African Palliative Care Association

# A review of national opioid estimation procedures and supply chain mechanisms

***Review done in three African countries: Swaziland, Mozambique and Zimbabwe***

African Palliative Care Association
APCA
Relieving Pain and Suffering

USAID
FROM THE AMERICAN PEOPLE

United States President's Emergency Plan for AIDS Relief

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| | |
|---|---|
| AIDS | Acquired Immunodeficiency Syndrome |
| APCA | African Palliative Care Association |
| ARV | Antiretroviral |
| CBHC | Community-Based Health Care |
| CMS | Central Medical Stores |
| DAC | Drugs Advisory Committee |
| EML | Essential Medicines List |
| FGD | Focus Group Discussion |
| HIV | Human Immunodeficiency Virus |
| HOSPAZ | Hospice and Palliative Care Association of Zimbabwe |
| HSSP | Health Sector Strategic Plan |
| INCB | International Narcotics Control Board |
| MCAZ | Medicines Control Authority of Zimbabwe |
| MoH | Ministry of Health |
| MOHCW | Ministry of Health and Child Welfare [in Zimbabwe] |
| MOPCA | Mozambique Palliative Care Association |
| NFM | National Formulary Of Medicines |
| NGO | Non-Governmental Organisation |
| NMS | National Medical Stores |
| SNAP | Swaziland National AIDS Program |
| SPSS | Statistical Package for Social Sciences |
| UN | United Nations |
| UNAIDS | The Joint United Nations Programme on HIV/AIDS |
| USAID | United States Agency for International Development |
| WHO | World Health Organization |
| WHPCA | Worldwide Hospice Palliative Care Alliance |

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# EXECUTIVE SUMMARY

## Introduction

Opioids are indispensable medicines in the management of moderate to strong pain. According to the Worldwide Hospice Palliative Care Alliance (WHPCA), around three-quarters of adults who need palliative care are in low- and middle-income countries where many African countries sit. The highest rates of people living with HIV and AIDS who need palliative care are also said to be in Africa. The WHPCA further reports that half of the children with palliative care needs are in Africa. According to the International Narcotics Control Board (INCB), four-fifths of the world's population (most of which resides in developing countries) do not have access to strong analgesia. The INCB also states that knowledge and attitudes towards controlled medicines, as well as restrictive national policies on such medicines, all affect opioid access and availability.

The knowledge, attitudes and practices of personnel in relation to opioid use in Swaziland, Mozambique and Zimbabwe, as well as the relevant national policies of those countries, had not previously been systematically assessed. This 2014 review comprised such an assessment.

## Methodology

The methodology used comprised a descriptive cross-sectional study employing both quantitative and qualitative approaches, and the study was conducted in the three chosen Southern African countries of Swaziland, Mozambique and Zimbabwe. A total of 121 respondents were recruited, 33 of whom were purposively selected for focus group discussions and 88 randomly selected for completing self-administered questionnaires on knowledge and attitudes.

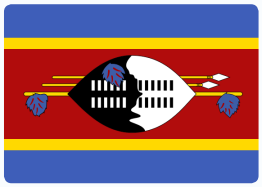
In each country, a focus group discussion consisting of 11 members was conducted, with respondents purposively selected from the Ministries of Health, Chief Pharmacists' offices, medicines regulatory authorities, national medical stores, national palliative care associations, public and private health care facilities and relevant sections of law enforcement bodies. In addition, secondary data on existing policies and regulations was collected for a document review. The development of the self-administered questionnaire on knowledge and attitudes was informed by literature from the INCB. The focus group discussions were conducted using a discussion guide in the form of a checklist adapted from the INCB, and a country-specific assessment checklist controlled analysis of national drugs control policies.

In each country, a tool for describing the estimation, importation, storage and other relevant opioid practices was filled in by an official who was purposively selected from the national medicines regulatory authority or equivalent body.

# Analysis and presentation of findings

Quantitative data was analysed using SPSS 16. The data from the focus group discussions and self-administered questionnaires on practices were typed out in predesigned WORD templates and analysed manually using content analysis. Findings, a discussion of those findings, conclusions drawn and recommendations made are presented for each of the three countries in the review. Cross-cutting issues have also been identified and discussed, and general recommendations made.

# Country-specific findings, conclusions and recommendations



## SWAZILAND

### *Findings and conclusions*

Swaziland has the highest HIV prevalence in the world, estimated by UNAIDS in 2014 to be 26.2%. Only just over half of those in Swaziland who are infected with HIV receive ARVs. At the time of the survey, Swaziland did not have a national palliative care association but the policy environment for palliative care had markedly improved since 2011, with palliative care and the use of opioids for pain relief being integrated in a number of relevant policy documents.

The laws for controlling the use of opioids, which included the Pharmacy Act of 1929 and the Opium Act of 1922, were outdated. However, there were Bills in existence dating from 2012 that were soon to be made law in order to replace the outdated Acts. In Swaziland, the estimation procedure for calculating the national annual level of opioid requirements was consumption-based and only doctors were permitted to prescribe opioid analgesics. In a 2014 publication by Treat the Pain, consumption of opioids analgesics in Swaziland for the year 2012 was very low. Based on the findings of this current review, there were knowledge gaps among respondents regarding regulation of the importation, distribution, storage and prescription of opioid analgesics. Moreover, this review indicated that respondents had undesirable attitudes towards regulating the storage, stocking and prescription of opioid analgesics.

In conclusion, the policy environment for palliative care in Swaziland was improving and relevant laws were being updated. However, the prescription of opioids being limited to doctors, gaps in knowledge and undesirable attitudes among relevant policy and technical people were identified as barriers that were likely to hamper availability and access and thus needed remedial action. In addition, the consumption-based estimation procedure used in Swaziland to determine annual required levels of opioids was stated by the INCB in 2012 to be inaccurate in contexts such as that of Swaziland and should be improved with the inclusion of morbidity and population data.

### *Recommendations*

Arising from this review, there are six main recommendations for Swaziland.

- The Swaziland Ministry of Health should establish a national palliative care technical working group or national palliative care committee to focus on advocating, facilitating and integrating palliative care at all levels of health service delivery and any other issues pertinent to palliative care such as training. APCA could facilitate the Swaziland National AIDS Programme (SNAP) under the Ministry of Health to make this possible.

- The Swaziland Ministry of Health should advocate for at least one more category of health workers – to be permitted to prescribe opioids. APCA could work with the Swaziland National AIDS Programme under the Ministry of Health to work on this while a national technical working group or country palliative care committee is being put in place.
- The method of estimation of annual opioid requirements in Swaziland should be revised to include consideration of morbidity and other data. The Office of the Chief Pharmacist, in consultation with the INCB and APCA, could do this.
- The Swaziland Ministry of Health, working with APCA, should organise training courses for its officers at policy level and for prescribers to be equipped with the necessary knowledge and skills to handle opioids without fear.
- The Swaziland Ministry of Health, perhaps in collaboration with APCA, should advocate for the Medicines and Pharmacy Acts of 2012 to be made law sooner rather than later.
- Officials in the Palliative Care Desk Office should advocate for consistent funding to be allocated by the Ministry of Health for palliative care activities, including the provision of opioids.

## MOZAMBIQUE

### *Findings and conclusions*

According to UNAIDS in 2014, Mozambique had an HIV prevalence rate of 11.5% at that time, and just over half of the population was living below the poverty line. The country has a very low human-resources-for-health ratio of 4 doctors and 39 nurses per 100,000 people, and findings from local stakeholders have indicated that only doctors are permitted to prescribe opioids for pain control. ARV coverage was reaching just over half those who needed it.

The country has Law 3/97 for regulating controlled substances but the review found that this needed revision since it focused more on the control of illicit drug use than finding a balance with allowing access for medical use. There was a new Palliative Care Policy published in 2012, and the essential medicines list of Mozambique (published in 2007) includes opioids as essential medicines for pain control. The country has an HIV and AIDS National Strategic Response Plan, but pain management in people living with HIV and AIDS does not feature. Generally, palliative care was not yet integrated into the health care system. The Worldwide Hospice Palliative Care Alliance classified Mozambique in 2014 as a country with "isolated palliative care provision".

The estimation method for Mozambique's national annual opioid requirements was consumption-based and it considered only the past year's consumption and existing stocks. In the year 2012, according to Treat the Pain, only 4.7kg of morphine equivalent, out of the expected 322kg according the estimated pain burden, was consumed in Mozambique.

Access to health care in Mozambique was limited by distances to the nearest health service provider and the scarcity of health workers, as well as frequent stock outs of medicines in general and opioids in particular.

Regarding knowledge, respondents had gaps regarding the need for other cadres to prescribe. Respondents believed in very stringent measures of control, including limiting opioids' access to hospitals only. Attitudes of respondents towards issues related to the estimation, importation, storage, distribution and prescription of strong pain relief drugs were mostly undesirable.

In conclusion, Mozambique – a country with a high HIV prevalence rate of 11.5% and just over half the population living below poverty line – was found to be a country where palliative care access was still very limited and not fully integrated into the health system. In addition, the relevant legislation needed revision. There were knowledge gaps and undesirable attitudes by policy and technical people in the sample.

## Recommendations

Arising from this review, there are six main recommendations for Mozambique:

- The Mozambique Ministry of Health and the Mozambique Palliative Care Association (possibly with support from APCA) should together advocate for review of the Controlled Medicines Act of 1997 in order to provide a supportive legal environment for opioid access.
- The Mozambique Palliative Care Association should advocate for the integration of palliative care into all health policies, including disease-specific policies such as the HIV or cancer strategic plans.
- The Mozambique Palliative Care Association should work with partners, including the Mozambique Government and APCA, to organise a systematic training programme for policy and technical people dealing with opioids, in order to improve knowledge levels regarding opioid use for medical and scientific purposes. The Mozambique Palliative Care Association should also take the lead by collaborating with APCA and the Government of Mozambique to organise training courses to target relevant health workers and training schools. More generally, palliative care content should be integrated into the curricula in training schools for health workers in Mozambique.
- It is recommended that the technical people in Mozambique's national medical store review the estimation procedure to make sure that, within the current resources, what could be competently utilised is available. This should be done in collaboration with APCA and the INCB.
- The Mozambique Palliative Care Association, in collaboration with APCA, should consistently advocate for at least one more category being permitted to prescribe opioids in Mozambique.
- The Mozambique Palliative Care Association should take the lead to advocate for palliative care activities being budgeted for, in order to avail resources that will enable the growth of infant palliative care services in Mozambique.
- The Mozambique Palliative Care Association should take the lead to advocate for palliative care activities being budgeted for, in order to avail resources that will enable the growth of infant palliative care services in Mozambique.

# ZIMBABWE

## *Findings and conclusions*

According to UNAIDS in 2014, Zimbabwe had an HIV prevalence rate of 15% and the disease was responsible for about half of the deaths in the country. The density of human resources for health was very low, being only 1.23 health workers per 1000 people. Even so, palliative care had existed in Zimbabwe since 1979, although it was limited to large cities such as Harare and Bulawayo. The country had a Dangerous Drugs Act, the Medicines Control Authority of Zimbabwe (MCAZ) and relevant policies for the integration of palliative care into the health system.

Statistics from Treat the Pain indicated that consumption of opioids in Zimbabwe in 2012 was only 10.1kg instead of the expected 177kg deduced from the disease burden. The estimation method for national annual opioid requirements for Zimbabwe was consumption-based, which was found to be not entirely suitable. Access to health services was affected by a scarcity of health workers, stockouts of medicines, and financial barriers since some hospitals charged user fees even for chronic conditions in an effort to raise money while nearly three-quarters of the population lived below the poverty line. Moreover, prescription by nurses required written permission from the Permanent Secretary of the Zimbabwe Ministry of Health.

There were knowledge gaps among respondents to the review survey, especially regarding stringent controls versus a more balanced approach allowing good access to opioids for medical and scientific reasons. Their attitudes, too, on topics relevant to opioid estimation, importation, storage, distribution, prescription and dispensing were less than desirable.

In conclusion, Zimbabwe had made some progress towards the integration of palliative care into its health systems but there were still some barriers to overcome: the Dangerous Drugs Act was outdated; policy restricted the availability of opioid analgesics to hospital level alone; user fees were being charged when so many of the population lived below the poverty line; the prescribing of drugs was limited to doctors (very few in number) and to those nurses who had obtained written permission from the Permanent Secretary of the Ministry of Health; a consumption-based estimation method was being used, which was known by the INCB to be inaccurate in dynamic contexts such as that of Zimbabwe.

## Recommendations

Arising from this review, there are six main recommendations for Zimbabwe:

- The Medicines Control Authority of Zimbabwe (MCAZ), possibly supported by APCA, should take the lead to advocate for a revision of the Dangerous Drugs Act to remove terms like 'dangerous' and 'narcotics'.

- The Hospice and Palliative Care Association of Zimbabwe (HOSPAZ) should take the lead, with technical support from APCA as necessary, to plan a systematic training programme for policy and technical people dealing with opioids, in order to improve knowledge levels regarding opioid use for medical and scientific purposes.

- HOSPAZ should work with Zimbabwe's Ministries of Health and of Education to ensure that relevant knowledge on the rational use of opioid analgesics is integrated into the curriculum for health workers in medical and nursing schools.

- The technical people in MCAZ, in consultation with INCB, should review the estimation procedure for annual national opioid requirements to make sure that, with the current resources, what could be competently utilised is available.

- HOSPAZ, in collaboration with APCA, should flag up to key stakeholders the current low usage of strong pain-relieving drugs among those needing them.

- HOSPAZ, working with the Ministry of Health and APCA, should advocate for the legal and policy changes needed whereby nurses trained in palliative care no longer need to obtain permission from the Permanent Secretary of the Ministry of Health to prescribe strong pain-relieving drugs.

# General findings, conclusions and recommendations

## *General findings and conclusions*

*The context of the review countries is such that access by the general populace to health services, including palliative care, could be limited by a number of factors:*

- The Human Development Index rankings for the review countries were 148th, 156th and 178th for Swaziland, Zimbabwe and Mozambique, respectively.
- With the exception of Swaziland, the other two review countries had lower per-capita expenditure on health than the minimum of US$44 recommended by the World Health Organization. The per-capita expenditures for 2012 were US$448 for Swaziland, US$28 for Zimbabwe and US$40 for Mozambique.
- •The proportion of people living below the poverty line in 2009 was 69% for Swaziland, 71% for Zimbabwe and 82% for Mozambique.
- The 2013 out-of-pocket health expenditure was 42% for Swaziland and 11.9% for Mozambique. For Zimbabwe, available literatures shows that out of pocket health expenditure was 29% in 2009.

Thus these are countries with limited resources, high out-of-pocket expenditure (Zimbabwe and Swaziland) but with a big burden of disease as evidenced by the high HIV prevalence. Such a context is likely to have poor access to health services in general. It is therefore not surprising that opioid access and consumption was found by Treat the Pain in 2014 to be less than 5% of the expected minimum for all the review countries. The opioids estimation procedures in the three countries of the review was noted to be consumption-based and prescription was limited to doctors except in Zimbabwe; yet the number of human resources available for health services in the region is poor. It was found that the policy environment for opioid availability and access was improving but the relevant laws were outdated.

Based on the findings in this study, it can be predicted that even if appropriate opioids could be imported in sufficient quantities, the probability was high that much of it would not be used because of the scarcity of health workers and the restrictions on who is permitted to prescribe drugs, as well as a lack of knowledge, a reluctance to prescribe and undesirable attitudes. The WHO has found that high out-of-pocket expenditure is associated with poor access and high rates of catastrophic health expenditures. Thus progress towards improved availability and access cannot be achieved quickly in Zimbabwe. Long-term, low-cost consistent efforts to holistically address all the barriers to access that have been identified should be made.

## General recommendations

The following eight general recommendations should be noted and acted upon:

- There needs to be an increase in the 'visibility' of palliative care issues through operational research and publications in peer-reviewed journals and other national and international forums. The national palliative care association in Zimbabwe and in Mozambique, as well as the palliative care desk in the Swaziland Ministry of health, in collaboration with APCA should take action on this.

- In consideration of the context, low-cost interventions such as task shifting should be advocated for, in order to allow nurses to prescribe. The national palliative care association in Mozambique, and the palliative care desk in the Swaziland Ministry of health should take the lead in implementation of this recommendation. This is because the availability of nurses is much greater throughout the national health systems than that of doctors.

- There should be policy changes to integrate palliative care into all levels of the national health system, so that those in need of pain relief do not have to travel long distances to reach hospitals. Moreover, there should be advocacy for palliative care content to be integrated in nursing, medical and other health workers' training curricula. APCA, collaborating with national palliative care associations, should advocate for palliative care to be included in health curricula to ensure that graduating health care workers are sufficiently prepared to practice palliative care without knowledge gaps and undesirable attitudes.

- There is a scarcity of human resources for health workers in the review countries. It is likely that palliative care is even more affected than other specialisms of health services, since it is a developing service in most African countries. APCA should advocate for, facilitate or engage in research to describe the situation of palliative care human resources and suggest realistic remedial actions for African countries. In the meantime, it is recommended that the road map for scaling up human resources for health for improved health service delivery in the African region for 2012–2025, as proposed by the World Health Organization, should be adapted by each of the reviewed countries.

- In the three countries of the review, the policy environment was found to be improving, particularly in Swaziland and Zimbabwe. Nonetheless, the laws to enforce the policies need revision and it is recommended that APCA should collaborate with the national palliative care associations and Ministries of Health to advocate for relevant revisions. Otherwise the policies will not be implemented properly.

- Access to all health services in the review countries is limited, partly because prepaid systems of financing are minimal and out-of-pocket expenses are thus high. Advocating for national prepaid systems of financing could help improve access to palliative care in these countries. Advocacy for prepaid systems should be done by the ministries of health in collaboration with WHO.

- The three countries of the review were found to be using a consumption-based method of estimation for national opioid requirements, yet this method, according to the INCB, does not give accurate estimates in contexts where data may not accurate and where the disease burden is still very dynamic – as is the case in the three countries reviewed. APCA could work with these countries and modify this approach to estimating demand, to suit each country's situation. The appropriate APCA guidelines should be used by the three countries.

# CHAPTER 1:

# INTRODUCTION

# 1 INTRODUCTION

## 1.1 Background to the review

The African Palliative Care Association (APCA) exists to ensure that palliative care is widely understood, integrated into health systems at all levels and underpinned by evidence, in order to reduce pain and suffering across Africa (APCA, 2014). APCA, USAID/Regional HIV/AIDS Program and other local partners embarked on a project with an aim of scaling up palliative care for people living with HIV and AIDS in southern Africa. Opioids are indispensable medicines in the management of moderate to strong pain (International Narcotics Control Board (INCB), 2011).

According to the Worldwide Hospice Palliative Care Alliance (WHPCA, 2014), a majority (78%) of adults who need palliative care are in low- and middle-income countries where African countries belong. The highest rates of people living with HIV and AIDS who need palliative care are said to be in Africa. Also, WHPCA (2014) states that almost half (49%) of the children with palliative care needs are in Africa. According to INCB (2011), about 80% of the world population, most of which is in developing countries, does not have access to strong analgesia.

