
INTERNATIONAL FEDERATION OF HEALTH AND HUMAN RIGHTS ORGANISATIONS

# Poor Access to Pain Treatment:

## Advancing a Human Right to Pain Relief

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**Report to the International Federation of Health and Human Rights Organisations (IFHHRO)**

## Contents

## List of Abbreviations

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| ACHPR | African Charter on Human and Peoples' Rights |
| CAT | Convention Against Torture and other Cruel, Inhuman and Degrading Treatment |
| CESCR | United Nation's Committee on Economic, Social and Cultural Rights |
| CIDT | Cruel, Inhuman and Degrading Treatment |
| CND | Commission on Narcotic Drugs |
| ECHR | European Convention on Human Rights and Fundamental Freedoms |
| EcommHR | European Commission on Human Rights |
| ECOSOC | Economic and Social Council |
| ECtHR | European Court of Human Rights |
| ESC | European Social Charter |
| ICESCR | International Covenant on Economic, Social and Cultural Rights |
| ICCPR | International Covenant on Civil and Political Rights |
| IFHHRO | International Federation of Health and Human Rights Organisations |
| INCB | International Narcotics Control Board |
| SCND | Single Convention on Narcotic Drugs |
| UDHR | Universal Declaration on Human Rights |
| UN | United Nations |
| UNGA | United Nations General Assembly |
| UNODC | United Nations Office on Drugs and Crime |
| WHO | World Health Organization |

## Preface

In over 150 countries proper pain and palliative care treatment is exception rather than rule. Hence over 80 per cent of the world's population has either no or poor access to pain relief services. The present report is written against the background of this contemporary public health deficit and is proffered to the International Federation of Health and Human Rights Organisations (IFHHRO), a NGO based in the Netherlands, as a research report in the context of the Open Society Institute's campaign: 'Stop Torture in Health Care'.

IFHHRO aims to counter the huge deficit of maltreated pain on a global scale by raising broad awareness to the topic and improving understanding of the relevant technical legal issues. To attain this goal, IFHHRO publishes reports, writes manuals, trains health workers on the subject of human rights and continues to shape debates in the field of drug policy reform from a pain patient's perspective.

At present, Marie Elske Gispen works as Ph.D. Candidate for the Netherlands Institute of Human Rights (SIM) and Ethics Institute of Utrecht University. Her work principally focuses on the role of human rights in maintaining a balance between access to controlled medicine and drug control as complementary, instead of mutually exclusive, obligations. She is also attached to the London based International Centre on Human Rights and Drug Policy as a Research Associate.

The author wishes to especially thank Adriaan van Es (director of IFHHRO) and Brigit Toebes (board member of IFHHRO) for sharing their expertise and their guidance in drafting the present report.

An earlier version of the present report was submitted as LL.M. thesis to Utrecht University, Faculty of Law, Economics and Governance, School of Law.[1]

[1] M.E.C. GISPEN, *Advancing Access to Opioid Analgesics: The Human Right to Pain Treatment vs the International Drug Regulatory Framework – the Human Rights Value of the Single Convention on Narcotic Drugs* (Utrecht: 2011) [LL.M. Thesis].

## Executive Summary

The Single Convention on Narcotic Drugs (SCND, Single Convention) of 1961, is the main international agreement that regulates the illicit use of opium and access to opioid analgesics. The SCND's foundational principle is the *principle of balance*. The principle translates into the dual obligation for States to: i) combat, amongst others, the illicit use, trafficking, manufacture and distribution of opium, and ii) allow access to opioids for medical purposes. Despite the positive role the Single Convention played in mainstreaming previous drug control treaties, its present implementation and treaty interpretation is detrimental to advancing access to opioid analgesics for medical purposes.

Even though the SCND was not intended to be established as a human rights treaty, its mandate covers various human rights issues ranging from poor pain relief treatment for pain patients to poor rehabilitation programs for risky drug abusers. The present report focuses on the position of the millions of people that suffer unbearable pain on a daily basis. According to the World Health Organization (WHO), pain treatment and palliative care services remain widely unavailable in over 150 countries. This affects around 80 per cent of the world's population which includes large groups of cancer and HIV/Aids infected patients. Inasmuch this global cry for pain relief is one of the gravest and transcending contemporary public health deficits. Pain relief could be easily attained if morphine, the key medicine used in effective pain treatment, was dispensed according to the WHO's standards.

Access to essential medicines is obstructed in many ways; this is in particular acute for the controlled opioid analgesics. Many barriers exist on the national and international level, ranging from legislative, policy and regulations barriers, to educational, informational, economic and political barriers, resulting in an aggravated and remaining stigma on the use of opioids in medical settings. This report, however, responds to the global public health deficit of poor access to pain treatment by advancing a human right to pain relief and explores the nexus between State obligations in the field of international drug control and human rights. Despite a wide range of other barriers limiting the medicinal use of opioids, the present report focuses on the SCND.

Adoption of the SCND was significant in establishing a strict and harsh approach to drug control. For instance, State parties to the SCND have to submit annual estimates and quarterly statistical returns to the International Narcotics Control Board (INCB), the treaty's monitoring body. These two monitoring mechanisms are highly burdensome for States as they require accurate statistics to be produced and a high level of bureaucracy to be maintained in order to monitor the use of opium. As a result, developing countries, in particular, fail to comply. To a large extent, this can be linked to developing countries often having poor levels of government administration, weaker economies, and arguably less reliance on functioning rules of law. These elements of governmental organisation form, more or less, a threshold to satisfactory treaty compliance. In consequence, licit access to opioids for medical purposes remains exceptional to the vast majority of people living in developing countries, even though the need for these medicines is highest in those countries. Even more disturbing is the setback of opioid availability which has been traced in developing countries over time. As part of their mandate, the INCB should assist States with treaty compliance, however, at present its efforts seemingly remain a 'rhetorical commitment'.

This major public health deficit should be addressed under the human rights framework, specifically, the right to health which enables individuals to claim a human right to pain relief as part of the right's minimum core. In addition to the general obligations to respect, protect and fulfil human rights, States need to

safeguard treaties' *raison d'être* through progressive realisation and obligations of immediate effect. Through the latter the international society aims to safeguard the minimum core standard of livelihood for individuals. The United Nation's (UN) Committee on Economic, Social and Cultural Rights (CESCR) distinguished in its general comments 3 and 14, access to essential medicines, including morphine, as one of the core obligation of immediate effect as part of the effective realisation of the right to health. The adoption of national health care strategies, including palliative care, is also part of this minimum core realisation. Accordingly, the human right to pain relief is reinforced by the prohibition of cruel, inhuman and degrading treatment, for it is increasingly argued that States failing to secure access to pain treatment do not adequately discharge their human rights obligations.

The present report demonstrates that State compliance with the SCND is at loggerheads with a States obligation to safeguard an individual's human right to pain relief. If heavily restricted under the SCND, developing countries are simply not able to allow individuals to access opioid analgesics. For the SCND demands States to comply with a highly burdensome, vastly developed administrative system that they often cannot rely on. Many attempts have been taken at an international level to counter this deficit, and to this end, the UN has managed a twofold approach. On the one hand it endeavours to advance the present level of drug control and at the same time calls on drug control liberalisation to advance access to opioid analgesics.

The report concludes that, even though the balance of interest that comes with regulating opium is maintained in theory, present-day interpretation and response to the global public health deficit of poor access to controlled substances like morphine, unfortunately signifies a counter-effective and renegade approach towards human rights protection and the realisation that serious action should be taken towards a paradigm shift reflecting a more holistic approach.

*Adding life to the days, not days to the life*
—Cicely Saunders[2]

# 1 Introduction

The Single Convention on Narcotic Drugs[3] (SCND, Single Convention) of 1961, the main international agreement regulating the production and supply of opioids, signifies the adoption of a strict and harsh approach to combat illicit drug use. The Single Convention is based on the *principle of balance*.[4] This principle reflects dual State obligations: i) to combat, amongst others, the illicit use, trafficking, manufacture and distribution of opioids, and ii) to allow, and further, access to narcotic drugs[5] for medical and scientific purposes. The efficacious discharge of this double obligation expects States to comply with a highly developed bureaucratic system.

Even though the SCND was not by intent established as a human rights treaty, its mandate covers various human rights issues ranging from poor access to controlled substances for medical purposes to poor rehabilitation programs for risky drug abusers.

Despite the positive role the SCND has played in mainstreaming previous drug control treaties, in practice, many States struggle with treaty compliance and access to pain and palliative care[6] treatment, by means of dispensing morphine, remains unattainable to 80 per cent of the world's population.[7] Hence, the realisation of one of the key components of the 8th Millennium Development Goal, to secure access to essential medicines in developing countries, seems further away for opioid analgesics than any other class of medicine.[8] As a matter of fact, the treaty's balanced emphasis has imbalanced consequences in practice. Overall, 90 per cent of the global amount of morphine used for medical purposes is traced back to big consumer countries, among which: the United States of America (USA), Canada, New Zealand and a number of Western European Countries.[9] By comparison, only 6 per cent of opioids used for medical purposes is traced back to developing countries, which represent about 80 per cent of the global population.[10] As a result, people are denied sufficient pain and palliative care treatment despite a pronounced need for such care. The individuals suffering unbearable pain relate, amongst other patients groups, to circa 70 per cent of all cancer patients and research highlights the wide-ranging prevalence of pain endured by patients infected with HIV/Aids.[11] Untreated pain leaves people suffering in undignified, and in some cases, inhuman situations. Pain, as being a complex interplay of different mediators, has, amongst others, a detrimental effect on a person's physical state has a significant psychological impact. It is generally accepted that pain treatment by means of using opioids like morphine —an essential medicine according to the World Health

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2 Quote by Dame Cicely Saunders, first modern hospice founder. Quoted in HRW, *Unbearable Pain, India's obligation to Ensure Palliative Care* (New York: Human Rights Watch, 2009), p. 11.

3 Single Convention on Narcotic Drugs (entered into force 13 December 1964) UN Doc E/RES/1961/833 (XXXII) B (1961) 520 UNTS 151 (SCND).

4 SCND, preamble.

5 Narcotic drugs is a legal term to refer to opioid analgesics.

6 The WHO defines palliative care as an: 'approach that improves the quality of life of patients and their families facing the problem associated with 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.' According to the WHO pain relief treatment is one of the key-elements of palliative care treatment. See <http://www.who.int/cancer/palliative/definition/en/> accessed 4 July 2012.

7 See <http://www.who.int/medicines/areas/quality_safety/access_Contr_Med/en/index.html> accessed 28 March 2012. See also IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011); UNGA, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health* (2010) UN Doc A/65/255; A.L. TAYLOR, 'Addressing the Global Tragedy of Needless Pain: Rethinking the United Nations Single Convention on Narcotic Drugs' 35 (2007) *Journal of Law, Medicines and Ethics*, pp. 556-570, at p. 556.

8 See M.J. SEYA *et al.*, 'A First Comparison Between the Consumption of and the Need for Opioid Analgesics at Country, Regional and Global Levels' 25 (2011) *Journal of Pain and Palliative Care Pharamcotherapy* pp. 6-18, at p. 6.; Millennium Development Goals, MDG 8, indicator 5. Available at: <http://www.undp.org/content/undp/en/home/mdgoverview/mdg_goals/mdg8/> accessed 9 May 2012.

9 INCB, *Annual Report 2009* UN Doc E/INCB/2009/1, para 80.

10 INCB, *Annual Report 2004* UN Doc E/INCB/2004/1, para 143.

11 D. LOHMAN *et al.*, 'Access to pain treatment as a human right' 8 (2010) *BMC Medicine* pp. 1-8, at p. 1.

Organization (WHO)[12]— relieves pain and enables individuals to maintain a level of human dignity.

## 1.1 Framework of analysis

The global political conception of human rights conveys the protection of individual's human dignity against abusive power by means of an established framework of fundamental rights.[13] Poor access to pain relief as a grave violation of human dignity, translates into a human right to pain relief under the present human rights framework.

Under the right to health, pain treatment is recognised as an integral aspect of its satisfactory realisation and palliative care harmonises well with the eminent goals set forth under the fulfilment of the right in general. Notably, the United Nation's (UN) Committee on Economic, Social and Cultural Rights (CESCR) emphasises, in its general comment 14, that free access to essential drugs, including morphine[14], is one of the minimum core obligations of States that require immediate implementation.[15]

In line with, Manfred Nowak, the former United Nation's Special Rapporteur on the question of torture, and Anand Grover, the present Special Rapporteur of the UN on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, it is also increasingly argued that States who fail to ensure access to pain and palliative care treatment through the use of opioids, have not adequately discharged the obligation to protect individuals against inhuman and degrading treatment.[16]

Various obstacles, however, have made it rather difficult for States to allow individuals to access essential medicines[17] and this problem is particularly acute for controlled opioid analgesics such as morphine.[18] Barriers on both the national and international level cause the inadequate availability and accessibility of opioids for medical purposes.[19] Within the international law arena, the present international drug control scheme is one of the radical barriers that obstruct patients' legitimate need to access opioid analgesics.

Though the domains of drug control and access to opioids for medical purposes are conceptually linked in the SCND, in practice the treaty's efficacy appears rather imbalanced

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12 WHO 'Model List of Essential Medicines' (2011), p. 2. Available at <http://whqlibdoc.who.int/hq/2011/a95053_eng.pdf> accessed 17 June 2011

13 B. DE GAAY FORTMAN, *Political Economy of Human Rights* (Abingdon: Routlegde, 2011), p. 5.

14 WHO 'Model List of Essential Medicines' (2011), p. 2. Available at <http://whqlibdoc.who.int/hq/2011/a95053_eng.pdf> accessed 4 July 2012. Analgesics is a term to refere to medication used to control pain, they are commonly refered to as 'pain killers'. Morphine is an analgesic essential to the treatment of pain, however, it may be used as an anaesthetic too. Anaesthetics are medicines used for instance in surgery. This difference only reflects on the type of medical intervention that demands the use of morphine. The lack of access to morphine is blind to this difference. See also PETER HOLZER AND FRED LEMBECK, 'Analgesia up to the twentieth century' in M.J. PARNHAM AND J. BRUINVELS (eds), *Discoveries in Pharmacology*, vol 1 (Amsterdam: Elsevier, 1983), pp. 357-377.

15 CESCR, *General Comment No. 14 (2000): The right to the highest attainable standard of health*, UN Doc E/C.12/2000/4, 11 May 2000.

16 HRC, *Report of the Special Rapporteur on Torture and other Cruel, Inhuman or Degrading Treatment or punishment* (2010), UN Doc A/HRC/10/44, para 72. See also M. NOWAK AND A. GROVER, *Joint letter to Mr Best, Vice-Chairperson of the Commission on Narcotic Drugs (52nd Session) in their capacity as Special Rapporteurs*, UN Doc G/SO 214 (53-21), 10 December 2008.

17 STEPHAN MARKS, 'Access to Essential Medicines as a Component of the Right to Health' in A. CLAPHAM AND M. ROBINSON (eds), *Realizing the Right to Health* vol. 3. (Zurich: Rueffer & Rub, 2009), pp. 80-99, at p. 84.

18 See amongst others UNGA, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health* (2010) UN Doc A/65/255, p. 13; IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011); D. LOHMAN *et al.*, 'Access to pain treatment as a human right' 8 (2010) *BMC Medicine* pp. 1-8; HRW, *"Please do not make us suffer anymore…" Access to Pain Treatment as a Human Right* (New York: Human Rights Watch, 2009).

19 See for an overview of all barriers, identified so far, that obstruct free access to opioid analgesics. KATHLEEN FOLEY *et al.*, 'Pain Control for People with Cancer and AIDS' in D.T. JAMISON *et al.* (eds), *Disease Control Priorities in Developing Countries*, 2nd edn (New York: Oxford University Press, 2006), pp. 981-991, at p. 981; F. BRENNAN *et al.*, 'Pain Management: A Fundamental Human Right' 105 (2007) *Anesthesia & Analgesia* pp. 205-221; D. LOHMAN *et al.*, 'Access to pain treatment as a human right' 8 (2010) *BMC Medicine* pp. 1-8; UNGA, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health* (2010) UN Doc A/65/255.

in how it affects peoples' day-to-day lives. The treaty interpretation of the International Narcotics Control Board (INCB), the SCND's treaty based monitoring body, in light of advancing access to controlled medicine for medical purposes is of key importance in this respect. Its interpretation is a token of how the principally USA driven global 'war on drugs' has completely overshadowed the realisation of access to essential controlled medication and palliative care, aspects indispensable to the full enjoyment of the right to health.[20]

### 1.1.1 Research approach

Due in part to the SCND's significant impact on the effective realisation of elementary aspects of the right to health, various human rights violations occur and remain to exist in the field of access to controlled medication. This report will respond to the global public health deficit of poor access to pain treatment by advancing a human right to pain relief and exploring the nexus of State obligations in the field of international drug control and human rights.

In chapter 2, the significance of advancing a human right to pain relief is elaborated by tracing an overview of the global impact of the unavailability of opioids for medical purposes in pain treatment and palliative care settings. The section will trace an overview of the present public health deficit by: i) elaborating a non-limitative overview of categories of people eligible for treatment, ii) addressing what pain constitutes and how pain functions as a diminishing factor to a person's ability of living life in dignity, and iii) expanding the dual character of opium and the predicament that underlies the present international control mechanisms.

In chapter 3, the broader contextualisation of barriers that obstruct access to opioids for medical purposes will be addressed for poor access to controlled medication in pain and palliative care settings is subject to a larger set of barriers at both international and national level. The section will divide into a section on i) legislative, policy and regulations barriers, ii) education and informational barriers, and iii) economical and political barriers.

In chapter 4, the international drug control scheme, in particular the SCND, as a radical barrier for States to allow access to controlled medication will be highlighted. In order to gain insight in the respective State obligations and the balance of interest that comes with regulating opium, the section will elaborate on: i) the scheme's drafting history and in particular the drafting process of the SCND, and ii) the present scheme and its instruments and mechanisms that maintain the present level of drug control.

In chapter 5, the report will expand a broader understanding of the context of human rights prior to establishing a human right to pain relief. The section will address: i) the international bill of rights as the leading codification of contemporary human rights, ii) a normative conception of its foundational conception of human dignity, and iii) the different rights and obligations as stemming from the present framework.

In chapter 6, the report will advance the human right to pain relief and will normatively position pain treatment within the field of human rights. The report will elaborate this right on the basis of: i) the right to health and the relevant minimum core obligations that foster a right to pain relief, and ii) the prohibition of inhuman and degrading treatment for it is increasingly argued that the denial of pain treatment is a breach of States' obligation to protect individuals against this type of treatment.

In chapter 7, the report will discuss the nexus of State obligations deriving from the international drug control scheme and human rights framework. It will provide for an analysis on treaty adherence and will highlight the twofold approach of leading international bodies.

In chapter 8, the report will elaborate several concluding observations.

[20] See for example UNGA, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health* (2010) UN Doc A/65/255.

### 1.1.2 Methodology

The research that underlies the present report is carried out according to the traditional legal approach. Amongst others, relevant legislation, case-law and policy is analysed at international, regional and national level. The report is based on a literature study of academic writing from various disciplines (law, ethics, medicine and pharmacy). In addition, the report has taken into account the relevant work of monitoring bodies, leading UN bodies, civil society and other actors in the field by the use of, amongst others, research reports, annual reports, declarations, general comments, recommendations and factsheets.

## 2 The Global Crisis of Denied Pain Treatment

The significance of the research that underlies the present report is traced to one of the major contemporary impediments in advancing global public health. Poor pain relief treatment, due in large part to a lack of access to opioids for medical purposes, is of detrimental effect to a vast majority of the world's population.

### 2.1 Pain patients

According to the WHO, over 150 countries have serious problems with providing pain treatment and palliative care facilities. On a daily basis this results in about 80 per cent of the population suffering maltreated or even untreated pain.[21] According to a recent study of the WHO, only 7 per cent of the world's population (460 million people) have adequate access to pain and palliative care services and only 4 per cent (250 million people) have moderate access against the background of 83 per cent of the world's population that suffer poor and non-existent pain treatment services.[22]

Pain is commonly understood as a prevalent symptom of cancer diseases. Evidence-based research demonstrates that approximately 50 per cent of cancer patients undergoing treatment experience chronic pain and that 60-90 per cent of patients in an advanced stage of their disease experience moderate to severe pain.[23] Based on the GLOBOCAN statistics the world calculated around 12.7 million cancer patients in 2008.[24] Though HIV/Aids has not always been considered a 'painful disease', recent statistics demonstrate the prevalence of similar to worse pain experiences under HIV/Aids patients.[25] According to UNAIDS, the UN joint programme on Aids, at the end of 2010 the global number of people living with HIV/Aids is estimated at around 34 million.[26] Due in main part to the increasing availability of antiretroviral treatment the number of HIV/Aids infected patients annually increases.[27] Research demonstrates that an estimated 29-74 per cent of all patients receiving antiretroviral treatment experience pain.[28] Pain experiences in cancer and HIV/Aids are often classified as chronic pain syndromes.[29] The number of cancer and HIV/Aids patients who experience pain reflect only a sample of the world's health crisis of mal- and under treated pain patients.

