

# THE DRUGS ACT

(XXXI OF 1976)

[11th May, 1976]

An Act to regulate the import, export,  
manufacture, storage, distribution  
and sale of drugs

**Preamble :** Whereas it is expedient to regulate the import,  
export, manufacture, storage, distribution and sale of drugs;  
It is hereby enacted as follows:--

## COMMENTS

Violation of patent rights, Defence against. Registration under Drugs Act, 1976, would not constitute defence against infringement regulated by Patents and Designs Act, 1911, two statutes covering different fields and controlling distinct classes of activities.

Prosecution for violation of Act cannot be launched without permission of Drug Quality Control Board. Requisite permission would not be given by Board in presence of negative report of Laboratory.

**Process of grant of registration.** - Process of grant of registration for drugs. Requires examination of various aspects of case including premises, methodology of manufacturing, efficacy, quality and economic value of drug sought to be registered. Manufacture of drug is a delicate matter and concerned authorities have to see that its results are beneficial to people. Order of Registration Board rejecting application for registration would not be

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amenable to interference in writ jurisdiction during pendency of appeal before Appellate Board constituted under Drugs Act, 1976.

**Sanction for prosecution.** - Proviso. Sanction for prosecution which does not mention that public interest required institution of prosecution against accused, would not be a legal sanction and Drug Court cannot proceed further in the matter.

**Spurious drug cannot be declared as such without Lab Test.** - Spurious drug. Case of. Conviction for. Challenge to. Complainant admitted during cross-examination that he had not obtained sample(s) of drug and he had not sent any sample to concerned Laboratory for analysis. In view of clear-cut admission how complainant in absence of any report by any expert came to conclusion that drug in question was in fact spurious drug or that same looked like drug. Held: Prosecution failed to prove guilt of appellant beyond reasonable doubt.

**Spurious drug.** - Appreciation of evidence. No sample of the drug seized by the complainant Drug Inspector having been taken and sent to the concerned Laboratory for analysis, it could not be said to be a spurious drug. Drug Inspector, although alleged, that the drug seized by him resembled a medicine manufactured by a local pharmaceutical company, yet he admittedly did not contact the said pharmaceutical company in this respect and failed to obtain the view of that company regarding the drug in question. Accused was acquitted in circumstances.

**Counterfeit drug.** - Mere resemblance of label and outer packing of a carton would not be covered by definition of "counterfeit drug" as given in S. 3 (f). Accused facing prosecution u/ss. 23, 24 in such case would be entitled to acquittal by accepting his application u/s. 249A, CrPC.

**Initiation of proceeding.** - Registration of case. Drug Inspector should make a report against contravention of Act to Provincial Quality Control Board for initiating criminal action. Case for contravention of Act cannot be registered at Police Station on report of Drug Inspector.

Mere averment in FIR that accused was carrying contraband injections of Chloramphenicol for sale, would not make accused liable u/ss. 23/27. Accused in such case would be entitled to bail.

Recovery of Calcium Sandoz Syrup and cotton bandages which did not have surgical bandages, would be no offence when there is no proof that accused was selling these items as drugs. Accused in such case would be entitled to acquittal.

**Who Can institute the case.** - Appeal against acquittal. Prosecution could be instituted under the law either by a Federal Drug Inspector or Provincial Drug Inspector and the complainant in the case did not hold any of these positions. Complainant being not competent to institute the case/prosecution before the Drug Court, the entire proceedings stood vitiated. View taken by High Court resulting in acquittal of accused was

Constitution of Pakistan, 1973, Art.199.  
PLJ 1996 (Pesh.) 114 (DB).  
1996 PCr LJ 540  
1996 CrLJ 399  
1996 CrLJ 414.  
1996 CrLJ 401.

correct and in consonance with law. Leave to appeal was refused accordingly.

**Cognizance of offences.** - Non-compliance of S. 30 of Drugs Act, 1976. Effect. Failure to raise objection to proceedings by the defence would not validate the proceedings otherwise invalid. Requirement of law enjoined by S. 30 of the Drugs Act, 1976 is meant to be complied with by the prosecution and if no objection had been raised by the defence at the trial, it would not validate the proceedings which otherwise stood vitiated for non-compliance of S. 30 Drugs Act, 1976.

**Permission of Drug Quality control Board is essential.** - Prosecution for violation of Act cannot be launched without permission of Drug Quality Control Board. Requisite permission would not be given by Board in presence of negative report of Laboratory.

**Repetition Violation of patented rights.** Defence against. Registration under Drugs act, 1976 would not constitute defence against infringement regulated by Patents and Designs act, 1911, two statutes covering different fields and controlling distinct classes of activities.

## CHAPTER I

### INTRODUCTORY

1. **Short title, extent and commencement:** (1) This Act may be called the Drugs Act, 1976.
- (2) It extends to the whole of Pakistan.
- (3) It shall come into force at once.

### COMMENTS

**Object:** The Act provided for the control of import, export, manufacture, sale, supply and distribution of the drugs.

In recent years there has been a great increase in the number of objectionable advertisements published in newspapers or magazines or otherwise relating to alleged cures for venereal diseases, sexual stimulants and cures for certain other deadly diseases. These advertisements tended to cause the ignorant and the unwary to resort to self-medication with harmful drugs and appliances or to resort to quacks who indulge in such advertisements for treatment which cause great harm. It was, therefore, considered necessary in the public interest to put a stop to such undesirable advertisements.

The Act it should be noted is not in derogation of the Dangerous Drugs Act, 1930 which still holds the field. The Drugs Act, 1940 has of course been repealed and superseded by this Act. A comparison of the two Acts will show that the present Act is much more exhaustive and covers a large number of new grounds, legislation in respect of which was an imperative necessity due to the advance of times and change of tactics by manufacturers and dealers

1996 SCMR 767  
NLR 1989 CrLJ 42.

of drugs in jointly making the best use of their profession to their personal advantage and gain regardless of the welfare of the nation as a whole.<sup>11</sup>

**Islamisation of Laws.-** The Drugs Act, 1976 is not repugnant to Sharia.<sup>12</sup>

**Investigation.-** The Police Officers could investigate into offences under the Drugs Act, 1976 either upon their own information or on information given under Section 154, Criminal Procedure Code, 1898 irrespective of fact whether the informant was Drugs Inspector or someone else.<sup>13</sup>

**Jurisdiction.-** The alleged offence was committed prior to enforcement of the Drugs Act, XXXI of 1976. The Drugs Court, had no jurisdiction to take cognizance of such offence. Offence was committed under the Drugs Act, 1940. Provision of new law did not permit the Drugs Court to take cognizance of offence committed under the Act, 1940 proceedings were illegal. Prosecution could take steps to refer case to a Court of the competent jurisdiction.<sup>14</sup>

**Renewal of Licence under Drugs Act, 1976.-** The petitioner a licensed manufacturer of the drugs, under the Drugs Act, 1976 submitted the application for renewal of licence under new law as required by Rules. Facts revealing petitioner having been dealt with left-handedly and adverse action having been taken rather irresponsibly in rejecting petitioner's application. Appeal filed by petitioner heard by Appellate Board including two such members who complained of having not been treated with respect by petitioner and launching criminal proceedings against petitioner through Martial Law authorities in consequence whereof petitioner arrested and remained in jail until released on bail. The Board in circumstances, could not be said to have acted in the manner to let justice appear to be done. Justice not only to be done but has manifestly to appear being done. Order of the Appellate Board, not with lawful authority. The case was remitted back to be decided keeping in view background of the case, facts as well as law.<sup>15</sup>

**"Hexa-Chlorophene liquid soap"—Nature of product.-** Nature of product, could be gauged from properties of compound and primary use of the product. "Hexa-Chlorophene Soap" containing 0.25% of the Hexa-chlorophene and 12% solution of potassium soap, registered in the National Pharmacology as drug and primarily used for care and treatment of skin was essentially medical drug. Such product could not be treated as article of perfumery, cosmetic or toilet preparation.<sup>16</sup>

**Counter file.-** Mere resemblance of label and outer packing of a carton would not be converged by definition of "counterfeit drug" as given in S. 3 (f). Accused facing prosecution u/ss. 23, 24 in such case would be entitled to acquittal by accepting his application u/s. 249A Cr.P.C.<sup>17</sup>

**Misbranded.-** "Misbranded drug" A drug would be deemed as misbranded when such drug is not labelled in the prescribed manner or

labelling of which is against the Rules or misleading or which is camouflaged to conceal damage etc., or on which the name of the pharmacopoeia under specifications of which the drug is manufactured is not mentioned.<sup>18</sup>

Mere registration of substances, etc., as drugs or declaration by Federal Govt. notifying a substance as drugs, cannot bring such substance under classification "medicaments (including veterinary medicaments) in head 30.03 (Pakistan Customs Tariff) so as to make its import free from customs duty/sales tax.<sup>19</sup>

Any isolated or synthesised substance mentioned as monograph or as a preparation appearing in the several publications referred to in section 3(g) (v) of Drugs Act would be itself constitute a Drug and fall within the fold of the said definition clause irrespective of the fact whether the same is used in any of the four excepted systems of medicine in question, in the later case if intended to be used for any of the purposes mentioned in sub-clauses (i), (ii) and (iii) of clause (g) of section 3 of Drugs Act. In such category would fall such isolated or synthesised Acts constitutions as are converged in the publications referred to in section 3(g) (v) of the Act.<sup>20</sup>

**Misbranded.-** Misbranded drug. Case of Acquittal of respondent. Challenge to. Only point for determination is as to whether non-mention of "Oleoresins of Ginger" on label of drug would be a ground for treating it as misbranded or sub-standard as required by Section 23(1)(a) read with Section 27(2) of Act. Defence of respondent is that Oleoresins of Ginger is added as a flavouring agent and not as active ingredient. Woodward's Gripe Water is being manufactured for last 100 years. A drug would be deemed as misbranded when such drug is not labeled in prescribed manner. Held: There is nothing manifestly wrong or perverse in conclusion arrived at by Drug Court and no interference called for. Appeal dismissed.

Drug methyl salicylate which is included both in National Formulary as well as in British Pharmacopoeia. Falls within definition of "drug" given in S. 3 (g).<sup>21</sup>

**Substandard drugs.** Drugs manufactured by respondents were declared by Analyst that same although conformed to the stated specifications chemically; yet did not conform to the physical specifications being adulterated with particles and fibres. High Court in Constitutional jurisdiction set aside Analyst's report Validity. Held, to hold the samples as spurious or adulterated drugs, Analyst was required to have stated so, or to have declared the same as filthy, putrid or decomposed or to contain vermin, worm, rodent or insect or the same had been prepared under unsanitary conditions so as to be contaminated with dirt, filth or any foreign matter, whereby same could have been rendered injurious to health. Definition of adulterated drug clearly laid down a test and a report which did not conform to the test provided bylaw could not be considered to be valid and legal report. Analyst's report in question, when considered within meaning of the definition of spurious drugs, fell outside the category of that definition.

11 LD 1991 Kar. 252.  
12 PLD 1986 FSC 29.  
13 1972 P Cr LJ Note 6 at p 4.  
14 1950 P Cr LJ 738.  
15 PLD 1972 Lah 1249.

18 PLD 1992 Kar. 347.  
19 NLR 1988 Tax Lah. 109.  
20 1990 MLD 1524.  
21 NLR 1987 Criminal Kar. 745.

Finding of High Court in Constitutional jurisdiction was confirmed in intra-Court appeal in circumstances.<sup>22</sup>

**Definition of Drug.**— "Strepsils" manufactured by petitioner was a medicament and being a drug was exempted from sales tax. Strepsils lozenges was in fact a medicinal preparation within the meaning of Drugs Act, 1976 and that being so, it could not be termed as sugar confectionary and as such could not be charged for purposes of sales tax. Ministry of Health had uniformly pointed out that Strepsils lozenges were used as a remedy for treatment of infections of the mouth and throat and a valuable adjunct to the systematic treatment of tonsils and other deep throat infections. Levy of sales tax on such product would not be justified. Circulars issued for imposition of sales tax were declared to be without lawful authority, of no legal effect and were quashed.<sup>23</sup>

**Definition of Drug.**— "Drug". Definition. Term "drug" includes medicines for internal or external uses. Expressions "substance" and "mixture of substances", explained.<sup>24</sup>

Basic test report of drugs not in conformity with the provisions of law. Such report was wholly without jurisdiction and incapable of being acted upon. Contention that, another efficacious remedy being available to respondent by reverting to Federal Test Laboratory, was nothing but to perpetuate the tyranny; thus, same was repelled. No exception could be taken to the finding of single Judge of High Court whereby Analyst's report was set aside and same was affirmed in appeal.<sup>25</sup>

Report of Govt. Analyst which does not prove that drug was adulterated drug, spurious drug or substandard drug, cannot be made basis of prosecution of manufacturer on ground that Test Report described drug as adulterated with particles. Quashment of prosecution by Single Judge in exercise of writ jurisdiction upheld by ICA Bench as unexceptionable.<sup>26</sup>

**Conformity to test.**— Analyst report about nature of drug which does not conform to test provided by law, cannot be considered as valid and legal report.<sup>27</sup>

Non-mention on label of flavouring agent which is not active ingredient of drug, would not make drug a misbranded drug. Acquittal of accused in such case with finding that drug was not misbranded drug would be unquestionable.<sup>28</sup>

**Definition of Drug.**— Mere registration of substances, etc., as drugs or declaration by Federal Govt. notifying a substance as drugs, cannot bring such substance under classification "medicaments (including veterinary medicaments)" in head 30.03 (Pakistan Customs Tariff) so as to make its import free from customs duty/sales tax.<sup>29</sup>

<sup>22</sup> 1992 MLD 481.  
<sup>23</sup> 1994 CLC 1144.  
<sup>24</sup> 1994 CLC 1144.  
<sup>25</sup> 1992 MLD 481.  
<sup>26</sup> NLR 1992 AC 563.  
<sup>27</sup> NLR 1992 AC 563.  
<sup>28</sup> NLR 1992 Criminal Kar. 655.  
<sup>29</sup> NLR 1998 Tax Lah. 109.

Drug methyl salicylate which is included both in National Formulary as well as in British Pharmacopia. Falls within definition of "drug" given in S. 3 (g).<sup>30</sup>

"Spurious drug". Meaning. Medicine recovered from accused which he was selling at his shop purported to be the drug and which according to the Chemical Analyser's Report contained only lactose and starch which meant that it had no active ingredient of the drug. Held, drug in question was deregistered and spurious drug in circumstances.

**2. Application of other laws not barred:** The provisions of this Act, shall be in addition to, and not in derogation of, the Dangerous Drugs Act, 1930 (II of 1930), and any other law for the time being in force.

**3. Definitions:** In this Act, unless there is anything repugnant in the subject or context.—

- (a) "adulterated drugs" means a drug—
  - (i) which consists in whole or in part of any filthy, putrid or decomposed substance or which contains any foreign matter, vermin, worm, rodent or insect; or
  - (ii) which has been manufactured, packed, or held under unsanitary conditions whereby it may have been—
    - (a) contaminated with dirt, filth or any other foreign matter or its internal decomposed matter; or
    - (b) rendered injurious to health; or;
- (iii) the container of which releases any poisonous or deleterious substance which may render the contents injurious to health; or
- (iv) which bears or contains as an ingredient a substance other than the prescribed substance; or
- (v) with which any substance has been mixed or packed so as to reduce its quality or strength or for which any substance has been substituted wholly or in part;
- (b) "Appellate Board" means the Board constituted under Section 9;
- (c) "batch" means a quantity of any drug produced during a given cycle of manufacture;
- (d) "batch number" means a designation printed on the label of a drug that identifies the batch and permits the production

<sup>30</sup> NLR 1987 Criminal Kar. 745.  
<sup>31</sup> PLD 1992 Quetta 67.  
<sup>32</sup> Subs. "sub-clause (ii)" by Drugs (Amendment) Ordinance No. XXII of 1998, dated 23.12.1998.

history of the batch, including all stages of manufacture and control, to be traced and reviewed;

- (e) "Central Licensing Board" means a Board set up under Section 5;
- (f) "Imitation product" means a drug or any other substance or preparation or any homeopathic, unani, ayurvedic or bio-chemic medicine or any other preparation offered for treatment or prevention of any disease the label or outer packing of which is an imitation of, or resembles or so nearly resembles as to be calculated to deceive the label or outer packing of a drug of another manufacturer;
- (g) "drug" includes—
- (i) any substance or mixture of substances that is manufactured, sold, stored, offered for sale or represented for internal or external use in the treatment, mitigation, prevention or diagnosis of diseases, an abnormal physical state, or the symptoms thereof in human beings or animals, or the restoration, correction, or modification of organic functions in human beings or animals, not being a substance exclusively used or prepared for use in accordance with the ayurvedic, unani, homeopathic or bio-chemic system of treatment except those substances and in accordance with such conditions as may be prescribed;
  - (ii) abortive and contraceptive substances, agents and devices, surgical ligatures, sutures, bandages, absorbent cotton, disinfectants, bacteriophages, adhesive plasters, gelatine capsules and antiseptic solutions;
  - (iii) such substances intended to be used for the destruction or repulsion of such vermin, insects, rodents and other organism as cause, carry or transmit disease in human beings or animals or for disinfection in residential areas or in premises in which food is manufactured, prepared or kept or stored;
  - (iv) such pesticides as may cause health hazard to the public;
  - (v) any substance mentioned as monograph or as a preparation in the Pakistan Pharmacopoeia or the

Substituted clause (f) by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998, the original text is as under:-

"counterfeit drug" means a drug the label or outer-packing of which is an imitation of, or resembles or so nearly resembles as to be calculated to deceive the label or outer-packing of a drug of another manufacturer;

Pakistan National Formulary or the International Pharmacopoeia or the British Pharmacopoeia or the British Pharmaceutical Codex or the United States Pharmacopoeia or the National Formulary of the United States, whether alone or in combination with any substance exclusively used in the unani, ayurvedic, homeopathic or biochemic system of treatment, and intended to be used for any of the purposes mentioned in sub-clauses (i), (ii) and (iii); and

- [(vi) immediate packing containers for sterile preparations which are in direct contact with the drug, blood bags, disposable giving sets for infusion or blood, disposable syringes or any other substance or device which the Federal Government may, by notification in the official Gazette, declare to be a "drug" for the purposes of this Act;]
- [(vii) Infant formulas, follow up milks, milk substitutes, baby foods, baby gruels, baby teas and juices, bottles and treats and any other product used as infant formula as such;
- (viii) Cosmetics including hair Sprays, perfumes, facial and talcum powders, hair treatment shampoos, hair conditioning aids and devices and all formulas and lotions connected therewith for conditioning and cleansing of hair, hair colours, facial make-up foundations, vanishing and cold creams, creamy make-up sticks, bath lotions and oils, blushers and blush-ons, texture improvement devices, moisturisers of all kinds, maskaras, vaselines, sunnas, wrinkle-care creams, hair oils/herbal preparations for texture and facial glow and improvement, shower creams, skin lotions and oils, sun-burn lotions and oils, shaving cream and lathers, after shave lotions and any other preparation or material connected therewith;]
- (h) "expiry date" means the date stated on the label of a drug after which the drug is not expected to retain its claimed efficacy, safety, quality or potency or after which it is not permissible to sell the drug;

Subs sub-clause (vi)" by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998. The original clause (VI) is as under:-

- (vi) any other substance which the Federal Government may, by notification in the official Gazette, declare to be a "drug" for the purposes of this Act;

35 Added by New Sub-Section (VII) (VIII) second (Amend.) Act, 1996.

- (i) "expert" means a specialist through university education and experience in the relevant field;
- (j) "export", with its grammatical variations and cognate expressions, means to take out of Pakistan by sea, land or air;
- (k) "generic name" means the non-proprietary, scientific or official name of a drug as approved by the Federal Government;
- (l) "Government Analyst" means a Federal Government Analyst or Provincial Government Analyst appointed under Section 16;
- (m) "import" with its grammatical variations and cognate expressions means to bring into Pakistan by sea, land or air;
- (n) "Inspector" means a Federal Inspector or a Provincial Inspector appointed under Section 17;
- (o) "label" means a display of written, printed or graphic matter upon the immediate container, or the outside container or wrapper of a drug package;
- (p) "labelling" means all labels and other written, printed or graphic matter accompanying any drug;
- (q) "licensing authority" means such authority as may be prescribed;
- (r) "manufacture", in relation to a drug, means all operations involved in the production of the drug, including processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing and labelling with a view to its storage, sale and distribution, but does not include the compounding and dispensing or the packing of any drug in the ordinary course of retail business or on a prescription of a registered medical practitioner or dentist or of a veterinarian and "to manufacture" shall be construed accordingly;
- (s) "misbranded drug" means a drug—
  - (i) which is not labelled in the prescribed manner ; or
  - (ii) on the label or labelling of which any word, statement, or other matter or information required by the rules to appear on the label or labelling is not prominently placed with such conspicuousness (as compared with other words, statements, designs, or devices on the label or labelling) and in such terms as may render it likely to be

- read and understood by the ordinary individual under customary conditions of purchase and use ; or
- (iii) which is not labelled with such directions for use and such warnings against use in indications where its use may be dangerous to health, or against unsafe dosage or duration of administration or application in such manner and form as are necessary for the protection of users or as may be prescribed ; or
- (iv) the label or container of which, or anything accompanying which, bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular ; or
- (v) which is so coloured, coated, powdered or polished that damage is concealed, or which is made to appear of better or greater therapeutic value than it really is ; or
- (vi) which is manufactured according to the specifications of a particular pharmacopoeia or any other document as may be prescribed and the label does not bear the name of that pharmacopoeia or document;
- (t) "prescribed" means prescribed by rules;
- (u) "Provincial Quality 'Control Board' means a Board set up under Section 11;
- (v) "Registration Board" means a Board set up under Section 7;
- (w) "registered drug" means any drug registered under Section 7;
- (x) "rules" mean rules made under this Act;
- (y) "Drug Court" means a Court established under Section 31 ;
- (z) "specifications" when applied to a drug mean—
  - (i) such specifications as may be prescribed ; or
  - (ii) when the specifications are not prescribed, the specifications as contained in the most recent edition of any of the following publications, namely:--
    - (1) the Pakistan Pharmacopoeia;
    - (2) the International Pharmacopoeia;
    - (3) the European Pharmacopoeia;
    - (4) the United States Pharmacopoeia;
    - (5) the British Pharmacopoeia;
    - (6) the British Pharmaceutical Codex;



- (7) the United States National Formulary ; and
- (8) such other publication as may be prescribed:

Provided that, if the specifications do not appear in the most recent edition of any such publication, the specifications appearing in the next preceding edition of such publication in which the specifications appear shall apply ; or

- (iii) if no specifications are either prescribed or contained in any of the publications referred to in sub-clause (ii), the specification approved for the purpose of registration under this Act;
- (za) "sell" means sell, offer for sale, expose for sale, have in possession for sale and distribution and "to sell", "sold" or "sale" shall be construed accordingly;
- (zb) "spurious drug" means a drug—
  - (i) which purports to be a drug but does not contain the active ingredient of that drug ; or
  - (ii) which purports to be the product of a manufacturer, place or country of whom or of which it is not truly a product; or
  - (iii) which is imported or exported or sold or offered or exposed for sale under a particular name while actually it is another drug ; or
  - (iv) the label of which bears the name of an individual or company purposing to be its manufacturer or producer which individual or company is fictitious or does not exist;
- (zc) "storage" means storage for sale and "to store" or "stored" shall be construed accordingly ; and
- (zz) "sub-standard drug" means a drug which is not of specifications.