In 2010a, APCA and partners (USAID, PEPFAR, the Open Society Institute and national palliative care associations) conducted a study to investigate the state of opioid availability in six African countries, namely Ethiopia, Malawi, Kenya, Rwanda, Tanzania and Zambia (APCA, 2010a). The purpose was to assess the opioid estimation procedures and supply chain mechanism in each country, including reviewing of policies governing the use of opioids in the respective countries in order to assess their effects on the supply chain mechanisms. One of the key findings was that legal and policy restrictions impeded the availability of opioids. APCA has built on this work by conducting a similar review in three additional African countries: Mozambique, Swaziland and Zimbabwe.

## 1.2 Problem statement

APCA, USAID and other local partners are progressing with a project whose aim is to scale up palliative care for people living with HIV and AIDS in Southern African countries. Foley et al (2006) state that around half the people dying from AIDS experience moderate or severe pain. It is estimated that globally up to one million end-stage HIV/AIDS patients suffer disease, pain and death where pain levels are higher than they could be – partly because those patients do not have access to controlled medicines such as opioids, which are essential for the control of moderate to severe pain (INCB, 2011). Most of these end-stage HIV/AIDS patients are likely to be in sub-Saharan Africa, where about 70% of people living with HIV/AIDS are found (UNAIDS, 2014b).

According to the INCB (2011 and 2012), knowledge and attitudes towards controlled medicines, as well as restrictive national policies, affect opioid availability. The knowledge, attitudes and practices as well as policies relevant to opioid availability in Swaziland, Mozambique and Zimbabwe, had not previously been systematically assessed. In addition, opioid estimation procedures and supply chain mechanisms had not been studied to identify potential barriers to the availability of strong analgesics for people with HIV and AIDS as well as for people with other conditions requiring their use. This was the motivation for the current review.

## 1.3 Objectives

### *1.3.1 General objective*

To examine the country level availability of opioids for use by people living with HIV and AIDS in the three countries and make recommendations on how this could be improved.

### *1.3.2 Specific objectives*

Specific objectives were fourfold:

- To describe the knowledge and attitudes relating to opioid supply chain mechanisms and consumption estimates among those responsible for these functions.
- To review legislation in the target countries and benchmark them against recommendations by INCB.
- To assess actual practices in regard to opioid supply chain mechanisms and consumption estimation procedures.
- To make recommendations for improving the opioid supply chain mechanisms and opioid consumption estimates for palliative care reasons.

# CHAPTER 2:

# METHODOLOGY

# 2 METHODOLOGY

## 2.1 Study design

The review comprised a descriptive cross-sectional study. It used both quantitative and qualitative approaches.

## 2.2 Area and population of study

### *2.2.1 Area*

The area under study comprised three countries in Southern Africa: Swaziland, Mozambique and Zimbabwe. In each country, the following officials were the focal points for investigations:

- The chief pharmacist or other personnel who handled estimates and policy issues at the Ministry of Health (MoH)
- The national drug authority, or equivalent regulatory body or person or office, responsible for medicine licensing issues
- The drug-importing bodies of the country, such as the National Medical Stores, for the assessment of supply chain issues
- Institutions that are users of opioids, eg hospitals, and the national palliative care associations/programmes.
- Ministries of Internal Affairs or the Police Departments or equivalent law enforcement bodies.

### *2.2.2 Population*

The populations under study were the officials at policy level and those who were involved in estimating national opioid need, as well as those involved at various levels in the opioid supply chain including prescribers. Specifically, data was collected from the following officials:

- Policy personnel who were identified at the MoH, and these included the Chief Pharmacists or equivalent technical persons
- Licensing personnel, eg national drugs authority directors or technical people directly responsible for licensing
- Technical personnel who estimate and import opioids, including procurement officers Users of opioids, inclusive of service provider personnel (both public and private), including the representatives of palliative care associations or similar programmes in each country, along with doctors and pharmacists
- Officials from the pharmaceuticals control unit of each country's police service.

## 2.3 Sample size and selection procedure

Sampling was at two levels in each country under review, and was purposive. The two-level sampling strategy was chosen to ensure that key players relevant to opioid estimation procedures and the supply chain mechanisms were captured. Contact persons from the national palliative care associations or the national Ministries of Health assisted in identifying and contacting respondents to arrange for the interviews.

At the first level, at least one person from each of the following positions or roles in each country of the review was selected to form a focus group. These focus groups then systematically filled the country assessment checklists adapted from the INCB (2011) checklist for analysis of national drug control policies. The targeted people to form the focus groups were:

- Policy persons
- Licensing persons
- Officials from the national palliative care association or Ministry of Health
- A police or Internal Affairs person
- At least two persons (selected to represent public service providers on the one hand and private service providers on the other)
- Two technocrats (one with a bias towards the estimation of opioid requirement levels and the second with a bias towards the importation of opioids).

During data collection, those undertaking the review had discretion to interview additional respondents based on an analysis of the data obtained.

At the second level of sampling, each of the offices or departments from which focus group participants were derived received at least five questionnaires, and these were completed by officers working with the respective participants. The respondents who completed the questionnaires were randomly selected using the entire staffing in the focus group participants' respective departments as the sampling frame (except in situations where there were five or fewer staff in an office, in which case all staff members were recruited into the study).

## 2.4 Data collection methods and tools

### *2.4.1 Review of relevant documents*

A desktop-based review of documents on policies and regulations relating to opioids was conducted. The documents reviewed included the national laws governing the use of controlled medicines, national AIDS Control Programme (or equivalent body) reports, or policy documents such as strategic plans, national palliative care policies, reports of previous related studies, essential drug lists and any other relevant documents. Some of these documents were obtained before field data collection to inform protocol development. Additional documents were collected during primary data collection from the respective countries. The INCB Guidelines were also reviewed during protocol development.

### 2.4.2 Focus group discussions

One focus group discussion (FGD) was organised, facilitated and documented for each of the review countries by the consultants hired by APCA to conduct the review. Participants in each FGD were purposively selected with the help of an in-country review coordinator from the relevant Ministry of Health or national palliative care association. The target was to have each of the categories of personnel listed in section 2.3 above represented in the FGD as well as for filling in questionnaires. This approach to analyse the national drug control policies using a 'taskforce' – which in this case was in the form of an FGD, with the intention of hastening the process – was adapted from suggestions by the INCB (2011:40). The FGDs were guided by a checklist which was adapted from the WHO checklist for guiding analysis of national drug control policies (WHO, 2011).

An FGD guide, in a checklist format, was adapted from guidelines for analysis of national drug control policies (WHO, 2011) – see Appendix D [Q: Is it OK that the first reference to an Appendix is to Appx D (rather than A)? Do you wish to reorder the appendices?]. Questions in the checklist for data collection were arranged following known key barriers to controlled drugs' availability as described by the INCB. These barriers include regulatory and policy issues, tight drug controls and health care professional issues.

The FGD was used to provide information on the following themes:

- Policies and legislation issues for controlled medicines
- Policy planning for availability and accessibility of controlled medicines
- Issues related to tight drug controls and storage
- Issues relating to health care professionals
- Estimation and stocking procedures.

### 2.4.3 Self-administered questionnaires

A self-administered hard-copy questionnaire was used to collect quantitative data on knowledge and attitudes relating to opioid supply chain mechanisms and consumption estimates among those responsible for these functions. The questionnaire (see Appendix E) was adapted from literature by the INCB (2011 and 2012).

## 2.5 Data collection dates and teams

Data was collected at different times because of differences in dates for when ethical approval to undertake the review was granted. Table 1 shows the data collection dates by country.

**TABLE 1 Data collection dates by country**

| Country | Date of data collection |
|---|---|
| **Swaziland** | 3rd to 7th February 2014 |
| **Zimbabwe** | 27th to 31st October 2014 |
| **Mozambique** | 3rd to 7th November 2014 |

On arrival in each country, the review team contacted either the national palliative care association (Mozambique and Zimbabwe) or the Ministry of Health palliative care office (Swaziland) and briefed the relevant staff about the protocol for the review. The next day, the in-country teams (officers from national associations or the Ministry of Health) were oriented to the protocol and the data collection tools. The in-country teams coordinated the booking of interviews with targeted respondents, took part in data collection and provided relevant documents for the review in instances where these could not be obtained before primary data collection.

## 2.6 Data analysis

The qualitative data was typed out in pre-designed word templates and analysed thematically, presented by themes and by country.

Quantitative data was entered into, and analysed using, SPSS version 16. Descriptive analysis was performed and data was presented using summary tables.

## 2.7 Quality assurance

To reduce bias and errors, the findings from each of the review countries were shared with respective respondents for validation before the final report was written. This was done by emailing each country's specific draft report to key respondents for review and comment. A semi-structured tool customised from the INCB (2011) checklist for ensuring balance in national policies on controlled substances was used. Limitations were identified and documented (see section 2.9 below).

## 2.8 Ethical approval

Approval to undertake the review was obtained from the respective countries' Ethics Review Board; The Scientific and Ethics Committee of the Ministry of Health in Mbabane, Swaziland (ref MH/599C/FWA 000 15267, August 2013); the *Comité National de Bioética para a Saúde* (CNBS)/Mozambique National Committee for Bioethics (ref 26/CNBS/13, August 2014) and the Medical Research Council of Zimbabwe (ref MRCZ/A/1800, August 2014). Written approval to participate in the review was obtained from all participants in the respective countries.

## 2.9 Limitations

The respondents for the questionnaires were not adequate numerically to allow for application of inferential statistical tests on sample subcategories, and this had the potential to compromise the validity of the conclusions drawn. However, since the target populations were policy level officials and they were purposively selected, it is reasonable to assume that this sample was adequate for drawing useful conclusions in the review.

In Swaziland and Mozambique there were no representatives from their respective Ministries of Internal Affairs to participate in the FGDs. This limited discussion on the role of law enforcement in relation to controlled medicines availability in those countries.

In Mozambique, language compromised the research team's ability to comprehensively undertake the document review, since all policy documents were written in Portuguese. Nonetheless, during the data collection process a professional translator was used to translate the tools, which increased the validity of those findings.

# CHAPTER 3:

# RESULTS

# 3 RESULTS

## 3.1 The review participants

For the qualitative component, a total of three FGDs were conducted, one in each review country. For the quantitative component of the review, 88 respondents (30 for Swaziland, 26 for Mozambique, and 32 for Zimbabwe) completed self-administered questionnaires. Further details are given below.

### *3.1.1 Qualitative sample*

A total of three FGDs were conducted, one in each review country, with 11 participants per group. FGD participants were spread across the various identified roles as set out in Table 2.

**TABLE 2 Summary of the focus group discussion sample (by country)**

| CATEGORY OF RESPONDENTS | COUNTRY | | | |
|---|---|---|---|---|
| | Swaziland | Mozambique | Zimbabwe | Totals |
| National AIDS programme or palliative care association personnel | 4 | 4 | 1 | 9 |
| Govt policy personnel | 2 | 4 | 2 | 8 |
| Govt licensing personnel | 1 | 1 | 1 | 3 |
| Govt supply chain technocrats | 0 | 1 | 1 | 2 |
| Service providers | 4 | 1 | 5 | 10 |
| Law enforcement personnel | 0 | 0 | 1 | 1 |
| **Totals** | **11** | **11** | **11** | **33** |

[a] *Technical personnel who estimate and import opioids. Govt = government.*

### *3.1.2 Quantitative sample*

The quantitative sample was composed of respondents from policy, licensing, law enforcement, national AIDS control programmes, national palliative care associations and service providers. A total of 88 respondents were recruited, and Table 3 shows the distribution across the various staffing categories.

**TABLE 3 Sample size for self-administered questionnaire key informants (by country)**

| CATEGORY OF RESPONDENTS | COUNTRY | | | |
|---|---|---|---|---|
| | Swaziland | Mozambique | Zimbabwe | Totals |
| National AIDS programme or palliative care association personnel | 3 | 2 | 7 | 12 |
| Govt policy personnel | 8 | 3 | 1 | 12 |
| Govt licensing personnel | 5 | 1 | 1 | 7 |
| Govt supply chain technocrats | 0 | 0 | 2 | 2 |
| Service providers | 9 | 20 | 16 | 16 |
| Law enforcement personnel | 5 | 0 | 5 | 5 |
| **Totals** | **30** | **26** | **32** | **88** |

*Govt –government*

## 3.2 National morphine consumption by country

Table 4 shows morphine equivalent consumption per country as well as the percentage gap in coverage of deaths in pain with analgesic treatment. Swaziland did not submit morphine consumption data to the INCB for the year 2012; Mozambique consumed 4.7kg, which is much less than the 322kg that is estimated to be needed to meet the minimum demand for pain relief among people dying of cancer and HIV/AIDS in Mozambique. Zimbabwe consumed 10.1kg of morphine in the year 2012 – this too is far less than the estimated quantity of 177kg needed to meet the minimum demand for pain relief among people dying of cancer and HIV/AIDS in Zimbabwe.

**TABLE 4 Average consumption of pain relief medications in the review countries for the year 2012**

| DESCRIPTION | COUNTRY | | |
|---|---|---|---|
| | Swaziland | Mozambique | Zimbabwe |
| Total amount of morphine equivalent consumed | 0kg | 4.7kg | 10.1kg |
| Morphine needed to meet minimum demand from deaths due to HIV or cancer (kg) | 20kg | 322kg | 177kg |
| Deaths with moderate/severe pain | 3,252 | 52,114 | 28,638 |
| People dying of HIV or cancer with untreated moderate/severe pain: | 3,252 | 51,348 | 27,001 |
| Based on morphine equivalent consumed, coverage of deaths in pain with treatment | 0.0% | 1.5% | 5.7% |
| Percentage gap in coverage of deaths in pain with analgesics treatment: | 100% | 98.5% | 94.3% |

*Source of data:Treat the Pain (2014)*

## 3.3 Review of policies and other documents

Policies and other relevant documents were reviewed to establish the extent to which they include palliative care and opioids. Appendix A gives an overview of general literature relating to opioid availability for medical and scientific purposes. Appendix B describes the literature analysed for each of the three countries in the review. Details of the literature content analysis are given in Appendix C.

Table 5 shows the policies and documents reviewed in each country.

**TABLE 5 Documents reviewed in each country**

| | COUNTRY | | |
|---|---|---|---|
| | Swaziland | Mozambique | Zimbabwe |
| POLICIES | • National Palliative Care Policy (MoH Swaziland, 2011b).<br>• National Pharmaceutical Policy (MoH Swaziland, 2011c) | • National Palliative Care Policy of 2012:12 | • The National Medicines Policy of Zimbabwe (Ministry of Health and Child Welfare, 2011) |
| STRATEGIES | • Swaziland Pharmaceutical Strategic Plan, 2012–2016 (MoH Swaziland, 2012a) | | • Zimbabwe National HIV and AIDS Strategic Plan II, 2011–2015 (National AIDS Council of Zimbabwe, 2011) |
| GUIDELINES | • Standard Treatment Guidelines and Essential Medicines List of Common Medical Conditions in the Kingdom of Swaziland (MoH Swaziland, 2012b) | | |
| OTHER | • Pharmacy Bill (No 7 of 2012) and Medicines Bill (No 8 of 2012) (in draft at that stage)<br>• National Palliative Care Trainees Manual (MoH, 2012c)<br>• Curriculum for Pharmacy Certificate programme (no date) | • Criminal Jurisdiction Legal Framework Applicable to Trafficking and Consumption Narcotic Drugs, Psychotropic Substances, Precursors and Other Substances' Similar Effects (Law No. 3/97, dated 13 September)<br>• APCA Standards for Providing Palliative Care in Africa (2011). These were adopted by Mozambique in 2012<br>• Pocket Guide to Pain Management , 2nd edition (2012). Adopted from APCA publication and translated into Portuguese.<br>• National formulary of medicines (NFM) | • Dangerous Drugs Act (Chapter 15:02) of Zimbabwe<br>• The Medicines and Allied Substances Control Act (Chapter 15:03) of 1969 |

As Table 5 shows, Swaziland had a number of policies relevant to palliative care and opioid availability which have been developed in recent years and are now in operation. Even in Mozambique and Zimbabwe, several policies and documents that include palliative care and opioid analgesics are in place.

Following the review of documents in each country, the key areas were noted and are shown in Table 6.

**TABLE 6 Inclusion in national policies/documents of key areas relating to palliative care**

| KEY AREA | Mozambique | Swaziland | Zimbabwe |
|---|---|---|---|
| Palliative care | ✓ | ✓ | ✓ |
| Pain management | ✓ | ✓ | ✓ |
| Opioids | ✓ | ✓ | ✓ |
| WHO analgesic ladder | | ✓ | |
| Need to train medical personnel in use of opioids | | ✓ | |
| Equity in access to WHO analgesic medications | | ✓ | |

✓ *If mentioned in policy /document or guideline*

### *3.3.1 Legislation and policy issues for opioid use*

The results on policy and legislation are based on focus group discussions that were conducted with purposively selected respondents. The results were substantiated by findings from the document review.

## SWAZILAND

Notable in the content of Swaziland's Pharmaceutical Strategic Plan for 2012–2016, page 17, is the positive approach to access to essential medicines. The vision of the strategic plan is to "support the improvement of the health status of the Swazi population by ensuring equitable access and rational use of quality essential medicines". The opioids are listed as essential medicines.

Regarding regulation and legislation of the pharmaceutical industry in Swaziland, the current National Pharmaceutical Policy (2011c) states on page 11 that "The Pharmacy Act of 1929 … is outdated, does not provide for licensing … and regulatory functions … licensing of premises and registration of medicines is not done". According to the National Pharmaceutical Policy (2011c), there is a Chief Pharmacist who is responsible for providing policy advice and guidance to the MoH. Participants in the current review noted that Swaziland's 1929 Pharmacy Act and 1922 Opium and Habit Forming Drugs Act were long outdated; but they also pointed out that two new bills (a Pharmacy Bill of 2012 and a Medicines Bill of 2012) were in their last stages of being made law in Swaziland. The bills were to replace the outdated acts.

The National Pharmaceutical Policy of 2011 states its goal as to "contribute to the health of the Swaziland population by ensuring high-quality essential medicines". Among the essential medicines on the official list are opioids. The Pharmaceutical Policy of 2011 talks about control (Article 6.2.2) as well as the supply of all essential medicines (Article 6.3). The National Palliative Care Guidelines (MoH Swaziland, 2011a:15) state that "morphine is the most commonly used opioid and is still the absolute standard".

