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United Nations Office on Drugs and Crime

Misuse of Prescription Drugs: a South Asia Perspective



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Competent Authorities, Experts and Representatives of the pharmaceutical industry and trade from Bangladesh, Bhutan, India, Maldives, Nepal and Sri Lanka

UNODC:

Ms. Cristina Albertin
Representative

Mr. Rajiv Walia
Regional Programme Coordinator
Strengthening drug law enforcement capacities in South Asia (XSA J81)

Mr. K. Raghavan
Project Officer
Strengthening drug law enforcement capacities in South Asia (XSA J81)

Mr. Kunal Kishore
Regional Project Coordinator
Prevention of transmission of HIV among drug users in SAARC countries (Project RAS H13)

Mr. Ravindra Rao
Technical Officer
Prevention of transmission of HIV among drug users in SAARC countries (Project RAS H13)

Mr. Debashis Mukherjee
Research Officer
Prevention of transmission of HIV among drug users in SAARC countries (Project RAS H13)

Ms. Madhyama Subramanian
Communications Officer

Mr. Johnathan Allen
BSc Physiology and Pharmacology
Intern, 2010

Foreword

The last decade has seen a substantial rise in the recreational use of pharmaceutical drugs across South Asia. Ready availability, affordability and high purity of narcotic and psychotropic pharmaceuticals make them attractive substitutes for illicit drugs among current and former users. The health consequences are severe as more and more people appear to be switching towards injecting methods, carrying the serious risks of spreading HIV and hepatitis C which have already become priority public health issues.

Concerned by the health impact of illicit pharmaceutical drug use, UNODC brought together policy makers and experts from the fields of drug law enforcement, drug treatment and representatives from the pharmaceutical industry with the objective of assessing in each country (Bangladesh, Bhutan, India, Maldives, Nepal, Sri Lanka) the nature and extent of pharmaceutical use; the manner in which pharmaceuticals are sourced illegally; and the legal, regulatory and enforcement gaps. At the end of the debate, country experts made their recommendations on the manner in which pharmaceutical abuse can be curtailed.

Pharmaceutical drugs have traditionally been omitted from national drug use surveys and this report provides a preliminary (non data-based) expert assessment of the nature and extent of the problem in the context of drug use in general.

The methodology adopted was to discuss and assess the various aspects of the issue in a series of seminars and brain storming sessions in Bangladesh, Bhutan, India, Maldives, Nepal and Sri Lanka.

While making their assessments and recommendations, experts were conscious of the fact that the availability of pharmaceutical drugs for non-medical use is a highly sensitive issue to address, given their essential role in pain management and other areas of medicine.

UNODC hopes that the report will be used by policy makers to address the serious issues concerning the diversion and misuse of essential pharmaceuticals. The report highlights the important role that members of the pharmaceutical trade and industry can play in improving systems.



Cristina Albertin

Representative

United Nations Office on Drugs and Crime

Regional Office for South Asia

Abbreviations and technical terms

Alkaloid	A naturally occurring nitrogenous organic molecule that has a pharmacological effect on humans and other animals
AIDS	Acquired Immunodeficiency Syndrome
ATS	Amphetamine-type Stimulants
BNCA	Bhutan Narcotics Control Agency
CDDA	Cosmetics, Devices and Drugs Authority (Sri Lanka)
DCGI	Drugs Controller General of India
DDA	Department of Drug Administration (Nepal)
DEA	Drugs Enforcement Agency (USA)
DNC	Department of Narcotics Control (Bangladesh)
DRA	Drug Regulatory Authority (Bhutan)
EXIM	Export / Import
FDA	Food & Drug Authority (Maldives)
HIV	Human Immunodeficiency Virus
Hypertension	High blood pressure.
Hypotension	Low blood pressure
IDU	Injecting Drug User
INCB	International Narcotics Control Board
LOPPS	Licit Opiate / Psychotropic Pharmaceuticals
MoF	Ministry of Finance
MoH	Ministry of Health
MoHFW	Ministry of Health and Family Welfare
MSM	Men who have Sex with Men
NDCLEU	Narcotics Drug Control Law Enforcement Unit (Nepal)
NDLEU	National Drug Law Enforcement Unit (Bhutan)
NDPSSAA	Narcotic Drugs, Psychotropic Substances and Substances Abuse Act
NSAID	Non-steroidal Anti-inflammatory Drug
RBP	Royal Bhutan Police
Rs	Rupees
SAARC	South Asian Association for Regional Cooperation
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNODC	United Nations Office on Drugs and Crime
WHO	World Health Organisation

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Introduction



Pharmacy

The human brain and body are among the most complicated and intricately-organised systems in the universe and many of their neurochemical signaling systems orchestrate multiple functions. Therefore, pharmacological attempts to selectively intervene in one feature of a disease are typically fraught with unwanted effects elsewhere. Likewise, drugs which are prescribed to alleviate symptoms of illness such as pain can induce pleasurable feelings when taken in the absence of disease and this rewarding feeling can lead to the repeated use of the substance. As the brain and body adjust physiologically to the presence of the drug, addiction manifests as the development of tolerance to - and habitual use of - the drug. As a consequence of this adaptive process, increasingly higher doses are often required by the user to achieve the same initial subjective effect. When the drug is withdrawn these dynamic changes in the brain initially persist, inducing a feeling of craving and other unpleasant psychological - and sometimes physical - symptoms.

The focus of this report is the misuse of pharmaceuticals (both narcotic and psychotropic), which in most of South Asia are largely available through pharmacies. The position of the pharmacist therefore becomes important since he often replaces the traditional role of the doctor in diagnosing illnesses and prescribing treatment, primarily due to lack of affordable health care systems for the common man in the region. As the pharmacopeia is vast and technical, consequently many patients and pharmacists alike usually possess only a cursory knowledge of the risks posed by different classes of drugs. This adds a dangerous dimension to the issue of illicit pharmaceutical use in the region and exacerbates the possibility of misdiagnosis and exposure of the public to potentially addictive substances.



A patient requiring opioids for palliative care (Picture courtesy - Pallium India)

Narcotic and psychotropic pharmaceuticals are also often obtained by dependent heroin users as a substitute for, or an adjunct to, illegal opiate use and as such the diversion of these drugs is a factor in sustaining addiction. All countries in the region need to build awareness of and vigilance towards the growing public health concerns associated with addiction to pharmaceuticals and take steps to protect the most vulnerable addicts, especially injecting drug users who are particularly susceptible to the HIV and hepatitis C epidemics.



A drug user injecting drugs

It is a matter of some concern that illicit pharmaceutical drug use has surpassed the use of illicit drugs in many parts of South Asia (INCB 2008). A complex problem with a multitude of causal and confounding factors, this situation demands a multi-faceted and highly sensitive approach towards tackling it. The pharmaceuticals mentioned in this report are valuable and necessary tools and any systematic efforts to prevent their diversion for non-medical use need to be gradual and must not rid pharmacists' shelves of essential medicines. Availability of much-needed opioids - especially

morphine - for cases such as cancer pain is extremely low in South Asia and must be increased rather than further diminished. Top-down supply control approaches to the issue of illicit pharmaceutical drug use should be made in the most sensitive manner, streamlined for achievable priority targets and combined with treatment and awareness campaigns at the grass roots level in order to minimise the demand for, and harm caused by the non-medical use of narcotic and psychotropic pharmaceuticals, especially by the injection route.

Objectives of this report

In the absence of national surveys there is little data available on the use of pharmaceuticals in South Asia. The broad objective of the report thus was to make an expert assessment on critical issues that concern the illegal use of pharmaceuticals. Specifically, the first objective was to assess the nature and extent of pharmaceutical use and identify the pharmaceuticals that are generally used. The second objective was to assess the prevalent legal and regulatory regimes and the organizational, regulatory and enforcement capacities. The third objective was to identify the manner in which pharmaceuticals are sourced illegally or domestically and externally through either smuggling or trafficking.



Morphine, an opioid painkiller

Finally, the report makes recommendations on the manner in which pharmaceutical abuse can be curtailed. In the process, the report addresses demand and supply issues; the need for creating better awareness among the various stakeholders; the importance of a proper assessment of the licit requirement of pharmaceuticals; understanding legal and enforcement gaps; focusing on organizational capacities; need for enhancing treatment and outreach services; and importantly highlighting the role of the pharmaceutical Trade and Industry. In short, this report provides a preliminary (non data-based) expert assessment of the illicit use of pharmaceuticals in the context of drug use in general.

The methodology adopted by UNODDC was to conduct a series of seminars and brain storming sessions in Bangladesh, Bhutan, India, Maldives, Nepal, and Sri Lanka in 2009, assembling policy makers and professionals from relevant fields (drug regulatory ministries and agencies, law enforcement personnel, NGOs, and representatives of the pharmaceutical industry and trade) to discuss issues concerning illicit use of pharmaceutical drugs in specific countries.

This report presents the conclusions of these seminars, as well as additional research in the field of drug dependence, to begin the process of developing intervention strategies where necessary by policy makers and members of the Trade and Industry.



Seminar on pharmaceutical drug use in Bhutan

2

Nature & extent of illicit drug use

Pharmaceutical drugs have recently gained popularity among recreational drug users in South Asia due to the following perceptions in the mind of the user:

- It is legal to obtain such substances as they are available through pharmacies
- They do not have a damaging effect on health unlike banned hard drugs
- They do not attract a stigma unlike banned hard drugs

The increasing acceptability among the medical fraternity for the use of opiates and opioids for pain management has also contributed to an increase in the production and clinical use of synthetic opioids. Whilst there is an overwhelming consensus in the minds of experts that opioids are needed for pain management, their low price, high purity and easy availability from pharmacies has led to their widespread illicit use across the region.



South Asia

The broad country specific trends on the nature and extent of illicit pharmaceutical use are discussed below.

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2.1 Bangladesh

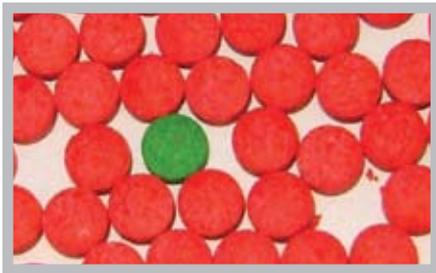
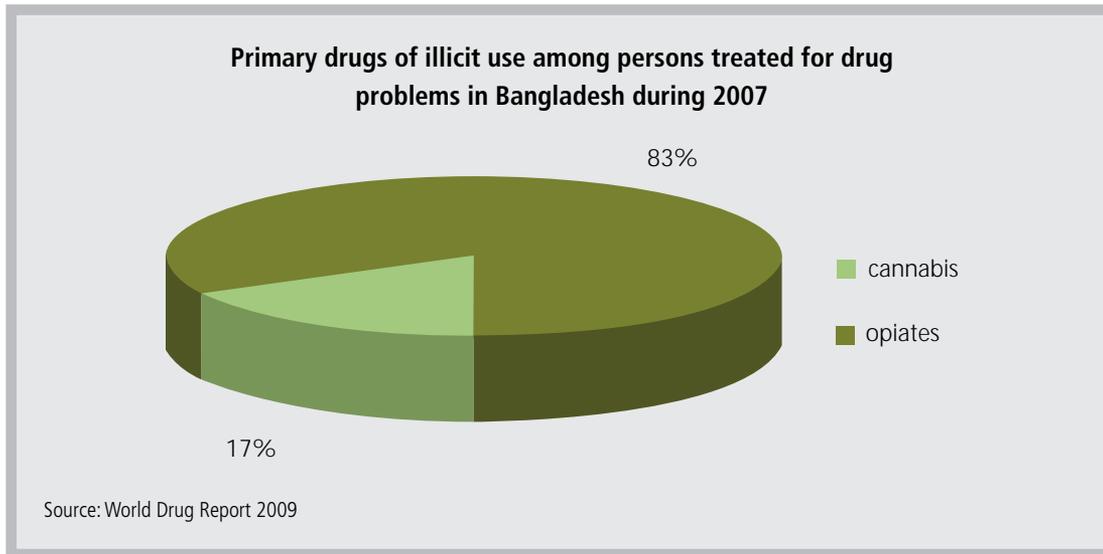
Bangladesh has a thriving pharmaceutical industry with a fairly large scale manufacturing capability that produces a variety of licensed medicines including benzodiazepines such as nitrazepam and non codeine-based cough syrups. The industry is growing at an impressive annual growth rate of 9% and, as one of the more technologically developed industries, contributes sizably to the national exchequer.

The industry, which is dominated by local companies, manufactures over 6,000 brands, meeting the demand for around 95% of the country's pharmaceuticals and even supplies to 72 countries worldwide. The export of pharmaceuticals is currently growing by 50 percent per annum (Financial Express Bangladesh 2009).

In the absence of a survey, there are no official estimates of the extent of illicit drug use in Bangladesh. Nonetheless, according to experts, the main drugs of illicit use are cannabis, heroin and recently, amphetamine-type stimulants (ATS) commonly known as 'Yaba'. While cannabis grows wild and may be cultivated in some parts, heroin is trafficked into the country from Myanmar and India; lately, heroin of Afghan origin has also found a market in Bangladesh. Law enforcement officials acknowledge that opium poppy may be illicitly cultivated in small tracts in the country.

ATS drugs are a recent phenomenon that is believed to largely come from Myanmar and have become widespread in Bangladesh's urban areas. The most common synthetic drug is "Yaba" (illegally manufactured pills containing methamphetamine). Young people are displaying a preference for these types of drugs because rather than sedating

the user, they have strong social dis-inhibitive and energy releasing components. They also induce feelings of pleasure and encourage young people to become socially active. However, these drugs can be habit forming and can cause neurological and cardiovascular problems during chronic use and / or at high doses.



Yaba pills

Other than banned drugs, pharmaceuticals are an equally serious problem in Bangladesh. However, like other drugs, the nature and extent of the illicit use of pharmaceuticals remains in the realm of speculation. But according to knowledgeable experts, the problem is getting serious and has already become a grave issue, particularly with respect to injecting drug users (IDUs) using pharmaceuticals. In fact, in the view of some representatives of the pharmaceutical trade, illicit pharmaceutical use is already far more serious in rural parts of the country than the use of banned drugs. According to

them there is an organized parallel system of distribution of pharmaceutical drugs that is fueling the illicit use.

The main pharmaceutical drugs of abuse in Bangladesh as identified by experts are as follows:

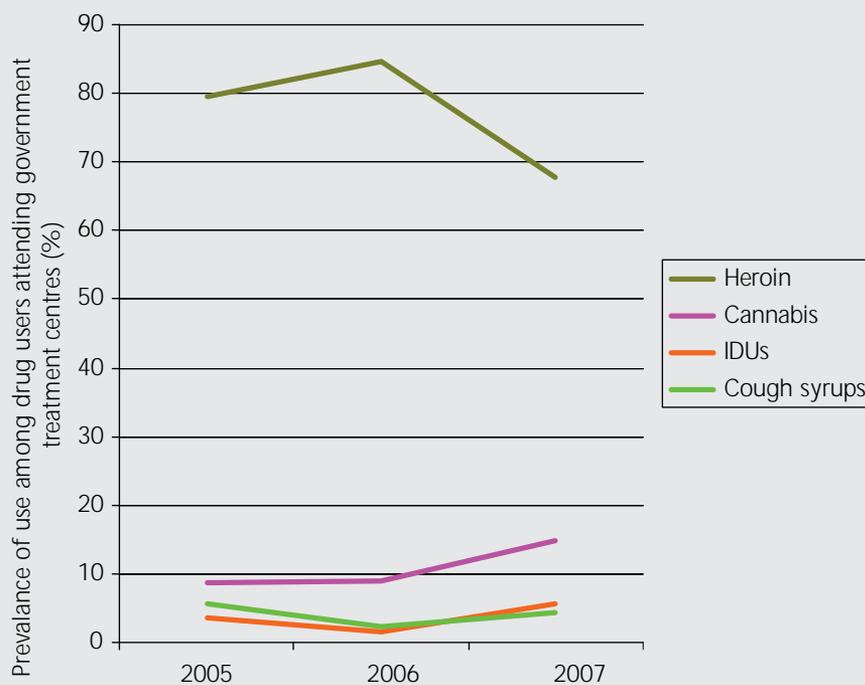
- Codeine based cough syrups
- Dexpotent, expotent (non codeine based cough syrups)
- Diazepam, other sedatives, hypnotics, anxiolytics
- Pethidine
- Buprenorphine
- Codinal tablets
- Pain killers – Nelben 1 & 2 Nalbuphine hydrochloride
- Anabolic steroids
- Antihistamines
- Anesthetic nitrous oxide
- ATS derivatives
- Poly drugs – mixture of antihistamines, sedatives, cough syrups and vitamins

Statistics available with the Department of Narcotics Control (DNC) indicate that 12% of drug users seeking treatment are users of pharmaceutical drugs (http://www.dnc.gov.bd/CMS_Table_04_09.htm). Pharmaceuticals including psychotropic substances are known to be used as substitutes for hard drugs in times when the latter is in short supply.

