



# THE WHITE PAPER ON OPIOIDS AND PAIN: A PAN-EUROPEAN CHALLENGE

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"Treatment to alleviate chronic pain is a human right" World Health Organization, 11th October 2004

The aim of this White Paper is to identify inequalities in government policies towards opioids that contribute to the inadequate treatment of pain. It calls for their replacement with policies that will support doctors and patients in their efforts to relieve pain.

## **OPEN Minds**



OPEN Minds is a group of leading experts from across Europe specialising in research and the management of persistent pain. We are committed to helping healthcare professionals, decision makers and patients increase their knowledge and understanding of pain and to raising the standards of its management across Europe.

www.OPENmindsonline.org

## **European Pain Network**



The European Pain Network is a group of patients' organisations from across Europe united under the mission statement: to represent and actively support people with pain, raise awareness of their needs and campaign to improve their lives. One of its key objectives is to drive pain onto the political agenda to get the problem of pain addressed by governments and other decision makers.

The EPN is supported by various organisations including Mundipharma International. www.europeanpainnetwork.org

The OPEN Minds initiative is funded by an educational grant from Mundipharma International Limited.

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# **FOREWORD**

The recent history of opioid use in chronic pain is one of progress, of the gradual increase in understanding by doctors of their efficacy and safety, government changes to the restrictions affecting their use and improved access by patients.

However, policies regulating strong opioids are usually aimed at limiting criminality, abuse and addiction. They often restrict the use of opioids by physicians, limiting access to pain relief. Although international narcotics control treaties from 1961 dictate that national policies recognise that opioid analgesics are necessary for the relief of pain and suffering, many national laws do not. The reputation of strong opioids has been damaged by a singular "war on drugs" emphasis aimed only at their potential for abuse.

In 1969, the World Health Organization (WHO) abandoned its interpretation that medical use of morphine inevitably results in addiction. The WHO clarified that tolerance and physical dependence by themselves do not constitute 'drug dependence', a diagnosis which is characterised primarily by compulsion to use drugs and persistent use despite harm.

Another turning point came in 1986, when the WHO began its global initiative to relieve pain caused by cancer using a three-step approach that required the use of opioid analgesics like morphine. The WHO 'pain ladder' distinguished between strong and weak opioids and established clear roles for them in treating pain.

The management of cancer pain began to improve, and this in turn precipitated a scientific and clinical reappraisal of the use of opioids for chronic non-cancer pain.

Since then, opioids have become more widely accepted and used by both general practitioners and specialists. The International Association for the Study of Pain (IASP) has furthered understanding of the appropriate use of opioids and organisations such as the British Pain Society and Amsterdam Group have developed Guidelines on their optimal use.

Nevertheless, as this White Paper reveals, in some countries outdated rules and regulations remain, continuing the legacy of past attitudes when fear about opioids prevailed. This is a crucial point as it illustrates that what is required in Europe above all is a straightforward process of updating, of spring cleaning the numerous rules and regulations that are identified in this White Paper.

This process should be directed by the guiding principle of balance, as proposed by the WHO\*. Governments should control and monitor the consumption of opioid medicines, but should also ensure that patients have access to them, and doctors can prescribe them, without undue inconvenience or stigma.

Even when outmoded laws are gone, outmoded perceptions remain, and these must be corrected by a combination of communication, leadership and education.

In its recent reports, the International Narcotics Control Board (INCB) has congratulated governments, particularly in Europe for improving access to the medicines required for pain management. As this White Paper shows, however, there is still much work to be done.

\*http://www.who.int/medicines/library/qsm/who-edm-qsm-2000-4/who-edm-qsm-2000-4.shtml



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#### Dear Friend

In October 2004, the European Pain Network was created bringing together patient organisations from across Europe under the Mission Statement to represent and actively support people with pain, raise awareness of their needs and campaign to improve their lives.

In establishing the Network and its objectives, much of our time together was spent comparing experiences of living with chronic pain and accessing the treatments and resources available to manage it.

