REVIEW ARTICLE

# Regulation of Controlled Drugs in Emerging Countries: Unique Attention to BRICS

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**Abstract**

BRICS is an association of five major emerging national economies: Brazil, Russia, India, China, and South Africa. The BRICS members are all developing newly industrialized countries, but all are distinguished by their large, fastest-growing economies and significant influence on regional affairs; all five are G-20 members. As of 2015, the five BRICS countries represent over 3 billion people or 42% of the world population; all five members are in the top 25 of the world by population, and four are in the top 10. Previously, the emerging markets have had little commercial interest or impact on the pharmaceutical industry with their limited gross domestic product (GDP). Comparing the E7 (Brazil, China, India, Indonesia, Mexico, Russia, and Turkey) with the G7 in terms of pharmaceutical expenditure helps to highlight this. In 2004, the E7 spent 0.94% of their GDP on prescription medications compared to 1.31% by the G7, and for the same year, the E7 accounted for only 8% of the global market versus 79% by the G7. If these countries manage to reach their predicted GDP growth targets and continue to spend the same proportion of their GDP on prescription medications, then by 2020 the E7 is estimated to account for 14% of a global pharmaceutical market worth $800 billion. This demonstrates just how big of a potential the emerging markets hold for the future of the pharmaceutical industry in terms of trade and research. Regulation of controlled drugs with regulatory authorities, import - export criteria and offenses & penalties among different BRIC countries.

**Key words:** Import and export, offenses and penalties, regulatory authorities

## INTRODUCTION

BRICS is the acronym for an association of five major emerging national economies: Brazil, Russia, India, China, and South Africa.[1] The grouping was originally known as 'BRIC' before the controversial inclusion of South Africa in 2010.[2] The BRICS members are all developing or newly industrialized countries, but they are distinguished by their large, sometimes fastest-growing economies and significant influence on regional affairs; all five are G-20 members.[3] As of 2015, the five BRICS countries represent over 3 billion people or 42% of the world population; all five members are in the top 25 of the world by population, and four are in the top 10. The five nations have a combined nominal gross domestic product (GDP) of US$16.039 trillion, equivalent to approximately 20% of the gross world product, and an estimated US$4 trillion in combined foreign reserves.

## HISTORY

The term "BRIC" was coined in 2001 by the chairman of Goldman Sachs Asset Management, Jim O'Neill, in his publication Building Better Global Economic BRICS with the premise that by 2050, the combined BRIC economies could eclipse the combined economies of the world's current richest countries.[4] In 2011, South Africa joined the group. The first five-member BRICS summit was held in 2011. The BRICS have a pooled economy of $15.435 trillion and are

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fundamentally the fastest-growing emerging markets. It is expected that by 2025, they account for over half the size of the G6 countries (US, UK, France, Germany, Italy, and Japan) in economic terms. Furthermore, by 2025 the US dollar expenditure by the BRICS will be increased annually and could possibly be double that of the G6 and even quadruple by 2050.[5]

If these countries continue to spend the same proportion of their GDP on prescription medications, then by 2020 the E7 is estimated to account for 14% of a global pharmaceutical market worth $800 billion. This reveals how big of a prospective the emerging markets hold for the future of the pharmaceutical industry in terms of trade and research.[6]

## BRAZIL

### About country

Area: 8,514,877 km$^2$
Population: 206,202,000
Language: Portuguese
Capital: Brasília
Currency: Brazilian real

Brazil borders all of South America's cocaine producing countries and is both a major transit and destination country for cocaine and a destination country for Paraguayan marijuana. The Brazilian drug trade is controlled by large, violent and well-organized drug trafficking organizations operating throughout the country.

### Pharmaceutical market

Among Latin American Countries, Brazil has the largest market share with an estimated worth of $25billion. Expected to become the fourth biggest global pharmaceutical market by 2016, Brazil currently leads the Latin American region and is the second largest only to China among emerging markets. With its 191 million inhabitants, Brazil is currently the world's eighth largest prescription drug market and has been the target of large investments and significant expectation from big pharmaceutical companies.[7]

### Regulatory authority

Therapeutic goods in Brazil are regulated by the Brazilian Health Ministry, through its National Health Surveillance Agency (equivalent to USA's FDA). There are five main categories:

