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A 'STEP-BY-STEP' ALGORITHM FOR THE PROCUREMENT OF CONTROLLED SUBSTANCES FOR DRUG SUBSTITUTION TREATMENT

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Internal Document

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A 'Step-by-step' Algorithm for the Procurement of Controlled Substances for Drug Substitution Treatment

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ABBREVIATIONS

AIDS	Acquired Immune-Deficiency Syndrome
CEEHRN	Central and Eastern European Harm Reduction Network
HIV	Human Immunodeficiency Virus
IDU	Injecting Drug Use
INCB	International Narcotics Control Board
MoH	Ministry of Health
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNODC	United Nations office on Drugs and Crime
WHO	World Health Organization

A 'Step-by-step' Algorithm for the Procurement of Controlled Substances for Drug Substitution Treatment

1 Background

1.1 Introduction

The use of contaminated injection equipment among injecting drug users is among the major forces driving the HIV/AIDS epidemic, contributing about 5-10 per cent of all HIV transmissions world wide. An essential package to prevent HIV transmission from injecting drug use includes needle and syringe programmes, drug substitution treatment, condom programmes, sexually transmitted infection control, HIV/AIDS-related treatment and care, information, education and communication and peer outreach.

Drug substitution treatment especially for heroin users is of paramount importance in order to assist drug injectors with the opportunity to stop injecting by taking drug substitution treatment orally. Today many countries, including in South and East Asia are interested in providing drug substitution treatment as part of a comprehensive package of interventions to decrease the incidence of HIV transmission amongst injecting drug users.

Methadone and buprenorphine added to the WHO Model List of Essential Medicines

Methadone and buprenorphine were added to the WHO Model List of Essential Medicines in 2005 (14th edition of the Model List – revised March 2005). While the Model List specifies the strengths and dosage forms in respect of methadone, it is left to individual countries to specify these for buprenorphine, depending upon local availability and price. The specifications for methadone are:

- *oral solution 5 mg/5 ml, 10 mg/5 ml,*
- *concentrate for oral solution 5 mg/ml, 10 mg/ml (hydrochloride)*

Narcotic drugs and psychotropic substances are regulated by international treaties and national drug control policies. The International Narcotics Control Board (INCB), WHO and national governments report that such controlled substances are not sufficiently available for medical purposes. Reasons for this include greatly exaggerated fears of dependence, overly restrictive national drug control policies and problems in procurement, manufacture and distribution of controlled substances.[1]

The need for controlling narcotic drugs and psychotropic substances makes 'access' to these products highly challenging: the market size of these products is limited

[1] *Achieving balance in national opioids control policy – Guidelines for assessment*, WHO, 2000.

since such products are not market driven but are influenced primarily by regulatory controls, therefore there are few suppliers; availability therefore is a challenge. Furthermore, the documentation and approvals required prior to shipping make procurement a slow and bureaucratic process. In view of these various factors, it becomes necessary for concerned programme managers to be well acquainted with the relevant international and national regulations and to plan the procurement of such controlled substances well in advance.

It is to facilitate such planning – that would ease the obstacles and expedite processes – that the United Nations Regional Task Force on IDU and HIV/AIDS decided to produce this brochure, which describes a 'step-by-step' process on how to import internationally controlled substances, such as methadone or buprenorphine.

1.2 Purpose of this brochure

The purpose of this brochure is to provide guidance to national governments, which have decided to procure drugs for substitution treatment for heroin dependence (e.g. methadone, buprenorphine). The brochure includes the following:

- An outline of the relevant aspects of international and national regulation of controlled substances (covering legal procedures, INCB requirements, import/export procedures, reporting);
- An easy and practical 'step-by-step' guidance/tool for managing procurement in consonance with regulatory requirements;
- Summary information on market options with a focus on Asia; i.e. national requirements, supply sources, prices;
- Country based examples and references to guide the international procurement of controlled substances for the Asia region.