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21 See <http://www.who.int/medicines/areas/quality_safety/access_Contr_Med/en/index.html> accessed 28 March 2012.

22 See M.J. SEYA *et al.*, 'A First Comparison Between the Consumption of and the Need for Opioid Analgesics at Country, Regional and Global Levels' 25 (2011) *Journal of Pain and Palliative Care Pharamcotherapy* pp. 6-18, at p. 6.

23 P. LESAGE AND R.K. PORTENY, 'Trends in Cancer Pain Management' 2 (1999) *Cancer Control* pp. 136-145. See also FOLEY *et al.*, 'Pain Control for People with Cancer and AIDS' in D.T. JAMISON *et al.* (eds), *Disease Control Priorities in Developing Countries*, 2nd edn (New York: Oxford University Press, 2006), pp. 981-991, at p. 982. Although there are no 'population-based studies of AIDS-related pain', researchers do emphasise that 80 per cent of HIV/Aids patients are in need of pain treatment through opioid use in the final stage of their disease due to phase of illness and the degree of pain they experience.

24 See <http://globocan.iarc.fr/factsheets/cancers/all.asp> accessed 27 March 2012.

25 'Pain in Aids: A Call for Action', IV (1996) *Pain Clinical Updates*, pp. 1-8, at p. 1. Available at <http://www.iasp-pain.org/AM/AMTemplate.cfm?Section=HOME&CONTENTID=7601&TEMPLATE=/CM/ContentDisplay.cfm&SECTION=HOME> accessed 27 March 2012.

26 The exact number fluctuates between 31.6 and 35.2 million people. See UNAIDS, *How to Get to Zero: Faster. Smarter. Better.* (Geneva: UNAIDS, 2011), p. 6.

27 UNAIDS, *How to Get to Zero: Faster. Smarter. Better.* (Geneva: UNAIDS, 2011), p. 6.

28 HRW, *"Please do not make us suffer anymore…" Access to Pain Treatment as a Human Right* (New York: Human Rights Watch, 2009), p. 5.

29 FOLEY *et al.*, 'Pain Control for People with Cancer and AIDS' in D.T. JAMISON *et al.* (eds), *Disease Control Priorities in Developing Countries*, 2nd edn (New York: Oxford University Press, 2006), pp. 981-991, at p. 982.

## 2.2 Pain as a disease entity

There is no comprehensive definition of pain, though it is often referred to as a subjective experience of an unpleasant sensation that differs from person to person and is mediated by a complex interplay of pain mediators.[30] Or, as the International Association on the Study of Pain defines it, pain is '[a]n unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage'[31]. Evidently, the experience of pain is generally hard to define and depends on several pathophysiological mechanisms.

Typically, pain is a response to tissue damage caused by injury, inflammation, cancer and aids. Many medical conditions are accompanied by pain and pain as a disease entity exists in various different types. From a patient perspective, pain distinguishes in disease related pain and treatment related pain.[32] From a medical perspective, pain classifies as temporal and physiologic pain. Temporal, or neuropathic pain comprehends acute and chronic or persistent pain. Physiologic, or nociceptive pain is somatic, visceral and neuropathic pain. Both nociceptive and neuropathic pain may lead to acute or chronic pain syndromes.[33] Pain treatment and palliative care serve amongst others the purpose to redress chronic pain.

Chronic pain is, as Brennan puts it aptly: 'lined with a constellation of maladaptive physical, psychological, family and social consequences and can be regarded as a disease entity *per se*.'[34] The experience of moderate to severe pain generally has a major impact on an individual's quality of life.[35] This profound impact is in part attributed to a physical impact on the human body and also, in part, to a significant psychological impact on the human spirit.[36]

On the physical level, patients living with chronic pain syndromes face problems such as reduced mobility, loss of strength, sleep disruption and dependence on medication.[37] Additionally, according to a study on persistent pain in primary health care of the WHO, pain patients are four times more likely to suffer from depression or anxiety.[38] Pain has a huge impact on one's ability to function in social and economic life too. Chronic pain patients face more difficulties regarding employment and job maintenance, participation in social activities, enjoyment of leisure time and the inability to take care of children.[39] In addition to affecting those who actually experience pain, unbearable pain also negatively impacts caregivers which are mostly family members. Due to pain the patients they care for suffer, family-members or other caregivers may face, for example, sleep deprivation, which can result in an inability to work, loss of income or worse consequences.[40]

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30 J.M.A. SITSEN *et al.*, (eds), *Farmacologie*, 2nd edn (Amsterdam: Elsevier, 2001) pp. 101-105.

31 See <http://www.iasp-pain.org/AM/Template.cfm?Section=Pain_Defi...isplay.cfm&ContentID=1728#Pain> accessed 18 April 2012.

32 In developing countries, disease related pain is most reported unlike treatment related pain because in developing countries people often only start seeing a doctor at the time they already experience pain. See FOLEY *et al.*, 'Pain Control for People with Cancer and AIDS' in D.T. JAMISON *et al.* (eds), *Disease Control Priorities in Developing Countries*, 2nd edn (New York: Oxford University Press, 2006), pp. 981-991.

33 Nociceptive pain is associated with inflammation and can be somatic or visceral. Neuropathic pain, on the other hand, 'is an intense central originated pain, and is the consequence of damage, compression or dysfunction of the peripheral nerves or of the' central nerve system. L.A. URGELLÉS-LORIÉ, 'Nociceptive Pain vs Neuropathic Pain - A New Classification For Pain Control' 1 (2008) Physiological Regulating Medicine, pp. 39-42, at p. 40-41.

34 F. BRENNAN *et al.*, 'Pain Management: A Fundamental Human Right' 105 (2007) *Anesthesia & Analgesia* pp. 205-221, at p. 206.

35 HRW, *"Please do not make us suffer anymore…" Access to Pain Treatment as a Human Right* (New York: Human Rights Watch, 2009), p. 6. With regard to chronic pain it should be noted that even if no obvious organic disorder (disease) can be diagnosed, a person may suffer from chronic pain. See J.M.A. SITSEN *et al.*, (eds), *Farmacologie*, 2nd edn (Amsterdam: Elsevier, 2001) pp. 101-105.

36 See HRW, *Unbearable Pain, India's obligation to Ensure Palliative Care* (New York: Human Rights Watch, 2009).

37 HRW, *Unbearable Pain, India's obligation to Ensure Palliative Care* (New York: Human Rights Watch, 2009).

38 O. GUREJE *et al.*, 'Persistent pain and well-being: a World Health Organization study in primary care' 280 (1998) *JAMA* pp. 147-151, at p. 149.

39 R.L. DAUT *et al.*, 'Development of the Wisconsin Brief Pain Questionnaire to Assess Pain in Cancer and Other Diseases' 17 (1983) *Pain* pp. 197-210.

40 HRW, *"Please do not make us suffer anymore…" Access to Pain Treatment as a Human Right* (New York: Human Rights Watch, 2009), p. 6. See also R.L. DAUT *et al.*, 'Development of the Wisconsin Brief Pain Questionnaire to Assess Pain in Cancer and Other Diseases' 17 (1983) *Pain* pp. 197-210. Notably, according to the WHO, palliative

## 2.3 Effective pain treatment

At the time a patient's pain is recognised as either a symptom or disease entity, it is a matter of assessment whether or not the pain is treated effectively. A 'one size fits' all approach does not apply to pain relief treatment and the WHO established a 'pain relief ladder' that may serve as a treatment guide. Pain relief, however, has been and still is one of the most prominent priorities in the search for pharmacotherapies that ameliorate complications of disease related pain.

According to the WHO, pain can be divided into mild, moderate and severe categories.[41] If a patient experiences mild pain, procurement of non-opioid analgesics such as aspirin and paracetamol is considered sufficient. If the pain persists or increases it is identified as moderate pain. Moderate pain should be adequately treated with 'light' opioids. However, if 'light' opioids appear insufficient and the pain persists or increases, doctors should move to 'strong' opioid treatments and procure reasonable dosages of (oral) morphine. Morphine should be used until the patient is pain free. With regard to treatment maintenance, the WHO supposes that it is important to dispense 'by the clock', which means a dose every three to six hours. Using this scaled approach, together with administration of the right doses, leads to 80-90 per cent effective treatment.[42] Not only research but, even more so, practice shows that there is an apparent indispensable need for opioids in pain relief treatment.

## 2.4 The predicament that underlies opium

Modern pharmacotherapy owes a great debt to the observation by the Babylonians, circa 4000 BCE, that the dried extract from 'unripe seed capsules of the poppy (*Papaver somniferum*) called opium'[43]. On a global scale, opium use can be traced to 4000 BCE in Asia and north-western China, 900 BCE in the Near and Middle East, 800 BCE, in Europe, 2nd century CE, in South-Asia, 11th century CE in Africa, and the 19th century in America.[44] Its use 'relieves both pain and anxiety and promotes sleep and a feeling of peace and well-being'[45].

For thousands of years, opium has been used as a successful analgesic treatment, often in combination with alcohol. The term 'analgesia' is derived from Greek and means painlessness. As of the 17th century, opium was used as an alcoholic tincture. In the early 19th century, the chief active ingredient in opium was isolated and termed morphine (named after the Greek god of sleep, Morpheus).[46] Until the 20th century, opium and morphine were easily obtained and their use in medicine was not subject to severe regulations.[47] When in the 19th century, the hypodermic syringe and needle were invented and applied to relieve pain, unwanted side effects of morphine treatment became apparent. Specifically, the intravenous administration of morphine began to give rise to drug dependence and subsequent addiction.[48] A difficulty in this respect is the impact drug addiction has on situations in which health matters are at stake. Opium has been predominantly used for

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care encompasses care and support for family members involved in end of life cases. See <http://www.who.int/cancer/palliative/definition/en/> accessed 4 July 2012.

41 See <http://www.who.int/cancer/palliative/painladder/en/> accessed 18 April 2012.

42 See <http://www.who.int/cancer/palliative/painladder/en/> accessed 18 April 2012; WHO 'Model List of Essential Medicines' (2011), p. 2. Available at <http://whqlibdoc.who.int/hq/2011/a95053_eng.pdf> accessed 18 April 2012.

43 PETER HOLZER AND FRED LEMBECK, 'Analgesia up to the twentieth century' in M.J. PARNHAM AND J. BRUINVELS (eds), *Discoveries in Pharmacology*, vol 1 (Amsterdam: Elsevier, 1983), pp. 357-377, at p. 361.

44 UNODC, *100 Years of Drug Control*, ch. 2. World Drug Report (Vienna: UNODC, 2008), p. 15.

45 PETER HOLZER AND FRED LEMBECK, 'Analgesia up to the twentieth century' in M.J. PARNHAM AND J. BRUINVELS (eds), *Discoveries in Pharmacology*, vol 1 (Amsterdam: Elsevier, 1983), pp. 357-377, at p. 361.

46 PETER HOLZER AND FRED LEMBECK, 'Analgesia up to the twentieth century' in M.J. PARNHAM AND J. BRUINVELS (eds), *Discoveries in Pharmacology*, vol 1 (Amsterdam: Elsevier, 1983), pp. 357-377, at pp. 357-362. The structure of Morphine was determined in 1902.

47 See paragraph 0 for a more in-depth discussion on the drafting history of the present international drug control.

48 H. P. RANG *et al.,* (eds), *Pharmacology*, 5th edn (Edinburgh: Churchill Livingstone & Elsevier, 2003), pp. 562-563.

medical purposes, and in certain parts of society, for religious or cultural practices.[49] Hence, free access to opium use for medical purposes only became problematic after the use, manufacture and distribution became regulated in response to a perceived growth of illicit hazardous use.

### 2.4.1 A public health deficit

The dual character of opium is what makes the present need for morphine so pressing. Other alkaloids, both narcotic as well as non-narcotic derive from poppy too. Heroin is such a different (narcotic) opium alkaloid and is a synthesised form of morphine.[50] It is widely acknowledged that substances like heroin are illicit drugs and those who misuse it are a major concern for society.

Needle misuse, or sharing, is often the case with drug abusers which also significantly correlates to an increase of HIV/Aids and Hepatitis C incidence.[51] In individual cases,[52] the use of illicit drugs can set in motion a veritable tragic result: drug abusers have a higher risk of HIV/Aids contraction[53], which in turn may lead to unbearable pain experiences resulting in the need for morphine as a medicine essential to pain treatment and palliative care.[54] Opioids for medical purposes, however, are hardly available and difficult to access because of their potential highly addictive character (see Figure 1)[55].

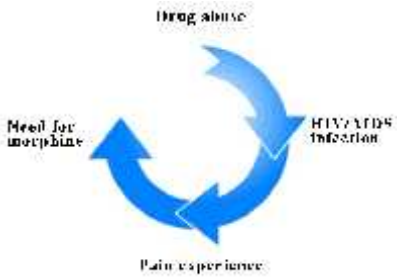

Figure 1: Opium's public Health Deficit

The side effect of drug addiction has very much stimulated further research for new analgesic drugs that possess fewer side effects and do not cause dependence and addiction.[56] Unfortunately, such drugs have not yet been discovered. Hence, the current situation is that a successful and needed drug in the therapy of pain is also a drug that, when misused, causes addiction and other health-related problems. It is this horrible predicament that underlies the conflicting legislation with respect to the accessibility and use of opioid analgesics in pain and palliative care treatment.

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49 H. P. RANG *et al.,* (eds), *Pharmacology*, 5th edn (Edinburgh: Churchill Livingstone & Elsevier, 2003), pp. 562-563. Poppy refers to *Papaver Somniferum*. See also SCND, art 1 sub q.

50 'Opium', *Columbia Electronic Encyclopedia*, 6th edn,(2010), p. 1. Available at <http://web.ebscohost.com.proxy.library.uu.nl/ehost/resultsadvanced?sid=a2dbf387-9a8e-4799-b1a2-383eafdad146%40sessionmgr114&vid=3&hid=104&bquery=(JN+%22Columbia+Electronic+Encyclopedia%2c+6th+Edition%22+AND+DT+20100701)+and+(opium)&bdata=JmRiPWFmaCZ0eXBlPTEmc2l0ZT1laG9zdC1saXZl> accessed 7 May 2011.

51 See amongst others R. JÜRGENS *et al*., 'Interventions to reduce HIV transmission related to injecting drug use in prison' 9 (2009) *Lancet Infect Dis,* pp. 57–66, at p. 57; D. VLAHOV *et al .,* 'Prevention of HIV Users in Resource-Limited Settings' 5 (2010) *CID, Suppl 3,* pp. 114-121, at p. 114. <http://www.who.int/hiv/topics/idu/en/index.html> accessed 30 March 2012.

52 In this report it is not sustained that in all cases of drug misuse an individual will contract HIV/Aids and eventually faces pain experiences which remain untreated because of heavily and over restrictive drug control regulations. Though the example demonstrates a horrible scenario of a possible effect of opium's underlying predicament.

53 See <http://www.who.int/hiv/topics/idu/en/index.html> accessed 30 March 2012.

54 The link between opium misuse and the need for pain treatment only reflects one out of the many issues related to illicit opium use and the interlink with the unavailability of opioids for pain treatment. The same holds true for the possible contraction of HIV/Aids in case of needle misuse. There are numerous root causes to pain experiences and there are also many other ways in which people contract HIV/Aids.

55 This figure was drafted by the author for the purpose of this report, with special thanks to Saskia Bal, informationspecialist at the SIM.

56 H.P. RANG *et al.,* (eds), *Pharmacology*, 5th edn (Edinburgh: Churchill Livingstone & Elsevier, 2003), pp. 562-563.

# 3 Barriers to Access Pain Treatment

Poor access to opioid analgesics in pain treatment is traced back to a variety of barriers. Though the international drug control scheme forms a serious obstruction towards opioid availability, the inadequate use of opioids for medical purposes is causal to a broader set of barriers rooted in legislation, policy, regulations, education, information services, economic incentives and politics at both an international and national level.[57]

## 3.1 Legislative, policy and regulations barriers

Often governments fail to enact palliative care and pain treatment policies. According to the WHO, under-treatment of cancer pain is rooted in the absence of national policies on cancer pain relief.[58] On a broader perspective, governments have failed to establish and implement comprehensive national strategies on pain treatment in general.[59] As a result, opioid analgesics are often missing on national essential medicine lists.[60] Additionally, governments have failed to establish policy guidelines regarding pain management training for health workers.[61] Furthermore, national drug legislation ignores the necessity of opioids for adequate pain treatment. This has resulted in the failure to recognise government obligations to allow individuals access to essential medicines such as morphine.[62]

Although the INCB has stipulated the importance of including the indispensable nature of opioids in pain treatment in national legislations, in 1995 only 48 per cent of responding governments had laws in place that made this reference.[63] In many countries, national governments also fail to ensure effectively functioning drug supply systems. Drug control regulations and enforcement mechanisms are often even more restricted by national governments. In many cases, health workers find themselves in difficult positions since the possession, prescription and procurement of opioid analgesics requires a special license.[64] Government policies remain, based on the fear that opioid diversion will lead to abuse and addiction.[65] This results in a special prescription procedure that requires the filling out of specific forms and multiple copies. In many cases, a colleague or superior has to consent to the amount prescribed.[66] Sometimes, other health workers are required as witnesses to the actual dispensing of opioids.[67] This results in a huge bureaucracy that hinders health workers from defining the needs of a patient and providing for customised pain treatment.

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57 The present overview is non-exhaustive and addresses the barriers in a random order. To a large extent this section is based on discussions that took place at the two-day workshop 'Pain Treatment as a Human Right' organised by IFHHRO and the Open Society Institute on 20-21 January in de Bilt, the Netherlands. See IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011).

58 D. LOHMAN *et al.*, 'Access to pain treatment as a human right' 8 (2010) *BMC Medicine* pp. 1-8, at pp. 2-5, at p. 3. See WHO, *Cancer Pain Relief*, 2nd edn, (Geneva: WHO, 1996) p. 42.

59 D. LOHMAN *et al.*, 'Access to pain treatment as a human right' 8 (2010) *BMC Medicine* pp. 1-8, at p. 3. See JAN STJERNSWÄRD AND DAVID CLARK, 'Palliative medicine: a global perspective' in G. DOYLE *et al.*, (eds), *Oxford Textbook of Palliative Medicine* 3rd edn (Oxford: Oxford University Press, 2003) pp. 1199-1224. According to Stjernswärd and Clark government policy is essential to ensuring adequate palliative care in a cost-effective manner. Additionally, the WHO maintains that government policy is one of the key features necessary to access opioids for medical purposes.

60 R. HARDING *et al.*, *Pain relieving drugs in 12 African PEPFAR countries: Mapping current providers, identifying current challenges, and enabling expansion of pain control provision in the management of HIV/Aids* (London: King's College London, APCA, 2007) pp. 19-21.

61 D. LOHMAN *et al.*, 'Access to pain treatment as a human right' 8 (2010) *BMC Medicine* pp. 1-8, at pp. 2-5, at p. 3.

62 IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011), p. 10; D. LOHMAN *et al.*, 'Access to pain treatment as a human right' 8 (2010) *BMC Medicine* pp. 1-8, at pp. 2-5, at p. 3.

63 INCB, *Availability of Opiates for Medical Needs* (Special Report) pursuant to ECOSOC Res 1990/31 and 1991/43 UN Doc E/INCB/1995/1, para 17.

64 D. LOHMAN *et al.*, 'Access to pain treatment as a human right' 8 (2010) *BMC Medicine* pp. 1-8, at pp. 2-5, at p. 4.

65 F. BRENNAN *et al.*, 'Pain Management: A Fundamental Human Right' 105 (2007) *Anesthesia & Analgesia* pp. 205-221, at p. 209.

66 IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011), p. 10.

67 See D. LOHMAN *et al.*, 'Access to pain treatment as a human right' 8 (2010) *BMC Medicine* pp. 1-8, at pp. 2-5, at p. 4.; V. ADAMS *et al.*, 'Access to Pain Relief: An Essential Human Right A Report for World Hospices and Palliative Care Day 2007' 22 (2008) *Journal of Pain and Palliative Care Pharmacotherapy* pp. 101-129.

