



**UNODC**

United Nations Office on Drugs and Crime



# **Technical Guidance: Increasing access and availability of controlled medicines**

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**Disclaimer**

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# Executive Summary

During the last ten years, increased discussions and debates have centered around the barriers to accessing controlled medicines, and the need for governments to overcome those barriers in order to provide access for more than 80% of the world's population still without access to controlled medicines. While information on barriers is important, it is critical to provide concrete information about actions Member States can take to address the negative health outcomes, such as the enormous burden of untreated pain around the world, associated with inadequate access to controlled medicines. Untreated pain that lasts beyond the expected healing time, or for more than 3 months, becomes the disease itself, with the expected clinical, social, economic, and psychological impacts on the patients and families.<sup>1</sup>

Inclusive in this document is the understanding that the medical use of controlled drugs should be based on scientific evidence and the highest acceptable medical standards. However, we acknowledge that this document reflects current ideas and best practices building upon three seminal documents referenced in the introduction. The current research does not provide a strong platform to recommend concrete actions but rather supports practical strategies within a framework of monitoring and evaluation.

This document focuses on the critical components essential to create change, move forward, and implement the best medical care available for patients, inclusive of access to essential controlled medicines. These critical components are not stand-alone elements but are rather intended to be systematically inter-linked and part of a comprehensive approach to quality healthcare, including the rational medical use of controlled medicines, for all persons around the world who need them.

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<sup>1</sup> Monti S., Caporali, R. Chronic pain: the burden of disease and treatment innovations. *Reumatismo*, 2015; 67 (2): 35-44.

# Introduction

Initial mandates for the work of the UNODC-WHO-UICC Joint Global Program on increasing access to controlled drugs while preventing diversion, included the Commission on Narcotic Drugs' resolution 53/4 on availability of internationally controlled licit drugs for medical and scientific purposes, and resolution 54/6 on availability of internationally controlled narcotic drugs and psychotropic substances for medical and scientific purposes. Additionally, the World Health Assembly resolution 67.19 on palliative care further enhances the importance of this work.<sup>2</sup>

Over the past years, increased high level policy attention has focused on this area of work, including unanimous adoption of the Outcome Document from the UN General Assembly Special Session on the World Drug Problem (Chapter Two), and of the 2030 Agenda for Sustainable Development. The Outcome Document of the thirtieth special session of the General Assembly, entitled “Our joint commitment to effectively addressing and countering the world drug problem,”<sup>3</sup> contained seven operational recommendations that address existing barriers to improving access to controlled substances for medical and scientific purposes.

While a case can be made that many of the seventeen Sustainable Development Goals, or SDGs, can be connected to the cross-cutting themes related to increasing access to controlled medicines while preventing diversion it is most strongly connected to SDG 3, ensuring healthy lives and promoting well-being for all at all ages. Specifically, the UNODC-WHO-UICC Joint Global Program aligns with SDG 3.8, focusing on “access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all”.

Rational use of internationally controlled essential medicines – i.e. those medicines listed in the Schedules of the international drug control treaties *and* contained in the WHO Model List of Essential Medicines, is essential to optimal health outcomes as based on scientific evidence. Medicines used to treat moderate to severe pain include non-opioids, opioids and adjuvant medicines. Despite the universally recognized indispensability of narcotic drugs and psychotropic substances in tackling pain in medical settings, under-treatment of pain due to unavailability of controlled medicines, represents a fundamental global inequity.

It is critical to take steps now to address this disparity. Under-treatment results in people suffering from unnecessary moderate and severe pain in more than 150 countries, accounting for about 80% of the world's population. While the rational use of opioids is essential to health, their non-medical use can also produce serious negative health consequences, including death. Opioids are subject to national and international control under the international drug conventions to ensure that they are prescribed only for legitimate medical purposes, and that patients' needs are met through a safely and securely managed supply chain, to prevent possible diversion.

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<sup>2</sup> Strengthening of palliative care as a component of comprehensive care throughout the life course  
[http://apps.who.int/gb/ebwha/pdf\\_files/WHA67/A67\\_R19-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R19-en.pdf)

<sup>3</sup> General Assembly resolution S-30-1, annex, Adopted on 19 April 2016.

The principle of balance between provision and control of essential medicines listed in the Schedules of the drug conventions ensures the protection and promotion of health and public safety. The goal of controlling for diversion and non-medical use should not interfere with, or limit, the rational and use of essential medicines for patients with legitimate medical needs.

The most recent UN policy documents addressing the challenges related to ensuring access to controlled medicines for patients in need, include but are not limited to:

- Ensuring balance in national policies on controlled substances: Guidance for availability and accessibility of controlled medicines, World Health Organization<sup>4</sup>
- Ensuring availability of controlled medications for the relief of pain and preventing diversion and abuse: Striking the right balance to achieve the optimal public health outcome, UNODC<sup>5</sup>
- Availability of Internationally Controlled Drugs: Ensuring adequate access for medical and scientific purposes – indispensable, adequately available and not unduly restricted, INCB<sup>6</sup>

Readers are strongly encouraged to be familiar with the normative guidance, including information related to scheduling of drugs at the international and national level and the definitions of controlled pharmaceuticals, contained in the foundation documents mentioned above. These serve as the preliminary steps and discussion points to address when tackling the issues of increasing access to and availability of controlled medicines.

Additionally, the World Health Organization regularly publishes the WHO Model List of Essential Medicines (EML). In 2017 the 20<sup>th</sup> WHO Model List of Essential Medicines and the 6<sup>th</sup> WHO Model List of Essential Medicines for Children (EMLc) were published.<sup>7</sup> The EML provides a core list of minimum medicine needs for a basic health-care system, listing the most efficacious, safe and cost-effective medicines for priority conditions. Priority conditions are selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment. The complementary list presents essential medicines for priority diseases, for which specialized diagnostic or monitoring facilities, and/or specialist medical care, and/or specialist training are needed.<sup>8</sup>

In September 2017, UNODC convened an informal technical meeting of experts and key stakeholders to identify appropriate tools, strategies and measures that Member States could use to ensure that patients under the care of a trained professional, and with a diagnosis that warrants use of controlled medicines, have access to said medications. This meeting complemented the

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<sup>4</sup> Ensuring balance in national policies on controlled substances: guidance for availability and accessibility of controlled medicines, World Health Organization, Geneva, 2011.

<sup>5</sup> Ensuring availability of controlled medications for the relief of pain and preventing diversion and abuse: striking the right balance to achieve the optimal public health outcome, Discussion Paper, UNODC, 2011.

<sup>6</sup> United Nations: International Narcotics Control Board, January 2016. E/INCB/2015/Supp. 1.

<sup>7</sup> <http://www.who.int/medicines/publications/essentialmedicines/en/>

<sup>8</sup> 20<sup>th</sup> WHO Model List of Essential Medicines, 2017

ongoing work of the UNODC-WHO-UICC Joint Global Program to increase access to controlled medicines for legitimate medical needs and dove-tailed with the existing high-level policy frameworks including but not limited to SDG Target 3.8 and SDG 3b, and the UNGASS Outcome Document.

The aim of the meeting was to establish concrete technical guidance to support Member States as they implement the recommendations of the UNGASS Outcome Document related to increasing legitimate access to controlled medicines. The major outcome of the Expert Group Meeting was the current document, focused on concrete technical guidance for Member States as they ensure access to controlled medicines for medical and scientific purposes while controlling for potential non-medical use.

A Note Verbale circulated to all Member States invited them to nominate their own experts to participate in the meeting. Ten countries responded, and UNODC invited other leading researchers and organizations that have been active in the field, including World Health Organization (WHO), International Narcotics Control Board (INCB), International Atomic Energy Agency (IAEA), Union for International Cancer Control (UICC), Pain and Policy Studies Group with the University of Wisconsin, International Association for Hospice and Palliative Care (IAHPC) and Human Rights Watch.