Some of the reasons cited by experts for illicit drug use are: curiosity; lack of alternative social activities; family and social problems; and lack of awareness of their effects and associated risks.

Stimulant use is particularly rampant in Bangladesh, and sympathomimetics are reportedly used as cheaper substitutes for "Yaba"; they are also more widely available.

Percentage prevalence of the use of various drugs among people seeking treatment in government de-addiction centers in Bangladesh from 2005 – 2007



Source: DNC Website (http://www.dnc.gov.bd/CMS_Table_04_09.htm)



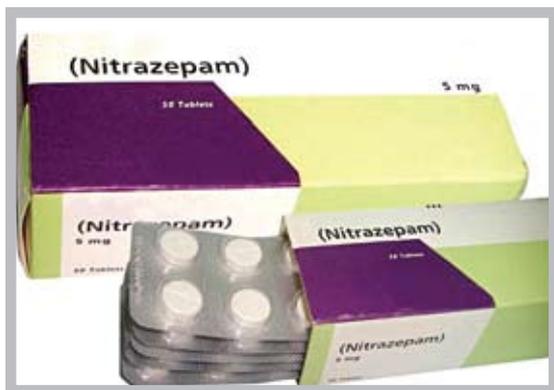
Codeine based cough syrup

There is consensus that the most popular illicitly-used pharmaceutical drug is codeine-based cough syrup, large quantities of which are seized by law enforcement authorities every year. Codeine and buprenorphine are banned in Bangladesh, but there is large scale smuggling from India. The illegal status of codeine, as for other illicitly-used drugs, has its impact on crime in general because the variable supply causes fluctuations in street price and encourages drug users to resort to criminal activity such as theft to continue feeding their habit.

Illicit poly-drug use is considered another major problem and one that poses extra challenges for the rehabilitation process. Popular combinations include antihistamines with opioids, and opioids and benzodiazepines (diazepam) with or after ATS and other sympathomimetics to reduce their side effects and withdrawal symptoms. Diazepam is also commonly used to lessen opioid withdrawal syndrome.

As mentioned above, the illicit use of pharmaceuticals is already serious, particularly among injecting drug users (IDUs). Among the 20,000 IDUs in Bangladesh (Mathers et al 2008), buprenorphine is the most commonly injected drug due to its relatively easy availability and the low cost of injectable preparations (Kumar, 2006). HIV infection rates among IDUs in Bangladesh increased dramatically from 1.4% in 2000 to 4% in 2002, and remained at 4% until 2004. By 2007, another source (sentinel survey) estimated that 7% of IDUs in central Bangladesh were infected with HIV (Reddy et al, 2008).

2.2 Bhutan



Nitrazepam

Bhutan has a low crime rate (Bureau of Consular Affairs) and illicit drug use there has been relatively minimal. The country has traditionally been guarded against outside influence perceived as negative and levies rather high visa tariffs for foreign tourists. The “hippie” culture that began to spread from the US and Europe to South Asia during the 1960s never reached Bhutan despite it having taken firm roots in parts of neighbouring India, Nepal and Thailand.

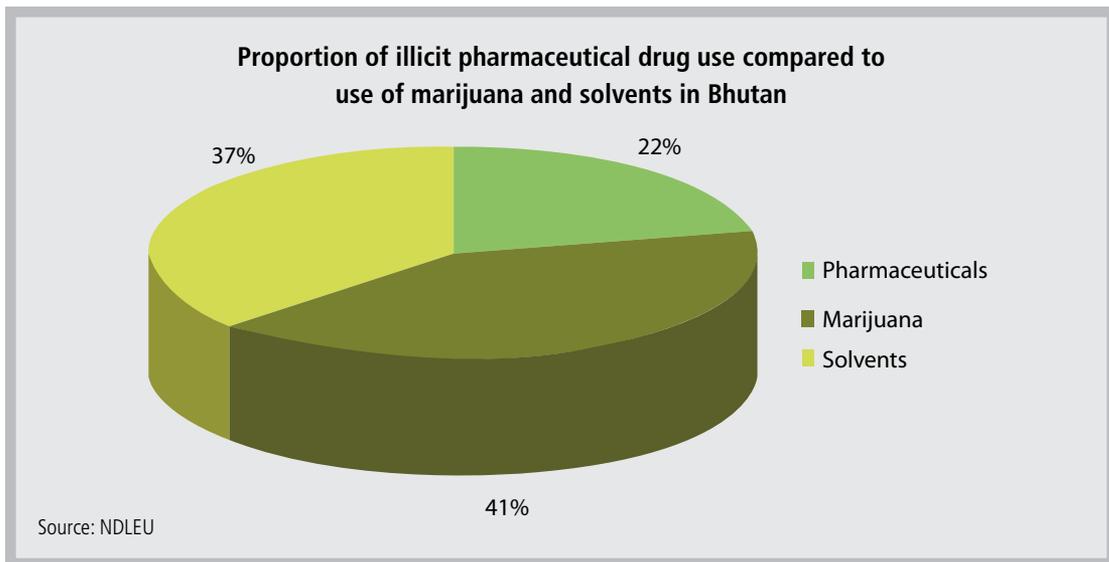
However, the general consensus among experts is that illicit pharmaceutical use is increasing in Bhutan and is beginning to become a serious issue - in particular the

use of opioids such as dextropropoxyphene and benzodiazepines like nitrazepam. Sporadic use of decongestants containing adrenergic stimulants as well as anti-cholinergics and antihistamines has also been reported. Bhutan has minimal history of cultivation of either cannabis or opium and generally experts consider pharmaceuticals to be preferred drugs rather than being substitutes for other plant-based or illegal synthetic drugs - although there are anecdotal reports of combining them with cannabis.

The main pharmaceutical drugs of abuse in Bhutan as identified by experts are as follows:

Brand name	Generic name / Ingredients
Corex / Recodex	Codeine Phosphate
Nitrosun (N-10)	Nitrazepam
Relipen	Dextropropoxyphene
Spasmoproxyvon	Dextropropoxyphene + Dicyclomine
Diazepam	Diazepam
Sinarest	Cold tablets containing ephedrine
Tiffy	Cold tablets containing ephedrine
Alprazolam	Alprazolam
Phenergan	Cough syrup
Tramadol	Tramadol
Pethidine	
Pentazocine	
Fortwin	

Although no rigorous studies have probed the extent of illicit pharmaceutical use, the data that does exist shows that illicit pharmaceutical use accounts for 22% of the entire recreational drug use in Bhutan – as much as half that of cannabis despite the latter’s relatively low cost. The younger generation and urban areas are predominantly affected by this trend, with 85.5%, as of 2009, of drug users reportedly below 24 years of age with the majority of these being under 18. 86% of arrests between 1989 and 2005 were made in the capital, Thimphu (BNCA, 2006).



As the country gradually opens up and pressures of development grow, the Bhutanese society - particularly the youth - could become more vulnerable to the negative impacts of illicit drug use.

2.3 India

India is the fourth largest producer of pharmaceuticals globally, poised to become the “pharmacy of the world”. Because of its vibrant pharmaceutical manufacturing industry, the country is susceptible to diversion of narcotic and psychotropic pharmaceuticals produced by its industry. Common illicitly-used pharmaceuticals are codeine-



Sedative pills

based cough syrups and other narcotic (opioid) painkillers as well as a variety of benzodiazepine tablets - all of which are widely available through retail pharmacies.

In 2002, the first ever national drug survey was carried out in India, but it was limited to tobacco, alcohol, cannabis and opiates. Since then, the pattern of illicit drug use has changed. The economic growth over the last decade has resulted in the use of new drugs like stimulants, designer drugs and most importantly pharmaceuticals.

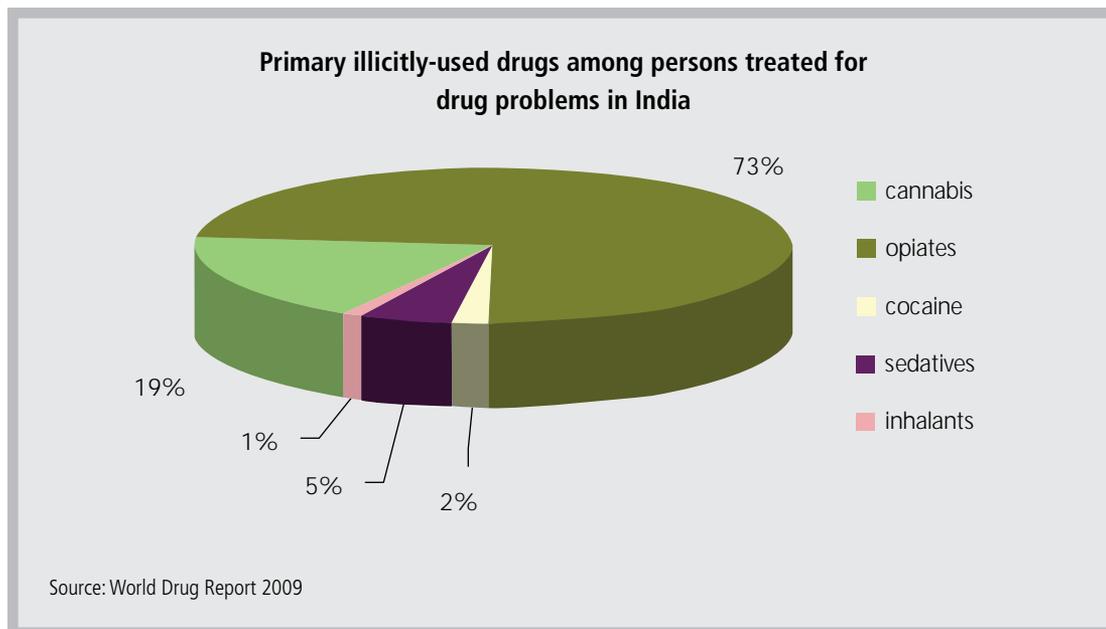
It is the considered view of experts that many former as well as current illicit drug users in parts of the country appear to have shifted from narcotics to pharmaceutical use, with evidence of poly drug use; in some areas like Nagaland, pharmaceuticals (in this case dextropropoxyphene) are the main recreational drugs of choice. This may be because their low cost relative to that of their illegal counterparts outweighs the difference in narcotic or psychotropic potency. A history of difficult political and socio-economic conditions in the north-east as well as its proximity to Myanmar, has led to high levels of use of a range of drugs in that region. Mizoram, for example, shares borders with Myanmar and is an entry point for heroin trafficking. This not only fuels heroin addiction but also creates demand for narcotic and psychotropic pharmaceuticals as cheaper replacements for heroin.

The north-east is not the only region that is negatively impacted by pharmaceutical and injecting drug use. New areas like Punjab, Orissa, Haryana etc, have also emerged as consumers.

Though there is no base line data to estimate the nature and extent of the problem in India, experts opine that illicit pharmaceutical use is a major trafficking and health concern.

The main pharmaceutical drugs of abuse in India as identified by experts are as follows:

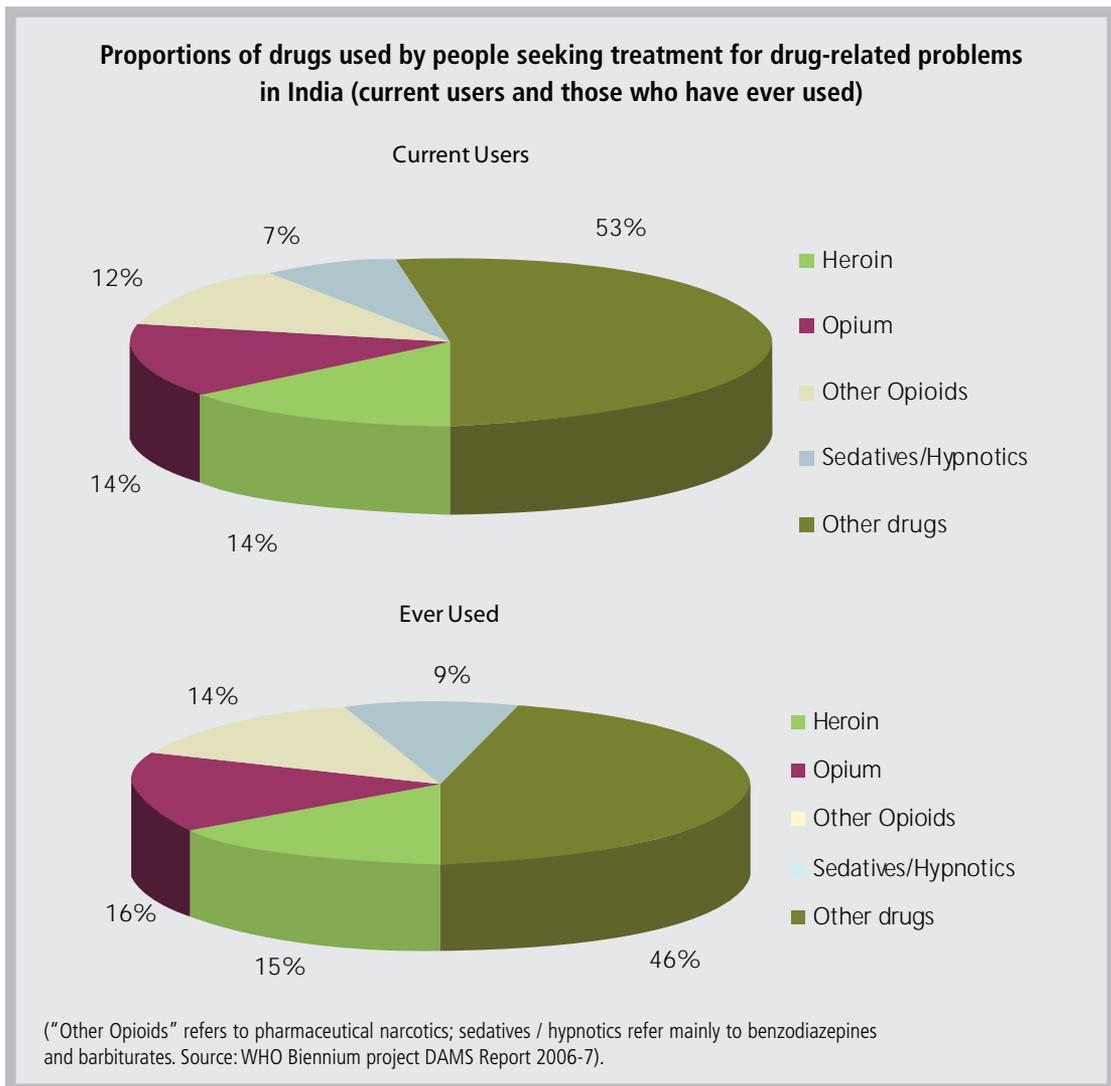
- Pain killers – Buprenorphine, Spasmo proxyvon
- Codeine based cough syrups
- Injectable opiates - Morphine, Pethidine and Pentazocine (Fortwin)
- Depressants: Diazepam, Lorazepam, Nitrazepam, Alprazolam, Zolpidem
- Antihistamines: Avil, Phenergan
- Benzodiazepines
- Sedatives
- Ketamine
- Anabolic steroids: Nandralone, body building foods



According to local experts in the field of de-addiction psychiatry, the majority of pharmaceutical drug addicts seeking treatment in India are first exposed to the substance in question when it is prescribed to them for a genuine medical condition. This highlights the need for careful management of palliative care; the presence of pain may protect a patient from addiction but if the patient continues – wittingly or not – to take a drug after having regained his or her normal health status, the risk of addiction rises dramatically, particularly for outpatients who are more likely to sustain a drug habit that was initiated within their home environment.