In many countries health care workers fear legal sanctions when prescribing, procuring or dispensing controlled substances.[68] There is a precedence of prosecutions of health workers for unintended maltreatment or mishandling of pain treatment.[69] National criminal codes often prescribe severe legal sanctions for illegal opioid possession, trafficking and manufacture.[70] The precedence of lawsuits against physicians prescribing opioid analgesics has had a 'chilling effect' on this practice.[71] Thus, because of the ambiguity in regulations and the poor communication between regulators, health care workers discourage pain treatment.[72]

## 3.2 Educational and informational barriers

Huge disparities exist within different training manuals of health workers. Most medical curricula lack a special training program on pain management or effective pain treatment.[73] If pain is identified there is, in general, inadequate knowledge on how to assess and treat pain effectively.[74] Many myths and misconceptions based on ignorance about severe pain treatment by use of strong medication, for instance, there are no reasonable doses of morphine, remain prevalent.[75] Unfounded assumptions, such as, opioid use would impair quality of life, opioid use should be the final option and therefore only dispensed in the final stage of disease and the unrealistic fear of adverse side-effects, abound.[76] Evidence-based research, however, demonstrates that controlled morphine use does not necessarily lead to addiction. Indeed, amongst many it is still commonly accepted that pain is necessary for an accurate diagnosis, even when studies show that this is not the case.[77] The belief that pain has 'negligible consequences' is rebutted by numerous studies that demonstrate and advocate pain as a multidimensional medical issue that demands an interdisciplinary approach.[78]

Many patients have inadequate access to reliable and 'user-friendly' information flyers because the majority of health care institutions simply do not provide for it. Misperceptions and ignorance through misinformation remain in relation to pain, pain medication and adequate treatment.[79] For the most part, governments fail to establish pain treatment policies, though in cases, where relevant policies are in place they are often malfunctioning.[80] As a result, patients lack sufficient communication about their disease and related symptoms.[81] The policies in place that aim to further their position as untreated pain patient remain unclear because these policies are often malfunctioning.

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68 IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011), p. 11.

69 F. BRENNAN *et al.*, 'Pain Management: A Fundamental Human Right' 105 (2007) *Anesthesia & Analgesia* pp. 205-221, at p. 209. Brennan amplifies the American 'doctrine of balance'. This resulted in a list of Frequently Asked Questions published by the United States Drug Enforcement Administration in 2004. This list anchored the 'doctrine of balance' between physicians prescribing opioids and regulators regulation the illicit use of it, even though the non-liability of opioid prescription was reassured. After 2004 lawsuits were filed against physicians prescribing too large amounts of controlled substances. As of 2007 the physicians remain in prison. See also IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011), p. 11.

70 IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011), p. 11.

71 D. LOHMAN *et al.*, 'Access to pain treatment as a human right' 8 (2010) *BMC Medicine* pp. 1-8, at pp. 2-5, at p. 5. Lohman emphasises that some people believe that it is the core obligation of a doctor to treat its patient. If this doctor, by any reasons neglects to do so he should be held individually accountable. Others believe that it is not the doctor who is to blame the inadequacy in pain treatment since they are bound by the strict rules set out by the government.

72 IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011), p. 11.

73 V. ADAMS *et al.*, 'Access to Pain Relief: An Essential Human Right A Report for World Hospices and Palliative Care Day 2007' 22 (2008) *Journal of Pain and Palliative Care Pharmacotherapy* pp. 101-129, at p.118.

74 F. BRENNAN *et al.*, 'Pain Management: A Fundamental Human Right' 105 (2007) *Anesthesia & Analgesia* pp. 205-221, at p. 209. See in particular Brennans paragraph 'Medical and Lay Ophiophobia and Opioignorance'.

75 IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011), pp.6-7.

76 F. BRENNAN *et al.*, 'Pain Management: A Fundamental Human Right' 105 (2007) *Anesthesia & Analgesia* pp. 205-221, at p. 209.

77 D. LOHMAN *et al.*, 'Access to pain treatment as a human right' 8 (2010) *BMC Medicine* pp. 1-8, at pp. 2-5, at p. 4. See WHO, *Cancer Pain Relief*, 2nd edn, (Geneva: WHO, 1996) p. 42.

78 See paragraph 0

79 F. BRENNAN *et al.*, 'Pain Management: A Fundamental Human Right' 105 (2007) *Anesthesia & Analgesia* pp. 205-221, at p. 208.

80 See paragraph 0.

81 IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011), p. 10.

Many other barriers exist, for example, in the form of the attitudes of health workers and patients. This is strongly affiliated with health ethics, and strong power relations within health care systems as well as political influences.[82]

## 3.3 Economical and political barriers

Pain treatment and the accompanied costs of treatment and medication are often subject to inflation.[83] Morphine is one of the cheaper medicines[84], though large differences appear in pricing between countries. The central government often regulates morphine pricing or the pricing of other opioid analgesics.[85] Local production has a high overhead and low demand.[86] Furthermore, non-generic, and thus, costly, opioid analgesics are promoted throughout many countries.[87]

Another barrier is the lack of (political) will on part of the government and physicians. Providing sufficient palliative care, up to a decent standard, is for most governments not a priority, or of no interest at all.[88] This notion is further strengthened by governments' fear that an increase of drugs misuse will occur if regulations on opioid use for medical purposes become more pliable, despite convincing 'best practices' examples like the United Kingdom, Switzerland and the Netherlands.[89]

Due to the lack of adequate training for health workers, some physicians show no interest in, or are not aware of the need for, pain treatment or palliative care issues.[90] In particular, in the USA, physicians enrolled in 'the government's war on drugs often find themselves in difficult positions since 'they assume the role of assisting regulators in preventing drug diversion and excessive prescribing of analgesics'.[91]

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82 IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011), p. 11.

83 IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011), p. 11.

84 The use of morphine is inexpensive in terms that the manufacture of the actual medicine is rather cheap compared to for example more expensive antiretroviral medicines. Based on a quantitative cost analysis, however, oral morphine is rather expensive. According to Foley the sum of all costs would include cost made by government, insurers, patients and charity initiatives. Yet, this sum does not even include all administrative costs. Furthermore Foley notes that it is difficult to calculate the actual costs of oral morphine in developing countries since it is widely unavailable 'or is manufactured for finished use at different points in the distribution chain'. See KATHLEEN FOLEY *et al.*, 'Pain Control for People with Cancer and AIDS' in D.T. JAMISON *et al.* (eds), *Disease Control Priorities in Developing Countries*, 2nd edn (New York: Oxford University Press, 2006), pp. 981-991, at p. 987.

85 IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011), p. 11.

86 IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011), p. 11. See also V. ADAMS *et al.*, 'Access to Pain Relief: An Essential Human Right A Report for World Hospices and Palliative Care Day 2007' 22 (2008) *Journal of Pain and Palliative Care Pharmacotherapy* pp. 101-129, at p. 124. Oral morphine or a generic substitute is not of interest to pharmaceutical companies for in developing countries usages is expected to be low because of licensing systems and bureaucracy,

87 IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011), p. 11.

88 IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011), p. 11.

89 GLOBAL COMMISSION ON DRUG POLICY, *War on Drugs* (report) (2011), p. 7. Available at <http://www.globalcommissionondrugs.org/Report> accessed 26 April 2012.

90 V. ADAMS *et al.*, 'Access to Pain Relief: An Essential Human Right A Report for World Hospices and Palliative Care Day 2007' 22 (2008) *Journal of Pain and Palliative Care Pharmacotherapy* pp. 101-129, at pp. 119, 122.

91 F. BRENNAN *et al.*, 'Pain Management: A Fundamental Human Right' 105 (2007) *Anesthesia & Analgesia* pp. 205-221, at p. 209.

# 4 The International Drug Control Scheme

The lack of access to opioid analgesics in pain and palliative care treatment is of multi-faceted origin due to a range of different barriers. The international drug control scheme, in particular its main convention, the SCND, acts as a significant limitation to the use of opioids in medical settings as it burdens states with its administrative control mechanisms to maintain the present level of drug control.

## 4.1 The beginning of 100 years of drug control

After the British introduced opium to China in the 16th century, followed by two failed opium drug wars, the so-called 'Chinese opium epidemic' came into existence in the late 19th and early 20th centuries.[92] This provoked the beginning of over 100 years of international drug control.[93] China's history in opium (mis-) use ended up being devastating for the country. Although the problem appeared beneficial for some players in the field with regards to health matters and social harmony, the rapidly growing number of drug addicts became a huge cost burden for the Chinese government.[94] Attempts to regulate this immense increase of hazardous opium use resulted in an international call for help.[95] In 1909, the International Opium Commission, held its first Drugs Conference in Shanghai, better known as the 'Shanghai-Conference'. At this conference, delegates resolved that governments all over the world should eradicate the illicit use of opium.[96] At the same time delegates recognised that the only one licit way of using opium is for medical purposes. All other use should be prohibited.[97] The grave danger for society that illicit drug use was seen as made the International Opium Commission:

> desire to urge strongly on all governments that it is highly important that *drastic measures* should be taken by each government in its own territories and possessions to control the manufacture, sale and distribution of this drug, and also of such other derivatives of opium as may appear on scientific enquiry to be liable to similar abuse and productive of like ill effects.[98]

This approach became the interpretation of the —back then originating and currently effective— drug control scheme: free access for medical purposes was acknowledged, though the fear of opioid addicted societies was such that regulation of illicit use became the emphasis.[99] In spite of, for instance, the qualification of the British Royal Commission on

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92 L. LU *et al*., 'Drug Abuse in China: Past, Present and Future' 29 (2008) *Cellular and Molecular Neurobiology* pp. 479-490, at p. 481. See also UNODC, *100 Years of Drug Control*, ch. 2. World Drug Report (Vienna: UNODC, 2008), pp.15-27. The 'Chinese opium epidemic' has been one of the major drug abuse and addiction problems throughout the world.

93 UNODC, *100 Years of Drug Control*, ch. 2. World Drug Report (Vienna: UNODC, 2008), p. 13. By the end of the 19th century there was a huge influx of 'illicit' (in absence of any international drug control convention drugs abuse was formally licit) drug use, manufacture, distribution and traffic in China. Millions of people became addicted to opium, heroine.

94 UNODC, *100 Years of Drug Control*, ch. 2. World Drug Report (Vienna: UNODC, 2008), p. 29.

95 UNODC, *100 Years of Drug Control*, ch. 2. World Drug Report (Vienna: UNODC, 2008), p. 13.

96 H. WRIGHT, 'International Opium Commission' 3 (1909) *American Journal of International Law* pp. 828-868, at p. 828.

97 H. WRIGHT, 'International Opium Commission' 3 (1909) *Suppl Off Doc American Journal of International Law* pp. 275-276, at pp. 275-276.

98 H. WRIGHT, International Opium Commission 3 (1909) *Suppl Off Doc American Journal of International Law* pp. 275-276, at p. 276 (emphasis added).

99 See R.W. GREGG, 'Single Convention for Narcotic Drugs' 16 (1961) *Food Drug Cosmetic Law Journal* pp. 187-208, at p. 189; A.L. TAYLOR, 'Addressing the Global Tragedy of Needless Pain: Rethinking the United Nations Single Convention on Narcotic Drugs' 35 (2007) *Journal of Law, Medicines and Ethics*, pp. 556-570, at p. 557; M.C. BASSIOUNI, 'The International Narcotics Control System: A Proposal' 19 (1973) *Catholic Lawyer* pp. 119-168, at p. 121. In principal the underlying notion of the system is the *principle of balance,* however, the system as it is evolved over the course of time was never intended to function as global health system even though States were cautious at the time of the Shanghai Conference and it was never aimed to *de facto* exclude opioids from society but to regulate upon its double character.

Opium in 1895, that the non-medical use of opium was harmless. Accordingly the Commission recommended that States should not interfere in this practice.[100] The report the Commission based itself on, however, lacked information on the effect of the Indian poppy production abroad and failed to take into account the effect of opium on China's society.[101]

The USA took a leading role in the global lobby to initiate the 1909 Shanghai Conference and convinced China of the merits of such an international initiative.[102] Delegates did not only aim to discuss the dreadful effect of non-medical opioids to society. The Shanghai Opium Commission also had a strong agenda in tracing an evidence-based overview of poppy cultivation, production and use.[103] Governments had to provide the commission with country specific estimates; a practice that is traceable to the current estimate system anchored in the SCND.[104]

Three years after the Shanghai Conference, the Hague International Opium Convention was enacted in 1912. Parties to the treaty were '[d]etermined to bring about the gradual suppression of the abuse of opium […].'[105] Although the International Opium Convention of 1912 only aimed to restrict the non-medical use of opium, regulation of the medical use of opium was emphasised too.[106] The impact remained limited because only 13 countries signed the convention.[107] By means of including the International Opium Convention 1912 into the World War I Peace Treaties in 1919, the global impact increased.[108]

### 4.1.1 Drug control under the League of Nations

With the creation of the Opium Advisory Committee in 1920, international drug control became a matter of concern to the League of Nations.[109] This committee had a strong focus on gauging the import, export, consumption and production of opium.[110] Up to this point, the international drugs control system only covered opium and poppy derivatives. In 1925, however, the Hague International Opium Convention was extended to cover cannabis too. The so-called '1925 Convention' concluded that contracting parties should adopt legislation to secure the effective control of raw opium, however, 'they were still under no obligation to 'limit' production to medical and scientific needs'[111]. As the 'American principle for a limitation of production to medical and scientific purposes' was not adopted as binding obligation, the USA and China refused to sign the '1925 Convention'.[112] After a strong lobby by the USA, accompanied by Canada, the Convention for Limiting the Manufacture and Regulating the

100 UNODC, *100 Years of Drug Control*, ch. 2. World Drug Report (Vienna: UNODC, 2008), p. 30. In this respect a comparison was made with the number of alcohol abuse in the United Kingdom. It was postulated that the negative effects of opium use in India arrived at substantial similar results as alcohol abuse in the United Kingdom.

101 UNODC, *100 Years of Drug Control*, ch. 2. World Drug Report (Vienna: UNODC, 2008), p. 31. The British Royal Commission on Opium faced huge critics from anti-opium defenders. They contested the outcome by stating that economic opium trade interests muddled the objective value of the report.

102 UNODC, *100 Years of Drug Control*, ch. 2. World Drug Report (Vienna: UNODC, 2008), p. 32.

103 UNODC, *100 Years of Drug Control*, ch. 2. World Drug Report (Vienna: UNODC, 2008), p. 33.

104 UNODC, *100 Years of Drug Control*, ch. 2. World Drug Report (Vienna: UNODC, 2008), pp. 33-34.

105 'International Opium Convention' 6 (1912) *Suppl Off Doc American Journal of International Law* pp. 177-187, at p. 178. The *principle of balance*was not yet anchored in the preamble of the first international drug convention. Indeed, State parties emphasised on the need of regulation with due regard the devastating effects of opium as addictive substance.

106 'International Opium Convention' 6 (1912) *Suppl Off Doc American Journal of International Law* pp. 177-187. Contracting parties to the International Opium Convention should restrict, amongst others, all use, manufacture, and distribution of raw and prepared opium (Chapter I & II) and regulate by pharmacy laws the licit use of medicinal opium for medical purposes (Chapter III).

107 M.C. BASSIOUNI, 'The International Narcotics Control System: A Proposal' 19 (1973) *Catholic Lawyer* pp. 119-168, at p. 126.

108 UNODC, *100 Years of Drug Control*, ch. 2. World Drug Report (Vienna: UNODC, 2008), p. 51. After including the Hague International Opium Convention in the World War I Peace treaties the number of signatory countries raised to 67.

109 UNODC, *100 Years of Drug Control*, ch. 2. World Drug Report (Vienna: UNODC, 2008), p. 51. The League of Nations is the predecessor of the UN.

110 UNODC, *100 Years of Drug Control*, ch. 2. World Drug Report (Vienna: UNODC, 2008), p. 51.

111 UNODC, *100 Years of Drug Control*, ch. 2. World Drug Report (Vienna: UNODC, 2008), p. 52.

112 UNODC, *100 Years of Drug Control*, ch. 2. World Drug Report (Vienna: UNODC, 2008), p. 53.

Distribution of Narcotic Drugs was concluded in 1931.[113] Primarily at the request of the USA, the international community deemed it necessary to aim for international restriction of the supply and demand of medicinal opium. With a practice that can be traced to the current 'estimate-system', the international legal foundation of estimating the medical needs of opium of a specific country is found, amongst others, in the '1931 Convention'.[114] Hence the '1931 Convention' is significant for adopting a clause on the limitation of manufacturing raw opium. Indeed, States were only allowed to manufacture within the limits of the estimate submitted to the Drug Supervisory Body.[115]

Although from the perspective of illicit drug control, the collection of treaties enacted up until 1936 appeared fruitful, fears regarding illicit traffic in dangerous drugs kept rising. After having established an international drug control scheme and corresponding supervision mechanisms to monitor legitimate activities with harmful substances, governments repeated their admonitions to control the illicit traffic of those substances.[116] Thus, the combined 1925 and 1931 Conventions did not solve the international drug problems for it appeared that legal sanctions had retained a loophole within the system until then.[117] As a result, the League of Nations initiated the 1936 Convention for the Suppression of the Illicit Traffic in Dangerous Drugs.[118] The focus in international drug control shifted to the field of international criminal law. The illicit traffic of narcotic drugs became an international crime.[119] Still, the impact remained limited and political tensions in the mid 1930-40's and key-players leaving the League of Nations caused a phase of non-compliance.[120]

### 4.1.2 Drug control under the United Nations

The development of the present international drug control system continued to be shaped, when in 1946 international drug control became a matter of concern to the, then recently established, UN under the auspices of the Commission on Narcotic Drugs (CND), a sub-commission under the Economic and Social Council (ECOSOC).[121] Foundations were laid for the present framework prior to forming one overarching convention —the Single Convention on Narcotic Drugs— when an opium optional protocol was adopted in 1953. The international society aimed to, once more, stipulate that opium use should be restricted to the use for medical purposes only.[122]

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113 Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs (open for signature 13 July 1931, entered into force 9 July 1933) 139 UNTS 303 (1931 Convention). See 'Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs' 28 (1934) *Suppl Off Doc American Journal of International Law* pp. 21-44.

114 Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs (open for signature 13 July 1931, entered into force 9 July 1933) 139 UNTS 303 (1931 Convention). See 'Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs' 28 (1934) *Suppl Off Doc American Journal of International Law* pp. 21-44, at pp. 28-30. Chapter 2, articles 2-5 contain the estimate system.

115 Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs (open for signature 13 July 1931, entered into force 9 July 1933) 139 UNTS 303 (1931 Convention). See 'Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs' 28 (1934) *Suppl Off Doc American Journal of International Law* pp. 21-44, at pp. 30-31. Chapter 3, articles 6-9 contain the limitation of manufacture clause.

116 J.G. STARKE, 'The Convention of 1936 for the Suppression of the Illicit Traffic in Dangerous Drugs' 31 (1937) *The American Journal of International Law* pp. pp.31-43, at p. 32.

117 R.W. GREGG, 'Single Convention for Narcotic Drugs' 16 (1961) *Food Drug Cosmetic Law Journal* pp. 187-208, at p. 190.

118 UNODC, *100 Years of Drug Control*, ch. 2. World Drug Report (Vienna: UNODC, 2008), p. 56.

119 J.G. STARKE, 'The Convention of 1936 for the Suppression of the Illicit Traffic in Dangerous Drugs' 31 (1937) *The American Journal of International Law* pp. pp. 31-43, at p. 32.

120 UNODC, *100 Years of Drug Control*, ch. 2. World Drug Report (Vienna: UNODC, 2008), p. 57.

121 R.W. GREGG, 'Single Convention for Narcotic Drugs' 16 (1961) *Food Drug Cosmetic Law Journal* pp. 187-208, at p. 192. The ECOSOC is one of the UN's principal organs concerned with facilitating international cooperation on the world's socioeconomic issues.

122 UNODC, *100 Years of Drug Control*, ch. 2. World Drug Report (Vienna: UNODC, 2008), p. 60. See also 'The Beginnings of International Drug Control' 35 (1998) *UN Chronicle* pp. 8-9. The 1953 opium protocol authorised 7 countries to the licit production of medicinal opioids.

Many gaps remained within the framework of eight different treaties.[123] For instance, too many international organs, mostly UN subsidiary bodies, functional commissions and specialised agencies, were involved and concerned with drug control. In fact, the mandate of drug control was shared amongst the CND, the Permanent Central Opium Board, the Drug Supervisory Body and the WHO. The principal UN bodies, such as the UN General Assembly (UNGA), The ECOSOC, the UN Security Council, and the UN Secretary-General maintained more permanent functions within this framework. Overlap of mandates was present between some experts regulating drug control.[124] Until then, the State parties involved, for multiple reasons, showed difficulties to fully comply with the desired level of administrative control.[125] It appeared that, overall, national laws executed stricter rules than the international framework. Furthermore, government licensing with regard to the licit traffic of drugs did not apply to all substances.[126]

With a variety of legal documents in place, the international community lacked a comprehensive and overarching document that enshrined all relevant regulations regards combating illicit drug use, while, at the same time, embodying the margin for States to allow individuals access to opioid analgesics for medical purposes.[127]

### 4.1.3 Drafting history of the SCND

In 1948, the CND first considered creating a Single Convention. After ten years of preparatory works, a working paper was discussed at the plenipotentiary conference.[128] From the early 1950's to actual adoption in 1961, three draft resolutions were circulated within the UN. With major revisions in mind, the CND faced multiple obstructions by Member States.[129]

The first draft opted for the establishment of an international organ that would simplify the international administrative machinery.[130] Furthermore, according to the first draft, this international organ would be granted the right to revise a country's submitted estimate after consultation with the respective government, though revision would be possible without the governments consent thereafter.[131] Member States rejected this idea, fearing the profound impact the adoption of such construction would have upon their State sovereignty.[132]

The second draft circulating between Member States granted an independent international organ the right 'to impose a mandatory import and export embargo upon countries violating convention's provisions'[133]. These mandatory limitations would also affect the access to controlled substances for medical purposes.[134] The second draft was

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123 M.C. BASSIOUNI, 'The International Narcotics Control System: A Proposal' 19 (1973) *Catholic Lawyer* pp. 119-168, at p. 132. When the SCND was signed in 1961 and came into force in 1964, all previous treaties cease to exist.