Participants in the Expert Group Meeting contributed concrete strategies and actions in ten focus areas:

- Step up education and training of the healthcare workforce
- Adopt an integrated, coordinated systems approach
- Set up a safe and responsive supply chain
- Encourage a positive environment for family, caregivers, and community to raise awareness and overcome the stigma associated with controlled medicines
- Address pricing
- Ensure consistent policy messages
- Support patient-centeredness
- Include key populations
- Prevent non-medical use
- Improve data collection and research

During the course of the meeting, experts determined the draft document structure, embedding the ten strategies within the UNGASS Outcome Document recommendations, the SDGs, and the core areas of, education, supply chain management and systems integration. The actions, as determined by the experts, are divided into two groups, “foundation” and “enhancing actions”, to assist Member States as they prioritize a sustainable approach to increasing access, and availability while preventing potential diversion and non-medical use.



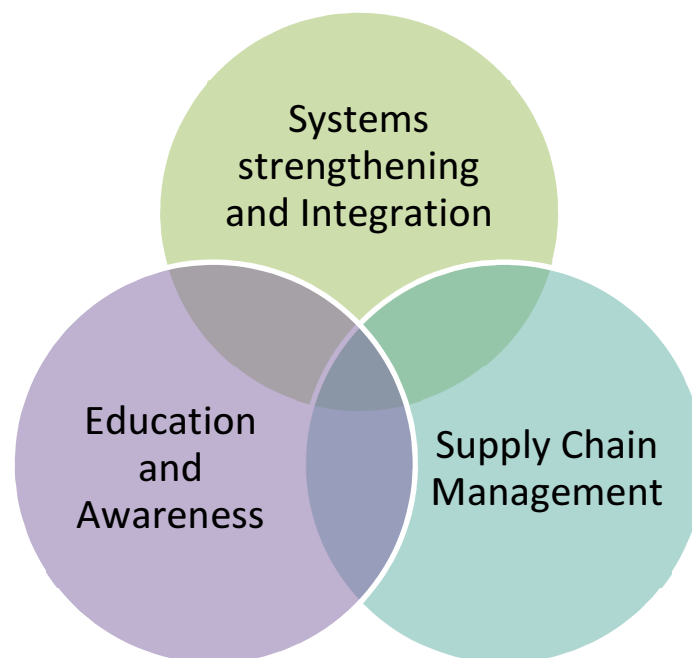
# Core Areas

While there are international mandates and policy documents to guide actions at the national level, the complexities of the unique situations in each country make it difficult to create a “one size fits all step-by-step template” to increase access to and availability of controlled medicines. However, three components consistently remain the core areas of focus and it is essential for Member States to simultaneously take action in all three areas with a strategic view to balancing the impact of each. These three “core” areas are:

- Systems integration
- Education and awareness
- Supply chain management

As the graphic below demonstrates, these three core areas overlap and intersect. A coordinated, multi-sectoral response is required to ensure consistent momentum with resulting positive impact on patients with medical needs receiving the medication and treatment interventions appropriate for their care.

It is crucial that each Member State make a commitment to assess progress made at the country level in each core area, and then take a strategic approach with a strong focus on monitoring outcomes in each of the other core areas. Gaining a full understanding of where to begin on the continuum of expanding health services to include adequate access to and availability of controlled medicine for patients is the initial step.



## Systems Strengthening and Integration

Increasing access to controlled medicines requires a variety of government organizations and civil society healthcare providers to exchange basic information about their work. Approaches that focus on one challenge at a time are unlikely to be successful since all aspects are intertwined, and an action in one system influences the other systems.

Systems approaches are historically and scientifically validated. The science of systems takes an interdisciplinary approach and is usually characterized by diverse perspectives, approaches and elements of focus. General systems theory can be applied in virtually any circumstance since the definition of a system is a set of interconnected components that form a whole. Therefore, a system can be defined as extensive as a galaxy or as minutely as a single cell. Using a systems approach implies using a “framework of thought that helps to deal with complex things in a holistic way”.<sup>9</sup>

Applying a systems framework to increasing access to controlled medicines within a patient driven health system requires a multi-disciplinary approach, improvements in communication, and political will to collaborate toward a common goal. The two most prominent systems to strengthen and integrate are the public health and the drug regulatory systems.

Public health systems include, but are not limited to, the assessment of patients, the prescription of medications and the dispensing of medications in the public sphere. Drug regulatory systems include all aspects of managing the requirements of the three International Drug Control Conventions. It is important to note that these two systems are inherently connected since the International Drug Control Conventions govern the production, manufacture, distribution, storage, and consumption, of all medicines designated as having an “abuse potential.” The Convention control mechanisms include requirements such as prescription practices and the availability of medications for victims of natural disasters.

However, supply and demand for the medical and scientific use of controlled medicines is more complex and potentially requires the integration of a number of national and local systems. These include but are not limited to the education system, the commerce or trade system, the labor or workforce system, the justice system and the foreign affairs, and development systems.

It is important that each of the systems share a common vision and buy-in around the issue of legitimate access to controlled medicines. The following statements may be touchstones to engage diverse systems:

- People have a human right to have access to a continuum of available and affordable treatments, including controlled medicines, in a timely manner.
- Availability of and accessibility to controlled medicines for medical purposes is dependent upon a system of services.
- All patients deserve quality healthcare, which includes controlled medicines, regardless of whether they live in rural and urban areas, of the level of healthcare system available —

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<sup>9</sup> Flood and Carson, p.4

primary or tertiary care — of the setting: public, private hospital, clinic, home, or long-term care center.

- Medications for the treatment of severe pain and dyspnoea must be available, accessible and affordable, to guarantee that patients' pain is treated regardless of its cause or the overseeing medical specialty.
- In the majority of cases, pain can be effectively managed.
- A number of controlled essential medicines are part of a comprehensive pharmacological approach to drug use disorder treatment and as such should be considered in discussions related to increasing access to and availability of controlled medicines.

Applying systems model theory at the level of the patient and family, it is helpful to take a multi-disciplinary approach to meet the unique needs of the individual. In the case of patients with severe pain, or those with palliative care needs, a team approach with the possibility for case management is appropriate.

Below are a series of strategic actions intended to be a starting point for each country. Many countries already have implemented several or all of these actions and are applying them on a regular basis. These strategic actions are not intended to be taken in a linear form, but rather are points of focus to guide national implementation. The initial set of strategic actions are considered to be “foundation actions,” and as the name implies, it is critical to implement them early in the process of change. The second set of strategic actions are considered to be “enhancing actions” which can be taken to continuously improve and sustain change that meets the health needs of patients.

## **Strategic Actions**

### *Foundation*

- Appoint a lead agency and within it, a focal person, with the overall responsibility for moving the initiative forward. This agency/person should have a strong understanding of both the health and the drug regulatory aspects.
- Convene regularly scheduled meetings of all stakeholders involved with controlled medicines at the Ministerial level to coordinate actions and agree upon a common strategy. Initially, it is preferable for these meetings to be held often, even once a month with actions tapering off as progress is made.
- Map the area of overlap among the ministries involved (usually ministries of health, defense, justice, police), as it relates specifically to increasing access to controlled medicines. Clarify roles of each sector.
- Regularly schedule a stakeholder meeting to include civil society, researchers, community leaders, practitioners, professional associations and patient voices at the local level.
- Identify all controlled medicine-related data available at both the local and national level, such as the quantity and type of controlled medicines prescribed or dispensed and the patient diagnosis.