### COMMENTS

Basic test report of drugs not in conformity with the provision of law. Such report was wholly without jurisdiction and incapable of being acted upon. Contention that another efficacious remedy being available to respondent by reverting to Federal Test Laboratory, was nothing but to perpetuate the tyranny, thus, same was repelled. No exception could be taken to the finding of single Judge of High Court whereby Analyst's report was set aside; and same was affirmed in appeal.<sup>38</sup>

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Any isolated or synthesised substance mentioned as monograph or as a preparation appearing in the several publications referred to in section 3(g)(v) of Drugs Act would be itself constitute a Drug and fall within the fold of the said definition clause irrespective of the fact whether the same is used alone or in combination with any other substance exclusively used in any of the four excepted systems of medicine in question, in the later case if intended to be used for any of the purposes mentioned in sub-clauses (i), (ii) and (iii) of clause (g) of section 3 of Drugs Act. In such category would fall such isolated or synthesised active constituents as are covered in the publications referred to in section 3(g)(v) of the Act.<sup>40</sup>

**Misbranded.- Misbranded Drug.** Case of. Acquittal of respondents. Challenge to. Only point for determination is as to whether non-mention of "Oleresins of Ginger" on label of drug would be a ground for treating it as misbranded or substandard as required by Section 23(1)(a) read with Section 27(2) of Act. Defence of respondents is that Oleoresins of Ginger is added as a flavouring agent and not as active ingredient. Woodward's Gripe Water is being manufactured for last 100 years. A drug would be deemed as misbranded when such drug is not labelled in prescribed manner. There is nothing manifestly wrong or perverse in conclusion arrived at by Drug Court and no interference is called for. Appeal dismissed.<sup>41</sup>

Drug methyl salicylate which is included both in National Formulary as well as in British Pharmacopoeia. Falls within definition of "drug" given in S.3(g).<sup>42</sup>

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on which the name of the pharmacopoeia under specifications of which the drug is manufactured is not mentioned.<sup>42</sup>

Mere registration of substances, etc., as drugs or declaration by Federal Govt. notifying a substance as drugs, cannot bring such substance under classification "medicaments, (including veterinary medicaments) in head 30.03 (Pakistan Customs Tariff) so as to make its import free from customs duty/sales tax.<sup>43</sup>

**Sub-clause (g)-Drug.**—The Oxford Concise Dictionary defines drug as "original simple medicinal substance, organic or inorganic, used alone or as an ingredient". The word as defined in this Act has, however, a much wider connotation. As per definition of the word drug as defined in the Act any substance or mixture of substances used in the treatment, mitigation, prevention, or diagnosis of disease in human beings or animals, or the restoration, correction, or modification of the organic functions in human beings or animals, not being a substance exclusively used in accordance with the Ayurvedic, Unani, Homeopathic or Biochemic system of treatment, abortive and contraceptive substances and devices, surgical ligatures, sutures, bandages absorbent cotton, disinfectants, adhesive plasters, gelatine capsules, antiseptic solutions, pesticides, any substance mentioned as monograph or as a preparation in the Pakistan Pharmacopoeia or International or British Pharmacopoeia or United States Pharmacopoeia or formulary, whether alone or in combination with any substance exclusively used in the Unani, Ayurvedic, Homeopathic or Biochemic system of treatment, and such substance as the Federal Government may declare to be a drug for purposes of this Act shall be deemed to be a drug. It will thus appear that it is not only the drugs that are used in the cure, prevention, mitigation, etc., of a disease that fall within the definition but even such articles as are used in the diagnosis, treatment, prevention or mitigation of diseases are covered within the term.

The definition of drug is comprehensive enough to take not only medicines but also substances intended to be used for or in the treatment of diseases of human beings or animals. This artificial definition introduces distinction between medicines and substances which are not medicines strictly so-called. The expression 'substances' or 'mixture of substances, therefore, is something other than medicines but which are used for the treatment of diseases of human beings or animals. The term 'drug' includes medicines for internal or external uses.<sup>44</sup>

According to the case of *The State v. Abdullah Shamim*,<sup>45</sup> any substance mentioned as monograph or preparation in British or Pakistani Pharmacopoeia or National Formulary is included in the definition of "drug". Methyl Salicylate finds mention in National Formulary and British Pharmacopoeia. Certain preparations used in the manufacture of the Ayurvedic or Unani medicines are no doubt excluded but all such preparations are not excluded and such a question is purely of fact to be established by the evidence. Not only the manufacture and sale of drugs without licence and registration is punishable offence but even their counterfeiting is an offence. Where *prima facie* case was made out by the

<sup>42</sup> PLD 1992 Kar. 347.  
<sup>43</sup> NLR 1988 Tax Lah. 109.  
<sup>44</sup> 1994 C.L.C. 114.  
<sup>45</sup> 1987 MLD 2160.

prosecution, the Trial Court, was not justified in throwing out case without recording evidence.

Any substance mentioned as a preparation in the Pakistan National Formulary, or Pakistan Pharmacopoeia for treatment, mitigation, prevention or diagnoses of disease being a drug would fall under the " "

**Counterfeiting drug.**—A drug so packed that its label or outer-packing imitates, or resembles or so nearly resembles as to deceive and cause it to be taken as the label or outer-packing of another manufacturer is a counterfeit drug. It is only the packing which is calculated to deceive and cause it to be taken as the manufacture of another manufacturer which is the essence of the definition. The quality of the drug has nothing to do with this definition.

If any substance or mixture of substances is exclusively used or prepared for use in accordance with the Ayurvedic, Unani, Homeopathic or Biochemic system of treatment then (unless such substance is excepted in accordance with such conditions as may be prescribed) the same would not be included in the definition of "Drug" occurring in section 3(g) (i) of the Drugs Act.<sup>46</sup>

Any isolated or synthesised substance mentioned as monograph or as a preparation appearing in the several publications referred on in Section 3(g)(v) of the Drugs Act would by itself constitute a drug and fall within the fold of the said definition clause irrespective of the fact whether the same is used alone or in combination with any other substance exclusively used in any of the four excepted systems of medicine in question, in the later case if intended to be used for any of the purposes mentioned in sub-clauses (i), (ii) and (iii) of clause (g) of Section 3 of the Drugs Act. In such category would fall such isolated or synthesised active constituents as are covered in the publications referred to in Section 3(g) (v) of the Act. 1990 MLD 1524

**Word "medicament"—Meaning.**—Definition of the word "medicament" as given by the Drugs Act, 1976 would be relevant. P L D 1992 S C 455.

**Adulterated drug.**—A drug which either in whole or in part consists of any filthy, putrid, or decomposed substance or which contains any foreign matter, vermin, worm, rodent, or insect, or which has been manufactured or packed or kept under unsanitary conditions rendering it likely to be contaminated with dirt, filth or any other foreign matter and making it likely to be injurious to health or whose container releases any poisonous or deleterious substance rendering the contents injurious to health, or which bears or contains as an ingredient a substance other than the prescribed substance or with which any substance has been mixed or packed so as to reduce its quality or strength or for which any substance has been wholly or partly substituted is an adulterated drug.

According to the case of *Woodwards (Pakistan) Ltd. v. The State*,<sup>47</sup> the test report containing finding that sample was adulterated. Test report not found to be consistent with definition of the "adulterated drug". The test report not saying whether black particles found in test were of foreign matter. The report not saying that contents of sample were injurious to health or containing an ingredient or substance other than the prescribed substance. Negative remarks about standard of sample speaking only of physical

<sup>46</sup> P.T.D. Hdq. 30.03 P L D 1992 S /c 455.  
<sup>47</sup> P.T.D. Hdq. 30.03 P L D 1992 S /c 455.  
<sup>48</sup> 1985 P Cr.LJ 2064.



appearance and not of the equality. Physical appearance of contents not mentioned in the definition. Number and size of particles found in sample not given. The report found useless for comparison with specifications. The report not made on prescribed form No.8 and not fulfilling requirements of rule 16 of the Drugs (Federal Inspector, Federal Drug Laboratory and Federal Government Analysts) Rules, 1976. Such test report, was not admissible in evidence.

**Registered drug.**— A registered drug is one which has been registered according to the specified rules by the Registration Board set up by the Federal Government.

**Sub-clause (d)—Manufacture.**— The term "manufacture" includes packing, finishing and labelling of a drug. Workers founding labelling and packing of unregistered drug, would amount to "manufacture" for the purposes of the Drugs Act.<sup>49</sup>

Manufacture would include process of "packing" or "re-packing" of a drug.<sup>50</sup>

**Sub-clause (s)—Misbranded drug:** A drug which is not labelled in the prescribed manner is a misbranded drug. Similarly a drug on the label of which any word or statement is required by the Rules to appear but does not so appear or is not prominently placed with such conspicuousness, and in such terms as may render it likely to be read and understood by the ordinary individual under customary conditions of or purchase and use or which is not labelled with the directions for use and such warnings against use in cases where its use may be dangerous or against unsafe dosage or duration of administration or application or whose label or anything accompanying it bears any statement, design or device which makes any false or misleading claim or which is so coloured, coated, powdered, or polished, or as to conceal damage, or which is made to appear of letter or greater therapeutic value than it really is or which does not bear the name of the pharmacopoeia or document according to whose specifications it is manufactured is a misbranded drug.

A drug would be deemed as misbranded when such drug is not labelled in the prescribed manner or labelling of which is against the Rules or misleading or which is camouflaged to conceal damage, etc., or on which the name of the pharmacopoeia under the specifications of which the drug is manufactured is not mentioned.<sup>51</sup>

**Sub-clause (zb)—Spurious drug:** A drug which purports to be a drug but does not contain the active ingredient of that drug or which purports to be the manufacture of a person, place, or country whose product it is not in fact, or which is imported or exported or sold or exposed for sale under a name which actually does not fall within that name, or where label bears fictitious name of manufacturer or producer is a spurious drug.

According to the case of *Salim Siddiqui v. The State*,<sup>52</sup> the petitioner tried for manufacturing spurious drug. Analysis/test not carried out by the concerned Gazetted Government Analyst. The report of the Analyst other

than Gazetted Government Analyst was legally valueless and the complaint having no legal foundation. The accused acquitted of the charge.

**Sub-standard drug:** Sub-standard drug is a drug which does not conform to the specification or which is not of the identity, purity, and strength specified in Pharmacopoeias or other relevant documents.

Drugs manufactured by the respondents were declared by Analyst that the same although conformed to the stated specifications chemically; yet did not conform to the physical specifications being adulterated with particles and fibres. The High Court in Constitutional jurisdiction set aside Analyst's report, held: to hold the samples as spurious or adulterated drugs Analyst was required to have stated so, or to have declared the same as filthy, putrid or decomposed or to contain vermin, worm, rodent or insect or the same had been prepared under unsanitary conditions so as to be contaminated with dirt, filth or any foreign matter, whereby the same could have been rendered injurious to health. Definition of adulterated drug clearly laid down a test and a report which did not conform to the test provided by law could not be considered to be valid and legal report. Analyst's report in question, when considered within the meaning of the definition of spurious drugs, fell outside the category of that definition. Finding of the High Court in Constitutional jurisdiction was confirmed in the intra-Court appeal in circumstances.

**Strepsils:** "Strepsils" manufactured by the petitioners was a medicament and being a drug was exempted from sales tax. Strepsils lozenges was in fact a medicinal preparation within the meaning of the Drugs Act, 1976 and that being so, it could not be termed as sugar confectionery and as such could not be charged for the purposes of sales tax. Ministry of Health had uniformly pointed out that the Strepsils lozenges were used as a remedy for treatment of infections of the mouth and throat and a valuable adjunct to the systematic treatment of tonsils and other deep throat infections. Levy of sales tax were declared to be without lawful authority, of no legal effect and were quashed.<sup>53</sup>

## CHAPTER II

### Administration and Enforcement

4. **Regulation and prohibition of import, etc., of drugs:** (1). The Federal Government shall regulate the import and export of drugs in the prescribed manner and for that purpose may make such orders and issue such directions to the importers and exporters as it may deem fit.

(2) If in the opinion of the Federal Government the public interest so requires, the Federal Government may, by notification in the official Gazette,—

(a) direct that a drug or a class of drugs specified in the notification, or drugs generally, shall not be imported or

<sup>49</sup> 1983 P Cr LJ 401

<sup>50</sup> 1983 P Cr LJ 2491.

<sup>51</sup> P L D 1992 Kar. 347

<sup>52</sup> 1987 SCMR 2100

<sup>53</sup> 1992 M L D 481

<sup>54</sup> 1991 C L C Note 39.

exported otherwise than under the authority of a licence issued under this Act or except by an importer or exporter or through an indenter registered in accordance with the rules:

- (b) direct that a drug or class of drugs specified in the notification shall not be imported except by an agency of Government so specified; or
- (c) prohibit the import or export of any drug or class of drugs specified in the notification.

### COMMENTS

**Scope:** This section empowers the Federal Government to allow or disallow the import and export of drugs and if all need to do so in accordance with a prescribed manner and subject to directions as may be issued. The Federal Government may also direct that a licence would be required for the export or import of a certain drug or class of drugs or that as certain drug or class of drugs should not be imported or exported at all or that any drug or class of drugs shall be imported only by a specified agency of Government.

Import and export of Drugs is regulated by the Drugs (Import and Export) Rules, 1976, printed *infra*.

**5. Regulation of manufacture of drugs:** (1) The grant of licences to manufacture drugs shall be regulated in accordance with such conditions and procedure as may be prescribed, by a Central Licensing Board to be set up by the Federal Government and consisting of such representatives of the Federal Government and the Provincial Governments as may be prescribed.

(2) The members of the Central Licensing Board shall exercise such powers, including the powers of an Inspector, as may be prescribed.

(3) The Central Licensing Board shall make regulations to regulate the conduct of its business.

(4) Any member of the Central Licensing Board may, at any time, by writing under his hand addressed to the Federal Government, resign his office or shall vacate his office if the Federal Government, being of opinion that in the public interest it is necessary so to do, so directs.

(5) Subject to sub-section (4), a member of the Central Licensing Board shall hold office for the prescribed period.

### COMMENTS

**Scope:** This section regulates the manufacture of drugs. Manufacture of drugs requires a licence which will be issued subject to such conditions and procedure as may be prescribed by a Central Licensing Board set up by the Federal Government.

**Renewal of Licence-Refusal grounds un-suitable:** The renewal of a licence was refused on ground of un-suitability of building. Mere user of a portion of premises or building for residential purpose. Held does not render the same un-suitable for a Licensed premises and manufacturing place only required to be separate from residential place.<sup>75</sup>

**Interpretation of section—Presumption:** A manufacturer of drugs was prosecuted for offence under Section 27 of the Drugs Act, 1940 after a report had been received from the Government Analyst that drug was not of standard quality. No copy of the report was supplied, as required under Section 25(3) of the Act, to manufacturer. It was, therefore, contended that the manufacturer in the circumstances could not be prosecuted for offence under Section 27 of the Act. It was held, the effect of the second part of sub-section (3) of Section 25 of the Drugs Act, 1940 is only this that the report of the Government Analyst cannot be treated as conclusive evidence against the person, from whom the sample was taken, where no copy of the report was supplied to him. But under the first part of sub-section, there is presumption that the facts stated in the report are correct. This presumption, unless rebutted by contrary evidence, can be a sufficient basis for the conviction of the accused.<sup>76</sup>

**6. Regulation of sale of drugs:** The Provincial Governments shall regulate the sale of drugs in the prescribed manner and may for that purpose make such orders, and issue such directions to the importers, manufacturers, stockists, retailers or other dealers of drugs, as they may deem fit.

### COMMENTS

**Scope:** It may be noted that Section 4 regulates the import and export of drugs, Section 5 regulates the manufacture of drugs, while this Section 6 regulates the sale of drugs. The Federal Government may make such orders and issue such directions to importers, manufacturers, stockists, retailers or other dealers of drugs as it may deem fit in this regard.

**Criteria for issuance of Licence should have logical nexus with object of law:** Drug Act, 1976 is an independent enactment and has been promulgated for a specified purpose of regulating the sales etc. of the Drugs, therefore, to require a person to obtain licence under the said Act, for the sale of drugs that he should qualify an examination prescribed for a pharmacist would amount to negation of his fundamental right as guaranteed under Article 18 of the constitution. The criteria for prescribing terms and conditions for issuance of licence to regulate a trade or business should be such which has logical nexus with the object of the law.<sup>77</sup>

The provision of Rule 20, Punjab Drugs Rules, 1988, whereby any person who was not registered as a pharmacist under the Pharmacy Act, 1967 was debarred from entering upon trade or business of sale of drugs, was violative of the Fundamental Right under Article 18 of the Constitution guaranteed to a citizen to enter upon any lawful profession or business.<sup>78</sup>

<sup>75</sup> P.L.D. 1978 Lah. 445.

<sup>76</sup> P.L.D. 1967 Kar. 80.

<sup>77</sup> P.L.D. 1992 Lah. 415.

<sup>78</sup> P.L.D. 1992 Lah. 415.

7. **Registration of drugs:** (1) The Federal Government shall cause all drugs to be registered in accordance with such conditions and procedure as may be prescribed and for that purpose set up a Registration Board, consisting of such number of persons, possessing such qualifications, as may be prescribed.

*Explanation:* In this section, "drugs" means drugs which are in the finished form ready for use.

(2) The members of the Registration Board shall exercise such powers, including the powers of an Inspector, as may be prescribed.

(3) The Registration Board shall make regulations to regulate the conduct of its business.

(4) Any member of the Registration Board may, at any time, by writing under his hand addressed to the Federal Government, resign his office or shall vacate his office if the Federal Government, being of opinion that in the public interest it is necessary so to do, so directs.

(5) Subject to sub-section (4), the members of the Registration Board shall hold office for the prescribed period.

(6) The Federal Government shall, by notification in the official Gazette, fix the date after which no drug which is not registered shall be allowed to be exported, imported, manufactured, stored, distributed or sold.

(7) A person applying for the registration of a drug shall furnish such information in respect of the drug as may be prescribed, including information relating to its efficacy, safety, and quality, or as may be required by the Registration Board for the purpose of the evaluation of the drug.

(8) Single-ingredient drugs shall be registered generally by their generic names while compound drugs shall be registered generally by their proprietary names.

*Explanation:* In this sub-section,--

(a) "single-ingredient drugs" means drugs containing one active ingredient;

(b) "compound drugs" means drugs containing more than one active ingredient.

(9) The registration of a drug shall be subject to such conditions, if any, as the Registration Board may specify at the time of its registration.

(10) Where the Registration Board registers a drug, it shall inform the person applying for its registration and the Provincial Governments of its having done so and of the conditions subject to which it has been registered.

(11) If the Registration Board, on the basis of information received or an inquiry conducted by it, is of opinion that—

- (a) the registration of a drug was procured by fraud or misrepresentation ; or
- (b) the circumstances in which a drug was registered no longer exist ; or
- (c) there has been a violation of the conditions subject to which a drug was registered ; or
- (d) it is necessary in the public interest so to do;

the Registration Board may, after affording to the person on whose application the drug was registered an opportunity of showing cause against the action proposed to be taken, cancel or suspend the registration or specify any further conditions to which the registration shall be subject and inform such person and the Provincial Governments accordingly.

