pain

Patients with chronic pain require a controlled-release medication a short-acting drug for breakthrough pain

Slide 35

**Opioid Side-Effects**

- Constipation
- Nausea/Vomiting
- Myoclonus
- Respiratory Depression
- Mental Clouding/Confusion/Sedation

**Pearls:**

Tolerance rapidly develops to all except constipation. Softeners AND Laxatives are essential from day one.

Aggressive side effect management is often an essential component of patient care

Slide 36

**Side Effect Management**

- Treat a single side effect
- Change the drug for multiple side effects
- Reserve Naloxone for hemodynamically unstable patients. ABCs come first.
- No one ever died of respiratory depression while awake!

**Slide 37**

**Opioid Rotation**

Reasons to change:
- Dose-limiting toxicity
- Refractory and multiple side-effects
- Convenience (e.g., transdermal route preferred)
- Less-invasive route desired
- Strategy: Calculate the equi-analgesic dosage and decrease by 50% (assuming adequate pain control)
- Rationale: Cross-tolerance among opioids is incomplete

**Slide 38**

**Frequency of Opioid Rotation**

In the management of cancer pain:
- 80% of patients require one switch
- 44% of patients require two switches
- 20% of patients require three or more switches
Pearl: Treat single side-effects. Rotate for multiple side effects.


**Slide 39**

**Recent Advances in Analgesia**

- Transmucosal fentanyl for breakthrough pain
- COX-2 inhibitors for pain and arthritis
- Topical lidocaine for post-herpetic neuralgia
- Opioid efficacy in neuropathic pain
- N-methyl D-aspartate antagonists as analgesic agents
MR TOKUO YOSHIDA

Slide 1

Mr Tokuo Yoshida
Quality Assurance and Safety: Medicines
Essential Drugs and Medicines Policy
World Health Organization

Slide 2

Assuring Availability of Opioid Analgesics
Budapest, 25-27 February 2002

Dependence & Control of Drugs

Application of WHO Terminology about Dependence to Medical Use of Opioid Analgesics for Pain Relief

Speaker: Tokuo YOSHIDA
Quality Assurance & Safety: Medicines
Essential Drugs & Medicines Policy
Fear of “Addiction”

Regulatory Agencies
Policy-Makers
Mass Media
GPs & Medical Specialists
Medical Educational Institutions

Slide 4
Terminological Confusion

ABUSE
ADDITION
DEPENDENCE

Slide 5
Confusion No.1

Drug laws prohibit DEPENDENCE

No! They exist to prevent
“DRUG ABUSE”
**Slide 6**

**What is “Drug Abuse”?**

DRUG ABUSE = Excessive Non-Medical Use

Medical use, whether it results in dependence or not, is NOT Abuse

---

**Slide 7**

**Confusion No.2**

Habituation  →  Addiction

Dependence

DEPENDENCE = ADDICTION

---

**Slide 8**

**No! Dependence is NOT Addiction!**

Dependence

“Carries no connotation of the degree of risk to public health or need for a particular type of drug control”

ADDICTION = Drug Abuse by Dependent-Users
Confusion No.3

Withdrawal -> “Physical dependence”

Physical dependence = Dependence

WITHDRAWAL = DEPENDENCE

No! Withdrawal is NOT Dependence!

WITHDRAWAL is only one of the 3 requirements for “DRUG DEPENDENCE”

Definition of “Dependence”

“A need for repeated doses of the drug to feel good or to avoid feeling bad” (Lexicon)

“A cluster of physiological, behavourial and cognitive phenomenon in which the use of a psychoactive substance or a class of substances takes on a much higher priority for a given individual than other behaviours that once had greater value” (Exp. Committee)
Slide 12

**ICD-10 Guidelines**

**DEPENDENCE SYNDROME**

“Three or more of the following have been experienced at some time during the previous year”

---

**Slide 13**

**Six symptoms of Dependence**

- (a) strong desire/sense of compulsion to take the drug
- (b) difficulty in controlling drug-taking behaviour
- (c) physiological withdrawal state
- (d) tolerance
- (e) neglect of alternative interests
- (f) persistent use despite trouble

---

**Slide 14**

**Confusion No. 4**

**Repeated use develops dependence**

*No! It may, but not always. Cancer patients rarely develop dependence.*
Slide 15

**WHY SO RARE???

They do not feel “opiate euphoria”

They can take “withdrawal discomfort” much better than others

They are under medical supervision

Slide 16

**“Drug Dependence” in ADR database**

- Butorphanol 570
- Nicotine resin 515
- Diazepam 462
- Alprazolam 376
- Lorazepam 278
- Tramadol 236
- Flunitrazepam 201
- Methadone 46
- Codeine 34
- Morphine 24

Slide 17

**“Withdrawal Syndrome” in ADR database**

- Paroxetine 1,644
- Alprazolam 799
- Hyoscine 503
- Venlafaxine 464
- Sertraline 430
- Fluoxetine 343
- Methadone 292
- Tramadol 222
- Morphine 19
- Pethidine 11
Dependence is one of the common Adverse Drug Reactions. It rarely occurs in cancer patients receiving opioid analgesics.

If it ever occurs, it can be managed by gradual dose reduction.
Role of UN Agencies in Controlling & Ensuring Availability of Opioid Analgesics

Tokuo YOSHIDA
Quality Assurance & Safety: Medicines
Essential Drugs & Medicines Policy

HISTORY OF DRUG CONTROL

- Shanghai Conference (1909)
- Opium Convention (1912)
- Protocols/Conventions 1925, 1931, 1936, 1949, 1948, 1953
- Single Convention on Narcotic Drugs (1961)
- Convention on Psychotropic Substances (1971)
- UN Convention Against Illicit Traffic (1988)

CONTROL MEASURES

- Licensing of handlers
- Export/Import Permits
- Estimate System
- Safe storage
- Prescription drugs
- Record-keeping
- Reporting to the UN
Slide 4

**ROLES OF AGENCIES**

United Nations
- Commission on Narcotic Drugs (CND)
- ECOSOC/General Assembly
- UNDCP (Secretariat)

INCB (International Narcotics Control Board)
- Independent body to ensure successful implementation of the conventions

WHO
- Only specialized agency given a specific role

Slide 5

**ROLE OF WHO**

Updating of the lists (“Schedules”) of Narcotic Drugs & Psychotropic Substances
- Shared mandate with CND
  - WHO recommends, CND decides
- Proposal from Governments (“Parties”) reviewed first by WHO
  - Shared responsibility for successful implementation of the Conventions (WHA resolution)

Slide 6

**DRUGS UNDER CONTROL**

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Slide 7

**ROLES OF INCB**

- **MONITOR compliance**
  - Identify deficiencies & recommend remedial measures
- **PREVENT diversion & ENSURE availability**
  - Import/Export Control
  - Statistical report
  - Estimate/Assessment system

Slide 8

**ESTIMATE SYSTEM (Narcotics)**

Governments to submit to INCB estimated requirements for coming year

INCB to confirm/modify, and publish estimated requirements

Exporting governments to prevent exports in excess of estimates

Slide 9

**STATISTICS**

Governments to submit to INCB statistical reports on production/manufacture, trade and stocks

INCB to analyse supply & demand equation and publish an annual report
Slide 10

**ROLE OF CONVENTIONS**

Conventions themselves do not improve drug availability but define the procedures to follow in ensuring the availability of controlled medicines.

Therefore, manpower and expertise to comply with the conventions is indispensable if Governments are to ensure their availability for medical use.

Slide 11

**ROLE OF INCB IN ENSURING AVAILABILITY**

ADVOCACY - dual objectives of the conventions

LEGAL/TECHNICAL ADVICE - reduce excessive control measures

MONITOR DEVELOPMENTS - Statistics showing improvement or identifying problem areas

Slide 12

**ROLE OF WHO IN ENSURING AVAILABILITY**

ADVOCACY - collaboration with INCB

TECHNICAL ADVICE for

(1) reducing excessive fear of addiction
(2) promoting appropriate use of medication
(3) supporting development of national drug policies and effective supply systems
Slide 1

Dr David Joranson
Senior Scientist
Director of Pain and Policy Studies group
University of Wisconsin Comprehensive Cancer Centre

World Health Organization Collaborating Centre

Slide 2

International Drug Control Policy

Opioid Analgesics…

- Are “indispensable for the relief of pain and suffering” (Single Convention, 1961)
- Have a potential for abuse; controlled as “narcotic drugs”

Slide 3

“Balance” is the Fundamental Principle

- National narcotics control system should ensure availability for medical use, while preventing diversion
- Efforts to control diversion should not interfere with availability of opioid analgesics
The Government Obligation to Ensure Availability of Opioids

*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*”

Survey of National Governments (INCB 1996)

- identify barriers to improving availability of opioids for relief of pain
  - Only 48% of national policies recognize opioids as “indispensable”
  - 59% identify excessively strict laws and regulations as barriers
  - 72% identified concern about addiction as a barrier to improving opioid availability

Highlights of INCB Survey (INCB, 1996)

Top 5 Impediments Ranked by 32 Governments

1. (72%) Concern about addiction to opioids
2. (59%) Insufficient training of HCP about opioids
3. (59%) Restrictive laws over manufacture, prescribing and dispensing
4. (47%) HCP reluctance due to concerns about legal sanctions
5. (38%) HCP reluctance due to concerns about theft or robbery
6. (34%) Burden of regulatory requirements
   (34%)
Slide 7

National Drug Control Policy

Governments have a duty to...

- Ensure that adequate amounts are available to meet national medical needs
- Establish a system of controls that limits use to legitimate medical and scientific purposes; prevent diversion and abuse
- Empower practitioners to provide opioid analgesics in the course of professional practice, allowing them to prescribe, administer, or dispense according to individual medical needs of patients


Slide 8

The distribution system for opioid analgesics is as strong as its weakest link

By: University of Wisconsin Pain & Policy Studies Group/WHO Collaborating Center, 2000

Slide 9

Distribution System-Ensuring Availability

International Narcotics Control Board
- Plan poppy cultivation
- Confirm national estimates

National “Competent Authority”
- Estimate requirements, report statistics
- License products, all entities in distribution chain

Manufacturers and Importers
- Produce/import sufficient amounts
- Distribute promptly to retail level

Hospitals, Pharmacies, Palliative Care
- Obtain license, training
- Purchase adequate supplies
- Dispense according to prescription
- Anticipate needs

Physicians/Nurses
- Assess patients’ pain
- Prescribe, dispense according to need

Patients
Method for Improving Availability of Opioid Analgesics

1. Examination
2. Diagnosis
3. Treatment
4. Follow-up

“Achieving Balance in National Opioids Control Policy”
WHO, 2000

1. Evaluate national narcotics control policy
2. Estimate annual requirements (by Mr. Yoshida)
3. Administer an effective distribution system to the patient
Evaluate National Policy/Admin

- **Guideline 1:** Government should conduct examination for overly restrictive policies
- **Guideline 2:** National policy should recognize opioids as necessary
- **Guideline 3:** National policy should recognize govt’s obligation to ensure availability
- **Guideline 4:**

Evaluate National Policy/Admin

- **Guideline 13:** Establish NCCP with palliative care
- **Guideline 14:** Terminology should not confuse pain relief and drug dependency
- **Guideline 15:** Avoid restricting prescription amount or duration of treatment
- **Guideline 16:** Avoid prescription requirements that restrict physician

Obtaining and Distributing Opioids

- **Guideline 9:** Dialogue with health professionals
- **Guideline 10:** Cooperation between regulators and health professionals
- **Guideline 11:** Eliminate shortage, interruption of supply
- **Guideline 12:** Maximize patient access and prevent abuse and diversion
1. List institutions, programs that provide care for patients with cancer, AIDS (hospitals, outpatient, hospice, home care, elder homes)

2. Is each authorized to prescribe, dispense opioids to their patients?

Slide 17

Diversion of Opioid Analgesics (Global)

Despite the large quantities of substances involved and the large number of transactions no cases involving the diversion of narcotic drugs from licit international trade into the illicit traffic were detected

Slide 18

WHOCC

www.medsch.wisc.edu/painpolicy

- Links to WHO, INCB documents
- Monographs, consumption trends
- Global efforts to achieve “balance”
- Cancer Pain Release
Per Capita Global Consumption of Morphine, 1999

Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 1999
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2002

- Global mean: 5.9 mg
- European Regional mean: 11.1 mg
- Hungary: 7.2 mg
- Poland: 6.5 mg
- Lithuania: 2.2 mg
- Bulgaria: 2.0 mg
- Croatia: 0.7 mg
- Romania did not report for 1999

Per Capita Global Consumption of Pethidine, 1999

Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 1999
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2002

- Global mean: 3.9 mg
- European Regional mean: 4.4 mg
- Hungary: 2.4 mg
- Lithuania: 2.3 mg
- Bulgaria: 3.2 mg
- Poland: 4.7 mg
- Croatia: 0.1 mg
- Romania did not report for 1999

Consumption of Selected Opioid Analgesics, 1999 (mg/capita)

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Per Capita Consumption of Morphine: Europe 1999

Per Capita Consumption of Pethidine: Europe 1999

Status of Adherence to Conventions, Receipt of Statistics, and Estimates

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</table>

Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 1999
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2002
### Estimated requirements for selected opioids, 2001 and 2002 (in grams)

<table>
<thead>
<tr>
<th>Country &amp; Population</th>
<th>Year</th>
<th>Fentanyl</th>
<th>Methadone</th>
<th>Morphine</th>
<th>Oxycodone</th>
<th>Propidone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Romania</td>
<td>2001</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>20,000</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>2002</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>20,000</td>
<td>0</td>
</tr>
<tr>
<td>Croatia</td>
<td>2001</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>2002</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hungarian</td>
<td>2001</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>2002</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Switzerland</td>
<td>2001</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>2002</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Poland</td>
<td>2001</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>2002</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Croatia</td>
<td>2001</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>2002</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Lithuania</td>
<td>2001</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>2002</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>2001</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>2002</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Belgium</td>
<td>2001</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>2002</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Greece</td>
<td>2001</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>2002</td>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Note: Estimated requirements were calculated based on the World Population Prospects and the World Drug Report 2002. The figures represent average daily requirements for the period 2001-2002.

Source: International Narcotics Control Board

Quarterly Supplement, International Narcotics Control Board Estimated World Requirements of Narcotic Drugs for 2001

Advance Copy, International Narcotics Control Board Estimated World Requirements of Narcotic Drugs for 2002

United Nations "Demographic Yearbook," 1999

By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2002
DR CECILIA SEPULVEDA

Slide 1

Dr Cecilia Sepulveda
Coordinator
Programme on Cancer Control
World Health Organization

Slide 2

WHO Cancer Control Programme

Dr. Cecilia Sepulveda,
Coordinator
email: sepulvedac@who.ch
CANCER IS A GLOBAL PROBLEM

Worldwide there are 10 million new cases of cancer and 6 million deaths annually. 60% of deaths occur in developing countries where the majority of cases are diagnosed in advanced stage. The burden will double in 20 years time.

WHO Cancer Control Programme

Main Activities

• Advocacy for policy development,
• Technical Assistance for programme implementation
• Resource Mobilization
• Networking

WHO Cancer Control Programme

Priorities

• Comprehensive Cancer Control Programmes
• Primary prevention (tobacco control, healthy diet, regular exercise)
• Early Detection of Cervical & Breast cancer
• Curable tumors
• Pain Relief & Palliative Care
Slide 6

CANCER Treatment Prevention Palliation Early Detection

National Cancer Control Programme A Systemic and Comprehensive

Slide 7

Comprehensive Cancer Control Programs

Prevention Early detection Treatment Palliative care

Real Desired

CCCP performance Acceptability Accessibility Appropriateness Competence Continuity Effectiveness Efficiency Safety

Slide 8

How to improve the performance of a cancer control program? sound decisions about health policy and management, considering:

Evidence Values Resources

Source: M Gray
Slide 9

Percentage of cancer cases amenable to the different cancer strategies

If dg. & treatment resources are available

If dg. and treatment resources are limited

Slide 10

Every country should develop a national cancer control program which includes pain relief and palliative care as part of the country’s health priorities

Slide 11

WHO’s definition of palliative care 2002

“Palliative care is an approach which improves quality of life of patients and their families facing life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual”
**Slide 12**

**Disease-modifying Therapy**
- Curative, life prolonging, or palliative in intent

**Continuum of Care**
- Presentation diagnosis
- Illness
- Death

**Bereavement**

Source: Adapted from EPEC 1999

**Slide 13**

**Quality of life dimensions in palliative care**
- Physical
- Psychological
- Spiritual
- Social

**Dying and death**
- Bereavement

**Slide 14**

**Quality of life of cancer and HIV/AIDS terminal patients**
- Physical
- Psychological
- Spiritual
- Social
- Dying and death

**Pain**
- Others symptoms
- Functional
- Others
Relief from cancer pain can be achieved in about 90% of patients. The main obstacles to pain relief are:

- insufficient availability of opioid drugs due to regulatory and pricing obstacles,
- ignorance and false beliefs.