## MOZAMBIQUE

A detailed document review was not conducted for Mozambique because of the language barrier. The findings are thus mainly based on a content analysis of FGD data as well as data from the questionnaires. Mozambique has several documents that refer to palliative care and opioids, and these include: Criminal Jurisdiction Legal Framework Applicable to Trafficking and Consumption Narcotic Drugs, Psychotropic Substances, Precursors and Other Substances Similar Effects Law No 3/97, dated 13 September 1997, which is outdated. Other documents available include the National Palliative Care Policy, Standards for Palliative Care , and Mozambique's 2012 version of APCA's Pocket Guide to Pain Management (2nd edition) The country also has a National Formulary of Medicines (NFM) document, which lists the following narcotics as essential medicines: codeine phosphate tablets, morphine sulphate solution plus injection as well as the tablet form, pethidine injection, and fentanyl injection. The country also had a National Strategic HIV and AIDS Response Plan 2010–2014, but this document did not address issues of pain management and only briefly mentioned palliative care under the home-based care section. A new version of HIV and AIDS Response Plan was not available at the time of writing this report.

## ZIMBABWE

Review participants were aware of the existence of the Dangerous Drugs Act (Chapter 15:02) of Zimbabwe, which they all agreed needed to be revised to accommodate the concept of 'balance' so that it did not focus only on the prevention of the illicit use of opioids but needed also to create an environment for supporting availability and access for the rational medical and scientific use of opioids. The National Medicines Policy (Ministry of Health and Child Welfare, 2011) states that the Zimbabwe Government is aware of its obligation to provide 'vital' medicines including opioids. The Medicines and Allied Substances Control Act (Chapter 15:03) of 1969 established the Medicines Control Authority of Zimbabwe (MCAZ), which controls the manufacturing, import/export and distribution of medicines, including opioids. Specific to HIV and AIDS, Zimbabwe has a national HIV and AIDS Strategic Plan for 2011–2015 (National AIDS Council of Zimbabwe, 2011), which states that palliative care is one of the services to be provided under community-based health care (CBHC), with a goal to scale it up to 85% by 2015.

### *3.3.2 Regulation issues*

## SWAZILAND

Swaziland did not have a medicines regulatory authority in 2014 when the review was done; it was the Office of the Chief Pharmacist undertaking this role, and thus regulation was weak. A Medicines Regulatory Authority had been organised and was waiting to be authorised by the Swaziland Government. This authority was to be supported by existing committees at facility and national levels. There were Pharmacy and Therapeutic Committees, which were responsible for ensuring the rational use of medicines at the facility level.

The committees also advocated for reviews of the Essential Medicines List (EML) and for any additions if needed. At the national level there was a Drugs Advisory Committee (DAC) formed from the various facility pharmacy and therapeutic committees. The DAC was charged with responsibility of setting standards and overseeing pharmaceutical practice. There was also a National Task Force whose main responsibility was to prevent the illicit use of controlled medicines. The membership of this task force was drawn from the major pharmacy stakeholders, including the national police force, Interpol, the MoH (Chief Pharmacist), the Customs Department, the Ministry of Trade and the Swaziland Standards Authority.

In terms of framework, there is a Pharmacy Bill (No 7 of 2012) and a Medicines Bill (No 8 of 2012); these were due to be submitted to Parliament and these, together with the above policies, will ensure regulation and availability of essential medicines including opioids. It was reasonable to assume that implementation of these policies would improve the supply of strong pain killers and other essential medicines as well as ensure control of illicit use. However, findings from the FGD suggested that the prescribers and dispensers of opioids were sometimes reluctant to prescribe for fear of investigation, prosecution and disproportionate punishment for minor or unintentional breaches of the drug control rules. Only doctors were allowed to prescribe opioid analgesics in Swaziland.

## MOZAMBIQUE

In Mozambique, the Pharmaceutical Department in the MoH is responsible for all activities related to medicines regulation and law enforcement. That department is therefore responsible for licensing medical products and premises where pharmacies are placed for storage or dispensing. All regulatory activities are regulated by the Medicines Act 4/98 of 1998.

## ZIMBABWE

At the time of the review, Zimbabwe had a medicines control authority (MCAZ) which was the national competent authority responsible for licensing and controlling of opioids. The country also had a National Medicines Policy (MOHCW, 2011), which was intended to be (page 6) a "reference guide and directive for the implementation of the essential medicines concept and the management and financing of medicines throughout the country", Zimbabwe has an essential drugs list, where morphine and codeine are listed as essential medicines and classified as 'vital' – defined as "considered lifesaving or [where] unavailability would cause serious harm and efforts should always be aimed at making them 100% available" (NDTPAC, 2006).

### *3.3.3 Estimation procedures and supply chain issues*

In the three countries under review, morbidity data and the total population were not being used in estimating opioid need. Table 7 below gives details on estimation and supply chain issues for each of the three countries.

In Mozambique, challenges related to delays in the tendering process and financial constraints were found to be barriers to ensuring a consistent supply of opioids, leading to frequent stockouts, In Swaziland it was noted that a lack of technical personnel to liaise with the INCB was a challenge, which in practice hampered national reporting for five years. In Zimbabwe, MCAZ was responsible for the estimation of opioid requirements for the nation, resulting in estimates being sent to the INCB in a timely manner and a buffer stock being kept so as to minimise stockouts.

**TABLE 7 Self-reported opioid estimation methods**

| COUNTRY | SELF-REPORTED METHOD OF OPIOID ESTIMATION |
|---|---|
| MOZAMBIQUE | Participants in the FGD stated that the Government considers the previous year's consumption and then makes an estimation of opioid need for the next year. For the 2012 consumption data submitted to the INCB, itself an estimate, 10% was added and this is the routine approach and then the totals are submitted to the INCB. If supply becomes exhausted before the end of the year, a supplementary order is placed with the INCB. Participants did not mention whether morbidity data or the total population size was considered in estimating opioid need; however, they all agreed that stockouts of opioids were common and they attributed these shortages to delays in the tendering process. Another limiting factor identified was the scarcity of resources, particularly dollars, required for the importation and distribution of opioids. |
| SWAZILAND | The Government of Swaziland, through the office of the Chief Pharmacist in the Ministry of Health, estimated opioid requirements based on consumption during the previous year, but it had not yet critically examined the efficiency of this method or validated it against the methods recommended by WHO and INCB. The Government submitted its opioid estimate for the following year by the 3rd of June. However, it had not been able to submit to the INCB the required quarterly and annual statistical reports because of the lack a technical person to take on this role for the last five years; this technical officer had just been recruited and hired in 2014. |
| ZIMBABWE | In estimating for opioid need in Zimbabwe, past consumption was the main factor considered. Participants did not mention consideration of the burden of disease or total population size; but they stated that a surplus was included to prevent shortages before the year ends, and that in case the estimated amount was not sufficient, a supplementary estimate was sent to the INCB. Estimates were sent by MCAZ to the INCB in a timely manner. |

*Source: Focus group discussions*

### *3.3.4 Barriers to opioid access*

In the three countries under review, geographical coverage affected access to opioids. In Mozambique only 3% of the 1,414 health facilities are hospitals and morphine is only available in these facilities. This compromises access in the sense that there are only a few access points in a large country with 801,590 square kilometres (Food and Agriculture Organisation, 2007). Frequent stockouts were also mentioned as a barrier to access. The rural–urban inequity regarding access to opioids was noted in all three countries, and respondents noted that this was largely explained by the distribution of health facilities and prescribers, which are urban biased. In Zimbabwe, user fees were mentioned as a barrier to access.

Greater detail on these barriers to access to pain relief are given in Table 8.

**TABLE 8 Barriers to opioid access (by country)**

| COUNTRY | BARRIERS TO OPIOID ACCESS |
|---|---|
| MOZAMBIQUE | The issue stated to be affecting access more significantly was distance to the nearest health facility with the right mix of services. In Mozambique, the number of hospitals is small as a proportion of the total number of health facilities. According to the Mozambique Palliative Care Policy of 2012 only 3% of the 1,414 health facilities were hospitals and the distance to the nearest health facility was estimated to be an average of 10km. Inadequacy of health worker numbers and the fact that morphine was only available in hospitals, where there were doctors to prescribe it, were other limiting factors. Access barriers of distance and scarcity of health workers were worse in rural than in urban areas. Mozambique charged a user fee of 5 metical (equivalent to about 17 US cents) at the point of access, but there were total exemptions for the very poor and those with chronic diseases such as HIV, cancer and TB. |
| SWAZILAND | On the issue of the geographical coverage of opioid supply, it was noted that pharmacies were mostly located in towns and that liquid morphine was not easily accessed by users in rural areas because prescribers, who were limited to registered doctors, were mostly in urban areas. There was a user fee of 10 emalangeni (equivalent to about US$1) at the point of access, after which all services and medicines could be accessed. |
| ZIMBABWE | In the National Medicines Policy of Zimbabwe (MOHCW, 2011), opioids are classified as vital drugs but with 'B' availability – meaning that, as a matter of policy, these medicines were to be found at district hospital level or higher but they were not supposed to be stocked at the primary health care level.<br>According to the National Health Strategy of Zimbabwe for 2009–2013 page 9), access to all essential drugs was not good, ranging between "29% and 58% for vital items and 22% to 36% for all items". The aforementioned strategy document also refers to the existence of "financial barriers to access to health and safety nets".<br>Distance-wise, according to the National Health Strategy, by 1997 about 85% of Zimbabwean people were within 8km of a primary health facility; but population dynamics as a consequence of 'agrarian land reforms' had resulted in reduced geographical accessibility. Although Zimbabwe had a user fee policy, treatment for HIV and AIDS was supposed to be free; in reality, there was high out-of-pocket expenditure because essential medicines were not always available in public health facilities and patients had to buy them from the open market. Also, according to the Health Sector Strategic Plan for 2009–2013 (page 85), "In a bid to raise funds to purchase vital and essential medicines and supplies, some institutions have been charging user fees for services that normally would be free." This increases costs for all health services, including palliative care and access to opioid analgesics. |

## *3.3.5 Knowledge, attitudes and practices relating to opioid supply*

### 3.3.5.1 Characteristics of respondents

A total of 88 respondents were recruited for this component of the review (Mozambique = 26, Swaziland =30 and Zimbabwe =32). The majority (63.6%) were female; nurses constituted 51.1% of the sample; and non-medical professionals constituted 20.4% of the sample. For about half (51%) of the sample, the role of the respondents in opioid availability was as a service provider.

Table 9 gives further details of the characteristics of the respondents.

**TABLE 9 Characteristics of respondents**

| CHARACTERISTIC | | COUNTRY | | | TOTAL |
|---|---|---|---|---|---|
| | | Mozambique (n=26) | Swaziland (n=30) | Zimbabwe (n=32) | Total (n=88) |
| Gender | Male | 9(36%) | 15 (50%) | 8(25%) | 32(36.4%) |
| | Female | 17(64%) | 15(50%) | 24(75%) | 56(63.6%) |
| Age categories (years) | ≤ 30 | 8(16%) | 5(16%) | 3(9%) | 16(18.2%) |
| | 31 – 40 | 5(19%) | 12(40%) | 8(25%) | 25(28.4%) |
| | 41 – 50 | 9(35%) | 8(27%) | 13(41%) | 30(34.1%) |
| | ≥51 | 4(15%) | 5(17%) | 8(25%) | 17(19.3%) |
| Professional qualification | Medical doctor | 1(4%) | 5(16%) | 3(9%) | 9(10.2%) |
| | Nurse | 14(54%) | 14(47%) | 17(53%) | 45(51.1%) |
| | Pharmacist | 7(27%) | 2(7%) | 7(22%) | 16(18.2%) |
| | Non-medical | 4(15%) | 9(30%) | 5(16%) | 18(20.4%) |
| Last time in pain management training | <1yr | 7(27%) | 13(43%) | 14(44%) | 34(39%) |
| | 1-5 yrs. | 10(39%) | 9(30%) | 9(28%) | 28(32%) |
| | >5yrs | 9(34%) | 5(17%) | 4(13%) | 18(20%) |
| | Do not know/ missing | 0 | 3(10%) | 5(15%) | 8(9%) |
| Role in opioids availability | Policy formulation | 3(11%) | 8(27%) | 1(3%) | 12(13.2%) |
| | With palliative care programme | 2(8%) | 3(10%) | 7(22%) | 12(13.2%) |
| | Licensing Authority | 1(4%) | 1(3%) | 1(3%) | 3(3.4%) |
| | Service provider | 20(77%) | 9(30%) | 16(50%) | 45(51.1%) |
| | Law enforcement | 0 | 5(17%) | 5(16%) | 10(11.4%) |
| | Other | 0 | 4(13%) | 2(6%)* | 6(6.8%) |

**responsible for licensing … not filled/no information provided/missing*

### 3.3.5.2 Awareness of WHO three-step pain ladder by respondents

The level of awareness about the WHO three-step pain ladder was never 100% among doctors and nurses in the three countries under review. The level of awareness among non-medical staff who participated in the processes for policy, availability and accessibility of opioids in their routine work was below 50% in all instances.

Table 10 gives further details of the respondents' awareness, categorised according to their medical profession.

**TABLE 10 Respondents' awareness of who three-step pain ladder (by profession)**

| PROFESSION | COUNTRY | | | | | |
|---|---|---|---|---|---|---|
| | Mozambique (n=25*) | | Swaziland (n=30) | | Zimbabwe (n=32) | |
| | Aware | n | Aware | n | Aware | n |
| Medical doctor | 0 | 1 | 4 (80%) | 5 | 2(66%) | 3 |
| Nurse | 12(86%) | 14 | 11(79%) | 14 | 13(76%) | 17 |
| Pharmacist | 3(50%) | 6 | 2(100%) | 2 | 3(60%) | 7 |
| Non-medical | 2(50%) | 4 | 1(11%) | 9 | 2(40%) | 5 |
| Overall level of awareness (%) | 17(68%) | 25 | 18(60%) | 30 | 20(62%) | 32 |

**one missing value*

### 3.3.5.3 Knowledge of respondents of opioid estimation and supply

In this review it was assumed that when 70% or more of respondents chose the correct option, on average the respondents were knowledgeable on issues related to opioid consumption, estimates, importation, distribution, storage and prescription.

Overall, from Table 11 it can be seen that, on questions 2.2–2.9 for Swaziland, the nurses, doctors and pharmacists among the respondents were generally knowledgeable. These particular questions were relevant to the national collaboration with the INCB, to inclusion of opioids in relevant policy documents and to national programmes. However, most respondents, including some doctors and pharmacists, were not aware that their country was a signatory to the relevant conventions (see question 2.1, Table 11, Swaziland).

In Mozambique, respondents were generally knowledgeable about questions relevant to the national collaboration with the INCB, the inclusion of opioids in relevant policy documents, and the national programmes. The level of awareness on the country being a signatory to relevant conventions (question 2.1, Table 11, Mozambique) was very low. The four non-medical respondents seemed to be generally more knowledgeable than the nurses and doctors; this was probably because, as revealed by further analysis of the data, three of the four non-medicals had been in training on pain management less than one year before the review.

Respondents in Zimbabwe were generally knowledgeable about questions relevant to the national collaboration with the INCB, the inclusion of opioids in relevant policy documents, and the national programmes. The level of awareness on the country being a signatory to relevant conventions (question 2.1, Table 11, Zimbabwe) was low among doctors and pharmacy staff.

**TABLE 11 Prevalence of correct knowledge on national collaboration with INCB requirements (by profession, across the three countries)**

| Statement of knowledge Yes, aware of national collaboration with INCB requirements | Doc-tors and phar-macists (n=7) | | | Nurses (n= 14) | | | Non-medical staff (n=9) | | |
|---|---|---|---|---|---|---|---|---|---|
| COUNTRY | Swaziland | Mozambique | Zimbabwe | Swaziland | Mozambique | Zimbabwe | Swaziland | Mozambique | Zimbabwe |
| 2.1 My country is signatory to the international drug control conventions. | 3 (43%) | 3 (38%) | 5 (50%) | 6 (43%) | 3 (21%) | 11 (65%) | 6 (67%) | 1 (25%) | 4 (80%) |
| 2.2 Government is required to submit quarterly and annual statistical reports on import and exports. | 6 (86%) | 8 (100%) | 7 (70%) | 11 (79%) | 8 (57%) | 12 (71%) | 5 (56%) | 3 (75%) | 4 (80%) |
| 2.3 The WHO has model drug lists of essential medicines which includes opioid analgesics. | 7 (100%) | 6 (75%) | 9 (90%) | 10 (71%) | 14 (100%) | 12 (71%) | 6 (67%) | 3 (75%) | 4 (80%) |
| 2.4 It is the Government's obligation, in collaboration with the International Narcotics Control Board (INCB), to ensure that opioid analgesics are adequately available. | 7 (100%) | 8 (100%) | 9 (90%) | 13 (93%) | 11 (79%) | 11 (15%) | 6 (67%) | 3 (75%) | 3 (60%) |
| 2.5 INCB recommends that member countries develop a tailored practical method, through national competent authorities, to select, quantify, procure, store, distribute and use controlled medicines including opioid analgesics. | 7 (100%) | 8 (100%) | 7 (70%) | 10 (71%) | 9 (64%) | 12 (71%) | 7 (77%) | 3 (75%) | 4 (80%) |
| 2.6 In a case of underestimation of controlled medicines, the Government has the option of submitting supplementary estimates to the INCB. | 5 (71%) | 3 (38%) | 7 (70%) | 10 (71%) | 4 (28%) | 12 (71%) | 6 (67%) | 2 (50%) | 3 (60%) |

### 3.3.5.4 Awareness on regulating opioid distribution

The level of awareness about regulating the distribution of opioids was good (above 70%) in all three countries for medical personnel (see Table 12).

**TABLE 12 Prevalence of correct knowledge on regulating opioid distribution**

| Statement of knowledge Yes, aware of national collaboration with INCB requirements | Doc-tors and phar-macists (n=7) | | | Nurses (n= 14) | | | Non-medical staff (n=9) | | |
|---|---|---|---|---|---|---|---|---|---|
| COUNTRY | Swaziland | Mozambique | Zimbabwe | Swaziland | Mozambique | Zimbabwe | Swaziland | Mozambique | Zimbabwe |
| 2.7 Government should include the availability and accessibility of controlled medicines, including opioids, for all relevant medical uses in their national pharmaceutical policy plans. | 7 (100%) | 6 (75%) | 9 (90%) | 13 (93%) | 13 (93%) | 14 (82%) | 7 (77%) | 3 (75%) | 4 (80%) |
| 2.8 Access to and availability of strong opioid analgesics should be included in specific national disease control programmes such as that of HIV and AIDS. | 5 (71%) | 6 (75%) | 9 (90%) | 11 (79%) | 12 (86%) | 15 (88%) | 7 (77%) | 3 (75%) | 5 (100%) |
| 2.9 Similar to any other medicine, controlled medicines need to be in stock in order for them to be continuously available for prescription when needed. | 7 (100%) | 7 (87%) | 9 (90%) | 13 (93%) | 13 (93%) | 15 (88%) | 5 (56%) | 3 (75%) | 5 (100%) |

### 3.3.5.5 Awareness on regulating the distribution, storage and prescription of opioids

Regarding questions on regulating the distribution, storage and prescription of opioids, most respondents from Swaziland did not have the desirable knowledge (questions 2.10–2.12, 2.15 and 2.17).