(12) The Provincial Governments shall take all such steps as may be necessary to ensure compliance with the conditions subject to which a drug is registered and to prevent the manufacture or sale of a drug—

- (a) which has not been registered ; or
- (b) the registration of which has been cancelled or stands suspended.

### COMMENTS

Application for registration of drug. Its rejection without issuing show-cause notice as required by rule 29(9) of Drugs (Licensing, Registering and Advertising) Rules, 1976. Illegal.<sup>59</sup>

Application for registration of drug "Zebtron Tablets" manufactured by applicant in accordance with British Pharmaceutical Codex, 1973. Its rejection on ground that dosage of drug was inconvenient for older children and its administration was not possible for very young children and that composition of drug was irrational. Not warranted.<sup>60</sup>

Certain steps in manufacture of unregistered drug being carried out in factory of accused immediately on day following cutoff date. Basically drug in question being manufactured by accused long before cut off date and even completion certificate in respect of whole consignment of such drug issued by Directorate of Inspection by that date. Offence committed by accused, held, technical in nature. Nominal fine of Rs.1,000 imposed, in circumstances.<sup>61</sup>

**Registration of Drugs:** Registration of drugs is not automatic but subject to fulfilment of specified conditions and satisfaction of Registration Board.<sup>1</sup>

The Federal Government has fixed 15th August, 1977 to be the date after which no drug which is not registered under the said Act would be allowed to be stored, distributed or sold.

Certain steps in the manufacture of unregistered drug being carried out in the factory of the accused immediately on day following cut-off date. Basically drug in question being manufactured by accused long before cut-off date and even completion certificate in respect of whole consignment of such drug issued by the Directorate of Inspection by that date. Offence committed by the accused was technical in nature, hence, Nominal fine of Rs. 1,000 was imposed, in circumstances.<sup>2</sup>

Application for registration of drug. Its rejection without issuing show-cause notice as required by rules 29(9) of Drugs (Licensing, Registering and Advertising) Rules, 1976. Illegal.<sup>3</sup>

### LIST OF DE-REGISTERED DRUGS

Notification No.S.R.O.1069 (1)/85, dated 24th October, 1985: Whereas in the opinion of the Registration Board the public interest so requires and in exercise of the powers conferred by clause (d) of sub-section (11) of Section 7 of the Drugs Act, 1976 the said Board is pleased to notify the list of drugs that have been de-registered from time to time.

Sl. No.	Regn.No.	Name of the Drug(s)	Name of Manufacturer	date
1.	2.	3.	4.	5.
1	003312	Nikethamide Drops.	M/s. Anglo French (Pak) Ltd., Karachi.	18-10-1984
2	003822	Vitamin A & D Capsules.	M/s. Scherer, Australia.	31-10-1984
3	003609	Surgical Silk Suture with or without Needles (4/0, 3/0, 2/0, 0.1, 2).	M/s. J. Primmer, W. Germany.	Do.
4	003610	Surgical Catgut with or without Needles (4/0, 3/0, 2/0, 0.1, 2).	M/s. J. Primmer, W. Germany.	Do.
5	002525	Seven Seas Cod Liver Oil.	M/s. British Cod Liver Oils, U.K.	Do.
6	002526	Seven Seas Cod Liver Oil Capsules.	Do.	Do.
7	002822	Silk Suture with or without Needles (4/0, 3/0, 2/0, 0.1, 2).	M/s. Ledelre, U.K.	Do.

<sup>1</sup> 1979 P Cr. LJ Note 6 at p 4.

<sup>2</sup> 1983 P Cr. LJ 401.

<sup>3</sup> NLR 1988 Civil Lah. 490.

8.	004123	Cod Liver Oil Capsules.	M/s. Takeda, Japan.	Do.
9	003585	Gentamycin sulphate Injection.	M/s. Shanghai Pharma, China.	5-11-1984
10.	004131	Kimotab Tablets.	M/s. Mochida, Japan.	Do.
11.	001849	Gentamycin Injection.	M/s. Dai Han Chong, Korea.	Do.
12.	004167	Chymotypsin Tablets	Do.	Do.
13.	001280	Catgut Plain with or without Needles (4/0, 3/0, 2/0, 0.1, 2, 3).	M/s. Euro Satures, W. Germany.	6-11-1984
14.	000814	Phisoex Cream.	M/s. Sterling, U.S.A.	11-11-1984
15.	000815	Weprowin Tablets.	Do.	Do.
16	002109	Phillips Gripe Medicine.	Do.	Do.
17.	002890	Fergon Tablets	Do.	Do.
18.	004098	Netroferol Plus Syrup.	Do.	Do.
19.	004099	Intergrin Capsules.	Do.	Do.
20.	004179	Izal Germicide.	Do.	Do.
21.	004513	Rocal Liquid.	Do.	Do.
22.	004600	Franel Syrup.	Do.	Do.
23.	002562	Fish Liver Oil Capsules.	M/s. Changhai Pharma, China	Do.
24.	001030	Theodrex Tablets	M/s. Riker, England.	20-10-1984
25	005124	Tandalgesic Capsules.	M/s. Caba-Geigy (Pak.) Ltd. Karachi.	18.9.1984.
26	000638	Irgapyrin Tablets	Do.	Do.
27.	001370	Tanderil Cream.	Do.	7-1-1985
28.	001014	Gentamycin Injection.	M/s. Dong Shin, Korea.	16-4-1985
29.	001180	Vitamin A & D Capsules.	M/s. Polfa, Poland.	12-2-1985
30.	002558	Tetracycline Eye Ointment.	M/s. Shanghai Pharma, China	5-2-1985
31.	000128	Bendryl Capsules.	M/s. Parke Davis & Co., Karachi.	31-3-1985
32.	000129	Taka-Combex Capsules	Do.	Do.
33.	000209	Elec Capsules.	Do.	Do.
34.	000207	Abdec Capsules.	Do.	Do.
35.	005309	Anethol Trithion Tablet.	M/s. Ferozsons, Nowshera.	26-6-1985
36.	007292	Vibramycin Paediatric Drops.	M/s. Pfizer Laboratories, Karachi.	14-7-1985
37.	000475	Terramycin Paediatric Drops.	Do.	Do.
38.	000502	Nardelazine Tablets.	M/s. Warner Lambert (Pak) Ltd., Karachi	16-7-1985
39.	000142	Peritrate S.A. Tablets.	M/s. Warner Lambert (Pak) Ltd., Karachi.	Do.
40	000144	Peritrate Tablets.	Do.	Do.

41.	000520	Isokin T. Forte Tablets.	Do.	Do.
42.	000334	B.G. Phos Elixr.	M/s. Merck Sharp & Dhome (Pak) Ltd., Karachi.	31-7-1985
43.	000307	Cyreneptadine Capsules.	S/R Do.	Do.
44.	000319	Indocid Suppositories.	Do.	Do.
45.	004547	Periactin Vita Tablets.	Do.	Do.
46.	001682	Prednisolone Tablets.	M/s. Merck Sharp & Dhome (Pak) Ltd., Karachi.	Do.
47.	000333	Injection Redisol.	Do.	Do.
48.	001605	Tetracycline Capsules.	Do.	Do.
49.	001606	Tetracycline Syrup.	Do.	Do.
50.	000316	Tryptanol Syrup.	Do.	Do.
51.	002815	Haemostate Tablets.	M/s. Consolidate Chemical Labs., Lahore.	25-8-1985
52.	002816	Haemostate Injection.	Do.	Do.
53.	001951	Haemostop Tablets.	M/s. The Schazo Laboratories Ltd., Lahore.	Do.
54.	001498	Styptobion Injection.	M/s. Marker Alkaloids, Quetta.	Do.
55.	001499	Styptobion Tablets.	Do.	Do.
56.	003985	Hepahionta Tablets.	Do.	Do.
57.	001939	Anaroxyl Tablets 25 mg.	M/s. Hormone Laboratories (Pak) Ltd., Karachi.	Do.
58.	001620	Guanimycin Suspension.	M/s. Glaxo Laboratories (Pak) Ltd., Karachi.	Do.
59.	001173	Phthalylsulphathiazole Tablets.	M/s. Polfa, Poland.	Do.
60.	000951	Intestine Euvornit Tablets.	M/s. Von Hyden, West Germany.	Do.
61.	001843	Alkaselzer Effervescent Tablets.	M/s. Miles Laboratories, Australia.	Do.
62.	005029	Pentafen Tablets.	M/s. ... Italy.	Do.
63.	005165	Heomex Tablets.	M/s. ... Laboratories, Karachi.	25-8-1985
64.	002767	Hemestine Tablets.	M/s. Pakistan Pharma ... Ltd. Karachi.	Do.
65.	003182	Noxyl Tablets.	... Works	Do.
66.	001115	Phthalylsulphathiazole Tablets.		Do.
67.	004259	Rutin Compound Tablets.	M/s. Reger, Karachi.	
68.	003230	Rutin K Tablets.	M/s. ... Mendoza, Karachi.	Do.

69.	002662	Femidol Tablets.	M/s. Lepetit, Italy.	Do.
70.	003385	Clotin Tablets.	M/s. Hakimsons Chemical Indus. Ltd., Karachi.	Do.
71.	003906	Rutin Compound Tablets.	M/s. Dosaco Laboratories, Lahore.	Do.
72.	005270	Kagulin C Tablets.	M/s. Geofman Pharmaceuticals, Karachi.	Do.
73.	004436	Lamofen Suspension.	M/s. Searle (Pak) Ltd., Karachi.	Do.
74.	003558	Phthalylsulphathiazole Tablets.	M/s. Medexport, USSR.	Do.
75.	004182	Rutin Compound Tablets.	M/s. Cyrus Pharma, Lahore.	Do.
76.	004749	Rutin Compound Tablets.	M/s. Harman Pharmaceutical, Lahore.	Do.
77.	006190	Intestopen Q.A. Tablets.	M/s. Sandoz (Pak) Ltd., Karachi.	9-9-1985
78.	000127	Adroxyd Tablets.	M/s. Parke Davis & Co., Karachi.	30-9-1985

**Drug "Fucidin Leo Interlullo gauze" registered as drug, being not exempt was liable for Customs duty & Sales Tax:** It is not disputed that the "Fucidin Leo Interlullo gauze" is a drug within the meaning of Section 3 (g) of the Drugs Act XXXI of 1976, and is also registered as a drug under Section 7 of the said Act, but the mere registration of substances, mixtures, powders, solutions, bandages, agents devices as "drugs" under the Drugs Act or any other substances which the Federal Government may by notification in the official Gazette declare to be "drug" for the purposes of that Act, does not mean that in the classification of medicaments (including veterinary medicaments) as given in heading 30.03 of the Pakistan Customs Tariff all what comes under the definition of "drug" under the Drugs Act, 1976, will stand included. The classification of drugs for the purposes of the Pakistan Customs Tariff is totally different.<sup>65</sup>

**Registration of a Drug under Drugs Act, 1976, cannot exempt from claim under Patent Act:** The contention that the drug has been registered under Drugs Act, 1976 and registration certificate under Section 7 of the Act has been issued by the Ministry of Health. Held, mere cannot immunise the defendants against claims of aggrieved parties under the Patents and Designs Act, 1911.<sup>66</sup>

**8. Pakistan National Formulary:** The Federal Government shall compile and publish in the official Gazette Pakistan National Formulary comprising all drugs allowed to be imported, manufactured or sold and such Formulary may be reviewed and modified from time to time.



(6) The Provincial Quality Control Board may entrust any of its powers or functions under sub-section (5) to any one or more of its members.

### COMMENTS

No prosecution could be launched without the permission of the Quality Control Board. Permission for prosecution should not be given by the Board in the presence of the negative report of laboratory.<sup>69</sup>

Sanction for prosecution granted by Board without issuing show-cause notice to accused manufacturer would be violative of requirement of rule 4(3)(4). Complaint lodged before Drugs Court, on basis of such illegal sanction would be null and void. Such violation of rule 4(3)(4) is a serious illegality and not merely an omission with result that inception of proceedings before Drugs Court on basis of such sanction/complaint would stand invalidated and nullified. Accused manufacturer in such case would be entitled to discharge by Drugs Court in exercise of its powers u/s. 265K, Cr.P.C.<sup>70</sup>

**12. Power to fix maximum prices of drug, etc.:** (1) The Federal Government may, by notification in the official Gazette,--

- (a) fix the maximum price at which any drug specified in the notification <sup>71</sup>[shall be sold or imported]; and
- (b) specify a certain percentage of the profits of manufacturers of drugs which shall be utilised, in accordance with the rules for purposes of research in drugs.

(2) For the purpose of the exercise of its powers under sub-section (1), the Federal Government may require a manufacturer, stockist, importer, exporter, retailer or other dealer in drugs to furnish such relevant information as may be necessary.

(3) The Federal Government may, by notification in the official Gazette, delegate any of its powers under this section to any Board or other authority.

**13. Directions to Provincial Governments:** The Federal Government may give such directions to a Provincial Government as may appear to the Federal Government to be necessary for carrying into execution in the Province of any of the provisions of this Act or of any rule or order made thereunder or for maintaining supplies of drugs of standard quality at reasonable price or for the achievement of uniformity in respect of any matter in different parts of Pakistan.

**14. Federal Drugs Laboratory and institutes, etc.:** The Federal Government shall, as soon as may be, establish a Federal

<sup>69</sup> 1989 P Cr. LJ 566.

<sup>70</sup> NLR 1994 CrLJ. 848.

<sup>71</sup> Subs. for the words "is to be sold" by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998.



Drug Laboratory and may also set up such other institutes and drugs testing and research laboratories for the purposes of this Act as may be prescribed.

**15. Provincial Drugs Testing Laboratory:** Each Provincial Government shall, as soon as may be, set up a Provincial Drugs Testing Laboratory for such purposes as may be prescribed.

### COMMENTS

Anti-Narcotics Force is discharging very onerous duty but it does not mean that it should be allowed to play with rights and liberty of citizens. Arguments as to misuse of phenobarbitone are beyond competence of ANF. It would be actionable under Drugs Act, 1976 and not under ANF Act, 1996. Proceedings against petitioners are illegal, unwarranted and clearly abuse of process of Court. This Court is proposing action against concurred officials of ANF but if in future, this attitude continued then responsible officials have to suffer consequences of their illegal acts. Upshot of this discussion is that if this petition is accepted, Proceedings quashed, petition accepted.<sup>72</sup>

**16. Government Analysts:** The Federal Government or a Provincial Government may, by notification in the official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications to be the Federal Government Analysts or, as the case may be, Provincial Government Analysts <sup>73</sup>[\*\*\*\*\*].

Provided that no person who has any financial interest in the manufacture, import, export or sale of drugs shall be so appointed.

Provided further that a person serving under the Federal Government or another Provincial Government shall not be so appointed without the previous consent of that Government.

### COMMENTS

Government Analyst exercise power u/s. 16 only with regard to those drugs which are specifically mentioned in notification of his/her appointment. Words "such" and "classes" in S.16 restrict exercise of power by Government Analyst.<sup>74</sup>

Test reports in case for violation of Drugs Act, cannot become an authentic proof regarding conclusion drawn by Government Analyst. Question of issuing false warranty would fall through in event of non-substantiation of reported drugs to be not of standard quality.<sup>75</sup>

<sup>72</sup> 1999 P.Cr.R. 4

Omitted the words comma and words "and in respect of such drugs or classes of drugs as may be specified in the notification;" by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998.

<sup>74</sup> NLR 1989 TD 378.

<sup>75</sup> NLR 1989 TD 378.



Authority of Government Analyst to examine drugs is restricted only to those drugs which are specifically mentioned in his appointment notification itself. This interpretation of S.16 is supported by reference to qualificatory words "such" and "classes" as to scope of expressions "areas" and "classes".<sup>76</sup>

**Scope:** This section is not *ultra vires* the provisions of the Constitution as it has sufficiently, protected the basic right of an accused to defend himself.<sup>77</sup> (Under the section it is open to the accused to rebut to report of the analyst and the Court to reject the report when it is satisfied with the rebuttal).

The report itself when it embodies the protocols of tests applied by the analyst would become conclusive evidence of the results therein.<sup>78</sup> (The official statement or account which is the description of the experiment or clinical report is the protocol of test within the meaning of R.5 of the Drugs Rules.)

A report of the Analyst which simply states the result of the test but does not give the protocols at all is not conclusive evidence of the facts stated in it.<sup>79</sup> Failure to give the protocol would seriously prejudice the accused in his defence and hence his conviction cannot be sustained.<sup>80</sup> Report not containing factual data cannot be treated as conclusive evidence.

The report of the analyst becomes conclusive only when it has not been challenged according to the procedure prescribed in the section.<sup>81</sup>

Requirement about appointment of a person as Drug Inspector is mandatory. Proceedings from stage of taking test upto filing of complaint by a person who is not notified as Drug Inspector would be unwarranted.<sup>82</sup>

Positive report of Government Analyst which does not conform with requirements of S. 16 and Rules 15, 16, cannot be relied upon and cannot be used as evidence in case against him.<sup>83</sup>

**Chemical Examiner's opinion—Evidentiary value:** The Chemical Examiner's opinion is sought for the aid and assistance of the Court. Court is, however, competent to disbelieve such report if no plausible reasons have been put forth by the expert in support of his opinion.<sup>84</sup>

**17. Inspectors:** The Federal Government or a Provincial Government may, by notification in the official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Federal Inspectors or, as the case may be, Provincial Inspectors for the purposes of this Act within such local limits as it may assign to them respectively:

Provided that no person who has any financial interest in the manufacture, import, export or sale of any drug shall be appointed:

76 NLR 1989 TD 189.  
77 AIR 1958 All 865.  
78 AIR 1959 Cal. 427.  
79 AIR 1959 All 634.  
80 AIR 1958 All 865.  
81 NLR 1993 CrLJ 102.  
82 NLR 1993 CrLJ 102.  
83 P.L.D. 1992 Quetta 67.

Provided further that a person serving under the Federal Government or another Provincial Government shall not be so appointed without the previous consent of such Government.

### COMMENTS

Expression "local limits" used in S.17 means a particular and not country as a whole. Appointment of persons as Federal Drug inspectors for whole of Pakistan is not contemplated by S.17 read with rule 4(1)(a).<sup>84</sup>

Record showing no order of appointment of the Drugs Inspector having been produced before the trial Court at all and Notification issued in this behalf not indeed a notification as stipulated by Section 17 of the Act. Since no prosecution can be instituted except by a properly appointed Drug Inspector, conviction and sentence awarded to appellant, were set aside, in circumstances.<sup>85</sup>

Complaint lodged by Inspector whose notified appointment did not conform with Section 17. The recovery not witnessed by two respectable persons of locality as required by Section 103, Cr.P.C. Circumstances not suggesting any probability of accused being convicted of any offence in the long run. The Drug Court accepting accused's application under Section 149-A Cr.P.C. and ordering their acquittal.<sup>86</sup>

Requirement about appointment of a person as Drug Inspector is mandatory. Proceedings from stage of taking test upto filing of complaint by a person who is not notified as Drug Inspector would be unwarranted.<sup>87</sup>

**Drug Inspector not notified effect:** Prosecution for offences under Section 23(1), (b), 23(1)(a) (vii) launched by an Inspector who is not notified within meaning of Section 17 should not be allowed to sustain, such prosecution being incompetent under Section 30.<sup>88</sup>

**Requirement of Drug/Inspector:** Requirement about appointment of a person as Drug Inspector is mandatory proceedings from stage of taking test upto filling of complaint by a person who is not notified as Drug Inspector would be unwarranted.<sup>89</sup>

A notification appointing all District Medical Officers as inspectors under the Act can be in general terms. Failure to state in the Notification that such Medical Officer should possess qualifications laid down in the rules will not render the notification invalid.<sup>90</sup>

An officer of the Public Health Department who is also a registered medical practitioner can be appointed as *ex officio* inspector for the purposes of inspecting retail shops. Such an appointment is justified by R 49, Proviso

84 NLR 1989 TD 189.  
85 1982 P Cr.LJ 48.  
86 NLR 1985 Cr.LJ 264.  
87 NLR 1993 CrLJ 102.  
88 1984 Cr.L.J. 492.  
89 N.L.R. 1993 Cr.L.J. 102(a).  
90 1955 All. WR (HC) 328.  
91 A.I.R. 1958 All. 163.