**WHO’s Programme on Pain Relief & Palliative Care**

Key Components

- Education/Training
- Health Care/Home Care
- Government Policy
- Drug Availability

**Levels of care in Palliative Care**

- Home based care
- Community care
- primary care center
- Hospital
An Systemic Approach To Palliative Care

Primary health care

Community organizations

Hospital

Home

Management

Slide 19

WHO-PCC Country projects

Ongoing

A Community Health Approach to Palliative Care for HIV/AIDS & Cancer Patients in Africa

Design in process

Improving the efficiency and effectiveness of Cancer Control Programmes in Europe (focus in Central & Eastern Europe)

Slide 20

A COMMUNITY HEALTH APPROACH TO PALLIATIVE CARE IN AFRICA

JOINT PROJECT
WHO-CANCER, HIV/AIDS PROGRAMMES
/BOTSWANA/ETHIOPIA/TANZANIA/
UGANDA/ZIMBABWE

GOAL

Contribute to the improvement of the quality of life of HIV/AIDS and Cancer patients in Southern African countries, by strengthening the development of palliative care programmes with a community health approach.
**Community Health Approach to Palliative Care for HIV/AIDS and Cancer Patients in Africa**

**Participating Countries**

<table>
<thead>
<tr>
<th>Country</th>
<th>Population (Millions)</th>
<th>2000 Life expectancy at birth (years)</th>
<th>1999 Incidence</th>
<th>1999 Mortality</th>
<th>Adult prevalence %</th>
<th>People living with</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethiopia</td>
<td>62.9</td>
<td>42.4</td>
<td>64657</td>
<td>39920</td>
<td>10.63</td>
<td>3,000,000</td>
</tr>
<tr>
<td>Tanzania</td>
<td>35.1</td>
<td>45.0</td>
<td>33409</td>
<td>21002</td>
<td>8.09</td>
<td>1,300,000</td>
</tr>
<tr>
<td>Uganda</td>
<td>23.3</td>
<td>42.1</td>
<td>17058</td>
<td>10504</td>
<td>8.30</td>
<td>820,000</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>12.6</td>
<td>40.4</td>
<td>13030</td>
<td>8648</td>
<td>25.06</td>
<td>1,500,000</td>
</tr>
<tr>
<td>Botswana</td>
<td>1.5</td>
<td>39.4</td>
<td>1168</td>
<td>810</td>
<td>35.80</td>
<td>290,000</td>
</tr>
</tbody>
</table>

**The context of the problem**

- **Social context**
- **HIV/AIDS and Cancer**
  - Prevention
  - Treatment
  - Palliation
- **Other Health Problems**
Slide 24

**Project Objectives**

Where we are?
- Evidence
- Problem
- Resources

Where do we want to be?
- Desired outcome

Develop and implement a plan

Slide 25

**Palliative Care Project in Africa**

**Products**
- A country team developed for the project
- Palliative Care Project proposal from each country
- A network of countries related with the project

**ACTIVITIES**
- Project design
- Team building
- Situation analysis
- Elaboration of plans of action

**PHASE I**
- Oct 01-June 02

**PHASE II**
- 2002-2005

**Resource Mobilization**

Slide 26

“A dream of one individual can be a nice dream

A dream shared by many individuals, is a dream come true”
CROATIA

Slide 1

OPIOID AVAILABILITY IN CROATIA

Marinko Bilušić, MD

Division of Clinical Pharmacology
Clinical Hospital Center Zagreb
CROATIA

Slide 2

COMPETENT AUTHORITY FOR NARCOTICS CONTROL

MINISTRY OF HEALTH
DEPARTMENT OF DRUGS

WHOLESALERS
(10% with license)

PHARMACIES

PHYSICIANS

International Narcotics Controle Board (INCB)

NATIONAL HEALTH INSURANCE AGENCY
MINISTRY OF HEALTH

- QUARTERLY STATISTICS OF IMPORTS AND EXPORTS OF NARCOTIC DRUGS
- ANNUAL ESTIMATES OF REQUIREMENTS OF NARCOTIC DRUGS
  - Quota has been practically constant till 2000
  - In the period 2000-2002 quota substantially increased, except for codeine:

<table>
<thead>
<tr>
<th></th>
<th>2000</th>
<th>2002</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>MORPHINE</td>
<td>12.12</td>
<td>50 kg</td>
<td>+313%</td>
</tr>
<tr>
<td>METHADONE</td>
<td>50</td>
<td>120 kg</td>
<td>+140%</td>
</tr>
<tr>
<td>PETHIDINE</td>
<td>4</td>
<td>12 kg</td>
<td>+200%</td>
</tr>
<tr>
<td>CODEINE</td>
<td>595</td>
<td>500 kg</td>
<td>- 16%</td>
</tr>
</tbody>
</table>

ANNUAL STATISTICS OF PRODUCTION,

OPIOIDS REGISTRATED IN CROATIA

<table>
<thead>
<tr>
<th>DRUG</th>
<th>DOSAGE FORMS</th>
<th>MANUFACT.</th>
<th>MAX AMOUNT PER PRESCR.</th>
</tr>
</thead>
<tbody>
<tr>
<td>MORPHINE chloride</td>
<td>Amp. 10, 20 mg; Caps. 20, 50, 100 mg</td>
<td>Alkaloid, Merck</td>
<td>-</td>
</tr>
<tr>
<td>MORPHINE sulfate continuous</td>
<td>Amp. 100 mg</td>
<td>Glaxo SmithKline</td>
<td>2.0 g</td>
</tr>
<tr>
<td>PETHIDINE</td>
<td>Amp. 100 mg</td>
<td>Aventis Pharma</td>
<td>-</td>
</tr>
<tr>
<td>PENTAZOCINE</td>
<td>Amp. 30 mg; Tbl. 50 mg</td>
<td>Krka</td>
<td>5.0 g</td>
</tr>
<tr>
<td>FENTANYL</td>
<td>Amp. 0.1, 0.5 mg; Patch 2.5, 5, 10 mg</td>
<td>Janssen Cilag</td>
<td>0.05 g</td>
</tr>
<tr>
<td>TRAMADOL</td>
<td>Amp. 50, 100 mg; Caps. 50, 100 mg; Supp. 100 mg</td>
<td>Belupo, Bayer, Mundipharma, Razesitak</td>
<td>Not under narcotic regimen</td>
</tr>
</tbody>
</table>

NATIONAL HEALTH INSURANCE AGENCY

- STATISTIC OF OPIOID CONSUMPTION (data for 2001)

1. PRESCRIPTION

<table>
<thead>
<tr>
<th>DRUG</th>
<th>CONSUMED IN PCS.</th>
</tr>
</thead>
<tbody>
<tr>
<td>MORPHINE SULPHATE</td>
<td>200 000 caps.</td>
</tr>
<tr>
<td>PENTAZOCINE</td>
<td>128 600 caps.</td>
</tr>
<tr>
<td>METHADONE</td>
<td>2 947 000 tblts.</td>
</tr>
<tr>
<td>FENTANYL</td>
<td>7 500 patches*</td>
</tr>
<tr>
<td>CODEINI PHOSPHATE</td>
<td>50 210 tbls.</td>
</tr>
<tr>
<td>TRAMADOL**</td>
<td>7 617 000 caps.</td>
</tr>
</tbody>
</table>
2. HOSPITALS

<table>
<thead>
<tr>
<th>DRUG</th>
<th>CONSUMED IN PCS.</th>
</tr>
</thead>
<tbody>
<tr>
<td>MORPHINE CHLORIDE</td>
<td>19,900 amp.</td>
</tr>
<tr>
<td>MORPHINE SULFATE</td>
<td>560,000 caps.</td>
</tr>
<tr>
<td>PENTAZOCINE</td>
<td>66,000 amp.</td>
</tr>
<tr>
<td>PENTAZOCINE</td>
<td>687,300 caps.</td>
</tr>
<tr>
<td>METHADONE</td>
<td>8,300 amp.</td>
</tr>
<tr>
<td>METHADONE</td>
<td>8,850 mL</td>
</tr>
<tr>
<td>PETHIDINE</td>
<td>164,000 tblts.</td>
</tr>
<tr>
<td>CODEINI PHOSPHATE</td>
<td>105,000 mL</td>
</tr>
<tr>
<td>TRAMADOL</td>
<td>17,500 supp.</td>
</tr>
</tbody>
</table>

Slide 7

PRESCRIBING REQUIREMENTS FOR OPIOID ANALGESICS

**PRESCRIBERS**
- THERE ARE NO STRICT REQUIREMENTS FOR GENERAL PRACTITIONERS TO DECIDE WHEN TO PRESCRIBE OPIOID ANALGESICS.
- IT IS MOST OFTEN A PAIN IN MALIGNANT DISEASE NOT RESPONDING ON OTHER ANALGESICS.
- PARTICULAR LICENSE FOR PHYSICIANS WHO PRESCRIBE OPIOID ANALGESICS IS **NOT REQUIRED**.
- SPECIAL EDUCATION FOR PHYSICIANS WHO PRESCRIBE OPIOID ANALGESICS IS **NOT REQUIRED**.
Slide 9

**PRESCRIBING REQUIREMENTS FOR OPIOID ANALGETICS**

**PRESCRIPTIONS**
- Prescription in duplicate
- Separate book with all patients receiving opioid analgetics (keep by physician who prescribe opioid analgetics)
- Prescription for opioid analgetic is valid for 5 days
- Amount per prescription is limited
- Duration of treatment is not limited

Slide 10

**Conclusions**
- Opioid analgetics are sufficiently available
- There are no particular regulatory restrictions which disable availability
- Lack of “Immediate release” morphine formulation
- Additional education of physicians who prescribe opioid analgetics

Slide 11

Hospice movement and palliative care in Croatia
The development is possible to observe through:

1. organisation of different associations;
2. Symposia, Conferences, Courses, Single lectures;
3. publications;
4. through developing practical activity of home care visits in single families and at the retired people home.

---

**Organisations**

**1994 Croatian Society for hospice / Palliative care**
as part of Croatian Medical Association. The branches were organised at Virovitica 1997 and at Koprivnica 2001. Their members are dealing first of all with professional development / education and promotion of hospice ideas. The Association is member of EAPC and inviting the lecturers from abroad to take part at conferences and sending the member to courses in London, Poland, USA, Budapest and so on.

---

**1997 Society Friends of Hope**

was founded for fund raising purposes at the city level.

**1999 Croatian Society of hospice friends**

was founded to enter into the republic budget.

**2000 Croatian Society for pain treatment**

as the part of Croatian medical Association developed from the former Section for pain treatment of Croatian society for hospice/palliative care into the independent society.
Ad 2. The education/promotion activities

**Symposia on hospice and palliative care**

**Symposia on malignant pain treatment**

**Conferences** (1-2 days) two on "Volunteers in palliative care", on "Psychological support", on "Palliative home care", on "Difficult decisions in palliative care, spirituality and bereavement", "First Zagreb's conference on neurological palliative care". "Nurses conference on palliative care", Virovitica, the first in 2001, should be repeated twice a year.

**Courses**
1997, 3 days for nurses,
1999, 5 weekend's modules for volunteer,
2001, every Tuesday, 3 months, twice a year
2002, bereavement course, every Friday, 2 months

*Postgraduate courses for physicians:*
Differential diagnostics and pain treatment in malignancy, 2000, 2001, 2002, 6 or 3 days,
*Postgraduate course in palliative care for physicians, nurses, social workers* (all in English) 2001.
Hospice movement and palliative care in Croatia

The education/promotion activities

Guest speakers from abroad were:

**England** - Nigel Sykes, Virginia Gumley (London), David Oliver, Ann McMurray, Chris Humphreys, Fliss Murthagh (Kent)

**Canada** - Robert Buckman, John Morgan, Susan Flower-Kerry

**USA** - Kathleen Foley, Nessa Coyle, Joanne Coury

**Italy** - Vittorio Ventafridda

**Germany** - Eberhard Klaschik, Inger Herman

**Holland** - Henk ten Have

**Poland** - Jacek Luczak, Krystyna de Walden-Galuszko

**Czech rep.** - Zdenek Bistricky, Darie Dytrychova

**Bulgaria** - Irena Hadjiiska

**Romania** - Gabriela Ticu

---

**Slide 19**

Many single lectures: Public health school, Faculty of law - Study centre for social work, High nursing school - Department for physical and occupational therapists, People's open university, Senat of Academy of medical sciences, Retired university teachers club, Rottry club, Former A.v. Humboldt fellows club, Military and Hospital order of St. Lazarus of Jerusalem, Zagreb's classical gymnasium society, Croatian society of catholic physicians and so on. Many hospitals or Health homes in Zagreb and in different croatian cities.

---

**Slide 20**

Oncology congresses with special session on palliative care:

Central European Oncology Congress, Opatija 2000; First croatian congress on radiotherapy and oncology, Plitvice 2001 (Terminal oncology patient and General /family practise - the foreign guest David Oliver); First croatian congress of oncology, Zagreb 2001 (the foreign guests Kathleen Foley and Nessa Coyle).
Hospice movement and palliative care in Croatia
The education/promotion activities

Courses/seminars abroad attended by the members of palliative care societies
- Palliative Cancer Care Course, Oxford: 3 students
- Overseas colleagues week, London: 6 students
- Hospice Buffalo, 2001: 5 students
- Puszczykowo:  1999, 2 students; 2000, 4 students; 2001, 1 student
- Budgosze 2001, 1 student
- Schweizer - OSI seminar Ljubljana, 2000: 10 students
- Schweizer - OSI seminar Budapest, 2000: 5 students

Ad 3. Publications
Books edited by “Školska knjiga”
- Anica Jušić i sur: Hospicij i palijativna skrb, 1995 (selected proceedings of 1st Symposium on hospice and palliative care, plus translation of Mary Baines: Drug control of common symptoms)
- Cicely Saunders and Nigel Sykes: Palijativna skrb u završnom stadiju maligne bolesti, 1996 (The management of terminal malignant diseases, 3rd ed.)
- Robert Buckman: Ne znam što reći. Kako pomoći i podržati umiruće, 1996 (I don't know what to say. How to help and support someone who is dying, 7th ed.)

Books and periodicals edited by Croatian society for hospice/palliative care
prepared for print: Cancer pain relief, 2nd ed. and Symptom relief in terminal illness
BILTEN for palliative medicine/care, 10 issues (now 40 pages) plus Supplement No 1, editor Anica Jušić
**Slide 24**

<table>
<thead>
<tr>
<th>Hospice movement and palliative care in Croatia</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Publications</strong></td>
</tr>
<tr>
<td><strong>Chapters in textbooks</strong> by Anica Jušić in</td>
</tr>
<tr>
<td>Psychological medicine, Oncology, Hospice care</td>
</tr>
<tr>
<td>on the International Scene (by C. S. and R.K)</td>
</tr>
<tr>
<td>Prepared for print are: Internal medicine,</td>
</tr>
<tr>
<td>Medical oncology.</td>
</tr>
<tr>
<td>More than 50 articles in different periodicals:</td>
</tr>
<tr>
<td>Liječnički vjesnik (14), Liječničke novine,</td>
</tr>
<tr>
<td>Acta medica croatica, Libri oncologici, Medicus,</td>
</tr>
<tr>
<td>Medix, Pharmaca, Obnovljeni život by Anica Jušić,</td>
</tr>
<tr>
<td>Marijana Persoli-Gudelj, Valentin Pozaić, Desa</td>
</tr>
<tr>
<td>Grubič-Jakupčević and oth.</td>
</tr>
</tbody>
</table>

**Slide 25**

<table>
<thead>
<tr>
<th>Hospice movement and palliative care in Croatia</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ad 4. Practical activities</strong></td>
</tr>
<tr>
<td><strong>Hospice home care visits - during 2001</strong></td>
</tr>
<tr>
<td>18 volunteers (physicians, nurses, physical</td>
</tr>
<tr>
<td>therapist, social worker, other professions)</td>
</tr>
<tr>
<td>have done 771 visits in 57 patients. The visits</td>
</tr>
<tr>
<td>lasted one to four hours, sometimes overnight.</td>
</tr>
<tr>
<td>Telephon consultations with physicians more</td>
</tr>
<tr>
<td>than 1000, and with nurses 691.</td>
</tr>
</tbody>
</table>

**Slide 26**

<table>
<thead>
<tr>
<th>Hospice movement and palliative care in Croatia</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Practical activities</strong></td>
</tr>
<tr>
<td><strong>Retired people home visits - during the 2001,</strong></td>
</tr>
<tr>
<td>with the aim to introduce the palliative care</td>
</tr>
<tr>
<td>there. 23 volunteers were visiting 20 people</td>
</tr>
<tr>
<td>making in all 10.880 visits. The single visit</td>
</tr>
<tr>
<td>lasted half to one hour, the whole visiting</td>
</tr>
<tr>
<td>time was two hours, repeated every Tuesday,</td>
</tr>
<tr>
<td>with supervision meeting afterwards lasting</td>
</tr>
<tr>
<td>for another two hours.</td>
</tr>
</tbody>
</table>
Slide 28

CANCER, PAIN AND PALLIATIVE CARE

What is the estimated prevalence and types of cancer in the country and the prevalence of pain?

- Cancer represents the second cause of death in Romania
- Mortality evolution
  - 1970 - 123,3 / 100000
  - 1980 - 135 / 100000
  - 1989 - 141,6 / 100000
  - 1995 - 165,5 / 100000
  - 2000 - 184,04 / 100000
- Main causes of cancer
  - Lung
  - Gastric
  - Breast
  - Uteri
  - Cervix and prostate
- No official statistics regarding the prevalence of pain

Slide 29

CANCER, PAIN AND PALLIATIVE CARE
Slide 30

**CANCER, PAIN AND PALLIATIVE CARE**

Slide 31

**Is there a national cancer control plan or program?**

- **1980 – THE NATIONAL PROGRAMME ON PREVENTION AND CONTROL OF ONCOLOGIC PATHOLOGY**
- Pain management and palliative care are not specifically addressed in this program.