Like in other countries of the region, comprehensive data on the extent of illicit pharmaceutical drug use is lacking in India as well. However, there have been thematic studies which illustrate to a degree, the nature and extent of the problem. These conclude that among those seeking treatment for drug related problems, opiate use accounts for 40 percentage of the total drug use in India of which 14.3% is heroin, 14.2% is opium and pharmaceutical opioids account for 12.1% (WHO Biennium project DAMS Report 2006-7); 6.5% use sedatives/hypnotics. The studies incidentally note that around one quarter of illicit drug users are homeless and 40% have not completed primary school education. Truck drivers are particularly susceptible to drug use.

The illicit use of pharmaceuticals is definitely an issue as accepted not only by experts but also by thematic studies. The problem gets a more serious dimension when the illicit use is through the IDU route. In India, injecting drug



use has spread extensively through many of the north-eastern states and urban areas, and recently the states of Kerala, Uttar Pradesh, Bihar, Orissa and Madhya Pradesh. Jammu & Kashmir, Punjab and Haryana are also noticing an increasing number of IDUs (Kumar, MS, 2006). Use of buprenorphine and pentazocine and a variety of sedatives (diazepam, promethazine and pheniramine) is common. Health care coverage among IDUs in these emerging nuclei in Haryana and Punjab is especially low, with only 0.1 – 8% of respondents in one study reporting to have ever received treatment of services, but never oral drug substitution (Ambikar & Tripathi 2008). This increases the likelihood of users sharing their injection equipment and indeed the same survey found that between 34% and 94% of respondents had shared needles and syringes.



A drug user injecting drugs

Estimates of the number of IDUs in India range from over 90,000 (RCSH, 2006) to almost 190,000 (National AIDS Control Organisation, 2006). However, most sources including the Government of India cite figures nearer the upper end of this range (Mathers et al, 2008).

Dextropropoxyphene is common among IDUs in the north-eastern states, especially in Kohima, Shillong, Jammu and Darjeeling; buprenorphine injection is more widespread in Delhi and Chennai as well as some smaller towns such as Jammu, Bhubaneswar, Muzaffarpur, Darjeeling and Jamshedpur (UNAIDS 2006b). Injecting drug use in these regions is fuelling an epidemic of blood-borne infections including HIV and hepatitis C. The states of Manipur and Nagaland are now among the top five states in India in terms of HIV infection (disproportionately affecting the 15- to 30-year old population in these states), due mainly to intravenous drug use (INCSR, 2009).

NACO 2007 surveillance data shows HIV prevalence among IDUs to be 7.2% and 2009 data shows to be 9.2%.

2.4 Maldives



Actifed

Drug laws in Maldives are strict, and close to three quarters of Maldivians serving prison sentences are doing so for drug offences (University of Pennsylvania / UNDP 2004). Drug use has become increasingly widespread since the 1970s. Infertile for crop cultivation and lacking a pharmaceutical industry, all of Maldives' drug supply comes from outside the country.

Cannabis use is common with conservative estimates at 1% of the population (though several sources claim a higher proportion to be more accurate). Heroin use is also

now highly prevalent. Forty percent of Maldivians are below 15 years old (WHO, 2000) and the average age of onset of heroin use is a mere 12 years, (UNICEF Newline 2006). Lack of job opportunities coupled with an inadequate secondary education system contributes to high unemployment rates and these are causal factors (EU 2007) for the rising drug use especially among young unemployed males, who are the worst-affected sector of society (UNDP/FASHAN/UNESCAP 2003). Population shifts and overcrowding are also thought to be catalytic factors in the country's drug problem.

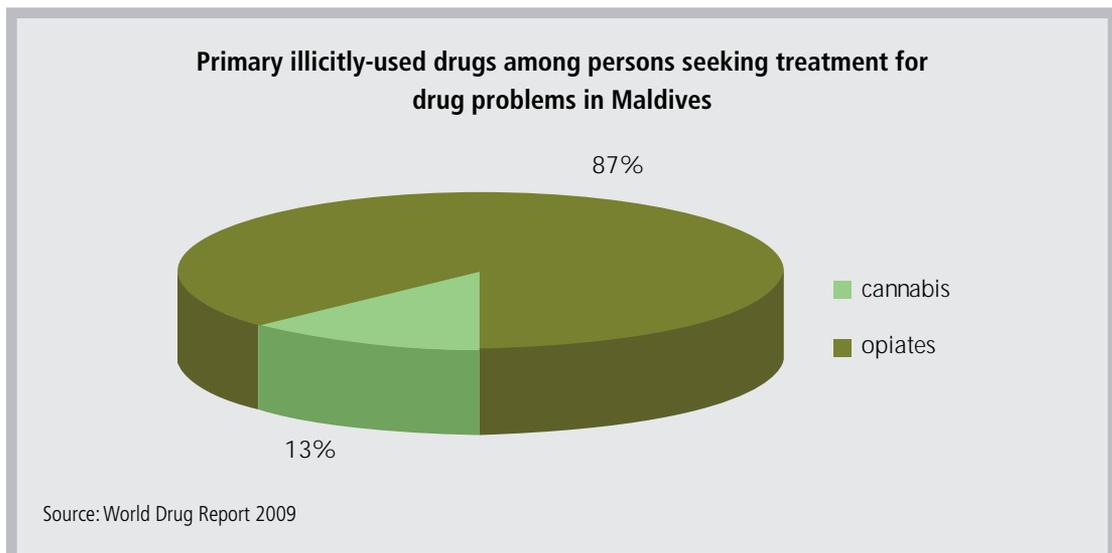
The main pharmaceutical drugs of abuse in Maldives as identified by experts are as follows:

- Valium (diazepam)
- Corex d (ephedrine, citrate, chlorpheniramine)
- Benadryl (diphenhydramine)
- Spamoproxyvon (paracetamol + dextropropoxyphene + dicyclomine)
- Avil (pheniramine)
- Actifed (phenylpropanolamine+triprolidine)
- Cetrizine (cetirizine hcl)
- Alprax (alprazolam)
- Brufen (ibuprofen)
- Buscopan (hyoscine butylbromide)
- Piriton (chlorpheniramine)
- Panadeine (codeine + paracetamol)
- Panadol (paracetamol)
- Proxyvon (paracetamol + dextropropoxyphene)

- Phenergan (promethazine)
- Cataprex (clonidine)
- Alerid (cetirizine)
- Melleril anti depressant
- Sarotena Arnitriphilym
- Sibelium anti depressant
- Inhalants Dunlop, glue
- Local plants



Group counseling session for drug users in Maldives



A highly extensive range of pharmaceutical drugs were identified as substances of illicit use by experts in the Maldives, including drugs from the full range of classes. Use of narcotic and psychotropic pharmaceutical drugs is believed to be widespread among users of banned drugs including heroin - supported by the common use of the antihistamines which are popular adjuncts to heroin and other opiate usage. In general, illicit pharmaceutical use is estimated to be more common on the islands outside of Malé and overall the problem is believed by experts, including the Maldivian Government, to be very serious.

While drug use is already serious, there are a few de-addiction centers operating in Maldives, although addicts lament the stigmatisation brought on by the concentric nature of the country's geography whereby - even in the capital city Malé - people lack anonymity, discouraging them from coming forward to seek assistance. Due to the traditional moral code of the country, high levels of stigma are also applied to drug users, further disenfranchising them from society. However, the Maldives government has established close ties with the UNODC and is taking many reformative measures to address illicit drug use.

Another cause for worry in Maldives is the spread of HIV. Before 2008, the only data on the HIV epidemic in the Maldives was available in the form of case reports: among Maldivians, 14 cases of HIV had been identified via this method between 1991 and 31 October 2009. In 2008, the first Bio-Behavioral Survey (BBS) was conducted in the Maldives, and specific high risk groups were also sampled. The mean age of debut of drug use of current injecting drug users [N=276] was 16 in Male' and 17 in Addu. A third (31%) of IDU in Male' and 23% in Addu reported sharing an unsterilized needle at the last time of injection. A large majority (86%) of IDU in Male' had been in jail. Two thirds (64%) of them used drugs while in prison and a third (32%) reported injecting drugs while in jail. For Addu the figures were 56% ever in jail, 66% using drugs and 14% injecting while in prison. Regarding sexual networking, IDUs have a wide ranging sexual network. In Addu and Male, 97% and 90% of IDU had sex in the past 12 months; 54% and 55% had a non-regular partner, 52% and 38% bought sex; sex with another man. Importantly, 59% of IDU reported unsafe sex in the past 12 months.

In conclusion, data to date show an epidemic characterized by low overall prevalence but with high vulnerability and risk, i.e. high epidemic potential. The most likely trigger for an HIV epidemic in the Maldives is injecting drug use. And with a serious illicit pharmaceutical consumption problem, this is only going to get exacerbated.

2.5 Nepal



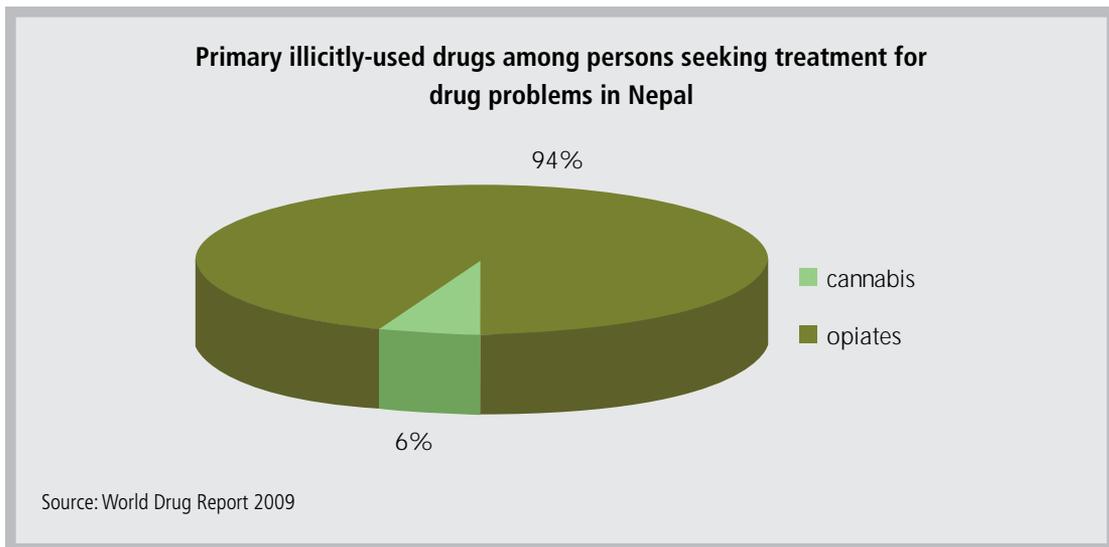
Buprenorphine

Nepal's sunny hills have the ideal climate for the cannabis sativa plant, which grows in abundance naturally and is of high quality at many altitudes including in parts of the Kathmandu valley. Cannabis and opium use was socially tolerated in Nepal until the advent of drug tourism during the 1960s. Possession of cannabis and other drugs was outlawed in the 1970s but the hilly terrain of the central and western parts of the country make crop eradication difficult (INCB 2003). Cultivation of both cannabis and small quantities of opium poppy rose again during the period of Maoist agitation in many districts during the politically unstable period. Heroin inevitably finds its way into the country due to its proximity to Myanmar and India and many anecdotal news reports from within the country document the popularity of "brown sugar" (Gorkhapatra 2009).

The pharmaceutical drugs used recreationally in Nepal are mainly of the opioid and antihistamine class, suggesting an entrenched opiate (opium and heroin) culture, as the opioids are reportedly used as a cheaper and more widely available substitute for their illegal counterparts. The availability and low cost of buprenorphine ampoules has been cited as a primary motivating factor for heroin users to switch from smoking to injecting methods (Chatterjee et al 1996). This may also reflect a perceived safety of pharmaceuticals compared to illegal drugs.

The main pharmaceutical drugs of abuse in Nepal as identified by experts are as follows:

- Buprenorphine
- Pheneramine



- Codeine
- Spasmo proxyvon
- Diephynhydramine
- Chloro-phinedia-maleate (CPM)
- Promethazine hydrochloride
- Tramadol
- Pentazocine (Fortwin)
- Nitrozepam
- Lorazepam
- Alprazolam
- Diazepam
- Phenobarbitone
- Morphine
- Corex
- Avil

Among the psychotropic and narcotic pharmaceuticals, codeine-based cough syrups (largely smuggled in from India), buprenorphine injections and nitrazepam tablets have been reported as the most common (Chatterjee et al 1996). Pharmaceutical drugs are also reportedly used in combination with heroin and also with cannabis. No raw data is available to measure the extent of the problem; however it is known that 86% of all drug users in Nepal are poly drug users of pharmaceuticals and chemicals, suggesting that the problem is extensive (Source: Summary Report of the Survey on Hard Drug Users in Nepal - 2063 conducted by the Department of Statistics, Government of Nepal).

The link between illicit pharmaceutical use and HIV is through the injecting of opioids. Since the first AIDS case was reported in 1988, the HIV epidemic in Nepal has evolved from a "low prevalence" to a "concentrated epidemic". Nepal's HIV epidemic, driven by unprotected sex, sharing of unclean needle by injecting drug users and sexual transmission, is characterized by higher HIV prevalence concentrated among groups. Prevalence among IDUs though

declining steadily over the period is still well above 5% in some areas. However, in some places such as Kathmandu, the HIV prevalence among IDUs is more than 20%. The total number of IDUs estimated in Nepal is about 28,000 with a majority of the IDUs reporting use of injection pharmaceutical opioids.

