UNITED NATIONS

E/NL.2004/1
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LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF
THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

In accordance with the relevant articles of the international treaties on narcotic drugs and psychotropic substances, the Secretary-General has the honour to communicate the following legislative texts.

COLOMBIA

Communicated by the Government of Colombia

NOTE BY THE SECRETARIAT

(a) Some editing of texts may be done by the Secretariat in the interest of clarity. In this connection, words in square brackets [ ] have been added or changed by the Secretariat.

(b) Only passages directly relevant to the control of narcotic drugs or psychotropic substances have been reproduced in this document. Non-relevant parts of laws and regulations have been deleted by the Secretariat; such deletions are indicated by [...].

RESOLUTION No. 000826 OF 2003

V.04-54271 (E)

E/NL.2004/1

MINISTRY OF SOCIAL WELFARE

RESOLUTION No. 000826 of 2003

(10 APRIL 2003)

Issuing regulations for the control and monitoring of the import, export, processing, synthesis, manufacture, distribution, dispensing, purchase, sale and destruction of raw materials subject to special control and medicinal products containing them and also raw materials under State monopoly.

THE MINISTER OF SOCIAL WELFARE

In the exercise of his statutory powers, in particular those conferred by Law No. 9 of 1979, chapter IV of Law No. 30 of 1986[1] and Decree No. 3788 of 1986[2]

WHEREAS:

In accordance with article 20 of Decree No. 205 of 2003, the National Narcotics Fund is a special administrative unit of the Ministry of Social Welfare whose purpose is to monitor and control the import, export, distribution and sale of raw materials subject to special control and medicinal products containing them and also raw materials under State monopoly, as referred to in Law No. 30 of 1986 and any other provisions issued by the Ministry of Social Welfare, and to support programmes implemented by the National Government with a view to preventing drug dependence;

When addictive medicinal products and raw materials are used illicitly, their improper use can lead to their unlawful handling and it is therefore necessary to strengthen monitoring and control systems;

It is necessary to amend Resolution No. 6980 of 1991 in order to include all procedures conducted by the National Narcotics Fund Special Administrative Unit, given the range of activities and functions which it carries out in fulfilment of its objectives;

HEREBY RESOLVES AS FOLLOWS:

CHAPTER I
GENERAL PROVISIONS, DEFINITIONS AND PROHIBITIONS

ARTICLE 1. The provisions of the present Resolution shall apply to clinical, chemical, pharmaceutical and quality control laboratories, wholesale and retail pharmaceutical establishments, drugstores, pharmacies, storage premises for drugs for human and veterinary use and physicians, dental practitioners, veterinary surgeons, pharmaceutical chemists and other personnel working in the pharmaceutical field such as pharmacy managers, professional pharmacists, drugstore directors and dispensers and also individuals, corporations, governmental

[1] *Note by the Secretariat*: E/NL.1986/12.
[2] *Note by the Secretariat*: E/NL.1987/70.

entities and entities handling substances subject to special control and medicinal products containing them which import, export, process, synthesize, manufacture, distribute, sell, dispense or effect local purchases of raw materials subject to special control, and medicinal products containing them, for medical and scientific purposes.

ARTICLE 2. For the purposes of the present Resolution:

REFERENCE STANDARD SUBSTANCES shall mean substances used as comparison models in official pharmacopoeial assays and tests;

NARCOTIC DRUG shall mean a substance with high dependence and abuse potential;

RAW MATERIAL OR SUBSTANCE SUBJECT TO SPECIAL CONTROL shall mean any pharmacologically active substance of whatsoever origin which produces direct and indirect effects of physical or psychological dependence in human beings or, owing to its abuse potential, may be highly dangerous in use or has been scheduled as such in the international conventions and/or so agreed by the Review Commission of the Ministry of Social Welfare;

MEDICINAL PRODUCT SUBJECT TO SPECIAL CONTROL FOR HUMAN OR VETERINARY USE shall mean a pharmaceutical preparation obtained from one or more active ingredients subject to special control, scheduled as such in the conventions on narcotic drugs, precursors and psychotropic substances or by the National Government with or without auxiliary substances, presented in a defined pharmaceutical form and used to prevent, diagnose, treat, cure or remedy illnesses in living beings;

MONOPOLY shall mean a right to exclusivity;

CHEMICAL PRECURSOR shall mean a substance or mixture of substances from which addictive drugs are produced, synthesized or obtained;

PREVENTION shall mean the series of activities intended to reduce and avoid the misuse of substances that may cause dependence;

ESTIMATE shall mean the quota of raw materials or medicinal products subject to special control allotted to the country by the International Narcotics Control Board (INCB) to satisfy medical and scientific needs;

ACTIVE INGREDIENT shall mean a compound or mixture of compounds having a pharmacological action;

OFFICIAL PRESCRIPTION BOOK shall mean an official, personal and non-transferable document supplied to prescribers in each of the departmental and district health directorates for prescribing medicinal products subject to special control;

SYNTHESIZING shall mean the artificial formation of a compound by the combination of its elements;

PSYCHOTROPIC SUBSTANCE shall mean a drug which acts on the central nervous system by producing neuropsychophysiological effects.

ARTICLE 3. Individuals and corporate entities as referred to in article 1 of the present Resolution who become aware that raw materials subject to special control

and/or under State monopoly or medicinal products containing them exist on the market without due legalization shall report such fact to the National Narcotics Fund of the Ministry of Social Welfare and to the competent authorities.

ARTICLE 4. For the purpose of granting health registrations in respect of medicinal products containing raw materials subject to special control, the competent authority shall request from the National Narcotics Fund of the Ministry of Social Welfare a certification stating that the medicinal product is subject to special control or under State monopoly. In cases where a medicinal product is under State monopoly, the health registration holder shall be the National Narcotics Fund of the Ministry of Social Welfare. Such certification shall be attached to the file concerned and be attested in the registration ruling.

If the requirements set out in this article are not complied with, the National Narcotics Fund of the Ministry of Social Welfare shall notify the competent authorities.

ARTICLE 5. Within the first five (5) days of each month, the competent entities shall furnish the National Narcotics Fund of the Ministry of Social Welfare with a report on the health registrations and licences granted during the previous month in respect of medicinal products containing raw materials subject to special control.

ARTICLE 6. The following prohibitions shall be laid down:

1. The use of heroin, methaqualone and mecloqualone and also substances included in the schedules of the 1971 Convention on Psychotropic Substances, with the exception of traditionally used natural preparations expressly referred to in the pharmacological regulations of the competent authority, and all substances whose use in the country the Ministry of Social Welfare and other national public entities consider, following technical, epidemiological or scientific studies, should be prohibited;

2. The manufacture and distribution of medical samples of medicinal products subject to special control;

3. The supply of medicinal products subject to special control to health personnel as a marketing strategy by laboratories;

4. The sale and supply of medicinal products subject to special control may not be effected by post, the Internet or any other similar means.

CHAPTER II
STATE MONOPOLY

ARTICLE 7. The following substances shall come under the monopoly of the National Narcotics Fund:

A. DERIVATIVES OF MALONYLUREA (barbituric acid) such as allobarbital, amobarbital, barbital and its salts, butobarbital, butalbital, cyclobarbital, phenobarbital acid, phenobarbital sodium, methylphenobarbital, pentobarbital, secbutabarbital, secobarbital and vinylbital;

B. COCA LEAF AND ITS DERIVATIVES;

C. HYDROMORPHONE in all dosage forms;

D. MORPHINE in all dosage forms;

E. MEPERIDINE (pethidine) in all dosage forms;

F. PAREGORIC ELIXIR;

G. METHYLPHENIDATE in all dosage forms;

H. METHADONE in all dosage forms;

I. OPIUM;

J. CHLORAL HYDRATE;

K. All substances which the Ministry of Social Welfare and other national public entities consider, following technical, epidemiological or scientific studies, should be under State monopoly.

CHAPTER III
RAW MATERIALS SUBJECT TO SPECIAL CONTROL AND MEDICINAL PRODUCTS CONTAINING THEM

ARTICLE 8. This shall comprise all substances and medicinal products manufactured from raw materials which are included in the Lists of Narcotic Drugs under International Control and which are as follows:

GROUP I

PART ONE
NARCOTICS AND SPECIAL ANALGESICS

A. Narcotics and/or narcotic analgesics included in Schedule I of the 1961 Convention and/or in Group I of the 1931 Convention

Acetorphine (3-*O*-acetyltetrahydro-7α-(1-hydroxy-1-methylbutyl)-6,14-*endo*-ethenooripavine)

Acetyl-*alpha*-methylfentanyl (*N*-[1-(α-methylphenethyl)-4-piperidyl]acetanilide)

Acetylmethadol (3-acetoxy-6-dimethylamino-4,4-diphenylheptane)

Alfentanil (*N*-[1-[2-(4-ethyl-4,5-dihydro-5-oxo-1*H*-tetrazol-1-yl)ethyl]-4-(methoxymethyl)-4-piperidinyl]-*N*-phenylpropanamide)

Allylprodine (3-allyl-1-methyl-4-phenyl-4-propionoxypiperidine)

Alphacetylmethadol (α-3-acetoxy-6-dimethylamino-4,4-diphenylheptane)

Alphameprodine (α-3-ethyl-1-methyl-4-phenyl-4-propionoxypiperidine)

Alphamethadol (α-6-dimethylamino-4,4-diphenyl-3-heptanol)

Alpha-methylfentanyl (*N*-[1-(α-methylphenethyl)-4-piperidyl]propionanilide)

Alpha-methylthiofentanyl (*N*-[1-[1-methyl-2-(2-thienyl)ethyl]-4-piperidyl]propionanilide)

Alphaprodine (α-1,3-dimethyl-4-phenyl-4-propionoxypiperidine)

Anileridine (1-*p*-aminophenethyl-4-phenylpiperidine-4-carboxylic acid ethyl ester)

Benzethidine (1-(2-benzyloxyethyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester)

Benzylmorphine (3-benzylmorphine)

Betacetylmethadol (β-3-acetoxy-6-dimethylamino-4,4-diphenylheptane)

Beta-hydroxyfentanyl (*N*-[1-(β-hydroxyphenethyl)-4-piperidyl]propionanilide)

Beta-hydroxy-3-methylfentanyl (*N*-[1-(β-hydroxyphenethyl)-3-methyl-4-piperidyl]propionanilide)

Betameprodine (β-3-ethyl-1-methyl-4-phenyl-4-propionoxypiperidine)