The results of these comparisons shocked and even angered us.

Whilst we agreed that, wherever you live in Europe, chronic pain is a devastating physical condition that can affect every aspect of a person's life, we also learnt that people's ability to manage their condition, and lead a normal and fulfilling life despite it, depends to a significant extent on the country that they live in.

The reason for this difference is the huge variety of government policies that exist across Europe affecting every aspect of pain treatment, from reimbursement and product availability to the prescription process. Whilst some policies support patients and help them to overcome their condition, others exacerbate their suffering through stigma and neglect, making their condition worse. The research caused us to pose certain questions:

Why, for example, if a treatment is proven to be safe and efficacious in one European country, should it be denied to people in another? Why should people living in pain be reimbursed for their treatment in one country and not another? Why should people be able to drive whilst undergoing treatment in one country and not another? And above all, why should chronic pain be so neglected by governments when compared with other disease areas?

These are not differences that can be explained by variations in different health systems but relate to fundamental healthcare principles. They contravene basic patient rights, recognised medical research and the recommendations of numerous international organisations. The time has come for governments to answer the question listed above and others, and to implement measures to remove the inequalities that they represent.

The European Pain Network fully supports the White Paper and the Call to Action, and looks forward to working with OPEN Minds and other organisations in seeing them implemented.

Yours sincerely

Mandy Leighton, President, European Pain Network

# INTRODUCTION

Chronic pain is a major European healthcare issue. Throughout 2004, OPEN Minds, a group of European experts in the use of opioids to treat chronic pain, carried out an investigation into the different policies in place across Europe that affect access by people with chronic pain to the strong opioids they need to treat their pain.

As you will read, the investigation identifies legal, regulatory, cultural and economic factors that impede effective treatment, and much of this document is spent arguing for their replacement on the grounds that they are based on outdated knowledge and have become a hindrance rather than a help.

These impediments illustrate a fundamental misunderstanding of the impact of pain and the role that strong opioids play in pain management. It is this role that specialists in pain management from across Europe are most concerned with, and it was the need to communicate this role that brought the OPEN Minds group together in the first place.

Our collective view, and the fundamental message of this White Paper, is that strong opioids, when used appropriately, can be an effective medication in the fight against pain and an important component of a comprehensive, multidisciplinary program looking to achieve overall improvements in patient function as well as their quality of life.

It is the view of the OPEN Minds group that this message should lie at the heart of government policies surrounding pain treatment. It is a conclusion that reflects our considerable experience and knowledge in this field, and which is backed up by clinical experience and medical research.

It is also a message that is supported by the World Health Organization (WHO), who enshrined the role of oral opioids in its WHO ladder on the treatment of cancer pain (through its by the mouth, by the clock, by the ladder approach). It has also been endorsed by guidelines created by numerous national and international pain societies.

That is not to say that strong opioids are for use whenever pain occurs, and certainly not without evaluation and monitoring. In this White Paper we ask only for a correct balance between control and use.

We have begun this White Paper by focusing on the medical significance of strong opioids, because that is what we would like to see governments do when formulating the policies that affect them.

We are delighted not only to be able to present this White Paper to governments, but to have its content endorsed by a member of the European Parliament and the European Pain Network.

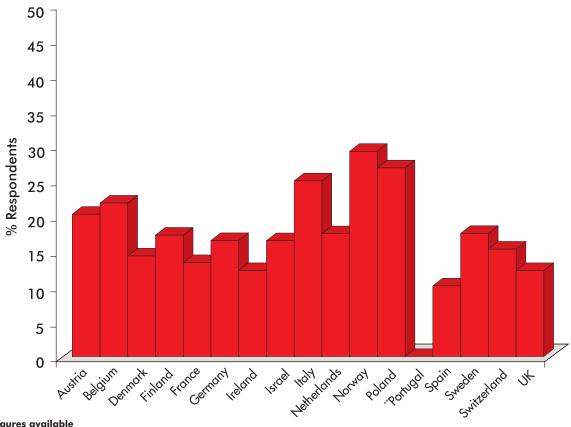
# CHRONIC PAIN IN EUROPE: A MAJOR PUBLIC HEALTH ISSUE

The Pain in Europe\* survey revealed the truly shocking nature, prevalence and impact of chronic pain in Europe and its devastating human, economic and social impact.