2.6 Sri Lanka

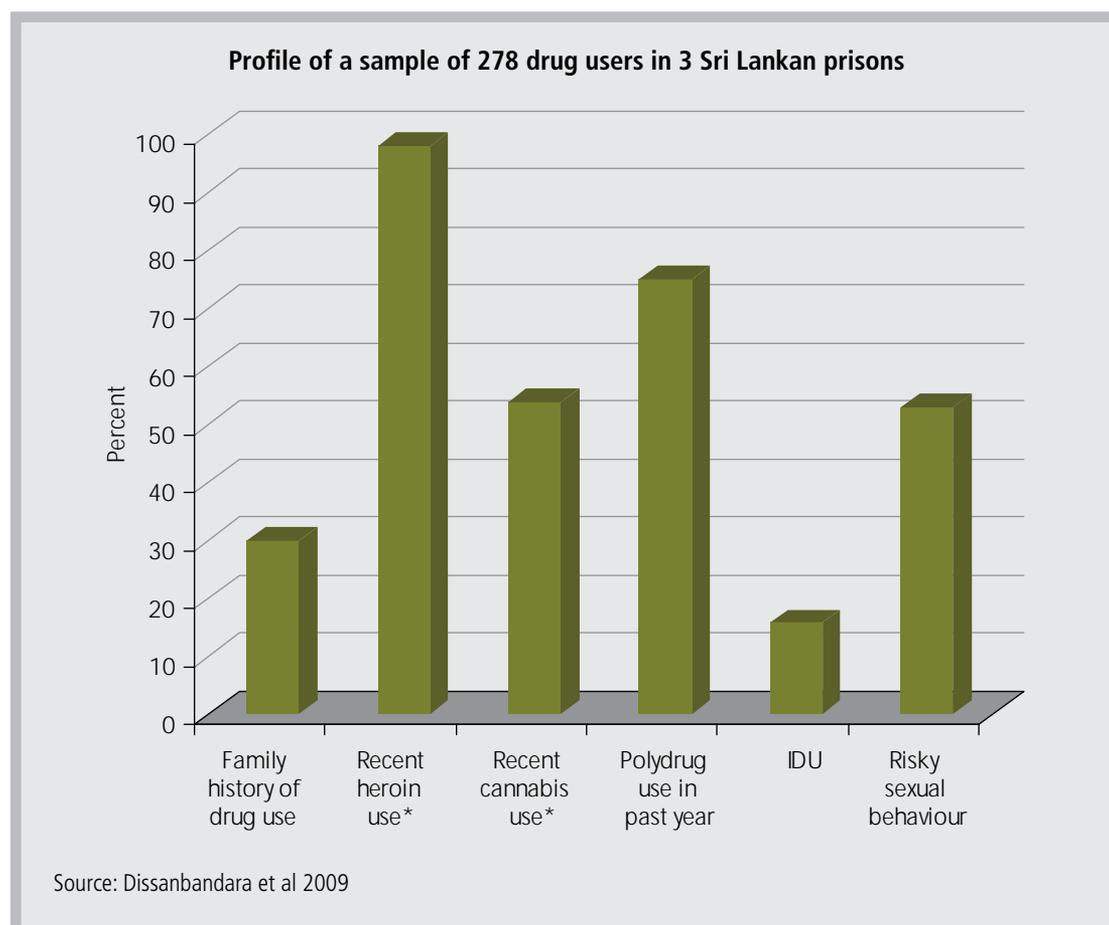


Diazepam

Due to its long history of Ayurvedic medicinal practice (which accepts cannabis and opium as valid therapeutic substances), Sri Lanka only began to take measures to quantify and reduce the non-medical use of psychoactive drugs in the late 1970s. The resulting survey conducted by the Narcotics Advisory Board found that opium, cannabis and barbiturates were the most common drugs taken for recreational purposes (Library of Congress - Country study: Sri Lanka). Opium was regulated during Sri Lanka's colonial period from the 16th century, and following independence in 1948 many governmental measures to control drug use have been unsuccessful (Jayasurya 1995).

Sri Lanka does however enjoy a vibrant culture of NGOs and religious bodies who are active in stemming drug use. Today, there are estimated 40,000 - 50,000 drugs users in Sri Lanka, equating to roughly 0.2% of the population (World Bank, 2006) and the government's stance has now evolved towards their current goal of completely eliminating illicit drug use (www.news.lk). The UN World Drug Report 2009 states that opiates are the primary drugs of choice for 100 percent of persons seeking treatment for drug problems in Sri Lanka.

Pharmaceutical drugs seem to be used either as adjuncts to, or replacements for, illicit narcotics and psychotropics. Preferred pharmaceutical substances seem to be chiefly of the benzodiazepine and opioid classes, also with



instances of Ayurvedic preparations and ephedrine. No studies to date have investigated the scale of the problem but the consensus among the expert community is that it is starting to become serious.

The main pharmaceutical drugs of abuse in Sri Lanka as identified by experts are as follows:

- Morphine
- Morphine Sulfate
- Corex D
- Perryton
- Diazepam
- Flunitrazepam / Rohypnol (used to sedate persons for stealing)
- Nitrazepam
- Clonazepam
- Ativan (anti depressant)
- Ephedrine Hcl
- Taralasaram } Ayurvedic preparations abused by preparing without
- Madhana modhagi } pharmacoepia standards

Perhaps due to its erstwhile lack of reported injecting drug use, Sri Lanka has not thus far experienced a severe HIV epidemic and infection rates are estimated to be below 0.1% (UNAIDS, 2006a). Sri Lankan authorities have reported low levels of IDUs in their country (1% of drug users); however the evidence presented in a peer-reviewed study of incarcerated drug users suggests that this figure is now similar to those of neighbouring countries – as high as 15% (Dissanbandara et al 2009) – though it should be noted that the proportion of incarcerated persons who inject drugs may not be representative of the whole population of drug users.

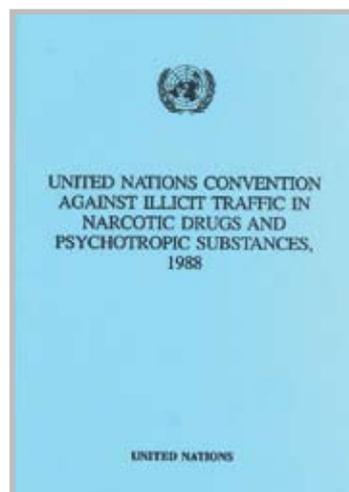
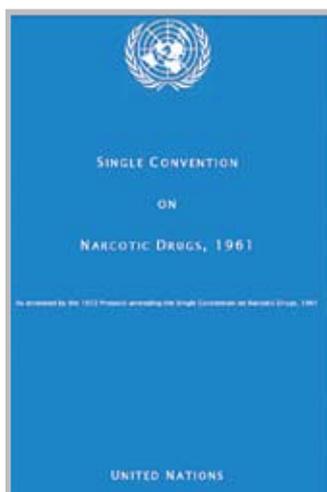
3

Laws, Regulations and Enforcement

United Nations Conventions

Bangladesh, Bhutan, India, Maldives, Nepal and Sri Lanka are signatory to (and have ratified) the following UN Conventions pertaining to narcotic drugs and psychotropic substances:

- The Single Convention on Narcotic Drugs, 1961
- The Convention on Psychotropic Substances, 1971
- The UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988



In addition, all participating countries have also signed the South Asian Association for Regional Cooperation (SAARC) Convention on Narcotic Drugs and Psychotropic Substances, 1990.

Countries in the region have a fairly well established legal, regulatory and administrative framework for the manufacture, distribution and sale of narcotic and psychotropic pharmaceuticals. This is not to say that the systems are perfect; in fact they need to be upgraded and strengthened to take care of certain new developments. For example, there are few regulations with respect to online pharmacies. Another example is of pharmaceutical preparations containing controlled substances (such as pseudoephedrine) that are being manufactured and traded freely without adequate controls, which makes them liable to be misused by traffickers. In some countries, there appears to be the need to harmonise domestic legislations on pharmaceuticals in line with their drug and criminal laws. What stands out in almost all countries is the fact that organisations are by and large inadequate in infrastructure and resources with the result that implementation and enforcement suffers. If enforcement were to improve, even the present legal and regulatory regimes will by and large deliver.

The general expert view is to avoid introducing additional and excessive controls that would restrict legitimate manufacture, distribution and availability of pharmaceuticals for those who need them.

3.1 Bangladesh

Regulatory agencies

1. Department of Narcotics Control (DNC)
2. Rapid Action Battalion
3. Bangladesh Police
4. Department of Drug Administration (DDA)
5. Bangladesh Rifles (Border Guards)
6. Bangladesh Customs
7. Bangladesh Coast Guard

NB: Bangladesh Police was not represented at the Dhaka seminar, so its role and views have not been fully incorporated into this report.

Although currently focused on illegal drugs rather than pharmaceuticals, the DNC is a body of considerable clout with a total of 1277 staff, serving: 4 zonal and intelligence offices; 25 regional and range offices; 108 circle offices plus a forensic laboratory and storage facilities.

As the chief enforcer of the Drug Acts (see below), the DDA is surprisingly a much smaller organization with only 27 inspectors tasked with regulating the country's 82,000 (licensed) pharmacies. As a consequence, searches, seizures and arrests are infrequent. Far greater manpower is required for the DDA to act as a sufficient deterrent for malpractice in pharmacies.

Licenses for the manufacture of narcotic and psychotropic pharmaceuticals are issued by both the DNC and the DDA in tandem, although these licenses do not place any restriction on quantities of drugs to be produced. This is seen as a major weakness that also impedes in the process of assessing the legitimate requirement of pharmaceuticals and controlling diversions.

Legal and regulatory regimes

The law governing narcotic and psychotropic substances in Bangladesh is dictated by the Drug Act (1940) and the Narcotics Control Act (1990). These acts are supplemented by the Drug Rules (1944) and the Narcotics Control Rules (1999) respectively. Although both sets of legislation are still effective, the one that was introduced later has overriding powers over the earlier one. This implies there is no contradiction or other legal disharmony between them. The later Rules also dictate more severe penalties.

The Special Powers Act (1974) was introduced in response to the hoarding and smuggling that occurred in the aftermath of Bangladesh's independence; the Police may invoke certain prejudicial powers under this enactment and do so with respect to drug offences.

The Drug Control Ordinance 1982 empowered the Government to regulate the manufacture, import and distribution of drugs as per the guidelines set by the WHO. This enactment includes provisions for constituting a Drugs Control Committee (Drug Administration). Import and export of pharmaceuticals is governed by the EXIM (export / import) Policy and enforced under the Customs Act (1969), which is overseen by Bangladesh Customs.

In 2009, the government of Bangladesh approved the Mobile Court Ordinance to relieve the courts of minor cases. The mobile courts have been invested with limited powers including imposing fines and a maximum of 3 months imprisonment for petty offences - although they do not have the power to revoke trading licenses.

The present legislation is considered thorough and adequate by Bangladesh experts without conflict within or between the laws. The perceived weaknesses are specifically in the manpower of the agencies tasked with enforcing them, notably of the DDA.

3.2 Bhutan

Regulatory agencies

1. BNCA (Bhutan Narcotic Control Agency)
2. RBP (Royal Bhutan Police)
3. DRA (Drug Regulatory Authority)
4. MoF, DRC (Ministry of Finance, Department of Revenue & Customs)
5. NCB (Narcotics Control Board)
6. BAFRA (Bhutan Agriculture and Food Regulatory Authority)

The RBP is the blanket law enforcement agency, responsible for enforcing all the laws in Bhutan including those relating to substance use. The Narcotic Drug Law Enforcement Unit (NDLEU) is the branch of the RBP involved in these matters.

DRA, under the provisions of the Medicines Act, 2003 and Regulation made thereunder, is empowered to regulate the import, export, sale, distribution and storage of the medicinal products. The Bhutan Medicine Rules and Regulation 2005, 2nd Edition 2008 has detailed procedures for the regulation of pharmaceuticals. Further, the Act and Regulation have provisions for controlled and restricted substances (including the narcotic and psychotropic substances) which demands strict monitoring and vigilance.

The DRA has been covering the length and breadth of the country as best as it can with the seven drug inspectors at its disposal. It obviously needs strengthening for better implementation and enforcing the laws.

The BNCA (secretariat to the NCB) is a nodal office responsible for coordination with other relevant stakeholders within the country and international agencies. It comprises two divisions dealing with demand reduction and supply reduction respectively.

The mandate of the above-listed law enforcement agencies regarding pharmaceutical drug regulation and enforcement is unclear. The role of the DRA needs to be expanded to include the provision of technical expertise and sensitisation to all stake holders.

Legal and regulatory regimes

The generic regulatory system governing pharmaceutical drugs and medicines in Bhutan are defined under The Medicine Act, 2003. This Act includes import and export licensing, sale of medicines and the requirement of competent persons for the sale of pharmaceuticals. Chapter VII section 25 of the Medicines Act has provisions for the restricted and controlled drugs. The BMRR (Bhutan Medicines Rules and Regulations, 2005, 2nd Ed. 2008) fleshes out the Medicines Act, defining a framework for the classification of medicines as well as detailed penal protocols for violations.

The NDPSSAA (Narcotic Drugs, Psychotropic Substances and Substance Abuse Act, 2005) was introduced to reinforce the rules and regulations for narcotic and psychotropic pharmaceuticals. Therein contains a classification system for licitly - and illicitly - produced narcotic and psychotropic drugs as well as precursors used in the manufacture of illicit drugs. The Act is broad (at the expense of specificity) and also deals with education, treatment and rehabilitation policies.

A remarkable feature of health system of Bhutan is that almost all the drugs which are dispensed from the Government Hospitals are free of cost.

Licenses for the import of these drugs are issued by the Department of Trade, and imports are authorised by the DRA, who then forward a copy of the authorisation to Customs at the consignment's point of entry whereby the importer must also submit his copy of the authorisation. The imports are initiated by the DVED (Drugs & Vaccines Equipment

Division), who register exporting companies and then float a tender for the import. The actual procurement is controlled by the Central Procurement Section of the DVED, and the products themselves are registered by the DRA. The import of the pharmaceuticals by pharmacies within the country is permitted only after presentation of the Import Authorization by the DRA at entry point.

Pharmacies are subject to similarly tight regulation. Restricted preparations (those containing narcotic or psychotropic ingredients) are dispensed only against prescription - a copy of which must be retained for 3 years and which is subject to inspection by DRA inspectors. Man power is lacking in this respect however; Bhutan's 60 registered pharmacies are regulated as mentioned above by a team of only 7 inspectors and this system is considered inadequate for the purpose of monitoring and controlling the diversion of psychotropic and narcotic drugs. Experts however felt that import of such drugs are adequately controlled.

The current regime is thorough in its design and reportedly well regulated. However, there is ambiguity between the Medicines Act and the NDPSSAA in regulation of certain narcotic and psychotropic substances. There is thus a need to harmonise these legislations so that the Medicines Act and the NDPSSAA can be made more effective instruments.

3.3 India

Regulatory agencies

1. Ministry of Health and Family Welfare (MoHFW)
2. Drugs Controller General of India (DCGI)
3. State Drug Controllers or Food and Drug Administrators
4. Ministry of Chemicals and Fertilizers
5. NPPA (National Pharmaceutical Pricing Authority)
6. Ministry of Finance (MoF) - Department of Revenue
7. Central Bureau of Narcotics (CBN)
8. Law Enforcement Agencies: Police, NCB, Customs

The regulatory apparatus in India for drugs and pharmaceuticals is rather complicated as there is more than one agency or ministry mandated to perform specific functions. However, the duties are clearly enumerated.

The Ministry of Health and Family Welfare and the DCGI under it act as custodians of the Drug and Cosmetics Act. Each of India's 27 states has a State Drug Controller or Food and Drug Administrator, each operating under his own state's MoHFW and reporting to the DCGI and implementing the provisions of the Drugs and Cosmetics Act.

Pharmaceutical licensing is the function of State Drug Controllers and the allocation of quotas which was hitherto done by them is presently under the charge of the Narcotics Commissioner which is a central authority under the Ministry of Finance, Department of Revenue. However, drug pricing is the mandate of NPPA, which is under the Ministry of Chemicals and Fertilisers.

The Department of Revenue under the Ministry of Finance administers the Narcotics Drugs and Psychotropic Substances Act (NDPS) which is implemented by both central agencies such as NCB, CBN, Customs including DRI, para military forces and State agencies such as Police, Excise, Forest and Drug Controllers / Food & Drug Administrators.

According to the assessment of experts, there is need for a greater awareness on the illicit use of pharmaceutical drugs across the board, and there is a universal need for training of police/regulatory personnel in the laws, investigation, seizure and arrests relating to pharmaceutical trafficking.

Legal and regulatory regimes

The Drugs and Cosmetics Act 1940 is an extensive and highly thorough dictation of the laws, penalties and inspection procedures concerning the manufacture, sale and import of drugs and cosmetics (including quality standards, branding, prohibition etc). In respect to prescription-only medicines, the Act states that all medicines that are classified under Schedule H and the NDPS Act must be labelled with the symbol “NRx” in red colour and the statement: “Warning: -- To be sold by retail on the prescription of a Registered Medical Practitioner only.”

Specific laws governing pharmaceuticals (and illicit) narcotic and psychotropic drugs are further detailed in the Narcotic Drugs and Psychotropic Substances Act (NDPS) 1985. Briefly, the Act restricts the import and export of narcotic and psychotropic substances by any method (including post) and places the authorisation of such activities under the jurisdiction of the Narcotics Commissioner. However, it does not regulate import and export of preparations containing narcotic drugs below a threshold limit (preparations listed in Schedule III of the Single Convention on Narcotic Drugs, 1961). Customs are also required to approve all such transshipments as per the Customs Act 1962.