- Normal medicines - Cough cold and fever medicines, antiseptics, vitamins, and others. Sold freely in pharmacies and some large supermarkets.
- Red stripe medicines - These medicines are sold only with a medical prescription. Antibiotics, anti-allergens, anti-inflammatories, and other medicines.
- Red stripe psychoactive medicines - These medicines are sold only with a "special control" white medical prescription with carbon copy, which is valid for 30 days. The original must be retained by the pharmacist after the sale, and the patient keeps the carbon copy. Drugs include antidepressants, anticonvulsants, some sleep aids, antipsychotics, and other non-habit inducing controlled medicines. Although some consider them habit inducing, anabolic steroids are also regulated under this category.
- Black stripe medicines - These medicines are sold only with the "Blue B Form" medical prescription, which is valid for 30 days and must be retained by the pharmacist after the sale. Includes sedatives (benzodiazepines), some anorexic inducers and other habit inducing controlled medicines.
- "Yellow A Form" prescription medicines - These medicines are sold only with the "Yellow A Form" medical prescription - the most tightly controlled, which is valid for 30 days and must be retained by the pharmacist after the sale. Includes amphetamines and other stimulants (such as methylphenidate), opioids (such as morphine and oxycodone), and other strong habit-forming controlled medicines.[8]

Brazilian National Health Surveillance Agency, ANVISA, is recognized as the strongest and most influential agency in Latin America and also has been used as a reference around the globe. ANVISA means *"Agencia Nacional de Vigilancia Sanitaria."* This abbreviation is in Portuguese language. In English, it means "National Health Surveillance Agency," or sometimes it is written as "Brazilian Health Surveillance Agency." ANVISA was created in 1999 Linked to the Ministry of Health; ANVISA is financially autonomous and independently administered. Its activities involve the setting of standards and rules, together with inspection and health surveillance enforcement. Product registration in Brazil is a laborious exercise. The registration is valid for 5 years and can be renewed continuously for the same period. Law must complete the registration process within 90 days after the registration is requested, or denied. For registration purposes, ANVISA classifies the products in various categories:[9]

- A1-Narcotics
- A2-Narcotics allowed in special concentration
- A3-Psychotropics
- B1-Psychotropics
- B2- Psychotropic Anorectics
- C1-Drugs subject to special control
- C2-Glycolic drugs
- C3-Antiretroviral drugs
- C4-Immunosuppressive drugs
- D1-Inputs for Narcotics and Psychotropic
- D2-Chemical inputs

### Import and export

Permits from sanitary institutions required to import medicines.

To import medicines with the purpose of selling in Brazil, it is necessary to have the following documents:

1. Import permit
   It is a document issued by the Health Surveillance Secretariat of the Ministry of Health, allowing import of substances in the lists A1, A2, A3, B1, B2, C3, and D1.
2. Certificate of special permit.
   License granted to exercise activities of extraction, production, processing, manufacture, fractionation, handling, packaging, distribution, transportation, repackaging, and import and export of drugs.
3. Import license
   The license is granted after approval of the Ministry of Health to import a product or raw materials under sanitary surveillance by demonstrating compliance with legal requirements that person, before customs clearance.
4. Annual import quota
   Document that specifies the amount of drugs from the lists A1, A2, A3, B1, B2, C3, and D1 that the company is allowed to import up to the first quarter of the year.
5. Supplementary import quota
   Document that specifies the amount of drugs from the lists A1, A2, A3, B1, B2, C3, and D1 the company is allowed to import in a supplementary to the annual quota.
6. Total annual import quota
   Sum of annual and supplemental quotas authorized for each company in the current year.

### Offenses and penalties

Under Brazilian law, possessing drugs for personal use is a crime that does not carry a penalty of imprisonment. Those convicted of the charges can be subject to the following penalties: A warning, community service, or attending an educational course. The illegal importing of medicines is subject of penalties of warning, confiscation, destruction, prohibiting, and cancellation of the registration of the product and fines.

Between 2007 and 2010, the number of people incarcerated for drug-related crimes increased by over 62%. This increase was due primarily to the imprisonment of first-time offenders who had no involvement with organized crime.

## RUSSIA

### About country

Area: 17.1 million km$^2$
Population: 143,456,918
Language: Russian
Capital: Moscow
Currency: Russian ruble

### Regulation of controlled substances

The Russian pharmaceutical regulation is based on Federal Law No. 323-FZ which is laid on the Fundamentals of Citizens' Health Protection in the Russian Federation (the "Fundamentals"). The main legislative act specifically governing the pharmaceutical market in Russia is Federal Law No. 61-FZ on the Circulation of Medicines, dated 12 April 2010, as amended (the "Law on Circulation of Medicines") [10] Other laws that are also important for the pharmaceuticals and health-care sector include Federal Law No. 184-FZ On Technical Regulation, dated December 27, 2002, and Federal Law No. 99-FZ On Licensing Certain Types of Activities, dated May 4, 2011.[11]

### Regulatory authorities

The regulatory bodies governing the health-care system and pharmaceutical market of the Russian Federation are the Ministry of Health care (the "MOH"), the Ministry of Industry and Trade (the "MIT") and the Federal Service for Surveillance in Health care (the "Federal Service").[10]

The MOH is responsible for drawing up state policy and regulation in health care, circulation of medicines for human use, sanitary and epidemiological welfare and numerous other areas. The MOH submits drafts of federal laws and acts of the president and the government on health care to the government. The MOH also adopts a significant number of important executive regulations on the circulation of medicines required by laws.