Betamethadol (β-6-dimethylamino-4,4-diphenyl-3-heptanol)

Betaprodine (β-1,3-dimethyl-4-phenyl-4-propionoxypiperidine)

Bezitramide (1-(3-cyano-3,3-diphenylpropyl)-4-(2-oxo-3-propionyl-1-benzimidazolinyl)piperidine)

Cannabis and cannabis resin and extracts and tinctures of cannabis (Indian hemp and resin of Indian hemp)

Clonitazene (2-(*p*-chlorobenzyl)-1-diethylaminoethyl-5-nitrobenzimidazole)

Coca leaf* (1)

Cocaine (methyl ester of benzoylecgonine*) (1)

Codoxime (dihydrocodeinone-6-carboxymethyloxime)

Concentrate of poppy straw (the material arising when poppy straw has entered into a process for the concentration of its alkaloids when such material is made available in trade)

Desomorphine (dihydrodeoxymorphine)

Dextromoramide ((+)-4-[2-methyl-4-oxo-3,3-diphenyl-4-(1-pyrrolidinyl)butyl]morpholine)

Diampromide (*N*-[2-(methylphenethylamino)propyl]propionanilide)

Diethylthiambutene (3-diethylamino-1,1-di(2'-thienyl)-1-butene)

Difenoxin (1-(3-cyano-3,3-diphenylpropyl)-4-phenylisonipecotic acid)

Dihydroetorphine (7,8-dihydro-7α-[1-(*R*)-hydroxy-1-methylbutyl]-6,14-*endo*-ethanotetrahydrooripavine)

Dihydromorphine

Dimenoxadol (2-dimethylaminoethyl-1-ethoxy-1,1-diphenylacetate)

Dimepheptanol (6-dimethylamino-4,4-diphenyl-3-heptanol)

Dimethylthiambutene (3-dimethylamino-1,1-di(2'-thienyl)-1-butene)

Dioxaphetyl butyrate (ethyl-4-morpholino-2,2-diphenylbutyrate)

Diphenoxylate (1-(3-cyano-3,3-diphenylpropyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester)

Dipipanone (4,4-diphenyl-6-piperidine-3-heptanone)

Drotebanol (3,4-dimethoxy-17-methylmorphinan-6β,14-diol)

Ecgonine, its esters and derivatives which are convertible to ecgonine and cocaine

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Additional clause 1. *For the calculation of estimates and statistics in accordance with the terms of the 1961 Convention, coca leaf preparations containing more than 0.1 per cent of cocaine and made direct from coca leaf should be considered to be coca leaf preparations.

Ethylmethylthiambutene (3-ethylmethylamino-1,1-di(2'-thienyl)-1-butene)

Etonitazene (1-diethylaminoethyl-2-*p*-ethoxybenzyl-5-nitrobenzimidazole)

Etorphine (tetrahydro-7α-(1-hydroxy-1-methylbutyl)-6,14-*endo*-ethenooripavine)

Etoxeridine (1-[2-(2-hydroxyethoxy)ethyl]-4-phenylpiperidine-4-carboxylic acid ethyl ester)

Fentanyl (1-phenethyl-4-*N*-propionylanilinopiperidine)

Furethidine (1-(2-tetrahydrofurfuryloxyethyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester)

Heroin (diacetylmorphine) (2)

Hydrocodone (dihydrocodeinone)

Hydromorphinol (14-hydroxydihydromorphine)

Hydromorphone (dihydromorphinone) (1)

Hydroxypethidine (4-*m*-hydroxyphenyl-1-methylpiperidine-4-carboxylic acid ethyl ester)

Isomethadone (6-dimethylamino-5-methyl-4,4-diphenyl-3-hexanone)

Ketobemidone (4-*m*-hydroxyphenyl-1-methyl-4-propionylpiperidine)

Levomethorphan* ((-)-3-methoxy-*N*-methylmorphinan)

Levomoramide ((-)-4-[2-methyl-4-oxo-3,3-diphenyl-4-(1-pyrrolidinyl)butyl]morpholine)

Levophenacylmorphan ((-)-3-hydroxy-*N*-phenacylmorphinan)

Levorphanol* ((-)-3-hydroxy-*N*-methylmorphinan)

Metazocine (2'-hydroxy-2,5,9-trimethyl-6,7-benzomorphan)

Methadone (6-dimethylamino-4,4-diphenyl-3-heptanone) (1)

Methadone intermediate (4-cyano-2-dimethylamino-4,4-diphenylbutane)

Methcathinone

Methyldesorphine (6-methyl-Δ-deoxymorphine)

Methyldihydromorphine (6-methyldihydromorphine)

3-methylfentanyl (*N*-(3-methyl-1-phenethyl-4-piperidyl)propionanilide)

3-methylthiofentanyl (*N*-[3-methyl-1-[2-(2-thienyl)ethyl]-4-piperidyl]propionanilide)

Metopon (5-methyldihydromorphinone)

Moramide intermediate (2-methyl-3-morpholino-1,1-diphenylpropane carboxylic acid)

Morpheridine (1-(2-morpholinoethyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester)

Morphine** (1)

Morphine methobromide and other pentavalent nitrogen morphine derivatives including in particular the morphine-*N*-oxide derivatives, one of which is codeine-*N*-oxide

Morphine-*N*-oxide (1)

Additional clause 2. * Dextromethorphan ((+)-3-methoxy-N-methylmorphinan) and dextrorphan ((+)-3-hydroxy-N-methylmorphinan) are isomers specifically excluded from this Schedule.

MPPP (1-methyl-4-phenyl-4-piperidinol propionate (ester))

Myrophine (myristylbenzylmorphine) (1)

Nicomorphine (3,6-dinicotinylmorphine) (1)

Noracymethadol ((±)-α-3-acetoxy-6-methylamino-4,4-diphenylheptane)

Norlevorphanol ((-)-3-hydroxymorphinan)

Normethadone (6-dimethylamino-4,4-diphenyl-3-hexanone)

Normorphine (demethylmorphine or *N*-demethylated morphine)

Norpipanone (4,4-diphenyl-6-piperidino-3-hexanone)

Opium** (1)

Oxycodone (14-hydroxydihydrocodeinone)

Oxymorphone (14-hydroxydihydromorphinone)

Para-fluorofentanyl (4'-fluoro-*N*-(1-phenethyl-4-piperidyl)propionanilide)

PEPAP (1-phenethyl-4-phenyl-4-piperidinol acetate (ester)

Pethidine (1-methyl-4-phenylpiperidine-4-carboxylic acid ethyl ester)

Pethidine intermediate A (4-cyano-1-methyl-4-phenylpiperidine)

Pethidine intermediate B (4-phenylpiperidine-4-carboxylic acid ethyl ester)

Pethidine intermediate C (1-methyl-4-phenylpiperidine-4-carboxylic acid)

Phenadoxone (6-morpholino-4,4-diphenyl-3-heptanone)

Phenampromide (*N*-(1-methyl-2-piperidinoethyl)propionanilide)

Phenazocine (2'-hydroxy-5,9-dimethyl-2-phenethyl-6,7-benzomorphan)

Phenomorphan (3-hydroxy-*N*-phenethylmorphinan)

Phenoperidine (1-(3-hydroxy-3-phenylpropyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester)

Piminodine (4-phenyl-1-(3-phenylaminopropyl)piperidine-4-carboxylic acid ethyl ester)

Piritramide (1-(3-cyano-3,3-diphenylpropyl)-4-(1-piperidino)piperidine-4-carboxylic acid amide)

Proheptazine (1,3-dimethyl-4-phenyl-4-propionoxyazacycloheptane)

Properidine (1-methyl-4-phenylpiperidine-4-carboxylic acid isopropyl ester)

Racemethorphan ((±)-3-methoxy-*N*-methylmorphinan)

Racemoramide ((±)-4-[2-methyl-4-oxo-3,3-diphenyl-4-(1-pyrrolidinyl)butyl]morpholine)

Racemorphan ((±)-3-hydroxy-*N*-methylmorphinan)

Additional clause 3. **For purposes of estimates and statistics in accordance with the terms of the 1961 Convention, all preparations made direct from opium are considered to be opium (preparations). If the preparations are not made direct from opium itself but are obtained by a mixture of opium alkaloids (as is the case, for example, with pantopon, omnopon and papaveretum) they should be considered as morphine preparations.

Remifentanil (1-(2-methoxy carbonylethyl)-4-(phenylpropionylamino)piperidine-4-carboxylic acid methyl ester)

Sufentanil (*N*-[4-(methoxymethyl)-1-[2-(2-thienyl)ethyl]-4-piperidyl]propionanilide)

Thebacon (acetyldihydrocodeinone or acetyldemethylodihydrothebaine)

Thebaine

Thiofentanyl (*N*-[1-[2-(2-thienyl)ethyl]-4-piperidyl]propionanilide)

Tilidine ((±)-ethyl-*trans*-2-(dimethylamino)-1-phenyl-3-cyclohexene-1-carboxylate)

Trimeperidine (1,2,5-trimethyl-4-phenyl-4-propionoxypiperidine)

Additional clause 4. The isomers, unless specifically excepted, of the drugs in this Schedule whenever the existence of such isomers is possible within the chemical designations specified in this Schedule.

Additional clause 5. The esters and ethers, unless appearing in another Schedule, of the drugs in this Schedule whenever the existence of such esters or ethers is possible.

Additional clause 6. The salts of the drugs listed in this Schedule, including the salts of esters, ethers and isomers as provided above whenever the existence of such salts is possible.

B. Special analgesics (moderately narcotic analgesics)

Butorphanol

Buprenorphine

Nalbuphine

Pentazocine

Tramadol

Narcotic drugs included in Schedule II of the 1961 Convention and/or in Group II of the 1931 Convention

Acetyldihydrocodeine	
Codeine	(3-methylmorphine)
Dextropropoxyphene	(α-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-butanol propionate)
Dihydrocodeine	
Ethylmorphine	(3-ethylmorphine)
Nicocodine	(6-nicotinylcodeine)
Nicodicodine	(6-nicotinyldihydrocodeine)
Norcodeine	*(N*-demethylcodeine)
Pholcodine	(morpholinylethylmorphine)
Propiram	*(N*-(1-methyl-2-piperidinoethyl)-*N*-2-pyridyl-propionamide); and

The isomers, unless specifically excepted, of the drugs in this Schedule whenever the existence of such isomers is possible within the chemical designation specified in this Schedule;

The salts of the drugs listed in this Schedule, including the salts of the isomers as provided above whenever the existence of such salts is possible.