- Identify and analyze legislation and policies that directly impact or speak to access and availability of controlled medicines for patients in need.
- Align legislation and policies in a way to increase access and availability for medical purposes while preventing diversion and misuse.
- Networking mechanisms must be established or strengthened between healthcare sectors for effective referral and engagement of patients in a continuum of care for pain, pain management and palliative care.
- Explore options to ensure that all essential medicines, including controlled medicines, are included or covered in any national health plan or insurance scheme.
- Explore options to ensure that universal or national healthcare programs or insurance schemes are inclusive of pain management and palliative care measure
- Consider the benefits of having a competent national authority with a health background or significant experience working in partnership with the health system.
- Establish or strengthen networking mechanisms between healthcare sectors for effective referral and engagement of patients in a continuum of care for pain, pain management and palliative care, as well as other medical conditions best served by the medical use of controlled essential medicines.

### *Enhancing*

- Create a consistent policy expectation at the national level that can consistently drive policy decisions at the local level.
- Support the replication of an integrated and comprehensive model that engages all three core areas mentioned earlier in the document, at the local level to include the government, practitioners, civil society and patients.
- Create data collection hub with inputs from all systems in order to track and exchange data.
- Expand and improve the health system to include the following:
  - Focus on the workforce that provides community-based outreach, engagement, activation, motivational support, and self-management. This includes community health workers (CHWs) and peer support specialists (PSSs) with a focus on health promotion and wellness.<sup>10</sup>
  - Integrate electronic charts and other technology platforms into patient care
  - Explore options to ensure that universal or national healthcare programs or insurance schemes include essential medications for the management of pain and palliative care.
  - Improve access to healthcare for key populations, including but not be limited to women, children, older persons, indigenous communities, prisoners, people who use drugs, and other marginalized groups.
- Strengthen the regulatory system to include the following:

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<sup>10</sup> Allen S. Daniels, Ed.D., Sue Bergeson, Keris Jän Myrick, M.B.A., M.S. Defining Peer Roles and Status Among Community Health Workers and Peer Support Specialists in Integrated Systems of Care, Psychiatric Services 2017.

- Analysis of all policy and practice to identify control measures that limit access to healthcare in general; revise to limit only the risk of diversion and non-medical use;
  - Build partnerships between the physicians and the pharmacists with the core area of overlap being patient safety.
- Consider systems designed to meet specific needs of vulnerable populations such as nursing homes for older persons, psychiatric centers for persons with mental health disorders, or criminal justice settings.

## Education and awareness

In 2015 the International Narcotics Control Board issued a report based on a member state survey, indicating that lack of training and awareness of healthcare workers is the greatest barrier to availability of controlled medicines.<sup>11</sup> However, increased professional training of physicians, nurses, and pharmacists cannot address all aspects of the systems approach indicated above.

A balanced approach is required to ensure that all persons involved in the healthcare workforce receive training and education appropriate to their job description. Patients, family members and caregivers are also essential recipients of basic education and awareness regarding the use of controlled medicines. Inclusive of the already mentioned sectors it is recommended that policy makers, community leaders, faith leaders and emergency or first responders also receive education and awareness about the essential role, and rational use of controlled medicines.

Quality health education should (a) reflect current research evidence, (b) be outcome based and (c) responsive to patient needs. Effective policies, programs, procedures and coordination mechanisms for quality patient care related to pain management and palliative care must be defined in advance. Skills-based health education should be incorporated into all traditional education settings, and other non-traditional settings, to provide health education to students, the healthcare workforce, policy makers, community leaders, practitioners, caregivers, and patients.

Early education regarding assessment and management of pain, as well as the core elements of palliative care, are critical. This includes continuing education programs and skills-based training. Each member of the healthcare workforce should learn and know the details concerning procedures for assessment, care planning and provision of pain treatment. This should be considered a standard level of care and not reserved for only special cases or palliative care patients. This approach should also be in place for other medical conditions, such as ensuring education programs with a focus on the use of controlled medicines in cases of persons diagnosed with a drug use disorder.

An educated and qualified workforce are the cornerstone of an effective healthcare system. There should be a clear definition of each professional and staff members' role and responsibilities. Mechanisms for supervision of staff, appraisals and career development as well as training and time release to pursue further education or accreditation help to keep consistently high quality standards of care. Current students are the practitioners of the future and an investment in quality education is an investment in quality care for patients in the next generations.

Below are a series of strategic actions intended to be a starting point for each country. The strategic actions are not intended to be taken on a step-by-step basis but rather are points of focus to guide strategic implementation at the national level. The initial set of strategic actions are considered to

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<sup>11</sup> Report of the International Narcotics Control Board for 2015: Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes. Figure 32. Impediments to availability of narcotic drugs, pg. 29.

be “foundation actions” and as the name implies these are actions that are critical to implement early in the process of change. The second set of strategic actions are considered to be “enhancing actions” or actions that can be taken to continuously improve and sustain change that meets the health needs of patients.

## Strategic Actions

### *Foundation*

- Create a basic training for all physicians, pharmacists and nurses on the science behind the use of controlled medicines, including narcotics and psychotropic medicines. Include substantive knowledge of drug use prevention and treatment of drug use disorders, as well as a full understanding of the drug control system with mechanisms to prevent diversion and misuse.
- Develop a mechanism to ensure that all physicians, pharmacists and nurses entering the healthcare workforce have a minimum understanding of both the health and regulatory aspects related to the rational use of controlled medicines.
- Explore options to ensure the coming workforce receives compulsory training in how to assess patients for pain and how to assess patients for risk, when to prescribe, how to adequately prescribe, how to properly dispense controlled medicines, and how to monitor patients. Note that pharmacists will also receive additional training regarding pharmacovigilance.
- Sustain these efforts with annual mandatory continuing education requirements for all physicians, pharmacists and nurses.
- Engage already credentialed and practicing physicians, pharmacists and nurses in annual mandatory education requirements.
- Develop a package of training materials to be rolled out at the community level to increase awareness of the importance of identifying pain, managing pain and achieving optimum health.
- Establish national guidelines and treatment standards for the management of pain and the implementation of palliative care measures.
- Establish a system of effective clinical governance that makes all aspects of the healthcare system and workforce accountable for high quality patient care.
- Support an ongoing forum to inform and train hospital administrators on the most current medications for pain management and palliative care as well as the regulatory measures at the national level.

### *Enhancing*

- Implement basic training for the full healthcare workforce.
- Identify non-traditional partners and offer regular awareness sessions tailored to their needs.
- Pursue the development of curricula and incorporate into the higher education curriculum of all persons in the healthcare workforce.

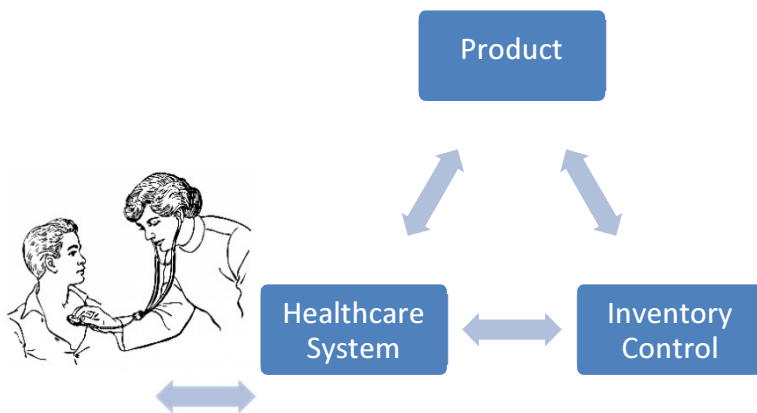
- Support the development or strengthening the professional associations related to pain management and palliative care.
- Design sector specific awareness messages and materials to be used across a variety of media platforms to increase awareness for policy makers, community leaders, caregivers, families, civil society partners and patients.
- Consider the development of a credentialing program for experts in pain management and palliative care.
- Partner with civil society, community leaders and faith based organizations to increase awareness and address the challenge of stigma through the use of social media, community forums, and patient testimonials.
- Establish mandatory training in the ethics of pain management and palliative care.
- Establish mentoring programs at the University level, the hospital level and the clinic/pharmacy level where those who are trained can support those who are less comfortable with meeting the pain management or palliative care needs of patients.
- Create peer-to-peer programs for caregivers and families, building on the experience and strength that they have gained supporting one or more patients.
- Consider the role of faith-based or traditional healing centers as both a source of information for education purposes and as persons to be included in education and advocacy efforts.