In a nutshell, the survey revealed that nearly one in five adults in Europe suffers from chronic pain. Of those, 35% experienced pain every day of their lives and 16% said that some days the pain made them want to die. For 26%, the pain had affected their careers, whilst on average sufferers live with chronic pain for seven years.

- 28% of sufferers said they didn't think their doctor knew how to control their pain.
- Only 2% had been referred to a pain management specialist.
- Most strikingly, 40% have not achieved adequate pain control.
- 21% were diagnosed with depression because of pain.
- 19% of people had lost their job due to pain.

## Prevalence of chronic pain



<sup>\*\*</sup>No figures available

Prevalence of chronic pain among 46,394 adults (>18 years) in 16 European countries responding to a computer-aided telephone screening interview. Chronic pain was defined as pain lasting more than 6 months and rated in intensity as five or greater on a one (no pain) to 10 (worst pain imaginable) Numeric Rating Scale.

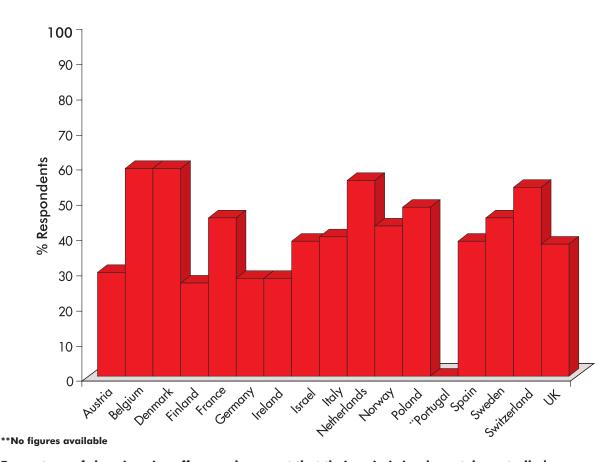
<sup>\*</sup>www.painineurope.com

Shocking though these figures are, they came as little surprise to us. As experts in the management and treatment of chronic pain in Europe, we were well aware of the impact that it has on millions of people's lives every year. What surprised and disappointed us most about the Pain in Europe data, however, was the picture it revealed about the treatment of chronic pain.

All in all it painted a picture not just of the widespread under-treatment of pain, but of the almost universal resignation amongst patients to this under-treatment.

Yet this need not be the case. The wealth of effective methods, treatments and models that exists means that the lives of many people with chronic pain can be improved enormously, and for some of these people, the key to successful treatment lies with the considered and appropriate use of strong opioids.

## Pain is inadequately controlled for many



Percentage of chronic pain sufferers who report that their pain is inadequately controlled.

# THE WHITE PAPER

In its 2004 annual report, the International Narcotics Control Board (INCB) declared that the global use of essential narcotic medicines to treat pain was inadequate and identified three main reasons for this:

- 1 Unnecessarily strict rules and regulations have created an impediment to providing adequate access of populations to certain controlled medicines.
- 2 The negative perception about controlled drugs among medical professionals and patients in many countries has limited their rational use.
- 3 Lack of economic means and insufficient resources have resulted in inadequate medical treatment, including the use of narcotic drugs.

INCB Press Release, Use of Narcotic Drugs to treat pain is inadequate, March 3 2004, www.incb.org

This statement is made all the more striking by the fact that it was made by the very organisation charged with limiting global drug abuse. Narcotic medicines, including strong opioids, have a potential to cause harm if abused and measures are necessary if this abuse is to be limited. But the INCB concluded that, in looking to control the illicit consumption of opioid medicines, governments have gone too far, and that control has become impediment and denial.

