RIGHT TO INFORMATION

GOVERNMENT OF KARNATAKA
(DRUGS CONTROL DEPARTMENT)

RPAD
24 JUL 2015

No.DCD/34/RTI/2014-15/

From,
Public Information officer,
And Deputy Drugs Controller,
Head Office,
Drugs Control Department,
Palace Road,
Bangalore-560001.

To,
Sri. Prashant Reddy .T,
Advocate ,
C/o: Advocate Harsh Parashar,
Lex One Partners, E-19, LGF,
Jungpura Extension,
New Delhi – 110 014.

Sir,

Sub:-Providing information under Right to Information Act, 2005- reg.
Ref:- Your application dated 20.07.2015, received in this office on 23.07.2015.

= = =

With reference to the above, you are hereby informed that the information sought by you under Right to Information Act, 2005 vide your letter cited at reference is of 07 pages and as per Right to Information Act, 2005 you are required to pay Rs. 2/- per page which amounts to Rs.14/- by Indian Postal Order or Bank Challan under Head Of Account (0070-60-118-0-01) Receipt and obtain the information.

Yours faithfully,

(Dr. N. VADIVELU)
Public information officer
& Deputy Drugs Controller
Head Office, Bangalore.

RIGHT TO INFORMATION

GOVERNMENT OF KARNATAKA
(DRUGS CONTROL DEPARTMENT)

RPAD
05 AUG 2015

No.DCD/34/RTI/2015-16
Encloses : 07 pages.

From,
Public Information officer,
And Deputy Drugs Controller,
Head Office,
Drugs Control Department,
Palace Road,
Bangalore-560001.

To,
Prashant Reddy .T
Advocate,
C/o., Lex One Partners, 3-19, LGF,
Jungpura Extension,
New Delhi – 110 014.

Sir,

Sub:-Information regarding Right to Information Act, 2005-reg.
Ref:- Your application dated 30.07.2015 received in this office on 03.08.2015.

= = =

With reference to the above, the requested document under the provisions of Right to Information Act, 2005 is here with enclosed.

First Appellate Authority Address;

B.T Khanapure,
First Appellate Authority &
Additional Drugs Controller
P.B No. 5377, Palace Road,
Bangalore – 560 001
e-mail ; adl.dcd-ka@nic.in
Office : 080-22282789
Mobile : 9448676939.

Yours faithfully,

(Dr. N. VADIVELU)
Public information officer
& Deputy Drugs Controller
Head Office, Bangalore.

GUIDELINES FOR TAKING ACTION ON SAMPLES OF DRUGS DECLARED SPURIOUS OR NOT OF STANDARD QUALITY IN THE LIGHT OF ENHANCED PENALTIES UNDER THE DRUGS AND COSMETICS (AMENDMENT) ACT, 2008

The Drugs and Cosmetics (Amendment) Act, 2008 passed by the Parliament on 5th December, 2008 provides deterrent penalties for offences relating to manufacture of spurious or adulterated drugs which have serious implications on public health. It will help regulatory authorities to handle anti-social elements involved in the manufacture of such drugs and playing with human safety. The penalty for manufacture of spurious or adulterated drugs has been enhanced to an imprisonment for a term which shall not be less than 10 years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakh rupees or three times value of the drug confiscated, whichever is more. In certain cases offences have been made cognizable and non-bailable. It also provides a tool of compounding of offences for dealing with certain minor offences.

Under the Drugs and Cosmetics Act, 1940 control over manufacture and sale of drugs is exercised by the State Licensing Authorities. Licences for drug manufacturing establishments and sale premises are granted by the said authorities. Inspections/raids are carried out by the Drug Inspectors appointed by the States to ensure compliance of the conditions of licences. Samples are drawn by Drug Inspectors to check the quality of drugs marketed in the country. Legal/ administrative actions as required under the said Act and rules for the violation of the provisions of the Act are taken by the State Licensing Authorities. The actions are normally initiated on the basis of test reports of Government analysts declaring the drug samples as not of standard quality. The major categorization of not of standard quality reports could be as under:—

Category A
(Spurious and Adulterated Drugs)

Spurious or imitation drug products are drug formulations manufactured concealing the true identity of the product and made to resemble another drug, especially some popular brand, to deceive the buyer and cash on the popularity of original product. The product may or may not contain the active ingredients. Spurious drugs are usually manufactured by unlicensed anti-social elements but sometimes licensed manufacturers may also be involved. The adulterated drugs are those drugs which are found to contain an adulterant/substituted product or contaminated with filth rendering it injurious to health.