PART TWO
PREPARATIONS INCLUDED IN SCHEDULE III OF THE 1961 CONVENTION

1. Preparations of:

Acetyldihydrocodeine,
Codeine,
Dihydrocodeine,
Ethylmorphine,
Nicocodine,
Nicodicodine,
Norcodeine and
Pholcodine

when compounded with one or more other ingredients and containing not more than 100 milligrams of the drug per dosage unit and with a concentration of not more than 2.5 per cent in undivided preparations.

2. Preparations of propiram containing not more than 100 milligrams of propiram per dosage unit and compounded with at least the same amount of methylcellulose.

3. Preparations for oral use containing not more than 135 milligrams of dextropropoxyphene base per dosage unit or with a concentration of not more than 2.5 per cent in undivided preparations, provided that such preparations do not contain any substance controlled under the 1971 Convention on Psychotropic Substances.

4. Preparations of cocaine containing not more than 0.1 per cent of cocaine calculated as cocaine base and preparations of opium or morphine containing not more than 0.2 per cent of morphine calculated as anhydrous morphine base and compounded with one or more other ingredients and in such a way that the drug cannot be recovered by readily applicable means or in a yield which would constitute a risk to public health.

5. Preparations of difenoxin containing, per dosage unit, not more than 0.5 milligram of difenoxin and a quantity of atropine sulfate equivalent to at least 5 per cent of the dose of difenoxin.

6. Preparations of diphenoxylate containing, per dosage unit, not more than 2.5 milligrams of diphenoxylate calculated as base and a quantity of atropine sulfate equivalent to at least 1 per cent of the dose of diphenoxylate.

7. *Pulvis ipecacuanhae et opii compositus*

10 per cent opium in powder
10 per cent ipecacuanha root, in powder well mixed with
80 per cent of any other powdered ingredient containing no drug.

8. Preparations conforming to any of the formulas listed in the Schedule and mixtures of such preparations with any material which contains no drug.

GROUP II
BARBITURATES OR MEDICINAL PRODUCTS CONTAINING BARBITURATES

Generic name

1. ALLOBARBITAL
2. AMOBARBITAL
3. BARBITAL AND ITS SALTS
4. BUTALBITAL
5. BUTOBARABITAL
6. CYCLOBARBITAL
7. METHYLPHENOBARBITAL
8. PENTOBARBITAL
9. PHENOBARBITAL ACID (1)
10. PHENOBARBITAL SODIUM (1)
11. SECBUTABARBITAL
12. SECOBARBITAL
13. VINYLBITAL

GROUP III
AMPHETAMINES, ANOREXICS AND GENERAL STIMULANTS

Generic name

1. AMFEPRAMONE (DIETHYL PROPION)
2. AMPHETAMINE
3. BENZPHETAMINE
4. CHLORPHENTERMINE
5. CLOBENZOREX
6. DEANOL
7. DEXAMPHETAMINE
8. FLUNITRAZEPAM
9. LEVAMPHETAMINE
10. LEVOMETHAMPHETAMINE
11. MAZINDOL
12. METHAMPHETAMINE
13. PHENDIMETRAZINE

14. PHENPROPOREX
15. PHENTERMINE

GROUP IV
TRANQUILLIZERS AND NON-BARBITURATE HYPNOTICS

Generic name

1. ADINAZOLAM
2. ALPRAZOLAM
3. BROMAZEPAM
4. BROMOPHENONE
5. BROTIZOLAM
6. CHLORAL HYDRATE (1)
7. CHLORDIAZEPOXIDE
8. CLOBAZAM
9. CLONAZEPAM
10. CLORAZEPATE DIPOTASSIUM
11. CLOXAZOLAM
12. DIAZEPAM
13. ESTAZOLAM
14. FLURAZEPAM
15. GLUTETHIMIDE
16. HALAZEPAM
17. KETAZOLAM
18. LORAZEPAM
19. LORMETAZEPAM
20. MECLOQUALONE (2)
21. MEDAZEPAM
22. MEPROBAMATE
23. METHAQUALONE (2)
24. MIDAZOLAM
25. NITRAZEPAM
26. OXAZEPAM
27. OXAZOLAM
28. PRAZEPAM

29. PYROVALERONE

30. TEMAZEPAM

31. TETRAZEPAM

32. TRIAZOLAM

The numbers appearing in parentheses alongside the generic names in this article shall signify the following:

(1) Exclusive use of the National Narcotics Fund of the Ministry of Social Welfare;

(2) Use prohibited in Colombia.

GROUP V
OXYTOCICS AND UTERINE ANTIHAEMORRHAGICS

Generic name

1. DESAMINOXYTOCIN (DEMOXYTOCIN)

2. ERGONOVINE MALEATE

3. METHYLERGONOVINE

4. OXYTOCIN

5. PROSTAGLANDIN E2

6. PROSTAGLANDIN F2 ALPHA

7. SYNTHETIC OXYTOCIN

GROUP VI
OTHER PSYCHOTROPIC SUBSTANCES

The raw materials, precursors and medicinal products subject to special control as listed below and also those referred to in this article shall, with the exception of those in Group V, for purposes of their importation, comply with the provisions of the present Resolution.

Generic name

1. AMITRIPTYLINE

2. AMOXAPINE

3. BROMPERIDOL

4. BUTRIPTYLINE

5. CHLORIMIPRAMINE

6. CHLOROLACTAM

7. CHLORPROMAZINE

8. CLOZAPINE

9. DIBENZEPINE

10. DOXEPIN

11. DROPERIDOL
12. ETOPERIDONE
13. FLUPENTIXOL
14. FLUPHENAZINE
15. HALOPERIDOL
16. IMIPRAMINE
17. LEVOMEPROMAZINE (METHOTRIMEPRAZINE)
18. LOXAPINE
19. MAPROTILINE
20. MESORIDAZINE
21. METAPRAMINE
22. MIANSERIN
23. MOLINDONE
24. NOMIFENSINE
25. NORTRIPTYLINE
26. OPIPRAMOL
27. PENFLURIDOL
28. PERICIAZINE (PROPERICIAZINE)
29. PERPHENAZINE
30. PIMOZIDE
31. PIPOTIAZINE
32. PIZOTIFEN
33. PROCHLORPERAZINE
34. PROTRIPTYLINE
35. QUINUPRAMINE
36. SULPIRIDE
37. SULTOPRIDE
38. THIOPROPAZATE
39. THIOPROPERAZINE
40. THIORIDAZINE
41. TIOTIXENE
42. TRANYLCYPROMINE
43. TRAZODONE

44. TRIFLUOPERAZINE (FLUOPIRAN)

45. TRIFLUPERIDOL

46. TRIFLUPROMAZINE

47. TRIMIPRAMINE

48. VILOXAZINE

GROUP VII

Substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances shall be controlled in compliance with the 1988 United Nations Convention, precursors, Table 1, as indicated below:

1. *N*-acetlyanthranilic acid and its salts

2. Ephedrine, its salts, optical isomers and salts of its optical isomers

3. Ergometrine and its salts

4. Ergotamine and its salts

5. Isosafrole and its optical isomers

6. Lysergic acid

7. 3,4-methylenedioxyphenyl-2-propanone

8. Norephedrine (phenylpropanolamine) and its salts, optical isomers and salts of its optical isomers (2)

9. 1-phenyl-2-propanone

10. Piperonal (heliotropine)

11. Pseudoephedrine and its salts [and salts] of its optical isomers

12. Safrole

(2) Use prohibited in Colombia

CHAPTER IV
INCLUSION AND EXCLUSION OF MEDICINAL PRODUCTS AND RAW MATERIALS SUBJECT TO SPECIAL CONTROL

ARTICLE 9. Once the National Narcotics Fund has been informed by the Secretary-General of the United Nations of the inclusion of a substance in the List of Narcotic Drugs, Precursors and Psychotropic Substances under International Control, it shall adopt the appropriate administrative measures within the following twenty (20) days and shall notify the competent entities for their information and the relevant purposes.

ARTICLE 10. The Ministry of Social Welfare shall, in accordance with the provisions set out in the international agreements, include or exclude substances or precursors in or from the above list and shall notify the National Narcotics Fund.

ARTICLE 11. Once the National Narcotics Fund has been notified of the decision of the Ministry of Social Welfare to include or exclude at the national level a raw

material or medicinal product subject to special control, it shall inform the public of the inclusion or exclusion of the medicinal product or raw material subject to special control.

ARTICLE 12. The Medicinal Products Review Commission of the competent authority shall notify the National Narcotics Fund of the opinions expressed by it on pharmaceutical products and substances subject to special control within a period of not more than thirty (30) days.

ARTICLE 13. All medicinal products and raw materials whose use in the country the Ministry of Social Welfare, the National Narcotics Fund and other national public entities consider, following technical, epidemiological or scientific studies, should be prohibited or which they consider should be under State monopoly, whether or not they are subject to special control, shall be included or excluded.

CHAPTER V
REGISTRATION, RENEWAL, EXTENSION AND AMENDMENT

ARTICLE 14. Individuals, corporations and/or governmental entities as referred to in article 1 of the present Resolution wishing to import, export, process, synthesize, manufacture, distribute, sell, dispense or effect local purchases of raw materials subject to special control or medicinal products containing them for medical and scientific purposes shall register with the National Narcotics Fund Special Administrative Unit of the Ministry of Social Welfare.

ARTICLE 15. Entities established for the purpose of providing different forms of ambulance services for the transfer of patients shall also register with the National Narcotics Fund. To that end, they shall comply with the requirements laid down in the present Resolution for the registration and handling of medicinal products subject to special control and/or under State monopoly.

In the case of ambulances attached to a health-care institution, a health promotion entity or an entity administering the subsidized scheme which is duly registered and authorized by the National Narcotics Fund to handle medicinal products subject to special control and/or under State monopoly, no additional registration shall be required. The provision of medicinal products for such ambulances shall be effected through the entity's pharmaceutical service in accordance with the procedure established in the present Resolution. The replacement of stocks shall be carried out solely on medical prescription and be effected once the emergency has been dealt with. The medical prescription shall in all cases comply with all the requirements set out in the present regulations and the recording of medicinal products subject to special control shall be effected in the ledgers which the entity's pharmaceutical service keeps for such purpose.