## Supply chain management

It is essential to create a seamless controlled medicine supply chain that assures timely and safe dispensing of controlled medicines wherever they are needed. The supply chain, in and of itself, is a complex system that requires consistent monitoring and flexible adjustments to meet the needs of patients at all levels of the pain spectrum, or at all points on the healthcare continuum of care for legitimate medical treatment.

As the name implies the supply chain is a series of interactions designed to move a product, in this case, controlled medicines, from the initial phase to the end-user or patient. The diagram below illustrates the basic process:



Effective supply chain management in this case includes oversight of the controlled substances that cultivated, manufactured, distributed and consumed for medical and scientific purposes. That product may be manufactured nationally, or imported. A set of policies and regulations are applied to maintain a strict inventory control in compliance with the three International Drug Control Conventions. Medications are then made available for use within the healthcare system, where another set of policies and regulations are designed to protect both patients and physicians from the harms of non-medical use. The patient, or end-user, interfaces directly with the healthcare system, with no direct contact with the inventory control or the initiation of the product. The patient however does directly feel the impact or the result of problems and challenges with the supply chain system, such as elevated pricing structures, stockouts, and the lack of availability of the product.

It is essential to manage an effective supply chain focusing on responsiveness to all aspects of the chain, so patients can have timely access to affordable essential medications, including controlled medicines. As a first and crucial step, it would be important to identify essential pain management medications for use in the healthcare system. It would then be important to determine if they are available in the market and to determine the cost. A number of essential steps in the supply chain pose a potential challenge to availability, accessibility and affordability. Listed below are a few areas to pay attention to:

- Trade policies that restrict competitive pricing on imports
- Taxes and other fees that increase price
- Ungainly documentation requirements above and beyond the mandates
- Labelling requirements that restrict availability
- Licensing requirements that constrain competitive pricing opportunities
- Dispensing practices significantly limiting the days, length of time or places where patients may access the essential medication
- Aspects of the supply chain that can serve as a check point for fraudulent medicines with a focus to protect patients

Below are a series of strategic actions intended to be a starting point for each country. The strategic actions are not intended to be taken on a step-by-step basis but rather are points of focus to guide strategic implementation at the national level. The initial set of strategic actions are considered to be “foundation actions” and as the name implies these are actions that are critical to implement early in the process of change. The second set of strategic actions are considered to be “enhancing actions” or actions that can be taken to continuously improve and sustain change that meets the health needs of patients.

## Strategic Actions

### *Foundation*

- Include all stakeholders in the development of a national policy for increasing availability of controlled medicines while preventing diversion and non-medical use. It is suggested that a full range of stakeholders, including but not limited to government ministries, healthcare practitioners, manufacturers, wholesalers and retailers, as well as patient voices with their families and caregivers.
- Map the supply chain and all elements contributing to its management.
- Hold regular meetings of focal points at all points of the supply chain to achieve consensus about the most pressing supply chain problems and strategize how to best address them.
- Analyze the benefits and challenges of procurement through a national procurement agency
- Increase the authority and resources available to support the competent national authority to increase their working knowledge and skills, supporting success and decreasing turnover rates.
- Strongly encourage the use of the existing electronic import/export system established by INCB and UNODC.
- Define the role of the pharmaceutical industry.
- Institutionalize a process to estimate stocks that includes the relevant health and regulatory systems, and ultimately allows the healthcare workforce to respond to patient needs.

- Analyze and streamline registration and licensing requirements that result in a lack of availability or access, such as a lengthy process to register pharmacies or a high fee to stock controlled medicines in particular.
- Incorporate strategies related to screening and identifying fraudulent controlled medicines in line with the existing national policies.

### *Enhancing*

- Identify leaders as focal points and “coaches” within the supply chain and build these coaches into strategic sessions and committees focused on problem solving.
- Explore the creation of a national network of pharmacies for well-balanced distribution and dispensing.
- Analyze the existence of and possible role of a “parallel” market, defined as a means for patients to get medications outside the regulated market and therefore often at higher cost and higher risk of fraudulent or unsafe practices.
- Explore a regional approach to procurement that allows for a more affordable product.
- Enhance an existing supply chain with electronic platforms such as web-based data capture and the use of Apps to track products.

## Core Area Summary

In summary, increasing access to and availability of controlled medicines that are affordable to the majority of patients requires the integration of actions within the three “core areas” of system integration, education and a supply chain that is responsive to the needs of patients. A key element of success is embedded in a high level of political commitment from the outset and a willingness to take an integrated and strategic approach with patient health as the focal point.

It is crucial to foster a common vision within the systems related to pain management that includes increasing availability and accessibility of pain medicines under a human right oriented and balanced approach.

Since Member States report the lack of education and awareness as one of the biggest barriers to the availability of pain medicines, they should address this deficit not only at the level of health care workers, but should include also policy makers, community leaders, faith leaders, emergency or first responders, caregivers, and patients.

Supply chain management is often seen within the single context of what is required to be reported to the International Narcotics Control Board. However, it is crucial to see the larger context of supply chain management to include but not be limited to the competitive pricing of essential controlled medicines, the ongoing and seamless stocking of pain medication and the safe and rationale dispensing of medications under a strong prescription practice dictated by the medical needs of the patient.



# Cross-cutting Themes

Five cross-cutting themes were also identified during the expert group meeting. These themes include:

- Economic structure
- Consistent messaging
- Patient-centred care
- Prevention of diversion and non-medical use
- Data and research

Each of these cross-cutting themes are crucial to identifying actions and strategies within the previously discussed three core areas. As the name implies, these themes are the aspects of the core areas that overlap or that tie the issue together. Again, it is necessary to closely monitor strategic actions to determine the impact an action taken has across not only the core areas but also within the cross-cutting themes. Member States are encouraged to set short-term and long-term measurable goals to determine the impact each strategic action has on the comprehensive approach.

The same format will be used as with the Core Areas, with strategic actions intended as points of focus to guide strategic implementation at the national level. The initial set of strategic actions are considered to be “foundation actions” and as the name implies these are actions that are critical to implement early in the process of change. The second set of strategic actions are considered to be “enhancing actions” or actions that can be taken to continuously improve and sustain change that meets the health needs of patients.

## Economic Structure

There are many elements that contribute to the economic aspects of this work. One key area is the focus on universal health coverage (UHC) as defined by WHO as “all people and communities can use the promotive, preventive, curative, rehabilitative and palliative health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship.”<sup>12</sup>

This WHO definition of UHC embodies three related objectives:

1. Equity in access to health services - everyone who needs services should get them, not only those who can pay for them;
2. The quality of health services should be good enough to improve the health of those receiving services; and

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<sup>12</sup> [http://www.who.int/health\\_financing/universal\\_coverage\\_definition/en/](http://www.who.int/health_financing/universal_coverage_definition/en/)

3. People should be protected against financial-risk, ensuring that the cost of using services does not put people at risk of financial harm.

UHC is firmly based on the WHO constitution of 1948 declaring health a fundamental human right and on the Health for All agenda set by the Alma Ata declaration in 1978. UHC cuts across all the health-related Sustainable Development Goals (SDGs) and brings hope of better health and protection for the world's poorest.<sup>13</sup>

Additionally, the relationship between manufacturing and procuring can have a significant impact on pricing. For example, in some countries the negotiated trade policies reduce the number of competing entities, resulting in less competition and higher price structures for medications. And in other examples, it may be a stronger economic approach to work at the regional level to procure essential controlled medicines within a competitive price structure.