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**Drug Inspector appointment improper—Sentence set aside:** Record showing no order of appointment of Drug Inspector having been produced before Trial Court at all and Notification issued in this behalf not indeed a notification as stipulated by Section 17 of Act. Since no prosecution can be instituted except by a properly appointed Drugs Inspector, Conviction and sentence awarded to appellant, set aside in circumstances.<sup>94</sup>

**18. Powers of Inspectors:** (1) Subject to the provisions of Section 19 and of any rules made in this behalf, an Inspector may, within the local limits for which he is appointed, and in any other area within the permission of the licensing authority,—

- (a) inspect any premises wherein any drug is manufactured, the plant and process of manufacture, the means employed for standardising and testing the drugs and all relevant records and registers;
- (b) inspect any premises wherein any drug is sold or is stocked or exhibited for sale or is distributed, the storage arrangements and all relevant records and registers;
- (c) take samples of any drug which is being manufactured, or being sold or is stocked or exhibited for sale or is being distributed;
- (d) enter and search, with such assistance, if any, as he considers necessary, any building, vessel or place, in which he has reason to believe that an offence under this Act or any rules has been or is being committed or may continue to be committed;
- (e) call any person to be present as witness in the course of search or seizure or in connection with any other matter where the presence of witnesses is necessary;

92 1982 P. Cr. L.J. 48  
93 N.L.R. 1985 Cr. L.J. 264  
94 1982 P. Cr. L.J. 48

- (f) seize such drug and all materials used in the manufacture thereof and any other articles, including registers, cash memos, invoices and bills, which he has reason to believe may furnish evidence of the commission of an offence punishable under this Act or any rules;
  - (g) require any person to appear before him at any reasonable time and place to give statement, assistance or information relating to or in connection with the investigation of an offence under this Act or the rules;
- Provided that the exemptions under Sections 132 and 133 of the Code of Civil Procedure, 1908 (Act V of 1908), shall be applicable to requisitions for attendance under this Clause;
- (h) lock and seal any factory, laboratory, shop, building, store-house or godown, or a part thereof, where any drug is or is being manufactured, stored, sold or exhibited for sale in contravention of any of the provisions of this Act or the rules;
  - (i) forbid for a reasonable period, not exceeding four weeks or such further period, which shall not be more than three months, as the Inspector may, with the approval of the Provincial Quality Control Board, the Central Licensing Board, the Registration Board, or the licensing authority, as the case may be, specify, any person in charge of any premises from removing or dispensing of any drug, article or other thing likely to be used in evidence of the commission of an offence under this Act or the rules; and
  - (j) exercise such other powers as may be necessary for carrying out the purposes of this Act or any rules;

Provided that the powers under clauses (f) to (j) shall be exercisable only by an Inspector specifically authorised in this behalf, by an order in writing, by the Government appointing him, subject to such conditions as may be specified in such order:

Provided further that the power under clause (h) may be exercised by an Inspector not authorised as aforesaid where the contravention is of a provision which requires a licence to be obtained for the manufacture, storage or sale of a drug.

(2) The provisions of the Code of Criminal Procedure, 1898 (Act V of 1898), in so far as they are not inconsistent with the provisions of this Act, shall apply to searches and seizures made under this Act.

## COMMENTS

**Powers of Inspectors:** The duties entrusted to the Inspectors conveniently called "Inspectors for the purpose of inspection of retail shops"

cover a wider range than mere inspection of retail shops. Such an Inspector can, therefore, search any premises (such as the dwelling house and not only the retail shop) in order to detect any sale of drugs in contravention of the Act.

Powers of search and seizure given to the Drugs Inspectors under Section 18 (1) is not restricted to such officers. Searches and seizures in respect of offences under Section 27 (1), could also be made by the Police Officers. Police Officers in such cases, was not required to follow procedure laid down in Section 19 but to follow procedure prescribed under the Code of Criminal Procedure, 1988, Section 109.

**Sanction of competent authority—Violation of licensing conditions—Sealing of premises:** Shop sealed by the Drugs Inspector for violation of licensing conditions for more than four weeks. Effect of no sanction from competent authority obtained for sealing premises beyond four weeks sealing of premises beyond four weeks, was in contravention of provision Section 18-H (1) and without lawful authority. Premises ordered to be desealed in circumstances.

**Effect of repeal:** Object of enacting Section 6 of the General Clauses Act is to protect rights and liabilities already accrued or incurred under repealed law. Drugs Act of 1976, while repealing Act of 1940, not providing a saving clause. Complaint not made regarding alleged offence under Section 18 of Act of 1940 before repeal of Act was a vested right or liability as envisaged under Section 6, could not be deemed to have accrued for enforcing same under the repealing enactment.

Sample of drugs was submitted by the Inspector of Drugs to Government Analyst for test and analysis. Report of the analyst was not received within the prescribed period of sixty days and necessary permission of the Quality Control Board not obtained for extension of time and Inspector was not communicating about submission of testing method to manufacturers. Report was received after prescribed period, not conclusive and the Drugs Analyst committed violation of relevant provision of law by submitting report without obtaining extension of time from the Board.

Recovery effected in derogation of provisions of S. 103 Cr P.C. cannot be used in support of prosecution case.

**19. Procedure for Inspectors:** (1) Where an Inspector seizes any drug of any other article under Section 18, he shall tender a receipt therefor in the prescribed form.

(2) Where an Inspector takes a sample of a drug for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he wilfully absents himself, shall divide the sample into four portions and effectively seal and suitably

mark the same and permit such persons to add his own seal, if any, and mark to all or any of the portions so sealed and marked:

Provided that, where the sample is taken from premises whereon the drug is being manufactured, it shall be necessary to divide the sample into three portions only:

Provided further that, where the drug is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the drug be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary, sealing them:

Provided further that if the contents of one container are insufficient for the laboratory test and analysis, the Inspector may increase the number of the containers in order to make the sample sufficient for this purpose.

(3) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same within <sup>(1)</sup>[forty eight hours] as follows:--

- (i) one portion of sample he shall send to the Government Analyst concerned for test and analysis;
- (ii) the second he shall send to the Chairman, Provincial Quality Control Board or the Central Licensing Board or the Registration Board, as the case may be; and
- (iii) the third, where taken, he shall send to the warrantor, if any, named under the proviso to sub-section (3) of Section 32.

(4) Where an Inspector seizes any drug containing any filthy or putrid substance, vermin, worm, rodent, insect or any foreign matter which is visible to the naked eye, and the sample is such that it cannot or need not be divided, he shall effectively seal and suitably mark the same and permit the person from whom he seizes the drug to add his own seal, if any, and mark to it and shall produce the same before the Drug Court or the Central Licensing Board or the Registration Board, as the case may be, before which proceedings are instituted or action is initiated in respect of the drug.

(5) Where an Inspector takes any action under section 18 he shall, as soon as possible inform the Board concerned or its

95 A.R 1958 All 163.  
96 1979 P Cr LJ Note 6 at p.4.  
97 1988 P Cr LJ 1328.  
98 PLD 1980 Lah.195.  
99 1984 P Cr LJ 1580.  
NLR 1993 CrLJ 102.

<sup>(1)</sup> Subs. for the words "seven days" by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998.

<sup>(2)</sup> Subs. "sub-section (5)" by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998. The original text is as under:-

Chairman and take order as to the custody of the stocks of the drug seized by him:

Provided that where a Federal Inspector is not competent to take action under section 30, he shall as soon as may be report the matter and hand over the stock, if any, to the Provincial Inspector for further action under this Act.]

(6) The Provincial Inspector on finding any contravention of this Act shall, unless the Board otherwise directs, always refer the case to the Provincial Quality Control Board and seek orders as to the action to be taken in respect of such contravention.

(7) The Federal Inspector on finding any contravention of this Act for which he is authorised shall, unless otherwise directed, always refer the case to the Central Licensing Board or the Registration Board or any other authority as may be specified for the purpose and seek any further orders as to the action to be taken in respect of such contravention.

### COMMENTS

Analysis of drug. Sample of drug submitted by Inspector of Drugs to Government Analyst for test and analysis. Report of analyst not received within prescribed period of sixty days and necessary permission of Quality Control Board not obtained for extension of time and Inspector not communicating about submission of testing method to manufacturers. Report received after prescribed period. Held, not conclusive and Drugs Analyst committed violation of relevant provision of law by submitting report without obtaining extension of time from Board.<sup>104</sup>

The accused was charged for offence of the manufacturing drugs without obtaining registration of such drugs in the name of firm. Action was initiated against firm only within half an hour of expiry of date for the manufacture of drugs without registration and possibility that workers were cleaning machines when premises raided was not ruled out. Seizure of drugs also not strictly in accordance with law as no receipt after seizure passed on

(5) Where an Inspector takes any action under Section 18,--

(a) he shall as soon as practicable ascertain whether or not the drug contravenes any of the Provisions of this Act and, if it is ascertained that the drug does not so contravene, he shall forthwith revoke the order passed under the said section or, as the case may be, take such action as may be necessary for the return of the stock seized and payment for the samples taken, under intimation to the Board concerned;

(b) if he seizes the stock of the drug he shall, as soon as may be, inform the Board concerned and take its order as to the custody thereof:

Provided that where a Federal Inspector is not competent to take action under Section 30, he shall as soon as may be, report the matter and hand over the stock, if any, to the Provincial Inspector for further action under this Act.

<sup>104</sup> 1984 P. Cr. L. J. 1580.

to accused in the prescribed form as required by Section 19 of the Drugs Act. All preparations to raid premises complete before mid-night of the date when firm still was within the permissible limits of the manufacturing drugs without registration. Deliberate efforts were made to harass the accused in circumstances. The conviction and sentence were set aside.<sup>104</sup>

Directions in regard to making and submission of test reports, held, not directory but mandatory and the Drug Court could not convict accused if directions not strictly observed and reports not submitted in the prescribed manner.<sup>105</sup>

Registration of case. Drug Inspector should make a report against contravention of Act to Provincial Quality Control Board for initiating criminal action. Case for contravention of Act, cannot be registered at Police Station on report of Drug Inspector.<sup>106</sup>

Search and seizure, *bona fides* of. Evidence, appreciation of. Accused charged for offence of manufacturing drugs without obtaining registration of such drugs in name of firm. Action initiated against firm only with half an hour of expiry of date for manufacture of drugs without registration and possibility that workers were cleaning machines when premises raided not ruled out. Seizure of drugs also not strictly in accordance with law as no receipt after seizure passed on to accuse in prescribed form as required by s. 19 of Drugs Act, 1976. All preparations to raid premises complete before mid-night of date when firm still within permissible limits of manufacturing drugs without registration. Deliberate efforts, held, made to harass accused, in circumstances. Conviction and sentence set aside.<sup>107</sup>

20. **Persons bound to disclose place where drugs are manufactured or kept:** Every person for the time being in charge of any premises whereon any drug is being manufactured or is kept for sale or distribution shall, on being required by an Inspector so to do, disclose to the Inspector the place where the drug is being manufactured or is kept, as the case may be.

21. **Disclosure of the name of the manufacturer:** Every person, not being the manufacturer of a drug or his agent for the distribution thereof, shall if so required by an Inspector, disclose to him the name, address and other particulars of the manufacturer or other person from whom he acquired the drug.

22. **Reports of Government Analysts:** (1) The Government Analyst to whom a sample of any drug has been submitted for test and analysis under sub-section (3) of Section 19 shall deliver to the Inspector submitting it a signed report in quadruplicate in the prescribed form and forward one copy thereof to the authority as may be prescribed.

(2) The Government Analyst, as far as may be, shall submit the report referred to in sub-sec. (1) within sixty days of the receipt

<sup>104</sup> 1982 P. Cr. L. J. 175.

<sup>105</sup> 1985 P. Cr. L. J. 281.

<sup>106</sup> 1996 P. Cr. L. J. 414.

<sup>107</sup> 1982 P. Cr. L. J. 175.

by him of the sample of the drug and, if he is not able to do so for reasons beyond his control, shall communicate the reasons to the Inspector in writing and shall endorse its copy to the Board concerned who shall have the sample tested from the same or any other Government Analyst or a Government Drug Testing Laboratory or any other Laboratory and shall ensure the receipt of results of such test and analysis within a further period as may be prescribed and shall make the test report available to the Inspector for further action.

(3) On receipt of the report, the Inspector shall—

- (a) deliver one copy thereof to the person from whom the sample was taken;
- (b) forward one copy to the warrantor, if any, named under the proviso to sub-section (3) of Sec.32;
- (c) forward one copy to the Board concerned for its directions as to the action to be taken on the report; and
- (d) retain the fourth copy for use in any prosecution or for any other purpose.

(4) Notwithstanding anything contained in any other law for the time being in force, any document purporting to be a report signed by a Government analyst shall be admissible as evidence of the facts stated therein without formal proof and such evidence shall be conclusive unless the person from whom the sample was taken or the said warrantor has, within <sup>100</sup>[seven] days of the receipt of a copy of the report notified in writing to the Inspector or the Drug Court or, as the case may be, the Central Licencing Board or the Registration Board <sup>101</sup>[or the Provincial Quality Control Board or such other Authority as may be prescribed for this purpose] before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.

(5) Where a person has, under sub-section (4), notified his intention of adducing evidence in controversion of a Government Analyst's report, the Drug Court or <sup>102</sup>[as the case may be, the Central Licensing Board, the Registration Board, the Provincial Quality Control Board or such other Authority as may be prescribed for this purpose] may, of its own motion or in its discretion at the request either of the complainant or the accused, cause the sample of

<sup>100</sup> Subs. for the word "thirty" by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998.

<sup>101</sup> Inserted the words by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998.

<sup>102</sup> Subs. for the words "the Board concerned" by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998.

the drug lying with the Board concerned under sub-section (3) of Section 19 to be sent for test or analysis to the Federal Drug Laboratory or any other laboratory specified for the purpose by the Federal Government which shall make the test or analysis and report in writing signed by, or under the authority of, the person for the time being incharge of the Federal Drug Laboratory, or, as the case may be, such other laboratory, the result thereof and such report <sup>103</sup>], within thirty days of the receipt of the sample] shall be conclusive evidence of the facts stated therein.

(6) The cost of a test or analysis made by the Federal Drug Laboratory or other laboratory under sub-section (5) shall be paid by the complainant or accused as the Drug Court or the Board concerned shall direct.

## COMMENTS

**Interpretation of section—Presumption:** A manufacturer of drugs was prosecuted for offence under Section 27 of the Drugs Act, 1940 after a report had been received from the Government Analyst that the drug was not of standard quality. No copy of the report was supplied, as required under Section 25 (3) of the Act, to manufacturer. It was, therefore, contended that the manufacturer in the circumstances, could not be prosecuted for offence under Section 27 of the Act. It was held that the effect of the second part of sub-section (3) of Section 25 of the Drugs Act, 1940, is only this that the report of the Government Analyst cannot be treated as conclusive evidence against the person, from whom the sample was taken, where no copy of the report was supplied to him. But under the first part of the sub-section there is presumption that the facts stated in the report are correct. This presumption, unless rebutted by contrary evidence, can be a sufficient basis for the conviction of the accused.<sup>112</sup>

**Substandard drugs:** Record not showing that after purchasing drugs from manufacturer whether the same were stored under the conditions laid down or stated on carton. Reasonable possibility of sample obtained by the Drug Inspector and subsequently sent to the National Health Laboratory having been deteriorated due to its improper storage after purchase from the manufacturers not ruled out. Accused, held, entitled to the benefit of doubt. Conviction and sentence were set aside.<sup>113</sup>

**Mere non-compliance with section does not make report inadmissible:** Sub-section (2) of Section 25 of the Drugs Act, 1940 requires that a copy of the report of the Government Analyst shall be delivered to the person from whom the sample is taken and another copy to the warrantor, if any, named under the proviso to sub-section (3) of section 19. Then comes sub-section (3) which makes the report evidence of the facts stated therein and furthermore makes it conclusive "unless the person from whom the sample was taken or the said warrantor has, within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court,

<sup>111</sup> Inserted the words by Drugs (Amendment) Ordinance XXII of 1998, dated 23.12.1998.

<sup>112</sup> PLD 1967 Kar.80.  
<sup>113</sup> 1985 P Cr. LJ 281.



before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report". It will thus be seen that the contents of the report not only prove themselves but are also considered to be conclusive unless objection is made. Sub-section (3) of Section 25 provides the consequence of non-compliance with the provisions of sub-section (2) of the said section. Thus, if no report is supplied all that happens is that the contents of the report do not become conclusive evidence; but they are nevertheless evidence and rebuttable at the stage of the trial. This does not mean that at the trial the contents of the report cannot be utilised as evidence. The intention of the legislature appears to be to merely give an adequate opportunity to the person charged to challenge the correctness of the report. If this has not been done, then the contents of the report become conclusive evidence. If any event, the provisions are clear and leave no room for doubt that if the copy of the report is not supplied to the accused, the report is, nevertheless, admissible in evidence and proves itself but its contents are not conclusive evidence. On the other hand, if a copy has been supplied and the appellant does not raise any objection within the time prescribed, then the report becomes conclusive evidence and cannot even be rebutted.<sup>114</sup>

Report of Public Analyst did not complete with "full protocols of tests" and silent as to how he arrived at conclusion regarding low percentage of tetracycline hydrochloride in sample. Order of the trial Court rejecting application for summoning Public Analyst as witness was set aside, in circumstances. Court further directed to summon witness to produce full Protocols of tests, in the interest of justice.<sup>115</sup>

Accused failed to challenge the Government Analyst's report within statutory period of 30 days by notifying to any of the authorities specified in sub-section (4) of Section 22 of the Act, regarding their such intention. Report was conclusive proof of its contents. Contention that report being silent about full protocols was of no consequence.<sup>116</sup>

Potency and the state of certain drugs, was depended to some extent upon conditions in which they were required to be stored and had actually been stored prior to test by the concerned laboratory.<sup>117</sup>

Analyst submitting his report beyond the period prescribed by law without obtaining extension from the Quality Control Board. Drug Analyst committed violation of provisions of law and report sent by him not in the prescribed form.<sup>118</sup>

**Appeal against acquittal:** The accused respondents had a right to request for retesting of samples and Section 22(5) of the Drugs Act, 1976, makes it compulsory for prosecution to send the samples for retesting to the Federal Drugs Laboratory or any other laboratory specified for the purpose by the Federal Government. The accused had not given up their such request and their right could not be brushed aside on basis of their letters which did not amount to unconditional admission of guilt as provisions of law have to be strictly followed. Letters were addressed to the Provincial Quality Control Board and not to proper quarters. The trial Court, held, had rightly given

<sup>114</sup> PLD 1973 SC 299.

<sup>115</sup> 1977 P Cr. LJ 822.

<sup>116</sup> 1984 P Cr. LJ 2007.

<sup>117</sup> 1984 P Cr. LJ 1580.

<sup>118</sup> 1985 P Cr. LJ 281.

benefit of doubt to the accused in view of clear violation of Section 22(5) of the Drugs Act, 1976. Appeal against the acquittal was dismissed in circumstances.<sup>119</sup>

Finding of the Drugs Court that test report was not according to law was correct. Drugs Court had also rightly concluded that the said report would not be conclusive as provided under Section 22(4) of the Drugs Act. Provincial Quality Control Board had sent the sample for re-testing in contravention of sub-sections (4) and (5) of Section 22 of the Drugs Act and as such second report was illegal under such circumstances appeal against the acquittal of the accused was dismissed.<sup>120</sup>

After an accused has secured acquittal from a Court, the Appellate Court will not interfere until prosecution shows conclusively that inference of guilt is irresistible and indications of error in the judgment are clear and evidence more cogent and convincing in support of prosecution case is available.<sup>121</sup>

## CHAPTER III

### Prohibitions

**23. Import, Manufacture and sale of drugs :** (1) No person shall himself or by any other person on his behalf—

- (a) export, import or manufacture for sale or sell:
  - (i) any spurious drug;
  - (ii) any <sup>122</sup>[imitation product];
  - (iii) any misbranded drug;
  - (iv) any adulterated drug;
  - (v) any substandard drug;
  - (vi) any drug after its expiry date;
  - (vii) any drug which is not registered or is not in accordance with the conditions of registration;
  - (viii) any drug which, by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed;
  - (ix) any drug if it is dangerous to health when used in the dosage or with the frequency, or, for the duration

<sup>119</sup> 1990 P Cr. L.J. 865.

<sup>120</sup> 1991 P Cr. L.J. 1363.

<sup>121</sup> 1991 P Cr. L.J. 1363.

<sup>122</sup> Subs. for the words "counterfeit drug" by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998.



specified, recommended or suggested in the labelling thereof; or

- (x) any drug in contravention of any of the provisions of this Act or any rule;
- (b) manufacture for sale any drug except under, and in accordance with the conditions of, a licence issued under this Act;
- (c) sell any drug except under, and in accordance with the conditions of, a licence issued under this Act;
- (d) import or export any drug the import or export of which is prohibited by or under this Act;
- (e) import or export any drug for the import or export of which a licence is required, except under, and in accordance with the conditions of, such licence;
- (f) supply an incorrect, incomplete or misleading information, when required to furnish any information under this Act or the rules;
- (g) peddle, hawk or offer for sale any drug in a park, or public street or on a highway, footpath or public transport or conveyance;
- (h) import, manufacture for sale, or sell any substance, or mixture of substances, which is not a drug but is presented in a form or a manner which is intended or likely to cause the public to believe it to be a drug;
- (i) sell any drug without having a warranty in the prescribed form bearing the name and batch number of the drug issued.--
  - (i) in the case of a drug manufactured in Pakistan by the manufacturer holding a valid licence to manufacture drugs and permission to manufacture that drug or by his authorised agent;
  - (ii) in the case of an imported drug, by the manufacturer or importer of that drug or, if the drug is imported through an indenter by such indenter; \*\*\*
- (j) apply an incorrect batch number to a drug<sup>124</sup>; and

<sup>124</sup> Omitted the word "and" by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998.

<sup>125</sup> Subs. for the word "full stop" and added "new clause (k)" by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998

(k) sell or import a drug above the maximum price fixed under this Act on which the drug shall be sold or imported

(2) Nothing in sub-section (1) shall apply to the manufacture or subject to prescribed conditions, of small quantities or any drug or the purpose of clinical trial, examination, test, analysis or personal use.