A majority of respondents in Mozambique, as reflected by their responses to questions 2.10, 2.11, 2.12, 2.15 and 2.17, thought that stringent drug controls to stop illicit drug use were necessary yet this is listed by the INCB (2011) as one of the barriers to access. It is also evident that on most issues, some respondents had wrong responses, implying knowledge gaps.

The majority of respondents from Zimbabwe, as reflected by their responses to the same questions, were in favour of stringent drug controls to stop illicit drug use. Nurses and non-medicals did not know that it was the Government's obligation to provide opioids to those that need these medicines. On all issues enquired about, some respondents had wrong responses, implying a lack of the relevant knowledge.

Regarding questions on regulating the distribution, storage and prescription of opioids, almost all

respondents from the three countries were aware of the need to review control and safety measures. Respondents in the three countries were all aware of the need for analgesics among people with HIV and AIDS.

See Table 13 for an analysis of the data relating to these topics.

**TABLE 13 Prevalence of correct knowledge on regulating the distribution, storage and prescription of opioids**

| Statement of knowledge Yes, aware of national collaboration with INCB requirements | Doc-tors and phar-macists (n=7) | | | Nurses (n= 14) | | | Non-medical staff (n=9) | | |
|---|---|---|---|---|---|---|---|---|---|
| COUNTRY | Swaziland | Mozambique | Zimbabwe | Swaziland | Mozambique | Zimbabwe | Swaziland | Mozambique | Zimbabwe |
| 2.10 To avoid illicit use, controlled substances availability should be limited to hospital or large pharmacies with stringent safety measures. | 1 (14%) | 2 (25%) | 2 (20%) | 6 (43%) | 2 (25%) | 7 (41%) | 2 (22%) | 0 (0%) | 0 (0%) |
| 2.11 Very stringent safety measures regarding the storage of opioids are required to ensure prevention of diversion and to improve the availability and affordability of controlled medicines. | 0 (0%) | 0 (0%) | 1 (10%) | 0 (0%) | 0 (0%) | 2 (12%) | 3 (33%) | 1 (25%) | 1 (25%) |
| 2.12 The INCB recommends that, for a pharmacy to be allowed to stock controlled medicines such as opioid analgesics, it must first invest in additional safety measures to ensure safety of its medicines. | 0 (0%) | 1 (12.5%) | 2 (80%) | 0 (0%) | 0 (0%) | 2 (12%) | 1 (11%) | 0 (0%) | 0 0%) |
| 2.13 There is a need to review control and safety measures and the impact on controlled medicines pricing. | 7 (100%) | 5 (63%) | 7 (70%) | 12 (86%) | 13 (93%) | 16 (94%) | 7 (77%) | 3 (75%) | 5 (100%) |
| 2.14 End-stage AIDS patients may suffer from pain, which may require the use of strong opioid analgesics for pain control. | 7 (100%) | 6 (75%) | 9 (90%) | 12 (86%) | 12 (93%) | 14 (82%) | 4 (44%) | 3 (75%) | 4 (80%) |

| Statement of knowledge Yes, aware of national collaboration with INCB requirements | Doc-tors and phar-macists (n=7) | | | Nurses (n= 14) | | | Non-medical staff (n=9) | | |
|---|---|---|---|---|---|---|---|---|---|
| COUNTRY | Swaziland | Mozambique | Zimbabwe | Swaziland | Mozambique | Zimbabwe | Swaziland | Mozambique | Zimbabwe |
| 2.15 Physicians, nurses and other health professionals who are trained and qualified, at all levels of health care, should be allowed to prescribe. | 3 (43%) | 4 (50%) | 3 (30%) | 11 (79%) | 5 (36%) | 13 (76%) | 2 (22%) | 3 (75%) | 1 (20%) |
| 2.16 The medical prescription of opioids for pain control should only be for a limited time. | 5 (71%) | 0 (0%) | 6 (60%) | 7 (50%) | 11 (78%) | 10 (59%) | 2 (22%) | 3 (75%) | 2 (40%) |
| 2.17 To be eligible to receive opioid analgesics, patients must be specifically registered and authorised. | 2 (28%) | 0 (0%) | 3 (30%) | 4 (44%) | 4 (44%) | 7 (50%) | 1 (11%) | 0 (0%) | 1 (20%) |

### *3.3.6 Attitude of respondents regarding opioid consumption estimates and supply chain mechanisms*

Table 14 presents results on the attitude of respondents on consumption estimates, the Government's role, and the importation, storage, distribution and prescription of opioids. The attitudes were negative on all domains. All of the non-medical category of respondents had undesirable attitudes revealed by questions 3.2–3.4 on the subject of government obligations in availability, storage and supply chain.

The questions in this section were closely related to knowledge questions on regulating the storage, stocking and prescription of opioids. The findings in Table 13 show that respondents in this sample were not as knowledgeable as expected on the topic. They also did not have desirable attitudes.

Table 14 shows that the attitudes of all Mozambique respondents on all the issues asked about regarding opioid consumption estimates, importation, storage, distribution and prescription was less than desirable (i.e. most scores were found to be below 70%).

Findings in Table 14 show that in Zimbabwe, only doctors and pharmacists in this sample demonstrated a desirable attitude towards the topics being asked about. Generally, across all other professions, Zimbabwe respondents had less desirable attitudes on all aspects.

Respondents from Swaziland, as the case was in Mozambique, had less than desirable attitudes on all issues asked about regarding opioid consumption estimates, importation, storage, distribution and prescription.

**TABLE 14 Attitudes of participants regarding opioid consumption estimates, importation, storage, distribution and prescription**

| Statement of knowledge Yes, aware of national collaboration with INCB requirements | Doc-tors and phar-macists (n=7) | | | Nurses (n= 14) | | | Non-medical staff (n=9) | | |
|---|---|---|---|---|---|---|---|---|---|
| COUNTRY | Swaziland | Mozambique | Zimbabwe | Swaziland | Mozambique | Zimbabwe | Swaziland | Mozambique | Zimbabwe |
| 3.1 To prevent diversion and illicit use, only the Government should estimate, import, store and distribute opioid analgesics. | 1 (14%) | 1 (14%) | 7 (70%) | 4 (28%) | 4 (28%) | 8 (47%) | 1 (11%) | 1 (11%) | 2 (40%) |
| 3.2 Government's main obligation is to ensure that controlled medicines such as opioid analgesics are not diverted for illicit use. | 2 (28%) | 2 (28%) | 4 (40%) | 1(7%) | 1 (7%) | 3 (18%) | 0 (0%) | 0 (0%) | 0 (0%) |
| 3.3 Stores or pharmacies to be certified for the storage of opioids must, in addition to the usual requirements, have additional specific security. | 1 (14%) | 1 (14%) | 0 (0%) | 1 (7%) | 1(7%) | 2 (12%) | 0 (0%) | 0 (0%) | 0 (0%) |
| 3.4 To ensure prevention of abuse and illicit use, the distribution of controlled medicines, including opioids, should not be combined with that of other non-controlled medicine distribution systems. | 1 (14%) | 1 (14%) | 4 (40%) | 2 (14%) | 2 (14%) | 5 (29%) | 0 (0%) | 0 (0%) | 1 (20%) |
| 3.5 Only pharmacies and hospitals should be permitted to dispense controlled medicines. | 2 (28%) | 2 (28%) | 8 (80%) | 4 (28%) | 4 (28%) | 6 (59%) | 2 (22%) | 2 (22%) | 1 (20%) |
| 3.6 Only medical doctors and pharmacists should be allowed to prescribe opioid analgesics. | 3 (43%) | 3 (43%) | 8 (80%) | 8 (57%) | 8 (57%) | 7 (59%) | 2 (22%) | 2 (22%) | 1 (20%) |

### *3.3.7 Practices regarding opioid consumption estimates and supply chain mechanisms*

## SWAZILAND

In Swaziland, the Office of the Chief Pharmacist was found to be responsible for estimating the required national level of opioid importation. The estimated level was communicated to the INCB by a coordination focal person in the Ministry of Foreign Affairs.

Estimation was done annually. Three factors were considered when estimating opioid needs in Swaziland and these were stated to be:

- The previous year's consumption
- A record of requests for opioids
- Any recorded or observed shortfall.

The Central Medical Stores (CMS, an arm of the Ministry of Health) and the local pharmaceutical wholesalers imported opioids into Swaziland. Before the Medicines Regulatory Authority was in place, the Office of the Chief Pharmacist authorised opioid importation and licences were issued by the Ministry of Trade. Importation could be done at any time during the year. Opioids imported by CMS were stored at CMS storage locations before distribution; wholesalers stored what they had imported. Opioids were collected directly from CMS by a designated health professional for each relevant health facility – they were not loaded onto the distribution trucks like the rest of the essential medicines.

Before prescription, opioids were stored in lockable cabinets within the respective health facilities. Only doctors were generally permitted to prescribe opioids, although pharmacists were allowed to prescribe small quantities for short periods of time.

## MOZAMBIQUE

In Mozambique, pharmacists at the Central Medical Stores were responsible for estimating the national level of opioids required for importation. Estimation was done annually for the whole of the Mozambique national health system.

- The following factors were stated to be considered when estimating opioids needs in Mozambique:
- The previous year's consumption
- The existing stocks at national and provincial levels

Importation of controlled medicines was undertaken by the National Medical Stores (NMS) but with approval from the Pharmaceuticals Department of the Mozambique Ministry of Health. Importation was done annually; but when consumption was more than the imported opioids, supplemental importation was made to top up stock levels. In cases of emergency, importation could be direct but it was normally done through a tendering process where the cheaper tenderer was awarded the contract.

At provincial and district level health facilities, opioids were required to be kept under lock and key.

Morphine and other strong opioid analgesics were only prescribed by doctors, other health cadres only being permitted to prescribe weak opioids such as codeine. Pharmacists were not allowed to change what doctors had prescribed and were only permitted to give one dose before waiting for written instructions from doctors.

### ZIMBABWE

Estimation of the need for opioids in Zimbabwe was done annually. The Medicines Control Authority of Zimbabwe (MCAZ) was responsible for estimation and it also authorised the importation of opioids. Estimation was done once a year but supplemental importation was done if there was need. Importation was found to be undertaken by licensed wholesalers, and they also distributed the medicines.

The same distribution channel as for other medicines was used, but the transportation of opioids was done under lock and key. Also, only authorised persons were allowed to handle the controlled substances. In hospitals, there were lockable drawers for storing 'Dangerous Drugs'. Drugs were dispensed by registered nurses or pharmacy technicians. Estimation was reported to be based on usage of the substances for the previous year.

## 3.4 Discussion of results

### *3.4.1 Discussion of country-specific findings*

### SWAZILAND

There are six headings under which topics worthy of discussion for Swaziland can be grouped, as set out next.

***Knowledge of respondents regarding opioid consumption estimates, importation, storage, distribution and prescription***

Findings showed that nurses, doctors and pharmacists in the Swaziland sample – although there were some anomalies – were generally more knowledgeable than non-medical people at policy level on issues pertinent to regulating opioids, their distribution and the national collaboration with the INCB (see Tables 11 and 12 above). Respondents' knowledge about the storage, distribution and prescription of opioids suggested that they believed in very stringent measures as a necessity to avoid illicit use of such drugs – but those measures were found to be a barrier to opioid access since it meant that people at policy level could demand that the technical people who were involved in the storage, distribution and prescription of opioids must have additional measures in place to reduce the probability of illicit use. Given that some measures are necessary, they should not be excessively tight (INCB, 2011).

Additional measures could also increase costs and contribute to a reluctance to prescribe. In the Swaziland FGD, participants noted that prescribers were reluctant to prescribe for fear of breaking the law. According to the INCB (2011, page 1), "inadequate knowledge and fear of dependence are key reasons behind the unwillingness of health professionals to prescribe controlled substances".

Respondents in Swaziland were aware of the need to review control measures for handling opioid analgesics (see Table 13 above) and this validated the need to implement new laws to replace the outdated Acts of the 1920s.

## 2 *Attitudes of participants regarding opioid consumption estimates, importation, storage, distribution and prescription*

The findings for Swaziland in Table 14 above imply that respondents' attitudes were undesirable and inclined more towards control as a responsibility of Government and technical personnel rather than towards ensuring the availability of opioids for medical use. The INCB recommends that those in authority should aim at taking a balanced approach that ensures access as well as preventing illicit use. The findings in Swaziland were in agreement with evidence from the INCB (2012a), where the obstacles of the attitude and awareness of health workers and other stakeholders are described as one of the barriers to access.

## 3 *Practices in regard to opioid consumption estimates and supply chain mechanisms*

Concerning estimates of Swaziland's need for opioids, the review findings showed that estimates were based on the previous year's consumption, a record of requests for opioids, and any recorded or observed shortfall. According to the INCB (2012a), this is consumption-based method of estimation. The INCB (2012a, page 11) suggests that this method works best under the following circumstances:

- When reliable data on past use is available
- Where the demand for health care services has reached a relatively steady level
- When the demands of the health care system are met by a well-functioning supply management system that ensures an uninterrupted supply of controlled substances.

With regard to these constraints on the estimation method, the available literature on Swaziland's records of controlled drugs suggests that data was not as reliable (nor available) as required. For example, the INCB (2012b) report on narcotic drugs states that some countries, Swaziland included, did not submit statistics for the period 2009–2011. Furthermore, literature by the University of Wisconsin-Madson (2013) indicates that, by the time of publication, Swaziland had not submitted reports to the INCB for 2012 either. The dynamic HIV epidemic in Swaziland, with a prevalence of 26.2%, is another challenge, suggesting that health care services had not reached a steady level. This literature implies that using a consumption-based approach in a country where records are largely incomplete and where demand for health services might not yet be steady may yield an inaccurate estimate of required controlled medicines.

Certainly, as seen in Table 3 above, Swaziland's consumption of morphine equivalent in the year 2012 was very low and most of the sick that needed strong analgesics did not get them. It is therefore reasonable to assume that Swaziland's estimates and use were far below the levels required to meet actual need in that year.

## 4 *Opioid policy and legislation issues*

The review findings revealed that Swaziland was at a time of transition, from use of outdated legislation (eg, the 1929 Pharmacy Act and 1922 Opium and Habit Forming Drugs Act) and an absence of relevant policies (and therefore with little or no national regulation), to a time of availability of relevant policies for palliative care and opioid availability. The dearth of regulation probably partly explains why Swaziland was described by the INCB (2012b) as one of the countries in Southern Africa where cannabis growing existed. If the policies reviewed were fully implemented, this situation could change.

The policies reviewed were all developed between 2011 and 2014, and this was a commendable effort. The African Palliative Care Association, based on acknowledgements in Swaziland's Palliative Care Policy (2011), National Palliative Care Guidelines (2011) and National Palliative Care Trainees' Manual (2012), played a key role in bringing about this transition. A clear gap in these policies was the fact that prescription was still limited to registered doctors and yet these were few: Swaziland had an average of only 1 doctor per 5,600 of the population in 2014 (WHO recommends 1 per 600). Another possible challenge, according to Swaziland's National Pharmaceuticals Policy of 2011, relates to the implementation of these policies: human and financial resources remain limited and this may slow the implementation process.

### 5 *Cost of opioids and geographical coverage*

Like most other African countries, more than 70% of Swazis live in rural areas where services are fewer than in urban areas. This is compounded by the fact that in Swaziland only doctors are allowed to prescribe opioid analgesics and yet they are few and mostly located in urban areas (as validated in the Swaziland FGD findings). This limits access to opioids by the communities in rural areas. A user fee, although small, may also be a barrier to access in a country where more than two-thirds of the population (69%) live below the poverty line (World Bank, 2014a).

### 6 *Health care worker issues*

Swaziland had inadequate human resources for health and, according to Swaziland's Human Resources for Health Policy (MoH 2012d) the skills mix was also poor. This situation was considered likely to affect palliative care even more than other specialisms, given the fact that it is a relatively new consideration. The prescription of opioid analgesics was still limited to doctors who were, according to the Swaziland FGD, mostly urban-based and very few in number at 17.72 per 100,000 according WHO, 2014). Training capacity for health workers also seemed very limited, with only nurses being trained locally at the time of data collection.

## MOZAMBIQUE

There are six headings under which topics worthy of discussion for Mozambique can be grouped, as set out next.

### 1 *Knowledge of respondents regarding opioid consumption estimates, importation, storage, distribution and prescription*

The review findings showed that respondents in Mozambique were knowledgeable on some of the key issues, such as the responsibility of the Mozambique Government to provide opioid analgesics, the need for appropriate policies, and the occurrence of pain in end-stage AIDS patients (Tables 11–12 above). Findings, however, revealed that most respondents thought that stringent measures on importation, storage and prescription were necessary for minimising illicit use (Table 13 above). Whereas there is need to be careful, the key according to the INCB (2011) is to strike a balance to ensure that illicit use is prevented but not at the cost of reducing access and availability of opioid analgesics to those in need of pain control.

### 2 *Attitudes of participants regarding opioid consumption estimates, importation, storage, distribution and prescription*

According to the INCB (2012b:36) barriers to opioid use include "inadequate knowledge, misinformation and negative attitudes about controlled substances", and examination of Table 14 above shows that, on almost all statements of attitude that were enquired about, respondents

from Mozambique had undesirable responses. This might be related to the fact that palliative care is still a new concept in Mozambique (Monjane, 2013).

## 3 *Practices in regard to opioid consumption estimates and supply chain mechanisms*

Opioids in Mozambique were found to be imported through a tendering process, and one of the weaknesses identified was that usually the cheaper bidder was hired to import but the chosen organisation did not always have the right papers and this delayed the process. Also, opioids in Mozambique were transported by air to the different parts of the country. This was necessary because the country is large and roads to some rural areas are not good, but it is an expensive process and resources are limited. Also, estimation (which was consumption-based) did not seem to be accurate enough to meet the needs of people in pain in Mozambique. The consumption-based method, according to the INCB (2012), is dependent on reliable data on past use and is best applied where the demand for health care services has reached a relatively steady level.

These conditions were not immediately apparent in Mozambique: data on past use may not be readily available and may not be complete, although Mozambique had made some progress as evidenced by the fact that the INCB had current statistics on the country. The HIV/AIDS epidemic was still dynamic in Mozambique in 2014 and it was the second-highest cause of death after malaria. These factors suggested that the current estimates were likely to be below required levels and this was specifically implied by literature from Treat the Pain, which shows that Mozambique consumed about 4.7kg of morphine equivalent in 2012 and yet the minimum needed was calculated as 322kg.This very large gap implies that the estimates by technical people in Mozambique were much less than what was actually required.

## 4 *Opioid policy and legislation issues*

A number of policy documents relevant to opioid availability in Mozambique were reviewed and these included ;

- Palliative Care Policy (2012)
- Standards for Providing Palliative Care in Africa
- Pocket Guide to Pain Management in Africa
- Health Sector Strategic Plan (2013–2017)
- National Formulary of Medicines (Formulario Nacional De Medicamentos)
- National Strategic HIV and AIDS Response Plan, 2010–2014

The Palliative Care National Standards and the pocket guide were developed by APCA and adopted by Mozambique. The Act for Controlled Medicines, which dates from 1997 and has not been revised since, is silent on the availability and accessibility of opioids. The HIV and AIDS Response Plan mentions palliative care but very briefly under home-based care. Thus the policy environment – especially for access to pain control medicines for those living with HIV or AIDS – still had gaps and yet HIV, with a prevalence of 11.5%, was responsible for about 26% of the deaths in Mozambique in 2012 (MoH, 2013).