Again, Member States are urged to consider simultaneously addressing the issues of supply and demand. The balance between supply and demand is not as clear and simple as it might seem. In many developing countries physicians who have never learned to manage pain or used controlled medicines, do not prescribe them, and choose available medications such as NSAIDs, which carry their own associated health risks, although they are not under international control. When controlled medications out of stock, physicians who do know how to prescribe them, have become accustomed to using inappropriate or inadequate substitutes. This type of circular reasoning creates a misleading impression that there is no demand for medication and serves as a false justification for maintaining low supply. Instituting policies that support the assessment, diagnosis and prescription of the most appropriate medication to treat the needs of the patient will potentially put additional strain on the supply chain when the demand outweighs the supply.

## Strategic Actions

### *Foundation*

- Analyze the positive aspects of manufacturing controlled medicines in country as compared to procuring via importation.
- Ensure that essential medicines, including essential medicines that are also controlled medicines, are included and covered in national health care schemes, including insurance schemes.
- Analyze the market issues related to supply and demand that influence the availability and affordability of medication.
- Review availability of affordable essential medications at all levels of the healthcare system and particularly with a focus on the needs of rural populations.
- Identify any non-regulated markets that make medication available to patients outside the current supply chain.
- Encourage physicians to prescribe the appropriate medication to best treat the patient based on medical science and not based on cost or availability.

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<sup>13</sup> [http://www.who.int/health\\_financing/universal\\_coverage\\_definition/en/](http://www.who.int/health_financing/universal_coverage_definition/en/)

- Support diagnosis driven insurance coverage based on a physician’s assessment and not coverage of the pharmacological intervention.

### *Enhancing*

- Utilize the electronic platform provided through INCB.
- Analyze the true economic costs beyond the cost of the opioid medication, such as added costs to find a pharmacy that dispenses, additional medications that are concomitantly prescribed such as laxatives.
- Create a national health system that allows the majority of patients to receive quality medical treatment, for example, with insurance or reimbursement schemes.
- Build in costs for workforce education and development in budgets at the national level and local level.

## **Consistent messaging**

At the international level, policy coherence around the issue of increasing access to controlled essential medicines is a continuing process. While this document focus is on strategies at the national level, it should be noted that at the international level steps are being taken to more formally acknowledge the joint work being done between WHO and the regulatory mechanisms at the international level, such as the Commission on Narcotic Drugs and the International Narcotics Control Board.

Both the UNGASS Outcome Document and the 2015 INCB Report, identify barriers related to legislation and policy.<sup>14</sup> Stakeholders often report that, although national legislation allows for the use of controlled medicines, established policies and practices account for the lack of demand and therefore often contribute to the unaffordability, inaccessibility, and unavailability of controlled medicines.

With the UN 2030 Development Agenda, it is important to recognize Goal 3 related to good health for all at all ages, specifically targets increasing access to essential medicines as a priority. Countries around the world are encouraged to meet these seventeen goals and over one hundred targets. Integrating the 2030 Development Agenda, specifically Goal 3 with the recommendations of the UNGASS Outcome Document can serve as a strong foundation for consistent language and messaging around increasing access to and availability of controlled medicines.

Utilizing language that supports a patient-centered approach to quality medical care should be the cornerstone of all legislation and policy. Unfortunately, all too often what people think are policies are actually practices that have become so ingrained over time to seem to be policies. In the case of access and availability of controlled medicines for the management of pain many of these

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<sup>14</sup> <http://www.unodc.org/documents/postungass2016/outcome/V1603301-E.pdf> and [https://www.incb.org/documents/Publications/AnnualReports/AR2015/English/Supplement-AR15\\_availability\\_English.pdf](https://www.incb.org/documents/Publications/AnnualReports/AR2015/English/Supplement-AR15_availability_English.pdf)

“policies” are more accurately long-standing practices that are based on fear, stigma or misinformation.

## **Strategic Actions**

### *Foundation*

- Create a committee of experts to analyze the legislation related to access to controlled medicines.
- Match the legislation with the existing policies in hospitals and pharmacies with a consistent message that increases the access to and availability of controlled medicines for patients.
- Develop sector reports that dispel myths around the use of controlled medicines and can be used to encourage a consistent policy and practice message.
- Create opportunities for policy makers to do site visits and understand the critical work done by palliative care specialists and programming and contribute to a more informed health policy development.

### *Enhancing*

- Analyze an inclusive approach that does not limit the provision of services to certain patient conditions such as cancer, and does not limit prescribers to a small number of specialists.
- Establish healthcare service policy and protocols to clarify and facilitate common understandings about the treatment and management of pain, and palliative care. Include elements such as the philosophy, aims and objectives, strategic management, target population, ethics, human rights and procedures. These should align with existing operational policies, staffing plans, human resource management and development, access and referral information and policies, and the physical environment including accommodation and food.
- Design programs for palliative care experts to train regulators and policy makers to increase a base level of knowledge related to pain management and care.

## **Patient Centered Care**

Healthcare services, including those related to the use of controlled medications, should comply with human rights obligations and recognize the inherent dignity of all individuals. This includes responding to the right to enjoy the highest attainable standard of health and well-being, and ensuring non-discrimination based on any grounds, including gender, ethnic, religion, political belief, or health, economic, legal or social status.

All patients suffering from severe pain have some level of vulnerability as part of their health condition. However, there are a number of patients who may need specialized attention or require



slightly modified standard operating procedures for treatment of pain related conditions. These include but are not limited to:

- Children and adolescents – The treatment of pain in children and adolescents is inadequate and under-researched. Less than 10% of the children who need pain medications in the world receive it.<sup>15</sup>
- Women, pregnant women – Although in most cultures women bear large care responsibilities and suffer from gender specific illnesses and conditions, the majority of medical treatments have been developed to meet the needs of adult men. This significantly limits women’s access to treatment and services. Gender responsive services that consider the needs of women in all aspects of their design and delivery, including locations, staffing, program development, flexibility in opening hours, and child friendliness, are required. The full spectrum of interventions should be explored to relieve the pain of women who are pregnant and delivering.
- Older persons – Healthcare issues of older persons are challenging and under-researched. Adequate palliative care and pain treatment allows older persons to live with dignity up to and through chronic conditions and terminal illness. This is a relief for patients, families, and caregivers.
- Patients with mental health and substance use disorders. Patient retention and treatment outcomes are related to the diagnosis and adequate treatment of psychiatric conditions. Treatment services can improve their effectiveness by screening for psychiatric disorders and pain, adequate pharmacological treatment, taking into consideration drug-drug interactions.
- Marginalized persons – This includes but is not limited to persons with disabilities, those who are incarcerated, who are illiterate, residents of rural areas, migrants, refugees, persons living in a non-registered situation, sex-workers, persons in recovery or with a history of drug use, ethnic minorities, persons with cognitive impairment, persons who live and work on the street and those who are economically marginalized around the world.

## Strategic Actions

### *Foundation*

- Acknowledge that all patients in pain are vulnerable.
- Incorporate the assessment of pain levels into each interaction with a patient.
- Support comprehensive pain management and palliative care services that include non-pharmacological and pharmacological interventions as medically determined for all patients.

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<sup>15</sup> ICPCN and Atlas of Palliative Care

- Recognize the unique needs of certain populations such as children, persons with disabilities, incarcerated persons and traditionally underserved populations in healthcare settings such as women, illiterate persons, and poor persons.
- Involve the affected population, the family and caregivers as integral components of the patient care plan. Support the development of a contracting system between the care provider and the patient to enhance treatment compliance.
- Define family widely with the input of the patient.
- Create policies that allow healthcare in places where people live.
- Take into account the psychological and socio-economic realities of the patient and whenever possible engage in support measures that will allow patients to receive the highest level of quality medical care.