Slide 32

**Has the government endorsed the WHO method for relief of cancer pain?**

**NO**
Has the government sponsored or endorsed training programs in cancer pain relief and palliative care?

- The government has not sponsored any palliative care or pain training program
- Has endorsed the educational programs developed by the Study Centre for Palliative Care in Brasov by:
  - accrediting it as the National Resource and Training Centre in Romania
  - officially recognising palliative care as a medical subspecialty in Nov 1999
  - offering credits of continuing medical education (CME) for all the palliative care courses run at the Study Centre in Brasov

Has the government sponsored or endorsed training programs in cancer pain relief and palliative care?

- The government has supported the activities of the Romanian Association for the Study of Pain by:
  - accrediting RASP and the Anesthesiology and ICU clinic at the Bucharest University Hospital to organise the National Fellowship on Pain Management (2001)
  - offering CME credits for the courses held (2-3/year) held in different cities and for different medical specialties

Palliative care services in the country

Hospice “Casa Sperantei” in Brasov is the first pioneering palliative care service in Romania

- 4 home care teams in Brasov, Oradea, Cluj, Bucharest;
- 4 pediatric palliative care services: 2 homecare services in Brasov and Ordea for children with cancer and other terminal conditions (i.e. neuromuscular diseases, congenital diseases, etc.)
- 2 services in pediatric oncology hospitals in Tg. Mures and lasti.
- The first free standing Romanian Hospice to be opened in May 2002 in Brasov.
- Beds for symptom control in 5 oncology hospitals: Tg. Mures, Cluj, Bucharest, Birlad, Miercurea Ciuc
Pain Centres:

- University Hospital in Bucharest (1992)
- University of Medicine “Gr. T. Popa” in Iasi (2001).

National associations that have a primary interest in pain relief and/or palliative care

- Romanian Association for the Study of Pain (RASP) NGO funded in 1990 is currently having 325 members - IASP full chapter since 1997
- National Association for Palliative Care founded in 1998
Romanian Association for the Study of Pain


Is organizing CME credit courses every year

Optional course of Algesiology for medical students in Iasi. Pain control is part of the Anesthesiology Course for the students of the 6th year in Bucharest

Organization of the Fellowship on Pain Management with 16 trainers accredited by MFH

Web portal www.arsd.ro

Three publications:
- "Durerea" (6 issues/year),
- Journal of Acute and Chronic Pain (2 issues/year)
- Newsletter (2 issues/year)

National Association for Palliative Care


2 National Lobby conferences in 1999 and 2001. As a result, palliative care was recognized as a medical subspecialty. 10 national trainers were accredited. A consensus was signed by all the parties involved

A Balkan palliative care conference in 2001

Annual newsletter

Web page www.hospice.ro

Credited palliative care courses

Informational leaflets for the patients
CANCER, PAIN AND PALLIATIVE CARE

Slide 43

OPPIOID AVAILABILITY

* Competent authority for narcotics control in the country
  - Romania adhered the 1971 and 1988 International Conventions on the use of narcotics and psychotropic drugs
  - The General Pharmaceutical Direction (GPD) inside the MHF from Romania is the highest national authority in charge with the survey of special substances

Slide 44

OPPIOID AVAILABILITY

* Opioid analgesics are approved in the country
  
* 29 opioid containing commercial products
  - Fentanyl, vials
  - Morphine- vials, immediate and slow release tablets,
  - hidromorphon vials,
  - hidromorphon atropine, vials
  - hidromorphon scopolamine, vials
  - pethidine- vials,
  - methadone- tablets,
  - codeine – tablets,
  - DHC- slow release tablets,
  - tramadol and tramal sustained release,( vials and tablets)
  - pentazocine - vials and tablets
OPIOID AVAILABILITY

**Opioids not available:**
- Dextropropoxiphen
- Oxycodon
- morphine oral solution
- fentanyl patches
- Buprenorphine
- nalbuphine
- preservative free opioid solutions for spinal delivery; long term opioid delivery devices

**OPIOID AVAILABILITY**

**Opioids that are available, are they sufficiently available in the places where cancer patients are treated in the country?**

**NO**

---

**2000 OPIOID USE IN ROMANIA**

![Diagram showing opioid use in Romania in 2000](image-url)
OPIOID LEGISLATION IN ROMANIA

- Legal opioid use - law 72/1969
- MFH statements for its application nb.103/1970
- 2000- law 143 - control of illegal drug use.
- new law regarding opioid precursors in debate in Parliament

Penalties for not respecting law 143

- 3-10 years for individual persons
- 15- 25 years for proved association with the purpose of illegal drug use

OPIOID AVAILABILITY

*The basic requirements for a physician to prescribe an opioid such as morphine*

For the hospitalized patient opioids may be prescribed by any graduated specialist. The prescription is made on a special register; the pharmacist delivers the narcotics through the hospital pharmacy and the medical staff strictly surveys the administration of the drug.
The basic requirements for a physician to prescribe an opioid such as morphine

For the outpatient cancer patient authorization is delivered by the District Public Health Department (DPHD) on the basis of the medical report released by the oncologist physician. The authorization is valid three months. The oncologist physician designed by the DPHD prescribes the narcotics on a receipt with impressed stamp, for max. 15 days. The receipt is delivered on the basis of one of the 4 copies of the authorization and of the receipt with impressed stamp by the hospital pharmacy through the national oncology program is running (part financed by the National Health Insurance House). Prescribing and delivery of the narcotics used in medical purpose is verified by a team made up of representatives of the Ministry of Internal Affairs, MFH and Department of Public Health.
Annex 4

SUMMARY OF COUNTRY REPORTS

BULGARIA

1. Cancer, pain and palliative cares

In Bulgaria a specialized oncological health care system exists from 1952. It includes 13 Regional Oncological Centers and National Oncological Centre. Compulsory registration of malignant neoplasm in Bulgaria has been introduced in the same year, 1952. In the National Oncological Centre, in the Department of Cancer Control and National Cancer Register from all over the country are send “Rapid notification” for each case – newly diagnosed, suspected or dying of malignant neoplasm, and since 1975 for cancer in situ as well. At the National Cancer Register the date are verified and checked up for duplicates and inconsistency between clinical diagnosis, morphological diagnosis and topography of the malignancy.

The total number of registered with oncological diseases to the end of 2000 year – 201 226.

The most frequent locations:
Men: 1. lungs – 21%  
   2. stomach – 9%  
   3. prostate – 8%  
   4. colon – 6%

Women: 1. breast cancer – 25%  
   2. uterus cancer – 9%  
   3. cancer of coli uteri - 8%  
   4. ovary cancer – 6%

By now it doesn’t exist cancer control programme.
In Bulgaria patients receive opioids free of charge, prescribed by their GP and the specialists in dispensaries.

2. Opioid availability

a) The National Service of drug control is a specialized Institution authorized by the Ministry of health to control production, import, export, transport, trade, preservation, report, transfer and use of plants, drugs and medicines included at the Annexes 1,2,3 from the Law of control of drugs and precursors.

The Service helps the Minister of Health to exercise control on the Bulgaria obligations by the international contracts.

The National Drug Council by the name of Bulgarian Government prepares statistical reports and plans assessments for drugs and opioids to the UN International Council of Drug Control.

The chief of National Service of Drugs is MD Fani Emilova Michailova.
The following opioid substances are available in the Republic of Bulgaria.

<table>
<thead>
<tr>
<th>Activ substance</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>patch 100 mcg/h x 5</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>patch 25 mcg/h x 5</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>patch 50 mcg/h x 5</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>patch 75 mcg/h x 5</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>sol.inj. 50mcg/ml - 2ml</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>sol.inj.0.05mg/ml -2mlx10</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>sol.inj.0.05mg/ml-5mlx50</td>
</tr>
<tr>
<td>Morphine</td>
<td>tabl. SR 100mg x 20; x 100</td>
</tr>
<tr>
<td>Morphine</td>
<td>tabl. SR 10mg x 20; x 100</td>
</tr>
<tr>
<td>Morphine</td>
<td>tabl. SR 60mg x 20; x 100</td>
</tr>
<tr>
<td>Morphine</td>
<td>caps.modif.20mg x 20; x60</td>
</tr>
<tr>
<td>Morphine</td>
<td>caps.modif.100mg x 20; x 60</td>
</tr>
<tr>
<td>Morphine</td>
<td>caps.modif.50mg x 20; x 60</td>
</tr>
<tr>
<td>Morphine</td>
<td>tabl.modif.100mg x 60</td>
</tr>
<tr>
<td>Morphine</td>
<td>tabl.modif.10mg x 60</td>
</tr>
<tr>
<td>Morphine</td>
<td>tabl.modif.30 mg x 60</td>
</tr>
<tr>
<td>Morphine</td>
<td>tabl.modif.60mg x 60</td>
</tr>
<tr>
<td>Morphine</td>
<td>sol.inj.10mg/ml - 1ml x 10; x 1</td>
</tr>
<tr>
<td>Morphine</td>
<td>sol.inj.20mg/ml - 1ml x 10; x 1</td>
</tr>
<tr>
<td>Morphine</td>
<td>sol. 10mg/5ml - 100 ml; - 250n</td>
</tr>
<tr>
<td>Morphine</td>
<td>sol. 20 mg/ml - 20ml; - 100 ml</td>
</tr>
<tr>
<td>Morphine</td>
<td>tabl. 10 mg x 60</td>
</tr>
<tr>
<td>Morphine</td>
<td>tabl. 100 mg x 60</td>
</tr>
<tr>
<td>Morphine</td>
<td>tabl. 30 mg x 60</td>
</tr>
<tr>
<td>Morphine</td>
<td>tabl. 60 mg x 60</td>
</tr>
<tr>
<td>Morphine</td>
<td>sol. 10 mg/5 ml x 25</td>
</tr>
<tr>
<td>Morphine</td>
<td>sol. 100 mg/5 ml x 25</td>
</tr>
<tr>
<td>Morphine</td>
<td>sol. 30 mg/5 ml x 25</td>
</tr>
<tr>
<td>Morphine</td>
<td>tabl.10mg x 56</td>
</tr>
<tr>
<td>Morphine</td>
<td>tabl.20mg x 56</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>tabl.modif.10mg x 28; x 56</td>
</tr>
<tr>
<td>Drug</td>
<td>Formulation</td>
</tr>
<tr>
<td>--------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>tbl.modif.20mg x 28; x 56</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>tbl.modif.40mg x 28; x 56</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>tbl.modif.80mg x 28; x 56</td>
</tr>
<tr>
<td>Pethidine</td>
<td>sol.inj.50mg/ml - 2ml x 10; x 5</td>
</tr>
<tr>
<td>Piritramide</td>
<td>sol.inj.7,5mg/ml - 2ml x 5</td>
</tr>
<tr>
<td>Remifentanil</td>
<td>powd.inj.1mg - 3ml x 5</td>
</tr>
<tr>
<td>Remifentanil</td>
<td>powd.inj.2mg - 5ml x 5</td>
</tr>
<tr>
<td>Remifentanil</td>
<td>powd.inj.5mg - 10ml x 5</td>
</tr>
<tr>
<td>Tilidine</td>
<td>drops 100mg/ml - 10ml</td>
</tr>
<tr>
<td>Tramadol</td>
<td>caps.50mg x 10</td>
</tr>
<tr>
<td>Tramadol</td>
<td>sol.inj.100mg - 2ml x 5</td>
</tr>
<tr>
<td>Tramadol</td>
<td>sol.inj./inf.50mg/ml-1ml x100</td>
</tr>
<tr>
<td>Tramadol</td>
<td>sol.inj./inf.50mg/ml-2ml x100</td>
</tr>
<tr>
<td>Tramadol</td>
<td>supp.100mg x 10</td>
</tr>
<tr>
<td>Tramadol</td>
<td>sol.100mg/ml - 10ml</td>
</tr>
<tr>
<td>Tramadol</td>
<td>caps. 50 mg x 10; x 20</td>
</tr>
<tr>
<td>Tramadol</td>
<td>caps. 50 mg x 20</td>
</tr>
<tr>
<td>Tramadol</td>
<td>drops 100 mg/ml - 10ml</td>
</tr>
<tr>
<td>Tramadol</td>
<td>sol. inj. 50 mg/ml - 1ml x 5</td>
</tr>
<tr>
<td>Tramadol</td>
<td>sol. inj. 50 mg/ml - 2ml x 5</td>
</tr>
<tr>
<td>Tramadol</td>
<td>supp.100 mg x 5</td>
</tr>
<tr>
<td>Tramadol</td>
<td>tbl.prolong.100mg x 30</td>
</tr>
<tr>
<td>Tramadol</td>
<td>caps. 50mg x 10; x 30; x 50</td>
</tr>
<tr>
<td>Tramadol</td>
<td>drops 100mg/ml - 20ml</td>
</tr>
<tr>
<td>Tramadol</td>
<td>sol.inj. 50 mg/ml - 2ml x 5</td>
</tr>
<tr>
<td>Tramadol</td>
<td>tbl.film 50mg x 10; x 30</td>
</tr>
<tr>
<td>Tramadol</td>
<td>caps.50mg x 30; x 60</td>
</tr>
<tr>
<td>Tramadol</td>
<td>drops 100mg/ml - 10ml x 1; x 3</td>
</tr>
<tr>
<td>Tramadol</td>
<td>sol.inj.50mg/ml - 2ml x 10</td>
</tr>
<tr>
<td>Tramadol</td>
<td>caps. 50mg x 20</td>
</tr>
<tr>
<td>Tramadol</td>
<td>drops 100mg/ml - 10ml</td>
</tr>
<tr>
<td>Tramadol</td>
<td>sol.inj. 50mg/ml - 1ml</td>
</tr>
<tr>
<td>Tramadol</td>
<td>sol.inj. 50mg/ml - 2ml</td>
</tr>
<tr>
<td>Tramadol</td>
<td>supp.100mg x 5</td>
</tr>
<tr>
<td>Dihydrocodeine</td>
<td>tbl.modif.60mg x 56</td>
</tr>
<tr>
<td>Dihydrocodeine</td>
<td>tbl.modif.90mg x 56</td>
</tr>
<tr>
<td>Pentazocine</td>
<td>sol. inj. 30mg/ml - 1ml x 10</td>
</tr>
<tr>
<td>Pentazocine</td>
<td>sol. inj. 30mg/ml - 2ml x 10</td>
</tr>
</tbody>
</table>
The producer of opioid analgesics in the country is “SOPHARMA” Ltd. It is the only company that produces morphine, petidine and tilidine. Tramadol Lannacher 50 (50 mg.) is produced by the Pharmaceutical company Milve, together with “Lannacher Heilmittel”.

c) The available quantities of opioid analgesics are enough for the needs of onco-patients. The country budget covers all treatment with opioid analgesics.

d) The following are the statistics of consummation at last 5 years:

<table>
<thead>
<tr>
<th></th>
<th>Dihydrocodeine</th>
<th>Fentanyl</th>
<th>Morphine</th>
<th>Pethidine</th>
<th>Tilidine</th>
</tr>
</thead>
<tbody>
<tr>
<td>1995</td>
<td>638 g</td>
<td>58 g</td>
<td>8259 g</td>
<td>17547 g</td>
<td>32241 g</td>
</tr>
<tr>
<td>1996</td>
<td>0 g</td>
<td>42 g</td>
<td>5301 g</td>
<td>18498 g</td>
<td>14495 g</td>
</tr>
<tr>
<td>1997</td>
<td>480 g</td>
<td>74 g</td>
<td>10640 g</td>
<td>22240 g</td>
<td>22258 g</td>
</tr>
<tr>
<td>1998</td>
<td>1350 g</td>
<td>62 g</td>
<td>14492 g</td>
<td>17418 g</td>
<td>38040 g</td>
</tr>
<tr>
<td>1999</td>
<td>2948 g</td>
<td>71 g</td>
<td>16685 g</td>
<td>26383 g</td>
<td>31417 g</td>
</tr>
<tr>
<td>2000</td>
<td>4947 g</td>
<td>69 g</td>
<td>21705 g</td>
<td>26852 g</td>
<td>19545 g</td>
</tr>
</tbody>
</table>

e) At the regional centers, we keep special registers for the doctors who prescribe opioid substances without requirement to have special licenses.

According to the Law, the opioids can be prescribed only on triplicate yellow prescriptions. This prescription has code protection of the stamp, number and note that it is register on special reports.

All medicines that have a registration number from local health centers have permission to prescribe drug products.

f) A basic requirement for prescribing drugs according to Article 14 of Regulation for conditions and prescribing medicine that contains drug substance of MH is “quantities of the medicine that contains drug can not be more than therapeutically dose for 15 days.”

According to Article 11 from the same Regulation, the validity time limit of the prescription is no more than 7 days after the printing the prescription.

The law for the drug control doesn’t provide punishments for doctors that break the law. At the moment are prepared changes in that law.

Every hospital leads statistic with names of patients that take opioid analgesics. The Ministry of Health collects all information for all patients and consummation of opioid analgesics substances.

g) In Bulgaria, the law in this area is comparatively new. The law for control of drugs and precursors is from 1999. The regulations are in force since 2000 and 2001g. In the near future there will be changes in the law so to improve it.
SUMMARY OF COUNTRY REPORTS

HUNGARY

PART 1

Concerning Outline for Country Report my special area is the pain management, therefore I am not responsible the whole subject. In our Country there is a National Cancer Control Program, including rehabilitation and pain relief. Fortunately in Hungary the opioids are widely available:

- oral immediate release morphine tablet (10, 20 mg)
- oral controlled release morphine tablet (10, 30, 60, 100, 200 mg)
- morphine injectable
- methadone tablet, inj.
- pethidine tablet, inj.
- Durogesic patch (25, 50, 75, 100 microg/h)

The above-mentioned opioids are provided free of charge - except immediate release morphine tablet - for cancer patients.