### 5 Cost of opioids and geographical coverage

In Mozambique, findings in this review imply that users travel long distances to access health services, including access to opioid analgesics. This was due to the fact that the health facilities (hospitals only) where opioid analgesics could be available are very few in a relatively large country and thus users would have to travel long distances to access services. This could be associated with transport costs and yet many Mozambicans (82% according to World Bank (2014a)) live below the poverty line. The resources to import opioid analgesics were also limited, given that Mozambique is a low-income country. This situation sometimes contributed to stockouts, since dollars were needed to import the opioids.

### 6 Health care worker issues

Mozambique is one of the 57 countries listed by the World Health Organization with a critical shortage of human resources for health (WHO, 2006). According to Mozambique's HSSP (MoH, 2013) the Mozambique public health sector is run by approximately 34,500 health workers and only 3.2% of these are doctors. The country had a health workforce density of 0.3 per 1000, whereas WHO recommends a minimum of 2.28/1000 (WHO, 2006). These factors, combined with the fact that, in Mozambique, only doctors were found to be allowed to prescribe opioids, limited access even more. Limited knowledge and inappropriate attitudes worsened the situation. These findings agree with the limiting factors listed by Monjane (2013) as well as barriers listed by the INCB (2011).

## ZIMBABWE

The same six headings can be used to discuss the findings for Zimbabwean respondents, as set out next.

### 1 Knowledge of respondents regarding opioid consumption estimates, importation, storage, distribution and prescription

The findings in Tables 11, 12 and 13 above show that respondents from Zimbabwe lacked knowledge relevant to an improvement in the availability and accessibility of opioids. In particular, based on Table 13, participants believed that stringent measures were the right course of action to ensure the prevention of illicit use of opioids, yet the INCB (2011) mentions official Zimbabwean policies that are stricter than the international drug control conventions as one of the barriers to access. The Situation Analysis Report on Palliative Care in Zimbabwe (HOSPAZ, 2012a) also cites lack of knowledge among nurse managers and among patients as one of the barriers to the provision of palliative care in Zimbabwe.

Most respondents, with the exception of doctors and pharmacists, did not know that it was the Zimbabwean Government's obligation to ensure that opioid analgesics were available and accessible in the country. However, most respondents in this review were aware of the need to review the control measures for handling opioid analgesics, which validated the need pointed out in the Zimbabwe FGD to review the Dangerous Drugs Act of 2001.

### 2 Attitudes of participants regarding opioid consumption estimates, importation, storage, distribution and prescription

Examination of Table 14 above shows that on almost all statements of attitude given, respondents from Zimbabwe had undesirable responses. It was only doctors and pharmacists who had desirable attitudes towards the prescription and dispensing of opioids. Barriers to opioid use were known to include negative or biased attitudes (INCB, 2012b).

## 3 Opioid policy and legislation issues

A number of legal and policy documents relevant to opioid availability in Zimbabwe were reviewed and these included:

- The Constitution of the Republic of Zimbabwe
- Dangerous Drugs Act 2001
- Zimbabwe National Medicine Policy (MOHCW, 2011)
- Essential Drugs List and Treatment Guidelines (MOHCW, 2006)
- Palliative Care Standards for Zimbabwe (2009)
- Zimbabwe National HIV and AIDS Strategic Plan 2011–2015
- The National Health Strategy for Zimbabwe 2009–2013.

The phrase 'dangerous drugs' is a stigmatising term discouraged by the INCB (2011). Such language was likely to confuse the users and prescribers of narcotics. The Dangerous Drugs Act (Chapter 15:02) focuses on the control of illicit imports/exports, and the utilisation or possession of the dangerous substances. There is no evidence to the effect that the law facilitates availability of narcotics for medical and scientific purposes but instead it focuses on the control of illicit availability and use. The literature from Treat the Pain (2014) suggests that more needs to be done to improve the legal and policy environment because the percentage gap in coverage of deaths in pain between those with and those without analgesics in Zimbabwe was 94.3% in 2012. Overly restrictive laws and inadequate policies may be contributing to this situation.

## 4 Estimation procedures

The review findings showed that the method of estimation of opioid requirements for Zimbabwe, like in the other countries of the review, was consumption-based. It was noted, according to the INCB (2012), that this method depends on reliable data from past use, and is best applied where the demand for health care services has reached a relatively steady level. These conditions were not prevalent in Zimbabwe: data on past use might not always be readily available and might not be complete, although Zimbabwe had made some progress as evidenced by the fact that the INCB had current statistics on the country and also WHPCA had upgraded Zimbabwe from level 3 to a level where palliative care is at preliminary health system integration. The HIV/AIDS epidemic was still dynamic in Zimbabwe in 2014 and it was the highest cause of deaths. Although the situation regarding palliative care was improving, estimates of opioid need were judged to be far below actual need – as specifically implied by literature from Treat the Pain, which shows that Zimbabwe consumed about 10.1kg of morphine equivalent in 2012 and yet the minimum needed was 177kg.

## 5 Cost of opioids and geographical coverage

In Zimbabwe, opioid analgesics are restricted to hospitals. Some health facilities were also said to charge user fees even for treating pain in diseases which by policy they should not be charging for. This seemed to have occurred in an effort to find resources to sustain the services in a situation where government funding is inadequate. This scenario, in a country with 72% of the

population living below the poverty line, creates a barrier to access to opioid analgesics (World Bank, 2014a).

**6 *Health care worker issues***

In Zimbabwe, prescription of opioid analgesics is limited to doctors and clinical officers; nurses may only prescribe with written permission from the Permanent Secretary of the Zimbabwe MoH (HOSPAZa, 2012). Doctors in Zimbabwe are very few, as seen from the health-worker-to-population ratio of 1.23 per 1000 (MoH Zimbabwe, 2014). This health worker scenario, combined with the fact that opioid analgesics are limited to hospitals only, most of which are urban based, increases barriers to access.

### *3.4.2 Discussion of cross-cutting issues*

Five topics are worthy of further discussion under this heading, where the country-specific findings are common across the countries involved in the review. Comments are set out next.

#### 3.4.2.1 Knowledge of respondents regarding opioid consumption estimates, importation, storage, distribution and prescription

The review findings showed that gaps in knowledge regarding opioid consumption estimates, importation, storage, distribution and prescription were prevalent in the three countries among all respondents who comprised policy officials and technical people responsible for availability and accessibility of opioids analgesics (see Tables 11–13 above). In particular, respondents in Swaziland, Mozambique and Zimbabwe believed in very stringent measures to ensure the prevention of illicit use. Respondents across the three countries did not seem to know that, in addition to being responsible for the prevention of illicit use, governments were also responsible for ensuring availability of opioid analgesics for those who need them. These findings were consistent with barriers listed by the INCB (2012), where inadequate and/or outdated knowledge are described as barriers to rational use of opioid analgesics. However, findings in Table 13 show that awareness of a need to review controls was high among respondents in the three countries.

#### 3.4.2.2 Attitudes of participants regarding opioid consumption estimates, importation, storage, distribution and prescription

Across the three countries, with the exception of doctors and pharmacists from Zimbabwe on prescription-writing and dispensing, the attitudes of respondents regarding opioid consumption estimates, importation, storage, distribution and prescription were undesirable (see Table 14 above). Undesirable attitudes are a major barrier to opioid availability; especially if the poor attitudes are among the policy officials and technical people responsible for prescription and dispensing, such as doctors, nurses and pharmacists (INCB, 2012). Undesirable attitudes may be related to a lack of knowledge, to believing myths contrary to scientific evidence, and to fears about drug side effects. Undesirable attitudes among policy and technical officials can contribute to policy and distribution barriers (INCB, 2012).

#### 3.4.2.3 Opioid policy and legislation issues

The policy environment in relation to the availability of opioid analgesics, especially in Swaziland and Zimbabwe, was found to have improved. Mozambique was still lagging behind, but the Government approved a palliative care policy in 2012 (Monjane, 2013) and the country now has a functional palliative care association. Legislation, however – especially in Mozambique and Zimbabwe – is still outdated and the laws supporting the implementation of relevant policies require revision. The INCB (2011) describes outdated laws as one of the barriers to opioid access. If the laws that provide the principles to guide implementation are outdated, then implementation of new policies cannot be effective.

#### 3.4.2.4 Estimation procedures

The method of estimation for national opioid requirements that was prevalent in all three countries under review was consumption-based. This method, according to the INCB (2012), depends on reliable data from past use, and it is best applied where the demand for health care services has reached a relatively steady level. Bearing in mind the high and dynamic HIV prevalence and the growing problem of non-communicable diseases in the three countries, using a consumption-based estimation procedure would not yield accurate estimates without considering morbidity and facility data. Statistics from Treat The Pain (2014) showed that the actual consumption of opioid analgesics in the three countries was far below the estimated need (see Table 4 above) and an inaccurate estimation procedure may be one of the responsible factors.

There are two other estimation methods described by the INCB (2012): the service-based method, where current levels of use of each controlled substance in a sample of standard facilities is used as a basis for calculating the national requirement; and the morbidity-based method, which calculates the requirements for controlled substances based on morbidity data and on treatment guidelines for the health problems in question. These perhaps need to be considered by the three Governments as better methods for estimation.

#### 3.4.2.5 Health care worker issues

Statistics by the World Health Organization show that the three countries in the study were all experiencing critical shortages of health workers (WHO, 2014). The densities of skilled professionals per 100,000 people, according to the WHO (2014) were 3.7, 17.72 and 13.13 in Mozambique, Swaziland and Zimbabwe respectively. Compared with the WHO (2006) recommended minimum density of 228 per 100,000 population, the three countries were found to have critical shortages of skilled human resources for health, with Mozambique having the worst situation.

Statistics by the WHO (2014) show that doctors were even scarcer than other cadres such as nurses, yet prescription of opioids was limited to doctors in Swaziland and in Mozambique. In Zimbabwe, clinical officers could also prescribe but nurses could only prescribe with written permission from the Permanent Secretary of the Zimbabwe MoH. Scarcity of human resources for health, combined with a restriction of prescribing to doctors alone, who are very few, would certainly impede access to opioids in these countries.

## 3.5 Country-specific conclusions

### *3.5.1 Swaziland*

#### 3.5.1.1 Attitudes and knowledge of respondents regarding opioid consumption estimates, importation, storage, distribution and prescription

Based on the findings in Tables 11 to 13 above, it is evident that the various policy officials, technical people and officials from each drug control unit in the samples had inadequate knowledge regarding opioid consumption estimates, importation, storage, distribution and prescription. Table 14 indicates generally undesirable attitudes among the respondents regarding the same aspects of opioid control.

#### 3.5.1.2 Opioid policy and legislation issues

With the support of APCA and other stakeholders, since 2011 Swaziland had made commendable improvement in the policy environment for availability of and access to opioid analgesics. The outdated medicine control laws were in the process of being replaced by 2012 bills. However, only one category of health workers, namely doctors, were authorised by law to prescribe strong analgesics, yet doctors were also generally reluctant to do so, in addition to being critically scarce in number throughout the country.

#### 3.5.1.3 Estimation procedures

The consumption-based method of estimating levels of opioid that are required nationally each year, which Swaziland uses, does not yield accurate estimates in contexts like that of Swaziland. Current estimates by the Swaziland MoH are likely to continue to be far below the actual demand for opioid analgesics unless the estimation method is improved (INCB, 2012).

#### 3.5.1.4 Health worker issues

The combination of a critical shortage of health workers and the limitation on prescription solely to doctors increases the barriers to opioid access in Swaziland.

### *3.5.2 Mozambique*

#### 3.5.2.1 Attitudes and knowledge of respondents regarding opioid consumption estimates, importation, storage, distribution and prescription

In Mozambique, there was limited knowledge, especially regarding working towards a balance between straightforward access for those needing controlled drugs for their illness and the prevention of the illicit use of opioids. The attitudes of respondents suggested that they understood the primary responsibility of their Government to be that of controlling the illicit use of opioids. Findings from the review sample suggest that the respondents did not know that their Government and its technical people, in addition to being responsible for the prevention of illicit use, were also responsible for ensuring the appropriate availability of opioids for moderate to strong pain control.

#### 3.5.2.2 Opioid policy and legislation issues

Mozambique's palliative care policy was approved by its Ministry of Health in 2012 and opioids were listed in the National Formulary (2007) as essential medicines. However, the Controlled Drugs Act of 1997 does not create a supportive environment for opioid availability; moreover, the HIV/AIDS Response Strategic Plan of 2012 does not adequately address palliative care. Palliative care was also

not yet widely integrated into other health policies (Monjane, 2013) and the prescription of strong opioids was limited to doctors, who were critically few in number. The policy and legal environment for availability of opioid analgesics is therefore not yet sufficiently favourable for supporting the general population when they face painful and life-threatening disease.

#### 3.5.2.3 Estimation procedures

The findings in this review meant that the method of estimation of national annual opioid requirements for Mozambique was consumption-based. This method is said not to be accurate in contexts like that of Mozambique, and improvements in the method used would significantly improve the situation.

#### 3.5.2.4 Health worker issues

Health workers in Mozambique are very few. The limitation of prescribing strong analgesics solely to doctors, as well the sparse hospitals in a large country where those doctors are based, limits access to pain relief and other palliative care benefits to patients.

### *3.5.3 Zimbabwe*

#### 3.5.3.1 Attitudes and knowledge of respondents regarding opioid consumption estimates, importation, storage, distribution and prescription

In Zimbabwe, among the respondents in this review there was limited knowledge, particularly regarding the Zimbabwe Government's responsibilities. The attitudes of respondents regarding opioid consumption estimates, importation, storage, distribution and prescription were also generally undesirable.

#### 3.5.3.2 Opioid policy and legislation issues

The relevant policies for availability of opioid analgesics in Zimbabwe were found to be in place but the law for controlled medicines, the Dangerous Drugs Act 1997, requires revision as it is outdated.

#### 3.5.3.3 Estimation procedures

Findings imply that Zimbabwe, like Swaziland and Mozambique, uses a consumption-based method of estimation – which, according to the INCB (2012), does not yield accurate estimates in such contexts as that of Zimbabwe. Inaccurate estimating might be contributing to the dismal consumption of opioid analgesics in Zimbabwe as per data from Treat the Pain (2014).

#### 3.5.3.4 Health worker issues

Zimbabwe, like Swaziland and Mozambique, has a critical shortage of health workers; and although clinical officers and nurses may prescribe when permitted, still the shortage of health workers impacts availability and accessibility of opioids negatively.

## 3.6 Conclusions on cross-cutting issues

The context of the review countries is such that health service access, including palliative care and thus access to opioid analgesics, could be limited by a number of factors:

- The Human Development Index rankings for the review countries in 2013 were 148th, 156th and 178th for Swaziland, Zimbabwe and Mozambique, respectively (UNDP, 2014).
- With the exception of Swaziland, the other two review countries had lower per-capita expenditure on health than the minimum of US$44 recommended by the World Health Organization. The per-capita expenditures for 2012 were US$448 for Swaziland, US$28 for Zimbabwe and US$40 for Mozambique (WHO & Global Health Observatory, 2014; Zimbabwe Ministry of Finance, 2013; World Bank, 2015).
- The proportion of people living below the poverty line in 2009 was 69% for Swaziland, 71% for Zimbabwe and 82% for Mozambique (World Bank, 2014a).
- The 2013 out-of-pocket health expenditure was 42% for Swaziland and 11.9% for Mozambique. (World Bank, 2014b), For Zimbabwe, available literature states that out-of-pocket expenditure was 29% in the year 2009 (MoH Zimbabwe, 2009)
- The HIV prevalence in the review countries was considered high, being 26.2% for Swaziland, 15.0% for Zimbabwe and 11.1% for Mozambique in 2012. (UNAIDS 2012)

Thus these are countries with limited human and other resources, high out-of-pocket expenditure (Zimbabwe and Swaziland) but with a big burden of disease as evidenced by the high HIV prevalence. Such a context is likely to have poor access to health services in general. It is therefore not surprising that opioid access and consumption is less than 5% (Table 4) of the expected minimum for all the review countries as per data from Treat the Pain (2014). The opioid estimation procedures in the three countries of the review was noted to be consumption-based, and prescription was limited to doctors except in Zimbabwe; yet the number of human resources available for health services in the region is poor. It was found that the policy environment for opioid availability and access was improving but the relevant laws were outdated.

Based on the findings in this study, it can be predicted that even if enough opioid could be imported in sufficient quantities, the probability was high that much of it would not be used because of the scarcity of health workers and the restrictions on who is permitted to prescribe drugs, as well as a lack of knowledge, a reluctance to prescribe and undesirable attitudes. High out-of-pocket expenditure is associated with poor access and high rates of catastrophic health expenditures (WHO, 2010). Thus progress towards improved availability and access cannot be achieved quickly. Long-term, low-cost consistent efforts to holistically address all the barriers to access that have been identified should be made.

## 3.7 Country-specific recommendations

### *3.7.1 Recommendations for Swaziland*

Recommendations for Swaziland fall into four categories, as follows:

- It is recommended that Swaziland's Ministry of Health, working through the Swaziland National AIDS Program (SNAP):
  - Establishes a palliative care technical working group or national palliative care committee to focus on advocating, facilitating and integrating palliative care at all levels and in training institutions' curricula
  - Advocates for at least one more category of health workers to be permitted to prescribe opioids in Swaziland. This is necessary since the health workers, particularly doctors, were described as in acute shortage and urban-based (Swaziland National Pharmaceutical Policy of 2011). If only doctors are permitted to prescribe, this limits access to opioids in a community where doctors are not easily accessible. It is recommended that nurses be trained and allowed to prescribe opioids. According to the INCB (2011), nurse prescribing can be useful in situations where there is a shortage of physicians – as is the case in Swaziland, where there were 10 doctors per 100,000 and 56 nurses per 100,000 people in 2012 (MoH Swaziland, 2012a).
- The INCB (2012) recommends that at least a combination of two approaches be used to estimate national opioid requirements in contexts like that of Swaziland where statistics may not be complete, the health needs are dynamic and where supply chain management may not be adequate. Swaziland could use both past consumption records and morbidity-based data. It is recommended that the Swaziland Ministry of Health, through the Office of the Chief Pharmacist and in consultation with INCB as well APCA, critically review the estimation method and come up with a more accurate method of estimation for the Swaziland context.
- Reluctance to prescribe may be caused by believing myths or by a lack of adequate knowledge. It is recommended that APCA continues to facilitate the organisation of trainings for:
  - Officers at policy level
  - Prescribers to be equipped with the necessary knowledge and skills to handle opioids without fear.
- The Swaziland policy documents which were relevant to opioid availability were reasonable. What was lacking was a relevant law to back them up. This was in the pipeline in the form of the Medicines and Pharmacy Acts of 2012. Passing these Bills into law may require some level of advocacy by the Ministry of Health, perhaps in collaboration with APCA.