### *Enhancing*

- Analyze the cultural aspects that contribute to the access and availability of controlled medicines to include, but not be limited to, the perceptions as part of a set of religious beliefs, and other value structures as passed down from generation to generation.
- Make materials related to the assessment of pain, the prescription of pain medication and the dispensing of pain medication available in all languages understood by healthcare workers, caregivers, patients and their families.
- Support continuity of care between all levels of the healthcare system, creating a referral process with accountability at all levels for the highest level of medical care for each patient.
- Provide opportunities for patient to self-evaluate and include perceptions of pain as well as perceptions of care provided to address pain.

## **Prevention of diversion and non-medical use**

INCB reports that 92% of morphine is consumed by countries such as the United States, Canada, Australia, New Zealand and countries in Western Europe. These countries combined account for about 17% of the world population which means that approximately 80% of the world population has limited or no access to pain medication.<sup>16</sup> A more measured approach that targets specific high risk areas for potential diversion or misuse may allow for a measurable increase in access and availability for patients suffering in pain.

It should be noted that each of the strategic actions suggested for the core areas and the cross-cutting themes in and of themselves contribute to preventing diversion. Keeping a clear and consistent focus on the needs of the patient, building a relationship between the physician and the patient as well as the physician and the pharmacist, and increasing the knowledge and skills of the healthcare workforce will significantly contribute to prevent the diversion of controlled medicines for non-medical use.

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<sup>16</sup> [https://www.incb.org/documents/Publications/AnnualReports/AR2015/English/Supplement-AR15\\_availability\\_English.pdf](https://www.incb.org/documents/Publications/AnnualReports/AR2015/English/Supplement-AR15_availability_English.pdf)

## Strategic Actions

### *Foundation*

- Target control measures directly to prevent diversion through careful mapping of transfer points in the supply chain; utilize focused and smart regulations.
- Establish strong and consistent data collection practices that allow for the proper ability to estimate need for controlled medicines in-country; Capture data related to actual cases of diversion.
- Consider all aspects of the supply chain including policies related to proving or certifying the life of the patient and policies related to proper return and disposal of medication, including those opened and not used.

### *Enhancing*

- Utilize an electronic platform to track products at every step of the supply chain, including prescription and dispensing to the end user – patients.
- Build strong policies to report suspected fraudulent medicines with a framework of pharmacovigilance.
- Analyze the markets to determine demand for controlled medicines that is being met outside the regulated market.
- Analyze the pharmaceutical company role in promoting medication, including new products that may be marketed as abuse resistance.

## Data and research

The importance of collecting data and supporting the research to drive evidence based practice cannot be overstated. As Albert Einstein said, “If we knew what it was we were doing, it would not be called research, would it?”.

This document is meant to generate ideas and inspire the scientific community to research the applicability of these interventions. Although data also forms a strong foundation for policies and interventions, data can be misrepresented or misinterpreted. For example, national health coverage in some countries limits physician’s abilities to diagnose conditions that allow patients to fill prescriptions for pain treatment. This creates situations wherein many new patients have been diagnosed with conditions that are not their primary diagnosis in order to give them access to the pain medication. These practices skew the data for health conditions. Accurate and responsible data collection must be encouraged through appropriate legislation and regulations allowing access to controlled medicines for all appropriate diagnoses.

## Strategic Actions

### *Foundation*

- Prioritize the collection of accurate data at all levels of the healthcare system.
- Develop monitoring systems as a core element of a treatment services serving the needs of patients. Incorporate evaluation feedback on service and system performance for quality assessment and detailed record systems that include information about patients, services delivered and client experiences.
- Improve and institutionalize the collection of data on consumption at the local and national level.
- Identify process measures to include or to fine tune, including but not limited to:
  - Number of pharmacies that stock oral morphine – national, registered and private
  - Geographic mapping of supply stocks
  - Number of physicians actively prescribing
  - Diagnosis of patients receiving controlled medicines
  - Measure patient satisfaction
  - Gender
  - “setting” such as primary or tertiary services
  - Mechanism of administration
- Collect disaggregated data related to disparities between patients such as those based on socio-economic status, ethnicity, disability, age, location, or other data points.
- Design an effective monitoring system that is integrated with the medical community involved in monitoring and reporting as well as the regulators involved in identifying patients that need further referral.

### *Enhancing*

- Engage University programs with an interest in this topic to monitor and research the strategies implemented with a goal to publish results in a peer reviewed journal. Areas of study may include the economic burden-of-disease, capacity of workforce or the potentially different needs across geographic or different levels of a healthcare system.
- Build in costs related to monitoring and evaluation in the relevant budgets.
- Consider the use of technology or mobile monitoring using specialized Apps to capture data points.
- Use existing health systems technology to integrate comprehensive data analysis
- Strengthen the role that civil society plays in collecting and monitoring data and other trends.
- Expand data collection beyond retail consumption to include dispensing and end user consumption.
- Collect data on patient experience and patient perceptions.
- Collect data related to opioid price including cost in pharmacies and track fluctuation trends.

## **Cross-cutting Themes Summary**

In summary, cross-cutting themes are components that do just that, they cut across all aspects of the situation. The five themes detailed above, 1) economic structure, 2) consistent messaging, 3)

patient-centered care, 4) prevention of diversion and non-medical use, and 5) data and research should be thought of as integral to each of the core areas. In order to integrate systems, it is essential to consider economic impact, which may include contracting additional staff, promoting a clear advocacy message, educating policy makers unfamiliar with the complexity of patient-care decisions, and designing monitoring systems that capture multiple data points in one intervention. This is only one example of the interdependent nature of these components, the same case can be made for increasing education and awareness as well as strengthening a responsive supply chain.

As a reminder, neither the cross-cutting themes nor the core areas are meant to be addressed in a step-wise or isolated manner. Rather, it is critical to address the issue of increasing access to and availability of controlled medicines via a multi-faceted approach by means of short- and long-term measurable goals.

# Conclusions

States parties to all three drug control conventions are required to use a balanced approach that ensures access to controlled drugs for medical and scientific purposes. Within the high-level policy framework, the Outcome Document of the UN General Assembly Special Session on the World Drug problem, UN Member States reaffirmed their commitment to the goals and objectives of the three international drug control conventions. They also reiterated a strong commitment to improving access to controlled substances for medical and scientific purposes. This document demonstrates the combined knowledge of experts from around the world to provide technical guidance and strategies to assist Member States as they take action per the recommendations of the Outcome Document.

Additionally, the 2030 Agenda for Sustainable Development supports the need to increase access to essential medicines, some of which are listed in the Schedules of the three UN drug conventions. While the issue of increasing access to controlled medicines is most clearly tied to Goal 3, Good Health, specifically 3.8 focusing on “access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all”, a case can be made for inclusion of this complex issue in many of the sustainable development goals. Simply put, people living in pain are unlikely to contribute to the success of the 2030 Agenda for Sustainable Development, and will most certainly be “left behind.”

Nathaniel Katz (2002) demonstrated that failure to effectively treat and relieve serious pain has a detrimental effect on all aspects of quality of life including mental health and even employment. It is estimated that billions of days of work are lost to persons in pain, and that persons are twice as likely to have difficulty working if they are in pain.<sup>17</sup> The impact of untreated pain on parents may result in significant financial burdens placed on families, driving many into, or further into, poverty, impacting children’s quality of life, nutrition, education, mental health, violence and other areas connected to the sustainable development goals.

Rational access to pain management, including to controlled medication, has become an expected standard of quality healthcare. Health systems can no longer justify denying patients access to medication that, when used within a medical setting and in the context of a balanced control system, will alleviate their pain, and contribute to a higher quality of life.

The complexity of the technical guidance presented in this document within the structure of three core areas and five cross-cutting themes should not overshadow the simplicity of the needs of patients. Patients and families have the right to the best available medical treatment, which includes palliative care and the treatment of pain with internationally controlled essential medicines.