Reports of availability of spurious drugs in the country shake the confidence of indigenous as well as foreign buyers. As the problem is an emotive issue also, it is required to be handled with a firm hand and in co-ordination with other agencies.

Category B
(Grossly sub-standard drugs)

Drugs manufactured by licensed manufacturers and reported to have defects of serious nature to affect the quality of the drug. Such defects may arise out of gross

negligence or non-conformance to GMPs during manufacture. These defects may broadly be as under:

(*i*) Active ingredient contents below 70% for thermo labile products and below 5 % of the permitted limits for thermo stable products.

(*ii*) Tablets/Capsules failing in disintegration tests wherever prescribed.

(*iii*) Tablets/Capsules failing in dissolution test and active contents found less than 70% for thermo labile products and below 5% of the prescribed limits for thermo stable products.

(*iv*) Liquid preparations showing presence of fungus.

(*v*) Parental preparations failing in sterility, pyrogen/endotoxin test or undue toxicity.

(*vi*) Vaccines failing in potency, sterility, toxicity or moisture content.

(*vii*) Presence of any adulterant which renders the product injurious to health.

Category C
(Minor defects)

Drugs manufactured by the licensed manufacturers found not of standard quality because of defects arising out of minor variations in quality. Such defects may arise because of inadequate pre-formulation development studies, lack of in process controls exercised by the manufacturer or unsuitable conditions under which drugs are stored or transported. Examples of some such the defects are as under:

(*i*) Broken or chipped tablets.

(*ii*) Presence of spot/discolouration/uneven coating.

(*iii*) Cracking of emulsions.

(*iv*) Clear liquid preparations showing sedimentation.

(*v*) Change in colour of the formulation.

(*vi*) Slight variation in net content.

(*vii*) Formulations failing in weight variation.

(*viii*) Formulations failing to respond to the colour test.

(*ix*) Isolated cases of presences of foreign matter.

(*x*) Labelling error including nomenclature mistake, Rx, NRx, XRx, Red Line, Schedule H. Caution, Colour etc.

GUIDELINES

The following guidelines should be adopted as model guidelines by the State Drug Control Organizations for uniform implementation of the provision of the Drugs and Cosmetics Act and rules made thereunder. While implementing the new provisions, the State Regulatory Authorities should ensure that the law is implemented in a comprehensive way. In order to effectively use the said instrument of law, it is necessary to have Standard Operative Procedures set in each State to examine and process various violations of the provision of the Act. The State Drug

Control Organizations should have internal mechanism of checks and balances to ensure that law abiding manufacturers and sellers of drugs are not harassed or put to a disadvantageous position. Care should be taken that while violations with criminal intent or gross negligence leading to serious defects are dealt with heavy hand, the violations involving minor variations in quality by licensed manufacturers are resolved through administrative measures.