- In the National Pharmaceutical Policy of 2011, page 10, it is stated: "Health sector funding is limited and has declined over time, and it falls short of the 15% of the national budget recommended by the Abuja Declaration …". In the policy documents reviewed, it was not clear how the palliative care described will be funded; yet it was clear that resources were limited. This calls for advocacy by the officials in the Palliative Care Desk Officefor consistent funding to be allocated by the Ministry of Health for palliative care activities, including the provision of opioids.

### 3.7.2 Recommendations for Mozambique

- There are seven main areas of recommendation for Mozambique, as follows:

- It is recommended that there be a review the Controlled Medicines Act of 1997 to provide a supportive legal environment for opioid access. This is a big task requiring cooperation between legislators and technical people, but it is important for it to be done. The Mozambique Palliative Care Association could take the lead in this but will need support from APCA.

- Palliative care should be integrated into all health policies, including disease-specific policies such as the HIV or cancer strategic plans. The Mozambique Palliative Care Association could provide a lead in this.

- Fear of, and heightened concern with, the possibility of drug abuse, according to the INCB (2011), leads to development of "overly restrictive regulations". This situation requires a systematic training programme for policy and technical people dealing with opioids in order to improve their knowledge levels regarding opioid use for medical and scientific purposes. Provision of knowledge in a systematic and consistent way could also eventually affect the attitudes of relevant officials. The Mozambique Palliative Care Association should also take the lead by collaborating with APCA and the Government of Mozambique to organise training courses to target relevant health workers and training schools. More generally, palliative care content should be integrated into the curricula in training schools for health workers in Mozambique.

- The amount of morphine used in Mozambique was found to be very low compared with what was estimated by Treat the Pain (2012) to be the minimum required for the estimated pain burden. One of the areas that need improvement was the estimation of national opioid requirements. It should, however, be pointed out that this should be a gradual process and should be integrated with other changes, because even if the minimum amount of morphine required is provided, the health system in Mozambique may not be ready to use it competently since there are very few health workers authorised to prescribe it. However, it is recommended that the technical people in the Joint Medical Store review the estimation procedure to make sure that, within the current resources, what could be competently utilised is available. This they could do in collaboration with APCA and the INCB.

- The health worker population ratio was found to be very low, with only 4 doctors and 39 nurses per 100,000 people. Restricting prescribing to doctors was therefore considered a major impediment to opioid availability in Mozambique. It is therefore recommended that at least one more category of health worker be empowered to prescribe opioids. The Mozambique Palliative Care Association, in collaboration with APCA, should consistently advocate for this until at least one more category is permitted to prescribe opioids in Mozambique.

- It is recommended that palliative care activities be budgeted for, in order to avail resources that will enable the growth of infant palliative care services in Mozambique. The Mozambique Palliative Care Association should take the lead to advocate for this budget allocation.

### 3.7.3 Recommendations for Zimbabwe

For Zimbabwe, five areas of recommendation can be set out, as follows:

- It is recommended that there should be a review of the Dangerous Drugs Act to remove terms like 'dangerous' and 'narcotics'. This will contribute towards a reduction in any reluctance to prescribe opioids.

- Lack of relevant knowledge regarding rational use of opioid analgesics may lead to a reluctance to prescribe them even when they may be available. Fear of, and heightened concern with, the possibility of abuse, according to the INCB (2011), leads to the development of "overly restrictive regulations". This situation requires a systematic training programme for policy and technical people dealing with opioids to improve knowledge levels regarding opioid use for medical and scientific purposes. Provision of knowledge in a systematic and consistent way may also eventually affect the attitudes of the relevant officials. It is recommended that HOSPAZ, in collaboration with APCA, should work with the Zimbabwe Ministry of Health to organise training courses targeting relevant cadres of health workers.

- Relevant knowledge on the rational use of opioid analgesics should be integrated in the curriculum for health workers in medical and nursing schools. It is recommended that HOSPAZ, in collaboration with APCA, should advocate for this necessary change.

- The amount of morphine used in Zimbabwe in 2012 was very low, being only 10.1kg out of the expected 177kg estimated by Treat the Pain (2012) to be the minimum required for the burden of pain. One of the areas that need improvement is the estimation of national opioid requirements – although, it should be pointed out that this should be a gradual process and should be integrated with other changes because even if the minimum amount of morphine required is provided, the health system in Zimbabwe may not be ready to use it competently because of the shortage of the health workforce and other resources. Even so, it is recommended that MCAZ, in consultation with INCB, should review the estimation procedure to make sure that, with the current resources, what could be competently utilised is available. The current minimal use of morphine, despite much greater practical need for its use, should be communicated clearly to key stakeholders. This can be done by HOSPAZ in collaboration with APCA through meetings and publications.

- The health-worker-to-population ratio is very low, with only 1.23 health workers per 1000 of the population. It is recognised that doctors and clinical officers are permitted in Zimbabwe to prescribe, but these cadres are very few in number. It is recommended that the need for nurses trained in palliative care to get permission from the Permanent Secretary of the MoH in order to prescribe strong analgesics should be reviewed, because it is an obstacle to the prompt administration of essential opioid analgesics. HOSPAZ working with the Zimbabwe Ministry of Health, and in collaboration with APCA, should take the lead in advocating for these necessary legal and policy changes.

## 3.8 General recommendations

In terms of generally expressed recommendations, the following eight should be taken forward and seriously considered by the relevant authorities:

- There needs to be an increase in the 'visibility' of palliative care issues through operational research and publications in peer-reviewed journals and other national and international forums.

The national palliative care association in Zimbabwe and in Mozambique, as well as the palliative care desk in the Swaziland Ministry of health, in collaboration with APCA should take action on this

- In consideration of the context, low-cost interventions such as task shifting should be advocated for, in order to allow nurses to prescribe in Swaziland and Mozambique. The national palliative care association in Mozambique and the palliative care desk in the Swaziland Ministry of health should take the lead in implementation of this recommendation

- There should be policy changes to integrate palliative care into all levels of the national health system, so that those in need of pain relief do not have to travel long distances to reach hospitals. Moreover, there should be advocacy for palliative care content to be integrated in nursing, medical and other health workers' training curricula. APCA, collaborating with national palliative care associations, should advocate for palliative care to be included in health curricula to ensure that graduating health care workers are sufficiently prepared to practice palliative care without knowledge gaps and undesirable attitudes.

- There is a scarcity of human resources for health workers in the review countries. It is likely that palliative care is even more affected than other specialisms of health services, since it is a developing service in most African countries as evidenced in the literature by the Worldwide Hospice Palliative Care Alliance (WHPCA, 2014). APCA should advocate for, facilitate or engage in research to describe the situation of palliative care human resources and suggest realistic remedial actions for African countries. In the meantime, it is recommended that the road map for scaling up human resources for health for improved health service delivery in the African region 2012–2025 be adapted by each of the reviewed countries (WHO, 2012).

- In the three countries of the review, the policy environment was found to be improving, particularly in Swaziland and Zimbabwe. Nonetheless, the laws to enforce the policies need revision and it is recommended that APCA should collaborate with the national palliative care associations and Ministries of Health to advocate for relevant revisions. Otherwise the policies will not be implemented properly.

- Access to all health services in the review countries is limited, partly because prepaid systems of financing are minimal and out-of-pocket expenses are thus high (WHO, 2010). Advocating for national prepaid systems of financing could help improve access to palliative care in these countries. Advocacy for prepaid systems should be done by the ministries of health in collaboration with WHO.

- The three countries of the review were found to be using a consumption-based method of estimation for national opioid requirements, yet this method, according to the INCB (2012), does not give accurate estimates in contexts where data may not accurate and where the disease burden is still very dynamic – as is the case in the three countries reviewed. APCA could work with these countries and modify this approach to estimating demand, to suit each country's situation. The guidelines by APCA (2010b) on ensuring patient access to, and safe management of, controlled medicines should be better publicised so that the information in them is used by the three countries.

# APPENDICES

# APPENDIX A
## An overview of literature on opioid availability for medical and scientific use at the global level

Pain relief is an essential component of palliative care and access to pain relief is an essential human right (Help the Hospices, 2007). The constitution of the World Health Organization (WHO) recognises the enjoyment of the highest attainable standard of health as a fundamental right (UN, 2006). Attainment of the highest standard of health is difficult without access to effective pain relief medicines, including opioids. Opioids are essential for pain control and in the WHO pain relief ladder, they are essential in the second and third steps (WHO, 2013).

The countries that are covered in this review are parties to the 1961 Single Convention on Narcotics Drugs (UN, 1961 and1975). In the Single Convention, members agreed to exercise strict controls over narcotic drugs so that they are available and used exclusively for medical and scientific purposes (INCB, 1995–2013). The 1961 Single Convention and other conventions are not aimed at restriction of access to narcotics but, rather, their principal objective is to ensure adequate supply for legitimate medical and scientific purposes (INCB, 1999). However, adequate supply and utilisation is far from being achieved for everybody who needs opioids for pain control. According to Milani (2011), global consumption of morphine, which is an indicator of access to pain treatment, is on the rise but mostly in a few industrialised countries. Milani states that in 2003, developed countries consumed 79% of morphine and developing countries, with 80% of the world's population, accounted for only 6%. The INCB (2012:21) states that "Global consumption of morphine for the treatment of severe pain rose by a factor of more than four over the past two decades, reaching the record level of 42 tons in 2011". That increase was mainly due to the growing consumption in high-income countries, while consumption levels in most other countries is said to remain very low.

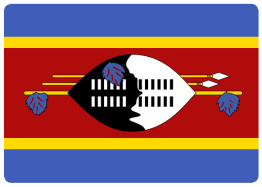
Table 4 in the main report shows morphine equivalent consumption per country as well as the percentage gap in coverage of deaths in pain with analgesic treatments, although Swaziland (one of the countries under review) did not submit morphine consumption data to the INCB for the year 2012. In the WHO (2011b) model list of essential medicines, morphine and codeine are included as essential analgesics; but in many countries, access to these medicines is very low and the situation is worse in developing countries (Milani, 2011). In Milani (2011) the following barriers to access narcotics are identified:

- Lack of medical knowledge
- Restrictive national policies and regulations
- Obstacles along the supply chain
- Inaccurate national annual estimates
- Complex systems of export and import authorisation.

In relation to pain arising from HIV and AIDS, it is said to be both under-diagnosed and undertreated. Yet according to the World Health Organization (2013), about half of the end-stage AIDS patients suffer from severe pain. This has serious negative consequences for people living with HIV and AIDS, the majority (70%) of whom are in sub-Sahara Africa (UNAIDS, 2012). The WHO advocates for improvements in availability, affordability and accessibility of opioids to those who need them, including people living with HIV and AIDS. Specifically, the WHO provides guidelines (2011a) for governments to identify and overcome regulatory and policy barriers to the rational use of controlled medicines which are essential for pain control in HIV and AIDS and other diseases.

# APPENDIX B

## An overview of literature relevant to HIV and AIDS and opioid availability at country level



### SWAZILAND

The population of Swaziland in 2013 was estimated to be 1.25 million (World Bank 2014a). The per capita expenditure on health in Swaziland was $ 448 in 2012 but about 63% of the population lives below poverty line (WHO 2015) The adult HIV prevalence is estimated at 26.2% which is said to be the highest in the world and ARV coverage is 55% (UNAIDS 2014b). These statistics indicate the magnitude of the HIV epidemic in Swaziland and are also suggestive of the need to provide strong analgesics for people living with HIV and AIDS. The health workforce density in Swaziland was 3.25 per 1000 population in 2009. This put Swaziland above the average (2.3/1000) for Africa and above the threshold (2.28/1000) recommended by the World Health Organisation to achieve the desired minimum level of health care coverage (WHO 2006). However, certain critical categories such as pharmacists and pharmacy technicians are very few; there were only 51 pharmacists and pharmacy technicians in Swaziland in 2009; attrition in the health workforce is high and HIV/AIDS is considered to be one of the main causes (AHWO 2010). In the INCB narcotics drug report of 2012, the amount of narcotics consumed in Swaziland was not reported on because the country had not submitted any consumption data for three consecutive years (2009-2011). The 1961 single convention on narcotic drugs Act 20:1c, which Swaziland joined in 1995 by accession (UN 1961& UN 1975), requires that all member countries submit consumption data annually. In the literature relevant to availability of palliative care and use of opioids among people with HIV and AIDS in Swaziland, the situation has been changing for the better; African Palliative Care Association (2012:45) in the review of legislation, policy documentation and implementation guidelines in ten Southern African countries found that in the Swaziland policy documents, "Opioid and palliative care issues are not integrated at all and only one document defines palliative care. Palliative care and opioid use are omitted, although there is great need for both considering the HIV statistics and the number of patients in need of home-based care." However, findings in this review showed that this had changed and there were now a number of Swaziland policy and other documents published since 2011, where palliative care availability and use of opioids was discussed and these included:

1. Standard Treatment Guideline and Essential Medicines List of Common Medical Conditions in the Kingdom of Swaziland (2012).

2. National Palliative Care Trainees Manual (2013).

3. National Palliative Care Guidelines (MoH [Kingdom of Swaziland] 2011a).

4. National Palliative Care Policy (MoH [Kingdom of Swaziland] 2011b).

5. National pharmaceutical policy (2011)

6. Curriculum for pharmacy certificate program (no date)

7. Swaziland Pharmaceutical Strategic Plan of 2012-2016 (MoH (Kingdom of Swaziland) 2012a)

Opioids are listed as essential medicines in the Standard Treatment Guidelines of Swaziland and it is reasonable to assume that they will be available and accessible as the Pharmaceutical Strategic Plan of 2012-16 gets implemented. Regarding regulation and legislation of the pharmaceutical industry in Swaziland, the current Pharmaceutical Policy (pg. 11) states that "The pharmacy Act of 1929… is outdated, does not provide for licensing ... and regulatory functions… licensing of premises and registration of medicines is not done..". According to the national pharmaceutical policy (2011), there is a chief pharmacist who provides policy advice and guidance to the MOH. It can therefore, be concluded that the pharmaceutical industry in Swaziland has been largely unregulated. But, there was a pharmacy bill (No 7 of 2012) and a medicines bill (No 8 of 2012) ready to be submitted to parliament and these, together with the above policies, should ensure regulation and availability of essential medicines including opioids.

In conclusion, after review of current policy documents which were relevant to palliative care and opioids availability in Swaziland, it was reasonable to conclude that over the years (2011-2013), there had been commendable effort to improve the policy environment which favoured improved availability of palliative care and opioids in Swaziland. The role of APCA is acknowledged in all the documents directly describing palliative care.

## MOZAMBIQUE

The population of Mozambique was estimated by World Population Review (2014) to be 26 million in 2014, up from 21.4 million in 2007 when a national census was held. Mozambique is a low-income country with a GDP per capita of $605, and about 54.7% of the population lives below poverty line (World Bank, 2015). Resources, according to the Health Sector Strategic Plan for Mozambique for the period 2013–17 (MoH, 2013), were very limited: only about 7% of national budget was spent on health; per capita expenditure on health in Mozambique was only about US$ 40, which was less than the WHO recommendation of a minimum of US$44 (WHO, 2012). The out-of-pocket expenditure was 9% (World Bank, 2014b). There was rural urban imbalance in access to health services in Mozambique as well as disparity between the poor and the wealthier in accessing services (MoH, 2013).

Article 94 of the Constitution of the Republic of Mozambique (Government of Mozambique, 1990) states that all citizens shall have the right to medical and health care, and Article 54 states that the Government pledges itself to organise medical and health care through a national health system to benefit all Mozambicans. In 2014 the HIV prevalence at national level was estimated to be 11.5% and Mozambique was among the top-10 most HIV-affected countries (UNAIDS, 2014b) ARV coverage was estimated to be 59% in 2013. However, according to the Mozambique National AIDS Council (2012), the number of new HIV infections is on the decline. Nonetheless, in the Mozambican National Strategic HIV and AIDS Response Plan of 2010–2014 there is no mention of pain relief or narcotics. According to Treat the Pain (2014), Mozambique consumed only 4.7kg of morphine equivalent in 2012 and yet it was estimated that 322 kg of morphine equivalent was needed to meet the minimum demand for pain relief among people dying from cancer and/or HIV/AIDS in Mozambique. Regarding health care professionals, Mozambique has one of the lowest health care professionals' densities, with 4 doctors and 39 nurses per 100,000 people (USAID, 2012).

A review of legislation, policy documentation and implementation guidelines conducted by APCA (APCA, 2012) found that opioid accessibility and practice was not mentioned in the documents reviewed then. The Worldwide Hospice Palliative Care Alliance (WHPCA, 2014:37) classified palliative

care development in Mozambique at that stage as "isolated palliative care provision" in which: there was development of palliative care activism that was patchy in scope and not well-supported; the sourcing of funding was often heavily donor-dependent; there was limited availability of morphine; and there were only a small number of hospice or other palliative care services relative to the size of the population.

## ZIMBABWE

Zimbabwe's population is currently estimated to be 13 million and growing at an annual rate of 1.1% (UNAIDS, 2014). The HIV prevalence in the adult population although declining, stood at 15% with about 76.9% adults and 46.12 children eligible for ARVs receiving the medicines (UNAIDS, 2014a). The per-capita health expenditure was estimated to be about US$28 dollars and, of this, 29% was out-of-pocket expenditure (Ministry of Finance, 2013). About 72% of Zimbabweans are living below the poverty line (World Bank, 2014a). The Zimbabwe Ministry of Health (2014) lists HIV/AIDS as the most frequent cause of death being responsible for more than 50% of all deaths.

In relation to the right to health care, the Founding Provision 76 in the (draft) Constitution of Zimbabwe (Parliamentary Monitoring Trust, 2013:46) states:

1. *(1) Every citizen and permanent resident of Zimbabwe has the right to have access to basic health-care services, including reproductive health-care services.*

2. *(2) Every person living with a chronic illness has the right to have access to basic healthcare services for the illness.*

This implies that, constitutionally, the Zimbabwe Government had the intension to prioritise the right to health care, including care for chronic illness such as HIV and AIDS. Palliative care was introduced into Zimbabwe in 1979 and since then it had grown, although the growth was slowed by the economic challenges of the 1990s and 2000s. Palliative care in Zimbabwe is mostly in major cities such as Harare, Bulawayo and Mutare (HOSPAZ, 2012a). A number of policy documents in Zimbabwe were relevant to palliative care and some directly mention opioid analgesics as essential for control of severe pain. These documents include:

- The National Health Strategy (2009–2013:116) where the goal of the health system at district level is said to be "to provide a comprehensive range of promotive, preventive, curative, rehabilitative and palliative health services"

- The Zimbabwe National HIV and AIDS Strategic Plan II, 2010–2015 (National AIDS Council, 2011:11), where it is stated: "Palliative care and psychosocial support are among the key services that will be provided under [community home-based care]"

- Palliative Care Standards for Zimbabwe (HOSPAZ, 2009) where the WHO pain ladder is adopted and it is stated that "analgesics should be available and accessible at all times"

- A Training Manual for Health Professionals and Communities in Zimbabwe (HOSPAZ, 2012b), where the WHO principles of pain management are adopted.