124 A. LANDE, 'The Single Convention on Narcotic Drugs, 1961' 16 (1962) *International Organization* pp. 776-797, at p. 778.

125 A. LANDE, 'The Single Convention on Narcotic Drugs, 1961' 16 (1962) *International Organization* pp. 776-797, at p. 779.

126 A. LANDE, 'The Single Convention on Narcotic Drugs, 1961' 16 (1962) *International Organization* pp. 776-797, at pp. 779-780.

127 R.W. GREGG, 'Single Convention for Narcotic Drugs' 16 (1961) *Food Drug Cosmetic Law Journal* pp. 187-208, at p. 188. As Gregg aptly puts it: 'the several international agreements amounted to a patchwork of obligations and commitments which was not wholly satisfactory'.

128 I.G. WADDELL, 'International Narcotics Control' 64 (1970) *The American Journal of International Law* pp. 310-323, at p. 315.

129 A. LANDE, 'The Single Convention on Narcotic Drugs, 1961' 16 (1962) *International Organization* pp. 776-797, at p. 783. CND was responsible to monitor drug control matters under auspices of ECOSOC.

130 A. LANDE, 'The Single Convention on Narcotic Drugs, 1961' 16 (1962) *International Organization* pp. 776-797, at p. 783.

131 A. LANDE, 'The Single Convention on Narcotic Drugs, 1961' 16 (1962) *International Organization* pp. 776-797, at p. 784. In this first draft it was even suggested to establish an international clearing house. Under this system drug trafficking would only be considered legal and permissible if the clearing house would have validated countries' import and export amounts and was intended to refine the estimate system.

132 A. LANDE, 'The Single Convention on Narcotic Drugs, 1961' 16 (1962) *International Organization* pp. 776-797, at p. 784.

133 A. LANDE, 'The Single Convention on Narcotic Drugs, 1961' 16 (1962) *International Organization* pp. 776-797, at p. 785.

134 A. LANDE, 'The Single Convention on Narcotic Drugs, 1961' 16 (1962) *International Organization* pp. 776-797, at p. 785.

considered rather conservative —and an implementation of the 1953 Protocol— extending drug control to Cannabis too.[135] Delegates rejected the second draft and a third draft was presented.

The third and final draft embodied most of the controversial character of the previous draft. Remarkably, however, the right to restrict opium use for medical purposes was granted to the INCB, the independent international organ monitoring implementation of the drafted convention.[136] The CND was aware of the controversial character of the draft and envisioned 'that not all provisions of the new treaty would be welcomed equally by all Governments'.[137] Yet again, fear of opioid addicted societies, of which China was shown the most devastating example, was such that States marginally overcame their objections with regard to potential impingement on State sovereignty.[138] Ultimately, in 1961, the ECOSOC adopted the Single Convention on Narcotic Drugs by 46 votes in favour, 8 abstentions and none against.[139]

The ECOSOC adopting the Single Convention was a result of aiming for, not only unified codification, but a simplified overview of the past framework and the restriction of opioid use for medical purposes. In addition, the SCND's drafters also aimed at administrative control.[140]

The international drug regulatory discourse, with its bedrock SCND landmark convention, was expanded in the 1970's by an additional protocol to the SCND, the Convention on Psychotropic Substances and in the 1980's, with the UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances , the '1988 Convention'.[141]

It shows that over the course of time it has been a struggle for governments to combat illicit drug use and other international crimes that arise from regulations, while at the same time effectively allowing access to essential medicines. The importance of the need of morphine for medical purposes has never been denied; however, it appears that over the course of time the emphasis of drug control has shifted to regulation instead of safeguarding access for medical purposes.

## 4.2 The Single Convention on Narcotic Drugs

The Single Convention on Narcotic Drugs is the primary international legal instrument influencing the regulation of opioid analgesics. In 2012 the SCND counted 183 States parties to the Convention.[142]

The SCND is based on the *principle of balance*. This assumption can be read in the aforementioned overview of the SCND's preparatory works, and as an underlying notion, has

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135 A. LANDE, 'The Single Convention on Narcotic Drugs, 1961' 16 (1962) *International Organization* pp. 776-797, at p. 786.

136 A. LANDE, 'The Single Convention on Narcotic Drugs, 1961' 16 (1962) *International Organization* pp. 776-797, at p. 786.

137 A. LANDE, 'The Single Convention on Narcotic Drugs, 1961' 16 (1962) *International Organization* pp. 776-797, at p. 786.

138 A. LANDE, 'The Single Convention on Narcotic Drugs, 1961' 16 (1962) *International Organization* pp. 776-797, at p. 789.

139 R.W. GREGG, 'Single Convention for Narcotic Drugs' 16 (1961) *Food Drug Cosmetic Law Journal* pp. 187-208, at p. 188. Even though bearing the name 'single convention', parties to the convention overall 'hoped that it would prove to be *greater* than the sum of parts it replaced'. See also SCND.

140 M.C. BASSIOUNI, 'The International Narcotics Control System: A Proposal' 19 (1973) *Catholic Lawyer* pp. 119-168, at p. 132. See also A. LANDE, 'The Single Convention on Narcotic Drugs, 1961' 16 (1962) *International Organization* pp. 776-797, at pp. 779-781.

141 The convention regulating psychotropic substances is an addition to the scope of the SCND for the latter only regulates opioids and poppy straw derivates and the first covers regulatory schemes for psychoactive drugs too. See Convention on Psychotropic Substances (open for signature 11 January 1971, entered into force 16 August 1976) 1019 UNTS 175 (CPS). The 1988 convention covers the aspect of international criminal law and respective sanctions for international narcotics trafficking transcend national boarders. See J. GURELÉ, 'The 1988 U.N. Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances – A Ten Year Perspective: Is International Cooperation Merely Illusory?' 22 (1998-1999) *Fordham International Law Journal* pp. 74-121. See also UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (open for signature, 20 December 1988, entered into force 11 November 1990) 1582 UNTS 95 (1988 Convention). The present report maintains a focus on the SCND and will not further elaborate on both latter conventions.

142 'Status of Ratification SCND' <http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=VI-18&chapter=6&lang=en> accessed 3 July 2012.

been adopted through codification in the SCND's preamble paragraphs. State parties recognise their concern with 'the health and welfare of mankind' and recognise 'that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes', while at the same time recognising that the 'addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind' resulting in a clear consciousness to 'prevent and combat this evil'.[143] The counterpart of defeating drug misuse —allowing access to controlled substances for medical purposes— has not been given the same priority as the duty pressed upon States to prevent and combat the evil of drug abuse.[144]

The two directives found in the SCND indicate the dual need: i) to allow the effective use of opioids for medical purposes to safeguard human dignity, and ii) to eliminate all illicit use of opium from society by expressing the need to ensure safe and healthy environments.[145]

### 4.2.1 State obligations

The SCND's *principle of balance,* as underscored in its preamble paragraphs, is given substantial legal significance by its codification as the general obligation incumbent on States included in Article 4 SCND. According to Article 4, States shall take all appropriate 'legislative and administrative measures […] to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs'.[146] The substances that are affected by this general obligation are divided into three schedules (I, II, III), which determine the scope of the Convention by maintaining different regulating schemes for each schedule.[147]

The need to control drugs as part of the SCND's foundational *principle of balance* is specifically addressed in additional provisions. Articles 33, 35-6 and 38 of the SCND urge States to take appropriate and practical measures in the field of fighting drug possession, illicit traffic and drug abuse. States are given a certain margin of appreciation respecting the adoption of 'adequate measures'.[148] The SCND is rather strict in embracing that States may not adopt stricter rules as set out in the Convention. Such an extra protection mechanisms is by omission not adopted in the SCND to strengthen the treaty's aim to safeguard individual health by allowing and protecting access to controlled medication for medical purposes.

### 4.2.2 Monitoring mechanisms

The general obligation anchored in Article 4 SCND, demonstrates that in principal the SCND leaves States a rather broad margin of appreciation with regard to treaty compliance. Subsequent requirements imposed on States, however, decline this margin. To monitor this general aim, the SCND allocates certain authority to different institutions; the CND and the INCB.[149] The INCB, as a treaty-based organ of international drug control, is responsible for monitoring and administrating, as well as furnishing and helping States, if deemed necessary, with submitting annual estimates and determining the follow-up procedure of

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143 SCND, preamble.

144 This is read by omission in the preamble paragraphs of the SCND.

145 A.L. TAYLOR, 'Addressing the Global Tragedy of Needless Pain: Rethinking the United Nations Single Convention on Narcotic Drugs' 35 (2007) *Journal of Law, Medicines and Ethics*, pp. 556-570, at p. 560. See also R.W. GREGG, 'Single Convention for Narcotic Drugs' 16 (1961) *Food Drug Cosmetic Law Journal* pp. 187-208, at p. 188.

146 SCND, art 4(c).

147 SCND, art 2. See also I.G. WADDELL, 'International Narcotics Control' 64 (1970) *The American Journal of International Law* pp. 310-323, at p. 318.

148 SCND, arts 33, 35, 38-39.

149 As made previous reference of, the CND is a subcommittee under the ECOSOC and the INCB is a treaty-based organ comprised of independent experts in the field of drug control either appointed by the WHO or the CND. See SCND, art 9.

statistical returns.[150] On the basis of Article 19 of the Convention States have to furnish the INCB with annual statistics:

1. The Parties shall furnish to the Board each year for each of their territories, in the manner and form prescribed by the Board, estimates on forms supplied by it in respect of the following matters:
   *a) Quantities of drugs to be consumed for medical and scientific purposes;*
   b) Quantities of drugs to be utilized for the manufacture of other drugs, of preparations in Schedule III, and of substances not covered by this Convention;
   c) Stocks of drugs to be held as at 31 December of the year to which the estimates relate;
   d) Quantities of drugs necessary for addition to special stocks;
   e) The area (in hectares) and the geographical location of land to be used for the cultivation of the opium poppy;
   f) Approximate quantity of opium to be produced;
   g) The number of industrial establishments which will manufacture synthetic drugs; and
   h) The quantities of synthetic drugs to be manufactured by each of the establishments referred to in the preceding subparagraph. […]
3. Any State may during the year furnish supplementary estimates with an explanation of the circumstances necessitating such estimates […].[151]

Notably only State parties are required to submit an annual estimate as determined in Article 19 SCND; however, the INCB is mandated to request similar estimates also from non-State parties to the SCND.[152] Non-State parties are not required to respond to the INCB's request.

Accordingly, with regard to Article 19 SCND, States are burdened with a huge bureaucratic institution that comes with estimating their needed opioids for medical purposes. They are not only required to submit estimates concerning their need for opioid analgesics, but States must also furnish the INCB with information covering their need for opium regarding manufacture, special stocks, production and synthetic drugs purposes. If a State fails to submit an adequate estimate (adequate in the sense that the estimates meet the needs of the population in the broadest interpretation), as a complement to the initial estimating system, States may submit an additional, or supplementary estimate with a sufficient explanation of the need for 'extra' opioids.

As previously stressed, establishing such estimates as required by the INCB is highly burdensome on States. To assist governments in fulfilling this requirement, the INCB published training and guiding manuals that may help drug control officials in preparing such schemes. The INCB highlights 'what constitutes an "adequate" estimate' denoting that '[a]n estimate can usually be considered "good" if it shows a maximum deviation of approximately 15 per cent from the corresponding statistic'[153]. States should use a 'sound method' to draft satisfactory estimates. The INCB counsels to use previously used methods and statistics that haven proven to be accurate and adequate.[154]

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150 Because the drug control system is in its essence decentralised States are required to work in a system in which they submit relevant information (State reporting) to the UN Secretary General, as well as estimates and statistical returns to the INCB. See I.G. WADDELL, 'International Narcotics Control' 64 (1970) *The American Journal of International Law* pp. 310-323, at p. 318. INCB's mandate enshrines in SCND, arts 5, 12-13.

151 SCND, art 19 (emphasis added).

152 SCND, art 12(2). With regard to the monitoring mandate of the INCB it is interesting to note that Bassiouni observes the scope of the SCND as applicable to *all* countries in the world, irrespective of treaty ratification. The SCND, however, does not include a legal basis for this assumption, though the outcome of the actual number of countries complying with the norms as set out in the SCND could reach a substantial similar result as to Bassiouni's statement. Because space does not permit greater exploration, this assumption shall not be subjected to further research. See M.C. BASSIOUNI, 'The International Narcotics Control System: A Proposal' 19 (1973) *Catholic Lawyer* pp. 119-168, at p. 122; A.L. TAYLOR, 'Addressing the Global Tragedy of Needless Pain: Rethinking the United Nations Single Convention on Narcotic Drugs' 35 (2007) *Journal of Law, Medicines and Ethics*, pp. 556-570, at p. 560.

153 INCB, *Training Material 1961 Single Convention on Narcotic Drugs Part 2: The Estimates System for Narcotic Drugs* (2005) UN Doc E/INCB/2005/NAR_2, p. 6.

154 INCB, *Training Material 1961 Single Convention on Narcotic Drugs Part 2: The Estimates System for Narcotic Drugs* (2005) UN Doc E/INCB/2005/NAR_2, p. 7, 10. The INCB fosters three types of methods used for establishing

This strategy could have a twofold outcome; either States sufficiently reach the needs of their populations, for they base their needs on previous estimates that adequately met population's needs or, States maintain a vicious circle by using incorrect estimates as a basis for current estimates, which then, most probably, fail to adequately cover the population's need. To counter the latter effect, the INCB stressed that 'in response to unmet needs, the method of estimation should take into account the extent of unmet needs and the potential effects on future demand or efforts to improve the rational use of narcotic drugs'.[155]

Recently, the INCB has furthered its approach in assisting States with treaty compliance through adoption of a compliance guide drafted in cooperation with the WHO. The report indicates the supply management framework as a mutual dependent cornerstone procedure that States sequentially need to follow: i) selection, ii) quantification, iii) procurement, iv) storage and distribution, v) use. In this cycle approach States should start with deciding which controlled medicines are necessary to address and redress the health problems of its country, estimate the exact number they need per controlled substance, select suppliers, check delivery of quantities and conduct a quality check up. The process continues with the need to keep record of storage and transportation for the purpose of monitoring and control, and finally States should keep close record of dispensing statistics and patient's rational use.[156]

In addition to this rather extensive type of regulation connected to the estimate system, States are required to submit so-called 'statistical returns' to the INCB as anchored in Article 20 of the Convention:

1. The Parties shall furnish to the Board for each of their territories, in the manner and form prescribed by the Board, statistical returns on forms supplied by it in respect of the following matters:
   a) Production or manufacture of drugs;
   b) Utilization of drugs
      Schedule III and of substances not covered by this Convention, and utilization of poppy straw for the manufacture of drugs;
   c) *Consumption of drugs;*
   d) Imports and exports of drugs and poppy straw;
   e) Seizures of drugs and disposal thereof;
   f) Stocks of drugs as at 31 December of the year to which the returns relate; and
   g) Ascertainable area of cultivation of the opium poppy.[157]

Furnishing the INCB with statistical returns means that States have to trace and take into account all manners of using the substances; a component that the INCB and the WHO recently referred to as indispensable to producing sound methods and statistics. As a result, the statistical return system results in another huge burden on part of the State and respective institutions.[158] In fact, the highly burdensome requirements as set out by the SCND, have a substantial impact on treaty compliance of many countries amongst which in particular developing countries. The INCB supports that in view of the information submitted

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sufficient quantities of drugs, which is one element of submitting an adequate estimate. States may base itself on either a population-based, service-based or consumption-based study.

155 INCB, *Training Material 1961 Single Convention on Narcotic Drugs Part 2: The Estimates System for Narcotic Drugs* (2005) UN Doc E/INCB/2005/NAR_2, p. 10. Remarkably the INCB denotes in its 2010 Annual Report that setbacks have been identified regards sufficient access to opioid analgesics in countries that, over the course of time, have proven to have limited, to no, opioid availability at all. See INCB, *Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes* (Suppl. *Annual Report 2010*) UN Doc E/INCB/2010/1/Supp.1, para 125.

156 INCB AND WHO, *Guide on Estimating Requirements for Substances under International Control* (New York: United Nations, 2012), para 18.

157 SCND, art 20 (emphasis added).

158 A.L. TAYLOR, 'Addressing the Global Tragedy of Needless Pain: Rethinking the United Nations Single Convention on Narcotic Drugs' 35 (2007) *Journal of Law, Medicines and Ethics*, pp. 556-570, at p. 560.

by States, only a selected number of developed States give effect to the SCND satisfactorily.[159]

In order to produce documents that meet the criteria as set out by the INCB, a country must rely on sufficient and well-functioning legal systems, State systems, health care and administrative systems. It applies well that the highly demanding effect of the SCND is foremost traced back to the situation of developing countries as they often fail, to a certain extent, clear and functioning systems. To some extent, the control mechanisms may imply an inherent inability on part of developing countries to give full effect to the SCND in a satisfactory manner.[160]

India makes a good example of a country that had fairly good access to opioids for medical purposes prior to ratification of the SCND but through the adoption of a complex licensing system in 1985 patients' road to access opioid analgesics was hindered. Mainly driven by the work of Pallium India, good practices show that in already thirteen Indian states, more flexible regulations are adopted. Nevertheless, the impact remains modest up until now.[161]

### 4.2.3 The monitoring mandate of the INCB

As the designated body, the Vienna based INCB monitors States' compliance with the SCND hence governs both the annual estimate and quarterly statistical follow up requirements. According to Article 12 of the SCND the Board has a fixed mandate:

1. The Board shall fix the date or dates by which, and the manner in which, the estimates as provided in article 19 shall be furnished and shall prescribe the forms therefore.
2. The Board shall, in respect of countries and territories to which this Convention does not apply, request the Governments concerned to furnish estimates in accordance with the provisions of this Convention.
3. If any State *fails to furnish estimates in respect of any of its territories by the date specified, the Board shall, as far as possible, establish the estimates.* The Board in establishing such estimates shall to the extent practicable do so in co-operation with the Government concerned.
4. The Board shall examine the estimates, including supplementary estimates, and, except as regards requirements for special purposes, *may require such information as it considers necessary in respect of any country or territory on behalf of which an estimate has been furnished, in order to complete the estimate* or to explain any statement contained therein.
5. The Board, *with a view to limiting the use and distribution of drugs to an adequate amount required for medical and scientific purposes and to ensuring their availability for such purposes, shall as expeditiously as possible confirm the estimates,* including supplementary estimates, or, with the consent of the Government concerned, *may amend such estimates.* In case of a disagreement between the Government and the

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159 In its 2010 Report the INCB underscores this deficit by recognising that only a very limited number of countries that appear able to supply drugs through reliance on adequate working mechanisms and a system machinery. See INCB, *Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes* (Suppl. *Annual Report 2010*) UN Doc E/INCB/2010/1/Supp.1, para 127.

160 This is not *per se* stressed in the documents referred to here. Notwithstanding the extensive manual as launched by the INCB is rather difficult to effectively work with if a country fails in any aspect clear and functioning systems. See INCB, *Training Manual 1961 Single Convention on Narcotic Drugs Part 1: The International Control System for Narcotic Drugs* (2005) UN Doc E/INCB/2005/NAR_1; INCB, *Training Material 1961 Single Convention on Narcotic Drugs Part 2: The Estimates System for Narcotic Drugs* (2005) UN Doc E/INCB/2005/NAR_2; A.L. TAYLOR, 'Addressing the Global Tragedy of Needless Pain: Rethinking the United Nations Single Convention on Narcotic Drugs' 35 (2007) *Journal of Law, Medicines and Ethics*, pp. 556-570, at p. 562; HRW, *Uncontrolled Pain: Ukraine's Obligation to Ensure Evidence-Based Palliative Care (*Report) (New York: Human Rights Watch, 2011).