2 International and National Regulations

This section gives an overview of the legal requirements relating to controlled substances at both national and international levels, covering both domestic manufacture and the import/export system.[2]

2.1 International treaties on Narcotic Drugs and Psychotropic Substances

The 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol (6, 8), is the principal international treaty regulating availability of opioids. Methadone is regulated under the Single Convention. Buprenorphine is controlled under another international treaty – the Convention on Psychotropic Substances, 1971; some of the controls to be applied to buprenorphine are therefore less strict than those applicable to narcotic drugs such as methadone. For example, imports and

[2] The information in this section is drawn extensively from the monograph *Availability of Opioid Analgesics in Asia: Consumption Trends, Resources, Recommendations, 2002* (pages 36-41). This is an excellent resource and users of this brochure are encouraged to refer to it for a deeper understanding of relevant issues.

exports of buprenorphine need not be reported to International Narcotics Control Board (INCB) on a quarterly basis but only on annual basis (also see Section 2.2.3). For practical purposes, however, it is not crucial to differentiate between the control measures for methadone and buprenorphine, since, under the national legislation of many countries, buprenorphine tends to be controlled as a narcotic drug.[3]

Salient requirements under the international treaties

The international treaties require that all individuals and enterprises in the procurement, manufacture and distribution system should be licensed or otherwise appropriately authorized, and that transfers of controlled substances take place only between properly registered parties. Patients may use controlled substances only according to a physician's prescription. Records must be kept, and reports on consumption must be filed with the competent national authority. These, along with security arrangements and inspections, are designed to prevent diversion from the legitimate system of drug distribution.

Competent national authorities under the international drug control treaties

Generally, the competent national authority for purposes of liaising with International Narcotics Control Board (INCB) and administering national regulations relating to controlled substances for medical use is the national drug/pharmaceutical regulatory authority, which is usually a part of the Ministry of Health. There are exceptions to this, however. For example: in India the competent national authority is the Central Bureau of Narcotics which is a part of the Department of Revenue, Ministry of Finance; in Papua New Guinea it is the National Narcotics Bureau; in the Philippines it is the Dangerous Drugs Board.

Programme managers involved in substitution treatment programmes should, as a preparatory step for planning procurement, identify the relevant competent national authority in their country.

2.2 The drug procurement/distribution system

2.2.1 National estimates of medical need for controlled substances

1. Every year, competent national authorities prepare an estimate of the amount of controlled substances that will be needed in the country during the following calendar year. The estimate must be submitted to the International Narcotics Control Board (INCB) by 30th June, that is, six months in advance of the year to which it applies. INCB notifies confirmed estimates by December of the same year. The treaty requires the INCB to confirm the national estimate before the national government may permit the export of controlled substances to a country.

[3] Communication from INCB.

2. Under the Single Convention, the quantity of controlled substances manufactured in or imported into a country must not exceed the government's official estimate of the amount needed.
3. When approved, the INCB publishes the list of the confirmed estimates for each country.
4. If an annual estimate proves to be inadequate, the competent national authority can submit supplementary estimates to INCB during the course of the year. In such circumstances the competent national authority has to provide an explanation of the circumstances necessitating the additional requirements. The updated totals of estimates of annual requirements for all countries are published on a monthly basis on the internet (at www.incb.org) and on a quarterly basis as hardcopies.

2.2.2 Domestic manufacture and distribution of controlled substances – typical regulations

Some or all of the controlled substances needed may be manufactured by enterprises in the country itself; such enterprises need to be licensed by the government.

***Regulation of manufacture of controlled substances includes the following*:** licensing; requirements for record-keeping and reporting; and quality control. Manufacturers need to provide resources for record-keeping, to provide secure facilities and maintain security procedures from the stage of acquisition of raw materials until the distribution of the finished products, in order to prevent diversion.