In the Zimbabwe, the law for controlling opioids is the Dangerous Drugs Act. The main objective of this Act, as stated within it, is "to control the importation, exportation, production, possession, sale, distribution and use of dangerous drugs". The country has a medicines policy (MOHCW, 2011) and essential medicines are defined within it as "medicines, which are of the greatest importance, are basic, indispensable and needed to satisfy the health needs of the majority of the population". A national competent authority called the Medicines Control Authority of Zimbabwe (MCAZ) has been in place since 1996 and is responsible for the administration of international conventions, including the UN Single Convention of 1961. MCAZ is also responsible for the control of narcotic and psychotropic substances.

The Worldwide Hospice Palliative Care Alliance (WHPCA, 2014:39) classified Zimbabwe as belonging to group 4a:

*where hospice-palliative care services are at a stage of preliminary integration into mainstream service provision: This group of countries is characterised by: the development of a critical mass of palliative care activism in a number of locations; a variety of palliative care providers and types of services; awareness of palliative care on the part of health professionals and local communities; the availability of morphine and some other strong pain-relieving drugs; limited impact of palliative care on policy; the provision of a substantial number of training and education initiatives by a range of organisations; [and] interest in the concept of a national palliative care association.*

The 2012 statistics from Treat the Pain (2014) show that Zimbabwe used only 10.1 kg of morphine equivalent, yet the minimum amount estimated to meet the need for strong pain control in the country that year was 177kg. The density for all categories of human resources for health in Zimbabwe, as given by the Zimbabwe Ministry of Health (2014), is 1.23 per 1000 population; however, the World Health Organization (2006) recommends that, for a country to meet its Millennium Development Goals, a density of doctors, nurses and midwives of 2.28/1000 is needed. Economic migration, leading to a 50% vacancy rate before 2009, is said to be a major contributor to the shortage; but bearing in mind a high prevalence, the effect of HIV on attrition cannot be underestimated.

# APPENDIX C
## Detailed document review findings

## SWAZILAND

| DOCUMENT | CONTENT REVIEW COMMENTS |
|---|---|
| *Standard Treatment Guideline and Essential Medicines List of Common Medical Conditions in the Kingdom of Swaziland* (Ministry of Health, 2012b) | Palliative care and pain are defined (p206); pain assessment in adults and children is discussed (pp207–208), pain management in HIV/AIDS, opioid analgesics and application of WHO pain ladder (p209) are also discussed. Pain management in HIV is referred to as part of comprehensive management of HIV/AIDS (p134). Opioids – including codeine phosphate tablets, methadone syrup, morphine injection, morphine powder for solution, pethidine injection, tramadol injection and tablets as well as a variety of adjuvants – are listed as essential drugs in Swaziland (pp277–278). |
| *National Palliative Care Trainees Manual* (2013) | Palliative care, pain management with the WHO pain ladder, and pain in HIV/AIDS, are discussed. Palliative care is defined and its guiding principles, different delivery models and components of the holistic approach are discussed (pp8–19). Pain and pain management are discussed in detail. Application of the WHO analgesic ladder is discussed and the use of weak opioids at stage two, strong opioids at stage three as well as adjuvants at any stage are explained (pp70–81). In the manual, it is stated on page 81: "Legislation on morphine use: Morphine is a controlled … class C drug in Swaziland. Prescribed by authorized clinicians – doctors". |
| *National Palliative Care Guidelines* (Ministry of Health, 2011a) | The opening statement in these guidelines on page 1 is that "Palliative care has been highlighted as an urgent need for patients with HIV/AIDS and other life threatening illnesses". On page 11 it is stated: "Providers of palliative care should be able to control pain in accordance with the WHO analgesic ladder model" and the WHO palliative care guiding principles are recommended. The goal of these guidelines is stated to be "to streamline the provision of palliative care in Swaziland". The guidelines also are stated to be implemented in conjunction with other relevant national policies and guidelines. |
| *Curriculum for Pharmacy Certificate Program* (Ministry of Health, n.d) | In this curriculum (p48), it is recognised that there is a critical shortage of clinical health personnel in Swaziland and it is stated that currently only professional nurses are trained in Swaziland. Although opioids are not explicitly mentioned, there is a section on analgesics (p66) and it is reasonable to assume that knowledge on opioid analgesics and their need for control of moderate to severe pain is taught to the certificate holders. |

| DOCUMENT | CONTENT REVIEW COMMENTS |
|---|---|
| *National Palliative Care Policy* (Ministry of Health, 2011b) | The policy has an overall objective of providing a framework to facilitate the provision and scale-up of quality of affordable palliative care services in Swaziland.<br>It is stated (p17): "The need for palliative care is perceived to be huge by key informants and service providers, as well as indicated by the high burden of diseases as a result of people sick with HIV and AIDS related illnesses, people sick from other terminal illnesses and the burden on families who have to take care of their terminally ill loved ones." |
| *National Pharmaceutical Policy* (Ministry of Health, 2011c) | This policy has an overall goal (p16) of "ensuring equitable access to, and rational use of, efficacious, high quality essential medicines, and medical supplies and devices at affordable cost, particularly for vulnerable people".<br>The intention of the policy, is therefore assumed to be making these controlled medicines accessible to those who need them in Swaziland. |
| *Swaziland Pharmaceutical Strategic Plan, 2012–2016* (Ministry of Health, 2012a) | The pharmaceutical strategic plan recognises (p17) that the following issues in the Swaziland pharmaceutical industry need to be addressed:<br>▪ Insufficient resources and capacity for pharmaceutical service provision<br>▪ Inadequate organisational structure of the pharmaceutical services<br>▪ Inadequacy of existing laws and regulations for the control of medicines and the practice of the pharmacy profession<br>▪ Limited management capacity in the supply chain<br>▪ Absence of quality assurance systems<br>▪ Absence of a national medical regulatory authority<br>▪ Inefficient use of pharmaceutical medicines and medical supplies. |
| Pharmacy Bill (No 7 of 2012) and Medicines Bill (No 8 of 2012) (in draft) | The objectives of the Pharmacy Bill are stated in the draft to be:<br>▪ Establishing the Pharmacy Council that will be responsible for regulating the pharmacy profession in Swaziland<br>▪ Providing for the registration of pharmacists, pharmacy interns, pharmacy technologists, pharmacy assistants and pharmacy technicians<br>▪ Providing for the registration and licensing of manufacturers, wholesalers, retail and hospital pharmacies<br>▪ Repeal and replacement of the Pharmacy Act 1929.<br><br>The objectives of the Medicines Bill are stated in the draft to be:<br>▪ Providing for the establishment of the Medicines Regulatory Authority<br>▪ Regulating the registration of medicines<br>▪ Providing for incidental matters. |

| DOCUMENT | CONTENT REVIEW COMMENTS |
|---|---|
| *Criminal Jurisdiction Legal Framework Applicable to Trafficking and Consumption Narcotic Drugs, Psychotropic Substances, Precursors and other Substances Similar Effects Law No 3/97, dated 13 September 1997* | The 1997 law has three objectives listed within it, namely:<br>▪ Depriving those who engage in trafficking narcotics the proceeds of their criminal activities<br>▪ Taking appropriate measures to control and monitor precursors, chemicals, solvents and usable substances in the manufacture of narcotic drugs<br>▪ Strengthening and complementing the measures under the Convention on Narcotic Drugs Act, 1961<br>These objectives focus on the control of illicit use of controlled substances and in the Act there is no mention of the need for use of controlled substances for scientific and medical purposes to control moderate to severe pain. |
| *Palliative Care National Policy* (2012) | This policy has a general objective stated as to "Standardize and regulate the quality of palliative care services, integrated in health care, helping to improve the quality of life of people living with cancer, HIV/AIDS and other chronic diseases".<br>Furthermore, the policy's Objective 5 is stated thus: "Advocate for the availability of morphine and other medications for appropriate relief of pain/symptoms and suffering at national level and decentralized". |
| *APCA Standards for Providing Palliative Care in Africa* (2011). These were adopted by Mozambique in 2012 and were translated into Portuguese (the official language in Mozambique) | Standards were developed by APCA to ensure that quality palliative care services are maintained while continuing the current efforts to extend coverage; to address current variations in quality of services provided within and between countries: to define an absolute minimum quality of services which will enable relative comparisons among countries with comparable levels of resources ; to inform the expectations of patients and families as service recipients, and staff members as service providers ; to define the framework and clarify the expectations of communities, service providers, administrators and other stakeholders of palliative care and home-based care across Africa and to promote access to comprehensive services. |
| *Pocket Guide to Pain Management*, 2nd Edition (2012). This guide was also adopted from APCA and translated into Portuguese. | This pocket guide is said to be "underpinned by the philosophy of palliative care and aims to provide useful quick-reference tips to assist practitioners to 'beat pain'" |

| DOCUMENT | CONTENT REVIEW COMMENTS |
|---|---|
| *National Formulary of Medicines* (MoH, 2007) | This document lists the following narcotic analgesics as essential medicines in Mozambique:<br>▪ Codeine phosphate tablet<br>▪ Morphine sulphate solution by injection, as well as the same drug in tablet form<br>▪ Pethidine injection<br>▪ Fentanyl injection. |
| *National Strategic HIV and AIDS Response Plan 2010–2014* | This policy document does not refer to pain management and it only briefly refers to palliative care under home-based care. |

## ZIMBABWE

| DOCUMENT | CONTENT REVIEW COMMENTS |
|---|---|
| *Dangerous Drugs Act (Chapter 15:02) of Zimbabwe* | Needs to be revised to accommodate the concept of 'balance' so that the legislation does not focus only on the prevention of illicit use of opioids but also creates an environment for supporting availability and access of such opioids for rational medical and scientific use. |
| *The Medicines and Allied Substances Control Act (Chapter 15:03) of 1969* | This legislation established the Medicines Control Authority of Zimbabwe, which controls the manufacture, import/export and distribution of medicines in Zimbabwe, including opioids. |
| *The National Medicines Policy of Zimbabwe (MOHCW, 2011)* | Communicates that government is aware of its obligation to provide 'vital' medicines, including opioids. |
| *National HIV and AIDS Strategic Plan II, 2011–2015 (National AIDS Council, 2011)* | This plan states that palliative care is one of the services to be provided under community-based home care, with a goal to scale it up to 85% by 2015. |

# APPENDIX D
## Focus group discussion guide

### *A review of national opioids estimation procedures and supply chain mechanisms*

***Source of discussion guide***

This guide is adapted from the International Narcotics Control Board (2011) checklist for ensuring balance in national policies on controlled substances, with modification to suit this review.

***Introduction***

The African Palliative Care Association (APCA), USAID and other local partners embarked on a project with an aim to scale up access to palliative care for people living with HIV and AIDS in southern Africa. In order to improve this access, APCA and partners intend to facilitate countries in southern Africa to overcome the following key barriers to pain and symptom controlling drugs' availability across Africa: unfavourable legislation and regulations, a lack of national policies on opioid use, tight drug controls, inadequate education and training about pain medicines among health professionals, limiting supply chain mechanisms and unreliable stocking mechanisms.

This is to request you to participate by giving answers to questions in this interview. Your responses will contribute towards understanding of issues on access to opioids in your country for people living with HIV and AIDS.

The data to be collected will be aggregated and reported on as a whole for each of the project countries. Individual names and positions of respondents will not be reported on without prior written consent.

***Instructions***

Tick the best option for you and fill in where necessary.

**Country**.....

**Category of respondent (tick as appropriate):**

Policy/Legislation personnel (Eg from MoH) ☐

Licensing Personnel (Eg from Licensing authority) ☐

Importer or Exporter ☐

Service provider? ☐ Private? ☐ Public? ☐

National Palliative Care Association Official ☐

Representing government authority for law and legislation implementation ☐

| SECTION A: POLICIES AND LEGISLATION ISSUES | ACTION REQUIRED? |
|---|---|
| 1. Is there a provision in the legislation or in official national policy documents that controlled medicines are absolutely necessary for medical and pharmaceutical care?<br>☐ yes, please list reference:<br>.....<br>☐ no ☐ unknown | |
| 2. Is there a provision in the legislation that establishes the government's obligation to make adequate provision to ensure the availability of controlled medicines for medical and scientific purposes, including the relief of pain and suffering?<br>☐ yes, please list reference of provision:<br>.....<br>☐ no ☐ unknown | |
| 3. Has the government established a national authority for implementing the obligation to ensure the adequate availability of controlled medicines for medical and scientific purposes, including licensing, estimates and statistics?<br>☐ yes, please list/name agency/agencies:<br>.....<br>☐ no ☐ unknown | |
| 4. Is there a mechanism (such as a regular meeting) among government agencies to coordinate drug control policies and to concert all sub-policies?<br>☐ yes, please describe mechanism:<br>.....<br>How often are such meetings held? ..... /year<br>☐ no ☐ unknown | |

| SECTION A: POLICIES AND LEGISLATION ISSUES | ACTION REQUIRED? |
|---|---|
| 5. Does the mechanism involve the agencies responsible for the following functions: | |
| ➔ drug control legislation?<br>☐ yes, please list agencies:<br>.....<br>☐ no ☐ unknown | |
| ➔ anti-drug diversion policies?<br>☐ yes, please list agencies:<br>.....<br>☐ no ☐ unknown | |
| ➔ Healthcare policies (pharmaceutical, cancer, HIV, etc)?<br>☐ yes, please list agencies:<br>.....<br>☐ no ☐ unknown | |
| ➔ Cusoms?<br>☐ yes, please list agencies:<br>.....<br>☐ no ☐ unknown | |
| ➔ police?<br>☐ yes, please list agencies:<br>.....<br>☐ no ☐ unknown | |
| ➔ judiciary?<br>☐ yes, please list agencies:<br>.....<br>☐ no ☐ unknown | |

| SECTION A:<br>POLICIES AND LEGISLATION ISSUES | ACTION REQUIRED? |
|---|---|
| 6. Does the mandate of the mechanism involve: | |
| ➔ the promotion of the availability and accessibility of controlled medicines for medical purposes?<br>.....<br>☐ yes ☐ no ☐ unknown | |
| ➔ the prevention of abuse and dependence?<br>.....<br>☐ yes ☐ no ☐ unknown | |
| ➔ dthe prevention of diversion?<br>.....<br>☐ yes ☐ no ☐ unknown | |

| SECTION A: POLICIES AND LEGISLATION ISSUES | ACTION REQUIRED? |
|---|---|
| 7. Is there a mechanism for cooperation between the government and healthcare professionals to ensure the availability and accessibility of controlled medicines for medical and scientific purposes, including for the relief of pain, treatment of opioid dependence and other medical illness, as well as the prevention of abuse, dependence and diversion?<br>☐ yes, please describe the mechanism:<br>.....<br>☐ no ☐ unknown | |
| ➔ Does the cooperation involve the agencies responsible for the following functions: | |
| a. drug control legislation?<br>☐ yes, please list agencies:<br>.....<br>☐ no ☐ unknown | |
| b. anti-drug diversion policies?<br>☐ yes, please list agencies:<br>.....<br>☐ no ☐ unknown | |
| c. Healthcare policies (pharmaceutical, cancer, HIV, etc)?<br>☐ yes, please list agencies:<br>.....<br>☐ no ☐ unknown | |
| d. customs?<br>☐ yes, please list agencies:<br>.....<br>☐ no ☐ unknown | |
| e. police?<br>☐ yes, please list agencies:<br>.....<br>☐ no ☐ unknown | |

| SECTION A: POLICIES AND LEGISLATION ISSUES | ACTION REQUIRED? |
|---|---|
| f. judiciary?<br>☐ yes, please list agencies:<br>.....<br>☐ no ☐ unknown | |
| g. Medical boards?<br>☐ yes, please list:<br>.....<br>☐ no ☐ unknown | |
| h. Representatives of health professionals?<br>☐ yes, please list oragisations:<br>.....<br>☐ no ☐ unknown | |
| i. Representatives of patients?.<br>☐ yes, please list oragisations:<br>.....<br>☐ no ☐ unknown | |
| j. Representatives of health insurances?<br>☐ yes, please list oragisations:<br>.....<br>☐ no ☐ unknown | |
| ➔ Does the mandate of the cooperation involve: | |
| a. the promotion of the availability and accessibility of controlled medicines for medical purposes?<br>☐ yes ☐ no ☐ unknown | |
| b. the prevention of abuse and dependence?<br>☐ yes ☐ no ☐ unknown | |
| c. the prevention of diversion?<br>☐ yes ☐ no ☐ unknown | |

| SECTION A: POLICIES AND LEGISLATION ISSUES | ACTION REQUIRED? |
|---|---|
| ➔ Does the cooperation comprise the following aspects: | |
| a. to assist the needs assessment for controlled medicines and to report on the degree of access?<br>☐ yes ☐ no ☐ unknown | |
| b. to advise on the promotion of rational use of controlled medicines?<br>☐ yes ☐ no ☐ unknown | |
| c. implementation of best practices, development of national treatment guidelines and implementation of international treatment guidelines?<br>☐ yes ☐ no ☐ unknown | |
| d. to advise on lifting overly-restrictive barriers for access to controlled medicines?<br>☐ yes ☐ no ☐ unknown | |
| e. to advise on improving prevention and control of substance abuse and dependence without establishing new barriers for accessibility and availability?<br>☐ yes ☐ no ☐ unknown | |

| SECTION A: POLICIES AND LEGISLATION ISSUES | ACTION REQUIRED? |
|---|---|
| 8. Did the government make adequate provision to ensure education of government officers and others whose work requires an understanding of the problems of abuse of drugs and of its prevention, including the relation to health policies and legitimate treatment with controlled medicines?<br>☐ yes, please describe the mechanism:<br>.....<br>☐ no ☐ unknown | |

| SECTION B:<br>POLICY PLANNING FOR AVAILABILITY AND ACCESSIBILITY | ACTION REQUIRED? |
|---|---|
| 1. Is there an approved national medicines policy plan that includes the availability and accessibility of controlled medicines for all relevant medical and scientific uses?<br>☐ yes, please reference:<br>.....<br>.....<br>when was the last update of the plan? .....<br>.....<br>☐ no ☐ unknown | |
| 2. Does the national medicines policy plan (or any government policy) make provision for a List of Essential Medicines, modelled after the WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children?<br>☐ yes, please reference for essential medicines list:<br>.....<br>.....<br>☐ no ☐ unknown | |
| 3. Does this List of Essential Medicines include all medicines currently on, or equivalent to the controlled medicines on, the WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children?<br>☐ yes<br>☐ no, please list missing medicines:<br>.....<br>.....<br>☐ unknown | |
| 4. Does the national medicines policy plan (or any government policy) make provision for policies that address the rational use of controlled medicines by the general population, including that patients and their families should be informed about the treatment of pain and treatment of dependence?<br>☐ yes, please specify:<br>.....<br>.....<br>☐ no ☐ unknown | |