Licensing regulations have also changed. Activities involving narcotic drugs, psychotropic or plants containing narcotics must be licensed with local Russian Federation authorities. The government will keep a registry of all the licenses.[12]

On December 31, 2009, the Government of the Russian Federation issued two regulations which extend the list of narcotic and psychotropic substances and establish a new procedure for their storage and preservation.[13]

### Import of controlled drugs requirements

1. Certified copies of documents issued by national drug regulatory authority of importing country indicating that the importer is duly licensed.
2. The product is duly licensed in the importing country.
3. Batch certificate issued by the manufacturer.
4. Any other relevant documents.
5. There should be an import certificate of narcotic drugs and import authorization for psychotropic substances.

6. The exporting country will provide an export authorization corresponding to it.

Import and export certificates should contain the following information:[14]

- The name of the narcotic drug or psychotropic substance.
- The quantity to be imported or exported expressed in terms of anhydrous base content.
- The pharmaceutical form and if in the form of preparation, the name of the preparation.
- The name and address of importer or exporter.
- The period of validity of the authorization.

The retail sale of medicines is regulated by the Rules for the Sale of Medicines in Pharmacy[15] Institutions, Fundamental Provisions (OST 91500.05.0007-2003), approved by Order No. 80 of the Russian Ministry of Healthcare, dated March 4, 2003, and by the Order on the Sale of Medicines, approved by Order of the MOH No. 785, dated December 14, 2005 ("Order No. 785)."

### Offenses and penalties

This may vary from 2 to 20 years depending on the type of offenses and quantity of drug in hand. Table 1 briefly shows the offenses and penalties with respect to different quantities of drugs.

## INDIA

The supreme substantial drug-related challenges facing by India are the rise in methamphetamine manufacturing and trafficking, the smuggling of pharmaceutical preparations containing narcotic drugs and psychotropic substances and limitations on administrative ability.

### About country

Area: 3,287,240 km$^2$
Population: 1,311,050,527

**Table 1:** Offenses & penalties of controlled drugs in Russia

| Sl. No | Offenses | Penalties | | |
|---|---|---|---|---|
| | | Small amounts | Larger quantities | Extremely large quantities |
| 1 | Acquisition, Storage, Transportation Production Processing (without intention to sell) | $130-160 fine or arrest for up to 15 days | Up to 3 years in prison | 3-10 years in prison |
| 2 | Production, sale transmission | 4-8 years in prison | 5-12 years in prison (by a group of cons pirators) | 8-20 years in prison (by a group of conspirators; involving minors; involving abuse of office) |
| 3 | Illegal cultivation of plants containing narcotic substances | $50-130 fine or arrest for up to 15 days | Up to 2 years in prison | Up to 8 years in prison |
| 4 | Violating of rules governing turnover of narcotic substances | Up to $4000 fine; up to 180 hours of compulsory work | For material gain; resulting in bodily injury up to 3 years in prison | |
| 5 | Theft | 3-7 years in prison | 6-10 years in prison | 8-15 years in prison |
| 6 | Inducement of drug abuse | 6 months in prison or more-up to 5 years in prison | 3-8 years in prison | 6-12 years in prison (involving minors; resulting in unintentional death or dismemberment) |
| 7 | Organizing and keeping drug houses | Up to 4 years in prison | 2-6 years in prison | 3-7 years in prison |
| 8 | Promotion of narcotic substances | $130-160 fine | $1300-1600 fine for officials and entrepreneurs | $2500-3200 fine for organizations |
| 9 | Drug use | $130-160 fine or arrest up to 15 days | Drug smuggling 3-7 years in prison | Illegal issue or counterfeiting of prescriptions: Up to 2 years in prison |

Language: Hindi, English, 21 other
Capital: New Delhi
Currency: Indian Rupee

### Pharmaceutical market

In 2017, India is predicted to move up to the 11th spot in global pharmaceutical spending. India is the only country authorized by the United Nations Single Convention on Narcotic Drugs (1961) to produce gum opium. Eleven other countries, i.e., Australia, Austria, France, China, Hungary, the Netherlands, Poland, Slovenia, Spain, Turkey, and Czech Republic cultivate opium poppy, but they do not extract gum.