ARTICLE 16. Registration with the National Narcotics Fund shall require the presentation of the documentation specified below:

(a) Health promotion entities, entities administering the subsidized scheme, individuals and public or private corporate entities shall present the following documents:

1. The application signed by the legal representative or his duly authorized proxy, attaching the relevant power of attorney, or by the individual concerned;

2. The list of raw materials subject to special control and medicinal products containing them. In the case of medicinal products, the generic name, trade mark, pharmaceutical form and concentration should be indicated;

3. Legible photocopies of the valid and up-to-date health registrations or licences issued by the competent authority;

4. A certificate of good manufacturing practices or documentary evidence thereof issued by the competent authority;

5. A certificate of existence and legal representation issued by the chamber of commerce concerned, whose date of issue may not be earlier than fifteen (15) days prior to the registration application and which shall be renewed every six (6) months;

6. Public entities shall submit the following documents:

   (a) The application signed by the director of the entity;

   (b) Lists of substances subject to special control and the purpose for which they will be used;

   (c) The administrative document of appointment and certificate of incumbency of the legal representative of the applicant entity;

   (d) The judicial order establishing the entity.

(b) Health service institutions (IPSs) shall comply with the following requirements:

1. The certificate of registration in the Special Register of Health Service Providers issued by the competent authority;

2. The record of the last inspection carried out by the departmental or district health secretariat or directorates in compliance with Decree No. 2309 of 2002 and other regulatory provisions and any regulations that extend or amend them;

3. A list of the medicinal products subject to special control to be handled;

4. A valid certificate from the chamber of commerce or office of the local representative;

5. A photocopy of the professional card (issued by the competent authority) of pharmaceutical chemists for IPSs with complexity levels 2 and 3 and/or pharmacy managers for IPSs with complexity level 1;

6. A registration letter of application signed by the legal representative of the health-care institution.

(c) Entities providing different forms of ambulance services for the transfer of patients shall comply with the following requirements in addition to the requirements set out in the preceding paragraph:

1. The number of ambulances intended for the provision of the service;

2. The identification particulars of the vehicles (licence number, owner, type);

3. The scientific director's forenames and surname, identity card number, professional registration and registration with the divisional health directorate or district health secretariat;

4. Compliance with the stipulations of Resolution No. 9279 of 1993 of the Ministry of Health, currently the Ministry of Social Welfare;

5. Possession of duly authorized ledgers for recording the movements of medicinal products subject to special control and/or under State monopoly.

ADDITIONAL CLAUSE 1. Should the documents cease to be valid, no procedures shall be conducted until the individuals or entities registered with the National Narcotics Fund update them.

ADDITIONAL CLAUSE 2. The National Narcotics Fund shall carry out an assessment inspection of entities responsible for ambulance services for the transfer of patients prior to granting the registration.

TRANSITIONAL CLAUSE. Entities which are currently registered with the National Narcotics Fund shall have a time limit of two (2) months from the entry into force or the present Resolution in which to submit the documentation specified in this article; if they fail to do so, the registration shall be cancelled.

ARTICLE 17. For the purpose of effecting such registration with the National Narcotics Fund, the individuals and corporate entities indicated in article 1 of the present Resolution shall comply with the procedures set out below:

1. Applications shall be received by the correspondence office of the National Narcotics Fund within the first five (5) days of each month;

2. Following submission of the application, the National Narcotics Fund shall carry out the necessary technical studies, for which it shall have a maximum period of ten (10) working days;

3. Upon the issue of the technical verdict, the National Narcotics Fund shall have ten (10) working days in which to issue the ruling approving or disallowing registration;

4. Once the ruling has been numbered and dated, the National Narcotics Fund shall have two (2) working days in which to inform the party concerned in order that notification may be given within the following five (5) working days. If the party concerned fails to appear, a public announcement shall be posted in the Secretariat of the Directorate of the National Narcotics Fund within ten (10) working days, upon the expiry of which the notification shall be deemed delivered;

5. Objections may be filed with the Director of the National Narcotics Fund and appeals with the Deputy Minister of Health and Welfare, as applicable, against the ruling within five (5) days following the date of notification, in accordance with Decree No. 01 of 1984. Objections shall be lodged and substantiated in writing;

6. If the registration application does not fulfil the requirements laid down in respect of the requested formality, it shall be returned in order that the party

concerned may rectify and resubmit the application, duly completed, within the first five (5) days of the following month.

ARTICLE 18. Registrations as referred to in this chapter shall have a period of validity of three (3) years and shall be renewable for equal periods, subject to a prior technical examination and opinion by the National Narcotics Fund. Renewal shall be requested two (2) months before the date of expiry. If no request is made within that period, the registration shall be automatically cancelled.

ADDITIONAL CLAUSE. If after a period of one (1) year the registered company or entity has not submitted any details of movements to the National Narcotics Fund, the registration ruling shall be automatically cancelled.

ARTICLE 19. For any renewal, extension or amendment of the ruling, it shall be necessary to submit the documents required for registration, and the procedures laid down in article 16 of the present Resolution shall be observed. In cases where the deletion of raw materials subject to special control or medicinal products containing them is requested, the corresponding supporting documentation shall be appended.

CHAPTER VI
RECORD BOOKS FOR RAW MATERIALS AND/OR MEDICINAL PRODUCTS SUBJECT TO SPECIAL CONTROL

ARTICLE 20. All individuals and corporations registered with the National Narcotics Fund shall, once they have been informed of the respective registration ruling, send to it a three-column ledger with pages numbered and stamped consecutively, in which all movements involving raw materials and/or medicinal products subject to special control shall be recorded and which shall be kept up to date by means of a physical inventory and audited on a periodic basis by officials delegated by the National Narcotics Fund.

CHAPTER VII
IMPORTS

ARTICLE 21. The importation of raw materials subject to special control and/or of medicinal products containing them as referred to in the present Resolution may be effected only by the National Narcotics Fund of the Ministry of Social Welfare, or through it, following the granting of an import authorization and the allocation of an order number by it, if the applicant complies with the following requirements:

1. Be duly registered with the National Narcotics Fund, as provided for in chapter V of the present Resolution;
2. Submit a legible photocopy of the health registrations and/or licences issued by the competent authority that are valid and up to date as at the date of the registration application;
3. Attach the manufacturer’s valid certificate of good manufacturing practices issued by the competent authority;
4. Have available the quota within the annual estimate approved by the National Narcotics Fund, for which purpose the provisions of chapter VIII of the present Resolution shall be taken into account;

5. Submit the application, signed by the legal representative or his duly authorized proxy, in respect of each of the imports which it is intended to make, indicating:

   (a) The quantity of raw materials subject to special control or medicinal products containing them to be imported;

   (b) The generic name and trade name in accordance with the registration granted;

   (c) In the case of raw materials subject to special control, the following particulars of the medicinal product to be manufactured shall be appended: name of the medicinal product (international non-proprietary name or generic name), pharmaceutical form, concentration, commercial presentation and quantity to be manufactured;

   (d) The numbers and period of validity of the health registration(s) or licence(s) issued by the competent authority in respect of the medicinal products to be imported or manufactured;

   (e) The supplier's name, town, postal address, telephone and fax numbers and e-mail address.

6. If the applicant company or entity complies with the requirements set out above, the National Narcotics Fund shall, within a period not exceeding eight (8) working days, allocate the import authorization (order number) or, failing that, the party concerned shall be informed of the reasons for its disallowance. The order number allocated by the National Narcotics Fund shall be valid for eight (8) months from its date of issue.

ARTICLE 22. Once the National Narcotics Fund has granted the import authorization or order number, the importing company or entity shall submit an official communication signed by the legal representative or his proxy enclosing the original and two (2) photocopies of the duly completed import licence with no erasures or amendments. The import licence shall be processed by the National Narcotics Fund for examination and approval by the Ministry of Trade, Industry and Tourism or by such entity as may serve in its stead, for which procedure the National Narcotics Fund shall have a period of eight (8) working days.

The import licence shall be processed within two (2) months following the date of issue of the order number granted by the National Narcotics Fund.

ARTICLE 23. In cases where individuals, corporations or governmental entities registered with the National Narcotics Fund wish to make any amendments to the import registration, they shall submit to it a request to that effect by means of an official communication signed by the legal representative or his proxy and, in the case of governmental entities, by the director, manager or chairperson.

ARTICLE 24. The National Narcotics Fund of the Ministry of Social Welfare shall issue the import certificate in respect of substances under international control subsequent to approval of the import licence by the Ministry of Trade, Industry and Tourism or by such entity as may serve in its stead.

ARTICLE 25. The procedure for partial or total cancellation of unused import licences shall be conducted by the National Narcotics Fund at the latest upon the

expiry of the import licences or when the importer so decides during the period of validity, the form prescribed by the competent authority being completed for that purpose.

ARTICLE 26. The importation of raw materials subject to special control and medicinal products containing them shall be subject to administrative restrictions in accordance with such regulations as the competent entity may issue.

ARTICLE 27. The sole customs body authorized for purposes of the entry of raw materials subject to special control and medicinal products containing them shall be Bogotá DC and the goods shall be sent by air.

ARTICLE 28. Upon the entry of the goods into the country, the party concerned shall notify the National Narcotics Fund by means of an official communication, requesting the release of the document of carriage, stating the order number, the air waybill number and the airline carrier and attaching a photocopy of that document for the purpose of requesting, by means of an official communication, its endorsement.

ARTICLE 29. Any individual or corporation having imported raw materials subject to special control or medicinal products containing them through the National Narcotics Fund of the Ministry of Social Welfare shall for the purpose of settling costs in respect of the CIF value of the goods comply with the stipulations of Resolution No. 02776 of 1 November 2000 issued by the Ministry of Heath, currently the Ministry of Social Welfare, and submit the following documents:

(a) A photocopy of the import licence;

(b) A photocopy of the commercial invoice;

(c) A photocopy of the air waybill;

(d) A photocopy of the import declaration together with the corresponding release granted by the competent authority;

(e) The order number allocated by the National Narcotics Fund;

(f) The application signed by the legal representative or his proxy.

ARTICLE 30. Once the release or withdrawal of the goods has been authorized by the competent authority, the party concerned shall notify the National Narcotics Fund of the Ministry of Social Welfare immediately in order that it may carry out an inspection of the goods and draw up the respective inspection record, which shall be signed by the authorized customs intermediary and the official of the National Narcotics Fund.

The National Narcotics Fund shall have a period of five (5) working days in which to complete the aforementioned settlement and inspection procedure.