A duplicate prescription is needed and permission has to be obtained from the National Health Institute, which is valid for 3 months, and possible to extend as required. Also are available:

Oxycontin tablet 10, 20, 40 mg, but the patients have to pay for it.

The WHO method for relief of cancer pain has been translated in Hungarian and widely distributed to the general practitioners.

In the last 8 years, more than 300 lectures were given by me, about cancer pain management, every part of Hungary was covered.

PART 2

OPIOID AVAILABILITY/NARCOTICS CONTROL

All the information and data presented here were provided - to the extent that they are available - by the so called “Competent Authority” of Hungary.

Actually the national office, i.e. the “Competent Authority” for narcotics control for the country is the Ministry of Health, Department of Narcotic Drugs. Chief of the Department is Dr. Ferenc Fábián and the chief of the Maindepartment of Pharmacy to which the Department of Narcotic Drugs belongs, is Dr. Attiláné Kelemen. The chief of the Department of Narcotic Drugs is in charge of the office and is in charge of submitting the annual estimate of medical and scientific requirements for narcotic drugs to the International Narcotics Control Board (INCB).
The opioid analgesics approved in Hungary (in different dosage forms) are the following: (see Annex I).

The “narcotic licence” holders, and among them the licensed manufacturers for the needed opioids are: (see Annex II)

All the opioids needed for medical treatments are available in Hungary. They are manufactured in Hungary, or they are imported. Furthermore, in special cases are individually imported preparates, which are not approved (they are no more, or not yet approved) in Hungary.

According to the evidences of the Competent Authority, the opioid analgesics must be sufficiently available in the places where cancer patients are treated in the country. In the last year, no restrictions were made when manufacturers or wholesalers requested import licences for amounts included in the national estimates. In a few cases, modification of estimates was proposed and relatively great quantities of preparations containing opioids and CPS were exported. The Competent Authority prohibited a poppy straw import planned to be made by a manufacturer against the 1961 Single Convention on Narcotic Drugs, without to be affected the availability of opioid analgesics needed for medical treatments in Hungary.

The consumption trends of strong opioid analgesics (e.g. morphine, pethidine, fentanyl) for the last five years presents no substantial changes. Only fentanyl presents a growing amount from year to year as reflected in the reports submitted to the INCB (see the table below):

<table>
<thead>
<tr>
<th>Consumed quantity (grams)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine</td>
</tr>
<tr>
<td>Pethidine</td>
</tr>
<tr>
<td>Fentanyl</td>
</tr>
</tbody>
</table>

The basic requirements for a physician to prescribe an opioid such as morphine are the following:

**Licences required:** A medical doctor does not need any special licence to prescribe an opioid such as morphine. If the patient needs a treatment longer than 10 days, then the prescription must be approved by the local public health authority (not the national “Competent Authority!”).

**Special prescription forms** are not required. The actual national regulation contains detailed rules that must be followed by the medical practitioner who prescribes narcotics, e.g.: prescription must be written manually with ink, signature and stamp on all copies, name of the patient and his/her age, dosage form, active ingredient content of the preparation with numbers and letters, doses that will be taken by the patient, the amount of narcotic substance, proposed duration of the treatment, etc. A special remark it must be made, if the maximum doses recommended are exceeded.

**No special training is required for the medical staff.**

**Other requirements for a physician to prescribe an opioid** such as morphine are - e.g. - the following:
There are fixed maximum amounts that can be prescribed at one time. Greater amounts must be justified and a special note will be applied on the prescription.

There is a time limit of 10 days that a patient can receive opioids or other narcotics without approval from the local public health authority, but no maximum length of time for overall treatment is established.

The period of time, that a prescription for an opioid such as morphine, or other narcotic is valid, theoretically extends to 30 days, as well in the case of other pharmaceutical preparations. Please note that without approval from the local public health authority, only an amount of narcotic drug enough for 10 days can be prescribed. In case of a longer treatment, the maximum length of the approved period is 3 months, but if needed, the approval can be repeated several times. In such treatments extended on longer periods of time, every 10 days a new prescription is issued by the medical doctor, and all prescriptions must be kept in the pharmacy. The approval usually is valid for one single pharmacy.

There are no different legal requirements for prescribing, dispensing or purchasing different dosage forms of the same opioid (e.g. oral, transdermal, injectable). The rules mentioned above that must be followed, are the same for the different dosage forms of the same opioid.

The penalty for a physician or pharmacist who violates the regulations can be 50,000 - 100,000 Ft, or several years of prison. There were only a very few cases, when physicians or pharmacists violated the regulations.

The national regulation does not require reporting names of patients who receive opioid prescriptions, to the government.

The Hungarian national regulation is planned to be substantially modified in the near future. In the year 2002. will be newly regulated the legally used narcotics on a higher - government order - level. Availability of narcotics for suffering people will be facilitated, but with a parallel enhancement of the control measures, to avoid diversion and abuse.

Annex I

OPIOID ANALGESICS APPROVED IN HUNGARY

<table>
<thead>
<tr>
<th>INN</th>
<th>Name</th>
<th>Licence owner</th>
<th>TK</th>
<th>ATC</th>
<th>kábítószer</th>
</tr>
</thead>
<tbody>
<tr>
<td>tramadol</td>
<td>ADAMON SR 50 mg kapszula</td>
<td>Asta Medica</td>
<td>6970</td>
<td>N02AX02</td>
<td>0</td>
</tr>
<tr>
<td>tramadol</td>
<td>ADAMON SR 100 mg kapszula</td>
<td>Asta Medica</td>
<td>6971</td>
<td>N02AX02</td>
<td>0</td>
</tr>
<tr>
<td>tramadol</td>
<td>ADAMON SR 150 mg kapszula</td>
<td>Asta Medica</td>
<td>6972</td>
<td>N02AX02</td>
<td>0</td>
</tr>
<tr>
<td>tramadol</td>
<td>ADAMON SR 200 mg kapszula</td>
<td>Asta Medica</td>
<td>6973</td>
<td>N02AX02</td>
<td>0</td>
</tr>
<tr>
<td>codeine+</td>
<td>ARDINEX tabletta</td>
<td>Abbott</td>
<td>7229</td>
<td>N02AA59</td>
<td>0</td>
</tr>
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<td>Hexal</td>
<td>8180</td>
<td>N02AX02</td>
<td>0</td>
</tr>
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<td>TRAMADOLOR 200 ID retard tabletta</td>
<td>Hexal</td>
<td>8181</td>
<td>N02AX02</td>
<td>0</td>
</tr>
<tr>
<td>tramadol</td>
<td>TRAMADOLOR 50 mg pezsgőtabletta</td>
<td>Hexal</td>
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<td>N02AX02</td>
<td>0</td>
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<tr>
<td>tramadol</td>
<td>TRAMALGIC csepppek</td>
<td>Nycomed</td>
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<td>N02AX02</td>
<td>0</td>
</tr>
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<td>tramadol</td>
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<td>Nycomed</td>
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<td>N02AX02</td>
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<tr>
<td>tramadol</td>
<td>TRAMALGIC kapszula</td>
<td>Nycomed</td>
<td>6565</td>
<td>N02AX02</td>
<td>0</td>
</tr>
</tbody>
</table>
Annex II

“NARCOTIC LICENCE” HOLDERS IN HUNGARY

(not all companies listed are manufacturers, some of them are wholesalers!)

- Bellis Gyógyszerkereskedelmi Rt.
- Béres Gyógyszergyár Rt.
- Biogal Gyógyszerkereskedelmi Rt.
- Chinoin Gyógyszer és Végyszeti termékek Gyára RT.
- Csanád Pharma Kft.
- Euromedic Pharma Gyógyszernagykereskedelmi RT.
- Exractum-Pharma Gyógyszergyártó, Forgalmazó és Szaktanácsadó RT.
- Fűzió-Pharma Gyógyszer-Gyógytermék Nagy- és Külkereskedelmi RT.
- Gyógyszeripari Ellenőrző és Fejlesztő Laboratórium Kft.
- Hajdú Gyógyszerkereskedelmi RT.
- Human Oltóanyagtermelő és Gyógyszergyártó RT.
- Hungaropharma Gyógyszerkereskedelmi RT.
- ICN Magyarország RT.
- Janssen Cilag Division of Johnson & Johnson Kft.
- Medimpex Gyógyszer-nagykereskedelmi RT.
- Medimpex Kereskedelmi RT.
- Naturland Magyarország Kft.
- Pannonmedicina Gyógyszerellátó Vállalat
- Papp Gyógyszer-nagykereskedés
- Parma Produkt Kft.
- Pharmachom Gyógyszernagyker. Kft.
- Phoenix Pharma Gyógyszerkereskedelmi RT.
- Richter Gedeon Végyszeti Gyár Rt.
- Sanovita Gyógyszer-Nagykereskedelmi RT.
SUMMARY OF COUNTRY REPORTS

LITHUANIA

Part 1. Cancer, pain and palliative care

Year 1999: Population of Republic of Lithuania 3,699,600. There were 13,888 new cancer cases, including 2,911 in IV stage of disease, and 7,686 deaths from cancer (Lithuanian Cancer Registry, 2000). Cancer pain statistic is problematic, cancer pain – about 6,000-7,000 cancer patients, severe pain – 2,000-3,000 patients.

The first National cancer control program was prepared in 1991. The other two such programs were prepared for 1996-2000, and 2001-2002. Unfortunately, pain relief, palliative care and opioids availability problems were not included in these programs.

Now the National cancer control and palliative care program for 2003-2010 is in the process of preparation. The coordinator of this program is Prof. Elona Juozaityte, the Head of Department of Oncology, Kaunas University of Medicine.

The Government has not endorsed the WHO method for relief of cancer pain, nor any training programs in cancer pain relief and palliative care. On the other hand, non-governmental organizations have done very big initiatives in this field.

Pain and palliative care services are not developed in Lithuania until now. Only one pain clinic functions since 1994 as the part of Anesthesiology department at the university hospital in Vilnius, the capital of the country. The main obstacles to development of such services are lack of financial support from government and lack of coverage of these services according to the state sickness fund scheme. As a result, more than 50 percent of cancer pain patients are under-treated and most dying patients do not receive adequate care. The situation may improve following the creation of pain and palliative care working group (task force) at the Ministry of Health in 2001.

The Lithuanian Pain Society (LPS), a non-governmental organization, was established in 1998. It functions as the National Chapter of the International Association for the Study of Pain. Main activities of the Society are related to education of health professionals by conferences and teaching seminars on various pain topics. Over 2,200 health professionals were among participants in these meetings in 2001 only. In the period 1998-2001, three annual meetings of the LPS with the international faculty were organized. In 2000-2002 is running the project related to development of Palliative care services in the Baltic countries. This project is the grant of the program of the Open Society Institute in New York. Another two non-governmental organizations taking an active part in the process of palliative care development are: the Lithuanian Palliative Medicine Society, and Lithuanian Oncology Society.
Part 2

In Lithuania, the Competent Authority for narcotics control is the Narcotics Commission of the State Medicines Control Agency at Ministry of Health, established in 1996. The head of this Commission is in charge and is responsible for submitting the annual estimate of medical requirements for narcotic drugs to the INCB.

The following opioid analgesics are registered in Lithuania:
Alfentanyl, Codeine, Dihydrocodeine, Ethylmorphine, Fentanyl, Methadone, Morphine, Pethidine, Piritramide, Remifentanil, Tilidine.

Dosage forms are: solution for injection, oral tablets, oral capsules, oral solution (e.g. Methadone), suppositories, transdermal patches. All together in Lithuania, there are 82 different forms and dosages of enumerated opioid analgesics registered.

In Lithuania, the manufacture of opioids is not performed; one manufacture (AB Endokrininiai preparatai, Kaunas) is licensed for preparation of the solution of morphine for injections from imported substance.

According to our data, there is not any shortage of registered opioid analgesics in Lithuania in places where cancer patients are treated.

<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>COCAINE</td>
<td>640.8 G</td>
<td>325 G</td>
<td>475 G</td>
<td>46.3 G</td>
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<td>CODEINE</td>
<td>708.7 G</td>
<td>883 G</td>
<td>232 G</td>
<td>77 G</td>
<td>160 G</td>
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<tr>
<td>DIHYDROCODEINE</td>
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<td>21 G</td>
<td>5 G</td>
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<tr>
<td>ETHYLMPHINE</td>
<td>752.5 G</td>
<td>24 G</td>
<td>49 G</td>
<td>-</td>
<td>-</td>
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<tr>
<td>FENTANYL</td>
<td>25 G</td>
<td>38 G</td>
<td>36.5 G</td>
<td>40.9 G</td>
<td>45.85 G</td>
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<td>METHADONE</td>
<td>5525 G</td>
<td>4408 G</td>
<td>6540 G</td>
<td>8610 G</td>
<td>7083 G</td>
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<td>MORPHINE</td>
<td>4435.3 G</td>
<td>5357 G</td>
<td>7870 G</td>
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<td>9753 G</td>
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<tr>
<td>PETHIDINE</td>
<td>-</td>
<td>2623 G</td>
<td>5666 G</td>
<td>8521 G</td>
<td>9513 G</td>
</tr>
<tr>
<td>PIRITRAMIDE</td>
<td>1247 G</td>
<td>1819 G</td>
<td>1080 G</td>
<td>383 G</td>
<td>1134 G</td>
</tr>
<tr>
<td>REMIFENTANIL</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>1 G</td>
</tr>
<tr>
<td>TRIMEPERIDIN</td>
<td>2656.6 G</td>
<td>678 G</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

The order of prescription of narcotic drugs in Lithuania is regulated by 27 12 1997 Decree of MoH No705 (Suppl.1). According to this order, every physician in principle can prescribe narcotic for the patient if this patient needs it according to health status. For prescription of narcotics, there are special prescription forms. On one prescription form is allowed only one name of narcotic drug narcotic substance.
Other requirements of writing a prescription for an opioid:

i. It is prohibited to prescribe narcotic drugs for the treatment course longer than 7 days (in the new prescribing order that will appear in the nearest future it is changed: the prescription of transdermal patches is allowed for 30 days); there is given a maximum amount of active substance that can be prescribed at one time.

*For the incurable patients, the amount of narcotics can be prescribed is thrice higher as usually.*
The prescription of narcotic drugs shall be valid for 5 days.
The prescription as for all reimbursed medicines is valid in the regional territorial patient fund pharmacies.
In the new prescribing order that will appear in the nearest future, the prescription of transdermal patches shall be allowed for 30 days.
The penalties for physician who violates prescribing law or regulations are not established; for the pharmacist who violates prescribing law may be cancelled private license and the same can be applied for pharmacy.
National law or regulations do not require reporting the names of patients to any institution.

The last Decree of MoH regarding medical use and availability of opioid analgesics was issued on 23 12 1997 (No705), after them some changes are done on 29 04 1999 (No198) and in the first quarter of 2002 will appear a new Decree of MoH with some changes mentioned above.
SUMMARY OF COUNTRY REPORTS

POLAND

38.6 millions of inhabitants
385.853 deaths a year
deaths from cancer 82.600 (2000)

1. CANCER, PAIN AND PALLIATIVE CARE

a) Prevalence and types of cancer and the prevalence of pain

The number of newly diagnosed patients with cancer is rising each year; 110.000 in 1996, about 125.000 cases in 2000. The leading cancers:

- women: cancer of breast (19%), colorectal (11,2%), cervical (8%), lung (8%), ovarian (6%) and uterine (6%).
- men: lung (29%), colorectal (17,7%), gastric (7%), prostate (5%), bladder (5%) and larynx (5%).

The prevalence of pain—about 150.000 cancer patients.

In only 30% of newly diagnosed patients in Poland is the cancer curable (data from 1996). Among 125.000 of newly diagnosed patients, 42.000 patients had curable and 83.000 had incurable cancer. The total number of patients with incurable cancer consists of above mentioned 83.000 causes and 110.000 patients diagnosed as incurable in last years. There is also in Poland another group of 200.000 patients with curable cancer (survivors). All together there are about 435.000 cancer patients each year in Poland.

Taking into consideration the 70% incidence of pain in incurable cancer and about 30% in actively treated patients, the number of patients with cancer pain in Poland yearly is about 150.000 (all mentioned above data obtained from Wronkowski Z. and all report on Epidemiology of malignant neoplasm published in the project of national programme of cancer 2001)

b) National cancer control plan, program. Program of pain relief and palliative care addressed opioid availability, name of the office and person in charge.

National cancer control program is developing by Polska Unia Onkologii, President Janusz Meder, MD, Roentgena 5,cod 02-718 Warszawa, but not started yet.