### COMMENTS

Constitutional petition. Quashing of F.I.R. Criminal case under S. 23/27 of the Drugs Act, 1976 could not be registered without the prior permission of the Quality Control Board set up under S. 11 of the Drugs Act, 1976 which had not been obtained by the Drug Inspector. Proceedings initiated against the accused, in the absence of their permission of the Competent Authority, were coram non judge, based on mala fides and without lawful authority. F.I.R. was quashed in circumstances and the Constitutional petition was accepted accordingly.<sup>125</sup>

Substandard drugs. Prosecution. No prosecution launched against company which manufactured drugs in question. Accused not shown to be acting as Agent of company for distribution of substandard drugs. In absence of company, accused, held, could not be prosecuted. Liability of manufacturer of drugs and his agent for distribution thereof would be co-extensive.<sup>126</sup>

Complaint by Federal Drug Inspector against manufacturer for manufacture of spurious drug within meaning of S.23(1)(a)(i) and substandard drug within meaning of S.23(1)(a)(v), would be incompetent in view of provisions of S.30 which does not provide for contravention of S.23(1)(a)(i)(v).<sup>127</sup>

Offence relating to manufacture of spurious or substandard drugs, would not be cognizable on basis of incompetent complaints by Federal Drug Inspector and defective reports by Government Analyst.<sup>128</sup>

Complaint against accused company for manufacture and sale of substandard drugs. Offence of manufacturing and sale of drugs allegedly committed at Karachi. Accused-company moving application u/s. 249-A, Cr.P.C. for their acquittal on ground that Drug Court (Punjab) had no territorial jurisdiction. Drug Court finding that offence if any committed by accused-company with regard to drug being substandard was allegedly committed at Karachi and not within its territorial jurisdiction. Drug Court (Punjab) would have no jurisdiction to take cognizance of offence allegedly committed in Karachi. Application u/s. 249-A allowed and accused-company acquitted of charge against them leaving it open for State to file a complaint against accused-company in Drug Court, Karachi.<sup>129</sup>

Analysis of drugs. "Dihydrallazine or "Dihydrallazine Sulphate". Protocols of tests (details of process of tests) not provided with report by Analyst. Sample sent to Federal Laboratory no appearing to be same sample as sealed and marked by Inspector. Federal Laboratory testing and analysing

1998 P.Cr.L.J. 181

1985 P.Cr.L.J. 268.

NLR 1989 TD 189.

NLR 1989 TD 189.

NLR 1984 Criminal (Drug Court) 52.

"Dihydroazine tablets. Provisions of Act and Rules with regard to despatch of samples and submission of report not observed with complete strictness. Accused, held, cannot be prosecuted and convicted in circumstances. Direction contained in S. 19(2) of Act and Rr. 14 & 15 in regard to making of sample, held further, not directory but mandatory. In absence of 'nil mark' Drug Court cannot convict accused on ground of report of analyst that sample was substandard. Importance of strict observance in regard to sample emphasised in Form No. 6.1.10.

Prosecution u/Ss. 23, 27 for manufacture of medicine Sun Gul Menthol jelly which is prepared under Unani System of Medicine regulated by Act II of 1965. Not warranted. Drug Court accepting accused's application u/s. 249-A, CrPC and ordering their discharge.111

Appeal against acquittal. Explanation given by accused for not complying with a direction of the Secretary, Registration Board, to mention "Oicorexin of Ginger" as an ingredient on the label was convincing. Nothing manifestly wrong or perverse was, therefore, found in the conclusion arrived at by the trial Court. Appeal against acquittal of accused was consequently dismissed.112

Appeal against acquittal. Accused respondents has a right to request for retesting of samples and S. 22(5) of Drugs Act, 1976, makes it compulsory for prosecution to send the samples for retesting to Federal Drugs Laboratory or any other laboratory specified for the purpose by Federal Government. Accused had not given up their such request and their right could not be brushed aside on basis of their letters which did not amount to unconditional admission of guilt as provisions of law have to be strictly followed. Letters were addressed to Provincial Quality Control Board and not to proper quarters. Trial Court, held, had rightly given benefit of doubt to accused in view of clear violation of S. 22(5) of Drugs Act, 1976. Appeal against acquittal was dismissed in circumstances.113

Sale of drug after expiry of date. Quashment of F.I.R. Case of sale of drug after its expiry date made out against petitioner, falling under Drugs Act, was exclusively triable by Drug Court and no Magistrate was competent to try the same. Case being non-cognizable, prosecution could be instituted against petitioner only by Drug Inspector and no order could be passed by Magistrate authorising police authorities to investigate same. Registration of F.I.R. as also investigation in pursuance thereof conducted by police officers, held, were without jurisdiction and devoid of any authority legally vested in them. F.I.R. and proceedings ordered to be quashed.114

Appraisal of evidence. It was not proved through qualitative and quantitative analysis of the ingredients in the offending preparation that the active ingredient/constituent Methyl Phenacetate. Analyst's report did not determine the ingredients in the offending preparation quantitatively or even fully. It could not, therefore, be found that accused did not use merely a herbal extract in its natural form for the purposes of his preparation. Offence

130 1984 P.C.L.J. 1580.  
131 NLR 1988 TD 18.  
132 PLD 1992 KAR 3347.  
133 1990 P.C.L.J. 1865  
134 1990 P.C.L.J. 1475.

alleged against accused, held, had not been proved beyond reasonable doubt. Accused was acquitted in circumstances.115

Appreciation of evidence. Marking 'DHS' on the packings and coverings of the drugs apparently indicated that they were the property of the Director Health Services, Punjab, or for that matter of the Health Department of the Provincial Government and if the story of prosecution regarding the transportation of some quantity of the drugs and medicines by the accused in his car was correct, then the possibility of such drugs and medicines being taken to the Medical Stores of Director Health Services (MSD) or the same being secretly brought from the MSD for sale to certain wholesale or retail dealers of drugs in a clandestine manner could not be excluded. Neither the Drugs Inspector nor the S.H.O. constituting the raid party had explained as to the destination of the drugs being transported by the accused in his case. To probe into such aspect of the matter to book the real culprits and also in the larger interest of justice the case was remanded to trial Court with necessary directions for deciding the same afresh in accordance with law.116

Appreciation of evidence. Prosecution witnesses were responsible Government officers who in the performance of their statutory duty without any male fides on their part had conducted the raid taking all pre-cautions and observing legal formalities. Defence evidence on the other hand did not inspire confidence. Conviction and sentence of accused were upheld in circumstances.117

Where drugs are stocked in a shop the presumption is that they have been stocked for sale. Distributing includes dispensing and the *Mens rea* is not necessary for conviction of the accused. It is not necessary that the accused should have known that it was an offence to stock drugs for sale without license.118

The charge against the accused was under Section 18(b) of the Drugs Act and therefore an essential ingredient of the evidence was that the drugs sold by the accused were drugs which has been manufactured by an unlicensed manufacturer. And it was in order to prove this ingredient of the offence that the Inspector of P.W. had produced the letter of the Health Department, that the alleged manufacturers did not have any licence to manufacture drugs. But the burden was on the prosecution to prove that the manufacturers did not have my licence under the Drugs Act, and as the accused had taken objection to the production of this letter the prosecution should have prove it in the manner prescribed under Section 67 of the Evidence Act. This it did not care to do. It was contended that the letter had not been proved. Held: This submission was supported by the unanimous view of the Supreme Court in the case of *Muhammed Khattak v. S.M. Ayub*.119 Additionally there was also no provision in the Drugs Act which could relieve the prosecution of its obligation to prove this letter under Section 67 of the Evidence Act. Held: Therefore that the letter had not been proved. The substandard drug for the manufacture of which the respondent herein was sought to be prosecuted was actually manufactured by Laboratories which being a Private Limited Company, incorporated under the

135 1990 MLD 1524  
136 1992 P.C.L.J. 1781.  
137 1992 P.C.L.J. 1781.  
138 1992 P.C.L.J. 1781.  
139 PLD 1992 KAR 3347.  
1974 P.C.L.J. Note 81.

Companies Act, 1913, would be a 'person' in its own right within the meaning of that expression as appearing in Section 18, Section 19(3) and Section 27, Drugs Act, 1940. By the plain language of the said three sections, therefore, *prima facie* Messrs Laboratories seemed to have brought itself within the mischief of the law. Therefore if the prosecution had proceeded against the said Company, in view of the bar contained in Section 19, it would not be open to it to plead in defence that it was ignorant of the nature, substance or quality of the said substandard drug or of the circumstances in which it was manufactured. In point of fact under Section 19(3), its liability would seem to be total. And consequently upon its conviction it could under Section 27 be awarded the punishment of fine. The difficulty in the way of the appellants, however, is that no proceedings were drawn up the against the said Company. Nor indeed the Company was made a co-accused in the challan submitted against the respondent, herein in the criminal Court. Insofar as the liability of the respondent is concerned, it would not only arise if he can be shown to have manufactured the said substandard drugs for and on behalf of Messrs. Nawabsons Laboratories Limited, as in the nature of things the said Company had to act through a living person. It was true that at the relevant time respondent was the Managing Director of the said Company. But then in the challan submitted against him in the trial Court no allegation was made that it was he who had manufactured the said drug on behalf of the said Company. Furthermore, it is common knowledge that in the hierarchy of a Limited Company, the Managing Director was assisted by other directors as well as executives, officers and workers. There was no reason to believe that in the case of Laboratories the system was any different. Therefore, it would be difficult to presume that the respondent was guilty of the manufacture of the said substandard drug for and on behalf of the Company, just because he happened to be its Managing Director.<sup>140</sup>

Omission by the prosecution to bring on record expert's opinion in proof of the allegation that drug allegedly recovered from accused's premises was spurious and such omission entitles accused to a clean acquittal even at the preliminary stage. Drug Court accepted accused's application under Section 249-A, Cr.P.C. on additional grounds that complaint was incompetently lodged and recovery was in contravention of Section 103, Cr.P.C.<sup>141</sup>

Prosecution on the basis of complaint of the Drug Inspector who is not duly notified under Section 17, cannot be sustained in a case where recovery was not, witnessed according to Section 103, Cr.P.C. The Drug Court accepting accused's application and ordering their acquittal.<sup>142</sup>

Where a dealer in medicines purchased drugs from a manufacturer and obtained a warranty that there had been no contravention of this section from the manufacturer and sent a copy of warranty with written notice to Inspector of Drugs and warrantor within 7 days of the service of summons upon him it was held that in such circumstances the dealer could not be held guilty.<sup>143</sup>

The word "building" in Schedule B, para.2 of the Drugs (Licensing, Registering and Advertising) Rules is synonymous with the word "premises". The word "premises" as used in various rules and the Schedule does not mean a defined or separate building or structure. Mere use of a portion of

<sup>140</sup> PLD 1978 SC 193, NLR 1978 SC 768; PLJ 1978 SC 283.

<sup>141</sup> NLR 1985 Cr LJ 266.

<sup>142</sup> NLR 1985 UC 386 (2).

<sup>143</sup> 1973 P Cr LJ 218.

premises or building for residential purposes does not render it unsuitable for a licenced premises and manufacturing place is only required to be separate from the residential place.<sup>144</sup>

Where the applicant committed a breach of the provisions of this section and also of rule, a charge can be framed even if the complaint does not expressly state the provision of law which has been contravened.<sup>145</sup>

For committing an offence under this section, intention to do the guilty act which is made penal by the statute is not required. The Act creates an absolute liability and rules out *mens rea* as a constituent part of the crime. It would only affect the question of punishment.<sup>146</sup>

The complaint against the accused for manufacturing for sale substandard Ampicillin Dry Syrup containing 89% Ampicillin against U.S.P. limits of 90% to 120% and thus violating provisions of the Drugs Act. The accused, however, explaining carton of drug containing instructions for its keeping in a cool and dark place and as per WHO pamphlet loss of activity of international standard if drug stored at temperature less than 20° C and such requirements having not been fulfilled, there appeared a slight discrepancy in quantum of active agent, Ampicillin according to B.P. to be in a well closed container at a temperature not exceeding 25° C but climatic conditions in Pakistan ranging from 30° C to 40° C. Drug after the purchase remaining in normal temperature and possibility of deficiency in contents as required by B.P. existing. The accused was given the benefit of doubt and acquitted, in circumstances.<sup>147</sup>

Offences falling under Sec.23 of the Drugs Act, being punishable upto 10 years prohibition under Section 497, Cr.P.C., was attracted. Offences related to clandestine sale of stolen Government medicines as well as their genuineness. Bail was declined, in circumstances.<sup>148</sup>

**Self-contradictory order:** Acquittal of the accused under Section 265-K, Cr.P.C. with observation tantamounting to punish him while the order impugned. Petitioner was acquitted and convicted by one and the same order being self-contradictory, petition was converted into appeal and impugned observations were expunged.<sup>149</sup>

**Quashing of proceedings:** Only allegation against the manufacturer being that sample pack of drug contained 15 ml. of drug and that under r.32 contents should have been less than 15 ml. No allegation made to the effect that manufacturer sold physician's sample to any one in contravention of the provisions of the Act or Rules. Nowhere in the complaint it was urged that quantity impack was unreasonable or that unreasonably large quantity of sample was supplied to any physician or institution. No fresh case could be permitted to be argued against the manufacturer in that behalf. Complaint being based on erroneous view of law no case, held, was made out against the manufacturer for violation of r.32 which could entail any punishment.

<sup>144</sup> PLD 1978 Lah 445.

<sup>145</sup> 1955 All. WVR (HC) 328.

<sup>146</sup> 1958-2 Mad. L. Jour. 308.

<sup>147</sup> 1979 Cr. LJ 872.

<sup>148</sup> 1981 P Cr. LJ 243.

<sup>149</sup> 1987 SCMR 2100.

under Sec.27(4) or 23(1)(x), Drugs Act, 1976. Proceedings were quashed in circumstance.<sup>150</sup>

**Substandard drugs:** Record not showing that after purchasing drugs from manufacturer whether same were stored under the conditions laid down or stated on carton. Reasonable possibility of sample obtained by the Drug Inspector and subsequently sent to the National Health Laboratory having been deteriorated due to its improper storage after the purchase from manufacturers not ruled out. Accused entitled to the benefit of doubt. And the Conviction and sentence were set aside.<sup>151</sup>

According to the case of *Fazal Elahi v. The State*,<sup>152</sup> no prosecution launched against the company which manufactured drugs in question. Accused not shown to be acting as agent of the company for distribution of substandard drugs. In absence of the company, accused held, could not be prosecuted. The liability of manufacturer of the drugs and his agent for distribution thereof would be co-extensive.

Mere averment in FIR that accused was carrying contraband injections of Chloramphenicol for sale, would not make accused liable u/ss. 23/27. Accused in such case would be entitled to bail.<sup>153</sup>

Recovery of Calcium Sandoz Syrup and cotton bandages which did not have surgical bandages, would be no offence when there is no proof that accused was selling these items as drugs. Accused in such case would be entitled to acquittal.<sup>154</sup>

Spurious drug. Case of. Conviction for. Challenge to. Complainant admitted during cross-examination that he had not obtained samples (s) of drug and he had not sent any sample to concerned Laboratory for analysis. In view of clear cut admission how complainant in absence of any report by any expert came to conclusion that drug in question was in fact spurious drug or that same looked like drug. Held: Prosecution failed to prove guilt of appellant beyond reasonable doubt. Appeal accepted.<sup>155</sup>

Refusal of permission to clear drugs on ground that remaining period of expiry was less than 75% of total period would be unwarranted and without lawful authority. Instructions authorising refusal in a case where remaining period of expiry was less than 75% of total period would be violative of express provisions of S. 23 whereunder importer is entitled to clearance of drugs of which period of expiry has not been completed.<sup>156</sup>

Quashing of F.I.R. Registration of the F.I.R. in respect of the offence was not a case classified by the Provincial Quality Control Board, nor the Provincial Inspector had submitted a report to the said Board. Provincial Inspector, had also not obtained instructions from the Provincial Quality Control Board regarding the registration of the F.I.R. and on his own had got the same registered which act being without lawful authority was declared to be of no legal effect. Constitutional petition was accepted accordingly.<sup>157</sup>

<sup>150</sup> PLD 1985 Lah 503.

<sup>151</sup> 1985 P Cr.LJ 281.

<sup>152</sup> 1985 P Cr.LJ 268.

<sup>153</sup> 1996 Cr.LJ 414.

<sup>154</sup> 1996 Cr.LJ 401.

<sup>155</sup> PLJ 1996 Cr.C. (Pesh.) 114 (DB).

<sup>156</sup> NLR 1995 Civil Lah. 62.

<sup>157</sup> 1994 P Cr.LJ 1065.

Appeal against acquittal. Explanation given by accused for not complying with a direction of the Secretary, Registration Board, to mention "Oleoresin of Ginger" as an ingredient on the label was convincing. Nothing manifestly wrong or perverse was, therefore, found in the conclusion arrived at by the Trial Court. Appeal against acquittal of accused was consequently dismissed.<sup>158</sup>

**Substandard drugs. Prosecution.** No prosecution launched against company which manufactured drugs in question. Accused not shown to be acting as Agent of company for distribution of sub-standard drugs. In absence of company, accused, held, could not be prosecuted. Liability of manufacturer of drugs and his agent for distribution thereof would be co-extensive.<sup>159</sup>

Prosecution on basis of complaint of Drug Inspector who is not duly notified u/s. 17, cannot be sustained in a case where recovery was not witnessed according to S. 103, Cr.P.C. Drug Court accepting accused's application and ordering their acquittal.<sup>160</sup>

Prosecution u/ss. 23, 27 for manufacture of medicine Sun Gul Menthogelly which is prepared under Unani System of Medicine regulated by Act II of 1965. Not warranted. Drug Court accepting accused's application u/s. 249A, Cr.P.C. and ordering their discharge.<sup>161</sup>

Report of Chemical Analyser that drugs are not adulterated/spurious would be no ground for bail in a case u/ss. 23/27.

Prosecution for offences u/ss. 23/27. Chemical Analyser's opinion is sought for aid and assistance of Court. Courts are competent to disbelieve such reports if no plausible reasons have been put forth and no reasonings have been stated how medicines are found not spurious.<sup>162</sup>

Prosecution of drug manufacturers for offences u/ss. 23/27. Contended that: (i) FIR was registered on complaint by Magistrate who was alien to Drugs Act. (ii) Prosecution was initiated by granting approval, without personal hearing to accused as required by rule 4(3), Drugs Rules (1988), (iii) Report of Government Analyst was inadmissible in evidence. Held: Prosecution and proceedings merited quashment u/s. 249A, Cr.P.C. as there was not probability of conviction of accused in view of force in contentions raised in support of application u/s. 249, Cr.P.C.<sup>163</sup>

Registration of a case under the Act (1976) by the Drugs Inspector. Held that Irrespective of the case being a cognizable the Provincial Inspector had to make a report to the Board as and when there was any contravention of this Act (1976) and only on reference to the Board and seeking orders the Provincial Inspector could proceed in the matter. No such report was submitted. And no orders were obtained from the Board for the registration of the case. Further Held: That the Provincial Inspector had thus acted on his own. The same declared to be without lawful authority. Petition accepted.<sup>164</sup>

Bail. Petition for. Allegation being that the petitioner was found in possession of some drugs of which he could not produce any warrant.

<sup>158</sup> PLD 1992 Kar. 347.

<sup>159</sup> 1985 P Cr.LJ 268.

<sup>160</sup> NLR 1985 UC 386 (2).

<sup>161</sup> NLR 1988 TD 18.

<sup>162</sup> NLR 1993 Criminal Quetta 76.

<sup>163</sup> NLR 1993 Cr.LJ. 31.

<sup>164</sup> 1994 PLR 143.

Contention that proceedings against the petitioner were bad as no sanction of the Provincial Quality Control Board was sought before the registration of the case. Held that: The case was got registered directly and even otherwise it had been more than three months yet the challan had not been submitted in the Court. Bail allowed.

**Constitutional petition concerned only with import of drugs and their clearance.** Applicant shareholder, desirous to become a party to Constitutional petition in view of disputes *inter se* between shareholders of the company. Applicant's *locus standi* to be impleaded as a party in Constitutional petition. Clearance of drugs being for the benefit of the company of which applicants were shareholders, they were, therefore, neither necessary nor proper party in such proceedings. As for applicant's dispute with other shareholders of the company regarding the affairs of the company, they could seek remedy in accordance with law.

**Appeal against acquittal:** Explanation given by the accused for not complying with a direction of the Secretary, Registration Board, to mention "Oleoresin of Ginger" as an ingredient on the label was convincing. Nothing manifestly wrong or perverse was, therefore, found in the conclusion arrived at by the trial Court, the appeal against the acquittal of the accused was consequently dismissed.

**24. Control of advertisement:** No person shall himself or by any other person on his behalf advertise, except in accordance with such conditions as may be prescribed.--

- (i) any drug;
- (ii) any substance used or prepared for use in accordance with the ayurvedic, unani, homeopathic or biochemic system of treatment or any other substance or mixture of substances as may be prescribed;
- (iii) any remedy, treatment or offer of a treatment for any disease.

**Explanation:** In this section, "advertise" means to make any representation by any means whatsoever for the purpose of promoting directly or indirectly the sale or disposal of a drug, a substance or a mixture of substances, a remedy or a treatment except the display of sign boards for a clinic, a dispensary or a hospital on such other institution offering treatment.