***Regulation of distribution*.** A manufacturer may distribute the finished products directly to licensed pharmacies or hospitals, or they may be distributed by a wholesaler. Wholesalers must also be licensed by the competent national authority, and must obey rules concerning security and record-keeping. The treaties do not require that health-care providers (when handling substances in their profession) or patients be licensed.

2.2.3 Regulatory system for import/export of controlled substances

In this section the steps in the regulatory process applicable to the import/export of controlled substances are outlined and illustrated with a figure. Section 3 combines these steps with the managerial processes involved. For a comprehensive understanding of the procurement process these two sections should be read in conjunction. Specific practices/requirements may vary from country to country.

1. Based on the requirement for a particular controlled substance communicated by the national programme manager, the authorized importing agency applies to its competent national authority for an import certificate.[4]

[4] In certain countries where the competent national authority is an agency other than the pharmaceuticals regulatory authority, the importer is generally required to obtain approval from the pharmaceuticals regulatory authority before submitting an application for import certificate to the competent national authority. In India, for instance, where the competent national authority is the Central Bureau of Narcotics (which is a part of the Department of Revenue, Ministry of Finance), the importer has to first obtain approval for import from the Drug Controller General (India) in the Ministry of Health.

2. The competent national authority considers whether the importing agency is properly licensed and whether the drug and amount are within the national estimate; if these are in order, the competent national authority issues an original import certificate/license[5] along with a copy. If the confirmed estimate is inadequate, the competent national authority submits supplementary estimates to INCB.
3. The importer sends a copy of the import certificate to the agency proposing to export the substance.
4. The exporter applies to its competent national authority for an export certificate.
5. The competent national authority in the exporting country verifies that an import certificate has been issued and that the exporter is properly licensed; if the application is approved, the competent national authority issues an export certificate.
6. The competent national authority in the exporting country sends a copy of the export certificate to its counterpart competent national authority in the importing country.
7. The exporter ships the drugs to the importer, along with a copy of the export certificate.
8. The shipment must pass a customs inspection.
9. The importer sends a report to its competent national authority giving details of the products imported, as required by the competent national authority.