161 IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011), p. 17.

Board, the latter shall have the right to establish, communicate, and publish its own estimates, including supplementary estimates. […][162]

The estimate system as adopted in the SCND is strictly controlled by the INCB. Not only does the INCB determine which formats should be used to construe adequate statistics, the INCB is also ultimately responsible for whether or not an estimate is confirmed and, thus, whether or not a State is able to allow its subjects access to essential opioid analgesics. To further access to opioids for medical purpose, it is incumbent upon the INCB to assist those countries that fail to furnish the INCB with adequate estimates, either by completing a country's estimate or by establishing a sufficient estimate on behalf of the failing country. This obligation is most important with regard to opioid availability in developing countries for it is commonly appreciated that scheduled or rescheduled substances that may be significant to addressing public health matters are often banned by developing countries because of the regulatory burden inherent to the SCND.[163] Despite the widely appreciated difficulties with regard to treaty compliance, the INCB recommends countries in a state of non-compliance to comply with the system by, amongst others, establishing reasonable estimates. At the same time they do call for diminishing all impediments on regulatory and policy level.[164]

The SCND establishes rather limited possibilities for the INCB to interfere in State practices or to demand States compliance with the convention's provisions. From the perspective of free access to essential medicines as a core obligation under the fulfilment of the right to health, however, the INCB has a far-reaching ability —it has the final say over all procedures concerning access to opioid analgesics on the international regulatory level. The INCB may commend, if deemed necessary, a drug embargo on States that fail treaty compliance.[165]

### 4.2.4 The treaty interpretation of the INCB

In 1999, the INCB adopted in its Annual Report a special section on the availability of opioid analgesics to relief pain and suffering. The SCND's dual character was stressed as comprising two complementary humanitarian standards pertaining to both the need to allow individuals access to opioid analgesics for medical purposes, as well as protecting them from the irreparable harm caused by drug dependence.[166] In subsequent Annual Reports, the INCB reinforced that it 'endeavours, in cooperation with Governments, to maintain a lasting balance between supply and demand'.[167] In its 2010 report, the INCB decided to include a supplement emphasising the importance of medical access to international controlled substances. In this report, the INCB concluded that, even though the global consumption of morphine for medical purposes has increased over the course of time, the effects remain limited such as that still too many people lack adequate access to opioid analgesics.[168] The

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162 SCND, art 12 (emphasis added).

163 A.L. TAYLOR, 'Addressing the Global Tragedy of Needless Pain: Rethinking the United Nations Single Convention on Narcotic Drugs' 35 (2007) *Journal of Law, Medicines and Ethics*, pp. 556-570, at p. 562. The INCB frequently updates the status of estimates. According to its May update in 2011 the INCB furnished estimates for a certain 50 countries <http://www.incb.org/pdf/e/estim/2011/EstMay11.pdf> accessed 4 June 2011. This rather high number demonstrates not only the actual need for the INCB to step in, moreover signifies the burdensome character of the regulations as set out in the SCND.

164 INCB, *Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes* (Suppl. *Annual Report 2010*) UN Doc E/INCB/2010/1/Supp.1, paras 52-57, 125-127. Seemingly recommendations and outcomes are unable to breach the vicious circle of too demanding regulations that cause insufficient outcomes which are recommended to counter by compliance with the same too demanding standards.

165 SCND, art 14(2). For reasons of limitations the effects of the INCB's contingence of imposing import and export embargo's upon States when States fail treaty compliance are not further elaborated in this report.

166 INCB, *Annual Report 1999* UN Doc E/INCB/1999/1, para 1.

167 INCB, *Annual Report 2009* UN Doc E/INCB/2009/1, para 75. See for substantial similar references; INCB, *Annual Report 2008* UN Doc E/INCB/2008/1, para 89; INCB, *Annual Report 2007* UN Doc E/INCB/2007/1, para 83; INCB, *Annual Report 2006* UN Doc E/INCB/2006/1, para 59; INCB, *Annual Report 2005* UN Doc E/INCB/2005/1, para 83; INCB, *Annual Report 2004* UN Doc E/INCB/2004/1, para 133.

168 INCB, *Annual Report 2010* UN Doc E/INCB/2010/1, p. v.

report calls upon governments to act and combat poor access to opioid analgesics.[169] However, this commitment remains ineffective, for in its practice, the INCB still overly emphasises prevention and drug control over medicinal use of opioids.[170] Maintaining the priority on law enforcement and drug control results in a breach of the convention; 'the INCB has not advanced any interpretation or application of the Single Convention in a manner that fulfils its obligation of advancing worldwide access to drugs for legitimate medical purposes'.[171] This imbalanced emphasis is defended by the INCB's constant concern that licit substances end up in illicit channels, a concern that also cast its spell on the present international drug control scheme's founding fathers.[172] In this respect, the INCB wholeheartedly maintains that the present scheme of international drug control is effective in 'preventing the diversion of drugs from licit to illicit markets and in protecting society from the consequences of dependence'.[173]

In fact, the INCB only commits rhetorically to a balanced treaty interpretation in accordance with the SCND's foundational principle of balance. Over the course of time, a setback in opioid availability is traced in developing countries. INCB statistics report that only a number of big consumer countries are accountable for 79 per cent of the global morphine consumption for medical purposes in 2004, amongst them the USA, Canada, New Zealand and European Union Member States. By comparison only 6 per cent was used by developing countries which represent 80 per cent of the world's population.[174] In 2009, the distributive failure increased and the big consumer countries are together accountable for 90 per cent of the global number of morphine use for medical purposes.[175]

Ultimately, the balanced emphasis adopted in the SCND and monitored by the INCB appears rather imbalanced in how it affects day-to-day lives.

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169 INCB, *Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes* (Suppl. *Annual Report 2010*) UN Doc E/INCB/2010/1/Supp.1, paras 51-57.

170 A.L. TAYLOR, 'Addressing the Global Tragedy of Needless Pain: Rethinking the United Nations Single Convention on Narcotic Drugs' 35 (2007) *Journal of Law, Medicines and Ethics*, pp. 556-570, at p. 562.

171 A.L. TAYLOR, 'Addressing the Global Tragedy of Needless Pain: Rethinking the United Nations Single Convention on Narcotic Drugs' 35 (2007) *Journal of Law, Medicines and Ethics*, pp. 556-570, at p. 562.

172 This emphasis is overly present in many INCB documents; however, striking significance is that since 1992 the INCB started with adopting a first Chapter in every Annual Report concerning a specific topic of drug control, only 2 out of a total of 19 reports emphasised on the availability of opioids for medical purposes. All other documents underscore the assumption that the INCB manages a strict criminal justice approach in interpreting the SCND. See A.L. TAYLOR, 'Addressing the Global Tragedy of Needless Pain: Rethinking the United Nations Single Convention on Narcotic Drugs' 35 (2007) *Journal of Law, Medicines and Ethics*, pp. 556-570, at p. 561. Subsequently, in previous paragraphs of this Chapter the preparatory works and interests at that time are addressed.

173 INCB, *Annual Report 2010* UN Doc E/INCB/2010/1, p. iii.

174 INCB, *Annual Report 2004* UN Doc E/INCB/2004/1, para 143.

175 INCB, *Annual Report 2009* UN Doc E/INCB/2009/1, para 80.

# 5 Human Rights

Alongside the obligations ensuing from the present international drug control scheme, States are bound by the obligations stemming from the human rights framework. The core principle underlying this framework is human dignity. Hence as a result, States need to ensure individuals to live a dignified life by means of realising the minimum standard of life at any rate.

## 5.1 The International Bill of Rights

The present understanding and codification of human rights only came into being after World War II. After this period of grave human rights violations and anti-law, the global political notion of human rights signified the fight for universal and non-discriminatory protection of the human dignity of each and every all, and the struggle for protection of individuals against abusive power through fundamental human rights.[176] Under the auspices of the UN, States' post World War II expressed aspirations led to the UN's General Assembly adopting the Universal Declaration of Human Rights (UDHR) in 1948.[177] With adoption of the UDHR, the UNGA aimed for advancement of human rights, socioeconomic development, peace and security worldwide.[178]

The UDHR builds upon the preamble to the UN Charter's emphasis on 'faith in fundamental human rights, in the dignity and worth of the human person, in the equal rights of men and women and of nations large and small'.[179] Hence the UDHR re-emphasis the pressing importance of human dignity as the leading principle within the human rights realm, stating that: 'the recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world'.[180] It is the universal character of human rights, their non-discriminatory character and inherent human dignity that are the grassroots of present human rights norms.

The adoption of the UDHR was significant to an enormous expansion of norms concerning human rights. The UDHR, being a declaration, has no legal force.[181] Therefore the intent underscored in both the preamble of the UN Charter and the UDHR were, in the mid sixties, re-emphasised and further explicated by adoption of the International Covenant on Economic, Social and Cultural Rights (ICESCR) and the International Covenant on Civil and Political Rights (ICCPR). Together with the UDHR, those two major human rights instruments form the International Bill of Rights.[182]

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176 B. DE GAAY FORTMAN, *Political Economy of Human Rights* (Abingdon: Routlegde, 2011), pp. 5-6.

177 See HEINER BIELEFELDT, 'Philosophical and Historical Foundations of Human Rights' in C. KRAUSE AND M. SCHEININ (eds), *International Protection of Human Rights: A Textbook* (Turku – Åbo: Åbo Akademi University Institute for Human Rights, 2009), pp. 3-18, at p. 14; M. SEPÚLVEDA *et al*., *Human Rights Reference Handbook* 4th edn (Reykjavic - Ciudad Colon: Icelandic Human Rights Centre, University of Peace, 2009), p. 3. Note that the historical antecedents of human rights can be traced to Greek philosophy; though the concept of human rights as known today was not documented. The *Magna Charta Libertum* (1215) is one of the earliest and most famous, written document that allocated rights to individuals. However, if read in detail, only a small group of people could rely on this limited set of rights.

178 Charter of the United Nations (open for signature 26 June 1945, entered into force 24 October 1945) (UN Charter) art 13. See also IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011), p. 5.

179 UN Charter, preamble.

180 Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A (III) (UDHR), preamble.

181 M.N. SHAW, *International Law* 6th edn (Cambridge: Cambridge University Press, 2010), pp. 278-279. See J. MORSINK, *The Universal Declaration of Human Rights, Origins, Drafting and Intent* (Philadelphia: PENN, 1999), p. 21. The Declaration was not intended as a binding document. It is not granted this legal status inasmuch the UDHR is a UNGA resolution, adopted without any votes against though with 8 abstentions (USSR, UKSSR, BSSR, Yugoslavia, Poland, South Africa and Saudi Arabia) aimed to anchor a 'common standard of achievement' and is therefore often addressed as a document with strong moral value and political authority. Some scholars, however, suppose that the UDHR has become part of international customary law. This would grant the rights codified in the UDHR a different legal position within international law.

182 M. SEPÚLVEDA *et al*., *Human Rights Reference Handbook* 4th edn (Reykjavic - Ciudad Colon: Icelandic Human Rights Centre, University of Peace, 2009), pp. 19-20.

By adopting the ICESCR and the ICCPR, human rights, as anchored in the UDHR, were not merely aspirations or political goals but became legal tools to protect individuals and to safeguard their inherent dignity.[183] Therewith the goals of advancing human rights, socioeconomic development as well as peace and security —the UN's initial goals— could be attained. Today, about 90 per cent of all countries have ratified these covenants.[184] This means that those governments have committed themselves to grant to their subjects the rights explicated in the treaties they have signed.[185] Ratification of one of those conventions results in legally binding obligations.

## 5.2 Human dignity as a core principle of human rights

Human dignity is the core principle of the human rights framework. The principle was also given legal significance through the adoption of the International Bill of Rights. Both covenants state: '[i]n accordance with the principles proclaimed in the Charter of the UN, recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world.'[186] The interrelatedness of human dignity, human rights and human beings is stipulated by '[r]ecognizing that these rights derive from the inherent dignity of the human person'.[187] In addition, human dignity is referred to as foundational principle in multiple international, regional and domestic human rights instruments which emphasises the concept's unique importance.[188]

Although addressing the concept differently, many theories centre on the notion of human dignity as the leading characteristic inherent to mankind.[189] The question of what this leading legal principle exactly encompasses remains seemingly difficult to answer because references to human dignity in the documents just mentioned do not delineate its content. Within human rights discourse, as McCrudden puts it aptly, it is widely appreciated that there is a concept of human dignity representing a minimum core of livelihood; however the concept knows various different interpretations.[190]

### 5.2.1 A normative conception of human dignity

Attempts to describe the somewhat 'indescribable' concept of human dignity often results in discussions of human rights norms. In order to establish a normative conception of

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183 See M. SEPÚLVEDA *et al*., *Human Rights Reference Handbook* 4th edn (Reykjavic - Ciudad Colon: Icelandic Human Rights Centre, University of Peace, 2009), p. 19.

184 See 'Status of ratification of the ICCPR' <http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-4&chapter=4&lang=en> accessed 5 July 2012; 'Status of ratification of the ICESCR' <http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en> accessed 5 July 2012; IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011), p. 5.

185 IFHHRO, *Workshop "Pain Treatment as a Human Right"* (Short Report) (Utrecht: IFHHRO, 2011), p. 5.

186 Both covenants anchor the exact similar reference that embodies the importance of human dignity within the human rights realm. See International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) UNGA Res. 2200A (XXI) UN Doc A/6316, 993 UNTS 3 (ICESCR), preamble. See also International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) UNGA Res. 2200A (XXI) UN Doc A/6316, 999 UNTS 171 (ICCPR), preamble.

187 Both covenants anchor the exact same phrase that emphasise the inalienable character of human rights because of their roots in human dignity. Human dignity, as stipulated in all prior referenced preambles, is inherent to mankind.

188 See for an overview of dignity in legal reasoning C. MCCRUDDEN, 'Human Dignity and Judicial Interpretation of Human Rights' 19 (2008) *The European Journal of International Law* pp. 655-724.

189 One of the mainstream philosophical traditions during the Enlightenment was the concept of natural law put forward by amongst others Grotius Aquinas and Locke.

190 C. MCCRUDDEN, 'Human Dignity and Judicial Interpretation of Human Rights' 19 (2008) *The European Journal of International Law* pp. 655-724, at pp. 679-680. McCrudden stressed that human dignity is used in a judicial context to provide a legal basis for human rights in general. Furthermore, it is a key-argument why human beings should have human rights in the first place. Resulting in the presumption that human dignity is the overall legal principle that is the basis for the human rights discourse.

contemporary human rights, it is important to address human dignity such that it is positioned within the field of human rights.[191]

Elaborating on earlier references made in the preambles of leading human rights instruments, human dignity is anchored in, e.g. the Convention on the Elimination of All Forms of Discrimination Against Women, the Convention Against Torture and Cruel, Inhuman and Degrading Treatment (CAT), the Convention on the Rights of the Child, the International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families, the International Convention for the Protection of All Persons from Enforced Disappearance, Convention on the Rights of Persons with Disabilities.[192] In regional legal documents the concept is embedded in, for instance, the American Convention on Human Rights, the African Charter on Human and Peoples' Rights (ACHPR), the Revised European Social Charter (ESC) and the European Convention on Human Rights and Biomedicine.[193] Respect for human dignity is furthermore binding upon all European Union Member States as it is embedded in the Charter of Fundamental Rights of the European Union.[194] Remarkably, the European Convention on Human Rights and Fundamental Freedoms (ECHR), one of the major regional human rights instruments, has not explicitly enshrined human dignity in its text.[195]

The normative content of human dignity is further substantiated through the principle's role in legal proceedings.[196] Judicial interpretation of human dignity provides for a minimum core standard of living.[197]

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191 KLAUS DICKE, 'The founding Function of Human Dignity', in D. KRETZMER AND E. KLEIN (eds), *The Concept of Human Dignity in Human Rights Discourse* (The Hague: Kluwer Law International, 2002), pp. 111-119. According to Dicke, human dignity is a transcendental norm that legitimises human rights. For dignity is not a substantive norm of which human rights immediately deduced but it rather has a legitimising function with regard to natural law.

192 See Convention on the Elimination of All Forms of Discrimination Against Women (open for signature 1 March 1980, entered into force 3 September 1981) 1249 UNTS 13 (CEDAW), preamble. See also Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (adopted 10 December 1984, entered into force 26 June 1987) 1465 UNTS 85 (CAT), preamble; Convention on the Rights of the Child (adopted 20 November 1989, entered into force 2 September 1990) 1577 UNTS 3 (CRC), preamble; International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families (adopted 18 December 1990, entered into force 1 July 2003) 2220 UNTS 3 (ICMW), art 17, 20; International Convention for the Protection of All Persons from Enforced Disappearance (open for signature 6 February 2007, entered into force 23 December 2010) 88 UNTS 25 (ICPPED), art 19-20; Convention on the Rights of Persons with Disabilities (open for signature 30 March 2007, entered into force 3 May 2008) 147 UNTS 99 (CRPD), preamble; C. MCCRUDDEN, 'Human Dignity and Judicial Interpretation of Human Rights' 19 (2008) *The European Journal of International Law* pp. 655-724, at p. 671.

193 American Convention on Human Rights (open for signature 22 November 1969, entered into force 18 July 1978) (1970) 9 ILM 99 (ACHR), preamble, arts. 5-6,11. See also African Charter on Human and Peoples' Rights (adopted 27 June 1981, entered into force 21 October 1986) (1982) 21 ILM 58 (ACHPR), preamble; European Social Charter (open for signature, 3 March 1996, entered into force 1 July 1999) (revised) CETS No 163 (ESC), preamble, art 26; European Convention on Human Rights and Biomedicines (open for signature 4 April 1997, entered into force 1 December 1999) CETS No 164 (ECHRB), preamble, art 1; C. MCCRUDDEN, 'Human Dignity and Judicial Interpretation of Human Rights' 19 (2008) *The European Journal of International Law* pp. 655-724, at p. 671.

194 The EU Charter enshrines the integral respect for human dignity and stresses its inviolable character. See Charter of Fundamental Rights of the European Union [2000] OJ C364/1 (CFREU), art 1. Through the Consolidated Version of the Treaty on European Union [2008] OJ C115/13 (TEU), art 6. The above is binding upon all European Member States.

195 See by omission European Convention for the Protection of Human Rights and Fundamental Freedoms (adopted 4 November 1950, entered into force 3 September 1953) CETS No 005 (ECHR). Although the ECHR lacks to enshrine human dignity, Protocol 13 embeds the principle. See the preamble paragraphs of Protocol 13 concerning the abolition of the death penalty in all circumstances (2002) CETS No 187, to the European Convention for the Protection of Human Rights and Fundamental Freedoms (adopted 4 November 1950, entered into force 3 September 1953) CETS No 005 (ECHR); C. McCrudden, 'Human Dignity and Judicial Interpretation of Human Rights' 19 (2008) The European Journal of International Law pp. 655-724, at p. 671.

196 The role of human dignity in legal proceedings remains subject of debate for some scholars hold that human dignity only provides for a different interpretation of the existing catalogues of human rights. Others at the same time uphold that human dignity fills an important feature to identify and further the catalogues of specific human rights because in some cases a perception of 'a minimum core of dignity' is translated into an individual right. See C. MCCRUDDEN, 'Human Dignity and Judicial Interpretation of Human Rights' 19 (2008) *The European Journal of International Law* pp. 655-724, at pp. 680-681; PAULO CÉSAR CARBONARI, 'Human Dignity as a Basic Concept of Ethics and Human Rights', in B. KLEIN GOLDEWIJK *et al*. (eds), *Dignity and Human Rights the Implementation of Economic, Social and Cultural Rights* (Antwerp, Intersentia, 2002), pp. 35-44, at p. 39.

197 C. MCCRUDDEN, 'Human Dignity and Judicial Interpretation of Human Rights' 19 (2008) *The European Journal of International Law* pp. 655-724, at pp. 679-680. McCrudden holds that there is a core minimum of human dignity consisting of the intrinsic worth of the concept and the perception that this value should be protected and respected by others. Those two elements are an ontological and relational claim of human dignity.

For instance, even though the ECHR does not enshrine an explicit reference to human dignity in its text, it emphasises the doctrine's importance in its case law. Article 3 ECHR (the prohibition of torture and cruel, inhuman and degrading treatment and punishment), in particular, is often interpreted along the lines of a human dignity yardstick.[198] The European Court of Human Rights (ECtHR) held in one its leading cases, *Tyrer v UK,* that corporal punishment was an assault 'on precisely that which […] is one of the main purposes of Article 3 to protect, namely a person's dignity and physical integrity'.[199] An analogue to this decision extended the ECtHR's reasoning concerning respect for human dignity and human freedom to '[t]he very essence of the Convention' in *Pretty v United Kingdom*.[200] In a way, human dignity is also embedded in the very foundations of European Union Law. The European Court of Justice emphasised in its *Christos Konstantinidis v Stadt Altensteig* judgment that 'the constitution[al] traditions of the Member States in general allow for the conclusion that there exists a principle according to which the state must respect […] his *dignity*, moral integrity and sense of personal identity'.[201]

The South African domestic case, *Dawood v Minister of Home Affairs,* signifies human dignity as a central feature within the human rights realm. The South African Constitutional Court reasoned that 'dignity is not only a *value* fundamental to our Constitution, it is a justiciable and enforceable *right* that must be respected and protected' too.[202] Stating that the Constitution should be interpreted in line with human dignity, 'the primary constitutional breach occasioned may be of a more specific right such as the right to bodily integrity'.[203]

## 5.3 Rights and obligations

Human rights today are perceived as being non-hierarchical and 'universal, interrelated, interdependent and indivisible'.[204] In contemporary debates, it is the trend to assert that it is impossible to deny differences between individual rights not only because individual rights all embody different elements of life, moreover because it is inherent to the nature of rights that they incite different State action towards realisation. As a matter of fact, not all individuals are capable of creating a dignified livelihood for themselves in which they can enjoy all human rights individually. Moreover, the role of the State is dominant to the level of human rights enjoyment on part of individuals. Enjoyment of all rights requires governments to adopt adequate policies, to refrain from interference, to promote certain conditions or to guarantee access to courts. All these actions, inactions, rights and freedoms result in cost burdens to governments as well as reticence. The investment of governmental funds, however, varies significantly between different individual rights.[205]

Though State responsibilities deriving from the normative human rights framework are frequently formulated differently in different human rights instruments, they all come down to the same variety of actions on part of the State. In some cases realisation and

198 C. MCCRUDDEN, 'Human Dignity and Judicial Interpretation of Human Rights' 19 (2008) *The European Journal of International Law* pp. 655-724, at p. 683.