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<sup>17</sup> J Pain Symptom Manage 2002; 24:S38-S47. U.S. Cancer Pain Relief Committee, 2002.

# Appendix

## Summary Charts

CORE AREAS

CROSS-CUTTING THEMES

**Core Elements Summary Chart**

<b>CORE element</b>	<b>Foundation Strategic Actions</b>	<b>Enhancing Strategic Actions</b>
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<p><b>Systems Strengthening and Integration</b></p>	<ol style="list-style-type: none"> <li>1. Appoint a lead agency and within it, a focal person, with the overall responsibility for moving the initiative forward. This agency/person should have a strong understanding of both the health and the drug regulatory aspects.</li> <li>2. Convene regularly scheduled meetings of all stakeholders involved with controlled medicines at the Ministerial level to coordinate actions and agree upon a common strategy. Initially, it is preferable for these meetings to be held often, even once a month with actions tapering off as progress is made.</li> <li>3. Map the area of overlap among the ministries involved (usually ministries of health, defense, justice, police), as it relates specifically to increasing access to controlled medicines. Clarify roles of each sector.</li> <li>4. Regularly schedule a stakeholder meeting to include civil society, researchers, community leaders, practitioners and patient voices at the local level.</li> <li>5. Identify all controlled medicine-related data available at both the local and national level, such as the quantity and type of controlled medicines prescribed or dispensed and the patient diagnosis.</li> <li>6. Identify and analyze legislation and policies that directly impact or speak to access and availability of controlled medicines for patients in need.</li> </ol>	<ol style="list-style-type: none"> <li>1. Create a consistent policy expectation at the national level that can consistently drive policy decisions at the local level.</li> <li>2. Support the replication of an integrated and comprehensive model that engages all three core areas mentioned earlier in the document, at the local level to include the government, practitioners, civil society and patients.</li> <li>3. Create data collection hub with inputs from all systems in order to track and exchange data.</li> <li>4. Expand and improve the health system to include the following: <ol style="list-style-type: none"> <li>a. Focus on the workforce that provides community-based outreach, engagement, activation, motivational support, and self-management. This includes community health workers (CHWs) and peer support specialists (PSSs) with a focus on health promotion and wellness.<sup>18</sup></li> <li>b. Integrate electronic charts and other technology platforms into patient care</li> <li>c. Explore options to ensure that universal or national healthcare programs or insurance schemes include essential medications for the management of pain and palliative care.</li> </ol> </li> </ol>
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	<ol style="list-style-type: none"> <li>7. Align legislation and policies in a way to increase access and availability for medical purposes while preventing diversion and misuse.</li> <li>8. Networking mechanisms must be established or strengthened between healthcare sectors for effective referral and engagement of patients in a continuum of care for pain, pain management and palliative care.</li> <li>9. Explore options to ensure that all essential medicines, including controlled medicines, are included or covered in any national health plan or insurance scheme.</li> <li>10. Explore options to ensure that universal or national healthcare programs or insurance schemes are inclusive of pain management and palliative care measure</li> <li>11. Consider the benefits of having a competent national authority with a health background or significant experience working in partnership with the health system.</li> </ol>	<ol style="list-style-type: none"> <li>d. Improve access to healthcare for key populations, including but not be limited to women, children, older persons, indigenous communities, prisoners, people who use drugs, and other marginalized groups.</li> <li>5. Strengthen the regulatory system to include the following: <ol style="list-style-type: none"> <li>a. Analysis of all policy and practice to identify control measures that limit access to healthcare in general; revise to limit only the risk of diversion and non-medical use;</li> <li>b. Build partnerships between the physicians and the pharmacists with the core area of overlap being patient safety.</li> </ol> </li> <li>6. Consider systems designed to meet specific needs of vulnerable populations such as nursing homes for older persons, psychiatric centers for persons with mental health disorders, or criminal justice settings.</li> </ol>
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<p><b>Education and Awareness</b></p>	<ol style="list-style-type: none"> <li>1. Create a basic training for all physicians, pharmacists and nurses on the science behind the use of controlled medicines, including narcotics and psychotropic medicines. Include substantive knowledge of drug use prevention and treatment of drug use disorders.</li> <li>2. Develop a mechanism to ensure that all physicians, pharmacists and nurses entering the healthcare workforce have a minimum understanding of both the health and regulatory aspects related to the rational use of controlled medicines.</li> <li>3. Explore options to ensure the coming workforce receives compulsory training in how to assess patients for pain and how to assess patients for risk, when to prescribe, how to adequately prescribe, how to properly dispense controlled medicines, and how to monitor patients. Note that pharmacists will also receive additional training regarding pharmacovigilance.</li> <li>4. Sustain these efforts with annual mandatory continuing education requirements for all physicians, pharmacists and nurses.</li> <li>5. Engage already credentialed and practicing physicians, pharmacists and nurses in annual mandatory education requirements.</li> <li>6. Develop a package of training materials to be rolled out at the community level to increase awareness of the importance of identifying pain, managing pain and achieving optimum health.</li> </ol>	<ol style="list-style-type: none"> <li>1. Implement basic training for the full healthcare workforce.</li> <li>2. Identify non-traditional partners and offer regular awareness sessions tailored to their needs.</li> <li>3. Pursue the development of curricula and incorporate into the higher education curriculum of all persons in the healthcare workforce.</li> <li>4. Support the development or strengthening the professional associations related to pain management and palliative care.</li> <li>5. Design sector specific awareness messages and materials to be used across a variety of media platforms to increase awareness for policy makers, community leaders, caregivers, families, civil society partners and patients.</li> <li>6. Consider the development of a credentialing program for experts in pain management and palliative care.</li> <li>7. Partner with civil society, community leaders and faith based organizations to increase awareness and address the challenge of stigma through the use of social media, community forums, and patient testimonials.</li> <li>8. Establish mandatory training in the ethics of pain management and palliative care.</li> <li>9. Establish mentoring programs at the University level, the hospital level and the clinic/pharmacy level where those who are</li> </ol>
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	<ol style="list-style-type: none"> <li>7. Establish national guidelines and treatment standards for the management of pain and the implementation of palliative care measures.</li> <li>8. Establish a system of effective clinical governance that makes all aspects of the healthcare system and workforce accountable for high quality patient care.</li> <li>9. Support an ongoing forum to inform and train hospital administrators on the most current medications for pain management and palliative care as well as the regulatory measures at the national level.</li> </ol>	<p>trained can support those who are less comfortable with meeting the pain management or palliative care needs of patients.</p> <ol style="list-style-type: none"> <li>10. Create peer-to-peer programs for caregivers and families, building on the experience and strength that they have gained supporting one or more patients.</li> <li>11. Consider the role of faith-based or traditional healing centers as both a source of information for education purposes and as persons to be included in education and advocacy efforts.</li> </ol>
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<p><b>Supply Chain Management</b></p>	<ol style="list-style-type: none"> <li>1. Include all stakeholders in the development of a national policy for increasing availability of controlled medicines while preventing diversion and non-medical use.</li> <li>2. Define the role of the pharmaceutical industry.</li> <li>3. Map the supply chain and all elements contributing to its management.</li> <li>4. Hold regular meetings of focal points at all points of the supply chain to achieve consensus about the most pressing supply chain problems and strategize how to best address them.</li> <li>5. Analyze the benefits and challenges of procurement through a national procurement agency</li> <li>6. Increase the authority and resources available to support the competent national authority to increase their working knowledge and skills, supporting success and decreasing turnover rates.</li> <li>7. Strongly encourage the use of the existing electronic import/export system established by INCB and UNODC.</li> <li>8. Institutionalize a process to estimate stocks that includes the relevant health and regulatory systems, and ultimately allows the healthcare workforce to respond to patient needs.</li> <li>9. Analyze and streamline registration and licensing requirements that result in a lack of availability or access, such as a lengthy process to register pharmacies or a high fee to stock controlled medicines in particular.</li> </ol>	<ol style="list-style-type: none"> <li>1. Identify leaders as focal points and “coaches” within the supply chain and build these coaches into strategic sessions and committees focused on problem solving.</li> <li>2. Explore the creation of a national network of pharmacies for well-balanced distribution and dispensing.</li> <li>3. Analyze the existence of and possible role of a “parallel” market, defined as a means for patients to get medications outside the regulated market and therefore often at higher cost and higher risk of fraudulent or unsafe practices.</li> <li>4. Explore a regional approach to procurement that allows for a more affordable product.</li> <li>5. Enhance an existing supply chain with electronic platforms such as web-based data capture and the use of Apps to track products.</li> </ol>
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**Cross-Cutting Themes Summary Chart**