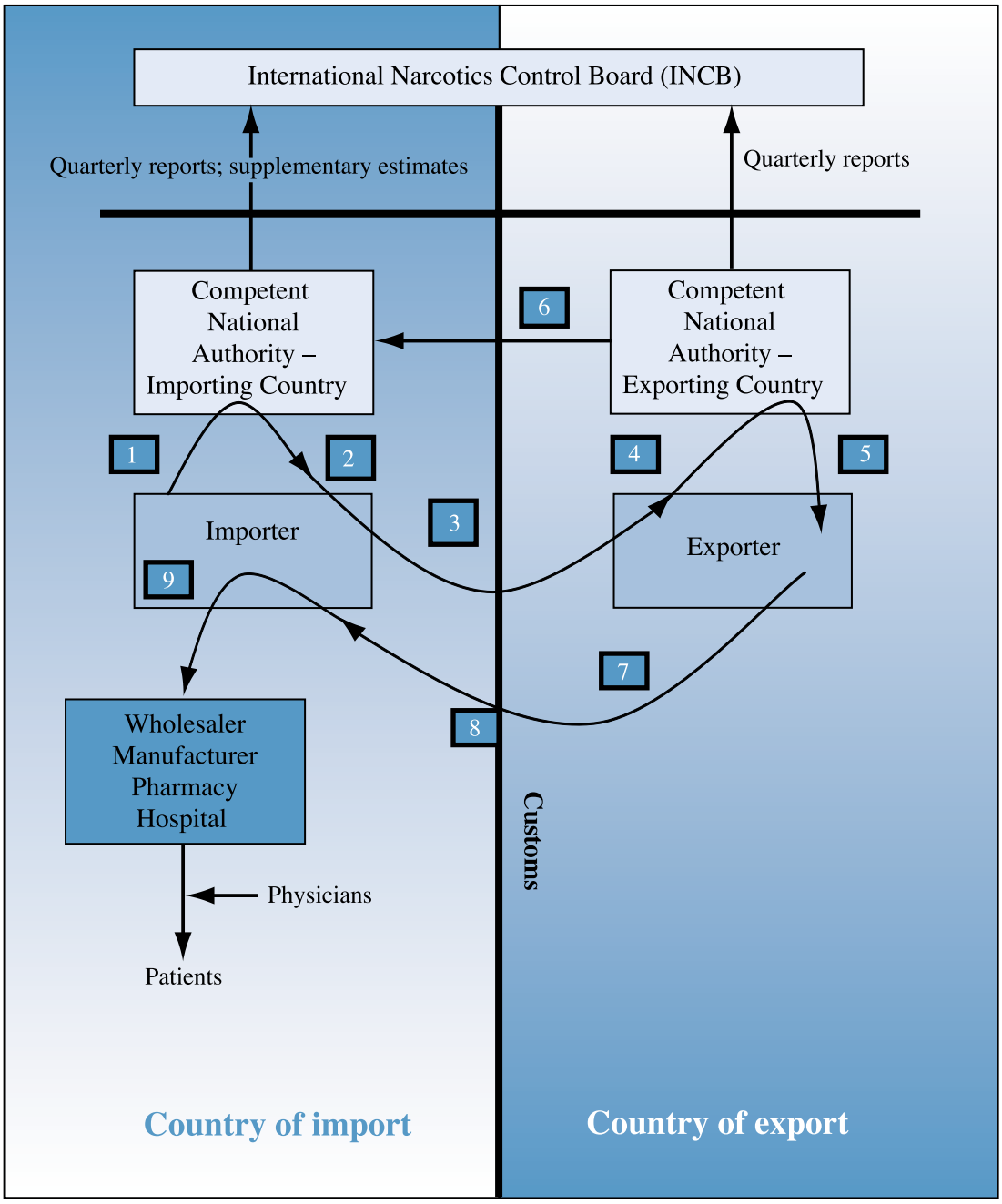
It should be noted that many countries also have a certification procedure to prevent marketing of pharmaceutical products that are falsely labelled, counterfeit or substandard.

Reporting to INCB. Competent national authorities must report all imports and exports of controlled substances to the INCB every quarter. They are also required to make an annual inventory and report the total amount of controlled substances manufactured, consumed and in stock. The annual inventory does not include drugs stored in pharmacies, which for official purposes are considered to have been consumed. The INCB, in turn, uses these data to prepare reports and monitor global production and consumption of controlled substances.

[5] There is no standard certificate, although a model import certificate has been developed by the United Nations Commission on Narcotic Drugs. Refer to web link: http://www.painpolicy.wisc.edu/publicat/cprguid.htm#selected

Figure: Regulatory system for import/export of controlled substances

The numbers in this figure[6] refer to steps 1-9 given above.



[6] This figure has been adapted from *Availability of Opioid Analgesics in Asia: Consumption trends, Resources, Recommendations, 2002* (page 40).

3 Country-level procedures for the procurement of controlled substances

For a comprehensive understanding, this section should be read in conjunction with Section 2.2.3.

This section outlines the procedures that a country manager for the oral substitution treatment programme, working jointly with the authorized importing agency(ies), needs to follow to procure controlled substances. These procedures are presented as an integrated package: combining the regular 'managerial' actions normally undertaken for procurement of any drug with the relevant 'legal' actions required by international and national regulations.

While the guidelines below are broadly applicable across countries, specific requirements may vary from country to country. Specific requirements could relate to: standard procurement guidelines of the ministry of health; requirements of the competent national authority; and, relevant requirements of other federal/state authorities, e.g. tax authorities. Hence programme managers should use the guidelines herein as a starting point to develop comprehensive plans specific to their country situation.

Since import of controlled substances involves decision making and authorization from several departments/agencies, it is crucial that strong coordination and partnerships are established among all such parties. This would be apparent from the country examples given in the Appendix.