CHAPTER VIII
ESTIMATES

ARTICLE 31. Individuals or entities registered with the National Narcotics Fund as importers of raw materials subject to special control and/or medicinal products containing them shall furnish no later than the fifteenth (15th) day of March of each year the total estimates required for the following year, attaching epidemiological

studies, records of consumption for the previous three (3) years and a preliminary evaluation by the National Narcotics Fund relating to the submission of reports in the two years immediately preceding.

ARTICLE 32. Estimate applications shall be effected by completion of the forms contained in annex 1 of this Resolution.

ARTICLE 33. For estimate applications in respect of imports of raw materials subject to special control, registered individuals or entities shall attach a feasibility study on annual production and on sales (in pharmaceutical units and their equivalent in grams) in the case of manufacturing importers and a feasibility study on sales in the case of marketing importers.

ARTICLE 34. For estimate applications in respect of imports of finished products containing raw materials subject to special control, registered individuals or entities shall attach the annual sales projection, in pharmaceutical units and their equivalent in grams, with supporting documentation.

ARTICLE 35. The Technical Committee of the Directorate of the National Narcotics Fund of the Ministry of Social Welfare shall approve the estimates on the basis of relevant examinations carried out on the documents provided for in this chapter.

ARTICLE 36. When two or more importing pharmaceutical laboratories furnish estimates for a raw material and the total of those estimates exceeds national needs, the National Narcotics Fund of the Ministry of Social Welfare shall allot to each of them a quota commensurate with their application and in accordance with the examinations carried out by the National Narcotics Fund.

ARTICLE 37. The results of the allocation or rejection of the estimate shall be communicated to the parties concerned within three (3) months following approval.

ARTICLE 38. Supplementary estimates shall be granted by the National Narcotics Fund of the Ministry of Social Welfare on the basis of medical, pharmaceutical and public health considerations. Extension applications shall include a description of the nature of the unforeseen circumstances that have necessitated modification of the initial estimates, such as trends in the medical use of the medicinal products in question, factors influencing national prescription practices, special public health situations and/or contracts concluded with public or private health entities.

ADDITIONAL CLAUSE: Supplementary estimate applications made by pharmaceutical laboratories, wholesale distributors and importers shall be submitted to the National Narcotics Fund of the Ministry of Social Welfare no later than the thirtieth (30th) day of September in the year for which estimates have been allocated.

CHAPTER IX
EXPORTS

ARTICLE 39. The export of medicinal products and raw materials subject to special control shall take place in accordance with the international conventions on narcotic drugs and psychotropic substances and following authorization by the National Narcotics Fund of the Ministry of Social Welfare.

ARTICLE 40. In order to obtain the export authorization referred to in the preceding article, exporters shall comply with the following requirements:

1. They shall be duly registered with the National Narcotics Fund of the Ministry of Social Welfare as provided for in chapter V of the present Resolution.

2. An application signed by the legal representative or proxy shall be submitted for each export that they intend to make, indicating:

   (a) The quantity of raw materials or medicinal products to be exported;

   (b) In the case of a medicinal product, the generic name, trade name, pharmaceutical form and concentration, quantity in pharmaceutical units and their equivalent in grams;

   (c) The number(s) of the health registration(s), if applicable, and their period of validity and type;

   (d) The country of destination and name of the importer.

3. If in accordance with the international conventions the importing country requires an export certificate, the exporter shall apply in writing for such certificate to the National Narcotics Fund of the Ministry of Social Welfare, attaching the corresponding certificate from the importing country.

Following receipt of the application, the National Narcotics Fund of the Ministry of Social Welfare shall carry out the respective examination and within a maximum period of eight (8) days shall notify the party concerned of the authorization number or, failing that, of the reasons why the application was disallowed.

ARTICLE 41. Exporters of medicinal products containing raw materials subject to special control shall be required to furnish to the National Narcotics Fund of the Ministry of Social Welfare a half-yearly export report indicating:

(a) The generic name and trade name, if applicable;

(b) The pharmaceutical form, concentration and commercial presentation, if applicable;

(c) The total quantity exported, in pharmaceutical units and their equivalent in grams;

(d) The export registration number;

(e) The country of destination.

CHAPTER X
LOCAL PURCHASE OF RAW MATERIALS IMPORTED THROUGH THE NATIONAL NARCOTICS FUND

ARTICLE 42. Individuals or legally constituted corporations shall be permitted to effect local sales and purchases of raw materials subject to special control provided that they are registered with the National Narcotics Fund of the Ministry of Social Welfare in accordance with the provisions of chapter V of the present Resolution.

ARTICLE 43. Individuals or corporations legally registered with the National Narcotics Fund shall require authorization to effect local purchases of raw materials

subject to special control, for which purpose they shall submit an application duly signed by the legal representative or proxy, indicating:

(1) The generic name and quantity of raw material subject to special control to be purchased;

(2) The supplier company;

(3) The name of the medicinal products to be manufactured (generic or trade name, as appropriate, pharmaceutical form and concentration), number of pharmaceutical units and their equivalent in grams, listing the relevant health registrations and their period of validity;

(4) An official communication from the supplier company endorsing the sale of the raw material and indicating the stocks held by it at the date of the application.

ARTICLE 44. The National Narcotics Fund of the Ministry of Social Welfare shall carry out the respective examination and within a maximum period of eight (8) days shall notify the party concerned of the order number allocated or, failing that, of the reasons why the application was disallowed.

The order number shall be referred to in all documents relating to the marketing of the raw materials.

CHAPTER XI
MANUFACTURE

ARTICLE 45. Manufacturing laboratories using substances or raw materials subject to special control in the manufacture of medicinal products shall submit to the National Narcotics Fund of the Ministry of Social Welfare in Bogotá DC or Cundinamarca or to the office for the monitoring and control of medicinal products in the respective health secretariat, or to such entity as may serve in its stead, an application for the processing of the raw material, signed by the technical director and giving ten (10) days' advance notification of the date, time and place of processing, using the form contained in annex 2 of the present Resolution.

ADDITIONAL CLAUSE. Every manufacturer shall hold a valid certificate of good manufacturing practice, a copy of which it shall submit to the National Narcotics Fund.

ARTICLE 46. The National Narcotics Fund of the Ministry of Social Welfare or offices for the monitoring and control of medicinal products in the respective departmental health secretariats, or such entities as may serve in their stead, shall authorize and directly supervise the processing of raw materials subject to special control, which shall take place in the presence of the technical director of the laboratory.

Should the processing fail to take place on the date fixed, the manufacturing laboratory shall notify the National Narcotics Fund of the Ministry of Social Welfare or the office for the monitoring and control of medicinal products in the respective health secretariat or such entity as may serve in its stead, as appropriate, with a view to rescheduling or cancelling the processing.

For each processing of raw material subject to special control a report shall be drawn up, numbered consecutively and signed by the technical director of the laboratory and by the official authorized by the National Narcotics Fund or offices for the monitoring and control of medicinal products in the health secretariats, or such entities as may serve in their stead, in whose presence the processing has taken place, using the form contained for that purpose in annex 3 of the present Resolution.

ADDITIONAL CLAUSE 3: Laboratories outside Bogotá shall dispatch to the National Narcotics Fund a copy of the report duly completed and signed by the official delegated by the health secretariat or by such entity as may serve in its stead or, failing that, the authorization issued by the health secretariat or by such entity as may serve in its stead.

ARTICLE 47. Authorized pharmaceutical laboratories which use or process raw materials subject to special control for the manufacture of medicinal products shall be required to keep a ledger, with numbered pages, registered with the National Narcotics Fund of the Ministry of Social Welfare and/or office for the monitoring and control of medicinal products in the respective health secretariat or such entity as may serve in its stead. The ledger shall record all movements relating to the raw material subject to special control for which it was completed and be signed by the representatives of the National Narcotics Fund or health secretariats, or such entities as may serve in their stead, on a regular basis.

ADDITIONAL CLAUSE. In the case of local purchases of raw materials subject to special control, the quantity to be acquired by the manufacturing laboratory or manufacturing company shall be deducted from the estimate authorized for local purchase, subject to a prior technical opinion.

ARTICLE 48. Legally authorized health service institutions which use or process raw materials acquired from or through the National Narcotics Fund for the purpose of manufacturing magistral medicinal products shall be required to record movements in a ledger, with numbered pages, registered with the National Narcotics Fund of the Ministry of Social Welfare.

ARTICLE 49. Pharmaceutical establishments may not hold stocks of raw materials or medicinal products subject to special control in quantities exceeding those authorized by the National Narcotics Fund of the Ministry of Social Welfare. Any negotiations held between laboratories with regard to such substances in the event of force majeure shall require the authorization of the National Narcotics Fund of the Ministry of Social Welfare.

ARTICLE 50. Every establishment legally authorized to manufacture medicinal products subject to special control or containing substances subject to special control shall possess secure and adequate means of storage in accordance with good storage practices.

ARTICLE 51. If the manufacturer is not the holder of the health registration, the holder shall submit:

(a) A certificate of good manufacturing practice;

(b) The manufacturing contract signed by the two parties and indicating the medicinal products that contain raw materials subject to special control;

(c) A certificate from the chamber of commerce to which the manufacturer belongs, valid for at least one month;

(d) A statement in which the manufacturing laboratory declares its awareness of the contents of the present Resolution and undertakes to comply with the requirements hereof insofar as they devolve upon it.

CHAPTER XII
DISTRIBUTION, SALE AND CONSUMPTION

ARTICLE 52. For the purposes of distribution, sale and consumption of raw materials and medicinal products containing them which are subject to special control or under State monopoly, individuals or corporations shall comply with the provisions of chapter V of the present Resolution and shall take into account the prohibitions laid down in the present Resolution and comply with the following requirements:

1. There shall be separate, secure areas that comply with the provisions of good storage practice regulations;

2. A professional technical director shall be responsible for the technical management of the pharmaceutical establishment and the proper handling of medicinal products subject to special control, in accordance with the regulations established by the Ministry of Social Welfare;

3. An inventory of medicinal products subject to special control to be handled shall be drawn up, containing the following information:

   (a) The generic and trade names, as applicable;

   (b) The pharmaceutical form and concentration;

   (c) The commercial presentation;

   (d) The pharmacological category.

ARTICLE 53. Medicinal products subject to special control under State monopoly shall be distributed and sold through the National Narcotics Fund of the Ministry of Social Welfare to the revolving funds of the local agencies and from them to legally authorized entities within the general social security health system, and solely on medical prescription to individuals.