| SECTION B: POLICY PLANNING FOR AVAILABILITY AND ACCESSIBILITY | ACTION REQUIRED? |
|---|---|
| 5. Does the national medicines policy plan (or any government policy) make adequate provision that patients who are hospitalized for other reasons are able to continue their treatment with controlled medicines?<br>☐ yes, please specify:<br>.....<br>.....<br>☐ no ☐ unknown | |
| 6. Does the national medicines policy plan (or any government policy) make adequate provision that treatment continues for people on controlled medicines when arrested or imprisoned, regardless whether they are on pain treatment, treatment for dependence or for other diseases?<br>☐ yes, please specify:<br>.....<br>.....<br>☐ no ☐ unknown | |
| **7. HIV and AIDS specific policy plans** | |
| ➔ Is there an approved national HIV/AIDS policy programme that: | |
| a. includes the treatment of moderate to severe pain through availability and accessibility of strong opioid analgesics and of services like hospice and palliative care where patients can obtain such treatment?<br>☐ yes, please specify:<br>.....<br>.....<br>☐ no ☐ unknown | |
| b. includes the prevention of HIV transmission through availability and accessibility of opioid agonist therapy and treatment centres where patients with opioid dependence can obtain such treatment?<br>☐ yes, please reference:<br>.....<br>.....<br>when was the last update of the plan?<br>.....<br>.....<br>☐ no ☐ unknown | |

| SECTION B: POLICY PLANNING FOR AVAILABILITY AND ACCESSIBILITY | ACTION REQUIRED? |
|---|---|
| c. Are sufficient resources available for the implementation of the policy?<br>☐ yes, please specify budget:<br>.....<br>.....<br>☐ no ☐ unknown | |
| d. Are sufficient resources available for the implementation of the policy?<br>☐ yes, please specify budget:<br>.....<br>.....<br>☐ no ☐ unknown | |
| e. are gender sensitive and culturally appropriate?<br>☐ yes ☐ no ☐ unknown | |
| 8. Does the approved national medicines policy plan allow for equal access and availability and do not discriminate, or result in being unintentionally discriminatory to: | |
| ➔ women?<br>☐ yes ☐ no ☐ unknown | |
| ➔ children?<br>☐ yes ☐ no ☐ unknown | |
| ➔ the elderly?<br>☐ yes ☐ no ☐ unknown | |
| ➔ people in lower income classes?<br>☐ yes ☐ no ☐ unknown | |
| ➔ ethnic minorities?<br>☐ yes ☐ no ☐ unknown | |

| SECTION B:<br>POLICY PLANNING FOR AVAILABILITY AND ACCESSIBILITY | ACTION REQUIRED? |
|---|---|
| ➔ prisoners?<br>☐ yes ☐ no ☐ unknown | |
| ➔ pain patients with a history of substance abuse?<br>☐ yes ☐ no ☐ unknown | |
| ➔ people living with HIV?<br>☐ yes ☐ no ☐ unknown | |
| ➔ sex workers?<br>☐ yes ☐ no ☐ unknown | |
| ➔ men who have sex with men?<br>☐ yes ☐ no ☐ unknown | |
| ➔ injecting drug users?<br>☐ yes ☐ no ☐ unknown | |

| SECTION C<br>ISSUES RELATED TO TIGHT DRUG CONTROLS AND STORAGE | ACTION REQUIRED? |
|---|---|
| 1. Has the government conducted an examination to determine if there are provisions in the national and lower legislation and in the official policies that are stricter than the international drug control conventions require? *(eg a rule provides a barrier for availability and accessibility, but does not contribute to the prevention of abuse, diversion and dependence syndrome)*<br>☐ yes, please specify which laws or regulations have been checked and which relevant laws and regulations still need examination<br>.....<br>.....<br>☐ no ☐ unknown | |
| 2. If such provisions are present, are they necessary or desirable for the protection of the public health or welfare and do they contribute to a better public health (as composed of the availability and accessibility to controlled medicines for rational medical use, and the prevention of abuse, diversion and dependence)?<br>☐ yes, please specify outcomes by provision<br>.....<br>.....<br>☐ no ☐ unknown | |
| 3. If provisions were identified that are not necessary or desirable for the protection of the public health or welfare and do not contribute to a better public health, were they either removed or replaced by alternative ways to provide the same level of prevention without posing a barrier to rational medical use?<br>☐ yes, please specify:<br>.....<br>.....<br>☐ no ☐ unknown | |

| SECTION C<br>ISSUES RELATED TO TIGHT DRUG CONTROLS AND STORAGE | ACTION REQUIRED? |
|---|---|
| 4. In particular, indicate if the legislation or the policies containing the following provisions that are stricter than required by the drug control conventions that impede prescribing, dispensing and distribution for rational medical use: | |
| ➔ is the time span for which controlled medicines may be prescribed more limited than for other medicines?<br>☐ yes, please specify maximum duration and difference with other medicines:<br>.....<br>.....<br>☐ no ☐ unknown | |
| ➔ is the validity of prescriptions for controlled medicines more limited than for other medicines?<br>☐ yes, please specify maximum validity and difference with other medicines:<br>.....<br>.....<br>☐ no ☐ unknown | |
| ➔ is the practitioner allowed to determine the appropriate pharmacological treatment (choice of medicine, formulation, strength, dosage and duration) based on individual patient needs and on sound scientific medical guidance?<br>☐ yes<br>☐ no; please specify restrictions and difference with other medicines:<br>.....<br>.....<br>☐ unknown | |
| ➔ is there a limitation on the use of strong opioids in moderate to severe pain to one or more specific diseases (e.g. cancer pain), while moderate to severe pain from other causes such as HIV and AIDS remains unaddressed?<br>☐ yes, please specify restrictions:<br>.....<br>.....<br>☐ no ☐ unknown | |

| SECTION C<br>ISSUES RELATED TO TIGHT DRUG CONTROLS AND STORAGE | ACTION REQUIRED? |
|---|---|
| ➔ is permission required for the patient to render him/her eligible to receive a prescription for a controlled medicine?<br><br>☐ yes ☐ no ☐ unknown | |
| ➔ can controlled medicines be prescribed on a single copy of regular prescription paper?<br><br>☐ yes<br>☐ no; please specify what is needed and at what cost:<br>.....<br>.....<br>☐ unknown | |
| ➔ is there a registration of patients treated with opioids for opioid dependence?<br><br>☐ yes<br>if yes, please specify if there are any such consequences as the refusal of a driver's license, government employment, housing, or denial of child custody, that will cause patients not to seek treatment;<br>.....<br>.....<br>if yes, please specify the period for which the registration is kept;<br>.....<br>.....<br>if yes, please specify what warrants are in place that ensure the privacy of the patient will not be breached<br>.....<br>.....<br>☐ no ☐ unknown | |
| ➔ are health workers with general prescribing authority, while performing their professional duties, allowed to prescribe controlled medicines without an additional license?<br><br>☐ yes ☐ no ☐ unknown | |

| SECTION C<br>ISSUES RELATED TO TIGHT DRUG CONTROLS AND STORAGE | ACTION REQUIRED? |
|---|---|
| ➔ are pharmacists with general dispensing authority, while performing their professional duties, allowed to dispense controlled medicines without a license?<br><br>☐ yes ☐ no ☐ unknown | |
| ➔ is providing information about treatment with and use of controlled medicines allowed and can people providing such information be free from fear of prosecution?<br><br>☐ yes ☐ no ☐ unknown | |
| 5. Is there terminology in the legislation that has the potential to confuse the medical use of controlled medicines with substance abuse (e.g. confusion between 'abuse' and 'long term medical use'?<br><br>☐ yes ☐ no ☐ unknown | |
| 6. Does a definition of "abuse" (or "misuse") exclude the long term medical use of controlled medicines concurrent with accepted medical practice, and is it clear that medical use of controlled substances, whether long-term or not, and whether adverse drug reactions (including "drug dependence") occur or not, is not "drug abuse"?<br><br>☐ yes ☐ no ☐ unknown | |
| 7. Is there definition of dependence in your policies? Does a definition of "dependence" require the presence of a strong desire or a sense of compulsion to take the drug and is it clear from this definition that the mere occurrence of tolerance or withdrawal symptoms does not warrant such a diagnosis?<br><br>☐ yes ☐ no ☐ unknown | |
| 8. Does the legislation contain stigmatizing terms for controlled medicines, such as the use of the legal terms "narcotic drugs" and "psychotropic drugs" for medicines beyond their legal meaning related to the international drug conventions?<br><br>☐ yes ☐ no ☐ unknown | |
| 9. Does the legislation refer to patients in a respectful way and in particular, does it avoid stigmatizing terminology such as use of the word "addict" for a patient with dependence?<br><br>☐ yes ☐ no ☐ unknown | |

| SECTION D<br>HEALTH CARE PROFESSIONALS' ISSUES | ACTION REQUIRED? |
|---|---|
| 1. Which categories of health care processionals are permitted/licensed to prescribe opioids?<br>.....<br>..... | |
| 2. Are pharmacists allowed to correct technical errors in prescriptions and to dispense small amounts of controlled medicines in case of emergencies?<br>☐ yes ☐ no ☐ unknown | |
| 3. Is there a government policy that urges medical, pharmaceutical and nursing schools to teach the medical use of controlled medicines, including the use of opioid analgesics and pain management?<br>☐ yes, please specify:<br>.....<br>.....<br>☐ no ☐ unknown | |
| 4. Are relevant WHO treatment guidelines or other international or national evidence-based guidelines for the various diseases including HIV and AIDS and disorders that need treatment with controlled medicines implemented throughout the country, including for: | |
| ➔ pain management?<br>☐ yes, please specify:<br>.....<br>.....<br>☐ no ☐ unknown | |
| ➔ treatment of opioid dependence?<br>☐ yes, please specify:<br>.....<br>.....<br>☐ no ☐ unknown | |

| SECTION D<br>HEALTH CARE PROFESSIONALS' ISSUES | ACTION REQUIRED? |
|---|---|
| ➔ prevention of HIV/AIDS?<br><br>☐ yes, please specify:<br>.....<br>.....<br>☐ no ☐ unknown | |
| 5. If the country is in a transition towards improved access and availability of controlled medicines, are training courses for physicians, pharmacists and nurses to teach the rational use of these medicines given throughout the country?<br>☐ yes<br>.....<br>.....<br>☐ no ☐ unknown | |

| SECTION E<br>STOCKING: ESTIMATION PROCEDURES | ACTION REQUIRED? |
|---|---|
| 1. Does the government have a method to realistically estimate the medical and scientific requirements for controlled substances?<br>☐ yes, please specify the method:<br>.....<br>.....<br>☐ no ☐ unknown | |
| 2. Does this method include a certain surplus in order to minimize chances that the estimates are insufficient towards the end of the year?<br>☐ yes ☐ no ☐ unknown | |
| 3. Has the government established a satisfactory system to collect information about requirements for controlled medicines from relevant facilities?<br>☐ yes, please specify:<br>.....<br>.....<br>☐ no ☐ unknown | |
| 4. Which on of the following information is considered in making national opioids needs estimates?<br>☐ Size of the population<br>☐ Number of hospital beds<br>☐ Morbidity datao The request of manufacturers/importerso Information from medical associations<br>☐ Past consumption patterns<br>☐ Guidelines of International Narcotics Control Board<br>☐ Others, specify<br>..... | |
| 5. Does the government furnish estimates to the INCB of the requirements for narcotic drugs and certain precursors for the next year in a timely manner?<br>☐ yes, please provide date of latest submission:<br>.....<br>.....<br>☐ no ☐ unknown | |
| 6. If it appears that the medical need for narcotic drugs (mainly opioid analgesics and long-acting opioid agonists for treatment of dependence) will exceed the estimated amount that has been confirmed by the INCB, is it government policy to furnish a supplementary estimate to the INCB?<br>☐ yes ☐ no ☐ unknown | |

# APPENDIX E
## Self-administered questionnaire
## Knowledge and attitudes relating to opioid supply chain mechanisms and consumption estimates

***Introduction***

The African Palliative Care Association (APCA), USAID and other local partners embarked on a project with an aim to scale up access to palliative care for people living with HIV and AIDS in southern Africa. In order to improve this access, APCA and partners intend to facilitate countries in southern Africa to overcome the following key barriers to pain and symptom controlling drugs' availability across Africa: unfavourable legislation and regulations, a lack of national policies on opioid use, tight drug controls, inadequate education and training about pain medicines among health professionals, limiting supply chain mechanisms and unreliable stocking mechanisms.

This is to request you to answer questions in this questionnaire. Your responses will contribute towards an understanding of issues on access to opioids in your country for people living with HIV and AIDS.

The data to be collected will be aggregated and reported on as a whole for each of the project countries. Individual names and positions of respondents will not be reported on without prior written consent.

There is no right or wrong response. The best response is a true reflection of what you know or your correct attitude.

***Source of questionnaire***

This questionnaire is based on the contents of International Narcotics Control Board (2011) guidance for availability and accessibility of controlled medicines for ensuring balance in national policies on controlled substances, as well as on the Guide on Estimating Requirements for Substances under International Control (INCB, 2012).

***Instructions:***

**MARK the best option for you.**

### 1. Background characteristics of participants

1.1 Gender:

| | | | |
|---|---|---|---|
| | *Male* | | *Female* |

1.2 Age (y)

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | *≤ 30* | | *31 – 40* | | *41 – 50* | | *≥51* |

1.3 Last time in pain management training or education (y)

| | | | | | |
|---|---|---|---|---|---|
| | *≤ 1* | | *1– 5* | | *≥5* |

1.4 Professional qualification

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | *Medical doctor* | | *Nurse* | | *Pharmacist* | | *Medical – other* | | *Non-medical* |

1.5 Employer

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | *Government,* | | *NGO* | | *Self-employed* | | *Other* |

1.6 My role in opioids availability is:

| | | | | | |
|---|---|---|---|---|---|
| | *Policy formulation/revision* | | *Work with National Palliative Care Association* | | *Work with Licensing Authority* |
| | *Responsible for estimation* | | *am a service provider/ prescriber of opioids* | | *I am from law enforcement* |

1.7 Awareness of WHO-guided three-step pain ladder

| | | | | | |
|---|---|---|---|---|---|
| | *Yes* | | *No* | | *Don't know the WHO-guided three-step pain ladder* |

## 2. Knowledge regarding opioid consumption estimates and importation/manufacture

2.1 My country is signatory to the international drug control conventions : Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, the Convention on Psychotropic Substances of 1971 and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |

2.2 Government is required to submit quarterly and annual statistical reports on import and exports of controlled substances including opioids to the INCB in accordance with international drug control conventions.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |

2.3 WHO has model drug lists of essential medicines which includes opioid analgesics and which can be adapted by member countries for use.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |

2.4 It is the government's obligation, in collaboration with International Narcotics Control Board (INCB), to ensure that opioid analgesics are adequately available, affordable and accessible by organising their procurement or manufacturing and distribution.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |

2.5 The INCB recommends that member countries develop a tailored practical method, through national competent authorities, to select, quantify, procure, store, distribute and use controlled medicines including opioid analgesics.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |

2.6 In cases of underestimation of controlled medicines, government has the option of submitting supplementary estimates to INCB.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |

2.7 Government should include the availability and accessibility of controlled medicines including opioids for all relevant medical uses in their national pharmaceutical policy plans.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |

2.8 Access to and availability of strong opioid analgesics should be included in specific national disease control programmes such as that of HIV and AIDS.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |

2.9 Similar to any other medicine, a controlled medicine needs to be in stock in order for it to be continuously available for prescription when needed.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |

2.10 To avoid illicit use, controlled substances availability should only be limited to hospital or large pharmacies with stringent safety measures.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |

2.11 Very stringent safety measures regarding storage of opioids are required to ensure prevention of diversion and to improve availability and affordability of controlled medicines.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |

2.12 The INCB recommends that, for a pharmacy to be allowed to stock controlled medicines such as opioid analgesics, it must first invest in additional safety measures to ensure safety of the medicines.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |

2.13 There is need to review control and safety measures and the impact on controlled medicines pricing.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |

2.14 End-stage AIDS patients may suffer from pain which may require use of strong opioids analgesics for pain control.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |

2.15 Physicians, nurses and other health professionals who are trained and qualified, at all levels of health care should be allowed to prescribe and administer controlled medicines, based on their general professional license, current medical knowledge and good practice without any further license requirements.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |

2.16 Medical prescription of opioids for pain control should only be for a limited time.

| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |
|---|---|---|---|---|---|---|---|---|---|

2.17 To be eligible to receive opioid analgesics, patients must be specifically registered and authorised.

| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |
|---|---|---|---|---|---|---|---|---|---|

## 3. Attitudes regarding opioid consumption estimates and importation/manufacture

3.1 To prevent diversion and illicit use, only government should estimate, import, store and distribute opioid analgesics.

| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |
|---|---|---|---|---|---|---|---|---|---|

3.2 Government's main obligation is to ensure that controlled medicines such as opioid analgesics are not diverted for illicit use.

| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |
|---|---|---|---|---|---|---|---|---|---|

3.3 Stores or pharmacies to be certified for storage of opioids must, in addition to usual requirements, must have additional specific security.

| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |
|---|---|---|---|---|---|---|---|---|---|

3.4 To ensure prevention of abuse and illicit use, the distribution of controlled medicines including opioids should not be combined with that of other non-controlled medicine distribution systems.

| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |
|---|---|---|---|---|---|---|---|---|---|

3.5 Only pharmacies and hospitals should be permitted to dispense controlled medicines.

| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |
|---|---|---|---|---|---|---|---|---|---|

3.6 Only medical doctors and pharmacists should be allowed to prescribe opioid analgesics.

| | *Strongly disagree* | | *Disagree* | | *Uncertain* | | *Agree* | | *Strongly agree* |
|---|---|---|---|---|---|---|---|---|---|

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# ABOUT APCA

The African Palliative Care Association (APCA) is a non-profit making pan-African membership-based organisation which was provisionally established in November 2002 and formally established in Arusha, Tanzania, in June 2004. Acknowledging the genesis of modern palliative care within the United Kingdom, APCA strives to adapt it to African traditions, beliefs, cultures and settings, all of which vary between and within communities and countries on the continent. As such, in collaboration with its members and partners, APCA provides African solutions to African problems, articulating them with what is the recognised regional voice for palliative care.

APCA's vision is to ensure access to palliative care for all in need across Africa, whilst its mission is to ensure palliative care is widely understood, underpinned by evidence, and integrated into all health systems to reduce pain and suffering across Africa. APCA's broad objectives are to:

- Strengthen health systems through the development and implementation of an information strategy to enhance the understanding of palliative care among all stakeholders;
- Provide leadership and coordination for palliative care integration into health policies, education programmes and health services in Africa;
- Develop an evidence base for palliative care in Africa;
- Ensure good governance, efficient management practices and competent human resources to provide institutional sustainability;
- Position palliative care in the wider global health debate in order to access a wider array of stakeholders and to develop strategic collaborative partnerships, and;
- Diversify the financial resources base to meet APCA's current funding requirements and to ensure the organisation's future sustainability.

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