# 1. UNNECESSARILY STRICT RULES AND REGULATIONS

In every country in Europe prescriptions for strong opioids must be filled in differently from those for other medicines.

Rules and regulations affect every aspect of the prescription process, and whilst the majority are both necessary and effective, others are unhelpful.

At the heart of the prescription process lies the form itself. Across Europe, rules are in place affecting the printing and distribution of narcotic prescription forms. These rules dictate how the forms must be completed and submitted, limiting their validity, the dosage they permit and describing how they must be kept, registered and monitored by doctors, pharmacists and the authorities.

All in all, doctors looking to prescribe strong opioids are faced with a minefield of bureaucracy and red tape that places an unnecessary burden on their already extremely limited time and resources.

Accessing, filling and registering the prescriptions, repeat appointments for new dosages and the need to lock away forms means that the process of treating a patient on a course of strong opioids is far more timeconsuming than it would be for other medicines.

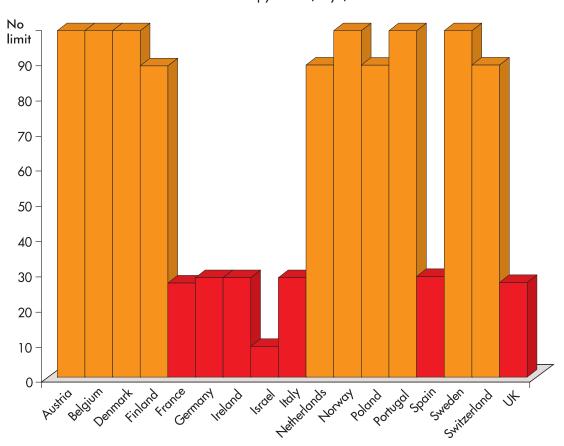
It is easy to see how this burden for doctors can quickly become an impediment for patients. Doctors can choose to avoid this entire process by replacing strong opioids with a less effective treatment, passing the burden of these unnecessary rules to the one person least able to bear this burden – the patient themselves.

#### UNNECESSARILY STRICT RULES AND REGULATIONS

- In Austria, Denmark, Finland, France, Germany, Italy, Norway, Poland, Portugal, Spain, Sweden, and Switzerland, the prescription forms for strong opioids themselves are different from those for other medicines.
- In Italy, Poland, Portugal and parts of Spain, doctors must travel in person to regional offices in order to access the prescription forms used to prescribe strong opioids. In Portugal, private doctors must even pay for the forms themselves!
- In Austria, Germany, Portugal, Italy and Switzerland triplicate forms must be filled in.
- In Germany, narcotic prescription forms are only valid for one week.
- In Israel, prescription forms for products treating non-cancer pain provide the patient with only ten day's treatment at a time.

# Therapy limits





There is a huge imbalance across Europe in the number of days of treatment that a doctor can prescribe opioid medication for at any one time, ranging from ten days worth of treatment (Israel) to countries where doctors are free to prescribe according to the needs of the patient.

# 2. NEGATIVE PERCEPTION

In Austria narcotics are referred to as "Suchtmittel", literally "the means to make you addicted", whilst the prescription

Strong opioids have always been stigmatised by an association with death, addiction and abuse, despite an overwhelming medical agreement as to

"the means to make you addicted", whilst the prescription forms are known as "Suchgiftrezepte", or "addictive poison prescription forms". In Germany, narcotics are referred to as "Betäubungsmittel", literally the means to "knock you out".

In Poland and Portugal, narcotic prescription forms are a different colour (pink and yellow respectively) from standard prescription forms.

In Finland and Switzerland pharmacists must keep the prescription forms for ten years.

In the Netherlands and Belgium, people taking strong opioids are forbidden from driving despite consensus in the medical community that untreated patients represent a greater safety risk.

Yet rather than look to dispel this stigma, many existing measures succeed only in exaggerating it.

The sum impact of these measures is significant. A cloud of uncertainty and even criminality hangs over strong opioids, casting doubt over their safety and efficacy and undermining confidence in their ability to improve people's lives.