Medicinal products subject to special control under State monopoly shall be dispensed, sold and supplied directly to the party concerned or to such person as that party may delegate, postal deliveries being prohibited.

ARTICLE 54. If the revolving narcotics fund of a particular department is unable to acquire medicinal products subject to special control under State monopoly, entities within the general social security health system of the local agency concerned may acquire them directly from the National Narcotics Fund of the Ministry of Social Welfare, subject to supporting documentation from the head of the departmental health secretariat or such entity as may serve in its stead.

ARTICLE 55. Medicinal products subject to special control under State monopoly coming within the administration of the National Narcotics Fund of the Ministry of Social Welfare may not be marketed between departments.

In the case of other medicinal products subject to special control which are not under State monopoly, wholesale or retail distributors wishing to despatch such products between departments shall notify in advance the respective departmental health directorate, or such entity as may serve in its stead, of the area of jurisdiction where the medicinal product is to be delivered, for its approval or disallowance in accordance with examinations carried out by each directorate on consumption and conduct of the establishment to which the transfer is being made.

For these purposes, the respective health directorate or such entity as may serve in its stead shall impose such requirements as it considers necessary in order to express its opinion.

ARTICLE 56. For the acquisition of medicinal products subject to special control under State monopoly, the revolving narcotics funds of the local agencies shall submit their applications in writing with the approval of the head of the health secretariat or director of such entity as may serve in its stead. Entities within the general social security health system shall also do so in writing with the approval of the scientific director or such person as may serve in his stead.

ARTICLE 57. Veterinary medicinal products subject to special control shall be distributed only through university and private veterinary clinics and registered practices. These distribution points shall comply with the legal requirements laid down for the dispensing of medicinal products subject to special control, in accordance with the regulations in force.

ARTICLE 58. The National Narcotics Fund of the Ministry of Social Welfare and departmental and district health directorates, or such entities as may serve in their stead, shall alone be authorized to issue, distribute and sell the official prescription book for prescribing medicinal products subject to special control.

ARTICLE 59. Patients wishing to leave or enter the country who are undergoing treatment with medicinal products containing narcotic drugs included in Schedules I and II of the 1961 Convention, as amended by the 1972 Protocol, or containing psychotropic substances included in Schedules II, III and IV of the 1971 Convention shall comply with the following:

1. The maximum authorized quantities of medicinal products that may be transported for personal use shall correspond to standard treatment lasting thirty (30) days, irrespective of the substance in question;

2. Patients undergoing treatment with these substances who travel to Colombia shall be required to furnish a copy of the medical prescription for the medicinal product. If the duration of the stay exceeds one (1) month, the patient, if needing to continue the treatment, shall consult a physician lawfully practising his profession in the country in order that he may issue the necessary prescription and shall be able to acquire the medicinal products in accordance with national regulations;

3. Should the patient wish to leave the country, he shall take into account the restrictions and prohibitions that may be applicable in the countries of destination. Upon leaving the country, the patient undergoing treatment shall carry a copy of the medical prescription in which the use of the medicinal product is authorized;

4. If any country imposes a requirement in addition to the medical prescription, for example certification of the use of the medicinal products in question for treatment purposes, such documentation may be issued by the National Narcotics Fund of the Ministry of Social Welfare or the departmental and district health directorates, or by such entities as may serve in their stead, on the basis of a case history summary issued by the IPS or attending physician.

ARTICLE 60. In accordance with the provisions of current taxation and customs regulations, medicinal products acquired by the revolving narcotics funds through the National Narcotics Fund shall be exempt from duty.

ARTICLE 61. Medicinal products subject to special control may be supplied only following submission of the original and one copy of the medical prescription, which shall state that the prescription has been filled; the original shall be filed by the pharmaceutical establishment and the copy shall be furnished to the party concerned.

ARTICLE 62. The medical prescription shall contain the following data:

1. The name, address and telephone number of the physician;
2. The date of issue;
3. The patient's name, address and identity document number, if applicable;
4. The generic name of the medicinal product and trade name, if applicable, pharmaceutical form and concentration, total quantity in numbers and words and daily dosage (frequency of administration), method of administration and duration of treatment;
5. The signature of the attending physician and his national registration number or the number of his registration with the respective health secretariat or such entity as may serve in its stead.

The medical prescription shall be solely for medicinal products subject to special control. It shall authorize no other medicinal products from different pharmacological groups.

ARTICLE 63. The total prescribed quantity of medicinal products subject to special control shall be in accordance with the following limits:

(a) Medicinal products listed in Group I A: "Narcotic analgesics": up to the quantity required for ten (10) calendar days;

(b) Medicinal products listed in Group I B: "Moderately narcotic analgesics", in Group II: "Barbiturates or medicinal products containing barbiturates, with the exception of phenobarbital", in Group III: "Amphetamines and general stimulants", and in Group IV: "Tranquillizers and non-barbiturate hypnotics": up to the dosage required for thirty (30) calendar days;

(c) Medicinal products listed in Group IV: "Oxytocics and uterine antihaemorrhagics": the dosage as prescribed under the responsibility of the attending physician;

(d) Phenobarbital: up to the dosage required for ninety (90) calendar days.

ADDITIONAL CLAUSE 1. If a prescription for medicinal products subject to special control is issued for dosages exceeding those laid down, their sale shall take place following authorization by the National Narcotics Fund of the Ministry of Social Welfare or the revolving narcotics fund of the departmental health directorates, or by such entities as may serve in their stead, which shall be permitted to authorize only up to twice the quantity indicated in this article.

ADDITIONAL CLAUSE 2. If, in the event of any change of treatment or the death of the patient, any part of the medicinal products supplied by the revolving narcotics fund or departmental health directorates or by such entities as may serve in their stead remains unused, the person responsible for them shall return the products to the funds, where he shall be reimbursed the value thereof, if applicable.

ARTICLE 64. Duly authorized pharmaceutical establishments shall be prohibited from filling prescriptions for medicinal products subject to special control if the prescriptions have been issued more than fifteen (15) days previously.

ARTICLE 65. With regard to the sale of medicinal products under State monopoly, the National Narcotics Fund shall authorize the revolving funds of the departmental health directorates, or such entities as may serve in their stead, to sell such products to health service institutions solely for use in hospitals. It shall also authorize the revolving funds to sell such medicinal products to health service professionals or institutions located outside the departmental capitals.

In the case of the capital district, the National Narcotics Fund shall authorize sales to health service institutions solely for use in hospitals. If such medicinal products are required by professionals, they shall be sold directly by the National Narcotics Fund, in accordance with the quantities authorized in the present Resolution.

ARTICLE 66. Pharmaceutical laboratories shall be permitted to supply medical and dental practitioners with medicinal products subject to special control in commercial presentations if so requested by them in writing using the appropriate official prescription book and in a quantity equivalent to an authorized commercial unit.

ARTICLE 67. Every establishment legally authorized to distribute, sell or handle medicinal products subject to special control or containing substances subject to special control shall possess secure and adequate means of storage in accordance with good storage practices.

CHAPTER XIII
LOSS AND DISPOSAL OF RAW MATERIALS AND MEDICINAL PRODUCTS SUBJECT TO SPECIAL CONTROL

ARTICLE 68. In the event of the loss of raw materials or medicinal products subject to special control, immediate notification shall be sent to the National Narcotics Fund of the Ministry of Social Welfare, together with a copy of the respective report.

ARTICLE 69. Should the disposal of raw materials subject to special control or medicinal products containing them be required, authorization shall be requested from the National Narcotics Fund of the Ministry of Social Welfare or relevant departmental health directorate, or from such entity as may serve in its stead, using the form contained in annex 4 of the present Resolution.

ARTICLE 70. The disposal of raw materials subject to special control and medicinal products containing them as a result of expiry, damage or other factors in Bogotá DC and Cundinamarca shall take place in the presence of the representative of the laboratory which is the importer or holder of the corresponding health registration or licence and an official delegated by the National Narcotics Fund of the Ministry of Social Welfare, who shall be notified ten (10) calendar days in advance of the date, time and place at which the procedure shall be carried out, and a draft disposal report shall be prepared using the form contained in annex 5 of the present Resolution.

In other departments and districts it shall be carried out in the presence of a representative of the office for the monitoring and control of medicinal products in the departmental or district health directorate or such entity as may serve in its stead.

Disposal shall take place in accordance with the technical regulations established by the Ministry of the Environment or by such entity as may serve in its stead.

ADDITIONAL CLAUSE 1. Should disposal fail to take place on the date specified, the importing or manufacturing laboratory and the health entity or pharmaceutical establishment, as applicable, shall notify the National Narcotics Fund or the office for the monitoring and control of medicinal products in the respective health secretariat or departmental health directorate, as applicable, with a view to its rescheduling.

ADDITIONAL CLAUSE 2. For each disposal of raw materials subject to special control and medicinal products containing them, a consecutively numbered report shall be drawn up and signed by those present during disposal and, in cases where the procedure takes place outside Bogotá, a copy of the report shall be sent to the National Narcotics Fund of the Ministry of Social Welfare. The report shall be recorded in the respective control ledger for raw materials and medicinal products subject to special control.

CHAPTER XIV
PRESCRIPTION OF MEDICINAL PRODUCTS SUBJECT TO SPECIAL CONTROL

ARTICLE 71. Qualified physicians, veterinarians, zoological veterinarians and dentists lawfully practising their profession shall be the only professionals permitted to prescribe medicinal products subject to special control and shall be required to issue their prescriptions in accordance with the requirements of the official prescription book with regard to their content.

ARTICLE 72. Newly qualified medical and dental practitioners completing their compulsory service year may issue prescriptions only if there are no legally authorized professionals at the institution where they are serving their compulsory first year and shall indicate the name of the university, their status as medical or dental graduates on compulsory service and their national identity card number.

ARTICLE 73. In order to prescribe medicinal products subject to special control, veterinarians and zoological veterinarians shall be registered with the Professional Council of Veterinary Medicine and Zoology of Colombia (COMVEZCOL), where they shall obtain their registration and professional membership in accordance with

Law No. 073 of 1985 and Law No. 576 of 2000 on professionals authorized to prescribe medicinal products subject to special control.

ADDITIONAL CLAUSE. COMVEZCOL shall keep the directory of registered professionals up to date and shall submit a monthly report on any changes to the National Narcotics Fund of the Ministry of Social Welfare.

ARTICLE 74. Duly registered dentists may prescribe only the following medicinal products subject to special control: moderately narcotic analgesics, anaesthetics and tranquillizers and non-barbiturate hypnotics.