1. In the case of detection of manufacture and/or sale etc. of spurious or imitation drug products by the unlicensed manufacturers or sellers, the case shall be investigated on top priority and provisions of Section 36-AC of the Act invoked under which these offences are considered cognizable and non-bailable. Necessary help from the enforcement agencies like police etc. should also be obtained, wherever required, so that the rackets are busted and culprits booked in time for taking legal action. The investigations in such cases should be expedited and prosecutions launched at the earliest. The quick and timely investigations would have deterrent effect on the unscrupulous persons involved in the neferious trade of spurious drugs.
2. In the case of detection of a case of manufacture and/or sale etc. of spurious drugs by a licensed manufacturer i.e. use of licensed premises for manufacture of spurious drugs and the criminal intent is apparent, the case is required to be pursued with equal vigour as in the case of unlicensed manufacturer. The investigations should also include the other activities carried out by the manufacturer in the premises.
3. In the case of drugs manufactured by a licensed manufacturer under a valid manufacturing licence has been found grossly sub-standard, the matter may be investigated at the manufacturer's end, and where criminal intent or gross negligence has been established and if the merits of the case so demand, and where it is felt that administrative measures would not be sufficient to meet the ends of justice, the re-course to prosecution should be resorted to.
4. In the case of drugs manufactured by a licensed manufacturer under a valid manufacturing licence and found grossly sub-standard and where criminal intent or gross negligence is not established, weapon of prosecution should be used judiciously, where it is felt that administrative measures like suspension or cancellation of licenses or compounding of offences would not meet the ends of justice.
5. In the case of not of standard quality reports because of minor defects arising out of variations from the prescribed standards or contraventions of other provisions of Chapter IV of the Act, administrative measures including suspension/cancellation or compounding of offences may be resorted to. Prosecution may only be launched where it is justifiably felt that above measures would not meet the ends of justice.
6. Section 36-AC which makes certain offences under the Act cognizable and non-bailable has been inserted to facilitate the arrest of anti-social elements involved in the manufacture of spurious or adulterated drugs.

The section should therefore be invoked with utmost care and only in cases where it is justifiably felt that it is essential to book the culprits for proper investigations in the case.

7. The State Drug Control Departments shall constitute screening committees comprising of at least three senior officers not below the level of Assistant Drugs Controllers or equivalent to examine the investigation reports of the cases where prosecutions are proposed to be launched. The committee may submit written opinion on the investigation reports regarding their feasibility of taking legal action. The criminal intent or gross negligence should be taken into consideration while recommending actions like prosecution etc. Care should be taken that charges framed are not based on inappropriate provisions which may be difficult to prove in the court of law in the absence of proper justification or evidence. Cases of failing in assay, brand name disputes and non-renewal of manufacturing licence in time should be examined on their merits before recommending prosecution in such cases.
8. Prosecutions by the Inspectors shall be launched on the basis of written permissions of the controlling authority and this authority in turn shall consider the recommendations of the screening committee while taking final decision in the matter.
9. The Patent and Proprietary formulations should be tested by the Government analysts as provided under Rule 46 of the Drugs and Cosmetics Rules. In the case of non-Pharmacopoeial or modified formulations, the samples may be tested as per procedure provided by the manufacturer, which has been duly approved by the licensing authority. In case of non-receipt of such procedure on request the sample may be tested as per method of analysis available with the Government Analyst.
10. The Drugs Consultative Committee had earlier in 1993 approved detailed guidelines for taking action in specific cases on reports of not of standard quality drugs. These recommendations but for the above shall also be taken into considerations while granting permission for prosecution or administrative action against the offenders (Annexure A).
11. Co-ordination between regulatory authorities is key to success in taking timely action in cases of violation of the provisions of the Drugs and Cosmetics Rules. The State Drug Control Organizations shall therefore, notify a nodal officer with telephone and fax number at the headquarter as well as circle levels, which could be contacted by other regulatory authorities for exchange of information and co-ordination in search/ seizures/raid or investigations in the cases of spurious and adulterated drugs. The detail of these officers shall also be forwarded to the office of DCG (I) so that this information is put on the website of CDSCO for the information of regulatory authorities as well as general public.

12. The State Drug Control Organizations shall create a rapid alert system so that any vital information in the cases of spurious/adulterated drugs is passed on to the appropriate authorities quickly for taking further action in the matter.

13. For combating the menace of spurious/adulterated drugs a robust infrastructure is essential to implement the provisions of the Drugs and Cosmetics Act. The Drug Control Organization in the States are therefore, needed to be strengthened by providing additional manpower, infrastructure, technical capabilities and financial resources for having continuous vigilance about the quality of drugs moving in the market.