199 *Tyrer v United Kingdom* (1978) Application no 5856/72, para 33.

200 *Pretty v United Kingdom* (2002) Application no 2346/02, para 65.

201 Case C-168/91 *Christos Konstantinidis v Stadt Altensteig - Standesamt and Landratsamt Calw - Ordnungsamt* [1993] ECR I-1191, AG Opinion, para 39 (emphasis added).

202 *Dawood and others v Minister of Home Affairs and Others* [2000] (3) SA 936 (CC), para 35.

203 *Dawood and others v Minister of Home Affairs and Others* [2000] (3) SA 936 (CC), para 35. See for an overview of other relevant case law of national courts that explicitly draw in human dignity to stress its utter importance within the human rights realm C. MCCRUDDEN, 'Human Dignity and Judicial Interpretation of Human Rights' 19 (2008) *The European Journal of International Law* pp. 655-724.

204 Proclaimed in the UNGA, 'Vienna Declaration and Programme of Action' (1993) UN Doc A/CONF.157/23, part I, para 5: 'All human rights are universal, indivisible and interdependent and interrelated. The international community must treat human rights globally in a fair and equal manner, on the same footing and with the same emphasis.' Therefore there is no hierarchical structure in the human rights framework.

205 I. E. KOCH, 'Dichotomies, Trichotomies or Waves of Duties?' 5 (2005) *Human Rights Law Review* pp. 81-103.

individual enjoyment of human rights imply a passive attitude of the State and in other cases a more active attitude is required of the State.[206]

A passive attitude of the State is on a primary level a States' obligation to respect and refrain from interference with for instance, individual resources, a person's freedom to find a job, to attend a school and speak out loud, to gather and to join associations.[207] In many other cases, however, human rights enjoyment and protection implies an active attitude of the State. In that respect, the State has an obligation to protect its subjects against human rights violations. This obligation clearly transcends the obligation to protect subjects against major atrocities and crimes against humanities for it also covers protection against violations committed by third parties.[208]

Individual's actual enjoyment of human rights through effective realisation has a substantial impact on State actions. Embedding in the human rights legal doctrine, the need to fulfil human rights requires a State to 'take measures to ensure, for persons within its jurisdiction, opportunities to obtain satisfaction of the basic needs as recognised in human rights instruments, *which cannot be secured by personal efforts*'.[209] In light of the emphasis of this report, individuals are not able to access essential opioid analgesics if the State, e.g., fails to adopt national health strategies or fails to create sufficient distribution networks.[210] In general terms this is emphasised in the Maastricht Guidelines on Violations of Economic, Social and Cultural Rights. The Guidelines address the interrelatedness of State obligations:

> [t]he obligation to *fulfill* requires states to take appropriate legislative, administrative, budgetary, judicial and other measures towards the full realization of such rights. Thus, the failure of states to provide essential primary health care to those in need may amount to a violation. The obligations to respect, protect and fulfil each contain elements of obligation of conduct and obligation of result. The obligation of conduct requires action reasonably calculated to realize the enjoyment of a particular right […]. The obligation of result requires states to achieve specific targets to satisfy a detailed substantive standard.[211]

The obligation to fulfil human rights includes aspects to facilitate, to improve and to provide for. The obligation to facilitate translates into the need to pro-actively diminish barriers both on a collective and individual level. Based on the need to improve, States are pressed to take appropriate steps to improve the general standard of human rights realisation. The obligation to provide for translates into the need to provide access to goods and services to empower individuals to live out and achieve a level of dignified livelihood.

A State can only give effect to human rights obligations within its limited, available (financial) resources. By no means the obligations as incumbent upon States, expects States to directly give effect to the full realisation of all human rights at the same time. As a result, in order to effectively fulfil its human rights obligations, a State has to work on the gradual and progressive realisation of all rights within a set period of time with use of its maximum available resources, despite its obligation to give immediate effect to the minimum core of every right.

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206 I. E. KOCH, 'Dichotomies, Trichotomies or Waves of Duties?' 5 (2005) *Human Rights Law Review* pp. 81-103. This dual obligation to either act passively or to act actively is a contemporary interpretation of the tripartite typology of human rights obligations: the responsibility to respect, protect and fulfil.

207 ASBJØRN EIDE, 'Economic, Social and Cultural Rights as Human Rights', in A. EIDE *et al.* (eds), *Economic, Social and Cultural Rights A Textbook* 2nd rev. edn (Dordrecht: Martinus Nijhoff Publishers, 2001), pp. 9-28, at pp. 23-24.

208 M. SEPÚLVEDA *et al*., *Human Rights Reference Handbook* 4th edn (Reykjavic - Ciudad Colon: Icelandic Human Rights Centre, University of Peace, 2009), p. 17.

209 M. SEPÚLVEDA *et al*., *Human Rights Reference Handbook* 4th edn (Reykjavic - Ciudad Colon: Icelandic Human Rights Centre, University of Peace, 2009), p. 17 (emphasis added).

210 See chapter 0.

211 C. FLINTERMAN *et al.* (eds), 'Maastricht Guidelines on Violations of Economic, Social and Cultural Rights' 20 (1998) *Human Rights Quarterly* pp. 691-704, at p. 694.

### 5.3.1 Progressive realisation and core obligations

Especially the work of the CESCR has contributed to a great extent to elaborating on the different types of State obligations and the content of rights. The CESCR has created a leading body of guidelines and commentaries that substantiate the content of the general provisions as adopted in the covenants. Although often regarded as soft-law documents, they do bear a considerable legal weight and national courts will take these documents into serious consideration.

The CESCR articulated in its general comment 3 that all rights enshrined in the Covenant are subject to a 'core minimum base' that States have to provide for, as well as to accommodate to, the underlying determinants of specific rights that are required to be realised within a States' available resources.[212] In this respect, the CESCR acknowledges that full compatibility with enshrined provisions cannot be achieved instantly or in a short defined period of time.[213] The CESCR accommodates explicitly for this situation and divides State obligations in two categories; obligations of *progressive realisation* and obligations of *immediate effect*.[214] Primarily States are expected to give progressive and gradual effect to the obligations as set forth by conventions and in that respect States rely on a certain margin of appreciation. Indeed, the CESCR addresses implementation of the ICESCR with due regard to country-specific situations and allows for a State-by-State approach to 'provide for progressive realization [and at the same time the CESCR] acknowledges the constraints due to the limits of available resources'[215]. Inasmuch, developing countries' situations are respected. Even though country specific situations are taken into serious account, by no means does the obligation of *progressive realisation* imply a passive attitude of States. According to established targets and benchmarks, States need to take serious action to foster the full realisation of all determinants of health.

In general comment 3, the CESCR amplifies what States should understand as an obligation of immediate effect. The core obligations the committee refers to in this respect need immediate State action, otherwise if such a minimum level is not enforced, the Convention is deprived of its *raison d'être*.[216] By all means the *raison d'être* of the Convention should be warranted and human rights realisation is subject to a question of priority. In this light the committee stresses that States need to meet these standards even in times of armed conflict, emergency situations or natural disaster.[217] The core obligations as outlined by the CESCR are a threshold to safeguarding individuals to enjoy at least a minimum core standard of living. Even though at a national level, the minimum core of a right is eventually decided upon by national courts.

Case law of the South African Constitutional Court contributed significantly to the discourse of the minimum core of rights and the enforceability of socioeconomic rights in general. One of the landmark cases in this respect is the *Grootboom Case*. In this case, the South African Constitutional Court ruled that the State was required to provide adequate housing for homeless people, leading the Court to declare that the State's housing programme was inconsistent with the right to housing.[218] The Court adopted a progressive approach towards establishing a minimum core and the realisation of socioeconomic rights

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212 CESCR, *General Comment 3 (1990): The Nature of State Parties obligations,* UN Doc E/1991/23, 14 December 1990, para 10.

213 CESCR, *General Comment 3 (1990): The Nature of State Parties obligations,* UN Doc E/1991/23, 14 December 1990, para 9; See also B.C.A. TOEBES, The Right to Health as a Human Right in International Law (Antwerp: Intersentia, 1999), p 139.

214 M. SEPÚLVEDA *et al*., *Human Rights Reference Handbook* 4th edn (Reykjavic - Ciudad Colon: Icelandic Human Rights Centre, University of Peace, 2009), p. 174. The terms obligation of immediate effect and core obligation are used interchangeably throughout this Report. This also applies to the terms obligation of progressive realisation and 'progressive realisation'.

215 CESCR, *General Comment 3 (1990): The Nature of State Parties obligations,* UN Doc E/1991/23, 14 December 1990, para 1.

216 CESCR, *General Comment 3 (1990): The Nature of State Parties obligations,* UN Doc E/1991/23, 14 December 1990, para 1.

217 M. SEPÚLVEDA *et al*., *Human Rights Reference Handbook* 4th edn (Reykjavic - Ciudad Colon: Icelandic Human Rights Centre, University of Peace, 2009), p. 369.

218 *Government of the Republic of South Africa v Grootboom* [2001] (1) SA 46 (CC), para 95.

by making explicit reference to the fact that the lack of adequate food and housing results in violations of human dignity.[219] The South African Constitutional's Court line of jurisprudence led to an innovative rights-based approach, for the Court held a similar position in the *TAC Case*. In this case the Court reasoned that the State breached the right to health by denying people access to the anti-retroviral medicine nevirapine in all public hospitals.[220] Both cases address States' failure in promoting and fulfilling socioeconomic rights. Some argue that the Court overstepped its authority in these cases and that it did not respect the division of power (the *Trias Politica* of Montesquieu).[221] Nevertheless, the South African Constitution's central concept is the respect for human dignity and the Court held in those cases that it was their task to safeguard compliance with the Constitution.[222] In the *TAC Case*, for instance, the Court held with regard to budgetary issues that its margin of appreciation was not itself 'directed at rearranging budgets', even though its ruling 'may in fact have budgetary implications'.[223] While the Court refrains from direct interrogation of the State's allocation decisions, budgetary rearrangements will never discourage the Court from finding unreasonableness within State policy.[224] Within this innovative approach, in which the Court might sometimes find itself on thin ice, the Court concludes that justiciability of economic and social rights might be a slippery slope that, at any time, requires a case-by-case approach.[225]

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219 *Government of the Republic of South Africa v Grootboom* [2001] (1) SA 46 (CC), para 23.

220 *Minister of Health v Treatment Action Campaign* [2005] (5) SA 721 (CC), paras 95, 135.

221 This issue is discussed in the Master Class Session with Justice Albie Sachs on his book *The Strange Alchemy of Life and Law* (Oxford University Press 2009), held at 10 December 2010, hosted by Utrecht University to the occasion of the Koningsberger Chair. See for a further reading on this topic A. SACHS, *The Strange Alchemy of Life and Law* (New York: Oxford University Press, 2009); I. E. KOCH, 'Dichotomies, Trichotomies or Waves of Duties?' 5 (2005) *Human Rights Law Review* pp. 81-103.

222 This was illustrated by Justice Albie Sachs in the Master Class Session on his book *The Strange Alchemy of Life and Law* (Oxford University Press 2009), held at 10 December 2010, hosted by Utrecht University to the occasion of the Koningsberger Chair.

223 *Minister of Health v Treatment Action Campaign* [2005] (5) SA 721 (CC), para 38.

224 DANIE BRAND, 'Socio-Economic Rights and Courts in South Africa: Justiciability on a Sliding Scale', in F. COOMANS (ed), *Justiciability of Economic and Social Rights, Experiences from Domestic Systems*, (Antwerp: Intersentia, 2006), pp. 207-236 at pp. 224-225. First concern raised with regard to justiciable socioeconomic rights is that States are considered 'ineffective agents' with regard to socioeconomic change. Secondly, democratic inappropriateness is raised.

225 DANIE BRAND, 'Socio-Economic Rights and Courts in South Africa: Justiciability on a Sliding Scale', in F. COOMANS (ed), *Justiciability of Economic and Social Rights, Experiences from Domestic Systems*, (Antwerp: Intersentia, 2006), pp. 207-236 at p. 226. The Court acknowledged this difficulty in the *Government of the Republic of South Africa v Grootboom* [2001] (1) SA 46 (CC), para 21.

# 6 A Human Right to Pain Relief

As evidenced in Chapter 5, the present human rights framework as build upon the notion of human dignity that translates into a minimum core standard of livelihood, is a valuable tool in establishing a human right to pain relief. The right stems from the key essential elements of the right to health as outlined by the CESCR and it is increasingly argued that the human right to pain relief is reinforced by the prohibition of inhuman and degrading treatment.

## 6.1 The right to health

The highest attainable standard of health and the adequate protection thereof has been construed as one of the fundamental human rights. Health is a crucial element of life and a matter of daily concern to all of us.[226] Essentially, good health is often what people have in mind whilst thinking about the wellbeing of themselves and their family members.[227] Individual health, as intangible and subjective as it may be, is therefore one of the most important conditions for a person's well-being and dignity, on which ill health can have a detrimental effect.[228]

The adoption of the UN Charter signifies the moment when the global aim of safeguarding public health as integral part of human rights was first documented as seen in Article 55.[229] Perhaps the most comprehensive definition of 'good health', however, emanates from the WHO constitution: 'health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity'.[230] The definition of health as global concern in the struggle for human rights protection resulted in multiple variations of codification at the international, regional and national level. For instance, it is conforming to Article 25 of the UDHR that States allow everyone to enjoy a 'standard of living adequate for the health and well-being of himself and of his family, including […] medical care'.[231] The margin that is left for States in their fulfilment of the right to health is similarly anchored in the ICESCR. According to Article 12 ICESCR, the right to health encompasses 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health'.[232] According to Article 16 ACHPR '[e]very individual shall have the right to enjoy the best attainable state of physical and mental health'.[233] On the contrary, in Article 11 ESC (Revised)[234], the ESC adopts a more progressive approach by specifically referring to 'the right to protection of health' and making explicit references to individual obligations of both public and private organisations.[235] Constitutional provisions may differ from country to country, though; at the same time arrive at substantial similar results.[236] For instance, the Dutch constitution requires the State to promote public health.[237] The South African constitution, being one of the most progressive constitutions today, anchors health in Article

226 OHCHR, *Fact Sheet No. 31, The Right to Health* (Geneva: United Nations, 2008), p. 1.
227 OHCHR, *Fact Sheet No. 31, The Right to Health* (Geneva: United Nations, 2008), p. 1.
228 BRIGIT TOEBES, 'The Right to Health', in A. EIDE *et al.* (eds), *Economic, Social and Cultural Rights A Textbook* 2nd rev edn (Dordrecht: Martinus Nijhoff Publishers, 2001), pp. 169-190, at p. 169; OHCHR, *Fact Sheet No. 31, The Right to Health* (Geneva: United Nations, 2008), p. 1.
229 Prior to that moment health was moreover a responsibility or concern to families, private charities or religious organisations. See M. SSENYONJO, *Economic, Social and Cultural Rights in International Law,* (Oxford: Hart Publishing, 2009), p. 316; See also UN Charter, art 55(b).
230 WHO Constitution, principles.
231 UDHR, art 25(1).
232 ICESCR, art 12.
233 ACHPR, art 16(1).
234 ESC, art 11.
235 M. SSENYONJO, *Economic, Social and Cultural Rights in International Law,* (Oxford: Hart Publishing, 2009), p. 320.
236 See for an overview of constitutions enshrining the right to health with an emphasis on access to essential medicines S.K. PEREHUDOFF, R.O. LAING AND H.V. HOGERZEIL, 'Access to Essential Medicines in National Constitutions' 88 (2010) *Bulletin World Health Organization* p. 800. See also BRIGIT TOEBES, 'The Right to Health', in A. EIDE *et al.* (eds), *Economic, Social and Cultural Rights A Textbook* 2nd rev edn (Dordrecht: Martinus Nijhoff Publishers, 2001), pp. 169-190; OHCHR, *Fact Sheet No. 31, The Right to Health* (Geneva: United Nations, 2008), p. 10.
237 Constitution of the Kingdom of the Netherlands (24 August 1815), Stb. 2009, 120, art 22(1).

27: '[e]veryone has the right to have access to health care services'.[238] This has been researched in a study of the WHO's Essential Medicines and Pharmaceutical Policies department. The WHO also undertook further studies in this field and conducted similar research with an emphasis on national legislation.[239]

The multi-layered references of the right to health in human rights law demonstrate that health has become a fundamental part of the human rights discourse. Principally, the normative content of the right to health is outlined in Article 12 ICESCR, which is understood as the most significant international legal provision concerning health matters:

1. The States Parties to the present Covenant recognise the right of everyone to the enjoyment of the *highest attainable standard of physical and mental health*.
2. The *steps to be taken* by the States Parties to the present Covenant to achieve the full realisation of this right shall include those necessary for: […]
   c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
   d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.[240]

Realisation of the right to health, according to Article 12 ICESCR, involves States taking steps towards achieving full realisation of the enjoyment of the highest attainable standard of physical and mental health. The exact implication of what States should actually do or withhold to foster the health of individuals remains rather unclear merely in context of Article 12 ICESCR. To ensure the scope of protection and realisation of the right to health as was intended by the ICESCR, the CESCR further elaborated the normative content of the right in general comment 14.[241]

General comment 14 extends the scope of the right to health to the right to enjoyment of certain facilities and goods that are preconditions for the realisation of good health.[242] The CESCR notes that widespread diseases such as HIV/Aids and cancer are cause to new obstacles regarding realisation and should therefore be taken into account specifically.[243] The committee also states that the right to health is an inclusive right and is therefore extended to the underlying determinants of health too.[244] The committee articulates these normative standards into a triple-AQ obligation: all entitlements that the right to health includes should be Available, Accessible, Acceptable and of good Quality.[245] Evidently, health as a comprehensive concept is significantly more than *i.e.*, access to emergency health care or hospital care.

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238 Constitution of the Republic of South Africa (18 December 1996), 108, as amended by the Second Amendment Act no 3, 2003, art 27.

239 Joint project of WHO-EMP Department under supervision of Dr H Hogerzeil and Professor M Forzley of Widener School of Law, Delaware. Work undertaken in June-August 2010 at WHO Headquarters in Geneva. See M. FORZLEY, D. WALKER AND M.E.C. GISPEN, 'Access to Essential Medicines in National Legislation'(Geneva: World Health Organization, 2010) (forthcoming publication in process of publication of research report series).

240 ICESCR, art 12 (emphasis added).

241 CESCR, *General Comment No. 14 (2000): The right to the highest attainable standard of health*, UN Doc E/C.12/2000/4, 11 May 2000, para 8.

242 CESCR, *General Comment No. 14 (2000): The right to the highest attainable standard of health*, UN Doc E/C.12/2000/4, 11 May 2000, para 9.

243 CESCR, *General Comment No. 14 (2000): The right to the highest attainable standard of health*, UN Doc E/C.12/2000/4, 11 May 2000, para 10.

244 CESCR, *General Comment No. 14 (2000): The right to the highest attainable standard of health*, UN Doc E/C.12/2000/4, 11 May 2000, para 11. The committee refers in this respect to underlying determinants of health such as access to safe and potable water, sanitation, supply of safe food and nutrition, access to housing and healthy occupational facilities. See also M. SSENYONJO, *Economic, Social and Cultural Rights in International Law,* (Oxford: Hart Publishing, 2009), pp. 327-330.

245 CESCR, *General Comment No. 14 (2000): The right to the highest attainable standard of health*, UN Doc E/C.12/2000/4, 11 May 2000, para 12.

### 6.1.1 The minimum core: essential medicines

On top of the so-called triple-AQ obligation incumbent on States with regard to fulfilment and realisation of all entitlements as part of the right to health, the CESCR further elaborated the normative content of the right to health by establishing its minimum core.

From time to time the WHO establishes a Model List of Essential Medicines. These medicines should cover the priority health care needs of a country's population as per the WHO. They are selected with due regard to disease prevalence, safety, efficacy, and comparative cost-effectiveness.[246] Every two years the WHO adopts an updated version of the Model List of Essential Medicines which can serve as guiding document in adopting national strategies with regard to medicine availability.[247] Discussions remain regards the normativity of the list; should it merely function as a model for countries or should all medicines on that list be available in every country?