### Regulation of controlled substances

The regulation of narcotic drugs and psychotropic substances is governed by the NDPS Act.[16] Prevention of narcotic drugs and psychotropic substances abuse is under the control of India's chief national drug control agency, named Narcotics Control Bureau (NCB). Other lawful authorities to track narcotics inquiries are the Directorate of Revenue Intelligence (DRI) and the Indian Customs Service.

The Central Bureau of Narcotics (CBN) is India's supervising agency over the licit cultivation of opium poppy in India. Abuse stoppage, investigation of violations of NDPS Act, issuance of licenses for the manufacture of synthetic narcotic drugs and import/export authorizations for narcotic drugs and psychotropic substances are the major responsibilities of CBN.

### Import and export

The Government of India has recently amended the NDPS Rules 1985 vide Gazette Notification No. GSR 224(E) dated March 25, 2015 that may be called the Narcotic Drugs and Psychotropic Substances (Second Amendment) Rules, 2015, which has become effective from 26.03.2015. After these amendments, the provisions relating to import and export of Narcotic Drugs and Psychotropic Substances are as follows:[17]

- Rule 53 of NDPS Rules 1985 provided that import into India or export out of India of narcotic drugs and psychotropic substances specified in Schedule 1 of these rules shall be for the purpose mentioned in Chapter VII A.
- The import of - (i) opium, concentrate of poppy straw, and (ii) morphine, codeine, thebaine, and their salts are prohibited save by the Government Opium Factory.
- The import of morphine, codeine, thebaine, and their salts by manufacturers notified by the Government for manufacture of products to be exported or to import of small quantities of morphine, codeine, and thebaine, and their salts not exceeding a total of 1 kg in a calendar year for analytical purposes is permitted after following the procedure under rule 55 and subject to the conditions as may be specified by the Narcotics Commissioner.
- As per rule 56 and rule 59, the Narcotics Commissioner shall issue or deny the import certificate/export authorization within a period of 21 working days from the date of receipt of an application completed in all respects.
- A fee of rupees 1000 shall be paid (in the form of Demand Draft drawn in favor of Drawing and Disbursing Officer, Central Bureau of Narcotics payable at Gwalior) to the Central Government along with the application for issue of each import certificate/export authorization.
- Applicant for import of Narcotic Drugs/Psychotropic substances will apply in the application form specified as "IMP-1" along with the Background Information specified as "IMP-2" whereas for issuance of export authorization for export of Narcotic Drugs the applicant will apply in the application form specified as "EXP 1" along with the Background Information specified as "EXP-2."
- Any correspondence which relates with "Narcotics Drugs" may be addressed to the Narcotics Commissioner in an envelope superscribed as "FOR NARCOTIC DRUGS"/ psychotropic substances as "FOR PSYCHOTROPIC SUBSTANCES."

### Offenses and penalties

NDPS Act views drug offences very seriously, and penalties are stiff. The quantum of sentence and fine varies with the offence. For many offences, the penalty depends on the quantity of drug involved [Table 2].

## CHINA

### About country

Area: 9,388,211 km$^2$
Population: 1.357 billion
Language: Standard Mandarin
Capital: Beijing
Currency: Renminbi

### Pharmaceutical market

If forecasts are correct, China will become the second largest pharmaceutical market in the world in 2017, overtaking Japan. In addition to domestic drug production problems, China's proximity to the Golden Triangle, North Korea, and the Golden Crescent facilitates the trafficking of drugs such as heroin and opium. National Narcotics Control Commission (NNCC) leads the efforts of narcotics control in China and is responsible for the national coordination of drug control