4 Market options: world requirements, suppliers and prices

Due to stringent regulatory controls the availability of controlled substances is constrained as compared with non-controlled drugs. Hence it is crucial for programme managers and other concerned parties to be well informed about the confirmed estimates of the relevant drugs for the country as also about the sources and market prices of these controlled substances. Furthermore, programme managers should update themselves on such information from time to time, especially since market options are likely to increase in response to the wider implementation and scaling up of substitution treatment programmes.

4.1 Confirmed estimates of global requirements

As mentioned in Section 2, the national estimates confirmed by INCB define the maximum quantity of drugs that a country may acquire through import and/or manufacture. The confirmed estimates are published by INCB on its website and are updated on a monthly basis based on supplementary estimates approved during the course of the year.

This information is useful as an initial reference for all parties involved in the procurement/distribution system for controlled substances; these parties include

Table: Country-level procedures for the procurement of controlled substances

Steps	Notes and explanations	
1. Explore potential for coordinating procurement with other programmes – if any – that use controlled substances	There could be potential synergy/advantage in combining or coordinating procurement with such other programmes. If such coordination is decided upon, plan the steps described below within the framework of the coordination.	Preparatory Phase
2. Determine which drug product(s) are to be used	This should be based on the national standard treatment guidelines for substitution therapy (specify strengths, dosage forms, packaging).	
3. Ensure that all agencies and individuals in the distribution system are appropriately authorized	Concerned agencies and individuals have to be authorized to import/stock/distribute/prescribe the product(s)	
4. For each drug, estimate quantity needed for the following calendar year	This should be based on: number of patients covered under existing programmes, plans for scaling up the programme, historical levels of doses used, buffer stock requirement (at least 6 months buffer is advisable).	
5. Notify competent national authority the estimated requirement of each drug latest by 31st March	This must be done in time since the competent national authority must communicate the total needs of the country to the INCB by 30th June of the same year (see Section 2.2.1).	
6. Identify likely manufacturer sources	To be done as per guidelines specified by government/donor/UN agencies.	Procurement Phase
7. Determine order size based on budget	Estimate total cost of procurement of each required drug based on drug prices of likely suppliers and import duties if any. Adjust order size based on funds/budget available. (Countries should consider waivers of import duties to reduce costs.)	
8. Conduct domestic procurement of those product(s) produced in the country. If a product needs to be imported, follow the steps below	For each drug, first determine whether the required strengths and dosage forms are produced in the country. Domestic procurement to be done as per applicable guidelines	
9. If the product is not registered in the country, apply for and obtain approval under 'special access' scheme	Many countries permit procurement of products that have not been registered, on a one-time, case-by-case basis, under a 'special access' scheme/programme. Such scheme – if in existence – may be invoked pending registration of the product.	
10. Apply for and obtain import certificate from competent national authority	Importing agency should coordinate with the competent national authority to verify if there is sufficient unused quantity from the confirmed estimates available for the import; otherwise competent national authority should submit supplementary estimates to INCB.	
11. Determine type of procurement method to be used	The procurement method could be, e.g., international tender, limited tender, direct negotiation, or otherwise. The choice of method would depend upon country policies and guidelines. Often, external sources of funding – e.g. UN agency or other donor – prescribe criteria for choice of procurement method.	
12. Conduct the tendering process and identify manufacturer/exporter	To be done as per applicable guidelines	
13. Arrange for tripartite contract if required	This may be required if funding is from an external source. E.g., a tripartite contract between donor/UN agency, government importing agency and exporter	
14. Place order and send copy of import certificate to the manufacturer/exporter	The exporter then fulfils the regulatory requirements in its country and obtains an export certificate.	
15. Prepare customs documentation and prepare for payment of any import duty	To be done as per national policies/procedures	
16. Facilitate the customs inspection of the shipment made by the exporter	To the extent possible, existing infrastructure and resources should be utilized for customs clearance.	
17. Receive goods, arrange for distribution, and send report on the import to the competent national authority as required	• Arrange for distribution of goods to treatment sites. • The competent national authority normally requires certain details on the product(s) imported.	
18. Make payment to the exporter	Terms of payment would be as per applicable guidelines/arrangements under the tender process.	
19. Submit periodic reports, as required, to the competent national authority	These reports pertain to distribution/consumption and balance stocks of each product and are prepared: (1) by the importing agency; and (2) by the programme manager based on reports from all treatment sites.	Utilization Phase