The Pharmacy Act was introduced in 1962 to empower state governments to restrict the dispensing of physician-prescribed medicines to suitably qualified pharmacists. The Act dictates, among other issues, the criteria for and process of the registration of pharmacists and the constitution and composition of the State Pharmacy Councils.

The current legislation is considered to be generally sufficient with the NDPS Act providing for a more stringent penal regime when compared with the Drugs and Cosmetics Act. In some cases there have been conflicts of jurisdiction which have had to be settled by courts of law. Some experts are therefore of the view that there may be need for harmonizing some aspects of the two Acts.

Experts also refer to the need for inclusion of pharmaceutical preparations containing ephedrine and pseudoephedrine in the EXIM (Export Import) policy; these chemicals, which are commonly used as airway dilators in decongestant medicines, are also used as precursors in the manufacture of amphetamine-type stimulants (ATS). ATS precursors are commodities in themselves and highly sought-after worldwide for clandestine ATS manufacture. South Asia, as a region, with India and Sri Lanka in particular, are being targeted by drug organizations to set up clandestine facilities for manufacturing ATS.

The issue of rampant smuggling of cough syrups containing codeine below the prescribed threshold levels from India to Bangladesh, Nepal, Bhutan and Sri Lanka is a matter of some concern. The provisions under the NDPS Act and the Drugs and Cosmetic Act do not recognize these as offences. Therefore there is a need to look into this issue.

The NDPS Act does not make any exception to sales of narcotic and psychotropic pharmaceuticals through internet. Offline and online transactions are subject to the same restrictions. Several cases have been registered by Indian law enforcement agencies against persons involved in smuggling of pharmaceuticals through online pharmacies. While the transaction and payment is done through the internet, in all such cases, the substances have to be physically transported out of the country and therefore are subject to controls irrespective of the fact whether the transaction is online or through conventional methods. Regulations in this regard are considered important since India is one of the source countries targeted by traffickers running internet pharmacies.

There is also a need to include collection of data on licit production and trade of narcotic and psychotropic pharmaceuticals in the country and for establishing a compliance mechanism under the NDPS Act. This has been recently notified by amending the NDPS Rules.

3.4 Maldives

Regulatory agencies

1. Food & Drug Authority (FDA) – Ministry of Health and Family
2. Maldives Police Service

3. Maldives Customs Service
4. Ministry of Trade and Economic Development
5. State Trading Organisation (STO)

The Food and Drug Authority (under the Ministry of Health and Family) is mandated to issue licenses for pharmacies and regulate the trade in pharmaceuticals. The Ministry of Trade and Economic Development issues the licenses for import which is channeled through the State Trading Organisation. The enforcement functions are carried out by the Police and Customs.

Legal and regulatory regime

There is no legislation governing the regulation and control of pharmaceutical products in Maldives. The current regime of controls is only administrative.

The import, sale and standards of all pharmaceutical drugs including controlled substances, for example, are regulated by the FDA. Import licenses are issued by the Ministry of Trade and Economic Development. All controlled drugs should be imported by the State Trading Organisation upon approval by the FDA, and pharmacies procure them directly from the STO after having gained approval from the FDA. There is no restriction on the distribution of non-controlled pharmaceuticals from registered importers to pharmacies. There is no routine forensic analysis of pharmaceuticals at the point of import; Customs only examine imports with the assistance of the FDA rather than in an autonomous, proactive manner.

Effective from 2010, The Maldivian Food & Drug Authority (FDA) is revamping its system of registering imported drugs in order to improve quality control procedures on pharmaceutical imports (Miadhu News, 2009).

As per standard procedure, controlled narcotic and psychotropic drugs may only be obtained from pharmacies through a doctor's prescription whereas non-controlled drugs may be bought without prescription. Records must be retained for every sale and controlled drugs require bills in triplicate - one copy for the FDA's records. The FDA however, has few officers for random inspection of records, stocks and sales of pharmacies vis-à-vis controlled drugs; there are only 4 or 5 inspectors for around 200 inhabited islands and this is considered too few for effective enforcement.

The general expert assessment is that the existing regulatory regime needs to be strengthened. Law enforcement and regulatory agencies operate independently without collaborating or sharing collaterally useful information. There is a general lack of awareness of the potential weaknesses in the system and its enforcement in controlling the use, illicit use and smuggling of narcotic and psychotropic pharmaceuticals.

3.5 Nepal

Regulatory agencies

1. Ministry of Home Affairs
2. Nepal Police
3. Narcotic Drug Control Law Enforcement Unit (NDCLEU)
4. Ministry of Health and Population
5. Department of Drug Administration (DDA)
6. Nepal Customs Service
7. Ministry of Industry
8. Ministry of Commerce and Supply

The Ministry of Home Affairs is tasked with the function of control of narcotics. Its enforcement arm is the Narcotic Drug Control Law Enforcement Unit (NDCLEU) of the Nepal Police that functions under its administrative control.

The DDA (under the Ministry of Health and Population) is the nodal agency for regulating pharmaceuticals in Nepal. It has branches at the border towns of Nepalganj, Biratnagar and Birganj - the entry points for much of the influx of pharmaceuticals from India. The main office in Kathmandu is understaffed with a team of 31 (including 14 technical staff) permanent staff, of which only 4 are tasked with inspection of the country's pharmacies. Given the difficulty of crossing the mountainous terrain in much of the country, this manpower is perceived as inadequate by experts.

The NDCLEU is the primary enforcement agency in the country which has 7 satellite units countrywide, staffed by a total of 75 personnel mandated to check trafficking of drugs including pharmaceuticals. The Nepal Customs service is authorized to carry out inspections at the entry and exit points on the land borders as well as at the airports.

The Ministry of Industry and the Ministry of Commerce and Supply are concerned with the domestic production, trade and supply channels in the country.

Although the mandates of the various agencies are well defined, in the view of experts, a greater consciousness of the situation of illicit pharmaceutical drug use and trafficking is required across the board.

Legal and regulatory regime

The Drugs Act (1978) and the following Rules and Regulations represent a fairly comprehensive legal regime for pharmaceuticals:

- Drug Registration Regulation
- Drug Standards Regulation
- Drugs Inspection Regulation
- Drug Manufacturers Code
- Drug Consultative Council and Drug Advisory Committee Formation Regulation

The above regulatory regime clearly and adequately describes the law governing the registration, production, distribution, (including export and import), standards and consumption of potentially harmful drugs including narcotic and psychotropic pharmaceutical drugs.

Inspection procedures and penalties of varying severity (including life sentence) for drug offences are also described, as is the formation and activity of the Drug Consultative Commission and the Drug Advisory Committee.

The other relevant legislation is the Narcotic Drugs (Control) Act (1976), although this does not mention legally produced (pharmaceutical) narcotic drugs. However, following settled case law pronounced by the Supreme Court, the NDCLEU have successfully prosecuted persons for offences relating to pharmaceutical narcotic drugs such as codeine-based cough syrups and buprenorphine (both of which are outside the remit of the Narcotics Act).

Whilst the Drugs Act is administered by the DRA, the Narcotics Act is enforced by the Nepal Police.

The Drugs Act neither distinguishes penalties for personal use nor dictates maximum sentences as for drug offences. The penal provisions under the Drugs Act also do not distinguish between narcotic / psychotropic pharmaceuticals and other pharmaceuticals such as antibiotics; amending this would enable a greater degree of awareness and focus among law enforcement agencies. Further, the judiciary has discretion while awarding punishments and can even levy fine and dispose off the case. In contrast, provisions under the Narcotic Drugs (Control) Act are stringent prescribing a minimum sentence of 10 years.

Be that as it may, there is a need for more effective enforcement of the Drug Act, requiring either a transfer of enforcement powers to the police or a strengthening of the framework and enforcement powers of the DRA.

Experts identified the following key issues pertaining to better regulation of pharmaceuticals:

- The penal provisions under the Drug Act do not make a distinction between narcotic / psychotropic substances and other category of drugs; the punishment for narcotic drugs and antibiotics for example are similar;
- The penal provisions do not indicate mandatory penalties for narcotic / psychotropic substances;
- The Drug Act does not have penal provisions based on quantities, i. e. provisions do not make a difference between an addict or a trafficker;
- There is need for harmonization of the legislations dealing with illicit drug use and trafficking;
- The DRA needs to establish a wing within itself to deal with narcotic/psychotropic drugs which should coordinate with police on pharmaceutical drug use.

3.6 Sri Lanka

Regulatory agencies

- Ministry of Defense
 - ◆ National Dangerous Drug Control Board
 - ◆ Department of Police
 - ◆ Police Narcotic Bureau
- Ministry of Health
 - ◆ Department of Health
 - ◆ Medical Technology and Supplies division - Cosmetic Devices and
 - ◆ Drugs Regulatory Authority (DGHS chairman)
 - ◆ Medical suppliers division
 - ◆ State Pharmaceutical Corporation (SPC) – government and private
 - ◆ National Drugs Quality Assurance lab
- Ministry of Indigenous Medicine
- Department of Import and Export
- Sri Lanka Customs
- Department of Excise
- Ministry of Justice
 - ◆ Attorney General Department
 - ◆ Government Analyst Department

The NDDCB and the Police (including the Police Narcotics Bureau) operate under the Ministry of Defence and are the country's nodal and primary enforcement agencies respectively in the country. While the NDDCB functions more as a coordinating agency, the PNB is purely an enforcement agency. The Department of Excise and Customs is another enforcement agency along with the Customs which regulates the import and export of pharmaceuticals in collaboration with the Department of Import and Export.

The following agencies under the Ministry of Health perform various functions relating to the regulation and control of pharmaceuticals (including the implementation of the Cosmetics, Devices and Drugs Act): The Medical

Technology and Supplies Division; Cosmetic Devices and Drugs Regulatory Authority; Medical Supplies Division; State Pharmaceutical Corporation (Government and private) and the National Drugs Quality Assurance lab.

The Ministry of Indigenous Medicine not only promotes production and use of indigenous medicine, but also exercises controls over standardization and quality control of indigenous medicines produced in Sri Lanka.

While the Attorney General's department prosecutes offenders, the Government Analyst is mandated to forensically examine - and provide evidence on - seized samples of drugs and pharmaceuticals forwarded by the enforcement agencies. Both operate under the Ministry of Health.

Legal and regulatory regimes

The Cosmetics, Devices and Drugs Act (CDDA) 1980 is a comprehensive legislation containing the following four schedules under which drugs are legally classified:

Schedule I: Over-the-counter drugs

Schedule II A: Dispensing by a pharmacist with or without prescription

Schedule II B: Dispensing by a pharmacist on prescription only

Schedule III: Other controlled narcotic and psychotropic drugs

Other than the CDDA, there are other legislations also concerned with the control of narcotic and psychotropic substances and precursor chemicals. The remit of the Narcotics Law 2008 for example is controlled narcotics; it also covers psychotropic drugs included in the CDDA.

The Poisons, Opium and Dangerous Drugs Act controls narcotics under the schedules of 'Opium' and 'Dangerous Drugs'. Import permits under the Act are processed at the Office of the Medical Technology & Supplies, and sent for signature of Director General of Health Services.

Dangerous Drugs Control Board Act No 11 (1984) lays out the constitution of the National Dangerous Drugs Control Board, which comes under the purview of Ministry of Defense and of which the Director General of Health Services (or his/her nominee) is the Director.

Precursor control is outlined under the first schedule of Conventions Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act No. 01 (2008). A Precursor Control Authority has been established under the Act and has started functioning from 25 October, 2010 at NDDCB. All importers and exporters of precursor chemicals need to register their business according to the regulations of the Act.

The Medical Technology & Supplies Division of the CDDD is a regulatory body charged with the following mandate:

- Grant market authorisation for medicinal drugs, medical devices and cosmetics after a scientific evaluation
- Inspection of premises for Good Manufacturing Practices (GMP)
- Issuing of drug manufacturing, sale and transportation licenses
- Post-marketing surveillances and handling complaints with regard to quality, safety and efficacy of authorised products that may lead to recall of products/licenses
- Approval of advertisements on medicines
- Legal proceedings against persons contravening provisions of the Act and its regulations (including counterfeit or smuggled products and trading on unauthorised premises).
- It also procures pharmaceutical consignments for the Government through the SPC, while imports for non-Governmental agencies are approved by the CDDD. All imports and exports of pharmaceutical drugs are subject to inspection by Sri Lanka Customs.

The police force has enforcement authority only over controlled substances under the Narcotics Law; it does not have powers under the CDDA. Enforcement of the CDDA is carried out at the national level by the CDDD's Food and Drug Inspectors, who can prosecute offenders and levy fines to a maximum of Sri Lankan Rs 100,000, with repeat offenders also being liable for a maximum 6 month prison sentence. The major limitation of the CDDD is that it only has 4 inspectors, which is insufficient for nation-wide jurisdiction. The provinces are better-served, however: each region has at least 3 local Drugs Inspectors (80 in total), although more would be needed to perform thorough and regular inspection of all pharmacies in the country.

According to experts, the basic problem is that a majority of the pharmacies operate without a pharmacist despite this being a compulsory license condition; this makes them more liable to malpractice. The expert assessment is that if the existing controls are stringently applied nation wide, 80% of Sri Lanka's pharmacies would be forced to close.

4

Distribution, smuggling and counterfeit drugs

Almost all countries of South Asia have a largely adequate legal and regulatory regime in place. The problem lies in improper implementation and there are various reasons that are assigned by country experts. These include weak organizations and a lack of will on the part of the regulatory agencies to deal with the obvious violations. For example, the dispensing of controlled pharmaceuticals over - the - counter and without prescriptions by pharmacies is widespread across the region and something that everyone is aware of. However, the law enforcer and even the policy maker struggle when it comes to taking steps to correct the anomaly. At another level, the regulators are rather unaware not just of the extent and nature of the pharmaceutical problem in their countries, but also of the authority that the various laws and regulations vest them with. The scenario is therefore one in which the lack of awareness or non sensitization of law enforcement is taken advantage of by traffickers who resort to diversion of pharmaceuticals from the legal to the illegal channels.

4.1 Smuggling

Traditional smuggling routes in South Asia have for centuries been used to illegally transport goods across borders. For example, the sea lanes between South India and Sri Lanka have been used to smuggle a variety of goods including electronics. Similarly the porous land borders between India and Bangladesh and between India and Nepal are used for smuggling various items, including drugs. There was a time when gold was a preferred commodity with smugglers along the Arabian Sea; today this space is used for trafficking different commodities. Pharmaceuticals are just another commodity that the smugglers and traffickers find attractive to transport within South Asia or from one country of region to another.

India, for example, has the fourth highest production of a vast range of pharmaceutical products at highly competitive prices (Source: Ministry of External Affairs, Government of India) and naturally these valued commodities are subject to smuggling not only because of their easy availability but also because of their price competitiveness. And the pharmaceutical industry is considered by experts to be susceptible to diversion. Hence, most of India's South Asian neighbour countries as well as many other parts of the globe are recipients of smuggled Indian narcotic and psychotropic drugs, the most common types being:

- Benzodiazepines (diazepam-type sleeping pills)
- Codeine-based cough syrups
- Buprenorphine
- Pethidine
- Dextropropoxyphene

On the issue of counterfeit drugs, the expert official view is that it is largely non - existent. There is, of course, the other view. The issue is highly contentious, sensitive and debatable.

The subsequent paragraphs discuss the distribution system, sources of supply of illicit pharmaceuticals including smuggling routes and the probability of counterfeit manufacturing.