### COMMENTS

**Presumption of fact:** No evidence having been produced by prosecution to prove factum of publication of advertisement in newspaper and souvenir by the accused. Accused having disputed the same. Mere fact that advertisement might have benefited the accused, held, would not justify raising of presumption against the accused under Section 114(f) of the

Evidence Act (I of 1872). Appeal was, therefore, allowed, conviction and sentence were set aside.

**Handbill displaying picture of healthy seminude male and female with writing "it is well-known about Knight Pills that husband who takes Knight Pills never gets old and Knight Pills keeps the potency of a male ready for action".** Ingredients of Knight Pills was totally missing from handbill. Language used in the handbill was calculated to induce persons interested in combating sexual weakness to buy pills mentioned in the handbill, thereby promoted sale of pills and as such handbill would fall within the definition of "advertisement".

**Burden of proof:** Advertisement in newspaper and pamphlet. Prosecution not producing any witness to prove fact that the accused caused publication of disputed advertisement in newspaper and pamphlet. Accused disputing publication of such advertisement to have been caused by him. Burden of proof, would lie squarely on prosecution.

**25. Control of sampling:** No person shall distribute or cause to be distributed any drug as a sample except in accordance with such conditions as may be prescribed.

**26. Control of printing of labelling:** No person shall print any labelling in respect of any drug which is required to be registered under this Act but is not so registered after the date fixed by the Federal Government under sub-section (6) of Section 7 or for a person who does not possess a licence under this Act to manufacture that drug.

### COMMENTS

**Appeal against acquittal.** Prosecution could be instituted under the law either by a Federal Drug Inspector or Provincial Drug Inspector and the complainant in the case did not hold any of these positions. Complainant being not competent to institute the case/prosecution before the Drug Court, the entire proceedings, stood vitiated. View taken by High Court resulting in acquittal of accused was correct and in consonance with law. Leave to appeal was refused accordingly.

**Cognizance of offences.** Non-compliance of S. 30 of Drugs Act, 1976. Failure to raise objection to proceedings by the defence would not validate the proceedings otherwise invalid. Requirement of law enjoined by S. 30 of the Drugs Act, 1976 is meant to be complied with by the prosecution and if no objection had been raised by the defence at the trial, it would not validate the proceedings which otherwise stood vitiated for non-compliance of S. 30, Drugs Act, 1976.



**CHAPTER IV****Offences, Penalties and Procedure**

**27. Penalties:** (1) Whoever himself or by any other person on his behalf:

- (a) exports, imports, manufactures for sale or sells any spurious drug or any drug which is not registered;
- (b) manufactures for sale any drug without a licence; or
- (c) imports without licence any drug for the import of which a licence is required;

shall be punishable with imprisonment for a term which shall not be less than <sup>173</sup>[five] years or more than ten years and with fine which may extend to <sup>174</sup>[five] lakh rupees:

<sup>175</sup>[\*\*\*\*\*]

(2) Whoever himself or by any other person on his behalf—

- (a) imports, manufactures for sale or sells any <sup>176</sup>[imitation product]; or
- (b) gives to the purchaser a false warranty in respect of any drug sold by him that the drug does not in any way contravene the provisions of Section 23 and is not able to prove that, when he gave the warranty, he had good and sufficient reason to believe the same to be true; or
- (c) applies or permits to be applied to any drug sold, or stocked or exhibited for sale, by him, whether on the container or a label or in any other manner, a warranty given in respect of any other drug; or
- (d) imports, manufactures for sales or sells any drug under a name other than the registered name; or
- (e) exports, imports, manufactures for sale or sells any drug with which any substance, which should not actually be its

<sup>173</sup> Subs. for the word "three" by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998.

<sup>174</sup> Subs. for the word "one" by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998.

<sup>175</sup> Omitted the proviso by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998, the original text is as under:-

Provided that the Drug Court may, for any special reasons to be recorded, award a sentence of imprisonment for a term of less than three years.

<sup>176</sup> Subs. for the words "counterfeit drugs" by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998.

component, has been mixed or packed so as to reduce its quality or strength or for which any such substance has been substituted wholly or in part;

shall be punishable with imprisonment for a term which may extend to seven years, and with fine which may extend to one lakh rupees.

(3) Whoever obstructs an Inspector in the exercise of any power conferred upon him by or under this Act, or disobeys the lawful authority of any Inspector, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to ten thousand rupees, or with both.

(4) Subject to the provisions of sub-section (1), sub-section (2) and sub-section (3), whoever himself or by any other person on his behalf contravenes any of the provisions of this Act or any rule shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to fifty thousand rupees, or with both.

**COMMENTS**

Constitutional petition. Quashing of F.I.R. Criminal case under S. 23/27 of the Drugs Act, 1976 could not be registered without the prior permission of the Quality Control Board set up under S. 11 of the Drugs Act, 1976 which had not been obtained by the Drug Inspector. Proceedings initiated against the accused, in the absence of their permission of the Competent Authority, were coram non judice, based on mala fides and without lawful authority. F.I.R. was quashed in circumstances and the Constitutional petition was accepted accordingly.<sup>177</sup>

**Substandard or misbranded drugs manufactured by the company:** The burden of proof, cast on Director or employee of such company to prove that substandard or misbranded drug was manufactured without their knowledge and or consent after prosecution discharged its initial burden. The presumption, held, would be that all such acts of manufacture of misbranded or substandard drugs were committed with knowledge and or with consent of every such director or employee.<sup>178</sup>

Offence being cognizable could be investigated into by the Provincial Police and therefore by the Federal Investigation Agency also. Prosecution in respect of offence could not, however, be instituted except by the Drugs Inspector.<sup>179</sup>

Where the warranty was signed not by the petitioner but by another partner of the firm and the drugs were not found of standard quality, the petitioner was also held liable in respect of offence relating drugs.<sup>180</sup>

It is a well-established proposition of law that whenever the legislature empowers a subordinate authority to attach any conditions to the grant of a

<sup>177</sup> 1998 P. Cr. L.J. 181

<sup>178</sup> 1986 P. Cr. L.J. 1265.

<sup>179</sup> PLD 1976 Lan 813.

<sup>180</sup> 1973 P. Cr. L.J. 809.



licence the conditions to be valid must fairly and reasonably relate to the object and purposes of law.<sup>121</sup>

The prosecution and conviction of a person for merely stocking certain medicines is misconceived where the rules have only prohibited the supply or sales of those medicines otherwise than under the personal supervision of a qualified person.<sup>122</sup>

Powers of search and seizure given to the Drugs Inspectors under Section 18(1) is not restricted to such officers. Searches and seizures in respect of offences under Section 27 (1), could also be made by the Police Officers. Police Officers in such cases were not required to follow procedure laid down in Section 19 but to follow procedure prescribed under the Code of Criminal Procedure, 1898, Section 103.<sup>123</sup>

Government Analyst's report proved the drug kept in store for sale and sold by the petitioner not containing relevant ingredients but some other powders. The petitioner though given a sample but not proving drug to have contained necessary components and being genuine and not spurious. The contention as to drug in question having not been proved to be spurious, was not maintainable in circumstances.<sup>124</sup>

Facts on record showing that there were conflicting reports of the Government Analyst in respect of the same drug. Circumstances not ruling out possibility that deterioration may be due to storage and climatic condition. Proceedings against the accused Nos. 2 to 4 instituted on application of the Special Prosecutor. The accused were entitled to the benefit of doubt and acquittal.<sup>125</sup>

**Criminal liability—Limited company:** A limited company or a Corporation is legal 'person' in the eye of law and by legal fiction capable of taking and defending civil actions in its own name; though even acting through its Directors/employees or agents, yet in the criminal law position was different. Despite generality of Section 11, Penal Code, it was not indictable for offences which could be committed by human being only or offences which must be punished with imprisonment. The Trial Court, held, could not punish company and if any one of its acts amounted to an offence some one or more of its Directors or employees who did that the act would have to be held responsible for it.<sup>126</sup>

**Substandard and misbranded drugs:** The person guilty of offence a limited company while accused its director and employees. Vicarious liability, held, was imposed on every such Director and the employees of the company unless they proved that offence was committed without their knowledge or consent.<sup>127</sup>

The Drug Analyst submitting his report beyond the period prescribed by law without obtaining extension from the Quality Control Board. The Drug

<sup>121</sup> PLD 1978 Lah. 445  
<sup>122</sup> AIR 1956 All 703  
<sup>123</sup> 1979 P Cr LJ Note 6  
<sup>124</sup> PLD 1981 SC 352  
<sup>125</sup> NLR 1982 Cr. LJ 280  
<sup>126</sup> 1986 P Cr. LJ 1265  
<sup>127</sup> 1986 P Cr. LJ 1265.

Analyst, held, committed violation of the provisions of law and report sent him not in the prescribed form.<sup>128</sup>

**Interpretation of statutes:** Where statutory powers are conferred and specific provisions made in statute as to manner in which powers are to be exercised they should be exercised by authority strictly in the manner specified in the statute.<sup>129</sup>

The charge against the accused was under Section 18 (b) of the Drugs Act and therefore an essential ingredient of the evidence was that the drugs sold by the accused were drugs which had been manufactured by an unlicensed manufacturer. And it was in order to prove this ingredient of the offence that the Inspector a P.W. had produced the letter of the Health Department, that the alleged manufacturers did not have any licence to manufacture drugs. But the burden was on the prosecution to prove that the manufacturers did not have any licence under the Drugs Act, and as the accused had taken objection to the production of this letter the prosecution should have proved it in the manner prescribed under Section 67 of the Evidence Act, and the prosecution did not care to do. It was contended that the letter had not been proved. This submission was supported by the unanimous view of the Supreme Court in the case of *Muhammad Khattak v. S.M. Ayub*.<sup>130</sup> Additionally there was also no provision in the Drugs Act which could relieve the prosecution of its obligation to prove this letter under Section 67 of the Evidence Act. Held, therefore, that the letter had not been proved.

The contention that the process of "packing" or "re-packing" of drug was not an offence, within the purview of Section 27 of the Drugs Act repelled.<sup>131</sup>

Laboratory report showing drug substandard and no indication on record that accused notified to any of the prescribed authorities of their intention to challenge such report. Contentions that whole process of manufacturing was not completed nor drug was ready for marketing when drug secured nor laboratory report disclosed requisite protocols. Contentions were of no consequence in circumstances. The conviction was maintained.<sup>132</sup>

The contention that pills sought to be advertised by handbill being harmless and use thereof to any extent not being dangerous to life therefore manufacturer was not liable for any offence under the Drugs Act. The contention was fallacious. Pills, held further, not having been manufactured as a drug in accordance with conditions of any licence obtained for the manufacture of any drug, manufacturer committed offence under Section 27 of the Drugs Act. Conviction and sentence were maintained, in circumstances.<sup>133</sup>

Conviction of accused by the Drug Court for having substandard drugs. Reasonable possibility existing that samples which was obtained by the Drug Inspector and subsequently sent to the National Health Laboratories

<sup>128</sup> 1985 P Cr. LJ 281.  
<sup>129</sup> 1985 P Cr. LJ 281.  
<sup>130</sup> 1974 P Cr. LJ Note 31  
<sup>131</sup> 1983 P Cr. LJ 2491.  
<sup>132</sup> 1984 P Cr. LJ 2007.  
<sup>133</sup> 1984 P Cr. LJ 2895.

deteriorated after the acquisition of same due to adverse climatic conditions. Accused, held, entitled to the benefit of doubt and acquitted.<sup>194</sup>

**Appeal:** The Trial Court before convicting the accused discussing evidence of witnesses as well as documents produced by them and facts deposed in evidence as well as given in documents not disputed by the accused. Conviction and sentence were maintained.<sup>195</sup>

**Burden of proof:** Advertisement in Newspaper and pamphlet. Prosecution not producing any witness to prove fact that the accused caused publication of disputed advertisement. Accused disputing publication of such advertisement to have been caused by him. Burden of proof, held, would lie squarely on prosecution.<sup>196</sup>

**Jurisdiction of the Drugs Tribunal:** Sub-standard drugs manufactured at 'L', sold at 'L' and thereafter sold within the territorial jurisdiction of the Drugs Court at 'K'. Consequences of manufacturing substandard drugs at place other than the place of sale of such drugs. Drugs Tribunal at 'K', would have jurisdiction to try offences under the Drugs Act and no exception could be taken to impugned order passed by the Tribunal at 'K'.<sup>197</sup>

**Petitioner's conviction based on his own plea of guilt:** Having admitted that the drugs recovered from him was sub-standard, declined to produce any evidence in defence. No interference called for. Leave to appeal was refused.<sup>198</sup>

**Substandard drugs—Prosecution:** Record not showing that after purchasing drugs from manufacturer whether the same were stored under the conditions laid down or stated on carton. Reasonable possibility of sample obtained by the Drug Inspector and subsequently sent to the National Health Laboratory having been deteriorated due to its improper storage after purchase from manufacturers not ruled out. Accused, was, entitled to the benefit of doubt. Conviction and the sentence were set aside.<sup>199</sup>

No prosecution launched against the company which manufactured drugs in question. Accused not shown to be acting as Agent of the Company for distribution of substandard drugs. In the absence of company, accused, held, could not be prosecuted. The liability of manufacturer of drugs and his agent for distribution thereof would be co-extensive.<sup>200</sup>

According to the case of *Fezal Ellahi v. State*,<sup>201</sup> substandard drugs manufactured by a private limited Company and not impleaded as a principal accused along with other accused who were directors of the Company. The accused was acquitted.

According to the case of *Muhammad Saeed v. the State*,<sup>202</sup> the trial Court convicting the accused on his statement treating the same as confession, without framing of charge under Section 242, Cr.P.C. Question of conviction of the accused on his statement in circumstances held, could not

194 1984 P Cr.LJ 1580.  
195 1986 P Cr.LJ 1265.  
196 1986 P Cr.LJ 486.  
197 1987 MLD 1619.  
198 1985 SCMR 1405.  
199 1985 P Cr.LJ 281.  
200 1985 P Cr.LJ 268.  
201 1985 P Cr.LJ 268.  
202 1985 P Cr.LJ 1440.

arise. Conviction and the sentence set aside and the case remanded for trial according to law.

**Conviction on charge of keeping substandard drugs on plea of guilty by accused:** Accused not only pleaded guilty but admitted that the drugs recovered from him were substandard and declined to produce any evidence. Leave to appeal refused on ground that there was no reason why after complaint and appearance in the Drug Court accused should remain unaware that he was making statement in Court in proceedings which might result in his conviction and the sentence on his own plea of guilty.<sup>203</sup>

**Appreciation of evidence.** No sample of the drug seized by the complainant Drug Inspector having been taken and sent to the concerned Laboratory for analysis, it could not be said to be a spurious drug. Drug Inspector although alleged that the drug seized by him resembled a medicine manufactured by a local pharmaceutical company, yet he admittedly did not contact the said pharmaceutical company in this respect and failed to obtain the view of that company regarding the drug in question. Accused was acquitted in circumstances.<sup>204</sup>

**Appeal against acquittal.** Prosecution could be instituted under the law either by a Federal Drug Inspector or Provincial Drug Inspector and the complainant in the case did not hold any of these positions. Complainant being not competent to institute the case/prosecution before the Drug Court the entire proceedings stood vitiated. View taken by High Court resulting in acquittal of accused was correct and in consonance with law. Leave to appeal was refused accordingly.<sup>205</sup>

**Substandard drug. Evidence, appreciation of.** Laboratory report showing drug substandard and no indication on record that accused notified to any of prescribed authorities of their intention to challenge such report. Contentions that whole process of manufacturing was not completed nor drug was ready for marketing when drug secured nor laboratory report disclosed requisite protocols. Contentions, held, of no consequences in circumstances. Conviction maintained.<sup>206</sup>

**Criminal liability. Limited company.** A limited company or a Corporation is 'legal person' in eye of law and by legal fiction capable of taking and defending civil actions in its own name; though even acting through its Directors/employees or agents, yet in criminal law position was different. Despite generality of S. 11 Penal Code, it was not indictable for offences which could be committed by human being only or offences which must be punished with imprisonment. Trial Court, held, could not punish company and if any one of its acts amounted to an offence some one or more of its Directors or employees who did that act would have to be held responsible for it.<sup>207</sup>

**Appraisal of evidence.** It was not proved through qualitative and quantitative analysis of the ingredients in the offending preparation that the active ingredient/constituent, Mathyl Pharmacopoeia. Analyst's report did not determine the ingredients in the offending preparation quantitatively or even fully. It could not, therefore, be found that accused did not use merely a herbal

203 1985 SCMR 1827.  
204 1996 PCrLJ 540.  
205 1996 SCMR(Pak) 767.  
206 1984 PCrLJ 2007.  
207 1988 PCrLJ 1265.

extract in its natural form for the purposes of his preparation. Offence alleged against accused, *held*, had not been proved beyond reasonable doubt. Accused was acquitted in circumstances.<sup>210</sup>

Conviction with sentence till rising of Court plus fine of Rs. 10,000.00 based on confessional statement of accused. Upheld, High Court feeling that sentence was not excessive but it was lenient. High Court in absence of revision on behalf of State not feeling inclined to consider enhancement of sentence.<sup>211</sup>

Substandard or misbranded drugs manufactured by company. Burden of proof, *held*, cast on Director or employee of such company to prove that substandard or misbranded drug was manufactured without their knowledge or consent after prosecution discharged its initial burden. Presumption, *held*, would be that all such acts of manufacture of misbranded or substandard drugs were committed with knowledge or with consent of every such Director or employee.<sup>212</sup>

Conviction for manufacture of substandard and misbranded drug. Conviction based on analysis of Govt. Analyst that quantity of Drug's components did not conform to requisite standard. Conviction upheld after repelling as untenable contention that Analysis Report was not in conformity with proforma provided under law.<sup>213</sup>

Marking 'DHS' on the packings and coverings of the drugs apparently indicated that they were the property of the 'Director Health Services', Punjab, or for that matter of the Health Department of the Provincial Government and if the story of prosecution regarding the transportation of some quantity of the drugs and medicines by the accused in his car was correct, then the possibility of such drugs and medicines being taken to the Medical Stores of Director Health Services (MSD) or the same being secretly brought from the MSD for sale to certain wholesale or retail dealers of drugs in a clandestine manner could not be excluded. Neither the Drugs Inspector nor the S.H.O. constituting the raid party had explained as to the destination of the drugs being transported by the accused in his case. To probe into such aspect of the matter to bring to book the real culprits and also in the larger interest of justice the case was remanded to Trial Court with necessary directions for deciding the same afresh in accordance with law.<sup>214</sup>

Prosecution witnesses were responsible government Officers who in the performance of their statutory duty without any *mala fides* on their part had conducted the raid taking all precautions and observing legal formalities. Defence evidence on the other hand did not inspire confidence. Conviction and sentence of accused were upheld in circumstances.<sup>215</sup>

FIR against druggist for sale of drugs after date prescribed for its sale. *Held*: Registration of FIR was not warranted under Drugs Act and as such it was liable to quashment under writ jurisdiction.<sup>216</sup>

Possession of sub-standard drug. Trial Court convicting accused on his statement treating same as confession, without framing of charge under S.