health programme managers, the competent national authorities of importing/ exporting countries, importing agencies and manufacturers/suppliers. For example, parties can monitor whether the quantity of a drug sought to be imported falls within the confirmed estimate of the importing country. The confirmed estimates of global requirements of narcotic drugs[7] and psychotropic substances[8] may be accessed from the INCB website.

4.2 Suppliers and prices

4.2.1 Suppliers and market prices of methadone and buprenorphine

The Central and Eastern European Harm Reduction Network (CEEHRN) in cooperation with UNAIDS has initiated a joint project with the aim to collect information and compile a database of substitution drug producers/vendorsand theirprices. As the most common opioid agonist treatment drugs are methadone and buprenorphine, information was collected on these drugs. The updated information is available in the document *Overview of Market Prices of Opioid Agonist Treatment Drugs, (last update 2005 June)*, Central and Eastern European Harm Reduction Network (CEEHRN).[9] CEEHRN proposes to update this database periodically. Country programme managers planning procurement are advised to refer to this document, and also to consult with their counterparts in other countries for information and recommendations based on their experience with specific suppliers.

4.2.2 Manufacturers of narcotic drugs and psychotropic substances

The UNODC publication *Manufacture of Narcotic Drugs, Psychotropic Substances and their Precursors – 2003* contains useful information on manufacturers of controlled substances. With information presented on a country-by-country basis, this publication contains a list of manufacturers authorized by Governments to manufacture narcotic drugs and psychotropic substances. Along with the name of the manufacturer, the reader will have access to the address and the list of narcotic drugs the manufacturer was authorized to produce. Detailed also, for each manufacturer, is a list of what narcotic drugs and psychotropic substances were actually manufactured. This is a priced publication; purchase related information is given in the Appendix *References*.

[7] Estimated World Requirements of Narcotic Drugs for 2006 – Supplement number 10/October 2006 – http://www.incb.org/pdf/e/estim/supp10.pdf.

[8] Assessments Psychotropic Substances 2005 – Assessments of Annual Medical and Scientific Requirements for Psychotropic Substances – http://www.incb.org/incb/psychotropic_substances_assessments.html.

[9] This document may be downloaded from the following link: http://www.ceehrn.org/index.php?ItemId=12232. For further information contact: info@ceehrn.org.

Appendices

A. Country examples

I. Indonesia – procurement of methadone

A programme for methadone substitution treatment was initiated in Indonesia during 2001-2002 by the Directorate General – Medical Care, Ministry of Health with active support from WHO. The methadone treatment services were started in February 2003. The procurement was done through WHO since that enabled considerable savings by way of exemption from import taxes.[10]

During the initial phase considerable effort was invested in building partnerships, capacity and coordination among concerned agencies, departments and policy makers. Apart from those involved in the actual procurement cycle, the following were involved in providing ministerial/policy level facilitation and support: a Minister who is also the Chair of the National AIDS Coordination Council; Directorate of Communicable Disease Control in the Ministry of Health; National Narcotic Board; and UNAIDS and AusAID.