There were some programmes, for example on the use of oral morphine in cancer pain, included to the governmental programmes worked out by Center of Oncology in Warszawa, but comprehensive programme of pain relief and palliative care was not developed as a part of National Cancer control programme.
2. CANCER PAIN RELIEF AND PALLIATIVE CARE

Cancer pain relief and palliative care are addressed in the Ministry of Health Programme of developing hospice palliative care in Poland prepared by the National Council for Hospice and Palliative Care, an advisory body for Ministry of Health in 1998. Professor Jacek Luczak, medical director of Palliative Care Department in Poznań, Chairman of National Council for Hospice and Palliative Care together with other members of this Council, founded in 1993, is actively working in improving the availability of opioids and cooperating with the Ministry of Health since 1991.

c) The role of government in endorsement of the WHO method for relief of cancer pain and in sponsoring and endorsing the training programs in cancer pain and palliative care

The Ministry of Health (government) has endorsed the WHO method for relief of cancer pain—in 1994, the handbook; Cancer pain management (Zwalczanie bólów nowotworowych Kujawska Tenner Janina, Luczak Jacek, Kotlinska Aleksandra, Dangel Tomasz), which also includes pharmacotherapy of cancer pain in children. More than 150,000 of copies of this book supplemented by recommendations of Ministry of Health have been distributed free of charge to physicians, nurses and pharmacists. It was followed by translation and publication of WHO brochures: Cancer pain relief and palliative care (1994) and Cancer pain relief and palliative care in children (2001).

The Ministry of Health since 1994 has endorsed and sponsored training programs in cancer pain and palliative care developed by University of Medical Sciences units: Palliative Care Department in Poznan linked with WHO palliative care collaborating center—Sir Michael Sobell House in Oxford, Section of Palliative Medicine in Gdansk, in Bydgoszcz, and recently in Katowice, also in other palliative care and hospice units including Kraków, St-Lasarius Hospice, Elblag St George Hospice, Palliative Medicine out patients and home care unit and stationary hospice in Szczecin, Wroclaw’s Palliative Care out patients and home care unit and Home Care Hospice, Stationary Oncological Hospice and Intensive Pain Therapy ward and Cancer pain clinic at the Oncological Center in Warszawa. All mentioned above units are designated by the Ministry of Health as centers for education and training for doctors specializing in palliative medicine and nurses specializing in palliative care (programmes started in 2000). Other sources of funding include Stefan Batory Foundation, and Open Society Institute (George Soros funding) in NY, Polish Hospices Fund and Polish Association for Palliative Care.
d) **description of availability of pain relief and palliative care services, access to services**

Hospice and palliative care services in Poland in 2000

All together 240 units

<table>
<thead>
<tr>
<th>In bedded units</th>
<th>number</th>
<th>beds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonpublic</td>
<td>22</td>
<td>250</td>
</tr>
<tr>
<td>Public</td>
<td>50</td>
<td>508</td>
</tr>
<tr>
<td>Planning</td>
<td>18</td>
<td>new units with 160 beds</td>
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</table>

3. **PALLIATIVE CARE HOME SERVICES**

There are 149 palliative care home services (64 nonpublic and 85 public), among them 100 outpatients pain and palliative care clinics. There are 8-day care centers and a few hospital supporting teams, 4 lymphoedema clinics and 7 pediatric palliative care home services. There are four academic palliative medicine sections: in Poznań (since 1991), Gdansk (1995) Bydgoszcz (1995), Katowice (2001) and two professors in palliative medicine. Palliative medicine became a physician specialization and palliative care specialization for nurses since 1999.

In 2000, cancer caused 82,600 deaths; more than 55% of pts’ died in hospitals, 7.6% died in hospices, 21% died at home cared for by hospice/palliative care services, about 35-40% of terminally ill cancer patients used hospice/palliative care services.

There are differences in distribution of hospice and palliative care services, less in rural areas, more in central (Warszawa, Bydgoszcz, Lublin) western (Poznan, Gdansk) and south (Kraków, Katowice, Wroclaw) regions of country.

e) **national associations (NG-organisations)**— **promoting pain relief and hospice palliative care**

- The Forum of Independent Hospice Movement (Ogólnopolskie Forum Ruchu Hospicyjnego ORFH), which represents the voluntary hospice movement, was founded in 1991. It is a meeting place for all independent hospices, helps their members to carry out their aims and has representatives in the National Council for Hospice and Palliative Care Services.
- The Polish Association for Palliative Care established in 1989 in Poznan. Branches of the society have been set up in 16 regions of the country. Its activities include: propagating hospice philosophy and fund raising, organizing various forms of education in palliative/hospice care, cooperating with EAPC.
- Polish chapter of IASP chaired by Maciej Hilgier MD, PhD promoting the idea of pain relief, is involved in education on cancer pain management; since 2000 the journal BOL (pain) is edited.
**ECEPT - Eastern and Central Europe Palliative Care Task Force*** is an international organization formed under Polish law, which embraces 120 members from 17 countries all committed to realizing the aims of the Poznan’s Declaration, which include development of national policies, promoting cancer pain relief and palliative care, fundraising and developing educational programmes for medical students, doctors, nurses, and the general public.

There are several initiatives performed by the national consultant in palliative medicine in cooperation with above mentioned organizations in cooperation with Ministry of Health, which promote cancer pain relief and palliative care****
SUMMARY OF COUNTRY REPORTS

ROMANIA

Mortality from cancer represents the second cause of death in Romania and has been having a constantly growing evolution in the latest 30 years from 123.3 \%\text{/0000} in 1970 to 135 \%\text{/0000} in 1980, 141.6 \%\text{/0000} in 1989, 165.5 \%\text{/0000} in 1995 and 184.04 \%\text{/0000} in 2000.
The main diseases within this group are broncho-pulmonary cancer, gastric cancer, breast cancer, uteri, cervix and prostate cancer.
As for age groups, it is noted that there is a constant growth of the frequency of death cases for each 10 years of life.

Since 1980, Romania has a National Program on Cancer, called Programme of Prevention and Control in the Oncologic Pathology, updated on a regular basis.

Description of the programme
The programme objective is to increase the case detections from the advanced stages III and IV to initially curable stages (0, I, II) and to update the normative acts concerning the evidence of cases and the circulation of information on the oncologic pathology.

Purpose
To improve the survival of persons with oncologic affections

Objectives
To increase the number of the cases diagnosed in stage I and II;
To update the National Cancer Register;
To update and complete the existing legislation;
Screening programmes for other cancers with significant incidence.

Coordinating departments. General department of medical assistance, Programmes and Medical Integrated Services

Institutions responsible for the implementation of the programme:
The Oncology Institute from Bucharest and the Oncology Institute from Cluj
District Public Health departments (41) through the Oncologic Department Centres Cluj, Dolj, Iasi, Tirgu Mures, Timis and Bucharest.
Oncology departments from territorial hospitals

Financing of the programme.
State budget, donations and other sources, according to the law

Indicators.
Incidence of the cases diagnosed on stages;
Updated and improved National Cancer Register.
Physical indicators
Number of persons put through screening (cervix cancer and mammary gland)
Number of cases in evidence in the National Cancer Register

Palliative care

In the classified list of specialties of the Ministry of Health and Family, the over specialization “palliative care” has been introduced for family physicians or for other medical specialties. Both during the University education and during the oncology specialty training “Diagnosis and treatment of pain” represents a fundamental chapter.

In every oncologic department in the hospitals, there are a number of beds for the symptomatic treatment of pain. Every medical unit has a specialists commission that establishes the diagnosis and the therapeutic indications, including the symptomatic treatment and pain treatment. Usually, the already registered patients who, because of the evolution of their disease, need treatment, are hospitalized in order to test their medication, the therapeutic response and the secondary effects, after which they may be discharged and follow the treatment at home under the strict supervision of the family physicians.

At the level of the Ministry of Health and Family, there is a Commission of Oncology that came with proposals for the improvement of medical oncologic care and palliative care.

Opioid analgesics

The authorization of prescription and delivery of narcotics is delivered by the District Public Health Departments (DPHD) and the Public Health Department of the Municipality of Bucharest on the basis of the medical report made up by the oncologist physician and of the medical certificate delivered by the medical unity (hospital). The authorization is valid for three months. On the basis of this authorization, the oncologist physician designed by the DPHD prescribes the narcotics on a receipt with impressed stamp, for a period of 10-14 days.

The receipt is delivered on the basis of one of the 4 copies of the authorization and of the receipt with impressed stamp by the hospital pharmacy through which the national oncology programme is running (the part financed by the National Health Insurance House).

Prescribing and delivery of the narcotics used in medical purpose is verified by a team made up of representatives of the Ministry of Interior and Ministry of Health and Family and the Department of Public Health.

Within the hospitals, the prescription of opioids is made on a special register, the pharmacist through the hospital pharmacy makes delivery of the narcotics, and the medical staff strictly surveys the administration of the treatment. The maxim quantity per day is presented in the Romanian Pharmacopoeia.
Cancer, pain and palliative care

Are pain relief and palliative care addressed? 
Not in the National cancer control program

Has the government endorsed the WHO method for relief of cancer pain? 
No

Has the government sponsored or endorsed training programs in cancer pain relief and palliative care? 
The government has not sponsored any palliative care training programs but has endorsed the educational programs developed by the Study Centre for Palliative Care in Brasov by:
- accrediting it as the National Resource and Training Centre in Romania
- officially recognising palliative care as a medical subspecialty in Nov 1999
- offering credits of continuing medical education for all the palliative care courses run at the Study Centre in Brasov

Describe in brief terms the availability of pain relief and palliative care services in the country and comment on the extent to which the needy population has access to such services

Hospice "Casa Sperantei" in Brasov is the first pioneering palliative care service in Romania and the one that is leading the palliative care movement

Palliative Care services today:
- 4 home care teams in Brasov, Oradea, Cluj, Bucharest. All are NGO’s offering palliative care for cancer patients. They are charities, with the main part of their budget being raised outside Romania, and a small part of it locally through fund-raising events in the community
- 4 paediatric palliative care services: 2 homecare services in Brasov and Oradea for children with cancer and other terminal conditions like neuromuscular diseases, congenital diseases, etc.
- 2 services in Paediatric oncological hospitals in Tg Mures and Iasi
- the first free standing Romanian Hospice to be opened in May 2002 in Brasov. Will be a centre of excellence of clinical practice and an educational unit for practical placements associated with the National Resource and Training Centre in Brasov
- Beds for symptom control in 5 oncological hospitals Tg Mures, Cluj, Bucuresti, Birlad, Miercurea Ciuc, and in a general hospital in Campina
- Day -centre in Brasov

There is just a small coverage of the needy population and an active involvement of the national medical authorities would be necessary in order to speed up the development of these services. Including palliative care services in the package of services paid by the National Insurance House will be a major step forward.
Identify national associations (non-governmental organisations) that have a primary interest in pain relief and/or palliative care, and mention their relevant activities.

The Nation Association for Palliative Care founded in 1998 has organised:

- 2 National Lobby conferences in 1999 and 2001. As a result, palliative care was recognised as a medical subspecialty, 10 national trainers in palliative care were accredited. A consensus as signed by all the parties involved.
- Balkan palliative care conference in 2001
- Annual newsletter

The Romanian association for the Study of Pain (vezi Dr Elena Copaciu)

**Opioid availability**

What opioid analgesics are approved in the country, and in what dosage forms?

- CODEIN tablets
- DIHYDROCODEINE slow released tablets
- TRAMAL tablets, vials, suppositories, solution
- PENTAZOCINE tablets, vials
- Morphine immediate and slow released tablets, vials
- Hidromorphone vials
- Methadone tablets
- Pethidine vials

List all licensed manufacturers for the needed opioids.

What opioids are not available?

- Dextropropoxifene
- Oxycodon
- Morphine solution
- Fentanyl patches
- Buprenorphine

For those opioids that are available, are they sufficiently available in the places where cancer patients are treated in the country, i.e., all hospitals with cancer units, hospices, pain clinics, palliative care programs, etc.?

NO

What are the basic requirements for a physician to prescribe an opioid such as morphine?

What licenses are required?

Are special prescription forms required?

Is special training required?

Only oncologists specially appointed working in out patients clinics are allowed to prescribe strong opioids for use outside hospitals. They write an authorisation in 3 copies that includes the
name of the opioid, the dosage per tablet/vial and the total daily dose. One of these copies goes to the GP who one a special prescription copies the recommended dose for 15 days not being allowed to make any changes. With this special prescription and the second copy the family goes to a special appointed pharmacy and takes the drugs.

What are the other requirements for writing a prescription for an opioid such as morphine? See above

Is there a maximum amount that can be prescribed at one time, for example a limitation on the number of dosage units or number of days? Yes just for 15 days and in some parts of the country the maximum dose per day is 60mg of morphine.

Is there a maximum length of time that a patient can receive opioids?
No

What is the period of time that a prescription for an opioid such as morphine is valid?
3 months for the authorisation.

What, if any, changes have been made in laws, regulations or commercialisation to improve the medical use and availability of opioid analgesics?
No changes
Annex 5

COUNTRY ACTION PACKET
(This packet contains all the materials you will need to complete these steps)

Country: ____________________________
Coordinator name: ______________________ (see Step 1)

Step (1) Select a Coordinator by filling in the blank above. The role of your country coordinator is to:

(a) guide your country group’s discussion to formulate a final Action Plan,
(b) review the necessary steps and keep track of the time available to complete the tasks,
(c) present your country group’s Action Plan to all workshop participants on the last day,
(d) submit your country group’s Action Plan to the meeting sponsors, and
(e) designate, if needed, another person in your country group to assist with note-taking, etc.

Step (2) Complete the self-assessment of your country’s national policy using the checklist. Achieve consensus in your group on each item, if possible. In the case of differing opinions, proceed to the next item and return later. Please avoid using “information not available” if possible.

Step (3) Identify the requirements for prescribing opioid analgesics by completing the matrix.

Step (4) Identify each item on the checklist (from Step 2) that is a problem (“No” responses for items 1-13; “Yes” responses for items 14-16) using the provided form. Briefly elaborate on each problem and its impact on adequate opioid availability, and list the reasons for or causes of the problem. Then prioritize the top 3-5 needs that present the most severe barriers to opioid availability and those with the most potential for positive impact and early success (less than one year).

Step (5) Prepare the Action Plan using the form provided. For each of the top 3-5 priority items that have been listed in Step 4, (a) state the objective (re-state the barrier as a desired outcome); (b) discuss, decide and then list the action steps needed to achieve the objective; (c) list who has responsibility for each step; (d) provide a timeline for each step; (e) identify needs for technical assistance, and who should provide it; and (f) list additional resources that are needed to achieve the objective.

Step (6) Identify the mechanism needed in your country to actively coordinate, foster cooperative efforts, monitor and communicate to achieve the objectives, using the form provided. Is there an existing governmental body able to manage this? Is there a need to establish a working committee or task force? Who should be members, both governmental and non-governmental?
Step (7) Decide who will report the workshop results in your country and to which persons and organizations, using the form provided.

Step (8) Decide who in your country group will be the follow-up contact person. The role of the follow-up contact person is to maintain central contact with country members following the workshop, and to liaise with the meeting sponsors and those who may provide technical follow-up assistance to the country group.

Step 2

Complete the self-assessment of your country’s national policy using this checklist. Achieve consensus in your group on each item, if possible. In the case of differing opinions, proceed to the next item and return later. Please avoid using “information not available” if possible.

Governments or other interested groups, including health care professionals, may use the following checklist to guide their analysis of national drug control policies.

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? 1

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

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
**Step 3**

Identify the requirements for prescribing opioid analgesics.

**REQUIREMENTS FOR PRESCRIBING OPIOID ANALGESICS**
*(Draft – preliminary information)*

<table>
<thead>
<tr>
<th>Country</th>
<th>Does national policy require the use of a special prescription form?</th>
<th>Does the physician or institution have to pay for the special prescription forms?</th>
<th>Does national policy establish a validity period for opioid prescriptions? If so, what is the period?</th>
<th>Does national policy establish a maximum amount that can be prescribed at one time? If so, what amount?</th>
<th>Does national policy limit the length of time that a patient may be treated with an opioid? If so, how long?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulgaria</td>
<td>Yes, triplicate form for opioids</td>
<td>Yes, 7 days</td>
<td>Yes, 15 days therapeutic dose</td>
<td>NO</td>
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<td>Croatia</td>
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<td>Hungary</td>
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<tr>
<td>Lithuania</td>
<td>Yes, for narcotics</td>
<td>Yes, 5 days</td>
<td>Yes, 7 days per prescription (30 days for fentanyl patch)</td>
<td>7 days?</td>
<td></td>
</tr>
<tr>
<td>Poland</td>
<td>Yes, duplicate form for opioids</td>
<td>Yes, 30 days</td>
<td>Yes, 10 times the single maximum dose as specified in the Polish Pharmacopoeia</td>
<td>NO</td>
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</tr>
<tr>
<td>Romania</td>
<td>Yes, triplicate form for opioids</td>
<td>Yes, 3 months</td>
<td>Yes, 15 days. In some parts of the country, maximum daily dose of morphine is 60 mg</td>
<td>NO</td>
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</tr>
</tbody>
</table>
Step 4

Identify each item on the checklist (from Step 2) that is a problem (“No” responses for items 1-13; “Yes” responses for items 14-16). Briefly elaborate on each problem and its impact on adequate opioid availability, and list the reasons for or causes of the problem. Then prioritize the top 3-5 needs that present the most severe barriers to opioid availability and those with the most potential for positive impact and early success (less than one year).

<table>
<thead>
<tr>
<th>Write the short title of each item that is a problem</th>
<th>Briefly elaborate on the situation</th>
<th>Describe how the situation affects opioid availability</th>
<th>List the reasons for the situation</th>
<th>List the 3-5 highest priorities for action</th>
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Write the short title of each item that is a problem
Briefly elaborate on the situation
Describe how the situation affects opioid availability
List the reasons for the situation
List the 3-5 highest priorities for action
<table>
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<th></th>
<th>Write the short title of each</th>
<th>Briefly elaborate on the</th>
<th>Describe how the</th>
<th>List the reasons for</th>
<th>List the 3-5 highest</th>
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<td>item that is a problem</td>
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Step 5

Country Action Plan

Prepare the Action Plan. For each of the top 3-5 priority items that have been listed in Step 4, (a) state the objective (re-state the barrier as a desired outcome); (b) discuss, decide, and then list the action steps needed to achieve the objective; (c) list who has responsibility for each step; (d) provide a timeline for each step; (e) identify needs for technical assistance, and who should provide it; and (f) list additional resources that are needed to achieve the objective.