CHAPTER XV
OFFICIAL PRESCRIPTION BOOK

ARTICLE 75. Medicinal products subject to special control for human or veterinary use as listed in Group 1 A (Narcotic analgesics) may only be prescribed using the official prescription books supplied by the health secretariats or departmental health directorates to medical and dental practitioners legally practising their profession or by COMVEZCOL to veterinarians. The prescription book shall comply with the form contained in annexes 6 and 6a of the present Resolution.

ARTICLE 76. The departmental health directorates or health secretariats or such entities as may serve in their stead and COMVEZCOL shall, when preparing their respective official prescription books, take into account the guidelines set out for that purpose by the National Narcotics Fund of the Ministry of Social Welfare.

ARTICLE 77. Health service institutions that have declared a pharmaceutical service to the departmental health directorates or health secretariats or such entities as may serve in their stead shall keep a special institutional prescription book for medicinal products subject to special control, incorporating any requirements laid down by the National Narcotics Fund of the Ministry of Social Welfare.

ADDITIONAL CLAUSE. The official and institutional prescription books for prescribing medicinal products subject to special control shall consist of an original, which shall remain at the dispensing pharmacy, and two copies, one of which shall be for the patient and the other for the necessary procedures with the health promotion entities and entities administering the subsidized scheme.

ARTICLE 78. A practitioner whose official or institutional prescription book becomes lost shall immediately notify in writing the office for the control and monitoring of medicinal products in the respective departmental health directorate or such entity as may serve in its stead.

CHAPTER XVI
FUNCTIONS OF THE OFFICES FOR THE MONITORING AND CONTROL OF MEDICINAL PRODUCTS IN THE HEALTH SECRETARIATS

ARTICLE 79. The offices for the control and monitoring of medicinal products in the health secretariats or departmental health directorates, or such entity as may serve in their stead, shall be headed by a pharmaceutical chemist legally practising his profession and shall perform the following functions:

1. Monthly review of ledgers and reports on movements of raw materials and medicinal products subject to special control involving wholesale and retail distributors and pharmaceutical laboratories, comparing physical stocks against records and verifying the authenticity of supporting documents;

2. Authorization of retail pharmaceutical distributors required to handle medicinal products subject to special control within their area of jurisdiction;

3. Conduct of inspection, monitoring and control activities on raw materials and medicinal products subject to special control within their area of jurisdiction;

4. Submission within the first five (5) days of each month to the National Narcotics Fund of the Ministry of Social Welfare of reports on processing and disposal operations that have taken place in the month immediately preceding;

5. Imposition of penalties where necessary;

6. Provision of technical assistance to the National Narcotics Fund whenever it deems this necessary.

ARTICLE 80. A record of any inspections made by the offices for the monitoring and control of medicinal products in the health secretariats or departmental health directorates, or such entity as may serve in their stead, shall be drawn up and shall be signed by the official conducting the inspection and the director of the establishment or his legal representative or duly authorized proxy, indicating possible irregularities detected and any observations deemed relevant.

CHAPTER XVII
REPORTS

ARTICLE 81. Importing and manufacturing laboratories shall produce the following reports:

1. A monthly report on the national distribution and export of medicinal products subject to special control and the acquisition of raw materials subject to special control (import and/or local purchase), within the first ten (10) days of each month, using the form contained in annex 7 of the present Resolution;

2. A quarterly report on the import, national distribution and export of non-controlled medicinal products containing active ingredients subject to special control, within the first ten (10) days of each quarter, using the form contained in annex 8 of the present Resolution.

ARTICLE 82. Wholesale distributors of medicinal products shall produce a report on the distribution of medicinal products subject to special control within the first ten (10) days of each month and shall furnish a copy thereof to the respective health directorate or secretariat, or such entity as may serve in its stead, using the form contained in annex 9 of the present Resolution.

ARTICLE 83. The central storage facility of the networks of retail pharmaceutical distributors shall furnish that report to the National Narcotics Fund of the Ministry of Social Welfare, using the form contained in annex 9 of the present Resolution.

ARTICLE 84. Wholesale distributors of raw materials subject to special control shall produce a report on the distribution of raw materials subject to special control,

within the first ten (10) days of each month, using the form contained in annex 10 of the present Resolution.

ARTICLE 85. Retail pharmaceutical distributors shall furnish to the respective health secretariats a report on the consumption of medicinal products subject to special control, within the first ten (10) days of each month, attaching the original prescriptions and using the forms contained in annex 11 of the present Resolution.

ADDITIONAL CLAUSE. Each location in the network of retail pharmaceutical distributors shall furnish the report on the consumption of medicinal products subject to special control to the respective health secretariat or health directorate.

ARTICLE 86. The revolving narcotics funds of the health secretariats or departmental health directorates, or such entities as may serve in their stead, shall furnish the following reports to the National Narcotics Fund of the Ministry of Social Welfare:

1. A consolidated monthly report on the consumption of medicinal products subject to special control within their area of jurisdiction, to be submitted within thirty (30) days following receipt of information from the retail distributors, distinguishing human use from veterinary use and using the form contained in annex 12 of the present Resolution;

2. A report on any changes regarding the registration of authorized pharmaceutical establishments, to be submitted using the form contained in annex 13 of the present Resolution;

3. A monthly report on the distribution of medicinal products under State monopoly, to be submitted within the first ten (10) days of each month using the form contained in annex 9 of the present Resolution;

4. A consolidated monthly report on the disposal of medicinal products subject to special control within their area of jurisdiction, to be submitted within the first ten (10) days of each month;

5. A report on the processing of raw materials, to be submitted within the first ten (10) days of each month;

6. A monthly report on anomalies noted within their area of jurisdiction, such as smuggling, the appearance of medicinal products reported stolen, distribution to non-authorized establishments, establishments that fail to render reports and any other aspects deemed necessary for effective monitoring and control action;

7. A monthly report on the seizure and confiscation of raw materials and medicinal products subject to special control;

8. A monthly report on penalties imposed for administrative breaches in the manufacture, distribution and dispensation of medicinal products subject to special control.

ARTICLE 87. The National Narcotics Fund of the Ministry of Social Welfare shall notify the Ministry of Social Welfare and the health secretariats or departmental health directorates of:

1. Losses of medicinal products subject to special control;

2. Analyses of national distribution and consumption of medicinal products subject to special control and corresponding recommendations made;

3. The distribution of medicinal products under State monopoly to the various entities within the general social security health system, whenever warranted;

4. The distribution of raw materials and medicinal products subject to special control in each department;

5. The inclusion or exclusion of active ingredients subject to special control by international bodies, by the Ministry of Social Welfare or by such entity as may be delegated for that purpose.

CHAPTER XVIII
REVOLVING NARCOTICS FUNDS

ARTICLE 88. In each departmental health secretariat or directorate or such entity as may serve in its stead there shall be a revolving narcotics fund responsible for managing medicinal products subject to special control under State monopoly.

ARTICLE 89. The revolving narcotics funds shall have a specific account for the management of their operations. Any profits obtained may be used solely to enhance the resourcing and functioning of the corresponding revolving narcotics fund and to support programmes for the prevention of drug dependence that are undertaken by the divisional health service within its area of jurisdiction.

The revolving narcotics fund shall possess the following:

1. A suitable storage area for medicinal products subject to special control under State monopoly that complies with good storage practices;

2. Skilled professional human resources.

ARTICLE 90. The functions of the revolving narcotics fund shall be:

1. To guarantee the permanent availability of medicinal products subject to special control under State monopoly;

2. To monitor the distribution, sale and consumption of medicinal products subject to special control;

3. To inspect the processing and destruction of raw materials and medicinal products subject to special control;

4. To draw up an inventory of incoming, outgoing and available stocks of medicinal products subject to special control as well as statistics on official and private requirements for such products;

5. To distribute official prescription books;

6. To conduct studies on the use of medicinal products subject to special control and carry out measures with a view to curbing the improper and irrational use of such products;

7. To submit a report on resources transferred in fulfilment of its functions;

8. To oversee compliance with the minimum operational requirements of addict treatment and rehabilitation centres;

9. To provide technical assistance to the National Narcotics Fund whenever the latter deems it necessary.

CHAPTER XIX
NATIONAL REGISTER OF DRUG-DEPENDENT PERSONS

ARTICLE 91. The National Narcotics Fund of the Ministry of Social Welfare shall maintain the National Register of Drug-dependent Persons with respect to Group 1A, which shall be confidential and whose data shall be used solely for the prevention of drug trafficking and drug dependence.

ARTICLE 92. For the purposes of the National Register of Drug-dependent Persons, the respective departmental health secretariats or directorates or the party concerned shall require medical professionals who prescribe drugs or medicinal products subject to special control for patients regarded as drug-dependent to complete the form contained in annex 14 of the present Resolution.

Once the attending physician has completed the form, he shall transmit it to the Comprehensive Addiction Support Unit (UAICA), which shall prepare a consolidated monthly data report and submit it to the corresponding departmental health directorate or secretariat or such entity as may serve in its stead, which shall in turn dispatch such reports to the National Narcotics Fund within the first five days of January and July of each year.

ADDITIONAL CLAUSE 1. If the attending physician does not possess the form referred to in this article, he shall send the basic data on the treatment of drug-dependent persons in his own prescription book to the corresponding departmental health directorate or secretariat or to such entity as may serve in its stead.

ADDITIONAL CLAUSE 2. If the attending physician is a newly qualified practitioner completing his compulsory service year, the data referred to in this article shall be endorsed with the signature and stamp of the director of the institution in which he serves.

ARTICLE 93. The form referred to in the preceding article shall contain at least the following basic data:

1. Name of patient;
2. Identity number of patient;
3. Address and telephone number of patient;
4. Generic name of medicinal product;
5. Daily dose, frequency of administration, method of administration and duration of treatment;
6. Name of attending physician;
7. Health registration number;
8. Address and telephone number of attending physician.

ARTICLE 94. The revolving narcotics funds of the departmental health secretariats or directorates shall be required to adopt the register of drug-dependent persons for their area of jurisdiction.

Should there be no revolving narcotics fund in the departmental health directorates or secretariats or such office as may serve in their stead, the obligation referred to in this article shall devolve upon the office for the control of medicinal products in the respective departmental health directorate or secretariat, or such entity as may serve in its stead, until such time as the departmental revolving narcotics fund has been organized.