<b>Cross-Cutting Theme</b>	<b>Foundation Strategic Actions</b>	<b>Enhancing Strategic Actions</b>
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<p><b>Economic Structure</b></p>	<ol style="list-style-type: none"> <li>1. Analyze the positive aspects of manufacturing controlled medicines in country as compared to procuring via importation.</li> <li>2. Ensure that essential medicines, including essential medicines that are also controlled medicines, are included and covered in national health care schemes, including insurance schemes.</li> <li>3. Analyze the market issues related to supply and demand that influence the availability and affordability of medication.</li> <li>4. Identify any non-regulated markets that make medication available to patients outside the current supply chain.</li> <li>5. Encourage physicians to prescribe the appropriate medication to best treat the patient based on medical science and not based on cost or availability.</li> <li>6. Support diagnosis driven insurance coverage based on a physician’s assessment and not coverage of the pharmacological intervention.</li> </ol>	<ol style="list-style-type: none"> <li>1. Utilize the electronic platform provided through INCB.</li> <li>2. Analyze the true economic costs beyond the cost of the opioid medication, such as added costs to find a pharmacy that dispenses, additional medications that are concomitantly prescribed such as laxatives.</li> <li>3. Create a national health system with insurance or reimbursement schemes that allow the majority of patients to receive quality medical treatment regardless of socio-economic status.</li> <li>4. Build in costs for workforce education and development in budgets at the national level and local level.</li> </ol>
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<p><b>Consistent Messaging</b></p>	<ol style="list-style-type: none"> <li>1. Create a committee of experts to analyze the legislation related to access to controlled medicines.</li> <li>2. Match the legislation with the existing policies in hospitals and pharmacies with a consistent message the increases the access to and availability of controlled medicines for patients.</li> <li>3. Develop sector reports that dispel myths around the use of controlled medicines and can be used to encourage a consistent policy and practice message.</li> <li>4. Create opportunities for policy makers to do site visits and understand the critical work done by palliative care specialists and programming and contribute to a more informed health policy development.</li> </ol>	<ol style="list-style-type: none"> <li>1. Analyze an inclusive approach that does not limit the provision of services to certain patient conditions such as cancer, and does not limit prescribers to a small number of specialists.</li> <li>2. Establish healthcare service policy and protocols to clarify and facilitate common understandings about the treatment and management of pain, and palliative care. Include elements such as the philosophy, aims and objectives, strategic management, target population, ethics, human rights and procedures. These should align with existing operational policies, staffing plans, human resource management and development, access and referral information and policies, and the physical environment including accommodation and food.</li> <li>3. Design programs for palliative care experts to train regulators and policy makers to increase a base level of knowledge related to pain management and care.</li> </ol>
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<p><b>Patient Centered Care</b></p>	<ol style="list-style-type: none"> <li>1. Acknowledge that all patients in pain are vulnerable.</li> <li>2. Incorporate the assessment of pain levels into each interaction with a patient.</li> <li>3. Support comprehensive pain management and palliative care services that include non-pharmacological and pharmacological interventions as medically determined for all patients.</li> <li>4. Recognize the unique needs of certain populations such as children, persons with disabilities, incarcerated persons and traditionally underserved populations in healthcare settings such as women, illiterate persons, and poor persons.</li> <li>5. Involve the affected population, the family and caregivers as integral components of the patient care plan.</li> <li>6. Define family widely with the input of the patient.</li> <li>7. Create policies that allow healthcare in places where people live.</li> </ol>	<ol style="list-style-type: none"> <li>1. Analyze the cultural aspects that contribute to the access and availability of controlled medicines to include, but not be limited to, the perceptions as part of a set of religious beliefs, and other value structures as passed down from generation to generation.</li> <li>2. Make materials related to the assessment of pain, the prescription of pain medication and the dispensing of pain medication available in all languages understood by healthcare workers, caregivers, patients and their families.</li> <li>3. Provide opportunities for patient to self-evaluate and include perceptions of pain as well as perceptions of care provided to address pain.</li> </ol>
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<p><b>Prevention of Diversion and Non-Medical Use</b></p>	<ol style="list-style-type: none"> <li>1. Target control measures directly to prevent diversion through careful mapping of transfer points in the supply chain; utilize focused and smart regulations.</li> <li>2. Establish strong and consistent data collection practices that allow for the proper ability to estimate need for controlled medicines in-country; Capture data related to actual cases of diversion.</li> <li>3. Consider all aspects of the supply chain including policies related to proving or certifying the life of the patient and policies related to proper return and disposal of medication, including those opened and not used.</li> </ol>	<ol style="list-style-type: none"> <li>1. Utilize an electronic platform to track products at every step of the supply chain, including prescription and dispensing to the end user – patients.</li> <li>2. Build strong policies to report suspected fraudulent medicines with a framework of pharmacovigilance.</li> <li>3. Analyze the markets to determine demand for controlled medicines that is being met outside the regulated market.</li> <li>4. Analyze the pharmaceutical company role in promoting medication, including new products that may be marketed as abuse resistance.</li> </ol>
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<p><b>Data and Research</b></p>	<ol style="list-style-type: none"> <li>1. Prioritize the collection of accurate data at all levels of the healthcare system.</li> <li>2. Develop monitoring systems as a core element of a treatment services serving the needs of patients. Incorporate evaluation feedback on service and system performance for quality assessment and detailed record systems that include information about patients, services delivered and client experiences.</li> <li>3. Improve and institutionalize the collection of data on consumption at the local and national level.</li> <li>4. Identify process measures to include or to fine tune, including but not limited to: <ol style="list-style-type: none"> <li>a. Number of pharmacies that stock oral morphine – national, registered and private</li> <li>b. Geographic mapping of supply stocks</li> <li>c. Number of physicians actively prescribing</li> <li>d. Diagnosis of patients receiving controlled medicines</li> <li>e. Measure patient satisfaction</li> <li>f. Gender</li> <li>g. “setting” such as primary or tertiary services</li> <li>h. Mechanism of administration</li> </ol> </li> <li>5. Collect disaggregated data related to disparities between patients such as those based on socio-economic status, ethnicity, disability, age, location, or other data points.</li> <li>6. Design an effective monitoring system that is integrated with the medical community involved in monitoring and reporting as well as the regulators involved in identifying patients that need further referral.</li> </ol>	<ol style="list-style-type: none"> <li>1. Engage University programs with an interest in this topic to monitor and research the strategies implemented with a goal to publish results in a peer reviewed journal.</li> <li>2. Build in costs related to monitoring and evaluation in the relevant budgets.</li> <li>3. Consider the use of technology or mobile monitoring using specialized Apps to capture data points.</li> <li>4. Use existing health systems technology to integrate comprehensive data analysis</li> <li>5. Strengthen the role that civil society plays in collecting and monitoring data and other trends.</li> <li>6. Expand data collection beyond retail consumption to include dispensing and end user consumption.</li> <li>7. Collect data on patient experience and patient perceptions.</li> <li>8. Collect data related to opioid price including cost in pharmacies and track fluctuation trends.</li> </ol>
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