**Table 2:** Offenses & penalties of controlled drugs in India

| Sl. No. | Offences | Penalty | Sections of the Act |
|---|---|---|---|
| 1 | Cultivation of opium, cannabis or coca plants without license | Rigorous imprisonment up to 10 years + fine up to Rs. 1 lakh | Opium - 18(c) Cannabis - 20 Coca-16 |
| 2 | Embezzlement of opium by licensed farmer | Rigorous imprisonment - 10-20 years + fine Rs. 1-2 lakhs (regardless of the quantity) | 19 |
| 3 | Production, manufacture, possession, sale, purchase, transport, import interstate, export interstate or use of narcotic drugs and psychotropic substances | Small quantity - Rigorous imprisonment up to 6 months or fine up to Rs. 10,000 or both. More than small quantity but less than commercial quantity - Rigorous imprisonment up to 10 years + fine up to Rs. 1 Lakhs. Commercial quantity - Rigorous imprisonment 10-20 years + fine Rs. 1-2 Lakhs | Prepared opium-17 Opium - 18 Cannabis - 20 Manufactured drugs or their preparations - 21 Psychotropic substances -22 |
| 4 | Import, export or transhipment of narcotic drugs and psychotropic substances | Same as above | 23 |
| 5 | External dealings in NDPS, i.e., engaging in or controlling trade whereby drugs are obtained from outside India and supplied to a person outside India | Rigorous imprisonment 10-20 years + fine of Rs. 1-2 lakhs (Regardless of the quantity) | 24 |
| 6 | Knowingly allowing one's premises to be used for committing an offence | Same as for the offence | 25 |
| 7 | Violations pertaining to controlled substances (precursors) | Rigorous imprisonment up to 10 years + fine Rs. 1-2 lakhs | 25A |
| 8 | Financing traffic and harboring offenders | Rigorous imprisonment 10-20 years + fine Rs. 1-2 lakhs | 27A |
| 9 | Attempts, abetment, and criminal conspiracy | Same as for the offence | Attempts - 28 Abetment and criminal conspiracy - 29 |
| 10 | Preparation to commit an offence | Half the punishment for the offence | 30 |
| 11 | Repeat offence | One and half times the punishment for the offence. Death penalty in some cases | 31 Death - 31A |
| 12 | Consumption of drugs | Cocaine, morphine, heroin - Rigorous imprisonment up to 1 year or fine up to Rs. 20,000 or both. Other drugs - Imprisonment up to 6 months or fine up to Rs. 10,000 or both. Addicts volunteering for treatment enjoy immunity from prosecution | 27 Immunity - 64A |
| 13 | Punishment for violations not elsewhere specified | Imprisonment up to 6 months or fine or both | 32 |

activities. The NNCC includes representatives from a range of government ministries.

### Regulation of controlled substances

The Ministry of Public Security, through the NCB, enforces narcotics control measures China Customs Anti-Smuggling Bureau also has significant involvement in narcotics control.

The People's Republic of China takes strong measures against the use and trafficking of narcotics and dangerous drugs. China produces and monitors all 22 of the chemicals on the tables included in the 1988 UN Drug Convention.

China continues to closely cooperate with the United States and other concerned countries in implementing a system of pre-export notification for dual-use precursor chemicals. China strictly regulates the import and export of precursor chemicals.

Due to China's effective law enforcement, opium poppies are only grown in small quantities by ethnic minority groups for local consumption. Chinese officials state that there are no heroin refineries in China. Coca is not cultivated in China. However, China is a main source for natural ephedra, which is used in the licit production of ephedrine. China is also one of the world's largest producers of ephedrine, licit synthetic pseudoephedrine, and ephedra products. China has a large pharmaceutical industry, and these products all have legitimate medicinal use, but they can also be used in the production of amphetamine-type stimulants (ATS).[18]

### Controlled drugs Act[19]Controlled drugs shall be regulated by this Act in addition to other related laws

#### *Article 2*

For purposes of this Act, the term "competent health authority" shall mean the Department of Health of the Executive Yuan at the central government level, the municipal governments at the municipality, and the county/city governments at the county/city level.

#### *Article 3*

The term "controlled drugs" as used in this Act refers to the following types of drugs:

1. Addictive narcotic drugs
2. Psychotropic drugs
3. Other drugs requiring regulation.

The controlled drugs mentioned above shall be classified into four schedules by their potential for habitual use, dependence, abuse, and danger to the society. Said controlled drugs may only be used for medical and scientific purposes. The schedules and items of the controlled drugs shall be reviewed and announced to the public by the Executive Yuan after consideration by the Controlled Drugs Review Committee established by the central competent health authority and published in the Government Gazette.

#### *Article 4*

The pharmaceutical plant of the Food and Drug Administration shall handle the import, export, manufacture and selling of the Schedule 1 and 2 controlled drugs.

#### *Article 16*

The import, export, manufacture, selling or purchasing of controlled drugs shall follow the following procedures and guidelines:

- The pharmaceutical plant listed in Article 4 Paragraph 1 may handle the export, import, manufacture and sales of Schedule 1 and 2 controlled drugs.
- Human medicine manufacturers or veterinary medicine manufacturers may handle the buying and export of the raw materials of controlled drugs, and the export, manufacture or sales of Schedule 3 and 4 controlled drugs.
- Human medicine companies or veterinary medicine companies may handle the import, export or transfer of Schedule 3 and 4 controlled drugs.
- Medical institutions, drug stores, veterinarian institutions, pasturage veterinarian institutions, and research laboratories may purchase controlled drugs.