ANNEXURE A

DCC GUIDELINES ON NOT OF STANDARD QUALITY (NSQ) DURGS APPROVED IN 1993

Category B Defects

TABLETS

(*i*) Presence of spot/discoloration
(*ii*) Lump formations in few containers due to moisture
(*iii*) Failing in uniformity of weight
(*iv*) Picking
(*v*) Chipping
(*vi*) Capping
(*vii*) Rough surface
(*viii*) Brittle tablets
(*ix*) Non-uniformity in diameter
(*x*) Uneven coating
(*xi*) Non-declaration of colour used on the label
(*xii*) Failing in limit test (e.g. free Salicylic acid)
(*xiii*) Assay — 70% and above of the label claim for thermolabile products and 5% within permitted limits for the thermostable products.
(*xiv*) Failing in particle size (Griseofulvin tablets)
(*xv*) Net content

CAPSULES

(*i*) Presence of spots/discoloration
(*ii*) Lump formation in container due to moisture
(*iii*) Failing in uniformity of weight
(*iv*) Cake/lump formation of content of capsule
(*v*) Failing in limit tests
(*vi*) Assay — 70% and above of the label claim for thermolabile products and 5% within permitted limits for thermostable products
(*vii*) Net content

LIQUID ORALS (Syrups/elixirs/solutions/suspensions/emulsions/mixtures etc.)

(*i*) Presence of foreign matter
(*ii*) Change of colour
(*iii*) Presence of suspended matter
(*iv*) Cracking of emulsion
(*v*) Sedimentation
(*vi*) Dispersible cake/lump formation
(*vii*) Net content

Category A Defects

TABLETS

(*i*) Assay — below 70% for thermolabile products and below 5% of the permitted limits for thermostable products.
(*ii*) Disintegration (except for marginal variation to be viewed on case to case basis)
(*iii*) Dissolution (except for marginal variation to be viewed on case to case basis)
(*iv*) Contamination with foreign matters
(*v*) Most of the tablets observed in powder form inside the strip pouches
(*vi*) Content uniformity
(*vii*) Addition of permitted colour when not recommended in Pharmacopoeia

CAPSULES

(*i*) Assay — below 70% for thermolabile products and below 5% of the permitted limits for thermostable products.
(*ii*) Disintegration (except for marginal variation to be viewed on case to case basis)
(*iii*) Dissolution (except for marginal variation to be viewed on case to case basis)
(*iv*) Content uniformity.

LIQUID ORALS

(*i*) Assay — below 70% for thermolabile products and below 5% of the permitted limits for thermostable products
(*ii*) Presence of foreign matter such as fly/insect
(*iii*) Fungus growth
(*iv*) Non-dispersible cake/lump formation.
(*v*) Addition of non-permissible colours.

EXTERNAL PREPARATIONS

(*i*) Assay — below 70% for thermolabile products and below 5% of the permitted limits for thermostable products

(*ii*) Phenol coefficient (RWC) less than label claim

Grade I : less than 16
Grade II : less than 8
Grade III : less than 4

For other soluble disinfectants: below 80% of the required limit

(*iii*) Fungal growth.

OPHTHALMIC PREPARATONS

(*i*) Assay — below 70% for thermolabile products and below 5% of the permitted limits for thermostable products
(*ii*) Foreign matter
(*iii*) Metal particles
(*iv*) Fungal growth
(*v*) Fails in sterility.

POWDERS (Oral use)

(*i*) Assay — below 70% for thermolabile products and below 5% of the permitted limits for thermostable products
(*ii*) Fungal growth

POWDERS (External use)

(*i*) Assay — below 70% for thermolabile products and below 5% of the permitted limits for thermolabile products
(*ii*) Fungal growth.

INJECTIONS INCLUDING TRANSFUSION FLUIDS

(*i*) Sterility
(*ii*) Pyrogen test
(*iii*) Toxicity
(*iv*) Assay — below 70% for thermolabile products and below 5% of the permitted limits for thermostable products
(*v*) Fails in any other biological test
(*vi*) Fungal growth in different samples from different sources of same batches.