This uncertainty can be traced directly back to the manner with which the authorities police strong opioids. It is an approach that is simultaneously both strict and vague. Doctors are given an overwhelming sense of personal responsibility for their prescribing habits, and yet the rules that govern these habits are poorly communicated and inconsistently implemented. They fear scrutiny, but are unsure what of. And this fear spreads. There are fears amongst family members about the impact that the treatment will have on their loved ones, particularly elderly ones, whilst caution in the behaviour of doctors swiftly translates into suspicion amongst the general public and media.

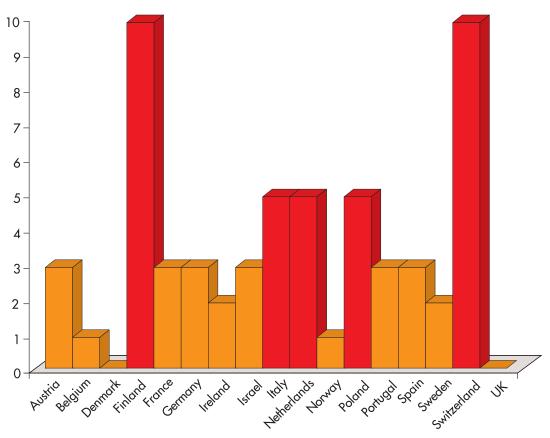
Patients meanwhile are confronted by a double stigma; an internal stigma caused by fear about the effects of their treatment, and an external stigma caused by fear of how those around them will judge them. This exacerbates their anxiety and sense of isolation, and can even mean they must choose between the misery of their condition and the measures they require to treat it.

Combating the negative perception surrounding strong opioids requires not only a revision of the policies that cause it, but also the active promotion of the positive effects of the treatments.

A positive educational programme is needed to change attitudes on the medical use of opioids – extending from the core curriculum of medical students to patients taking opioids and their families. This education should cover the rules governing their use, the management of their side-effects and, most importantly, an unequivocal, evidence based message from governments highlighting issues relating to abuse and misuse and distinguishing them from appropriate medical use.

# Monitoring of prescription habits

Duration records must be kept for (years)



All countries have rules about the monitoring of doctors' prescribing habits, requiring that doctors or the pharmacists keep records of all narcotic prescriptions, or even the forms themselves for a set period of time. In Denmark and the UK, prescriptions are registered by the authorities immediately and no records kept, whilst in Finland and Switzerland records must be kept for ten years.

# **Opioids and Driving**



Countries where driving whilst on a stable course of strong opioids is illegal

Countries where driving whilst on a stable course of strong opioids is legal, but heavily restricted (for insurance/professional reasons etc.)

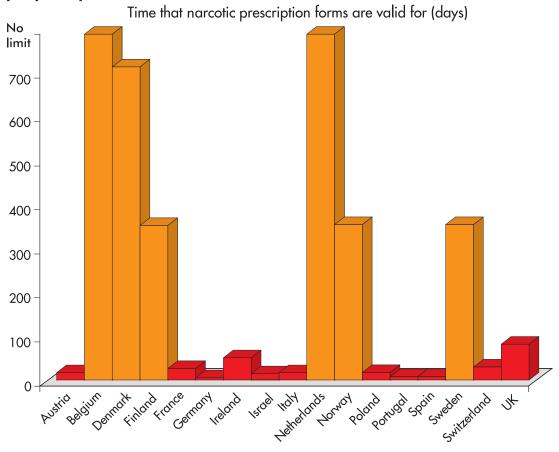
Countries where driving whilst on a stable course of strong opioids is legal

Belgium, the Netherlands

Austria, Denmark, Finland, Germany, Norway, Spain, Sweden

France, Ireland, Israel, Italy, UK, Portugal, Switzerland

# **Validity of prescription forms**



Regulations governing how long prescription forms for narcotics are valid for – i.e. how long the patient has in order to obtain their treatment after being prescribed – differ across Europe. On the whole this is about 3 weeks, but there is a range from no time limit in the Netherlands and Belgium to just seven days in Germany.