The actual procedures followed for procurement/distribution of methadone are as below:

1. Request from Directorate General – Medical Care, MoH to the Department of Pharmaceutical and Health Equipment, Ministry of Health (the competent national authority)[11] for approval to procure a specific quantity of methadone liquid
2. Approval issued by Department of Pharmaceutical and Health Equipment
3. Request to INCB by Department of Pharmaceutical and Health Equipment to adjust the confirmed estimate of methadone for Indonesia
4. Department of Pharmaceutical and Health Equipment issues import license to Kimia Farma (a semi-government pharmaceutical company authorized as sole importer of controlled substances for medical use)
5. Kimia Farma forwards the import license to WHO Indonesia country office which forwards it to WHO South-East Asia Regional Office which in turn forwards it to WHO headquarter
6. Assistance from WHO headquarter for procurement, including conduct of the tendering
7. After receiving the pre-advice together with complete shipping documents from the supplier, the WHO country office processes the documents for tax exemption.
8. Kimia Farma and WHO work jointly to arrange processing of shipment, clearance of shipment and forwarding to treatment sites

[10] Information on methadone procurement by WHO in Indonesia was provided by present and former staff of WHO Indonesia country office.

[11] Till recently, the competent national authority was Food and Drug Administration, MoH.

After usage, reporting is done as below:

9. Consumption (number of patients, mean dosage, total amount used) is reported by treatment sites to Directorate General – Medical Care which in turn submits consolidated report to Department of Pharmaceutical and Health Equipment
10. Kimia Farma reports the following information to Department of Pharmaceutical and Health Equipment – the quantity of methadone requested, the quantity entering the country, the quantity distributed and balance stock in the store
11. Department of Pharmaceutical and Health Equipment consolidates information from the above reports and reports to INCB as required

Time frames. During the first round of procurement, the time period between placing the order and delivery to sites was about 6 months. With experience and better understanding, this came down to 3 months. It has been observed that methadone on order needs about 1½-2 months for production and delivery. Strong partnerships and coordination among the concerned departments/agencies can considerably reduce the time taken for paperwork and other processes.

II. Malaysia – procurement of methadone and buprenorphine

Both methadone and buprenorphine are being imported into Malaysia. However, only methadone is being used under the government's substitution treatment programme. Buprenorphine is prescribed by individual medical practitioners to their patients for substitution treatment. The methadone substitution treatment programme was started, on a pilot basis, in October 2005.[12]

The importers in case of both methadone and buprenorphine are the product registration holders/manufacturers. In the case of methadone, only raw materials are imported which are then processed in the country to produce finished formulations. Only the liquid form of methadone is being used in the government's substitution treatment programme. In the case of buprenorphine, both raw materials and finished formulations are imported.

The competent national authority in Malaysia is the Pharmaceutical Services Division in the Ministry of Health (MoH). The Pharmaceutical Services Division is responsible for:

1. Compiling estimates of the total requirements of the country for methadone and buprenorphine
2. Allocating the total estimated requirement for each controlled substance among the product registration holders for import/manufacture
3. Issuing approval for import/export
4. Licensing of premises where the substances would be stored/processed
5. Enforcement activities

[12] Information on methadone and buprenorphine procurement in Malaysia was provided by the Director, Pharmaceutical Services Division, Ministry of Health, Malaysia.

The procedures followed to initiate imports are as follows:

1. The estimation of methadone requirements for the government's substitution treatment programme is done by Disease Control Division, MoH jointly with Pharmaceutical Services Division, MoH.
2. Importers/manufacturers are required to notify their estimated requirements of methadone and buprenorphine to Pharmaceutical Services Division latest by 31st March every year.
3. Pharmaceutical Services Division submits the estimated requirements to International Narcotics Control Board (INCB) by 30th June of the same year.
4. INCB issues confirmed estimates in December of the same year.
5. Importers apply to Pharmaceutical Services Division for import approval. The approval is required to be issued within 14 working days. An approval is valid for 6 months only.

Other relevant information

In the case of methadone the base amount approved for 2006 is 17,250 grams. The base amount of buprenorphine approved for 2006 is 15,000 grams.

In the case of methadone, the government has followed a policy of encouraging more than one company to register products. This has helped to ensure price competitiveness. Buprenorphine, however, is a patented product and as such there is only one product registration holder and one importer for it.

B. References

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