4.2 Sources of supply

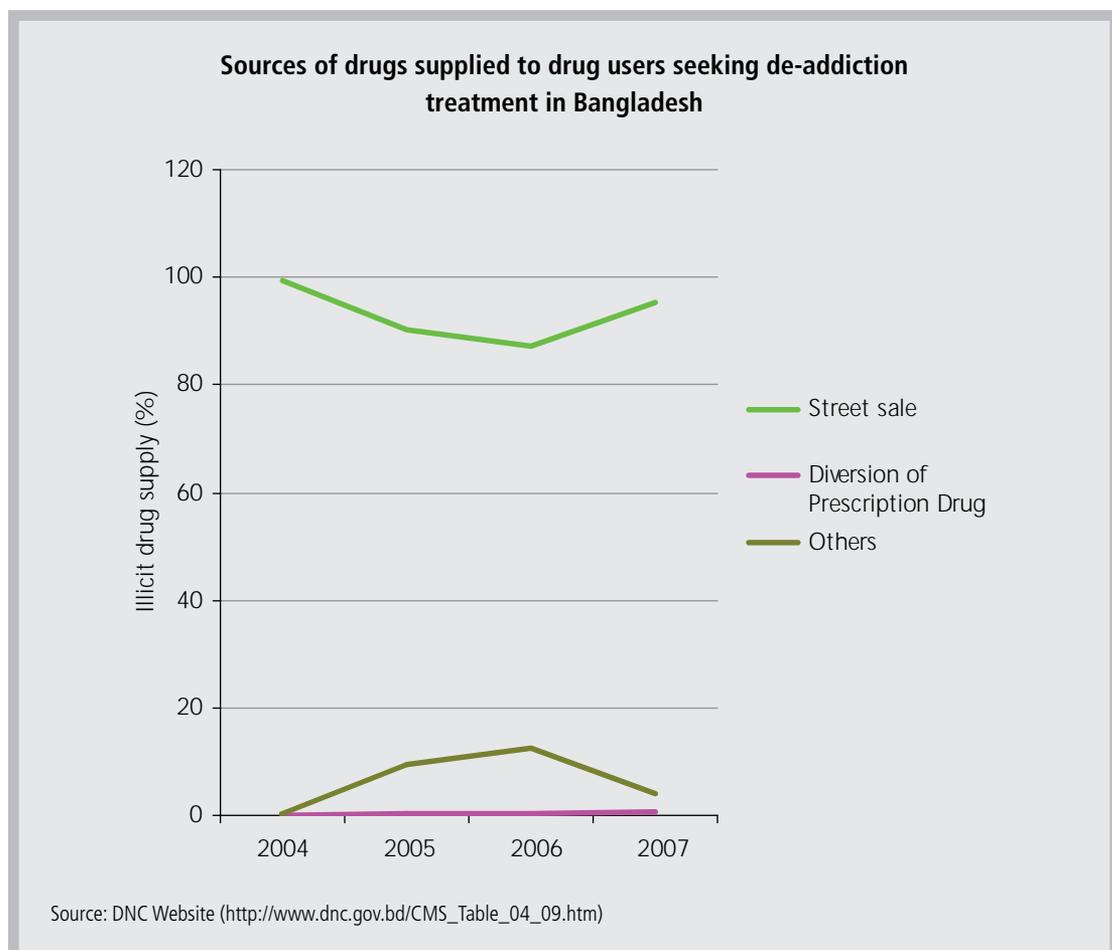
Bangladesh

Domestic sources

As mentioned in Chapter 3, Bangladesh has its own pharmaceutical manufacturing industry that is able to meet local demand substantially. The pharmaceutical manufacturing units are licensed by the Department of Drug Administration. For those units manufacturing narcotic or psychotropic drugs, an additional license is required from the DNC.

Importantly, the licenses make no provisions for recording the quantities produced, rendering monitoring of diversions difficult. In most cases, the manufacturer is also the distributor to pharmacies. The system is therefore, prone to diversion, particularly in the absence of information on the quantities that are manufactured and distributed and inadequate monitoring. In short, all points of the domestic supply chain – manufacturing, distribution and pharmacy – appear to be prone to diversions.

According to the Department of Drug Administration, there are about 40,000 licensed pharmacies in the country. All licensed pharmacies are required to have a pharmacist to dispense drugs. However, this is rarely the case. Another striking feature is that there are hundreds of pharmacies that operate without any license. Representatives from the



NB: the above statistical data represents seizures made by DNC alone and not by other law enforcement agencies. These figures thus may not represent the country position on illicit drug use.

pharmaceutical industry claim that their number exceeds that of the legitimate businesses and may be as many as 300,000, though the DDA estimates the figure to be close to 40,000.

This state of affairs is openly acknowledged by regulators in the government who claim lack of manpower as one of reasons for the low level of enforcement of the law. The situation is compounded by the fact that almost all manufacturers and distributors make regular and routine supplies to these unlicensed pharmacies.

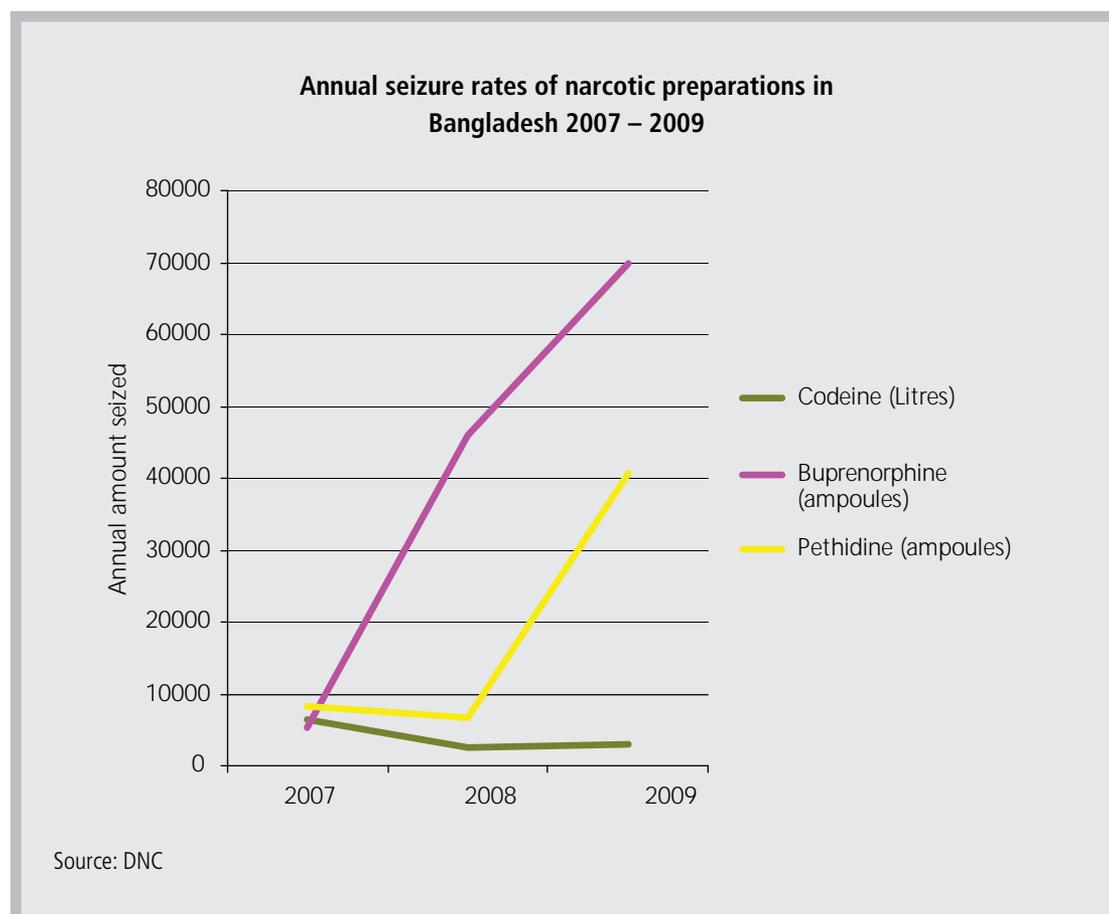
Representatives of the trade suspect a high degree of involvement of organised criminal activity in diverting psychotropic drugs from the supply chain - chiefly from the manufacturers - and even in smuggling of pharmaceuticals out of the country. According to them, there is a parallel system of distribution of pharmaceuticals that feed addicts. This system operates from small shops and other outlets including mobile units functioning out of suitcases and is in some manner, more accessible to the addicts than pharmacies; experts did not contradict this claim.

There are also concerns about the easy availability of scheduled drugs without prescription even in the licensed pharmacies and of diversion of drugs from hospitals and treatment centers. Even the narcotic and psychotropic pharmaceuticals are dispensed without prescriptions and there are no procedures of double or multi coloured prescriptions as existing in some countries.

In conclusion, the majority of pharmaceuticals are acquired from licensed or unlicensed pharmacies, and from the network of street dealers; the latter route accounts for the overwhelming majority of illicit sales.

External sources

The India-Bangladesh border is particularly susceptible to smuggling of pharmaceuticals. Both licit and allegedly illicit or spurious drugs are reportedly smuggled into Bangladesh, chiefly from West Bengal and the other north-eastern Indian states.



There is a high demand in Bangladesh for codeine; an opiate alkaloid added to cough syrups, some of whose contents place them outside the remit of India's NDPS Act (whereby codeine is compounded with one or more other ingredients which contains 100 milligrammes or less of the drug per dosage unit up to a maximum codeine concentration of 2.5%) making them liable to relatively low-risk smuggling. Other preparations which are easily accessible in India without a prescription, and which are frequently smuggled in bulk to Bangladesh, include codeine / diazepam combination tablets. Bangladesh has banned the use of codeine cough syrups even for therapeutic use in the country.

Of greater concern is the influx of Pethidine / Buprenorphine ampoules which are readily prepared for injection and hence encourage this highly dangerous practice. Although it is safer to inject a drug of known purity and dosage than a street drug which may contain any number of impurities, the injection route nonetheless accelerates the entrenchment of addiction and leaves the user vulnerable to deadly infections such as HIV and hepatitis.

India and Bangladesh have over the years, established a fairly sound working relationship between their respective border guards. In spite of this, smuggling continues but the two countries have a decent idea of its extent and nature. This is not true for Bangladesh and Myanmar where the nature and extent is a completely unknown factor. Myanmar is a known route for the trafficking of heroin and ATS into Bangladesh. Some representatives of the trade do not discount the possibility of pharmaceuticals from their country being trafficked to Myanmar.

Bhutan

Domestic sources

Bhutan does not have a pharmaceutical industry and imports all of its pharmaceutical requirements from outside, largely from India. Once the pharmaceuticals are imported into the country, they are dispensed through government hospitals and private pharmacies. The public health care system in Bhutan offers free medical treatment to its citizens. Consequently, 90% of the drugs dispensed from hospitals are available free of cost, and although controlled substances are required to be kept locked and monitored, there is the possibility of diversion through hospital staff. A few instances of this kind have been detected although the system has not been examined to assess its potential for diversion of narcotics and psychotropics.

Due to frequent long queues at Government hospitals, people tend to obtain drugs from pharmacies which are freely accessible and serve as an easy mode of supply. Although under the regulations in force, only over-the-counter drugs should be made available without prescriptions, the reality is just the opposite. The RBP (Royal Bhutan Police) have documented many cases of addicts acquiring prescription drugs from pharmacies, particularly those close to the Indian border and outside the capital city of Thimphu.

There are only 69 registered pharmacies in the country (which acquire drug stocks from authorised distributors) but experts have raised the possibility of unregulated and unregistered disbursement of pharmaceuticals from grocery stores.

Forging and misuse of doctors' prescriptions is not considered to be a key diversion route.

External sources

In the absence of a domestic pharmaceutical manufacturing industry, most of the illicitly-used pharmaceutical drugs are brought into the country illegally. The ubiquitous lack of licensing of pharmacists encourages many of these to cross the border to obtain drugs from Indian pharmacists or pharmaceutical distributors. Although the exact scale of smuggling is unknown, the majority of traffic is thought to reach the busy Phuntsholing-Thimphu highway (where the daily passage of more than 1,200 vehicles leaves the police ill-equipped to search every passenger) from the Jaigaon area in India. The remainder comes mainly through the other border towns of Guwahati, Siliguri, Rangya, Birpada, Palakhata, Dadgari, Dharanga, Saralpada and Bhanerkat.

The RBP have intercepted large consignments of pharmaceuticals containing codeine, nitrazepam and dextropropoxyphene coming from across the border with India.

Perhaps due to the wider availability of many narcotic and psychotropic pharmaceuticals in Thailand, many travelers are found entering the country from the Thai-Bhutan border with large quantities of these substances, apparently for their personal consumption.

India

Domestic Sources

Most of the pharmaceutical drugs consumed in India are manufactured locally. The Indian pharmaceutical industry is worth an estimated \$12 billion, holds 1-2% of the world market and is growing at an annual rate of around 10%. The Indian pharmaceutical industry makes around 40% of its revenue exporting generic alternatives to patented drugs, chiefly to developing countries. Following the introduction of the Patent Act in 1970 (which restricted or removed patent protection on food and drugs) the erstwhile dominant multinational companies made way for a majority of indigenous businesses. The amendment of the Patents Act in 2005 and the re-introduction of patent law in this sector then began a flurry of mergers from foreign companies. The industry is on a strong growth trajectory but remains fragmented with over 20,000 registered units, of which five are state-owned, with the leading 250 companies controlling 70% of the market. This high degree of competition - as well as government policies - keeps drug prices low and as such India enjoys a thriving export trade with the United States and Russia as well as developing countries including its neighbours.

Despite the strengths of the pharmaceutical industry, the quantity of prescription drugs containing narcotic or psychotropic substances produced annually in India is unknown. Each State Drug Controller issues licenses to produce unrestricted quantities of pharmaceutical products without any estimation of the requirements for each drug. This is a major hurdle in understanding the scale of illicit pharmaceutical use in India. However the Government of India has now designated the Narcotics Commissioner (in the place of state Drug Controllers) of India as the authority for allotment of quota of narcotic and psychotropic substances to manufacturers from the year 2010. India will thus, in the near future, be in a position to estimate its legitimate requirement. This will also result in a better understanding of the production capacity of the pharmaceutical industry in relation to pharmaceuticals containing narcotic and psychotropic substances.

Like in other countries of the region, most pharmaceuticals are obtained illicitly through pharmacies, both with and without prescription. Sales mean profit for pharmacists and some traders are willing to stray from ethical codes of conduct when approached by customers requesting scheduled drugs without a prescription, and this is a major factor in sustaining the illicit use of narcotic and psychotropic pharmaceutical drugs. As the chief medium through which the public is exposed to potentially habit forming drugs, a great responsibility rests with the pharmacist to dispense drugs in a legal and ethical manner to prevent the spread of pathological addiction among his or her customers.

Concerns have also been voiced about the quality of doctors writing prescriptions in many parts of the country (Patel *et al* 2005); for example one study in a rural region of Varanasi found that almost two thirds of prescriptions written were in an improper manner (Bhatnagar *et al* 2003). Adding to the issue is the practice of self prescription by the general population; this exacerbates the misuse of prescription and non prescription drugs.

Another potential source is the sale of medicines that have passed their sell-by date and can no longer be sold commercially. Drugs companies have also been accused of aggressive marketing campaigns such as discount schemes to promote medicines such as cough syrups for non-therapeutic purposes; some companies are also known to boost sales by offering incentives to medical practitioners for promoting their products.

Reports have also been received of theft of stock during transportation and the possibility that diversion from Government hospitals and veterinary clinics may also occur was raised.

External sources

India's domestic pharmaceutical industry supplies the entire range of products and therefore, there is no need to import medicines except for certain special purposes. Importantly, those that are imported are not ones prone to misuse.

Maldives

Domestic sources

Since Maldives does not have a domestic manufacturing industry, all of its pharmaceutical requirements are obtained from abroad. The majority of imports come from India, with smaller shipments also arriving from Sri Lanka, Pakistan, Bangladesh, Singapore and Malaysia.

Malé has 70 pharmacies which, according to the government, are adequately controlled. Nevertheless, the source of most of the pharmaceuticals of illicit use is these pharmacies which are owned by Indians who are known to bring large quantities of drugs from India. Because regulation of pharmacies is weak, addicts target them for procuring drugs.

Pharmacies in the islands off the shores of Malé, the capital city, are even more loosely regulated and improper dispensation of medicines is rife, both in selling scheduled drugs without prescription and in dispensing larger amounts than prescribed, for up to six months' requirement. There are some cases of prescription misuse and of tourists procuring pharmaceuticals for local addicts, but the overriding suspicion is that illegitimate channels are responsible for the majority of the diversion. The nature of these channels is unclear, however.