<table>
<thead>
<tr>
<th>State the objective</th>
<th>What action steps are needed to reach the objective?</th>
<th>Who is or should be responsible for taking action?</th>
<th>Timeline, date of completion</th>
<th>What technical assistance is needed, and from whom?</th>
<th>What resources are needed to complete the objective?</th>
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**Step 6**

Identify the mechanism needed in your country to actively coordinate, foster cooperative efforts, monitor and communicate to achieve the objectives. Is there an existing governmental body able to manage this? Is there a need to establish a working committee or task force? Who should be members, both governmental and non-governmental?

**Mechanism needed:**

________________________________________________________

________________________________________________________

________________________________________________________

**Members:**

________________________________________________________

________________________________________________________

________________________________________________________

**Step 7**

Decide who will report the workshop results in your country, and to which persons and organizations.

________________________________________________________

________________________________________________________

________________________________________________________

**Step 8**
Decide who in your country group will be the follow-up contact person. The role of the follow-up contact person is to maintain central contact with country members following the workshop, and to liaise with the meeting sponsors and those who may provide technical follow-up assistance to the country group.

Contact person:______________________________
Annex 6

Completed country action packets

Country: BULGARIA

Resource Person: Tokuo Yoshida

Coordinator: Elena Milanova

WHO GUIDELINES SELF-ASSESSMENT 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

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

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

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? Yes

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

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

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

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

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

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**

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**

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

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

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**

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**

13a. Has the government established a national cancer control programme to which it allocates health care resources? **No**

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? **Info 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? **No**

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

16. Are there prescription requirements in national drug control policy that may unduly restrict physician and patient access to pain relief? **No**

**COUNTRY REQUIREMENTS FOR PRESCRIBING OPIOID ANALGESICS**

1) Does national policy require the use of a special prescription form? **Yes, triplicate form for opioids.**

2) Does the physician or institution have to pay for the special prescription form? **No**

3) Does national policy establish a validity period for opioid prescriptions? **Yes**

   If so, what is the period? **7 days**
4) Does national policy establish a maximum amount that can be prescribed at one time? **Yes**
   If so, what amount? **15 days therapeutic dose**
5) Does national policy limit the length of time that a patient may be treated with an opioid? **No**
   If so, how long? 

**COUNTRY ACTION PLAN**

**Objective 1: Develop the National Cancer Control Program (NCCP)**

a. **Action Step:** Prepare a report to the Minister of Health on the conclusions at the workshop emphasizing the need for National Cancer Control Program

   **Who is responsible?** Elena Milanova (NDC), Fani Michailova (NSDC)

   **Timeline:** March 15, 2002

b. **Action Step:** To establish a working group authorized by the Minister of Health to develop the NCCP

   **Who is responsible?** Minister of Health

   **Timeline:** ???

c. **Action Step:** To identify expert resources – technical and financial – and to develop collaboration network between them.

   **Who is responsible?** ???

   **Timeline:** ???

**Objective 2: To evaluate the impact of the “15 days” prescription and modify a regulation, as appropriate**

a. **Action Step:** To prepare a letter to the Minister of Health to establish an expert group of oncologists

   **Who is responsible?** Fani Michailova (NSDC)

   **Timeline:** March 15, 2002

b. **Action Step:** The expert group will formulate recommendations on this matter

   **Timeline:** By the end of April 2002

c. **Action Step:** The recommendation should be sent to the working group responsible for drafting the new regulation

   **Who is responsible?** ???
Timeline: By the end of April 2002

Identify the mechanism needed in your country to actively coordinate, foster cooperative efforts, monitor and communicate to achieve the objectives. Is there an existing governmental body able to manage this? Is there a need to establish a working committee or task force? Who should be members, both governmental and non-governmental?

Mechanism needed: National Drug Council/The Secretariat will supervise the process of implementation of the objectives

Members: NDC/Secretariat/ - Elena Milanova

Decide who will report the workshop results in your country, and to which persons and organizations.

Eilia Lolova
Elena Milanova
Fani Michailova

Decide who in your country group will be the follow-up contact person. The role of the follow-up contact person is to maintain central contact with country members following the workshop, and to liaise with the meeting sponsors and those who may provide technical follow-up assistance to the country group.

Elena Milanova

Country: CROATIA

Resource Person: Harald Breivik

Coordinator: Marinko Bilusic

WHO GUIDELINES SELF-ASSESSMENT 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? No

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

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
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? **Yes**

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

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**

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

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

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

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**

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**

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**

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

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

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**

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**

13a. Has the government established a *national cancer control programme* to which it allocates health care resources? **No**
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? **No**

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? **No**

15. Are there provisions in national drug control policy that restrict the amount of drug prescribed or the duration of treatment? **No**

16. Are there prescription requirements in national drug control policy that may unduly restrict physician and patient access to pain relief? **No**

COUNTRY REQUIREMENTS FOR PRESCRIBING OPIOID ANALGESICS

1) Does national policy require the use of a special prescription form? **Yes, duplicate for opioids, but not special?**
2) Does the physician or institution have to pay for the special prescription form? **No**
3) Does national policy establish a validity period for opioid prescriptions? **Yes**
   If so, what is the period? **5 days**
4) Does national policy establish a maximum amount that can be prescribed at one time? **Yes**
   If so, what amount? **2 g morphine, 0.05 g fentanyl patch, 0.2 g methadone per prescription**
5) Does national policy limit the length of time that a patient may be treated with an opioid? **No**

COUNTRY ACTION PLAN

**Objective 1: Improve education in pain treatment**

a. **Action Step:** Include pain treatment education in the graduate and postgraduate education
   
   **Who is responsible?** Scientific board
   
   **Timeline:** 1-2 years
b. **Action Step:** Various courses, seminars, workshops
   
   **Who is responsible?** Societies
   
   **Timeline:** Ongoing
   
   **Technical assistance:** Funds, technical assistance from WHO, government, pharmaceutical industry
c. **Action Step:** Written material
   
   **Who is responsible?** WHO, societies
   
   **Timeline:** 6-12 months
Technical assistance: Funds, technical assistance from WHO, government, pharmaceutical industry

Objective 2: Establish a National Cancer Control Board (NCCB)

a. Action Step: Evaluation of experience of WHO and the countries that have already established the NCCB. Collecting information from WHO etc. according to NCCB and influence governmental authorities.
Who is responsible? Societies, governmental institutions

Timeline: 1 year

Technical assistance: WHO, funds, technical assistance, expert opinions, various countries

b. Action Step: Start the process of creating the core of the board

Who is responsible? Societies, governmental institutions

Timeline: 2 years

c. Action Step: Develop the functioning of the board

Who is responsible? Societies, governmental institutions

Timeline: Continuing

Identify the mechanism needed in your country to actively coordinate, foster cooperative efforts, monitor and communicate to achieve the objectives. Is there an existing governmental body able to manage this? Is there a need to establish a working committee or task force? Who should be members, both governmental and non-governmental?

Mechanism needed: Establish a governmental board (a person) who will manage the implementation and coordinate all efforts to achieve the objectives.

Members: Members who will participate in the achievement include all societies already involved in these activities, universities, governmental members.

Decide who will report the workshop results in your country, and to which persons and organizations.

Minister of Health; Director of National Health Insurance; Dean of Medical School; Rectors of Universities, Societies for Pain Treatment, palliative care, clinical pharmacology, oncology, haematology; Croatian Medical Society; Croatian Medical Chamber; Pharmaceutical Society; Anesthesiological Society

Decide who in your country group will be the follow-up contact person. The role of the follow-up contact person is to maintain central contact with country members following the
workshop, and to liaise with the meeting sponsors and those who may provide technical follow-up assistance to the country group.

Mia Balija
Country: HUNGARY

Resource Person: Friedemann Nauck

Coordinator: Erzsébet Podmaniczky

WHO GUIDELINES SELF-ASSESSMENT 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? **No**

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**

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? **No**

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? **Yes**

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

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**

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

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

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

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**

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**
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

9b. Has the government identified and addressed concerns of health care professionals about being investigated for prescribing opioids? No, there were none

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

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

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

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

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? No

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? No

15. Are there provisions in national drug control policy that restrict the amount of drug prescribed or the duration of treatment? No

16. Are there prescription requirements in national drug control policy that may unduly restrict physician and patient access to pain relief? No

COUNTRY REQUIREMENTS FOR PRESCRIBING OPIOID ANALGESICS

1) Does national policy require the use of a special prescription form? No, it requires a duplicate of the usual prescription form

2) Does the physician or institution have to pay for the special prescription form? No

3) Does national policy establish a validity period for opioid prescriptions? Yes
   
   If so, what is the period? 30 days

4) Does national policy establish a maximum amount that can be prescribed at one time? No
   
   If so, what amount? 

5) Does national policy limit the length of time that a patient may be treated with an opioid? No
   
   If so, how long? 

COUNTRY ACTION PLAN

Objective 1: Guideline 13b. Include the WHO Analgesic Method for cancer pain relief in medical, pharmacy, and nursing curriculum.

a. **Action Step:** Influence initiatives on taking part in the proper course.

   **Who is responsible?** Hungarian Medical Association (HMA)

   **Timeline:** near future

   **Technical assistance:** proper course materials.

   **Resources:** teach the teachers
Objective 2: Guideline 16. Remove barriers in the prescriptions for every day general practice

a. **Action Step:** Teaching and educations programs.

  **Who is responsible?** ???

  **Timeline:** ??

**Identify the mechanism needed in your country to actively coordinate, foster cooperative efforts, monitor and communicate to achieve the objectives. Is there an existing governmental body able to manage this? Is there a need to establish a working committee or task force? Who should be members, both governmental and non-governmental?**

**Mechanism needed:** There are no major formal barriers in the availability of opioid analgesics in Hungary. But there is an absolute need for the continuous education of health care providers in the field of pain relief, in the form of: successive postgraduate courses, written materials (books, leaflets, guidelines) for health personnel, patient and public education in the form of descriptive booklets.

**Members:** There is no governmental body but the task is delegated to the Hungarian Medical Association (HMA). Proposed members of the task force: HMA, ETI (Institution responsible for the continuing education of health professionals), Hungarian Hospice Association, Hungarian Anticancer League, other NGO’s.

**Decide who will report the workshop results in your country, and to which persons and organizations.**

Ferenc Fábián to the Ministry of Health
Erzsébet Podmaniczky to the National Institute of Oncology and to the HMA
Katalin Muszbek to the NGO’s
Lászlo Vimlai to the Medical Universities

**Decide who in your country group will be the follow-up contact person. The role of the follow-up contact person is to maintain central contact with country members following the workshop, and to liaise with the meeting sponsors and those who may provide technical follow-up assistance to the country group.**

Ferenc Fábián
WHO GUIDELINES SELF-ASSESSMENT 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? **No**

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**

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**

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? **Yes**

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

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**

5b. Has the government *critically examined* its method for assessing medical needs for narcotic drugs, as requested by the INCB? **No**

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

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

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**

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**
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**

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

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

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**

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**

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

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? **No**

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? **No**

15. Are there provisions in national drug control policy that restrict the amount of drug prescribed or the duration of treatment? **No**

16. Are there prescription requirements in national drug control policy that may unduly restrict physician and patient access to pain relief? **No**

**COUNTRY REQUIREMENTS FOR PRESCRIBING OPIOID ANALGESICS**

1) Does national policy require the use of a special prescription form? **Yes, triplicate for reimbursed narcotics**

2) Does the physician or institution have to pay for the special prescription form? **No**

3) Does national policy establish a validity period for opioid prescriptions? **Yes**  
   If so, what is the period? **5 days**

4) Does national policy establish a maximum amount that can be prescribed at one time? **Yes**  
   If so, what amount? **7 days per prescription (30 days for fentanyl patch)**

5) Does national policy limit the length of time that a patient may be treated with an opioid? **No**  
   If so, how long? **____________________**
COUNTRY ACTION PLAN

Objective 1: To include a provision in the Ministry of Health decrees to examine whether there are overly restrictive provisions.

a. **Action Step:** Issue new Ministry of Health decree

   **Who is responsible?** State Medicines Control Agency and Dept. of Pharmacy at Ministry of Health.

   **Timeline:** 2002-2003

   **Technical assistance:** May need to discuss the possibility of a longer maximum prescription period, from 7 days, to perhaps 2 weeks.

   **Resources:** Human resources
Objective 2: To encourage the government to critically examine its method for assessing medical needs for narcotic drugs.

a. **Action Step:** Develop or adapt a questionnaire to assess its estimation method.

   **Who is responsible?** Narcotics Commission of State Medicines Control Agency.

   **Timeline:** 2004

   **Technical assistance:** INCB

   **Resources:** Human resources, materials to print, copy, and send.

Objective 3: To ensure that the government supports the WHO Analgesic Method by continuing education programs and inclusion in practitioner curriculum.

a. **Action Step:** Learn more about other nations’ experiences.

   **Who is responsible?** Ministry of Health Group on Pain and Palliative Care

   **Timeline:** 2004

   **Technical assistance:** IASP, WHO Cancer Programme

   **Resources:** Human resources, technical support

Objective 4: To begin a new Public Education Initiative

a. **Action Step:** Develop a message for dissemination for mass media.

   **Who is responsible?** Ministry of Health would give a mandate to the Public Health Information Center.

   **Timeline:** 2005

   **Technical assistance:** WHO-Geneva, or WHOCC. Also, local public health centers.

   **Resources:** Money (from OSI?), various programs or foundations.

Objective 5: To include a provision in the law (Preamble) that narcotics are absolutely necessary

a. **Action Step:** Amend the national law of narcotic and psychotropic substances control.

   **Who is responsible?** State Medicines Control Agency – Department of Pharmacy

   **Timeline:** 2004

   **Resources:** Human resources
Identify the mechanism needed in your country to actively coordinate, foster cooperative efforts, monitor and communicate to achieve the objectives. Is there an existing governmental body able to manage this? Is there a need to establish a working committee or task force? Who should be members, both governmental and non-governmental?

**Mechanism needed:** Strategy Group of Pain and Palliative Care of the Ministry of Health - was created in 2001.

**Members:** Representatives of NGO’s, chief specialists of the Ministry of Health, university health professionals.

**Decide who will report the workshop results in your country, and to which persons and organizations.**

Anzelika Balciuniene at Ministry of Health  
Vytautas Basys at State Medicines Control Agency  
Dalia Normantiene at Pharmaceutical Activities

**Decide who in your country group will be the follow-up contact person. The role of the follow-up contact person is to maintain central contact with country members following the workshop, and to liaise with the meeting sponsors and those who may provide technical follow-up assistance to the country group.**

Anzelika Balciuniene  
Vytautas Basys
Country: POLAND  
Resource Person: Mary Callaway  
Coordinator: Jacek Luczak

WHO GUIDELINES SELF-ASSESSMENT 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

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

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

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? Yes

4b. Are adequate personnel (employees) available for the implementation of this responsibility? No

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? No

5b. Has the government critically examined its method for assessing medical needs for narcotic drugs, as requested by the INCB? No

5c. Has the government established a satisfactory system to collect information about medical need for opioid analgesics from relevant facilities? No

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

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

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
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? **No**

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

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

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**

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**

13a. Has the government established a national cancer control programme to which it allocates health care resources? **No, developing**

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**

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**

15. Are there provisions in national drug control policy that restrict the amount of drug prescribed or the duration of treatment? **No**

16. Are there prescription requirements in national drug control policy that may unduly restrict physician and patient access to pain relief? **No**

**COUNTRY REQUIREMENTS FOR PRESCRIBING OPIOID ANALGESICS**

1) Does national policy require the use of a special prescription form? **Yes, duplicate form for opioids**

2) Does the physician or institution have to pay for the special prescription form? **Doctors, no; institutions, yes**

3) Does national policy establish a validity period for opioid prescriptions? **Yes**

   If so, what is the period? **30 days**

4) Does national policy establish a maximum amount that can be prescribed at one time? **Yes**

   If so, what amount? **10 times the single maximum dose as specified in 1992 Polish Pharmacopoeia**

5) Does national policy limit the length of time that a patient may be treated with an opioid? **No**

   If so, how long? ________________________________
COUNTRY ACTION PLAN

Objective 1: Establish administrative capacity in Public or Politic Health Department (Ministry of Health) for implementing the obligations, or task force could develop estimation and data collection method.

a. **Action Step:** Present need and make proposal to vice-minister. Set up the Task Force Group, which consists of the Polish participants in the Budapest workshop.

   **Who is responsible?** Jacek Luczak

   **Timeline:** April 15, 2002

   **Technical assistance:** From the INCB, (International Narcotics Control Board) WHO (Cancer Control) and country palliative care person to train the new person in the MOH (Ministry of Health).

   **Resources:** Materials, palliative care training for new person.

b. **Action Step:** Create job description for Public or Politic Health Department officer which includes establishing methods of estimation needs data collection and informing health professionals. Cooperate with the Department of Drug Policy.