STERILE DISPOSABLE PERFUSION SETS

(*i*) Sterility
(*ii*) Pyrogen test
(*iii*) Toxicity

STERILE DISPOSABLE HYPODERMIC SYRINGES

(*i*) Sterility
(*ii*) Pyrogen test
(*iii*) Toxicity

STERILE DISPOSABLE HYPODERMIC NEEDLES

(*i*) Sterility
(*ii*) Pyrogen test
(*iii*) Toxicity

BULK DRUGS

(*i*) Assay — less than permitted limits
(*ii*) Heavy metal test/Arsenic test
(*iii*) Sterility
(*iv*) Toxicity
(*v*) Microbial limit test

AEROSOLS/INHALATIONS

(*i*) Assay — below 70% for thermolabile products and below 5% of the permitted limits for thermostable products
(*ii*) Leak test

SERA/VACCINE

(*i*) Toxicity
(*ii*) Sterility
(*iii*) Potency

SUTURES/CATGUTS

(*i*) Sterility
(*ii*) Tensile strength

MECHANICAL CONTRACEPTIVES

(*i*) Water leakage test
(*ii*) Tensile properties

INTRAUTERINE CONTRACEPTIVE DEVICES

(*i*) Memory test
(*ii*) Ash content
(*iii*) Sterility
(*iv*) Implantation test

COSMETICS

(*i*) Use of non-permitted colours/dyes
(*ii*) Presence of heavy metal

ACTION TO BE TAKEN ON CATEGORY B DEFECTS

1. Stoppage of further sale and recall of batch of the drugs from the market.
2. Manufacturer to be asked to intimate stock and distribution details etc. of the particular batch.
3. Calling of explanation from the manufacturer.
4. After receipt of explanation or investigation report, if any carried out, further appropriate action may be taken by issuing show cause notice etc. if so required.

ACTION TO BE TAKEN ON CATEGORY A DEFECTS

1. To enquire in the matter immediately.
2. Issue instructions for immediate recall of batch from the market and to stop further sale.
3. To ask for particulars of stock, distribution and production and test records.
4. Calling of explanation from the manufacturer by issuing a show cause notice as to why license for the product/entire licence should not be suspended/cancelled.
5. After receipt of explanation and/or investigation report, further appropriate action may be taken.

PRINCIPLES FOR INSTITUTION OF PROSECUTION UNDER DRUGS AND CONSMETICS ACT

The weapon for prosecution should be used sparingly and judiciously but due regard to merits of the case be given as a prudent measure. Prosecution should be launched where administrative measures have failed to have desired effects. However, while deciding to prosecute, due regard should be given to the nature of contraventions.

The persistent defaulter should be prosecuted but minor omissions may not form the basis of prosecution. Administrative action should be initiated wherever possible to ensure preventive measures to safeguard public health. A broad classification of cases where prosecutions should be launched is given below:

1. Where a spurious drug of drug falling within the meaning of adulterated/ spurious/misbranded under Section 17(A), 17(B) and 17 of Drugs and Cosmetics Act is manufactured, sold or stocked or exhibited for sale or is distributed.
2. Cosmetic falling within the meaning of spurious cosmetics under Section 17(D) and misbranded under Section 17(C).
3. Where drugs/Cosmetics are manufactured without a licence.
4. Where a parenteral preparation is reported by the Government Analyst to be non-sterile, pyrogenic or toxic and provided on investigation is found to be sub-standard due to lack of adequate quality control and adherence to the provisions of GMP in the manufacturing processes.
5. Where a drug is found grossly sub-standard repeatedly.

PROSECUTIONS ARE NOT ORDINARILY WARRANTED IN THE FOLLOWING CASES

The sub-committee feels that it is not necessary to specify the matters where prosecutions are not warranted as guidelines have already been suggested about the cases where prosecutions could not be considered.