The list provides for a detailed overview per disease type of medication, which medicine in which form (liquid or tablet) should be available. Under the section opioid analgesics, oral and tablet form morphine, either morphine hydrochloride or morphine sulfate, should be made readily available.[248] For the CESCR outlined in its general comment 14, the need to ensure free access to essential medicines, as advised upon by the WHO Model List of Essential Medicine, as one the core obligations translating the minimum core of the right to health:

> 43. In General Comment No. 3, the Committee confirms that States parties have a core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights enunciated in the Covenant, […] Accordingly, in the Committee's view, these core obligations include at least the following obligations: […]
> *(d) To provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs*[249]

In view of paragraph 43 of general comment 14, pain relief as a human right stems from the adequate fulfilment of the right to health. Morphine is essential to effective pain treatment and is considered an essential medicine according to the WHO Model list of Essential Medicine. As outlined in Chapter 0, the CESCR has explained these core obligations as demanding immediate action of States towards realisation at any rate. Accordingly, States should give effect to the other determinants underlying right to health progressively within their margin of appreciation.

With exemplifying the minimum core of the right to health, the CESCR also sets much store by the counter part of allowing access to controlled substances for medical purposes. The CESCR outlines States' obligation of *comparable priority* '[t]o take measures to prevent, treat and control epidemic and endemic diseases'.[250] Inasmuch, the human rights framework also protects the position of drug abusers and even an argument in favor of a right to harm reduction could be put forward. For the listed obligations do not specifically refer to the present level of drug control and more humane and softer options of harm reduction like clean needle programs and opioid substitute treatments have been proven effective in transmission decrease of HIV/Aids and Hepatitis C.[251]

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246 WHO, *Factsheet No 325: Medicines: essential medicines* rev. (2010). Available at <http://www.who.int/mediacentre/factsheets/fs325/en/index.html> accessed 2 May 2012. See also H.V. Hogerzeil, 'Essential medicines and human rights: what can they learn from each other? 84' (2006) *Bulletin World Health Organization* pp. 371-375, at p. 371.

247 WHO, *Factsheet No 325: Medicines: essential medicines* rev. (2010). Available at <http://www.who.int/mediacentre/factsheets/fs325/en/index.html> accessed 2 May 2012.

248 WHO 'Model List of Essential Medicines' (2011), p. 2. Available at <http://whqlibdoc.who.int/hq/2011/a95053_eng.pdf> accessed 17 June 2011

249 CESCR, *General Comment No. 14 (2000): The right to the highest attainable standard of health*, UN Doc E/C.12/2000/4, 11 May 2000, para 43 (emphasis added).

250 CESCR, *General Comment No. 14 (2000): The right to the highest attainable standard of health*, UN Doc E/C.12/2000/4, 11 May 2000, para 44 (emphasis added).

251 See M. MACDONALD *et al*., 'Effectiveness for Needle and Syringe Programmes for PreventingHIV Transmission'14 (2003) *International Journal of Drug Policy* pp. 353-357, at p. 356; M.S. SULKOWSKI AND D.L. THOMAS, 'Hepatitis C in

### 6.1.2 The minimum core: palliative care

The treatment of pain is one of the features of palliative care. Alongside the claims towards a human right to pain relief based on the core obligation to ensure access to essential medicines, the human right to pain relief can be further substantiated based on the key central position of palliative care services as part of the effective realisation of the right to health. As made prior reference to, the WHO defines palliative care as:

> an approach that improves the quality of life of patients and their families facing the problem associated with 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.[252]

The assumption dominates that an argument in favour of palliative care treatment is implied by the overall human rights instruments concerning health. As evidenced above, the WHO, in particular, manages to include health and palliative care in its comprehensive definitions.[253] Both the WHO's definition of health and palliative care refer to a status of physical, mental and social well-being in which palliative care is emphasised on physical, psychological and spiritual relief in settings of severe pain experiences.[254] Its key importance also stems from the interrelatedness of palliative care, good health and human dignity.

Duarte Enes established a perception of the meaning of dignity in end-of-life cases and analysed that dignity in palliative care settings reflects the desire to being heard, to give and receive love, to be in control over decisions relating to behaviour and your body, to be human by means of being treated as worthy and with respect, to have rights, to be of value and finally to maintain your individuality and independence by carrying on a normal life.[255] The regression of excruciating pain most definitely fits this notion as pain has a devastating effect on living a normal life.[256] The meaning of dignity in palliative care settings as Duarte Enes aptly puts it, demands a holistic approach: 'encompassing physical comfort as well as having psychological, social, cultural and spiritual perspectives'.[257] From this viewpoint a demand for palliative care based on the right to health as defined by the WHO is suitable because the WHO's definition of health is unique for of its holistic character.[258]

A right to access palliative care, hence a human right to pain relief, is part of the minimum standard of livelihood as outlined by the CESCR in general comment 14.

> 43. (a) To ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups; […]
> (f) To *adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population*; the strategy and plan of action shall be devised, and periodically reviewed, on the basis of a participatory and transparent process; they shall include methods, such as right to health indicators and benchmarks, by which progress can be closely monitored; the process by which the strategy and plan of action are

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the HIV-Infected Person' 138 (2003) *Annals of Internal Medicine* pp. 197-207; C.S. TODD *et al.*, 'Prevalence and correlates of HIV, in Kabul, Afghanistan: A cross-sectional assessment', 22 (2011) *Harm Reduction Journal* pp. 1-8.

252 See the WHO's definition of palliative care <http://www.who.int/cancer/palliative/definition/en/> accessed 5 April 2011.

253 F. BRENNAN, 'Palliative Care as an International Human Right' 33 (2007) *Journal of Pain and Symptom Management* pp. 494-499, at p. 495.

254 See the WHO's definition of palliative care <http://www.who.int/cancer/palliative/definition/en/> accessed 9 July 2012; Constitution of the World Health Organization (entered into force 7 April 1948) Official Records of the World Health Organization 2, 100 (WHO Constitution), principles.

255 S.P. DUARTE ENES, 'An exploration of dignity in palliative care' 17 (2003) *Palliative Medicine* pp. 263-269, at p. 264.

256 See chapter 0

257 S.P. DUARTE ENES, 'An exploration of dignity in palliative care' 17 (2003) *Palliative Medicine* pp. 263-269, at p. 268.

258 B.C.A. TOEBES, *The Right to Health as a Human Right in International Law* (Antwerp: Intersentia, 1999), p. 30. According to Toebes, the WHO's definition of health encompasses an extensive and fairly unrestricted definition of health.

devised, as well as their content, shall give particular attention to all vulnerable or marginalized groups.[259]

In terms of effective access to palliative care treatment, the core obligation to adopt and implement national public health strategies and plans should encompass palliative care considering epidemiological evidence to address the health interests of the population. As Brennan puts it aptly, these obligations imply: 'universal access to services, the provision of basic medications for symptom control and terminal care, and the adoption and implementation of national palliative care policies'.[260] The WHO has recommended that countries should adopt a national palliative care policy in which training of health care workers, professionals and awareness is put on the agenda.[261] Morphine should be made readily available and minimum standards of palliative care should be realised within the margin of 'progressive realisation' at all levels of care.[262]

## 6.2 The freedom from inhuman and degrading treatment

In line with the reasoning of former UN Special Rapporteur Nowak and present UN Special Rapporteur Grover (respectively mandate holders on torture and health), it is increasingly argued that the denial of pain relief also constitute a violation of the State obligation to ensure individuals freedom from inhuman and degrading treatment.

Torture and cruel, inhuman and degrading treatment and punishment (CIDT) are often mentioned or referred to in one breath. Differences, however, do exist. Even though no exact definition of CIDT is adopted in legal instruments, the Human Rights Committee holds that 'these distinctions depend on the nature, purpose and severity of the particular treatment'.[263]

In Article 1, CAT torture is explicitly stated as an act by which severe pain or suffering is intentionally inflicted for reasons of e.g., punishment or confession. Treatment that is not considered an act of torture in the meaning of Article 1 CAT may still constitute an act of CIDT. According to Article 16 CAT, CIDT is the State obligation to refrain from such treatment:

1. Each State Party shall undertake to prevent in any territory under its jurisdiction other acts of cruel, inhuman or degrading treatment or punishment which do not amount to torture as defined in article I, when such acts are committed by or at the instigation of or with the consent or acquiescence of a public official or other person acting in an official capacity. In particular, the obligations contained in articles 10, 11, 12 and 13 shall apply with the substitution for references to torture of references to other forms of cruel, inhuman or degrading treatment or punishment.[264]

The exact definition of inhuman and degrading treatment as element of CIDT is therewith not explicitly outlined. Both the ECtHR and the European Commission on Human Rights (EcommHR) have been progressive in conceptualising and formulating the doctrine of inhuman treatment or punishment.

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259 CESCR, *General Comment No. 14 (2000): The right to the highest attainable standard of health*, UN Doc E/C.12/2000/4, 11 May 2000, para 43 (emphasis added).

260 F. BRENNAN, 'Palliative Care as an International Human Right' 33 (2007) *Journal of Pain and Symptom Management* pp. 494-499, at p. 495.

261 F. BRENNAN, 'Palliative Care as an International Human Right' 33 (2007) *Journal of Pain and Symptom Management* pp. 494-499, at p. 495. See also WHO, *National Cancer Control Programmes Policies and Managerial Guidelines* (Geneva: WHO, 2002), pp. 83-91.

262 F. BRENNAN, 'Palliative Care as an International Human Right' 33 (2007) *Journal of Pain and Symptom Management* pp. 494-499, at p. 496. See also WHO 2002 (n 329) 83-91.

263 M. SEPÚLVEDA *et al*., *Human Rights Reference Handbook* 4th edn (Reykjavic - Ciudad Colon: Icelandic Human Rights Centre, University of Peace, 2009), p. 241.

264 ACHR, art 16(1).

Principally it was considered that inhuman treatment stems from a more general nature than torture.[265] In addition, being a separate branch of treatment, the EcommHR adopted the premise that inhuman treatment covers treatment that deliberately causes severe physical and/or mental treatment that is unjustifiable in any possible situation.[266] This is said to be evidenced by examining a threefold threshold: i) intent, ii) severe suffering and iii) the lack of justification of the act.[267]

The element of intent, especially whilst bringing pain treatment within the human rights realm covered by the freedom from inhuman and degrading treatment, is the most sweeping. According to Cassese, it is questionable whether intent is an indispensable element for establishing an act of inhuman treatment. Holding such an argument maintains recognition of the importance of intent as element of inhuman treatment, however 'it ought not to be regarded as one of the factors the absence of which warrants the conclusion that no inhuman treatment or punishment is meted out'.[268] This approach is underpinned, especially, by decisions of the EcommHR and later by cases of the ECtHR. As cited by Cassese in this regard, in *Cyprus v Turkey*, the Commission ruled that an act of withholding food and water of detainees was considered inhuman treatment, and thus a breach of Article 3 ECHR, irrespective of looking into the intention of those who inflicted this treatment.[269] In line with such argumentation, Cassese opts for managing a more substantive approach through focusing on 'suffering resulting from an act not involving any culpable negligence or recklessness'.[270] Thus inhuman treatment is considered as an act in which the intent or deliberate infliction is not decisively important; however, the act should cause a certain level of physical or mental suffering.[271]

### 6.2.1 The denial of pain relief as a violation of the freedom from inhuman and degrading treatment

According to the UN Human Rights Committee, the protection against torture and CIDT does not merely apply to prisons or detention centres but also to patients in health care settings.[272]

The denial of pain relief treatment leaves people to suffer unbearable, often excruciating, pain on a daily basis. Human Rights Watch has written several reports in which they give a voice to pain patients; it appeared that these people often describe similar experiences as torture survivors. Most pain patients interviewed by Human Rights Watch wanted to commit suicide, prayed for the pain to be taken away or expressed their wish to die whereas they could not stop the experience by putting up a confession or something similar.[273] Evidently, denial of pain treatment results in a certain level of physical or mental suffering, the vital element of what constitutes CIDT.

In response to the outcome of the 52nd session of the CND Special Rapporteurs Nowak and Grover wrote a joint statement on the lack of access to adequate pain treatment that underpins the above outlined approach. In this letter, addressed to Mr Best, vice-

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265 A. CASSESE, *The Human Dimension of International Law*, sel. papers (Oxford: Oxford University Press, 2008), p. 299.

266 A. CASSESE, *The Human Dimension of International Law*, sel. papers (Oxford: Oxford University Press, 2008), p. 299.

267 A. CASSESE, *The Human Dimension of International Law*, sel. papers (Oxford: Oxford University Press, 2008), p. 299.

268 A. CASSESE, *The Human Dimension of International Law*, sel. papers (Oxford: Oxford University Press, 2008), p. 316.

269 A. CASSESE, *The Human Dimension of International Law*, sel. papers (Oxford: Oxford University Press, 2008), p. 316. See *Cyprus v Turkey* (1976) Application no 6780/74 and 6950/75 (Commission Report), paras 395-405.

270 *Cyprus v Turkey* (1976) Application no 6780/74 and 6950/75 (Commission Report), para 317.

271 *Cyprus v Turkey* (1976) Application no 6780/74 and 6950/75 (Commission Report), para 317.

272 OSF, *Government Accountability for Torture and Ill-Treatment in Health Settings* (2011) (Open Society Foundations Briefing Paper)), p. 1. Available at <http://www.soros.org/initiatives/health/focus/law/articles_publications/publications/accountability-torture-health-20110511> accessed 30 May 2011. See also HRC, *General Comment No. 20* (1992): *Replaces General Comment No. 7 concerning prohibition of torture and cruel treatment or punishment*, UN Doc A/47/40, 30 April 1992. Analogues to this interpretation, torture and CIDT extends to being applicable to schools, orphanages and social care institutions.

273 HRW, *"Please do not make us suffer anymore…" Access to Pain Treatment as a Human Right* (New York: Human Rights Watch, 2009), pp. 6-7. See also OSF, *Government Accountability for Torture and Ill-Treatment in Health Settings* (2011) (Open Society Foundations Briefing Paper)), p. 2. Available at <http://www.soros.org/initiatives/health/focus/law/articles_publications/publications/accountability-torture-health-20110511> accessed 30 May 2011.

chairman of the CND at its 52nd session, both Special Rapporteurs observed denial of pain treatment through lack of access to adequate medication as inhuman and degrading treatment. Referring to international State obligations with relevance to pain treatment Nowak and Grover stated; '[g]overnments also have an obligation to take measures to protect people under their jurisdiction from inhuman and degrading treatment. Failure of governments to take reasonable measures to ensure accessibility of pain treatment, which leaves millions of people to suffer needlessly from severe and often prolonged pain, raises questions whether they have adequately discharged this obligation'.[274] Nowak subsequently underpinned this assumption by stating that 'de facto denial of access to pain relief, if it causes severe pain and suffering, constitutes cruel, inhuman or degrading treatment or punishment'.[275] Thus; according to both Special Rapporteurs the failure to provide access to essential opioid analgesics constitutes a breach of both the fundamental right to health as well as the freedom from inhuman and degrading treatment.[276] Some scholars and tribunals hold that the freedom from CIDT is part of customary international law and some go as far as suggesting that the freedom from CIDT also attains the status of *jus cogens*.

Besides patients, doctors themselves are victims of the horrible predicament that underlies poor access to opioid analgesics. They are often not allowed to prescribe opioids for pain treatment; they fear immense legal sanctions when doing so or on the basis of possessing opioids. Because of the vital importance of pain treatment and its core business for doctors and nurses, all health professionals should be enabled to execute this essential professional duty to their patients. It is the government that is accountable for not allowing doctors to administer or prescribe narcotic drugs and thus consequently fail to protect its subjects against inhuman and degrading treatment.[277]

## 6.3 Case law advancing a human right to pain relief

The human right to pain relief has been substantiated in seminal national and regional case law pertaining to the minimum core of the right to health and the scope of the prohibition of CIDT.

The minimum core, and its demand for immediate realisation, has been furthered in national case law. Judicial rulings of the Federal Supreme Court of Brazil have established the notion that the right to health is an indispensable and unalienable right stemming of the constitutional right to life.[278] Hence the Supreme Court recognised a right to medication to all, including HIV/Aids patients. For instance, in *Diná Rosa Vieira v Município de Porto Alegre*, the Supreme Court ruled that the free distribution of (essential) medicine responds to the claims of solidarity and humanity of those who have nothing more than a perception of their own human dignity.[279] In the *TAC Case*[280] it was the South African Constitutional Court that took up a progressive rights-based approach towards allowing individuals accessing

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274 M. NOWAK AND A. GROVER, *Joint letter to Mr Best, Vice-Chairperson of the Commission on Narcotic Drugs (52nd Session) in their capacity as Special Rapporteurs*, UN Doc G/SO 214 (53-21), 10 December 2008, para 4.

275 HRC, *Report of the Special Rapporteur on Torture and other Cruel, Inhuman or Degrading Treatment or punishment* (2010), UN Doc A/HRC/10/44, para 72.

276 M. NOWAK AND A. GROVER, *Joint letter to Mr Best, Vice-Chairperson of the Commission on Narcotic Drugs (52nd Session) in their capacity as Special Rapporteurs*, UN Doc G/SO 214 (53-21), 10 December 2008, para 4.

277 OSF, *Government Accountability for Torture and Ill-Treatment in Health Settings* (2011) (Open Society Foundations Briefing Paper)), p. 1. Available at <http://www.soros.org/initiatives/health/focus/law/articles_publications/publications/accountability-torture-health-20110511> accessed 30 May 2011.

278 FLAVIA PIOVESAN, 'Brazil: Impact and Challenges of Social Rights in the Courts', in M. LANGFORD (ed), *Social Rights Jurisprudence* (New York: Cambridge University Press, 2008), pp. 182-191, at p. 185.

279 *Diná Rosa Vieira v Município de Porto Alegre*, RE-271286 Agr/RS-Rio Grande do Sul (2000). See for an English interpretation of the case FLAVIA PIOVESAN, 'Brazil: Impact and Challenges of Social Rights in the Courts', in M. LANGFORD (ed), *Social Rights Jurisprudence* (New York: Cambridge University Press, 2008), pp. 182-191, at pp. 185-186.

280 *Minister of Health v Treatment Action Campaign* [2005] (5) SA 721 (CC).

essential medicines. The Court upheld earlier judgments and warranted the South African government to assure medicine availability.[281]

The *Azanca Alhelí Meza García* case that came before the Peruvian Constitutional Tribunal is a key precedent case for socioeconomic enforcement. The petitioner claimed access to comprehensive medical treatment including a permanent supply of drugs due to being financially unable to personally cover the costs. The Court ordered the Peruvian Ministry of Health to give top priority to establishing and enforcing a strategy to combat HIV/Aids and re-affirmed that the minimum core standards that demand immediate action are incumbent on States despite their available financial resources.[282]

A similar case came before the Supreme Court of Venezuela. In the *Glenda Lopez* case a group of applicants contested Instituto Venezolano de los Seguros Sociales with an *amparo* action.[283] They requested a regular and sufficient supply of triple-therapy drugs and other drugs to fight opportunistic diseases. The Court found a violation of the right to health and ordered the institution to provide social security benefits and drugs to all people living with HIV/Aids who requested so.[284]

In Egypt, a landmark case was decided in which the drug pricing system was successfully contested. In line with Article 16 ACHPR, the Egyptian Court of Administrative Justice upheld that the new pricing systems resulted in 'inevitable repercussions [...] principally increased prices of pharmaceutical drugs'.[285] The Court reasoned that such conditions would have consequences on the health of individuals and 'their right to obtain affordable medicine'.[286]

Palliative care, as part of the minimum core of the right to health, has been furthered by, for instance, an American lawsuit from 1990, in which the estate of Henry James sued the Guardian Care nursing home in North Caroline successfully.[287] Although the attending physician ordered that adequate doses of morphine should be administered according to a specific time scheme, staff of the Guardian Care nursing home decided to administer light opioids to control Henry James' cancer pain. The jury found the nursing home in violation of the State Division of Facility Services in which pain control was regulated. According to McIntire, such litigation is not unique; however, this case is the first in its kind in which the inadequate provision of pain treatment was accounted to a nursing home.[288]

A substantial similar case is the *Bergman v Chin* case. In this case, the Bergman estate charged Dr Chin with not prescribing adequate medication that suited Mr Bergman's need of pain relief. The jury held Dr Chin liable for inadequate pain control.[289]

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281 *Minister of Health v Treatment Action Campaign* [2005] (5) SA 721 (CC), paras. 95, 135. See also H.V. HOGERZEIL *et al.*, 'Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts?' 368 (2006) *Lancet* pp. 305-311, at p. 309.

282 See *Case Azanca Alhelí Meza García, Expte* (Amparo) No 2945-2003-AA/TC. (Peru, Constitutional Tribunal Decision 20 April 2004). Available at <http://www.escr-net.org/caselaw/caselaw_show.htm?doc_id=405156&focus=13991,13992,14020> accessed 10 May 2011.