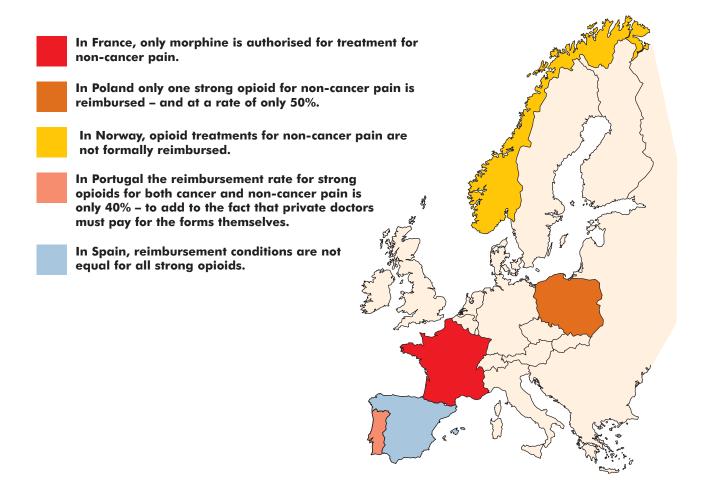
# 3. ECONOMIC MEANS

Even taking into consideration the trend for healthcare rationing in Europe there are strong social and humanitarian arguments for improving the availability of strong opioids to the people that need them, as well as economic arguments pointing to the benefits to society of doing so.

More often than not, chronic pain has a detrimental effect on sufferers' careers, frequently jeopardising them altogether. Add to this the additional costs caused by the need for carers and the psychological impact of pain, it becomes even more inexplicable why governments deny these most economically disadvantaged of people reimbursement for their treatments.

This situation is made all the more pressing when you consider the impact this treatment might have. Patients may well be only one treatment step away from being able to work to their full or an improved potential. The correct treatment might be the difference between them being a burden on society and a contributor to it.

And it must be the right treatment. Chronic pain is a highly complex, personalised condition and a wide variety of treatments, dosages and formulations – opioids and non-opioids – have been developed to treat it. These medicines and treatment options should be available to doctors to maximise their chances of giving their patients their careers, families and lives back.



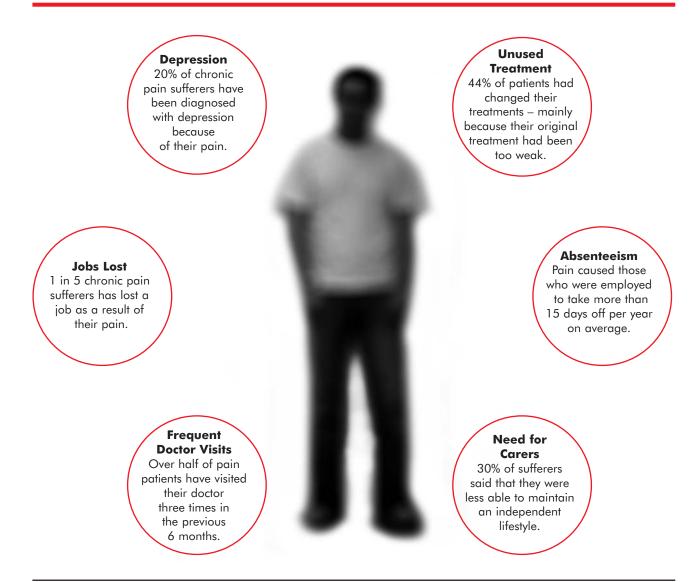
## **Economic Impact of Untreated Pain**

Such is the enormous and wide-ranging impact of untreated chronic pain on patients, their doctors, careers, families and carers that its true annual cost to society can only be guessed at.

But an estimated financial sum is unnecessary. One need only look at the illustration on page 15 that lays out some of the main factors that contribute to this cost to realise what a vast social burden chronic pain represents. To give one single example, it is estimated that absenteeism from work alone due to pain, costs European economies €34 billion per year.