INTERSTATE COORDINATION ON MATTERS REFERRED TO STATE DRUGS CONTROLLER

The sub-committee examined this specific issue and after detailed deliberations came to the conclusion that it may not be pragmatic to stipulate that a prosecution may be launched only by the Drugs Controller in whose state the sample has been drawn or by the Drugs Controller in whose State the manufacturer is situated. It should be left at the discretion of the concerned Drugs Controller to file a prosecution in his State or to refer the case to the Drugs Controller of the manufacturing State as circumstances warranted. Every Drugs Controller should invariably supply the information sought by other Drugs Controller in case the prosecution is contemplated. However, due regard should be given to the factual position or opinion supplied, if any, by the Drugs Controller of the State where the manufacturer is situated.

Note:

A. The above are broad guidelines for the guidance of State Drugs Control authorities. Cases not specifically covered by these guidelines or specific cases where a more serious/lenient view has to be taken, appropriate view can be taken by the State authorities, depending on circumstances of the case.

B. It is expected that final action after receipt of a note of standard quality report is taken within three months by the licensing authority/controlling authority and the same is informed to all concerned.

C. Repeated observance of Category B defects of a particular manufacturer should call for thorough inspection of manufacturing practices and facilities. If found deficient, it should be viewed seriously and stringent action is to be taken.

[85][73-B. **Certificate of renewal of licence in Form 25-B.**—The certificate of renewal of a licence in Form 25-B shall be issued in Form 26-B.]

[86][74. **Conditions of licence in [87][Form 25 and Form 25-F].**—A licence in [88][Form 25 and Form 25-F] shall be subject to the conditions stated therein and to the following further conditions, namely—

(*a*) the licensee shall provide and maintain staff, premises and the equipment as specified in Rule 71;

(*b*) the licensee shall comply with the provisions of the Act and of these rules and with such further requirements, if any, as may be specified in any rules subsequently made under Chapter IV of the Act, provided that where such further requirements are specified in the rules, these would come into force, four months after publication in the Official Gazette;

(*c*) the licensee shall either in his own laboratory or in any other laboratory approved by the licensing authority [89][under Part XV(A) of these Rules] test each batch or lot of the raw material used by him for the manufacture of his products and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U. The records or registers shall be retained for a period of 5 years from the date of manufacture;

(*d*) the licensee shall keep records of the details of manufacture as per particulars given in Schedule U of each batch of the drugs manufactured by him and such records shall be retained for a period of five years;

(*e*) the licensee shall allow an [90][Inspector authorised by the Act] to enter, with or without prior notice, any premises and to inspect the plant and the process of manufacture and the means employed in standardising and testing the drugs;

(*f*) the licensee shall allow an [91][Inspector authorised by the Act] to inspect all registers and records maintained under these rules and to take samples of the manufactured drugs and shall supply to such Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and the rules thereunder have been observed;

(*g*) the licensee shall, from time to time, report to the licensing authority any changes in the expert staff responsible for the manufacture or testing of the drugs and any material alterations in the premises or plant used for the purpose which have been made since the date of the last inspection made on behalf of the licensing authority;

[92][(*h*) the licensee shall, on request, furnish to the licensing authority, the controlling authority or to such authorities as the licensing authority or the controlling authority may direct, from every batch or batches of drugs

85. *Ins.* by S.O. 1196, dt. 6-5-1960 (w.e.f. 14-5-1960).
86. *Subs.* by S.O. 3868, dt. 26-10-1968 (w.e.f. 2-11-1968).
87. *Subs.* by GSR 462, dt. 22-6-1982 (w.e.f. 22-6-1982).
88. *Subs.* by GSR 462, dt. 22-6-1982 (w.e.f. 22-6-1982).
89. *Ins.* by GSR 1172, dt. 23-8-1977 (w.e.f. 10-9-1977).
90. *Subs.* by GSR 444, dt. 31-3-1973 (w.e.f. 28-4-1973).
91. *Subs.* by GSR 444, dt. 31-3-1973 (w.e.f. 28-4-1973).
92. *Subs.* by GSR 444, dt. 31-3-1973 (w.e.f. 28-4-1973).

as the licensing authority or the controlling authority may from time to time specify, a sample of such quantity as may be considered adequate by such authority for any examination and, if so required, also furnish full protocols of tests which have been applied;]