   **Who is responsible?** Task force will assist in the development of this method.

   **Timeline:** Uncertain, up to 6 months

   **Technical assistance:** From the INCB and WHO, to develop methods of estimation.

Objective 2: Develop with two comprehensive cancer pain and palliative care programs in cooperation: Cancer Care Program (Polish Oncological Union) and Hospice-Palliative Care Program (Council of Hospice and Palliative Care Program with contribution of National Consultant in Palliative Medicine, Polish association of palliative care and Polish Forum of Hospice Movement, Polish chapter of IASP), which includes education (also public) in cancer and non-cancer pain management and palliative care.

a. **Action Step:** Submit request for approval to Ministry of Health and Parliament.

   **Who is responsible?** Jacek Luczak and National Hospice-Palliative Care Organizations; Polish chapter of IASP, Polish Oncological Organization, WHO in Poland representative and other NGO organizations (e.g. Physician Chamber).

   **Timeline:** Up to 1 year

   **Technical assistance:** To lobby Parliament and Society.

   **Resources:** Funding and lobbying education.

Objective 3: Get the Department of Health Policy to inform health care professionals regarding changes in drug prescribing laws and consult with task force before finalizing.
a. **Action Step:** Send letters from 3 organizations to MOH requesting improvement in communication with health care professionals regarding changes in prescribing laws.

**Who is responsible?** Three organizations (National Council for Hospice and Palliative Care; Polish Oncological Union, Polish Chapter of IASP) and/or task force.

**Timeline:** within 6 months

**Objective 4:** Increase the number of available strong opioids to improve cancer pain treatment – use in opioid rotation.

a. **Action Step:** (1) Encourage reimbursement for pharmaceutical companies. (2) Do pilot studies in selected centers to make registration faster and easier.

**Who is responsible?** Task force in cooperation with MOH.

**Timeline:** 1 to 3 years.

**Objective 5:** Improve and implement minimal standards for cancer and non-malignant pain treatment.

a. **Action Step:** Collect and examine existing standards and modify as needed.

**Who is responsible?** Societies in cooperation with NGO’s. and representative of WHO in Poland

**Timeline:** 1 year

**Technical assistance:** Independent consultant from abroad (to be confirmed, Dr. Portenoy ?).

**Resources:** Collect existing standards from US, Canada, Australia, UK, other countries.

**Identify the mechanism needed in your country to actively coordinate, foster cooperative efforts, monitor and communicate to achieve the objectives. Is there an existing governmental body able to manage this? Is there a need to establish a working committee or task force? Who should be members, both governmental and non-governmental?**

**Mechanism needed:** Establish Task Force from existing members plus additional members as needed.

**Members:** Jacek Luczak, Jerzy Jarosz, Maciej Hilgier, Adam Bozewicz

**Decide who will report the workshop results in your country, and to which persons and organizations.**

Each member will present to their own organization:
Decide who in your country group will be the follow-up contact person. The role of the follow-up contact person is to maintain central contact with country members following the workshop, and to liaise with the meeting sponsors and those who may provide technical follow-up assistance to the country group.

Jacek Luczak and ECEPT
Country: ROMANIA

Resource Person: David Clark

Coordinator: Daniela Mosoiu

WHO GUIDELINES SELF-ASSESSMENT 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? No

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? No

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? No

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? Yes

4b. Are adequate personnel (employees) available for the implementation of this responsibility? No

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? No

5b. Has the government critically examined its method for assessing medical needs for narcotic drugs, as requested by the INCB? No

5c. Has the government established a satisfactory system to collect information about medical need for opioid analgesics from relevant facilities? No

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

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

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
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? **No**

9b. Has the government identified and addressed concerns of health care professionals about being investigated for prescribing opioids? **No**

10. Is there cooperation between the government and health care professionals to ensure the availability of opioid analgesics for medical and scientific purposes? **No**

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**

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**

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

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? **No**

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? **No**

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

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

**COUNTRY REQUIREMENTS FOR PRESCRIBING OPIOID ANALGESICS**

1) Does national policy require the use of a special prescription form? **Yes, triplicate form for opioids**

2) Does the physician or institution have to pay for the special prescription form? **No**

3) Does national policy establish a validity period for opioid prescriptions? **Yes**
   If so, what is the period? __3 months__

4) Does national policy establish a maximum amount that can be prescribed at one time? **Yes**
   If so, what amount? **15 days. In some parts of the country, maximum daily dose of morphine is 60mg**

5) Does national policy limit the length of time that a patient may be treated with an opioid? **No**
   If so, how long? ________________
COUNTRY ACTION PLAN

Objective 1: Government should recognize pain relief and palliative care as priorities within health care.

a. **Action Step:** Elaborate long-term action plan and identify short-term realistic goals. Identify a working group to include Ministry of Health, National College of Physicians and Pharmacists, National Commission for Cancer Control, Romanian Pain Society, Romanian Palliative Care Association.

   **Who is responsible?** Nania-Luminita Tronaru

   **Timeline:** end of March 2002 to establish the working group.

   The Minister of Health and Family has already signed the order to initiate this Committee (working group) that will elaborate the project of the National Programme on Palliative Care and Pain Management

   **Technical assistance:** MFH, WHO, IASP, EAPC

   **Resources:** Financial, secretarial work

Objective 2: Change and update the norms that restrict opioid prescriptions.

a. **Action Step:** Create proposals to come from NGO’s

   **Who is responsible?** Romanian Association for the Study of Pain, Romanian Palliative Care Association.

   **Timeline:** Proposal by end of May 2002; Completion, difficult to predict.

   **Technical assistance:** Department of Foreign Relations/MFH

   **Resources:** Logistic support

Objective 3: Inform health care professionals about legal requirements for opioid prescriptions and WHO Analgesic Ladder for cancer pain relief.

a. **Action Step:** Produce and distribute 2 types of leaflets.

   **Who is responsible?** Romanian Association for the Study of Pain, Romanian Palliative Care Association.

   **Timeline:** end of September 2002

   **Technical assistance:** Ministry of Health and Family

   **Resources:** Financial assistance for printing the leaflets.
Identify the mechanism needed in your country to actively coordinate, foster cooperative efforts, monitor and communicate to achieve the objectives. Is there an existing governmental body able to manage this? Is there a need to establish a working committee or task force? Who should be members, both governmental and non-governmental?

**Mechanism needed:** No existing government body. Establish a working group to ensure that opioids are available, and that pain relief and palliative care must be health care priorities.

**Members:** Nania-Luminita Tronaru is responsible for organizing this working group. Members will be MFH authorities, College of Physicians, NGO’s (IASP, Palliative Care Association).

**Decide who will report the workshop results in your country, and to which persons and organizations.**

Nania-Luminita Tronaru to Ministry of Health and Family, President of National Health Insurance House, College of Physicians and Pharmacists.

**Decide who in your country group will be the follow-up contact person.** The role of the follow-up contact person is to maintain central contact with country members following the workshop, and to liaise with the meeting sponsors and those who may provide technical follow-up assistance to the country group.

Elena Copaciu
SUMMARY OF WORKSHOP EVALUATION

1. How would you rate the overall quality of the workshop?

☐ Excellent  ☐ Good  ☐ Average  ☐ Poor
12  11

2. How probable is it that you will apply to your job what you have learned at the workshop?

☐ High probability  ☐ Somewhat probable  ☐ Low probability  ☐ Not probable
15  5  2  No

Answer Given = 1

Please explain:

a. As an NGO representative, I will know in what areas and how to promote community participation in policymaking for palliative care.
b. By the objectives I’ll try my best to incorporate the approaches of the workshop to my work.
c. I will participate at morning group for relief of restrictive limit for 15 day prescriptions according objective 2 of the Bulgarian Action Plan.
d. There are barriers which I’m suspicious have political nature, far from my work as a specialist. The administrative obstacles are not clear for me.
e. I’ll try to implement in my country a National Program to Palliative Care (with ??
f. According to our country action plan.
g. It is so more clear about availability and using of opioids in practical use.
h. Comprehensive view/presentation/guidelines/materials very useful, excellent work of every countries representatives.
i. I have been working in the cancer pain management for 21 years.

3. The workshop was relevant to the needs in my country.

☐ Totally agree   ☐ Partially agree   ☐ Undecided   ☐ Partially disagree   ☐
Totally disagree
12  9  No Answer Given = 2

4. How valuable was the presentation about the undertreatment of pain?

☐ Very valuable   ☐ Somewhat valuable   ☐ Not very valuable   ☐ Not at all valuable
18  5

5. How valuable was the presentation about opioid availability in Eastern Europe?

☐ Very valuable   ☐ Somewhat valuable   ☐ Not very valuable   ☐ Not at all valuable
19  4
6. How valuable was the presentation about the role of U.N. agencies in opioid availability?
   - Very valuable: 19
   - Somewhat valuable: 3
   - Not very valuable: 1
   - Not at all valuable: 1

7. How valuable was the presentation about WHO terminology regarding dependence?
   - Very valuable: 18
   - Somewhat valuable: 3
   - Not very valuable: 1
   - Not at all valuable: 1
   Answer Given = 1

8. How valuable were the presentations about the WHO guidelines?
   - Very valuable: 18
   - Somewhat valuable: 3
   - Not very valuable: 1
   - Not at all valuable: 1
   Answer Given = 1

9. How would you rate the country group meeting to develop your action plan?
   - Very valuable: 19
   - Somewhat valuable: 4

10. Did you find the “Country Action Packet” to be helpful to the process of developing your action plan?
    - Very helpful: 16
    - Somewhat helpful: 6
    - Not very helpful: 1
    If you answered “Not very helpful” or “Not at all helpful,” please explain why?
    a. Some questions might be more precisely defined pointing out the obstacles of availability which are not visible but subjective.

11. What was the most valuable part of the workshop?
    a. To see the big differences concerning palliative care facilities and opioid availability among the significant countries.
    b. Working together with the MHF to develop all action plans. Networking opportunity.
    c. Presentation of guidelines / work in groups with country reports
    d. To get information about opioid availability in different countries. To meet professionals, to have discussions, brainstorming.
    e. Country reports on availability of opioids for palliative care.
f. Country reports.
g. Developing action plans.
h. Country reports on availability of opioids for palliative care.
i. The presentation about the undertreatment of pain.
j. Methodology of the workshop. Because it’s easier with action plans. Continue with activities in each country.
k. Difficult to stress out the point but certainly very valuable is to acquire a knowledge about other countries’ experiences and to meet the people responsible in various areas within the WHO, and within the countries participants.
l. Meeting people from different countries, compare situations in countries, have a chance to contact some people from WHO and maybe get some needed help. It is excellent that we managed not just to recognize problems, but also did start some ways to solve them and to find solutions.
m. Meeting new people and see various ways of functioning.

What was the least valuable part of the workshop?
a. The whole workshop was valuable.
b. Tuesday morning.
c. No?
d. Overview of the WHO Guidelines
e. Any suggestions.
f. The luck of lectures materials (theses, abstracts).
g. Not any.
h. A luck of lectures materials (abstracts).
i. About WHO terminology.
j. No one was the last.
k. We can’t expect unique and same countries. Many things function for decades, and function very well considering history, wars. Sometimes it is a good thing to have varieties.
l. It is a very long distance between hotel and city center.
m. The sightseeing (!)
n. The presentation of the comprehensive guidelines.
o. None
p. None
q. Lunch break.
13. Any suggestions for future workshops, topics to be covered, methodology of the sessions:

a. Topics to be corrected: opioid side effects, how to at them. One lecture should be devoted to the adjuvant analgesics of radionucleoids (e.g. Streamline) to relief.

b. Follow up workshop. Interactive discussions.

c. Follow-up after 1-2 years.

d. Some more time for workshops (small groups) and for personal discussions.

e. Problems of monitoring of the use of narcotics and analgesics.

f. Concepts on pain management and palliative care.

g. Problems of monitoring of the use of narcotics and analgesics.

h. Other symptoms - relief in terminal illness.

i. Problem with medicines at home which are not used – need for international agreements and regulations (laws).

j. Working on better endpoints, i.e. endpoints which will describe and characterize the pain treatment much more accurately than simply estimation of opioid consumption within the countries.

k. Some sightseeing please. Maybe a topic: Dispensing of opioid drugs left at patients home after patient’s death.

l. It’s very good that this workshop showed, not just the problems, but also some concrete ways to solve it.

m. Methodology of collecting data about relief pain. Questions of the self-assessment checklist to be more clear (there are questions which have 2 other questions inside)

n. About team working, creating contacts with different authorities.

o. What will happen with the opioids after the death of the patients.

p. I think that the topics of the discussions should be analyzed in order to develop new topics. Maybe new topic to cover the question what will happen with the opioid qualities after the death of the patient.

q. Comparison and analysis of national regulations concerning supply with narcotics and psycho tropics, methods of establishing estimates, import-export issues.

r. Please refine questions no. They have double meaning or are too restrictive in options for answer. A team building interactive games would be very helpful before starting the country group meetings.

14. How can WHO, the WHO Collaborating Center, and OSI be of further assistance to you in your work?

a. To provide and send up-to-date information, brochures, videotapes, and selected publications.

b. Offering technical assistance. Providing the work of the partnership (work group) that will develop the national policy.

c. Continuing support.

d. Better communication on palliative care needs to the government.

e. Sent the whole infrastructure on the analyzed subject.

f. Sent the information.
g. WHO in pushing the government of member states to develop and implement policies on pain and palliative care. WHO Collaborating Center technical assistance, sending materials on internet experience. OSI arriving prognosis on required policy development grants.

h. Sent the whole information on the pain relief, palliative care and others.

i. Share information about palliative care: guidelines, CD-Rom, brochures, booklets, organize seminars, conferences, and workshops.

j. Support our action plan in our government, e.g. ministry of health, give us technical support, and organize workshops in our country.

k. Guidelines in pain treatment, in national cancer control board establishment, use of their authority, technical assistance or help.

l. It would be great to have a contact person if there is some problem. We appreciate the ideas about a letter to the Minister of Health, and it would be helpful if maybe someone from WHO came to Croatia and show new ideas.

m. By contacting, maybe send some materials, maybe by conning some of your members to one of our congresses or meetings.

n. Technical and financial support.

o. Email information about medical use of narcotic drugs, palliative care (studies in different countries), persons or committees in charge with these problems.

Technical support.

p. To choose a supervisor of our coordinator.

q. By providing a methodological and technical assistance.

r. By providing a methodological and technical assistance.

s. By providing a methodological and technical assistance. To help us in our reform of transforming hospitals into hospices.

t. Thank you. We will have some proposals later.

u. Assistance in developing national programs and teaching programs.

v. Sending written materials, leaflets, and guidelines.

Your country: Bulgaria=5, Croatia=4, Hungary=5, Lithuania=5, Poland=1, Romania=2

Your name (optional): ____________________________

THANK YOU FOR YOUR PARTICIPATION IN THE WORKSHOP
Annex 8

Availability of opioid analgesics in Eastern Europe and the world

Slide 1

Per Capita Global Consumption of Morphine, 1999

By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2002

- Global mean: 5.9 mg
- European Regional mean: 11.1 mg
- Poland: 6.5 mg
- Bulgaria: 2.2 mg
- Croatia: 0.7 mg
- Romania did not report for 1999

Slide 2

Per Capita Global Consumption of Pethidine, 1999

By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2002

- Global mean: 3.9 mg
- European Regional mean: 4.4 mg
- Poland: 4.7 mg
- Bulgaria: 3.2 mg
- Croatia: 0.1 mg
- Romania did not report for 1999

Slide 3

Consumption of Selected Opioid Analgesics, 1999 (mg/capita)

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<thead>
<tr>
<th>Country</th>
<th>Fentanyl</th>
<th>Methadone</th>
<th>Morphine</th>
<th>Oxycodone</th>
<th>Pethidine</th>
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By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2002
Slide 4

Per Capita Consumption of Morphine: Europe 1999

Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 1999
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2002

Slide 5

Per Capita Consumption of Pethidine: Europe 1999

Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 1999
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2002

Slide 6

Total Consumption of Morphine in BULGARIA 1980 - 2000

Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 1999
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2002
Slide 10

Total Consumption of Morphine in Hungary 1980 - 2000

Slide 11

Total Consumption of Pethidine in Hungary 1980 - 2000

Slide 12

Total Consumption of Morphine in Lithuania 1980 - 2000
Slide 16

**Total Consumption of Morphine in Romania 1980 - 2000**

- Regional mean - Morphine
- Global mean - Morphine

Slide 17

**Total Consumption of Pethidine in Romania 1980 - 2000**

- Regional mean - Pethidine
- Global mean - Pethidine

Slide 18

**Status of Adherence to Conventions, Receipt of Statistics, and Estimates**

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<tr>
<th>Country</th>
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<th>Estimated requirements for 2001</th>
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Estimated requirements for selected opioids, 2001 and 2002 (in grams)

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By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2002
## Annex 9