The institutions and companies mentioned in the preceding Paragraph shall apply to the Food and Drug Administration for registration and obtain controlled drugs registration license. On a change of circumstances regarding the registration mentioned in the preceding Paragraph, the registrants shall notify the Food and Drug Administration regarding the changes within 15 days.

Controlled drugs registration licenses shall not be lent to other people nor shall the ownership be transferred. Regulations governing the issuance, alteration of registration, reissuance, replacement, revocation, annulment, and management of the controlled drugs registration license shall be prescribed by the central competent health authority.

#### *Article 17*

The Food and Drug Administration shall make an estimate of the amount of Schedule 1 and 2 controlled drugs that will be needed each year. That estimate shall be submitted to the Executive Yuan for ratification through the central competent health authority.

#### *Article 18*

The Food and Drug Administration shall report the monthly increase and decrease of stocks, and the current inventory amount of Schedule 1 and 2 controlled drugs to the central competent health authority, which shall make an annual public announcement and publish it in the Government Gazette.

#### *Article 21*

When selling controlled drugs, the names of purchasers and their institutions, organizations, the person in charge, the registration numbers, purchased amount, and dates shall be recorded in detailed records and shall be kept together with the receipt containing the purchasers' signature.

#### *Article 22*

The Food and Drug Administration may allocate and limit the amount of Schedule 1 and 2 controlled drugs sold, and the regulations governing such sales shall be prescribed by the central competent health authority.

### *Article 23*

A permit shall be applied for and issued from the Food and Drug Administration before domestically transporting Schedule 1 and 2 controlled drugs. However, a transporter handling the destruction of the above-mentioned drugs with the local competent health authority's certificate shall be exempted.

### *Article 24*

Controlled Drugs shall be under the safekeeping of the business department. Schedule 1, 2, and 3 controlled drugs shall be kept and locked in special storage cabinets.

### *Article 25*

The labels of controlled drugs shall bear the schedule, written warnings in Chinese and alert signs or colors. Said labeling in the case of narcotic drugs shall bear the sign of narcotic drugs in Chinese.

### *Article 32*

The books, receipts and special prescription forms for controlled drugs required by this Act shall be retained for 5 years.

### *Article 33*

The competent health authorities and the Food and Drug Administration may inspect and oversee the import, export, manufacture, selling, purchasing, administering, dispensing, and management of controlled drugs. On a showing of proper documentation, the inspectors may sample for testing. Said samples shall be limited to the amount of controlled drug needed for examination.

### Offenses and penalties

Illegal opium cultivation no longer exists in China because of strong state control of land use and extensive domestic surveillance.[20] Whereas other drugs misused are as follows, with penalties ranging from 3 years to life imprisonment along with fine [Table 3].

## SOUTH AFRICA

### About country

Area: 1 219 090 km$^2$
Population: 51.77-million
Language: Afrikaans, English, Ndebele, Northern Sotho, Sotho, Swazi, Tsonga, Tswana, Venda, Xhosa and Zulu
Capital: Pretoria (administrative)
Cape Town (legislative)
Bloemfontein (judicial)
Currency: Rand

### Pharmaceutical market

Africa's fast-growing pharmaceutical market is attracting big drug manufacturers who are faced with thinning profits in tough developed countries markets. In just 10 years – between 2003 and 2013 – Africa's pharmaceutical industry grew from $4.7 billion in to over $20.8 billion, according to a Quartz Africa report, and was expected to grow at between 6 and 11 percent over the next 5 years driven by a growing middle class demanding more prescription medicines, generics, over the counter medicines, and medical devices. "By 2016, pharmaceutical spending in Africa is expected to reach US $30 billion," a popular study published by IMS Health Solutions in 2013 said.[21]

### Regulation of controlled substance

The basis for the national drug control framework is the (5 year) National Drug Master Plan (NDMP) adopted by Parliament in February 1999. The NDMP 2013-2017 of South Africa was formulated by the Central Drug Authority in terms of the Prevention and Treatment of Drug Dependency Act (20 of 1992), as amended, as well as the Prevention of and Treatment for Substance Abuse Act (70 of 2008) as amended, and approved by Parliament to meet the requirements of the international bodies concerned and at the same time the specific needs of South African communities, which sometimes differ from those of other countries.[22]

Narcotic drug also referred to as a controlled substance is any substance listed in Schedules 1 and 2 of the 1961 Single Convention on Narcotic drugs as amended by the 1972 Protocol, whether natural or synthetic. Psychotropic substance also referred to as a controlled substance is any substance whether natural or synthetic listed in Schedules 1, 2, 3, or IV of the 1971 Convention on psychotropic substances (Controlled substances mean narcotic drugs and psychotropic substances under international control).

## IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

Most of the requirements specified in these guidelines on import and export procedures for medicines also apply to the border control of controlled substances in addition to the requirements of relevant legislation and accordance with international conventions. Each member country shall be required to comply with the Treaty Obligations as enshrined in the United Nations International Narcotics Control Board's

**Table 3:** Offenses & penalties of controlled drugs in China

| Drug | Possession in lower amount | Penalty | Possession in larger amount | Penalty |
|---|---|---|---|---|
| Cocaine | 10-50 g | Up to 3 years in prison, up to 1 year in detention house or between 3 months and a year surveillance plus fine based on the amount in possession | >50 | 7 years to life imprisonment along with fine based on the amount in possession |
| Heroin | 10-50 g | | >50 | |
| Marijuana | 30-150 g (cannabis oil 1-5 kg, cannabis 2-10 kg) | | >150 | |
| Morphine | 20-100 g | | >100 | |
| Opium | 200-1 kg | | >1 kg | |
| Pethidine | 50-250 g | | >250 g | |

(INCB) 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances.

The authorized importer shall present to the customs authorities a copy of the respective import license issued by the DRA and other relevant documents issued by the competent authorities of the exporting country, a copy of which must accompany each consignment.

Import authorizations are required for psychotropic substances in Schedules 1, 2, 3, and 4 of the 1971 Convention so as to prevent attempts to divert psychotropic substances such as stimulants, sedative-hypnotics and tranquillizers into illicit trade. These import authorizations shall only be issued to authorized importers with valid pharmaceutical import and wholesale dealer's licenses and appropriate premises.

### The import and export authorizations shall contain at least the following information

a. Name of controlled substance(s) (if available, the international nonproprietary name)
b. Quantity to be imported/exported expressed in terms of anhydrous base content
c. Name and address of the importer and exporter
d. Period of validity of the authorization
e. Route of entry/exit through which importation/exportation shall be affected
f. Number and date of the corresponding import/export authorization and the name of the competent authorities of the importing/exporting countries by whom it was issued
g. Strength and dosage form.

An application for a license to import/export controlled substances will be made to the respective Drug Regulatory Authorities in the prescribed form backed by legislation.

## CRITERIA FOR ISSUE OF AUTHORISATION TO IMPORT[23]

The criteria for issue of a pharmaceutical import license shall entail that:

a. There are suitable premises, facilities and equipment for proper pharmaceutical warehousing
b. There are suitably qualified pharmaceutical personnel that shall oversee the quality assurance, i.e., pharmacist and pharmacy technologist/technician
c. There are suitable arrangements, programs and systems for procurement, storage, documentation, stock surveillance, and distribution.

## APPLICATION FOR ISSUE OF AN IMPORT PERMIT

An application accompanied by a prescribed fee for issue of an import permit shall be made on the prescribed form backed by legislation.

An application for issue of an import permit shall state, for each medicine to be imported at least the following:

a. Generic name or International Nonproprietary Name (INN)
b. Strength and dosage form
c. Name and strength of each ingredient; in case of a product containing more than one ingredient
d. Trade name or proprietary name; if any
e. Pharmacopeia specification of the medicine, where applicable
f. Total quantity to be imported
g. Name and address of the supplier
h. Name and address of the manufacturer
i. Country of origin
j. Route of entry
k. License/registration number
l. Cost, insurance, freight (CIF) value
m. Expected date of arrival.

A separate import permit for controlled substances will apply as prescribed by the national legislation and applicable treaty obligations. The application shall be accompanied by copies of the pro forma invoices.

## APPLICATION FOR ISSUE OF AN EXPORT PERMIT

An application accompanied by a prescribed fee for issue of an export permit shall be made on the prescribed form backed by legislation.

An application for issue of an export permit shall state, for each medicine to be exported at least the following:

a. Generic name or INN
b. Strength and dosage form
c. Name and strength of each ingredient; in case of a product containing more than one ingredient
d. Trade name or proprietary name; if any
e. Pharmacopeia specification of the medicine, where applicable
f. Total quantity to be exported
g. Name and address of the exporter
h. Name and address of the manufacturer
i. Name and address of consignee
j. Country of consignee
k. Route of dispatch
l. License/registration number
m. CIF value
n. Expected date of dispatch.

The application shall be accompanied by copies of the purchase orders.

In conclusion, importation of drugs that lack approval and is not in line with these guidelines whether for personal use or otherwise will be considered as illegal importation and could be refused entry into any of the SADC countries or seized by customs officials.