210 1990 MLD 1524  
211 NLR 1987 Criminal Lah 863  
212 1986 PCr.LJ 1265  
213 NLR 1986 Criminal Kar 526  
214 1992 PCr.LJ 1781  
215 1992 SCMR APP.C 3072  
216 1992 SCMR APP.C 3072

242. Question of conviction of accused on his statement in circumstances, *held* could not arise. Conviction and sentence set aside and case remanded for trial according to law.<sup>217</sup>

Offence. Sentence. Challenge to. Not a ward was stated by the said witnesses that the appellant was found selling the medicines without a licence. The nature of the drugs recovered from the shop of the appellant is such that these would be available almost in every house for their daily consumption. It was the bounden duty of the prosecution to have produced evidence to show that the appellant was selling the drugs recovered from his possession while keeping them in his shop. *Held*: Appellant is accepted. Sentence is set aside. The accused is acquitted.<sup>218</sup>

Drug found deficient of ingredients under warranty. Borax Glycerine manufactured under written warranty of containing 12% of borax (main active ingredient) but found substandard and deficient. Containing only 6.73% w/w and absorption of water to extent of 100% of total quantity of glycerine. Contention that glycerine being highly hygroscopic absorption moisture could be caused due to loosely fitted stoppers. No evidence, however, to indicate that bottles containing Borax Glycerine were not properly stoppered or not dried before use. Accused, *held*, guilty of offences, in circumstances. Borax Glycerine a drug where in even major variation of active ingredient can result in no serious consequences and accused manufactures also withdrawing entire batch from retailer. Heavy sentence, *held further*, not called for in circumstances. Accused sentenced to fine of Rs. 5,000/- or 1 year's R.I. in default.<sup>219</sup>

Search and Seizure. Powers of search and seizure given to Drugs Inspector under Section 18(1) not restricted to such officers. Searches and Seizures in respect of offence under Section 27(1), *held*, can also be made by Police Officers. Police Officers in such cases, *held further*, not required to follow procedure laid down in Section 19, but to follow procedure prescribed under Code of Criminal Procedure, 1898, Section 103.<sup>220</sup>

No offence u/s 23(1)(x) to entail punishment under Section 27(4). Proceeding quashed. Since the case of the Inspector of Drugs is based on anderroneous view of the law, no case stands made out against the petitioner Company for violation of rule 32 of the Drugs Rules, 1976, which may entail any punishment under Section 27(4) of the Act. Since there is no allegation that the Physician's Sample was sold by the petitioner, Company to any one in contravention of any of the provisions of the Act or the rules, no offence stands made out for violation of Section 23(1)(x) of the Act as to entail any punishment under Section 23/27 of the Drugs Act, 1976, read with Section 32 of the Drugs Rules quashed.<sup>221</sup>

Non-prosecution of Company—Directors or Employees could not be held vicariously liable. If the Company was found guilty of the offence then the burden was on the Directors or the employees of the Company to prove the non-existence of knowledge or consent on the part of the Directors or employees of the Company. Finding that Company was guilty of the offence was *sine qua non* to convict the Director or employees of

1985 PCr.LJ 1440.  
K.L.R. 1994 Cr.C. 445.  
1978 P Cr.L. 287  
1979 P.Cr.L.J. 4.  
P.L.D. 1985 Lah. 503

Board and not to proper quarters. The trial Court, held, had rightly given benefit of doubt to the accused in view of clear violation of section 22(5) of the Drugs Act, 1976. Appeal against the acquittal was dismissed in circumstances.<sup>232</sup>

Prosecution could be instituted under the law either by a Federal Drug Inspector or Provincial Drug Inspector and complainant in the case did not hold any of these positions. Complainant being not competent to institute the case/prosecution before the Drug Court, the entire proceedings stood vitiated. View taken by High Court resulting in acquittal of accused was correct and in consonance with law. Leave to appeal was refused accordingly.<sup>232</sup>

**Prosecution and Proceedings, Quashed:** Prosecution of drug manufactures for offences under Section 28/27, was challenged contending that (i) FIR was registered on complaint by Magistrate who was alien to Drugs Act; (ii) prosecution was initiated by granting approval without personal hearing to accused as required by R. 4(3), Drugs Rules (188); (iii) Report of Government Analyst was inadmissible in evidence. Held: Prosecution and proceedings merited quashing under Section 249-A, Cr.P.C. as there was no probability of conviction of accused in view of force in contentions raised in support of application under Section 249, Cr.P.C.<sup>233</sup>

**Petitioner stored and was selling spurious drug:** It was contended that the report of the Government Analyst on the basis of which it was held by the Courts below that the petitioner had stored for sale and was selling a spurious drug viz., Tetracycline Pediatric Powder was not comprehensive in providing that the drug recovered from the petitioner was in fact spurious. Held, that a Drug which purported to be a particular Drug but does not contain its active ingredients is a spurious drug. Further held, that the report of the Government Analyst proved that the Drug Tetracycline Pediatric powder which was kept in store for sale and was sold by the petitioner did not contain the relevant ingredients but rather contained Kaolin and Coco powder. The petitioner at the time the sample was taken was given a set of that sample but did not prove by leading any evidence that the Drug contained the necessary components and was genuine and not spurious. Thus the contention raised by the petitioner was repelled.<sup>234</sup>

**Quashing of F.I.R.:** Registration of the F.I.R. in respect of the offence was not a case classified by the Provincial Quality Control Board, nor the Provincial Inspector had submitted a report to the said Board. Provincial Inspector had also not obtained instructions from the Provincial Quality Control Board regarding the registration of the F.I.R. and on his own had got the same registered which act being without lawful authority was declared to be of no legal effect. Constitutional petitioner was accepted accordingly.<sup>235</sup>

**Leave to appeal:** The leave to appeal was granted to consider that the trial of the accused persons was illegal, in that, sanction from the Quality Control Board was obtained against the Company (Manufacturer) and not against the accused persons (General Manager and Director, Plant Manager, Production Manager, Quality Control Manager and Controller) and

<sup>232</sup> 1990 P.Cr.L.J. 865  
<sup>233</sup> 1996 S.C.M.R. (b) SC (Pak) 767.  
<sup>234</sup> N.L.R. 1993 Cr.L.J. 31.  
<sup>235</sup> P.L.O. 1981 SC 352.  
 1994 P.Cr.L.J. 1065

that the company as such was not impleaded as an accused and that the High Court erred in invoking section 34 of the Act in this behalf.<sup>236</sup>

Drug Inspector in the interest of secretary and protection had sought the assistance of the C.I.A. Staff excluding the participation and association of the police stations having jurisdiction or even the respectables of the locality. Such a caution on the part of the Drug Inspector would not make the proceedings suspect for non-inclusion of a respectables of the locality.<sup>237</sup>

The trial Court had omitted to extend benefit of section 382-B, Cr.P.C. to the accused without noticing any feature justifying such a denial. Benefit of section 382-B, Cr.P.C. was allowed to the accused accordingly.<sup>238</sup>

**28. Penalty for subsequent offence:** (1) Whoever having been convicted of an offence under sub-section (10 of Section 27 is again convicted of an offence under that sub-section shall be punishable with imprisonment for life or with imprisonment which shall not be less than [seven] years and with fine which may extend to [ten] lakh rupees.

(2) Whoever having been convicted of an offence under sub-section (4) of Section 27 is again convicted of an offence under that sub-section shall be punishable with imprisonment for a term which shall not be less than two years or more than ten years, or with fine which may extend to two lakh rupees, or with both.

(3) Whoever having been convicted of an offence under sub-section (4) of Section 27 is again convicted of an offence under that sub-section shall be punishable with imprisonment for a term which may extend to seven years, or with fine which may extend to one lakh rupees, or with both.

**29. Forfeiture:** (1) Where any person has been convicted under this Act, for contravening any such provisions of this Act or any rule as may be prescribed in this behalf, the Drug Court may order that the stock of drug or substance by means of or in relation to which the offence was committed or anything of a similar nature belonging to or in the possession of the accused or found with such drug or substance, and if such contravention is punishable under sub-section (1) of Section 27, any implements used in manufacture or sale of such drug and any receptacles, packages or coverings in which such drug is contained and the animals, vehicles, vessels or other conveyances, used in carrying such drug, be forfeited to the Federal Government or as the case may be, the Provincial Government and, upon such

P.L.D. 1991 SC 893.

1992 S.C.M.R. 2072.

1992 S.C.M.R. 20720.

Subs. for the word "five" by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998.

Subs. for the word "two" by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998.

the Company that they were guilty of the offence. When the Company was not before the Court then no adverse finding could be given against the Company and in such a situation the Directors or Employers could not be held vicariously liable. Non-prosecution of Company itself was, therefore, fatal for the prosecution.<sup>220</sup>

**Appraisal of evidence:** It was not proved through qualitative and quantitative analysis of the ingredients in the offending preparation that the active ingredient/constituent Methyl Salicylate had been used which formed part of the protected pharmacopoeias. Analyst's report did not determine the ingredients in the offending preparation quantitatively or even fully. It could not, therefore, be found that the accused did not use merely a herbal extract in its natural form for the purposes of his preparation. Offence alleged against the accused, held, had not been proved beyond reasonable doubt, the accused was acquitted in circumstances.<sup>221</sup>

If the company was found guilty of the offence the burden was on the Directors or the employees of the company to prove the non-existence of knowledge or consent on the part of the Directors or employees of the company. Finding that the company was guilty of the offence was *sine qua non* to convict the Directors or employees of the company that they were guilty of the offence. When the company was not before the Court then no adverse finding could be given against the company and in such a situation the Directors or employees could not be held vicariously liable. Non-prosecution of company itself, was therefore, fatal for the prosecution.<sup>222</sup>

**Appreciation of evidence:** Evidence on record did not show that the accused was found selling the drugs recovered from him. Possession while keeping them in his shop without a licence. Drugs recovered could be available almost in every house for daily consumption. Defence version was believable and the possibility of false implication if accused could not be ruled out. Accused was acquitted in circumstances.<sup>223</sup>

Charge against accused was two-fold; one that the drug recovered by the Drug Inspector from him was not registered and the other that it was spurious. Prosecution had not produced the concerned Authority of the Federal Government alongwith the record to prove non-registration of the drug. Sample taken into possession from the shop of the accused was also not sent to Public Analyst for analysis nor any public analyst was examined in Court. Sample having been sent to Quality Control Board for analysis four years after the recovery, no credence at all could be attached to its report which was not even proved. Spuriousness of the drug, therefore, was also not proved on record. Accused was acquitted accordingly.<sup>224</sup>

No sample of the drug seized by the complainant Drug Inspector having been taken and sent to the concerned Laboratory for analysis, it could not be said to be a spurious drug. Drug Inspector although alleged that the drug seized by him resembled a medicine manufactured by a local pharmaceutical company, yet he admittedly did not contact the said pharmaceutical company

<sup>220</sup> P.L.D. 1991 893.  
<sup>221</sup> 1990 M.L.D. 1524.  
<sup>222</sup> P.L.D. 1991 S.C. 893.  
<sup>223</sup> 1994 P.Cr.L.J. 2488.  
<sup>224</sup> P.L.D. 1997 Pesh. 49.

in this respect and failed to obtain the view of that company regarding the drug in question. Accused was acquitted in circumstances.<sup>225</sup>

Particles and fibres found in the drug could not make it adulterated or for that matter substandard. Government Analyst's report being silent about the protocols of the test or analysis as required under the Rules was fatally defective and even otherwise the same was un-authentic and inadmissible in evidence due to non-appointment of the Government Analyst within the meaning of the Drugs Act, 1976. No Notification was also available to show the appointment of the Drug Inspector prescribing the limits within which he could have acted as Provincial Inspector for the purpose of the Drugs Act as envisaged by S. 17. Accused being the Director and Manager of the Company manufacturing the seized drug could not be convicted of the offence unless proved to be having the knowledge or to have consented to such offence or when the company had been impleaded as an accused. Accused were acquitted in circumstances.<sup>226</sup>

**Non-Compliance of S. 30 of Drugs Act, 1976. Effect:** Failure to raise objection to proceedings by the defence would not validate the proceedings otherwise invalid. Requirement of law enjoined by S. 30 of the Drugs Act, 1976 is meant to be complied with by the prosecution and if no objection had been raised by the defence at the trial, it would not validate the proceedings which otherwise stood vitiated for non-compliance of S. 30, Drugs Act, 1976.<sup>227</sup>

**Appeal:** The Trial Court before convicting the accused discussing evidence of witnesses as well as documents produced by them and facts deposed in evidence as well as given in documents not disputed by the accused. Conviction and sentence were maintained.<sup>228</sup>

**Jurisdiction of the Drugs Tribunal:** Sub-standard drugs manufactured at 'L' and thereafter sold within the territorial jurisdiction of the Drugs Court at 'K'. Consequences of manufacturing substandard drugs at place other than the place of sale of such drugs. Drugs Tribunal at 'K' would have jurisdiction to try offences under the Drugs Act and no exception could be taken to impugned order passed by the Tribunal at 'K'.<sup>229</sup>

**Petitioner's conviction based on his own plea of guilt:** Having admitted that the drugs recovered from him was sub-standard, declined to produce any evidence in defence. There is no interference called for in the case. Leave to appeal was refused.<sup>230</sup>

**Appeal against acquittal:** The accused respondents had a right to request for re-testing of samples and Section 22(5) of the Drugs Act, 1976, makes it compulsory for prosecution to send the samples for re-testing to the Federal Drugs Laboratory or any other laboratory specified for the purpose by the Federal Government. The accused has not given up their such request and their right could not be brushed aside on basis of their letters which did not amount to unconditional admission of guilt as provisions of law have to be strictly followed. Letters were addressed to the Provincial Quality Control

<sup>225</sup> 1996 P.Cr.L.J. 540.  
<sup>226</sup> 1996 P.Cr.L.J. 1183.  
<sup>227</sup> 1996 S.C.M.R. 767.  
<sup>228</sup> 1986 P.Cr.L.J. 1285.  
<sup>229</sup> 1987 M.L.D. 1619.  
<sup>230</sup> 1985 S.C.M.R. 1405.



order being made, such drug, substance, implements, receptacles, packages or coverings, animals, vehicles, vessels or conveyance may be disposed of as that Government may direct.

(2) Without prejudice to the provisions of sub-section (1), where the Drug Court is satisfied on the application of an Inspector or otherwise, and after such inquiry as may be necessary that a drug contravenes the provisions of this Act, the Drug Court may order that such drug be forfeited to the Federal Government or, as the case may be, the Provincial Government and, upon such order being made, such drug may be destroyed or otherwise disposed of as that Government may direct.

(3) An Inspector shall release any drug or article seized by him under this Act when he is satisfied that all the provisions of this Act and the rules with respect thereto have been complied with.

### COMMENTS

Power of confiscation can be exercised provided the prosecution ends in conviction of the accused. When the Appellate Court acquitted the accused but maintained the order of confiscation of medical packets the order was set aside.<sup>241</sup>

**30. Cognizance of offences:** (1) Subject to the Provisions of Section 19, no prosecution shall be instituted under this Chapter except—

- (a) by a Federal Inspector, where the prosecution is in respect of a contravention of clause (h) of sub-section (1) of Section 23 or Section 24 or any of the provisions of this Act of the rules relating to the import or export of drugs or the manufacture for sale, or sale, of a drug which is not for the time being registered or for the manufacture for sale of which a licence is not for the time being in force; or
- (b) by a Provincial Inspector:

Provided that, where the public interest so requires, the Federal Inspector may, with the prior permission of the Federal Government, institute a prosecution for a contravention of any other provision of this Act.

(2) Notwithstanding anything contained in the Code of Criminal Procedure, 1898 (Act V of 1898),—

- (a) an offence punishable under this Chapter other than an offence mentioned in sub-section (1) of Section 27, shall be non-cognizable, and
- (b) no Court other than a Drug Court shall try an offence punishable under this Chapter.

<sup>241</sup> 1971 P Cr. LJ 641.

(3) Nothing contained in this Chapter shall be deemed to prevent any person from being prosecuted under any other law for any act or omission which constitutes an offence punishable under this Chapter or to require the transfer to a Drug Court of any case which may be pending in any Court immediately before the establishment of the Drug Court.

### COMMENTS

Question of lodging report with police and arrest of accused are not dealt with by the Drugs Act. Provisions of the Criminal Procedure Code, 1898 will, therefore, govern such matters.<sup>242</sup>

Where the witness was not cross-examined on the point the Magistrate was held to have erred in holding that the witness was not an Inspector of Drugs merely because he did not produce documentary evidence about his appointment.<sup>243</sup>

In a prosecution under the Act the complainant has to prove by bringing evidence on record that he is an Inspector, whether that fact is challenged by the accused or not. His mere allegation in the complaint that he is an Inspector and the failure of the accused to cross examine him on that point are not proof of his status.

The prosecution instituted by a person whose appointment as Drugs Inspector was not notified within the meaning of Section 17, violates provisions of Section 30 whereunder no prosecution could be instituted except by a properly appointed Drugs Inspector. It was held that since there was a legal defect in institution of instant case it was not possible to maintain conviction of the appellant or sentence awarded to him under Section 27 (4). Appeal was allowed, conviction was set aside and the appellant was acquitted.<sup>244</sup>

Sanction for prosecution which does not mention that public interest required institution of prosecution against accused, would not be legal sanction and Drug Court cannot proceed further in the matter.<sup>245</sup>

**Cognizance of offences.** Non-compliance of S. 30 of Drugs Act, 1976. Effect. Failure to raise objection to proceedings by the defence would not validate the proceedings otherwise invalid. Requirement of law enjoined by S. 30 of the Drugs Act, 1976 is meant to be complied with by the prosecution and if no objection had been raised by the defence at the trial, it would not validate the proceedings which otherwise stood vitiated for non-compliance of S. 30, Drugs Act, 1976.<sup>246</sup>

To consider whether in a criminal prosecution it was proper to exercise jurisdiction under Art. 199 of the Constitution particularly when remedies were provided under the statute to the accused. *Held that:* High Court would not in its discretionary jurisdiction short circuit the normal procedure of trial as provided by law. There was no justification in granting relief in exercise of

<sup>242</sup> PLD 1976 Lah. 813.

<sup>243</sup> 1974 P Cr. LJ Note 81, p. 50.

<sup>244</sup> NLR 1981 Criminal 369; 1982 P Cr. LJ 48.

<sup>245</sup> 1996 CrLJ 399.

<sup>246</sup> 1996 SCMR (Pak). 767.



Constitutional jurisdiction. Appeal allowed. The case to proceed before the Drugs Court.<sup>247</sup>

Evidence, appreciation of. Record showing no order of appointment of Drugs Inspector having been produced before Trial Court at all and Notification issued in this behalf not indeed a notification as stipulated by S. 17 of Act. Since no prosecution can be instituted except by a properly appointed Drugs Inspector, conviction and sentence awarded to appellant, set aside, in circumstances.<sup>248</sup>

Inspector notified by Provincial Government irrespective of any local area assigned to him, whether would be competent to file complaint u/s. 330 (b)? Quaere.<sup>249</sup>

Provincial inspector instituting proceedings against regional Manager of company. Drug Court issuing process against Managing Director, Production Manager and Quality Control Incharge on application of Special Prosecutor. Institution for proceedings against these accused, held, was illegal and unwarranted. No prosecution can be instituted, held further, save on complaint of concerned Inspector.<sup>250</sup>

Cognizance of offence which does not fall within four corners of S. 30 (1)(a) stands by proviso to S. 9 (5). Federal Government is empowered by proviso to S. 30 (1) to invest a Federal Drug Inspector with prosecution of offences not covered by S. 30 (1)(a).<sup>251</sup>

Authorisation, by Federal Government to federal Drug Inspector to prosecute for offences not covered by S. 30 Inspector without reference to particulars of cases, would not constitute authorisation within meaning of proviso to s. 30 (1). In such case, grant of permission by Central Licensing Board/Registration Board for prosecution would be meaningless and complaint for offences not converged by S. 30 (1), lodged by Federal Drug Inspector would be incompetent.<sup>252</sup>

To consider whether in a criminal prosecution it was proper to exercise jurisdiction under Art. 199 of the Constitution particularly when remedies were provided under the statute to the accused. Held that: High Court would not in its discretionary jurisdiction short circuit the normal procedure of trial as provided by law. There was no justification in granting relief the Drugs Court.<sup>253</sup>

**Report to Police:** Question of lodging of report with police and arrest of accused not dealt with by Drugs Act. Provisions of Criminal Procedure code, 1898, hence govern such matters.<sup>254</sup>

In the Court of Sindh 'Quality' Control Board of Drug M/s. Pioneer Laboratories Karachi: Having heard the appeal, the Supreme Court take up a more important question involved in principle namely, whether in a Criminal prosecution it is proper to exercise jurisdiction under Art. 199 of the constitution, particularly when remedies have been provided under the statute to the accused. In a prosecution under the Drugs-Act, the provisions of the

<sup>247</sup> 1994 PSC (Pak) 79.

<sup>248</sup> 1982 PCr LJ 48.

<sup>249</sup> NLR 1993 SCJ 496.

<sup>250</sup> NLR 1982 CrLJ 280.

<sup>251</sup> NLR 1982 CrLJ 280.

<sup>252</sup> NLR 1989 TD 198.

<sup>253</sup> 1994 PSC SC (Pak) 79.

<sup>254</sup> P.L.D. 1976 Lah. 813.

Code of Criminal Procedure are applicable, and the trial by the Drugs Court is conducted as provided by the Drugs Act as well as the Code of Criminal Procedure. Under section 31(4) of the Drugs Act a Drugs Court has all the powers conferred by the Code of Criminal Procedure on a Court of a Session exercising original jurisdiction. Therefore, whether the cognizance of offence could be taken under Section 30 in view of the objection raised by the respondent in the constitution petitioner before the High Courts, could be pressed before the Drugs Court under section 265-K, Cr.P.C. for challenging the proceedings if they were defective and not as provided by section 30 of the Drugs Act. In such circumstances the High Court should have refused to exercise discretion under Article 199 of the Constitution.

**31. Drug Courts:** (1) The Federal Government<sup>255</sup> and, if so directed by the Federal Government, the Provincial Government<sup>256</sup> may, by notification in the official Gazette, establish as many Drug Courts as it considers necessary and, where it establishes more than one Drug Court, shall specify in the notification the territorial limits within which, of the class of cases in respect of which, each one of them shall exercise jurisdiction under this Act.

(2) A Drug Court shall consist of a person who is, or has been, or is qualified for appointment as, a Judge of a High Court, who shall be the Chairman, and two members being persons who, in the opinion of the Federal Government, are experts in the medical or pharmaceutical fields.

(3) A Drug Court shall sit at such place or places as the Federal Government<sup>257</sup>, as the case may be, the Provincial Government<sup>258</sup> may direct.

(4) A Drug Court shall have all the powers conferred by the Code of Criminal Procedure, 1898 (Act V of 1898), on a Court of Session exercising original jurisdiction.

(5) A Drug Court shall not merely by reason of a change in its composition, be bound to recall and rehear any witness who has given evidence, and may act on the evidence already recorded by or produced before it.

(6) A Drug Court shall, in all matters with respect to which no procedure has been prescribed by this Act, follow the procedure prescribed by the Code of Criminal Procedure, 1898 (Act V of 1898), for the trial of summons cases by Magistrates.

(7) A person sentenced by a Drug Court may prefer an appeal to a Bench of the High Court consisting of not less than two Judges within thirty days of the judgment.