External sources

India and Sri Lanka are the primary sources of external trafficking. Few seizures have been made from Malé airport, giving little insight into the nature and extent of smuggling by air. The practicalities of policing sea travel into the Maldives renders monitoring smuggling by sea very difficult, and the extent of this practice is entirely unknown.

Nepal

Domestic sources

Nepal manufactures an unknown quantity of several psychotropic (alprazolam, phenobarbitone, diazepam, lorazepam, and nitrazepam) and narcotic (codeine) drugs; however the codeine-based cough syrups are of relatively low codeine content. It is not known to what extent these domestically produced drugs are diverted to the black market.

A survey conducted by the Nepali Government's Department of Statistics found that 21% of the country's drug supply was from medical stores; of the 10,000 pharmacies in Nepal, 90% function without the supervision of a pharmacist. They are however run by trained persons, facilitating access of prescription-only medicines for legitimate customers.

Misuse of doctor's prescriptions is also widespread, with illicit users making repeated purchases from multiple pharmacies using a single prescription.

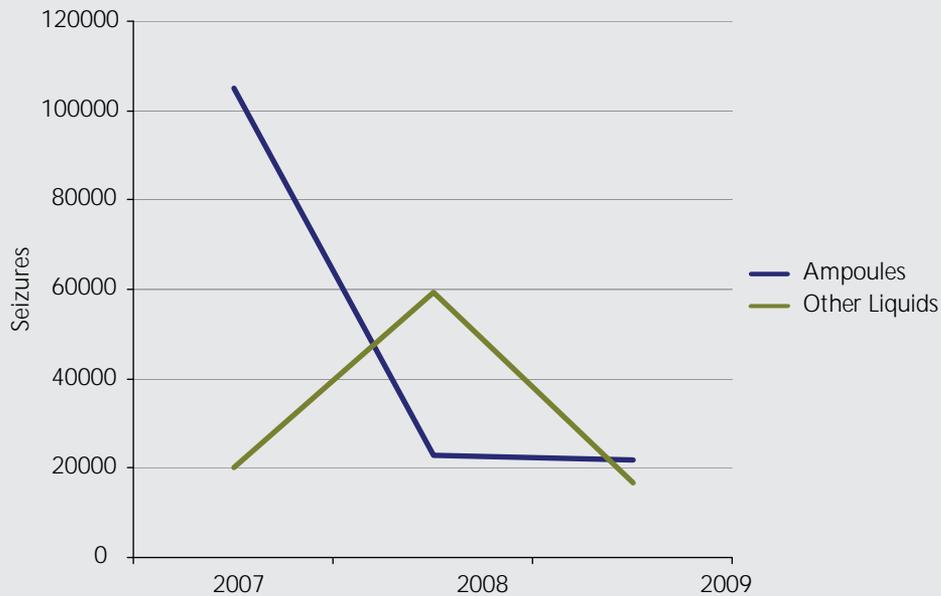
Trade in the misuse of doctors' drug samples by pharmaceutical representatives has also been reported. Hospitals were indicated as another major diversion source - notably for the narcotic drug pethidine. However no dedicated analysis of the system has been made with respect to its susceptibility to drug diversion.

External sources

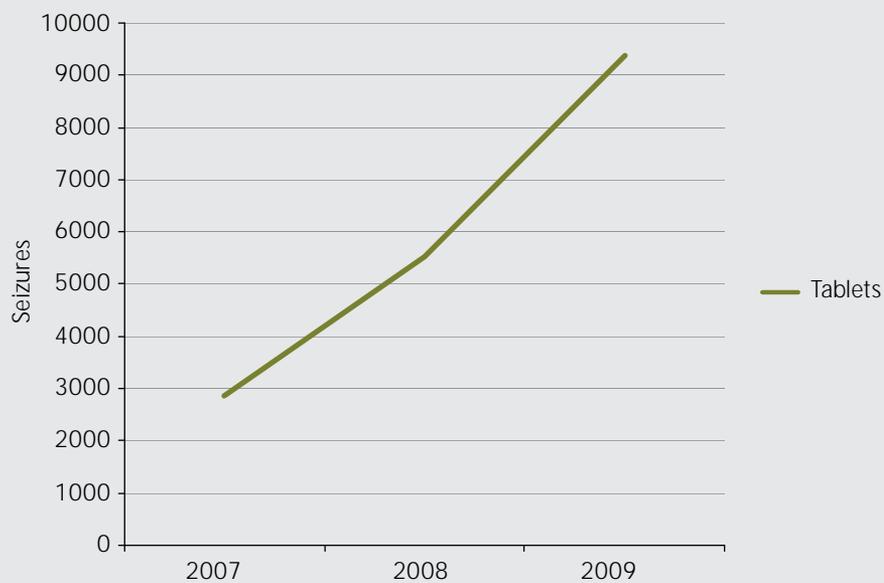
India and Nepal trade extensively in many different varieties of goods and services, making detection of illicit trade a challenging task. The borders between the two countries are notoriously porous and high rates of illicit use of buprenorphine and diazepam in the north-east of India fuels a substantial over-spill of these drugs into Nepal.

It is a matter of no surprise that the majority of pharmaceuticals seized by the NDCLEU (Narcotics Drug Control Law Enforcement Unit of Nepal) are of Indian origin and it was unanimously agreed by experts that cross-border smuggling from India is the principal source of narcotic and psychotropic pharmaceuticals in Nepal. The vulnerable border towns have been identified as: Birganj; Jogbani; Biratnagar; Nepalganj; Raxaul; Bairahabad; Sunavli and Dopedia. Seizure data suggest that smuggling of benzodiazepines and codeine is increasing.

Seizures of pharmaceutical drugs by the NDCLEU over the past 3 years



"Ampoules" refers to buprenorphine, pentazocine and diazepam; other liquid refers to codeine-based cough syrup.



"Tablets" refers to nitrazepam, diazepam and codeine.

Source: NDCLEU

Sri Lanka

Domestic sources

Due to the inadequacy of the enforcement of their regulation, pharmacies are the primary source of diversion. There is widespread violation of the terms of the pharmacists' personal user license (for example dispensing more than the mandated 100 doses or 3 - 6 month supply limit). According to experts, if the regulations were applied strictly to all of the country's pharmacies, 80% of them would be forced to close. Pharmacy departments of Sri Lanka's 51 supermarkets, which largely operate without the guidance of a trained professional, are often suspected of improper

dispensation and as such random checks are made on these retailers. Other sources of diversion include the misuse of doctors' prescriptions and the likely channeling of domestically produced diazepam to the illicit market.

External sources

The majority of pharmaceutical drugs entering Sri Lanka are believed to come from India via air and sea, and smuggling from Pakistan has also recently been detected.

There are many loop-holes in the system that allow for the undetected smuggling of pharmaceuticals. For example, Customs and Excise may only examine legal consignments with the assistance of the CDDA (Cosmetics, Drugs and Devices Authority) but there is lack of coordination and consequently, little information sharing among Customs, Police Departments, the Ministry of Health (Medical Supplies Division), the State Pharmaceutical Corporation and other relevant agencies. There is also a perceived lack of knowledge and awareness about the legal status, use, requirements and smuggling of narcotic and psychotropic pharmaceuticals among the responsible law enforcement agencies. Above all, there is a lack of clarity particularly regarding the private healthcare sector's legitimate requirements for pharmaceuticals, making it difficult to regulate the distribution of drugs in the domestic market.

4.3 Internet pharmacies

The recent emergence of illegal websites (established outside of South Asia in the USA, UK, Europe etc) offering unregulated trade in a range of prescription-only medicines over the internet has taken firm root in India as a key supplier. India, as mentioned above, champions a generic drug manufacturing industry that is price competitive and which gives distributors the opportunity to make vast profits from exporting them to the West. These online pharmacies transmit orders from paying customers to agents in India, who then procure the medicines from either legitimate or illegitimate sources before dispatching them to customers by mail and courier.



The global marketplace for online industries in general is booming and pharmacy is no exception: a recent survey conducted in the UK found that 14% of British adults have bought prescription-only medicines online (Times, 2010). Many of these businesses are legitimate and follow the same dispensing legislation and procedures as high street pharmacies, but due to high demand for many narcotic and psychotropic medications by recreational users and addicts, this system is prone to abuse. Besides, the potential identity mask offered by the internet attracts high levels of malpractice.

Illegitimate cyber pharmacies have flourished for a variety of reasons. First, the customers are not usually breaching any laws by ordering, receiving or consuming prescription-only medicines in this manner - even without possessing a valid prescription – and are attracted by the convenience factor and competitive prices. The high cost of medical insurance in the USA for example, pushes its citizens to find more affordable alternatives abroad. Due to the far-reaching power of internet search engines, there is an incredibly wide client base for such a business: in the USA, an estimated 8 million people use prescription pain relievers illicitly every year (www.drugabuse.gov) and the associated profitability attracts many willing unscrupulous doctors and postal traffickers to meet its demands. The sheer volume of international post makes it impossible to screen every package; a vast majority of illegal consignments therefore passes by undetected by the authorities.

There are serious health concerns about a system that allows people to access medicines that may harm rather than help them; this stems from the fact that no physical examination or consultation is performed by a doctor in order to inform a diagnosis and ascertain which medicine is appropriate. Indeed, many sites have marketed themselves with slogans such as “Buy X – no prescription required.”

There is another related concern. The European Alliance for Access to Safe Medicines (EAASM) estimates that between 50 and 90 per cent of all medicines supplied by online pharmacies may be counterfeit (The Times, 2010).

Internet pharmacies are usually tech-savvy and keep the identity of organizers tightly veiled. As a result there have been very few arrests of major internet pharmacies in South Asia. In India, the Narcotic Control Bureau (NCB) working alone or together with the United States Drug Enforcement Agency (DEA) has however been making at least one bust every year over the last few years. These peaked in 2008 when three busts were made in one year from which a total of USD 14.5 million assets were frozen. Convictions are not uncommon and sentences for those convicted of illegally dispensing narcotic and psychotropic pharmaceuticals using the internet have stretched to 12 years imprisonment (India Times, 2009).

At the global stage, a recent project spanning 22 countries was executed jointly by the World Customs Organisation, INTERPOL and the WHO's International Medicinal Products Anti-Counterfeiting Taskforce: Operation Pangea II tracked internet service providers, payment methods and mail delivery systems with the help of customs and police departments in order to investigate 751 suspicious websites, 72 of which were closed down and 22 individuals are currently under investigation (WCO, 2009).

An intercepted consignment of tablets suspected of being anabolic steroids awaiting laboratory analysis (Source: DEA)

4.4 Counterfeit drugs

“Trade trends clearly indicate an alarming increase in counterfeit medicines and other fake products that endanger consumer health and safety often with serious consequences for the end user” - Kunio Mikuriya (Secretary General, World Customs Organisation).

The term “counterfeit” carries multiple meanings where pharmaceutical products are concerned and has no singular international definition; this has been a source of friction concerning exports when definitions do not tally between the source and destination countries.

In 1992, a large group of Member States, INTERPOL, the World Customs Organization (at the time known as the Customs Cooperation Council), the International Narcotics Control Board, the International Federation of Pharmaceutical Manufacturers' Associations, the International Organization of Consumer Unions and the International Pharmaceutical Federation endorsed the following working definition:

A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with fake packaging.

In India, the DCGI (Drug Controller General of India) defines counterfeit to include sub-standard, spurious or misbranded products. According to The Drugs & Cosmetics Act, 1940 (revised, Act 68 of 1982, S.6, and w.e.f 01.02.1983 (24), a drug shall be deemed to be spurious under the following conditions:

- (a) If it is imported under a name which belongs to another drug; or
- (b) If it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug: or

- (c) If the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or
- (d) If it has been substituted wholly or in part by another drug or substance; or
- (e) If it purports to be the product of a manufacturer of whom it is not truly a product

While most countries in the region do not see counterfeit medical products as a major issue as yet, the Indian Drugs and Cosmetics Act was amended in 2008 to provide for enhanced penalties for violation of its provisions - maximum penalty has been enhanced to life imprisonment & fine of Rs 1 million in addition to classifying certain offences as cognizable & non bailable.

The Indian Pharmaceutical industry has expressed displeasure over the repeated projection that it is one of the major producers of spurious drugs in the world. However, Government of India took a serious note of the issue and commissioned a study to assess the actual extent of spurious drug circulation in the community at large. The Central Drugs Standard Control Organization (CDSCO) of the Ministry of Health and Family Welfare, Government of India compiled a Report on Country Wide Survey for Spurious Drugs in 2009 which has been published in 2010. According to this Report, a study of samples of drugs tested all over the country over the last 4-5 years reveals that about 0.3 % of around 40,000 samples fall within the category of spurious drugs. This is contrary to media reports that 10 -25% of drugs in India are spurious / counterfeit drugs.

The important issue is that if there is manufacture of counterfeit pharmaceuticals in the region, it is not perceived as a problem by experts and by representatives from the pharmaceutical industry and trade. The closest that experts commented on counterfeit pharmaceutical were allegations by Bangladesh of possible spurious production and smuggling of codeine based cough syrups from India. However, India's Central Drug Laboratory (which analyses seized narcotic and psychotropic drugs) has not found a single instance of codeine-based cough syrups which was found to be above the prescribed threshold levels to qualify as a "manufactured drug" under the NDPS Act of India. Nevertheless, seizures of spurious drugs are known to occur (Outlook India, 2010).

5

Recommendations

5.1 General points

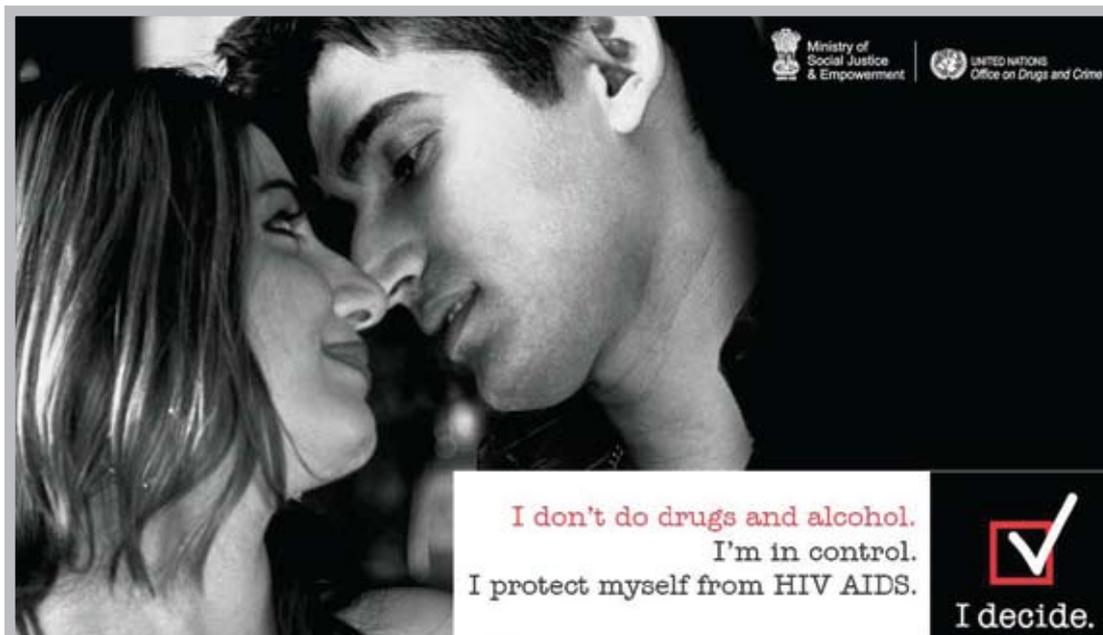
Illicit pharmaceutical use is a particularly difficult problem to address. Unlike other illicitly-used drugs that have limited or no medical use, pharmaceutical drugs are essential for public health. The very definition of the word narcotic originates from drugs derived from the alkaloids found in the opium poppy, and every opioid drug discovered or synthesised to date carries some degree of euphoria (well-being-inducing) and relaxant effect. Not strictly a side effect, these properties have therapeutic value in themselves: elevating the mood of a person in severe pain or suffering. The blocking of pain receptors and the elevation of mood have been intertwined by evolution for good reasons, and modern science thus far has been unable to disentangle them, meaning that the most effective painkillers are also narcotics and subjects of illicit use.