ARTICLE 95. The National Narcotics Fund of the Ministry of Social Welfare and the departmental health directorates or secretariats or such entities as may serve in their stead shall be required to maintain a record of monitoring of drug-dependent persons and update the information relating to the register referred to in this chapter.

The departmental health directorates or such entity as may serve in their stead shall submit the information contained in the register of drug-dependent persons for their area of jurisdiction to the National Narcotics Fund of the Ministry of Social Welfare on a quarterly basis.

CHAPTER XX
DRUG ADDICTION AND DEPENDENCE PREVENTION PROGRAMMES

ARTICLE 96. For purposes of the programme for the prevention of drug addiction and dependence, the Comprehensive Addiction Support Units (UAICAs) shall send to the National Narcotics Fund projects containing reliable information concerning needs, advisability, implications, location, size, cost, technical, financial, environmental and economic viability, coverage, effects and scope and other essential data so that the National Narcotics Fund may jointly finance the projects with the respective local agencies and State social enterprises (ESEs).

ARTICLE 97. Such projects shall be submitted within the first month of the year so that they can be included in the portfolio of projects of the National Narcotics Fund, which shall be evaluated for technical, legal and economic viability with a view to selecting those most beneficial to the community.

ARTICLE 98. For purposes of such joint financing, an agreement shall be signed between the local agency and the ESEs involved in the project, in which its implementing, reporting and monitoring conditions shall be laid down.

ADDITIONAL CLAUSE. For the functioning of the Comprehensive Addiction Support Units (UAICAs), the stipulations of Resolution No. 196 of 26 February 2002 of the Ministry of Health, currently the Ministry of Social Welfare, shall be complied with.

CHAPTER XXI
INFRINGEMENTS AND PENALTIES

ARTICLE 99. The following infringements shall constitute administrative breaches and shall be penalized by the National Narcotics Fund or the departmental and district health directorates or such entities as may serve in their stead:

1. Failure on the part of the entities or persons responsible to submit the reports with which they are required to provide the National Narcotics Fund;

2. Obstruction of inspection work through any act or omission by which it is hindered or delayed;

3. Dispensing of medicinal products subject to special control once the period of validity of the prescription has expired;

4. Dispensing of medicinal products subject to special control beyond the expiry date;

5. Failure to correctly follow the information and warnings that have to be contained in the prescription of medicinal products subject to special control;

6. Failure to record the movements of raw materials subject to special control in the corresponding ledgers;

7. Retailing by wholesalers of medicinal products subject to special control or their wholesaling by retailers;

8. Failure to keep medicinal products in the storage conditions required by the National Narcotics Fund of the Ministry of Social Welfare;

9. Maintaining, without supporting documentation, of surpluses and/or shortfalls of raw materials or medicinal products subject to special control;

10. Preparation, manufacture, import, export or distribution by unauthorized persons of raw materials subject to special control or medicinal products containing them;

11. Import, export, manufacture, dispensing, purchase, sale or distribution without the due authorization of the National Narcotics Fund;

12. Operation of pharmaceutical services and pharmacies without the attendance and professional intervention of the pharmacist in charge;

13. Prevention of the work of duly accredited inspectors in centres in which medicinal products are prepared, manufactured, distributed and dispensed;

14. Preparation of magistral prescriptions without the established legal requirements;

15. Dispensing of medicinal products at unauthorized establishments;

16. Dispensing of medicinal products subject to special control without a medical prescription;

17. Marketing of medicinal products subject to special control without prior health registration or authorization of the National Narcotics Fund;

18. Diversion of raw materials or medicinal products subject to special control into illicit channels;

19. Manufacture of medicinal products subject to special control without observance of the established requirements;

20. Offering of gifts, prizes, competitions or the like as a means of promoting or selling to the public medicinal products subject to special control;

21. Distribution of medical samples of medicinal products subject to special control;

22. Failure to comply with the stipulations of the present Resolution.

ARTICLE 100. The penalty proceedings shall commence ex officio at the request or on the information of a public official, or following the filing of a duly substantiated complaint by any person.

ARTICLE 101. Once the act has been reported or a complaint or notice has been received, the competent authority shall order the appropriate investigation with a view to establishing the act or omission constituting an infringement described in the present Resolution.

ARTICLE 102. For the purpose of verifying the act or omission, it shall be permissible to take any steps deemed relevant, such as visits, inspections, sampling, laboratory examinations, field or chemical tests, expert opinions and generally all measures deemed appropriate. The period for carrying out such procedure shall not exceed two (2) months from the date on which the investigation is initiated.

ARTICLE 103. Should the competent authority conclude from the measures taken that it is fully proven that the act under investigation did not take place, that the accused did not commit it, that the rules do not regard it as punishable or that the penalty proceedings could not be initiated or continued, it shall issue an administrative act stating that fact and shall order the cessation of the proceedings against the accused. That act shall be personally notified to the person under investigation or, in his absence, by public announcement, in accordance with the provisions of the Code of Administrative Litigation.

ARTICLE 104. If the measures taken show that there is reason to undertake the investigation, the accused shall be personally notified of the charges brought and the dossier shall be placed at his disposal to enable him to request that a copy be made at his own expense.

ADDITIONAL CLAUSE. Should it be impossible to notify him personally, a summons shall be delivered to the person dealing with the procedure, instructing the person named to appear for notification purposes within five (5) working days. Should he fail to do so, a public announcement shall be posted in a public place at the National Narcotics Fund or the departmental or district health directorate, or such entity as may serve in its stead, for a period of ten (10) working days, upon the expiry of which the notification shall be deemed delivered.

ARTICLE 105. Within ten (10) days of the notification, the accused shall, directly or by proxy, submit his plea in writing and furnish and request the taking of such evidence as he deems relevant.

ARTICLE 106. The competent authority shall determine the taking of such evidence as it deems appropriate, establishing for that purpose a period of fifteen (15) working days, which may be extended for an equal period if it has not been possible within the initial period to take the evidence so determined.

ARTICLE 107. Once the period referred to in the foregoing article has expired and within ten (10) working days thereafter, the competent authority shall consider the evidence on the basis of a free evaluation and shall assess the breach and impose the penalty due in accordance with that assessment.

ARTICLE 108. Should it be found that there has been no violation of the laws and regulations, the appropriate administrative act exonerating the accused shall be issued and the order given to close the dossier.

ARTICLE 109. Penalties shall be imposed through a reasoned ruling issued by the competent authority, and notification thereof shall be given to the individual concerned personally or to his legal representative or proxy within five (5) working days of its issue; appeals at law against the aforementioned administrative act shall be admissible in accordance with the provisions of the Code of Administrative Litigation.

ADDITIONAL CLAUSE. If notification cannot be given in person, it shall be delivered through a public announcement, in accordance with the provisions of the Code of Administrative Litigation.

ARTICLE 110. Should any of the infringements established in the present Resolution be committed, the National Narcotics Fund or the departmental and district health directorates or such entities as may serve in their stead may, pursuant to Law No. 9 of 1979, impose the following penalties, which shall be applied according to the infringement committed:

(a) A caution;

(b) Fines of up to 10,000 times the statutory minimum daily wage at the highest rate in force at the time the ruling is delivered;

(c) Seizure of products or substances;

(d) Suspension or cancellation of registration with the National Narcotics Fund.

ARTICLE 111. A caution shall consist of a written reprimand to a person violating any of the pertinent provisions without endangering human health or life and is intended to draw attention to the consequences of the act or omission and serve as a warning.

The caution shall specify the period within which the offender shall comply with any regulations applying to the infringement.

ARTICLE 112. A fine shall consist of a monetary penalty imposed on an individual or corporation for an act or omission that constitutes a violation of the laws and regulations in force.

ARTICLE 113. Fines shall be paid to the National Narcotics Fund of the Ministry of Social Welfare or to the revolving narcotics funds of the departmental or district health directorates or such entity as may serve in their stead, as applicable, within the first five (5) working days after the administrative act imposing the fine becomes enforceable.

Failure to pay the amounts established shall give rise to cancellation of the registration with the National Narcotics Fund, the departmental or district health directorates or such entity as may serve in their stead, as applicable. Payment of the fine may be enforced through coercive jurisdiction.

ARTICLE 114. The seizure of products, components or equipment shall consist of their permanent confiscation if there is proof of non-compliance with the laws and regulations governing the import, export, processing, synthesis, manufacture, distribution, dispensing, purchase or sale of raw materials subject to special control and medicinal products containing them or raw materials under State monopoly, or of a danger to the health of individuals or groups.

ARTICLE 115. The competent authority may, through a reasoned decision, order the seizure of raw materials subject to special control and medicinal products containing them or raw materials under State monopoly, as referred to in these regulations.

ARTICLE 116. The seizure shall be conducted by the official designated for that purpose. A record of the procedure shall be drawn up in triplicate and signed by the officials or persons taking part therein. A copy of the record shall be delivered to the person in whose care the seized property were placed.

ARTICLE 117. The suspension or cancellation of registration with the National Narcotics Fund shall be ordered by the competent authority. In the case of suspension, no procedure may be requested or conducted until such time as it is established that the reasons for which the suspension was effected have disappeared and there is strict compliance with the pertinent legislation. In the event of cancellation of registration, the party concerned may not apply for re-registration before one year immediately following cancellation.

ARTICLE 118. If an official entity other than those within the general social security health system or the social welfare system possesses evidence of acts or omissions under investigation by the authority, such evidence shall be placed at the disposal of the official authority, ex officio or at its request, so that it may form part of the investigation.

Without prejudice to the penalties imposed by the National Narcotics Fund, the competent authority may conduct any necessary investigations.

ARTICLE 119. OBLIGATION TO NOTIFY THE JUDICIAL AUTHORITIES: The penalties provided for in the present Resolution shall be applied to individuals or corporations violating the provisions contained herein without prejudice to the obligation to give notification to the judicial authorities of any alleged violation of Law No. 30 of 1986 or any regulations that extend or amend it, accompanied by a copy of the case documents.

ADDITIONAL CLAUSE. The existence of criminal or other proceedings shall not give rise to suspension of the penalty proceedings provided for in the present Resolution.

ARTICLE 120. VALIDITY AND REPEALING PROVISIONS: The present Resolution shall enter into force on the date of its publication and shall repeal Resolution No. 6980 of 29 May 1991 issued by the Ministry of Social Welfare and any other provisions at variance therewith.

TO BE PUBLISHED, COMMUNICATED AND ENFORCED

Done in Bogotá this tenth day of April, 2003

DIEGO PALACIOS BETANCOURT

Minister of Social Welfare