Patients in pain may find themselves unable to work, dependant on a carer or family member for support, frequently visiting their doctor for further diagnosis and prescription and in need of treatment for depression. While this might be a worst case scenario, it is an accurate indication of the true, but often invisible cost of untreated chronic pain.

A straight-forward cost-benefit analysis comparing these costs with those involved with increasing the treatment of pain will reach one conclusion – that treated pain patients cost society far less than untreated ones.



# 4. CONCLUSION

Having started this White Paper with a statement from one international organisation that pain relieving treatments are inadequately available, we would like to conclude with another.

On November 12 2003, the Committee of Ministers of the Council of Europe as part of its Recommendation (2003) 24 to Member States on the organisation of palliative care declared:

Legislation should make opioids and other medicines accessible in a range of formulations and dosages for medical use. The fear of abuse should not hinder access to necessary and effective medication. Countries may wish to consider whether this will require new legislation or an amendment to existing legislation.

The consensus is clear. Organisations concerned both with combating pain and combating drug abuse agree not only that access to pain treatments is inadequate, but that it is the job of governments to address this inadequacy.

The OPEN Minds Call to Action is designed to help governments address this inadequacy by identifying the stigma and regulatory and economic factors that cause it.

# 5. CALL TO ACTION

## 1. General

- European governments should review existing policies affecting access to strong opioids for use in pain management.
- These policies should have as their primary goal the provision of appropriate treatment to people suffering from chronic pain.
- In carrying out this review, governments should use the WHO's Self-Assessment Checklist for evaluating national opioids control laws, regulation and administration. The checklist was developed in 2000 to guide governments' analysis of their national drug control policies. Examples of the Checklist are as follows:
  - Is there a provision in national drug control policies that recognises that opioids are absolutely necessary for the relief of pain and suffering?
  - 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 opioids for medical and scientific purposes, including for the relief of pain and suffering?
  - Is there terminology in national drug control policy that has the potential to confuse the medical use of opioids for pain with drug dependence?
  - Are there provisions in national drug control policy that restrict the amount of drug prescribed or the duration of treatment?

## 2. Regulatory

- Whenever strong opioids are prescribed, excessive and burdensome regulations should not cause stigma, inconvenience or cost for patients or healthcare professionals.
- All doctors should have free and easy access to the forms necessary for prescribing strong opioids.
- Prescription lengths for strong opioid treatments should reflect the needs of the individual patient and should recognise the importance of regular monitoring by the prescribing doctor.

## 3. Economic

- Governments should recognise the rights of people with chronic pain to access the full range of treatments available to manage it. Opioids work differently in different people and so the full range of opioids needs to be made available for the treatment of chronic pain and all authorised treatments should be reimbursed to the same level.
- The cause of the pain should not be a factor in the provision of opioids to treat it. Reimbursement levels for the treatment of non-cancer pain should not differ from those for cancer pain.

## 4. Stigma

- Governments should take the lead in combating the stigma surrounding strong opioids amongst
  patients, the general public and the medical community by promoting their effectiveness in
  giving back quality of life and educating about the management and reduction of expected
  side effects.
- Strong opioids, particularly when consumed at a stable dose, should not be an absolute contraindication against driving. The decision of whether to drive whilst taking strong opioids should be made by the patient in consultation with the prescribing doctor.
- Governments need to ensure that pain management, and the role of opioids in pain management, form a more substantial part of undergraduate training and continuing medical education.



#### Dear Colleague

On October 11 2001, I hosted the launch, in the European Parliament, of the inaugural EFIC European Week Against Pain. The purpose of the Week was to raise awareness of chronic pain as a disease in its own right amongst decision-makers, doctors and the general public with a view to improving access by patients to the treatments available for it.

10 core objectives of the Week were identified. Three of them are as follows:

- To inform decision-makers of the significant impact that chronic pain has on patient morbidity and quality of life, avenues for improvement, and anticipated social and economic benefits for Europe.
- To inform decision-makers of the cost-effectiveness of available pain relief modalities and encourage their incorporation into health fund coverage and management modalities.
- To seek ways of reducing governmental obstacles to analgesic availability and use.