Therefore, attempts to tighten leaks in the regulatory system and supply chain where essential medicines are concerned must be conducted with the utmost care. Frightening pharmacists with penalties for improper dispensation has in the past led to the disappearance of scheduled medicines from the pharmacists' shelves - consequently those with genuine needs have gone without treatment. Nonetheless, there are potential measures that can be taken to improve the current situation that avoid jeopardising the requirements of bona fide patients.

5.2 Demand and supply

Awareness

When new drugs emerge in a country it is important for people, especially the younger generations (who are more liable to experiment) to be able to recognise them and be aware of their effects, side effects and associated dangers.



Poster produced under UNODC's 'I Decide – I won't use drugs' campaign



Leaflets produced under UNODC's 'I Decide – I won't use drugs' campaign

In this way the amount of harm caused by illicit substance use will be tempered by knowledge-based risk taking. It is rarely a casual user's intent to become an addict, and addiction does not set in immediately; in many cases a lack of awareness that a drug can be addictive can lead to ill-informed regular use of the drug. Because it is not practical for every teenager in South Asia to learn the entire narcotic and psychotropic pharmacopeia, regional monitoring of drug trafficking is imperative for local authorities to know how to prioritise awareness campaigns based on the likelihood of exposure to different chemicals. To be more focused and effective, these awareness campaigns must be implemented in schools during early teenage years before initial exposure.

Public campaigns to alert and educate people on the potential dangers of drugs have traditionally focused on illicit substances; however some licit drugs are in many cases more addictive and possibly harmful than a good many illicit ones. Given the easier availability of many prescription medicines, this anomaly needs to be corrected to enable patients and adventurous young people to make more informed decisions regarding their health and lifestyles.

Campaigns conducted by pharmacist associations to raise awareness among pharmacy traders of the abuse liability of the drugs they sell will encourage them to bolster the scrutiny of their codes of conduct and ethical practices in an informed manner. This should be combined with region-wide dissemination of good practices among doctors and other medical professionals as well as awareness and sensitisation programmes for the general public, government agencies and policy makers, and judiciary and stake holders. A particular emphasis on the latter should be placed on the psychological and other health risks associated with the injection of drugs.

Need for proper assessments and studies

The conclusions and recommendations presented in this report concerning the nature and extent of illicit pharmaceutical drug use are for the most part the opinions of experts in relevant fields. There is very little primary data on the subject and no large-scale surveys have been conducted. Therefore there is a pressing need for the inclusion of potentially harmful yet licit drugs such as narcotic and psychotropic pharmaceuticals in national household and thematic surveys in order to better understand the nature and extent of the problem; only then can focused campaigns be formulated that are tailored to the needs of each specific country in the region.

At the same time, there is a need for a proper assessment of the licit requirement of narcotic and psychotropic pharmaceuticals; this is a necessary first step towards having a monitored and better-regulated system. All countries

Rapid Situation and
Response Assessment
of Drugs and HIV in Bangladesh,
Bhutan, India, Nepal and Sri Lanka

A Regional Report

would benefit from this by imposing informed restrictions on the import of raw materials for manufacture of narcotic and psychotropic substances, while at the same time enable better regulation of manufacturing capacities.

A common observation across the region was that the pharmaceutical supply chains have not been studied with respect to diversion of narcotic and psychotropic pharmaceuticals. A detailed study of the supply chain from manufacture to the point of delivery to the pharmacists is needed in order to ascertain the points in the supply chain that are most vulnerable to being exploited.

Dedicated studies are also needed in order to find ways of tightening the system with respect to the use of doctors' prescriptions and to curb the current over-dispensing of potentially harmful or addictive drugs.

The introduction of a system to deal with the disposal of medicines that have passed their shelf lives would also prevent the diversion of this source.

5.3 Legal and policy

Strengthening the legal, policy and regulatory regimes

The legal regimes governing narcotic and psychotropic drugs are generally thorough and apply equally well to pharmaceutical preparations. However, certain anomalies have been flagged by experts where technical assistance

is needed in the refinement and harmonisation of legislation and policy. Some of these areas are as follows:

- In Bangladesh, like in most other countries, procedures for dispensing of narcotic and psychotropic pharmaceuticals at the pharmacy level only on proper prescription need to be formulated and implemented. The large numbers of unlicensed pharmacies need to be regulated as they are one of the key sources for addicts to obtain illicit pharmaceutical use.
- Bhutan's Medicine Act and Rules, NDPSSAA and Rules and Bhutan Penal Code need to be assessed for harmonisation, and more specific terminology should be employed in these laws to reduce their ambiguity. It is understood that the Penal Code of Bhutan 2004 and Civil and Criminal Procedure Code have since undergoing a major amendment in the 5th Session of National Council (Upper House of the Parliament) in May, 2010. Earlier, amendments and few new provisions were proposed and accepted by the Legislative Committee of the National Council.

It was also agreed that Bhutan would benefit from establishing specialist courts to conduct trials of drug cases, and improving border controls on the India – Bhutan border. Although not strictly under the pharmaceutical umbrella, recreational solvent use is also a major problem and the regulation in respect of these chemicals should be formulated.

- India requires amendments to the NDPS Act and EXIM Policy with respect to pharmaceuticals containing ephedrine and pseudoephedrine, offences made out of “manufactured drugs” under the NDPS Act which are within the threshold levels and to regulate internet pharmacies. Controls on the borders with Nepal, Bangladesh and Bhutan need to be enhanced as smuggling of pharmaceuticals from within India is currently extensive.
- Maldives has a general need for comprehensive legislation and regulations concerning narcotic and psychotropic pharmaceuticals. Presently, the regime is administrative in nature. Creation of a database on importers, distributors, pharmacists, drug - wise imports, sale, etc would be beneficial in assisting regulation of the industry. Better quality and more frequent audit of pharmacies and their stock management of scheduled drugs are also required.
- Establishment of better border controls on the India – Nepal border is considered a priority issue for the Government of Nepal; Home Secretary level talks between Nepal and India take place every year; more frequent operational level meetings with counterparts from India need to be held with the commitment of both countries to check cross-border trafficking.

The licences issued by the DDA, Nepal for manufacture of psychotropic substances do not prescribe any ceiling for production of these substances. The manufacturer is at liberty to produce quantities as per market requirements. There is no mechanism in place to monitor the quantity of psychotropic substances produced and this should be established under the DDA.

- In Sri Lanka, the issuing of licences for pharmacies needs to be streamlined, and one suggestion by Sri Lankan experts was to issue licences through a sub-committee including representatives of the pharmaceutical industry and trade instead of by individual officers. Reduction in the licence fee for operating pharmacies (which is currently Rs 7500 per month) will encourage pharmacists to register themselves and operate within the law. This could be implemented by members of the pharmacy association and stakeholders.

5.4 Capacity and implementation

Although the legal and regulatory regimes appear to be generally adequate in most countries, they require proper and better implementation by concerned agencies. For this, policy makers need to be sensitised to the issue of illicit pharmaceutical use and law enforcement agencies need to be properly motivated and trained to recognise the most dangerous drugs like narcotic ampoules. A series of training sessions, workshops and brainstorming sessions will help law enforcers and policymakers gain a better command of the vast and wordy narcotic and psychotropic pharmacopeia.



Demonstration of drug/precursor chemical test kit for law enforcement personnel, Nepal

Capacity building for regulatory and law enforcement officials needs to be coupled with a strengthening of their existing coordination mechanisms at policy and operational level, as the level of cohesion and information sharing is currently minimal.

Further, the mandates of each agency require absolute clarification and distinction.

Strengthening organisations and institutions

However thorough and extensive a country's drug legislation is, they are only as effective as far as they are enforced. The overwhelming consensus is that key implementing organisations across the region are generally lacking in manpower, capacity to understand and deal with the subtleties and complexities of rules and regulations as well as their mandates. In addition, cooperation between the organisations is also judged as inadequate.

It is for individual countries to make proper assessments of the areas where regulatory organisations need to be strengthened. However, certain critical aspects are as follows:

- For Bangladesh, the DDA needs to be institutionally and operationally strengthened, including a significant increase in its manpower. An assessment-based capacity building of the DDA, DNC, Police, RAB, Border Guards and Customs is also needed, and a greater sharing of information between all the fore-mentioned agencies would assist with the assessment of the problem at a national level and enforcement. Establishing more effective border controls on the India – Bangladesh border will curb the extensive trafficking of drugs into the country.
- Bhutan's DRA must be strengthened with more manpower for effective regulation and—along with the BNCA, RBP and Customs (especially concerning the border check points) and judicial officers—its capacity must be enhanced. Coordination mechanisms are needed at policy and operational levels: at the policy level, heads of DRA and RBP may be added as members in the Narcotics Control Board of BNCA; at operational level Chief of NDLEU should convene periodical meetings of all agencies - BNCA, Police, Customs, Immigration, DRA and BAFRA. Field-level operational meetings with their Indian counterparts would help in strengthening border control. This should be pursued under the newly signed Memorandum of Understanding with India. The establishment of a diagnostics lab for testing pharmaceuticals (as is presently being done in Thailand) would add considerable strength to the regulatory bodies.
- India's State Drug Control departments need to be strengthened and their manpower constraints addressed. For law enforcement: capacity building of State Drug Controllers and FDA departments is needed, as well



Computer based training for law enforcement officers in Maldives

as the sensitisation of Customs, Central Excise and narcotics departments to the nature and extent of illicit pharmaceutical use.

- Maldives requires capacity building of FDA officials and other regulatory and enforcement authorities including Police and Customs, combined with increased cooperation between the authorities. Forensic capacities of laboratories - including equipment and numbers of trained personnel - should also be enhanced. Many treatment facilities in Maldives have approached their maximum capacity (Himmafushi's is almost full); these need to be enhanced and manned by trained medical practitioners specialising in de-addiction and counselling.
- The Nepali DDA needs to be strengthened and its current manpower constraints should be addressed. Similar capacity building of the NDCLEU, Police, Immigration and Customs (especially border check points) is also needed. The possibility of strengthening the existing coordination mechanism at policy and operational levels was raised; however the existing coordination mechanisms are already extensive and include a Steering Committee chaired by the Home Minister with Secretaries of concerned departments as members. The Executive Committee is chaired by the Home Secretary and IDCCPC is chaired by the Joint secretary of the Ministry of Home Affairs.
- In Sri Lanka, the enforcement at the national level is done by the Food and Drugs Inspectors of the Cosmetic Devices and Drugs Department. The problem is that CDD has only 4 drug Inspectors with nationwide jurisdiction. At the province level however, for each of the 26 districts / medical regions, there is 3 to 4 drug Inspectors in each region making a total of 80 drug inspectors to enforce the CDD Act. The police act as enforcement authority under the Narcotics law in respect of pharmaceuticals controlled under the law. They do not have powers under the CDDA. Therefore, by and large, there is agreement among experts that inspection facilities are inadequate and not commensurate with number of pharmacies

5.5 Trade and industry

Stakeholders from the pharmacy trade and pharmaceutical industry will play a crucial role in any pharmaceutical-oriented strategy because much of the diversion takes place through their medium either at the pharmacy level, through leakages in the supply chain or via a parallel system of drug dispensation.

Bangladeshi Government stake holders and members of Bangladesh's pharmacy trade agree that there is a need for self regulation by the latter. There is also a need for an institutionalised and frequent interaction between law

enforcement and trade and industry to take necessary steps by mutual consultation; the representatives of the industry and trade have requested the government to initiate process of consultation and sensitisation of drug stores owners on procedures and classification of illicitly-used drugs.

Representation from the Indian pharmaceutical industry and trade at the seminar was minimal, thus the views of the few participants cannot be considered as that of the entire industry. Government stake holders were of the view that voluntary self regulation by the traders may not be of much help in India, though there was a need for it.

Maldives currently has too few qualified pharmacists to effectively run the country's pharmacies. The current system demands USD \$450 per month per pharmacist, necessitating a minimum daily sale of 2000 Rufiyaa per day to make business viable. Therefore a review of the present system is needed in order to accommodate more pharmacists.

In Sri Lanka, the Code of ethics is being followed by pharmaceutical manufacturers and good pharmacy practices have been developed in collaboration with WHO by the Pharmaceutical Society of Sri Lanka. Professional development programmes are also being conducted by the Pharmaceutical Society, which should be catalysed by and coupled with the formation of a National Pharmacy Council.

Pharmacists must be gently encouraged to comply with the existing regulations. According to psychiatrists practicing in the field of de-addiction, the majority of addicts seeking treatment were first exposed to the drug when it was prescribed to them for a genuine medical complaint. To stop treatment progressing into addiction, more stringent regulations on prescriptions (such as marking them with strict quantities) should be introduced; this will help to ensure that patients receive no more than the prescribed number of doses.

5.6 Treatment services for pharmaceutical opioid users, including injecting drug users

Given that the use of psychotropic and narcotic drugs for non-medical purposes has been a feature of human endeavour since pre-historic times, it is not realistic to expect it to ever disappear entirely. Any strategy thus should continue to have treatment and outreach options for illicit drug and pharmaceutical users. Efforts to reduce the



IDUs accessing services at a UNODC project site

harm caused to individuals, families and societies should be focused on protecting the most vulnerable, at-risk sub-populations of drug users, who are otherwise disenfranchised from health and social care systems.

Conventionally, there are two major ways of responding to the problem of drug use. The first strategy is that of 'supply reduction', wherein the emphasis is on reducing the availability of drugs, as well as legal and policy provisions restricting the availability of drugs. The second strategy is 'demand reduction', wherein emphasis is on reducing the demand for drugs among the population, either through prevention programmes for those who have not been initiated into drugs, or through treatment and care programmes for those who have initiated drug use and are dependent on them.

Various drug treatment centres exist in the South Asia region which are run by both Government as well as Non Governmental organizations. The services provided by these organizations range from management of withdrawal symptoms alone (detoxification) to long term treatment. Both medical and psychosocial treatment is available in many centres. The treatment duration also ranges from few days of indoor treatment to many months of long-term treatment.

In case of pharmaceutical opioid use, like any other opioids, most of the treatment programmes provide short-term detoxification followed by some form of psychosocial rehabilitation. In few countries, options of long-term medical treatment in the form of opioid substitution therapy (OST) have been initiated and are in pilot phase. OST involves the use of long acting opioid medications (e.g. Methadone and Buprenorphine) to help the drug user who is habituated/dependent on opioid drugs to overcome withdrawal and cravings leading on to stabilization of the individual. This in turn, helps him in stabilizing other areas of his personal, psychological and occupational life leading to re-integration with the society.

In case of those people who use pharmaceutical opioids through injecting route, other strategies are also being implemented in the South Asia region. Commonly labeled as 'harm reduction' services, the aim of this strategy is to



Client receiving OST medication



A person who injects drugs exchanging used syringe for a new one

prevent health complications associated with the use of injecting drugs, including prevention of HIV, Hepatitis B and Hepatitis C. The strategy uses multiple services to reduce the morbidity arising out of use of injections, and is called as 'comprehensive package of services'. The comprehensive package of services has been endorsed by UNODC, UNAIDS and WHO and consists, among others, Needle Syringe Programmes (NSP); OST and other forms of drug dependence treatment; detection and treatment of HIV; detection and treatment of Tuberculosis; and, prevention, detection and treatment of sexually transmitted infections.

These services are usually provided by NGOs in the areas where IDUs congregate/reside. These outreach services are provided using a network of community workers and current/ex-drug users, called as peer driven approach. The optimal use and scale-up of comprehensive package of services has been proven to be an effective way of reaching out to the marginalized section of drug users and help in prevention of HIV and other blood borne viruses, and lead to increased treatment utilization among IDUs.