## CENTRAL DRUG AUTHORITY

The CDA is a statutory body established and functioning in terms of the Prevention and Treatment of Drug Dependency Act (20 of 1992), as amended, as well as the Prevention of and Treatment for Substance Abuse Act (70 of 2008), as amended, and serves for 5 years in the following capacity:

Giving effect to the NDMP;

Advising the Minister of Social Development, who is the chairperson of the Inter-Ministerial Committee on Substance Abuse, on any matter associated with such abuse, and reviewing the NDMP after 5 years.

## TYPES OF SUBSTANCES OF ABUSE IN USE

The four types of substances or drugs on which the UNODC reports are:

Cannabis (dagga), which is usually smoked separately or in combination with other drugs;

Opiates or derivatives of the opium poppy, normally smoked but it may be injected in refined form, with heroin being the dominant opiate in South Africa; Cocaine, which is inhaled or "snorted" in powder form; ATS, such as Ecstasy tablets and the local version of crystal methamphetamine known as "tik," and usually smoked in some special holder; cultivation and production of illicit drugs in South Africa:

Cannabis: Cannabis is one of two drugs produced in South Africa. Altogether 22% of the world's harvest of cannabis comes from Africa, where it is produced in almost every country. The largest producer is South Africa with about 2 500 metric tons of the total of 8900 metric tons produced, i.e., 28% of the African production and 7% of the world production. Despite large-scale domestic cultivation of herbal cannabis, the latest vogue is hydroponic cannabis. Several hydroponic cannabis production facilities have been dismantled in the past couple of years.

ATS: Methamphetamine can be made using a variety of licit precursor chemicals and simple processes. Manufacturing takes place in mega and super laboratories, but more commonly in small kitchen laboratories. This convenience of manufacturing makes ATS the most widespread illicit drug but also the most difficult to determine the total amount produced. The detection of ATS laboratories is also becoming more difficult, as they are run in hard-to-detect spots. During the last estimate, there were 35 such laboratories still functioning. The number of such laboratories that were dismantled increased by 55% between 2005 and 2006, with 17 such laboratories reported dismantled in that time and another 15 in 2007/8. It is also important to bear in mind that South Africa is one of the world's largest importers of licit ephedrine and pseudoephedrine, two of the precursor chemicals used to manufacture methamphetamine.

The role of the internet in providing recipes/formulas to manufacture illicit drugs and information on sites offering illicit drugs and precursor chemicals for sale must be addressed in prevention and law enforcement programs. Unscrupulous drug traffickers are recruiting their mules/couriers on social networking sites.

### Precursor control

Precursor control is aimed at controlling the manufacture and supply of chemicals used in industry and the production

**Table 4:** Offenses & penalties of controlled drugs in South Africa

| Drug | Possession amount (lower) | Penalty | Possession amount (larger) | Penalty |
|---|---|---|---|---|
| Cocaine | 10-50 g | Up to 3 years in prison, up to 1 year in a detention house, or between 3 months and a year of surveillance, plus a financial penalty based on the amount of drugs you were caught in possession of | >50 g | At least 7 years to life imprisonment, plus a financial penalty based on the amount of drugs you were caught in possession of |
| Heroin | 10-50 g | | >50 g | |
| Marijuana | 30-150 kg (cannabis oil 1-5, cannabis 2-10 kg) | | >150 g | |
| Morphine | 20-100 g | | >100 g | |
| Opium | 200 g-1 kg | | >1 kg | |
| Pethidine | 50-250 g | | >250 kg | |
| Poppy shells | 50-200 kg | | >200 kg | |

of pharmaceuticals and illicit drugs. Three statutes govern precursor control in South Africa:

Article 12 of the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances;

Section 3 of the Drugs and Drug Trafficking Act (140 of 1992); and

Section 6 of the International Trade Administration Act (71 of 2002), which regulates the import and export of precursor chemicals.[24]

### Offenses and penalties

Possession of controlled drugs is liable to be punished with imprisonment and fine depending on the quantity [Table 4].

## CONCLUSION

Most fatal tasks threatening the world are narcotic drug consumption and smuggling. Illicit cultivation of opium mainly in Afghanistan and South East Asia and coca bush in South America continue to be a challenge globally.

Representatives of the five countries, Brazil, Russia, India, China, and South Africa, met in New Delhi, recently to find ways to tackle and curb the threat of drugs during a BRICS Anti-Drug Working Group meeting.

Anti-Drug Working Group was established with an aim to address the issue on counteracting the illicit trafficking of narcotic drugs, psychotropic substances, and their precursors. The latest theme of BRICS is "Stronger Partnership for a Brighter Future," which is meant for strengthening of international and regional cooperation and coordination to counter the global threat caused by the illicit production and trafficking of drugs, especially opiates. BRICS are developing so many schedules to combat illicit drug trade globally. If it became fruitful, we will have a world without illicit drug mafias.

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