283 See *Case López, Glenda y otros c Instituto Venezolano de los Seguros Sociales (IVSS)* (Amparo) Expediente 00-1343. Sentencia No 487. (Venezuela, Supreme Court Decision 6 April 2001). Available at <http://www.escr-net.org/caselaw/caselaw_show.htm?doc_id=412539&focus=13991,13992,14020> accessed 10 May 2011.

284 See *Case López, Glenda y otros c Instituto Venezolano de los Seguros Sociales (IVSS)* (Amparo) Expediente 00-1343. Sentencia No 487. (Venezuela, Supreme Court Decision 6 April 2001). Available at <http://www.escr-net.org/caselaw/caselaw_show.htm?doc_id=412539&focus=13991,13992,14020> accessed 10 May 2011.

285 See *Case No 2457/64 Challenging the New Drug Pricing System* (Egypt, Court of Administrative Justice Decision 27 April 2010). Available at <http://www.escrnet.org/caselaw/caselaw_show.htm?doc_id=1312208&focus=13670,15427,13991,13992,14000,13958,13959,13971,13982> accessed 10 May 2011.

286 See *Case No 2457/64 Challenging the New Drug Pricing System* (Egypt, Court of Administrative Justice Decision 27 April 2010). Available at <http://www.escrnet.org/caselaw/caselaw_show.htm?doc_id=1312208&focus=13670,15427,13991,13992,14000,13958,13959,13971,13982> accessed 10 May 2011.

287 T. MCINTIRE, 'Is the Pain Getting Any Better? How Elder Abuse Litigation Led to a Regulatory Revolution in the Duty to Provide Palliative Care' 11 (2003) *The Elder Law Journal* pp. 329-360, at p. 346.

288 T. MCINTIRE, 'Is the Pain Getting Any Better? How Elder Abuse Litigation Led to a Regulatory Revolution in the Duty to Provide Palliative Care' 11 (2003) *The Elder Law Journal* pp. 329-360, at pp. 346-347.

289 T. MCINTIRE, 'Is the Pain Getting Any Better? How Elder Abuse Litigation Led to a Regulatory Revolution in the Duty to Provide Palliative Care' 11 (2003) *The Elder Law Journal* pp. 329-360, at p. 347.

The increasingly debated issue of denied pain treatment, as a breach of the violation of inhuman and degrading treatment, has been further shaped by an ECtHR case pertaining to Article 3 ECHR.

In *D v The United Kingdom*, the ECtHR connected the principle of *non-refoulement* to palliative care and pain treatment. Under this principle, States are not allowed to extradite a person to another country if there is a reasonable danger of that person being subjected to either torture or CIDT in that particular country.[290] The case concerned the proposed extradition of terminally ill D to his homeland, St Kitts. D contested his extradition on the grounds that he would neither have a home to live in, nor family to rely on; however, more substantially, he would lack access to adequate medical treatment, therefore, in conjunction returning to St Kitts would breach Article 3 ECHR (freedom from torture and CIDT). Implicitly, the Court firmly takes the importance of palliative care treatment into account by acknowledging that in the United Kingdom D 'enjoys results from the availability of sophisticated treatment and medication […] and the care and kindness administered by a charitable organisation. He has been counselled on how to approach death and has formed bonds with his carers'.[291] Subsequently the Court determines the 'abrupt withdrawal of these facilities' as having drastic and dramatic consequences for the applicant.[292] According to the Court, extraditing D to St Kitts would not only 'further reduce his […] life expectancy' but also subject him 'to acute mental and physical suffering'.[293] Even though D practically does have family in his home country, the Court doubts whether they are capable of taking care of him in an end-of-life stage which is demanding on caregivers. It remained unclear whether D would be able to rely on some form of moral or social support as well as whether he would actually be guaranteed a hospital bed at all.[294] The Court holds that the situation, as stressed above, entails exceptional circumstances and together with the critical stage of the applicant's illness extradition of D would be a violation of Article 3.[295] The Court attenuates this position by maintaining that 'it cannot be said that the conditions which would confront him in the receiving country are themselves a breach of the standards of Article 3'.[296] In summary, the Court acknowledges pain treatment and palliative care as covered by the scope of Article 3, however, the Court refrains from creating a norm-setting argument for both levels of treatment, as such, as they are not put to a substantial test.

Case law pertaining advancement of access to medication demonstrates an upstream perspective and manages a rights-based approach. The cases presented above show that governments are held accountable for negligence to allow its subjects to access lifesaving or preventive medication.[297] The precedent case law does not directly reflect the access to morphine as controlled opioid analgesic, however, tracing an overview of relevant case law does underpin the enforceability of the obligations and justiciability of the human right to pain relief, as explicated above.

## 6.4 Civil society statements supporting a human right to pain relief

While it is difficult for States to allow their subjects access to essential medicines in general, major difficulties arise with regard to access to essential opioid analgesics. In this respect, IFHHRO recently adopted a position that embraces pain treatment as an integral part of the

290 This is amongst others included in CAT, art 3. For further reading on the principle of *non-refoulement* see for example MANFRED NOWAK, 'Torture and Enforced Disappearance', in C. KRAUSE AND M. SCHEININ (eds), *International Protection of Human Rights: A Textbook* (Turku – Åbo: Åbo Akademi University Institute for Human Rights, 2009), pp 151-182, at pp. 159-161.

291 *D v United Kingdom* (1997) Application no 30240/96, para 51.

292 *D v United Kingdom* (1997) Application no 30240/96, para 52.

293 *D v United Kingdom* (1997) Application no 30240/96, para 52.

294 *D v United Kingdom* (1997) Application no 30240/96, para 52.

295 *D v United Kingdom* (1997) Application no 30240/96, para 53.

296 *D v United Kingdom* (1997) Application no 30240/96, para 53.

297 See for a more in-depth overview of essential medicine litigation H.V. HOGERZEIL *et al.*, 'Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts?' 368 (2006) *Lancet* pp. 305-311.

right to health. In the position paper IFHHRO strongly recommends the instruction of pain treatment in medical curricula, revision of international and national drug policy and urges governments to put pain treatment on their political agenda by allowing individual's access to substitutes as morphine and other opioid analgesics.[298] The assumption that palliative care is an integral part of the right to health is further substantiated by statements and declarations adopted by civil society. For instance, according to the Cape Town Declaration of 2005, palliative care is a right of every person that should be provided at all levels of care by using appropriate drugs.[299] The Cape Town Declaration was adopted by a substantial number of actors in the international field of palliative care on the occasion of the First meeting of Palliative Care Trainers in Africa.[300] More recently, in 2010, one of the major actors in the field of combating poor access to pain treatment, the International Association for the Study of Pain adopted the so-called 'Declaration of Montreal' in which they list the lack of access, to often even poor, pain treatment facilities as a violation of human rights resulting in several binding obligations incumbent upon States.[301]

298 IFHHRO, 'Access to Adequate Pain Treatment' (Statement), (31 March 2011). Available at <http://www.ifhhro.org/news-a-events/212-position-statement-on-access-to-adequate-pain-treatment> accessed 13 May 2011.

299 'The Palliative Care Trainers Declaration of Cape Town, November 13th 2002' 6 (2003) *Journal of Palliative Medicine* pp. 339-340, at p. 339. See also F. BRENNAN, 'Palliative Care as an International Human Right' 33 (2007) *Journal of Pain and Symptom Management* pp. 494-499, at p. 496. Brennan presents an extensive overview of international statements and declarations. For instance Brennan also mentions the Korea Declaration that emerged from the 2nd Global Summit of National Hospice and Palliative Care Associations in 2005; stating that governments should make access to palliative care and hospice care an international human right; 'The Korea Declaration', 'Report of the Second Global Summit of National Hospice and Palliative Care Associations' (2005). Available at <http://www.eolc-observatory.net/global/pdf/NHPCA_2.pdf> accessed 9 May 2011. It should be noted that Declarations of this type should be deviated from Declarations with to a certain extent, a legal character such as the UDHR. Declarations as the Cape Town Declaration are international statements that may be used to underpin arguments or further elaborate the concept of Palliative Care.

300 'The Palliative Care Trainers Declaration of Cape Town, November 13th 2002' 6 (2003) *Journal of Palliative Medicine* pp. 339-340, at p. 339.

301 International Pain Summit and International Association for the Study of Pain 'Declaration of Montreal' (2010). Available at <http://www.iasp-pain.org/PainSummit/DeclarationOfMontreal.pdf> accessed 31 May 2011.

# 7 The Nexus of State Obligations

Under both the international drug control scheme, as well as the human rights framework, States are bound to comply with the obligations as set forth by the conventions they have ratified. Although both fields of law seem to exist separately, the scope of the international drug control scheme evidently covers a range of human rights issues and practice shows that States encounter serious difficulties with treaty compliance under both frameworks.

## 7.1 Treaty compliance

From a legal-technical perspective the *principle of balance* is anchored evenly, hence free access to opioid analgesics for medical and scientific purposes is possible. In a more substantive interpretation, the INCB's treaty interpretation shows a disguised focus on strict law enforcement and harsh control. Even though the SCND's general obligation to allow access and to control opioids at the same time grants States a certain margin of appreciation, this margin is practically restricted by the SCND's control mechanisms.

The highly administrative and bureaucratic annual estimate and quarterly statistical return requirements, demands States to rely on, amongst others, functioning State administration, rules of law and vibrant economies. This is particularly acute for developing countries who often fail treaty compliance. Notably, the unmet need of pain treatment by means of using opioid analgesics, is traced for 80 per cent to the developing world. According to its mandate, the INCB is responsible for assisting States that encounter difficulties to comply with the control mechanisms. The INCB continues to commit itself to fulfilling this obligation, however, practice shows that the INCB remains 'rhetorically committed' to addressing poor access to pain treatment by means of the use of opioid analgesics.

Indeed, compliance with the SCND is at odds with safeguarding the human right to pain relief on the basis of securing the minimum core of the right to health and protecting individuals against inhuman and degrading treatment. Apart from the inherent difficulties, especially for developing countries to comply with the applicable treaties —they encounter serious difficulties with medicine availability and SCND treaty compliance— States are bound, to a large extent, by obligations under the human rights framework.

The normative conception of a minimum core of the right to health, and as increasingly argued also the scope of the freedom from inhuman and degrading treatment, goes someway towards providing individuals with a human right to pain relief. States are bound to give effect to the obligations as set forth by the human rights framework in a progressive manner. This implies a burden of proof on part of the State to prove that it has given effect to the obligation, taking into account all available (financial) resources, within a set timeframe, measurable according to established benchmarks. At the same time, however, the *raison d'être* of a convention should be realised immediately, at any rate. Strictly put, there are no legitimate causes for non-compliance with due concern of country specific situations. Hence, the CESCR distinguishes the obligation of immediate effect to safeguard the minimum core of every individual right. Access to essential medicines, amongst which morphine, and the adoption of national health plans including an emphasis on palliative care are considered part of the minimum core of the right to health. Accordingly, it is increasingly argued that denied pain treatment is a violation of inhuman and degrading treatment.

According to Article 31 of the Vienna Convention on the Law of Treaties, treaties should be interpreted 'in good faith [and] in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose'.[302]

[302] Vienna Convention on the Law of Treaties (entered into force 27 January 1980) UN Doc A/Conf.39/27 1155 UNTS 331 (VCLT), art. 31.

Treaty compliance hence implies that States should give effect to both the regulatory scheme of the SCND and the human right to pain treatment. Even though the huge public health deficit of the unmet need of opioids in medical settings is caused by a spectrum of different barriers, the present report evidenced the delimiting effect of the SCND to adequate realisation of the right to health's minimum core and thus the human right to pain treatment.

## 7.2 The UN's twofold approach

At present, many leading international bodies claim the ineffectiveness and counter-effectiveness of the SCND at both sides of the equator. It fails to advance access to opioids for pain and palliative care treatment, and the global number of injection drug users is also increasing.

The UN, in all its facets, acknowledges the current problem of inadequate pain treatment through the lack of access to opioid analgesics and aspires to counter this deficit by establishing framework initiatives that aim to support national governments in implementing international standards as well as with complying with these standards. In aiming for pain treatment as a human right on the global agenda, however, the UN is paralysed by its own twofold strategy.[303]

To combat the INCB's one-sided treaty interpretation, the ECOSOC, in resolution 2005/25, emphasised the WHO's initiative of 'Achieving balance in national opioids control policy: guidelines for assessment'.[304] The guideline intends to assist government officials responsible for drug control policy and implementation, in bypassing impediments caused by the international drug control scheme.[305] Such a singular initiative, however, appeared insufficient and the ECOSOC, as well as the World Health Assembly, the WHO's decision-making body,[306] invited and called upon the WHO and the INCB to join forces and 'examine the feasibility of a possible assistance mechanism'.[307] As a result, the WHO and the INCB framed the *Access to Controlled Medications Programme* in 2007. By joining forces, both organisations aimed to promote a better understanding of the international drug control scheme, give guidance to national authorities, and give assistance in reviewing national legislation and in establishing suitable estimates and statistical returns.[308] The WHO's and the INCB's attempts to foster access to opioids by means of adopting a conjunct strategy was also supported by the CND.[309]

Acting counter-effectively to the treatment of pain through the effective use of opioid analgesics, the UN prioritises programmes on drug control and crime prevention. The United Nations Office on Drugs and Crime (UNODC), the product of a 1997 merger of the United Nations Drug Control Programme and Centre for International Crime Prevention, operates on a global scale to defeat and counter illegal drugs, crime and terrorism.[310] The UNODC is

303 With due regard the limits of this report it is throughout this paragraph not intended to present an all encompassing, comprehensive overview of all approaches and initiatives in the past and presently undertaken to combat the evil of denied pain treatment. Hence this report restricts itself to present an overview of approaches of the ECOSOC, the WHO, the INCB and the UN's main drug control agency. Consequently conclusions as derived from these findings merely cohere with and reflect upon the approaches presented.

304 ECOSOC, 'Treatment of pain using opioid analgesics' Res 2005/25. See also WHO, *Achieving Balance in National Opioid Control Policy* (Geneva: WHO, 2000).

305 WHO, *Achieving Balance in National Opioid Control Policy* (Geneva: WHO, 2000).

306 The World Health Assembly is WHO's decision-making body and its annual meeting in Geneva is attended by WHO Member States delegations. <http://www.who.int/mediacentre/events/governance/wha/en/index.html> accessed 26 June 2011.

307 ECOSOC, 'Treatment of pain using opioid analgesics', Res. 2005/25, para 2; World Health Assembly Res 58.22.

308 WHO, *Access to Controlled Medications Programme: Framework* (Geneva: WHO, 2007), p. 8. The programme subsequently aims to promote rational use of controlled substances, educate authorities concerned with regulatory and legal matters, formulate treatment principles, assist uninterrupted supply of controlled substances and collect relevant data and materials. See also 'Access to Controlled Medications Programme' (2009) *World Health Organization Briefing Note*. Available at <http://www.who.int/medicines/areas/quality_safety/ACMP_BrNoteGenrl_EN_Feb09.pdf> accessed 2 May 2012.

309 CND, 'Promoting adequate availability of internationally controlled licit drugs for medical and scientific purposes while preventing their diversion and abuse', Res. 53/4.

310 <http://www.unodc.org/unodc/en/about-unodc/index.html?ref=menutop> accessed 3 June 2011.

committed to enforce bans on narcotics[311] through law enforcement. The 'UNODC works to establish adequate, functional legal and institutional frameworks for drug control through effective implementation of international drug control conventions' and as such, strives to foster and contribute to the 'war on drugs' as first proclaimed by President Nixon in 1971.[312] The 'war on drugs' is known for its aggressive and harsh approach and for over 50 years it has been a leading assumption that such an approach would lead to 'an ever-diminishing market in controlled drugs […] and the eventual achievement of a "drug free world"'.[313] Actors such as the INCB give support to this assumption by pointing to the international drug control treaties' efficiency in combating illicit use of controlled substances. Notably the 'war on drugs' 'is now more widespread and higher in financial and human cost than ever' and has a substantial transcending negative impact on human rights protection.[314]

This predominant approach has recently been contested by the Global Commission on Drug Policy. This international commission, comprised of former and present world leaders and eminent scholars, is given the task of reviewing the present international drug control scheme to consider its effectiveness on the 'war on drugs'.[315] In its 2011 report, the Commission takes a firm stance to discredit the present international drug control scheme, stating: 'the Global War on Drugs has failed'.[316] Harsh law enforcement, as was standardised in times of adoption of the SCND, appears ineffective, since over the course of time global drugs markets have increased by about a third in size. On the contrary, softer and more humane approaches yield significant results, and overall the international community should be more lenient towards governments and allow States, within their capacities, to adopt measures that suit the needs of their respective countries. By opting for such a lenient approach the Commission holds that '[t]he idea that the international drug control system is immutable, and that any amendment —however reasonable or slight— is a threat to the integrity of the entire system, is short-sighted'.[317] Accordingly, just like all international agreements, the SCND and the international drug control scheme as a whole should be subjected to 'constant review and modernization in light of changing and variable circumstances'.[318]

The UN has undertaken, and currently participates in, initiatives that aim to increase access to opioid analgesics for medical purposes. These strategies also demonstrate, however, that the dual character of opium is central to all initiatives, and results in counter effectiveness on both sides of the equation. Moreover, the interpretation of the obligations on part of the State, deriving from both the human rights framework and the international drug control scheme, stand in stark contrast to each other.

311 Narcotics is considered a legal term for harmful substances as for example heroin.

312 See UNODC, *Making the World Safer from Crime, Drugs and Terrorism* (2007) (Brochure) Available at <http://www.unodc.org/unodc/en/about-unodc/index.html?ref=menutop> accessed 3 June 2011; M. JELSMA, 'The Development of International Drug Control: Lessons Learned and Strategic Challenges for the Future' 10 (2010) *Series on Legislative Reform of Drug Policies* pp. 1-16.

313 GLOBAL COMMISSION ON DRUG POLICY, *War on Drugs* (report) (2011). Available at <http://www.globalcommissionondrugs.org/Report> accessed 26 April 2012.

314 DAMON BARRETT AND MANFRED NOWAK, 'The United Nations and Drug Policy: Towards a Human Rights-Based Approach' in A. CONSTANTINIDES AND N. ZAIKOS (eds), *The Diversity of International Law* (Leiden: Martinus Nijhoff Publishers, 2009), pp. 449-477, at p. 449.

315 To learn more on the Global Commission's commissioners and mandate, see <http://www.globalcommissionondrugs.org/Commission> accessed 4 June 2011.

316 GLOBAL COMMISSION ON DRUG POLICY, *War on Drugs* (report) (2011), p. 4. Available at <http://www.globalcommissionondrugs.org/Report> accessed 26 April 2012.

317 GLOBAL COMMISSION ON DRUG POLICY, *War on Drugs* (Report) (2011), p. 8. Available at <http://www.globalcommissionondrugs.org/Report> accessed 26 April 2012.

318 GLOBAL COMMISSION ON DRUG POLICY, *War on Drugs* (Report) (2011), p. 8. Available at <http://www.globalcommissionondrugs.org/Report> accessed 26 April 2012.

# 8 Concluding Observations

Still the use of opium in health care settings remains an exception. The predicament that underlies the current poor access is opium's dual character of being both an essential medicine as well as an illicit drug. Not only is morphine derived from opium, substances such as heroin are opium derivates too. This dual character has led to strict and harsh international regulatory schemes, which practically disallow States to fulfil their human rights obligations. This strict approach —currently contested by multiple actors in the field— motivates the present public health deficit of poor pain treatment services.

Millions of people suffer from untreated pain because of poor access to opioid analgesics like morphine —essential to pain and palliative care treatment. Even though pain experiences are rather subjective and differ from person-to-person, denial of treatment generally results in undignified situations. Hence, the human rights framework, as effective today, proves to be a valuable tool to combat this deficit; for denial of pain treatment effectively translates into a human right to pain relief as part of the effective realisation of the right to health and, as increasingly argued, the freedom from inhuman and degrading treatment.

The present report advanced a human right to pain relief and explored the nexus between State obligations in the field of international drug control and human rights. As is evidenced in this report, a human right to pain relief derives from the right to health, as it is a core obligation on part of States to allow individuals to access essential medicines and to adopt national health care strategies including palliative care services. This right is reinforced by the prohibition of inhuman and degrading treatment. It is increasingly argued that this prohibition also covers the State obligation to safeguard individuals' relieve of pain through pain treatment and palliative care services.

As evidenced in the present report, the adequate discharge of the obligations deriving from both the international drug control scheme and the human rights framework seems inherently impossible. Even though the balance of interest that comes with regulating opium is maintained in theory, present-day interpretation and response to the global public health deficit of poor access to controlled substances like morphine, signifies a counter-effective and renegade approach towards human rights protection and realisation. Moreover, the control mechanisms of the SCND directly result in an excessive burden on part of developing countries. Hence compliance with human rights norms is inherently impossible.

In order to counter this grave public health deficit, serious action should be taken at international, regional and national levels to foster a paradigm shift reflecting a more holistic approach to drug control.

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## Colophon

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