(*i*) if the licensing authority [93][or the controlling authority] so directs and if requested by the licensee who had also furnished prima facie reasons for such directions, the licensee shall not sell or offer for sale any batch in respect of which a sample is or protocols are furnished under clause (*h*) until a certificate authorising the sale of the batch has been issued to him by or on behalf of the licensing authority [94][or the controlling authority];

(*j*) the licensee shall on being informed by the licensing authority [95][or the controlling authority] that any part of any batch of the drug has been found by the licensing authority [96][or the controlling authority] not to conform with the standards of strength, quality or purity specified in these rules and on being directed so to do, withdraw the remainder of the batch from sale, and, so far as may in the particular circumstances of the case be practicable, recall all issues already made from that batch;

(*k*) the licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed;]

[97][(*l*) the licensee shall maintain reference samples from each batch of the drugs manufactured by him in a quantity which is at least twice the quantity of the drug required to conduct all the tests performed on the batch. In case of drugs bearing an expiry date on the label, the reference samples shall be maintained for a period of three months beyond the date of expiry of potency. In case of drugs where no date of expiry of potency is specified on the label, the reference samples shall be maintained for a period of three years from the date of manufacture;]

[98][(*m*) the licensee, who has been granted a licence in Form 25-F, shall—

(*i*) forward to the licensing authority of the States concerned of manufacture and supply of the drug a statement of the sales effected to the manufacturers, wholesalers, retailers, hospitals, dispensaries and nursing-homes and Registered Medical Practitioners every three months;

(*ii*) maintain accounts of all transactions giving details as indicated below in a register bound and serially page numbered and such records shall be retained for a period of five years or one year after the expiry of potency, whichever is later:

A. Accounts of the drugs specified in Schedule X used for the manufacture:

1. Date of issue.
2. Name of the drug.

93. *Ins.* by GSR 444, dt. 31-3-1973 (w.e.f. 28-4-1973).
94. *Ins.* by GSR 444, dt. 31-3-1973 (w.e.f. 28-4-1973).
95. *Ins.* by GSR 444, dt. 31-3-1973 (w.e.f. 28-4-1973).
96. *Ins.* by GSR 444, dt. 31-3-1973 (w.e.f. 28-4-1973).
97. *Ins.* by GSR 444, dt. 31-3-1973 (w.e.f. 28-4-1973).
98. Clauses (*m*) and (*n*) *ins.* by GSR 462(E), dt. 22-6-1982 (w.e.f. 22-6-1982).

[67][Provided that if the application for the renewal of a licence is made before its expiry, or if the application is made within six months of its expiry, after payment of additional fee, the licence shall continue to be in force until orders are passed on the application and the licence shall be deemed to have expired if the application for its renewal is not made within six months of its expiry.]]

78. Conditions of licence.—A licence in [68][Form 28, Form 28-B or Form 28-D] shall be subject to the special conditions, if any, set out in Schedule F or Schedule F(1), as the case may be, which relate to the substance in respect of which the licence is granted and to the following general conditions:

(*a*) (*i*) The licensee shall provide and maintain an adequate staff and adequate premises and plant for the proper manufacture and storage of the substances in respect of which the licence is issued.

(*ii*) Without prejudice to the generality of the foregoing requirement, every holder of a licence who for any purpose engaged in the culture or manipulation of pathogenic spore-bearing micro-organisms shall provide to the satisfaction of the Licensing Authority separate laboratories and utensils and apparatus required for the culture or manipulation of such micro-organisms, the laboratories, utensils and apparatus so provided not being used for the manufacture of any other substance.

[69][(*b*) The licensee shall provide and maintain staff, premises and equipment as specified in Rule 76.

[70][(*c*) (*i*) The licensee shall maintain records of manufacture as per particulars given in Schedule U.

(*ii*) The licensee shall either in his own laboratory or in any laboratory approved by the Licensing Authority [71][under Part XV(A) to these Rules] test each batch or lot of the raw material used by him for the manufacture of his product and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U. The records or registers shall be retained in the case of a substance for which a potency date is fixed for a period of two years from the expiry of such date, and in the case of other substances for a period of five years from the date of manufacture.]