Four years and three "European Weeks Against Pain" later, and there is little evidence that these objectives have been heard by European governments, let alone met. The research carried out by OPEN Minds that is summarised in this document reveals that decision-makers remain poorly informed about the impact of chronic pain, that the obstacles to analgesic availability are still in place, and that the cost effectiveness of these treatments is still ignored.

Most critical of all, however, is that the fundamental message of the "European Week Against Pain", that chronic pain is a disease in its own right and should be treated as such, continues to be ignored. Whilst strategies are developed to combat other diseases across Europe, there is no such strategy for chronic pain, only an irregular hotchpotch of policies that provide little by way of a framework for improvement.

I would like to thank the OPEN Minds group for the research that they have carried out in producing this White Paper. I welcome it and in particular the Call to Action and look to governments to implement them as part of the concerted and focused strategies to combat chronic pain that patients of this devastating condition need and deserve.

Yours sincerely

Françoise Grossetête MEP President, European Parliament Pain Intergroup, 1999–2004

# A BALANCED REVIEW: A UK CASE STUDY

In the UK, the government is currently undergoing a thorough review of the manner with which patients access controlled drugs. The review comes in response to the recommendations of the Shipman Inquiry, the independent enquiry launched in February 2000, following specific criminal activities involving the misuse of morphine.

The objectives of the Inquiry included to enquire into the performance of the functions of those statutory bodies, authorities, other organisations and individuals with responsibility for monitoring primary care provision and the use of controlled drugs and to recommend what steps, if any, should be taken to protect patients in future, and to report its findings to the Secretary of State for the Home Department and to the Secretary of State for Health.

On July 15th 2004, the 4th report of the Shipman Inquiry was published. This report considered the systems for the management and regulation of controlled drugs, together with the conduct of those who operated those systems. In its response to the Inquiry recommendations, Secretary of State for Health, John Reid recognised the importance of balance in their implementation:

"We fully accept the need to improve current arrangements for the management of controlled drugs, and to do so in a way which does not hinder patients from accessing the treatment they need."

The Government plan of action includes the following:

## Education:

The Government will review the curricula for undergraduate and postgraduate education so that all newly graduating healthcare professionals understand the legal requirements and have the knowledge and skills to use controlled drugs appropriately and safely as an integral part of high quality care.

## • Prescription Limits:

The Government will issue guidance making clear that single prescriptions for controlled drugs in Schedules 2–4 should normally be limited to a supply of 28/30 days, unless exceptional circumstances, such as a patient travelling abroad, require this time to be extended.

## Validity of Prescription Forms:

The Government proposes to amend the Misuse of Drugs Regulations 2001 to limit the validity of prescriptions for controlled drugs in Schedules 2–4 to 28/30 days.

## Amendment of Prescription Forms:

The Government will redesign the standard NHS prescription form allowing for the inclusion of the patient's ID and a marker whenever the prescription is for a controlled drug.

## Monitoring of Prescription Forms:

Pharmacies dispensing such prescriptions will send copies of the form to a central data repository for analysis.

## • Best Practise:

The Government will introduce legislation enabling supplementary prescribers (nurses and pharmacists) to prescribe controlled drugs where there is genuine need and where patient safety can be assured.

The OPEN Minds Group welcomes the decision by the UK government to undertake such a review, a process that we have indicated in our Call to Action should be repeated in other countries across Europe. We also welcome the fact that the review has been guided by the principle that criminal activity should not dictate medical practice – something that all governments should acknowledge when looking to achieve the right balance between control and treatment.

# THE MEMBERS OF OPEN MINDS ARE AS FOLLOWS

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The OPEN Minds Group would like to acknowledge the advice and guidance of David E. Joranson of the University of Wisconsin Pain and Policy Studies Group.



The OPEN Minds initiative is funded by an educational grant from Mundipharma International Limited.