### PARTICIPANTS

#### BULGARIA

<table>
<thead>
<tr>
<th>Name and Position</th>
<th>Contact Information</th>
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<tbody>
<tr>
<td><strong>Dr Emilia Petrova Raicheva</strong>&lt;br&gt;Head&lt;br&gt;Intensive Care Unit&lt;br&gt;National Oncological Centre&lt;br&gt;Palliative Care Foundation&lt;br&gt;57-B, Vladaiska Street&lt;br&gt;1606 Sofia</td>
<td>Tel: +359 2 70 61 57&lt;br&gt;Email: <a href="mailto:emilia_raicheva@yahoo.com">emilia_raicheva@yahoo.com</a></td>
</tr>
<tr>
<td><strong>Ms Fani Elilova Michailova</strong>&lt;br&gt;Head&lt;br&gt;National Drug Service&lt;br&gt;Ministry of Health&lt;br&gt;5, Sv. Nedelja sq.&lt;br&gt;1000 Sofia</td>
<td>Tel/Fax +359 2 930 1463&lt;br&gt;Email: <a href="mailto:minister@mh.government.bg">minister@mh.government.bg</a></td>
</tr>
<tr>
<td><strong>Ms Elena Mihailova Milanova</strong>&lt;br&gt;Senior Expert&lt;br&gt;National Drugs Council - NDC&lt;br&gt;Stamboliyski blvd 39&lt;br&gt;1000 Sofia</td>
<td>Tel: +359 2 87 23 64 87&lt;br&gt;Fax +359 2 93 01 11 88&lt;br&gt;Email: <a href="mailto:emilanova@mh.government.bg">emilanova@mh.government.bg</a></td>
</tr>
<tr>
<td><strong>Dr Alexandar Alexandrov Belchev</strong>&lt;br&gt;National Centre of Addiction&lt;br&gt;Ministry of Health&lt;br&gt;5, Sv. Nedelja sq.&lt;br&gt;1000 Sofia</td>
<td>Tel: +359 2 31 90 15&lt;br&gt;Fax +359 2 32 10 47&lt;br&gt;Email: <a href="mailto:albelchev@hotmail.com">albelchev@hotmail.com</a></td>
</tr>
<tr>
<td><strong>Dr Emilia Velkova Rabanova-Lolova</strong>&lt;br&gt;Chief Expert&lt;br&gt;Inpatient care Department&lt;br&gt;Ministry of Health&lt;br&gt;5, Sv. Nedelja sq.&lt;br&gt;1000 Sofia</td>
<td>Tel: +359 2 930 13 18&lt;br&gt;Fax: +359 2 981 18 33&lt;br&gt;Email: <a href="mailto:elolova@mh.government.bg">elolova@mh.government.bg</a></td>
</tr>
<tr>
<td><strong>Ms Emilia Tontcheva</strong>&lt;br&gt;Program Director&lt;br&gt;Public Health Programs&lt;br&gt;Open Society Foundation&lt;br&gt;56 Solunska Str., Sofia 1000</td>
<td>Tel: +359 2 930 66 31&lt;br&gt;Fax + 359 2 951 63 48&lt;br&gt;Email: <a href="mailto:etontcheva@osf.bg">etontcheva@osf.bg</a></td>
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## CROATIA

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<tr>
<th>Name</th>
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<tr>
<td>Mrs Mia Balija</td>
<td>Senior advisor, Department of Pharmaceuticals</td>
<td>Tel/Fax: +385 1 460 7540 (work) Email: <a href="mailto:kabinet.ministra-zdravstva@zg.tel.hr">kabinet.ministra-zdravstva@zg.tel.hr</a></td>
</tr>
<tr>
<td></td>
<td>Ministry of Health Ksaver 200a 10 000 Zagreb</td>
<td></td>
</tr>
<tr>
<td>Dr Marinko Bilušić</td>
<td>Spezalist in clinical pharmacology and toxicology</td>
<td>Tel: +385 1 2388 275 Fax +385 1 2421 875 Email: <a href="mailto:marinko.bilusic@zg.tel.hr">marinko.bilusic@zg.tel.hr</a></td>
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<tr>
<td></td>
<td>Department for Clinical Pharmacology and Toxicology, Internal Clinic KBC REBRO Kipaticeva 12 10 000 Zagreb</td>
<td></td>
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<tr>
<td>Dr Nives Gojo Tomic</td>
<td>Specialisant in clinical pharmacology and toxicology</td>
<td>Tel: +385 1 2388 275 Fax +385 1 2421 875 Mobile: + 385 98 695 260 Email: <a href="mailto:marinko.tomic1@zg.hinet.hr">marinko.tomic1@zg.hinet.hr</a></td>
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<tr>
<td></td>
<td>Department for Clinical Pharmacology and Toxicology, Internal Clinic KBC REBRO Kipaticeva 12 10 000 Zagreb</td>
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<tr>
<td>Dr Anica Jusic</td>
<td>President Croatian Society for Hospice/Palliative Care HLZ Gunduliceva 49/I 10000, Zagreb Croatia</td>
<td>Tel: +385 1 4855 730 Fax +385 1 4855 730 Email: <a href="mailto:Anica.jusic@zg.tel.hr">Anica.jusic@zg.tel.hr</a></td>
</tr>
<tr>
<td>Dr Marijana Persoli-Gudelj</td>
<td>President Croatian Society for Pain Treatment</td>
<td>Tel: +385 47 431 222 Fax +385 47 431 337 Email: <a href="mailto:opcabolnica-karlovc@ka.tel.hr">opcabolnica-karlovc@ka.tel.hr</a></td>
</tr>
<tr>
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<td>Skopska 9 47000 Karlovac</td>
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<tr>
<td>Mrs Jasminka Srsen-Petanjek</td>
<td>Senior Adviser for Drugs Croatian Institute for Health Insurance Pharmaceutical Department Margaretska 3 10000 Zagreb</td>
<td>Tel: +385 1 4806 397 Fax +385 1 4806 307 E-mail: <a href="mailto:jasminka.srsen-petanjek@hzzo-net.hr">jasminka.srsen-petanjek@hzzo-net.hr</a></td>
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### HUNGARY

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<th>Name</th>
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<tr>
<td>Dr. Dezso Embey-Isztin</td>
<td>Consultant Anaesthetist</td>
<td>Tel: +36 1 224 87 56</td>
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<tr>
<td></td>
<td>Head Pain Clinic</td>
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<td></td>
<td>National Institute of Oncology</td>
<td>Mobile: +36 20 9 43 47 74</td>
</tr>
<tr>
<td></td>
<td>Rath Gyorgy street 7-9</td>
<td>Email: <a href="mailto:embey@oncol.hu">embey@oncol.hu</a></td>
</tr>
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<td></td>
<td>1122 Budapest</td>
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<tr>
<td>Dr. Katalin Muszbek</td>
<td>President</td>
<td>Tel: +36 1 388 7369</td>
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<tr>
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<td>Hungarian Hospice Association</td>
<td>Fax +36 1 250 5513</td>
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<tr>
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<td>Kenyeres u. 18</td>
<td>Email: <a href="mailto:mhospicea@matavnet.hu">mhospicea@matavnet.hu</a></td>
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<td>1032 Budapest</td>
<td><a href="mailto:mhospicea@axelero.hu">mhospicea@axelero.hu</a></td>
</tr>
<tr>
<td>Dr. Ferenc Fábián</td>
<td>Head of Division</td>
<td>Tel: +36 1 312 3216</td>
</tr>
<tr>
<td></td>
<td>Pharmaceutical Department</td>
<td>Fax +36 1 311 7255</td>
</tr>
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<tr>
<td>Dr. Erzsébet Podmaniczy</td>
<td>Head International Department</td>
<td>Tel: +36 1 224 87 66</td>
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<tr>
<td></td>
<td>National Cancer Institute</td>
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<tr>
<td>Prof. Dr. László Vimláti</td>
<td>Semmelweis University</td>
<td>Tel./Fax: +36 1 350 2209</td>
</tr>
<tr>
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</tr>
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<td>Ms. Erzsébet Fülöp</td>
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<td>Dr. Kálmán Szendrei</td>
<td>Professor Emeritus</td>
<td>Tel./Fax: +3662 317767</td>
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<td></td>
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<tr>
<td>Dr. Gábor Mikala</td>
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</tr>
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<td>-------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>Mrs Anzelika Balčiūnienė</td>
<td>Senior specialist of Health Care Division</td>
<td>Ministry of Health</td>
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<tr>
<td>Mr Vytautas Basys</td>
<td>Chairman of Narcotics Commission</td>
<td>State Medicines Control Agency</td>
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<tr>
<td>Mrs Dalia Normantiene</td>
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<tr>
<td>Mr Arunas Sciuokas</td>
<td>Associate Professor</td>
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<tr>
<td>Mr Arvydas Seskevicius, PhD</td>
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<td>Kaunas University of Medicine</td>
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# POLAND

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<th>Name</th>
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<tbody>
<tr>
<td>Professor Jacek Luczak</td>
<td>Chair of Oncology Palliative Care Department, Karol Marcinkowski University of Medical Science, ul. Lakowa 1/2, Poznan, 61-878</td>
<td>Tel: +48 61 853 01 06, Fax: +48 61 876 94 52, Email: <a href="mailto:jluczak@usoms.poznan.pl">jluczak@usoms.poznan.pl</a></td>
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<tr>
<td>Dr Maciej Hilgier</td>
<td>Head of Pain Study and Palliative Treatment Unit, Department of Anaesthesiology, Cancer Center &amp; Institute of Oncology, The Maria Sklodowska-Curie Memorial, 5 Roentgena Str., 02 781 Warsaw</td>
<td>Tel/Fax: +48 22 644 96 61, Email: <a href="mailto:hilgier@coi.waw.pl">hilgier@coi.waw.pl</a>, <a href="mailto:hilgier@wp.pl">hilgier@wp.pl</a></td>
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<tr>
<td>Mr Piotr Jablonski</td>
<td>Director, National Bureau for Drug Prevention, Ul. Dereniowa 52/54, 02-776 Warsaw</td>
<td>Tel: +48 22 641 15 01, Fax: +48 22 641 15 65, Email: <a href="mailto:bdsnark@medianet.pl">bdsnark@medianet.pl</a></td>
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<tr>
<td>Mr Adam Bozewicz</td>
<td>Head of narcotics control, General Pharmaceutical Inspectorate, 38/40 Dluga St., 00238 Warsaw</td>
<td>Tel: +48 22 831 48 23, Fax: +48 22 831 02 44, Email: <a href="mailto:bozewicz@gif.gov.pl">bozewicz@gif.gov.pl</a></td>
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<tr>
<td>Dr Jerzy Jarosz</td>
<td>Head of Department of Anaesthesiology, Cancer Centre and Institute of Oncology, The Maria Sklodowska-Curie Memorial, Ul. Roentgena 5, 02-781 Warsaw</td>
<td>Tel: +48 22 644 90 92, Fax: +48 22 644 96 61, Email: <a href="mailto:jarosz@coi.waw.pl">jarosz@coi.waw.pl</a>, <a href="mailto:jaroszj@acn.waw.pl">jaroszj@acn.waw.pl</a></td>
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<tr>
<td>Dr Nicolae Georgescu</td>
<td>Senior Consultant</td>
<td>Medical Oncologist Section</td>
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<td>Tulcea District Hospital</td>
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<tr>
<td>Dr Elena Copaciu</td>
<td>Consultant, ICU Department</td>
<td>University Hospital of Bucharest</td>
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<tr>
<td>Dr Nania-Luminita Tronaru</td>
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<td>Medical Care General Department</td>
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<tr>
<td>Dr Daniela Mosoiu</td>
<td>Medical Director</td>
<td>Hospice Foundation &quot;Casa Sperantei&quot;</td>
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<tr>
<td>Mr Ioan Florea</td>
<td>Counselor- Head of Service</td>
<td>General Department of Pharmaceuticals</td>
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## OBSERVERS

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<tr>
<th>Name</th>
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<th>Organization</th>
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</thead>
<tbody>
<tr>
<td>Dr Barbara Veh-Schmidt</td>
<td>Programme Manager</td>
<td>WHO Humanitarian Assistance Office</td>
<td>Bulevar mira 8, 11 000 Belgrade</td>
<td>Tel: +381 11 660 735 Fax: +381 11 664 557 Email: <a href="mailto:bvs@who.org.yu">bvs@who.org.yu</a> <a href="mailto:secretariat@who.org.yu">secretariat@who.org.yu</a></td>
</tr>
<tr>
<td>Ms Nataša Moravčević</td>
<td>Pharmaceutical Consultant</td>
<td>WHO Humanitarian Assistance Office</td>
<td>Bulevar mira 8, 11 000 Belgrade</td>
<td>Tel: +381 11 660 735 Fax: +381 11 664 557 Email: <a href="mailto:hvu@who.org.yu">hvu@who.org.yu</a> <a href="mailto:natasamo@yahoo.com">natasamo@yahoo.com</a></td>
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## TEMPORARY ADVISERS

<table>
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<tr>
<th>Name</th>
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<tr>
<td>Dr David Clark</td>
<td>Chair of Medical Sociology</td>
<td>The University of Sheffield</td>
<td>Trent Palliative Care Centre</td>
<td>Tel: +44 114 262 0174 Fax: +44 114 236 2914 Email: <a href="mailto:d.clark@sheffield.ac.uk">d.clark@sheffield.ac.uk</a> <a href="http://www.sheffield-palliative.org.uk">www.sheffield-palliative.org.uk</a></td>
</tr>
<tr>
<td>Dr Harald Breivik</td>
<td>Professor and Chairman</td>
<td>University of Oslo</td>
<td>Rikshospitalet 0027 Oslo</td>
<td>Tel: +47 23 073-691 Tel: +47 95 865 323 (mobile) Fax: +47 23 073 690 Email: <a href="mailto:harald.breivik@rh.klinmed.uio.no">harald.breivik@rh.klinmed.uio.no</a></td>
</tr>
<tr>
<td>Dr Friedemann Nauck</td>
<td>Consultant in Pain Therapy and Palliative Medicine</td>
<td>Malteser Krankenhaus Palliative Care Unit</td>
<td>von Hompeschstrasse 1 531 23 Bonn Germany</td>
<td>Tel: +49 228 64 810 Tel +49 228 6481 362 Fax +49 228 6481 851 Email: <a href="mailto:dgp-bonn.mtg@clinet.de">dgp-bonn.mtg@clinet.de</a></td>
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## THE OPEN SOCIETY INSTITUTE

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<tr>
<td>Dr Kathleen M. Foley</td>
<td>Director</td>
<td>Open Society Institute Palliative Care Initiative 400 West 59th Street New York, New York 10019 USA</td>
<td>Tel: 212 548-0150 Fax: 212 548-4613 Email: <a href="mailto:foleyk@mskcc.org">foleyk@mskcc.org</a></td>
</tr>
<tr>
<td>Mary Callaway</td>
<td>Associate Director</td>
<td>Open Society Institute Palliative Care Initiative 400 West 59th Street New York, New York 10019 USA</td>
<td>Tel: 212 548-0150 Fax: 212 548-4613 Email: <a href="mailto:MCallaway@sorosny.org">MCallaway@sorosny.org</a></td>
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## UNIVERSITY OF WISCONSIN, WHO COLLABORATING CENTRE

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<tbody>
<tr>
<td>Ms Karen M. Ryan</td>
<td>Senior Policy Analyst</td>
<td>Pain &amp; Policy Studies Group University of Wisconsin Comprehensive Cancer Center World Health Organization Collaborating Center 406 Science Drive, Suite 202 Madison, WI 53711-1068 USA</td>
<td>Tel: +1 608-262-7227 Fax +1 608-263-0259 Email: <a href="mailto:kmryan2@facstaff.wisc.edu">kmryan2@facstaff.wisc.edu</a></td>
</tr>
<tr>
<td>Mr David Joranson</td>
<td>Senior Scientist</td>
<td>Director of Pain &amp; Policy Studies Group University of Wisconsin Comprehensive Cancer Center World Health Organization Collaborating Center 406 Science Drive, Suite 202 Madison, WI 53711-1068 USA</td>
<td>Tel: +1 608-263-7662 Fax +1 608-263-0259 Email: <a href="mailto:joranson@facstaff.wisc.edu">joranson@facstaff.wisc.edu</a> <a href="http://www.medsch.wisc.edu/painpolicy">www.medsch.wisc.edu/painpolicy</a></td>
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### HEADQUARTERS

<table>
<thead>
<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Mr Tokuo Yoshida</td>
<td>Quality Assurance and Safety: Medicines</td>
<td>World Health Organization</td>
<td>+41 22 791 4317</td>
<td>+41 22 791 4730</td>
<td><a href="mailto:yoshidat@who.ch">yoshidat@who.ch</a></td>
</tr>
<tr>
<td></td>
<td>Essential Drugs and Medicines Policy</td>
<td>Via Appia 1211 Geneva Switzerland</td>
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<td></td>
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<tr>
<td>Dr Cecilia Sepulveda</td>
<td>Coordinator</td>
<td>World Health Organization</td>
<td>+41 22 791 3706</td>
<td>+41 22 791 4297</td>
<td><a href="mailto:sepulvedac@who.ch">sepulvedac@who.ch</a></td>
</tr>
<tr>
<td></td>
<td>Programme on Cancer Control</td>
<td>Via Appia 1211 Geneva Switzerland</td>
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### REGIONAL OFFICE FOR EUROPE

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<tbody>
<tr>
<td>Mr Kees de Joncheere</td>
<td>Regional Adviser</td>
<td>8, Scherfigsvej 2100 Copenhagen</td>
<td>+45 39 17 14 32</td>
<td>+45 39 17 18 55</td>
<td><a href="mailto:cjo@who.dk">cjo@who.dk</a></td>
</tr>
<tr>
<td></td>
<td>Pharmaceuticals and Technology</td>
<td>Denmark</td>
<td></td>
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<tr>
<td>Dr Rüdiger Krech</td>
<td>Manager, Healthy Ageing</td>
<td>8, Scherfigsvej 2100 Copenhagen</td>
<td>+45 39 17 12 69</td>
<td>+45 39 17 18 18</td>
<td><a href="mailto:rkr@who.dk">rkr@who.dk</a></td>
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