(*d*) The licensee shall allow an [72][Inspector appointed under the Act], to enter, with or without prior notice, any premises where the manufacture is carried on and to inspect the premises; and in the case of substances specified in Schedules C and C(1), to inspect the plant and the process of manufacture and the means employed for standardising and testing the substance.

(*e*) The licensee shall allow an [72][Inspector, appointed under the Act] to inspect all registers and records maintained under these rules and to take samples of the manufactured product and shall supply to such Inspector

67. *Subs.* by S.O. 2139, dt. 5-6-1972 (w.e.f. 12-8-1972).
68. *Subs.* by GSR 119(E), dt. 11-3-1996 (w.e.f. 11-3-1996).
69. *Subs.* by S.R.O. 2136, dt. 15-6-1957.
70. *Subs.* by S.O. 3868, dt. 26-10-1968 (w.e.f. 2-11-1968).
71. *Ins.* by GSR 1172, dt. 23-8-1977 (w.e.f. 10-9-1977).
72. *Subs.* by GSR 444, dt. 31-3-1973 (w.e.f. 28-4-1973).

such information as he may require for the purpose of ascertaining whether the provisions of the Act and Rules thereunder have been observed.

(*f*) The licensee shall from time to time report to the Licensing Authority any changes in the expert staff responsible for the manufacture or testing of the substance and any material alterations in the premises or plant used for that purpose which have been made since the date of the last inspection made on behalf of the Licensing Authority before the issue of the licence.

[73][(*g*) The licensee shall on request furnish to the Licensing Authority, controlling authority or to such authorities as the Licensing Authority or the controlling authority may direct, from every batch of drugs as the Licensing Authority or the controlling authority may from time to time specify, a sample of such quantity as may be considered adequate by such authority for any examination and, if so required, also furnish full protocols of the tests which have been applied.]

(*h*) If the Licensing Authority [74][or the controlling authority] so directs, the licensee shall not sell or offer for sale any batch in respect of which a sample is, or protocols are furnished under the last preceding sub-paragraph until a certificate authorizing the sale of the batch has been issued to him by or on behalf of the Licensing Authority [74][or the controlling authority].

(*i*) The licensee shall on being informed by the Licensing Authority [74][or the controlling authority] that any part of any batch of the substance has been found by the Licensing Authority [74][or the controlling authority] not to conform with the standards of strength, quality or purity specified in these Rules and on being directed so to do, withdraw the remainder of that batch from sale and so far as may in the particular circumstances of the case be practicable recall all issues already made from that batch.

(*j*) No drug manufactured under the licence shall be sold unless the precautions necessary for preserving its properties have been observed throughout the period after manufacture.

[75][(*k*) The licensee shall comply with the provisions of the Act and of these rules and with such further requirements, if any, as may be specified in any rules subsequently made under Chapter IV of the Act, provided that where such further requirements are specified in the rules, these would come into force four months after publication in the Official Gazette.]

[76][(*l*) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and defects noticed.]

[77][(*m*) The licensee shall maintain reference samples from each batch of the drugs manufactured by him in a quantity which is at least twice the quantity of the drug required to conduct all the tests performed on the batch. In case of drugs bearing an expiry date on the label the reference samples shall be maintained for a period of three months beyond the date of expiry of potency. In case of drugs where no date of expiry of potency

73. *Subs.* by GSR 444, dt. 31-3-1973 (w.e.f. 28-4-1973).
74. *Ins.* by GSR 444, dt. 31-3-1973 (w.e.f. 28-4-1973).
75. *Subs.* by S.O. 3868, dt. 26-10-1968 (w.e.f. 2-11-1968).
76. *Ins.* by S.O. 115, dt. 4-1-1961 (w.e.f. 14-1-1961).
77. *Ins.* by GSR 444(E), dt. 31-3-1973 (w.e.f. 28-4-1973).