Inserted by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998.

Inserted by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998.

(7A) A Federal Inspector or a Provincial Inspector may, on being directed by the Federal Government or, as the case may be, by the Provincial Government, prefer appeal against an order of acquittal or inadequacy of sentence passed by the Drug Court within thirty days of such order.]

(8) The provisions of Sections 5 and 12 of the Limitation Act, 1908 (IX of 1908), shall be applicable to an appeal referred to in sub-section (7).

### COMMENTS

Revisional jurisdiction of High Court, is available in cases tried under the Drugs Act, 1976. Even if the Drugs Act, 1976 did not confer High Court revisional jurisdiction, same could be invoked under Sections 435 and 439, Criminal Procedure Code. High Court, under Section 31, Drugs Act, could exercise appellate jurisdiction against decision of the Drugs Court thus Drugs Court is an 'inferior' Court. Use of the word 'inferior' in Section 435, Criminal Procedure Code, enables the High Court to exercise revisional jurisdiction in respect of those Courts also which were not subordinate to it in technical sense. High Court is competent to exercise revisional jurisdiction and could interfere to the extent of examining the correctness, legality or propriety of any finding, sentence or order recorded or passed and as to regularity of proceeding pending before the Trial Court. All powers allowed under Sections 435 and 439, Criminal Procedure Code, could be exercised by the High Court.<sup>258</sup>

Under repealed Act of 1940, in the event of conviction by a Magisterial Court, accused had a right to file an appeal against the order of conviction, in Sessions Court and yet a further remedy of revision in High Court, against dismissal of appeal, while under the repealing Drugs Act of 1976, accused having only one remedy by way of appeal to High Court. Rule of retrospectivity would not be applicable as change in procedural law affects a "vested right" of accused under old law unless an express provision to take such right made in new law. The trial of the accused by the Drugs Court, constituted under Section 31 of the Drugs Act, 1967, for an offence committed by him under Section 18 (a) of the Drugs Act, 1940 and his eventual conviction for such offence, was illegal and without jurisdiction. The conviction and sentence was set aside in circumstances.<sup>259</sup>

Complaint in the Drug Court for taking action against the accused for manufacturing substandard quality of vitamins. The accused challenged such action in the High Court through Constitutional petition, which was validly allowed. Exercise of the Constitutional jurisdiction by the High Court in a criminal prosecution was not proper particularly when remedies had been provided under the Statute (Drugs Act, 1976) to the accused. Case was directed to proceed before the Drug Court where the respondents would be at liberty to raise such objections as would be possible under law.<sup>260</sup>

<sup>257</sup> Inserted new sub-section (7A) by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998.

<sup>258</sup> PLD 1986 Kar.390.

<sup>259</sup> 1980 P Cr. LJ 1212.

<sup>260</sup> P.L.D. 1993 (Pak) 1177.

The word "inferior" substituted in Sec. 435 for the word "subordinate" appearing in Section 295 in order to keep hands of High Court quite free in dealing with a case in its ultimate stage of revision, etc. Drugs Court having been made subject to appellate jurisdiction of High Court, and, in such sense, inferior to High Court, High Court, could exercise revisional jurisdiction against the orders of the Drugs Court. Having made Drugs Court judicially inferior to High Court no necessity existed for duplicating matter over again by expressly providing for a revisional jurisdiction of High Court.<sup>261</sup>

**Sanction for lodging complaint:** Drug Inspector obtaining sanction for lodging complaint from the Provincial Quality Control Board against the accused who were actively connected with accused company and lodged complaint against them. But omitting to get such sanction and consequently to lodge complaint, regarding accused company. Second complaint lodged against the accused company afterwards without getting such sanction. The High Court finding that Provincial Quality Control Board after considering matter and reports from the laboratories had concluded that prosecution be launched against the manufacturer. Intention of Board very clear that manufacturer of drugs to be prosecuted which included company also. The defect of not getting sanction against the accused company, was merely procedural in nature and not vitiating proceedings. No bar was present against consolidation of both complaint by the trial Court.<sup>262</sup>

**"Dihydrallazine" or "Dihydralline Sulphate":** Protocols of tests (details of process of tests) was not provided with report by Analyst. Sample was sent to Federal Laboratory did not appear to be the same sample as sealed and marked by the Inspector, Federal Laboratory tested and analysed "Dihydrallazine tablets" instead of testing and analysing "Dihydrallazine Sulphate" tablets. Provisions of Act and Rules with regard to despatch of samples and submission of report not observed with complete strictness. Accused, held, could not be prosecuted and convicted in circumstances. Direction contained in Section 19(2) of Act and rules 14 and 15 in regard to making sample, could not convict the accused on ground of report of analyst that sample was substandard. Importance of strict observance in regard to sample emphasised in Form No.6.

**Appeal:** The Trial Court before convicting the accused discussing evidence of witnesses as well as documents produced by them and facts deposed in evidence as well as given in documents not disputed by the accused. Conviction and sentence were maintained.<sup>263</sup>

**Adulterated drug—Test report:** Action of the Provincial Quality Control Board for sending sample for second report when first test report was already adverse to accused was uncalled for. The report in second test also adverse but findings in both reports conflicting with each other. Test report not made on the prescribed form. Details of result of test or analysis not given in report. Report not to be relied upon in circumstances.<sup>264</sup>

Test report of sample showing that sodium bicarbonate was found to be 1.24% whereas limit was 0.981%. Sodium bicarbonate in sample was found to be in excess of by 0.24% as against 1%. Such excess found to be neither

<sup>261</sup> PLD 1981 SC 352.

<sup>262</sup> 1985 P Cr. LJ 2064.

<sup>263</sup> 1986 P Cr. LJ 1265.

<sup>264</sup> 1985 p Cr. LJ 2064.

dangerous nor detrimental as still the ingredient was within the range of normal dose. Prosecution, therefore, failed to prove case in circumstances.

Complaint the Drug Court for taking action against accused for manufacturing substandard quality of vitamins. Accused challenged such action in High Court through Constitutional petition, which was allowed. Validity. Exercise of Constitutional jurisdiction by the High Court in a criminal prosecution was not proper particularly when remedies had been provided under the statute (Drugs Act, 1976) to the accused. Case was directed to proceed before the Drug Court where respondents would be at liberty to raise such objections as would be possible under law.

Drug Court is judicially inferior to High Court. It is amenable to regional jurisdiction u/s. 439 and inherent jurisdiction u/s. 561A, Cr.P.C. of High Court Revisional jurisdiction and inherent jurisdiction like appellate jurisdiction u/s. 31 to be exercised by a Division and not Single Bench of High Court. Held: Powers of appeal, revision and inherent jurisdiction go hand in hand and can be exercised at equal footing by same forum.

Appeal. Appeal against decision of Drugs Court is competent before a Bench of two Judges of High Court. Power of appeal, revision and inherent jurisdiction go hand in hand and could be exercised at equal footing by High Court.

**32. Pleas:** (1) Save as hereafter provided in this section, it shall be no defence in a prosecution under this Act to prove merely that the accused was ignorant of the nature, substance or quality of the drug in respect of which the offence has been committed or of the circumstances of its manufacture or import, or that a purchaser, having bought only for the purpose of test or analysis, has not been prejudiced by the sale.

(2) A drug shall not be deemed to be misbranded or adulterated or sub-standard only by reason of the fact that there has been added thereto some innocuous substance or ingredient because the same is required for the manufacture or preparation of the drug fit for carriage or consumption and not to increase the bulk, weight or measure of the drug or to conceal its inferior quality or other defect or there is a decomposed substance which is the result of a natural process of decomposition:

Provided that such decomposition is not due to any negligence on the part of the manufacturer or the drug or the dealer thereof and that it does not render the drug injurious to health or does not make it substandard.

(3) A person, not being the manufacturer of a drug or his agent for the distribution thereof, shall not be liable for a contravention of Section 23 if he proves—

265 1985 P Cr.LJ 2064.  
266 1993 SCMR 1177.  
267 NLR 1986 Criminal Kar. 725.  
268 PLD 1986 Kar. 390.

- (a) that he did not know, and could not with reasonable diligence have ascertained, that the drug in any way contravened the provision of this Act and that the drug while in his possession remained in the same state as when he acquired it; and
- (b) that he acquired the drug from a duly licensed manufacturer or his authorised agent or an importer or an indenter resident in Pakistan under a written warranty in the prescribed form stating, in particular, the batch number of the drug and signed by such person that the drug does not in any way contravene the provisions of Section 23 and that the drug while in his possession was properly stored and remained in the same state as when he acquired it and that the drug has been manufactured by a manufacturer holding a valid licence to manufacture drugs and permission to manufacture that drug.

Provided that a defence under clause (b) shall be open to a person only—

- (i) if he has, within seven days of the service on him of the summons, sent to the Inspector a copy of the warranty with a written notice stating that he intends to rely upon it and giving the name and address of the warrantor, and
- (ii) if he proves that he has, within the same period sent written notice of such intention to the said warrantor.

### COMMENTS

Dying declaration recorded by Police Officer without procuring services of a magistrate, would be unreliable for conviction on a capital charge.

Oral dying declaration is admissible in evidence.

Protection u/s. 32 (3) cannot be invoked when medicines were purchased from registered Firm and warranty relied upon was not issued under lawful authority.

**33. Application of law relating to customs and powers of officers of customs:** (1) The law for the time being in force relating to customs and to goods the import of which is prohibited by or under the Customs Act, 1969 (IV of 1969), shall, subject to the provisions of Section 27 of this Act, apply in respect of drugs the import of which is prohibited under this Act, and officers of customs and officers to whom any of the functions of an officer of customs have been entrusted under the said Act shall have the same powers in

269 NLR 1995 CrLJ 378.  
270 NLR 1995 CrLJ 701.  
271 NLR 1993 Criminal Quetta 76.

respect of such drugs as they have for the time being in respect of such goods as aforesaid.

(2) Without prejudice to the provisions of sub-sec.(1) an officer of customs or a Federal Inspector or any other person as may be authorised by the Federal Government in this behalf may detain any imported package which he suspects to contain any drug the import of which is prohibited under this Act, and shall forthwith report such detention to the licensing authority and, if required by it, forward the package or samples of any suspected drug found therein to a laboratory specified by it.

**34. Offences by companies, etc.:** Where the person guilty of an offence under this Act, is a company, corporation, firm or institution, every director, partner and employee of the company, corporation, firm or institution shall, unless he proves that the offence was committed without his knowledge or consent, be guilty of the offence.

### COMMENTS

**Vicarious liability:** No evidence produced by Director of the accused firm that substandard drug manufactured without his knowledge or consent. The accused was equally responsible for offence by virtue of being a Director of accused firm. The conviction was maintained, in circumstances.<sup>272</sup>

According to the case of *Fazal Ellahi v. The State*,<sup>273</sup> where the person guilty of offence was a company, vicarious liability was imposed on a Director, a partner or employer unless they prove that offence was committed without their knowledge.

**Appeal:** The Trial Court before convicting the accused discussing evidence of witnesses as well as documents produced by them and facts deposed in evidence as well as given in documents not disputed by the accused. The conviction and sentence were maintained.

**Substandard and misbranded drug:** The person guilty of offence a limited company while the accused its director and employees. The vicarious liability, was imposed on every such Director and the employees of the company unless they proved that offence was committed without their knowledge or consent.<sup>274</sup>

**Substandard drugs—Manufactured by a Company—Responsibility:** The Drug Inspector to find out, as to, which of directors, partners or employees, etc., were *prima facie* concerned and responsible for manufacturing substandard drug, and would launch prosecution against such persons alongwith principal accused, i.e., Corporation, firm or institution.<sup>275</sup>

**Offence by company:** The company itself was not impleaded as an accused but the General Manager and Director, Plant Manager, Production Manager, Quality Control Manager and Controller of the Company were

<sup>272</sup> 1984 P Cr. LJ 2007.

<sup>273</sup> 1985 P Cr. LJ 268.

<sup>274</sup> 1986 P Cr. LJ 1265.

<sup>275</sup> 1985 P Cr. LJ 268.

convicted and sentenced under Section 27(2)(b) and (4). Held, company having not been impleaded as an accused in the proceedings constituted against the accused persons, conviction and sentence of the accused persons as such was not legal. The accused persons being the employees and Director of the company, could be held to be guilty of the offence, provided the company, was found guilty of the offence.<sup>276</sup>

**Conviction of employees of the company:** If the company which is a juristic person is not impleaded as an accused, its employees cannot be guilty of the offence.<sup>277</sup>

**Appeal:** The Trial Court before convicting the accused discussing evidence of witnesses as well as documents produced by them and facts deposed in evidence as well as given in documents not disputed by the accused. The conviction and sentence were maintained.<sup>278</sup>

**Leave to appeal:** The leave to appeal was granted to consider that the trial of the accused persons was illegal, in that, sanction from the Quality Control Board was obtained against the Company (Manufacturer) and not against the accused persons (General Manager and Director, Plant Manager, Production Manager, Quality Control Manager and Controller) and that the company as such was not impleaded as an accused and that the High Court erred in invoking section 34 of the Act in this behalf.<sup>279</sup>

**35. Publication of offender's name:** (1) If any person is convicted of an offence under this Act, it shall be lawful for the Drug Court to cause the offender's name, place of residence, the offence of which he has been convicted and the penalty which has been inflicted upon him, to be published at the expense of such person in such newspapers or in such other manner as the Court may direct.

(2) The expenses of such publication shall be recoverable in the same manner as a fine is recoverable.

**36. Powers to exempt:** Notwithstanding anything contained in this Act, the Federal Government may, if it is of opinion that the public interest so requires, at any time, of its own motion or on a representation made to it, by notification in the official Gazette, exempt any drug or class of drugs from the operation of any of the provisions of this Act, subject to such conditions, if any, and for such period, as may be specified in the notification.

### COMMENTS

S.R.O. 1090(1)/92, dated 5-11-1992: In exercise of the powers conferred by section 36 of the Drugs Act, 1976 (XXXI of 1976), the Federal Government being of the opinion that the public interest so requires, is pleased to exempt the drugs specified below from operation of the provisions of the said Act, except sections 24 and 25, till further orders, namely :-

<sup>276</sup> P.L.D. 1991 SC 893.

<sup>277</sup> 1996 P Cr. L.J. (b) 1183.

<sup>278</sup> 1986 P Cr. L.J. 1265.

<sup>279</sup> P.L.D. 1991 SC 893.

- (i) Infant formula; and
- (ii) Infant food.

**37. Inspectors to be public servants:** Every Inspector shall be deemed to be a public servant within the meaning of Section 21 of the Pakistan Penal Code (Act XLV of 1860), and shall be officially subordinate to such authority as the Government appointing him may specify in this behalf.

### COMMENTS

**Public Servant:** According to the Pakistan Penal Code the Public Servant is as follows:--

The words "public servant" denote a person falling under any of the description hereinafter following, namely:--

**First:** Omitted.

**Second:** Every Commissioned Officer in the Military, Naval or Air Forces of Pakistan while serving under the Federal Government or any Provincial Government;

**Third:** Every Judge;

**Fourth:** Every officer of a Court of Justice whose duty it is, as such officer, to investigate or report on any matter of law or fact, or to make, authenticate, or keep any document, or to take charge or dispose of any property, or to execute any judicial process, or to administer any oath or to interpret, or to preserve order in the Court and every person specially authorized by a Court of Justice to perform any of such duties;

**Fifth:** Every juryman, assessor, or member of a panchayat assisting a Court of Justice or public servant;

**Sixth:** Every arbitrator or other person to whom any cause or matter has been referred for decision or report by any Court of Justice or by any other competent public authority;

**Seventh:** Every person who holds any office by virtue of which he is empowered to place or keep any person in confinement;

**Eighth:** Every officer of the Government whose duty it is, as such officer, to prevent offences, to give information of offences, to bring offenders to justice, or to protect the public health, safety or convenience;

**Ninth:** Every officer whose duty it is, as such officer, to take, receive, keep or expend any property on behalf of the Government, or to make any survey, assessment or contract on behalf of the Government or to execute any revenue process, or to investigate, or to report on any matter affecting the pecuniary interests of the Government, or to make, authenticate or keep any document relating to the pecuniary interests of the Government, or to prevent the infraction of any law for the protection of the pecuniary interests of the Government and every officer in the service or pay of the Government or remunerated by fees or commission for the performance of any public duty;

**Tenth:** Every officer whose duty it is, as such officer, to take, receive, keep or expend any property, to make any survey or assessment or to levy

any rate or tax for any secular common purpose of any village, town or district, or to make, authenticate or keep any document for the ascertaining of the rights of the people of any village, town or district;

**Eleventh:** Every person who holds any office in virtue of which he is empowered to prepare, publish, maintain or revise an electoral roll or to conduct an election or part of an election.

### Illustrations

Municipal Commissioner is a public servant.

**Explanation 1:** Persons falling under any of the above descriptions are public servants, whether appointed by the Government or not.

**Explanation 2:** Wherever the words "public servant" occur, they shall be understood of every person who is in actual possession of the situation of a public servant, whatever legal defect there may be in his right to hold that situation.

**Explanation 3:** The word "election" denotes an election for the purpose of selecting members of any legislative, municipal or other public authority, of whatever character, the method of selection to which is by, or under, any law prescribed as by election.

**38. Indemnity:** Except as otherwise expressly provided in this Act, no suit, prosecution or other legal proceeding shall lie against Government or any other authority or person for anything which is in good faith done or intended to be done under this Act or any rule.

**39. Finality of order, etc.:** Save as otherwise expressly provided in this Act, every order passed or decision given by any Board, a Drug Court or any other authority under this Act shall be final and shall not be called in question by or before any Court or other authority.

### COMMENTS

Finality was attached to orders of Drugs Court, subject to any other provision provided otherwise. Such provision in case in hand, incident of Drugs Court being inferior to the High Court by virtue of its orders had been made appealable to High Court. Section 2 of Act not barring application of other laws and provisions of Act having been made subject to "any other law for the time being in force". Sections 435 and 439, Criminal Procedure Code, 1898 were fully attracted to the Drugs Court.

**40. Publication of result of test or analysis, etc.:** (1) It shall be lawful for the Federal Government to publish, in such manner as it may deem fit, the result of any test or analysis of any drug for public information and to pass such orders relating to the withdrawal of such drug from sale and its disposal as it may consider necessary.

(2) The Federal Government may, if it considers it necessary in the public interest so to do, publish for public information, in such



manner as it may deem fit, any information relating to a drug or to the use of a drug in specified circumstances.

### COMMENTS

Appreciation of evidence. No sample of the drug seized by the complainant Drug Inspector having been taken and sent to the concerned Laboratory for analysis, it could not be said to be a spurious drug. Drug Inspector although alleged that the drug seized by him resembled a medicine manufactured by a local pharmaceutical company, yet he admitted did not contact the said pharmaceutical company in this respect and failed to obtain the view of that company regarding the drug in question. Accused was acquitted in circumstances.<sup>281</sup>

Sanction for prosecution which does not mention that public interest required institution of prosecution against accused, would not be a legal sanction and Drug Court cannot proceed further in the matter.<sup>282</sup>

**41. Cancellation or suspension of licences:** <sup>283</sup>[(1)] Where any person has been found to have contravened any of the provisions of this Act, or the rules in respect of any drug and the contravention is of such a nature that the import, export, manufacture or sale of any drug by such person is, in the opinion of the licensing authority or the Central Licensing Board, likely to endanger public health, that authority may, after giving such person an opportunity of being heard, cancel the licence to import, export, manufacture or sell drugs issued to such person or suspend such licence for a specified period.

<sup>284</sup>[(2)] A Provincial Quality Control Board may, subject to the condition specified in sub-section (1), suspend the manufacturing licence of a manufacturer situated within the Province for a specified period not exceeding fifteen days and shall as soon as possible report the matter to the Central Licensing Board for such action as it may deem fit.

(3) The suspension of the licence made by the Provincial Quality Control Board shall, on the expiry of the specified period, cease to have effect unless it is extended or continued by the Central Licensing Board.]

**42. Cancellation or suspension of registration of registered drugs:** Where any person has been found to have contravened any of the provisions of this Act, or the rules in respect of any registered drug, the Registration Board may, after giving such person an

<sup>281</sup> 1996 PCr LJ 540.

<sup>282</sup> NLR 1996 Cr LJ 399.

<sup>283</sup> Numbered as sub-section (1)"

<sup>284</sup> Added new sub-sections (2), (3) by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998.

opportunity of being heard, cancel the registration of such drug or suspend such registration for a specified period.

### COMMENTS

**Registration cancelled without hearing:** Cancellation of registration of drug without hearing petitioner. Authority expressed its willingness to take up petitioner's case and to rehear him on condition that contesting respondent would also be heard alongwith petitioner. Petition disposed of in terms of statements of respondents.<sup>285</sup>

## CHAPTER V

### Miscellaneous

**43. Power of Federal Government to make rules:** (1) Subject to Section 44, the Federal Government may, by notification in the official Gazette, make rules for carrying out the purposes of this Act.

(2) In particular and without prejudice to the generality of the foregoing provision, such rules may—

- (a) prescribe the functions of the Federal Drug Laboratory and any other laboratory set up under Section 14 or specified under Section 22 or Section 33 and the procedure for the submission to any such laboratory of samples of drugs for analysis or test, the forms of the laboratory's reports thereon and the fees payable in respect of such reports and such other matters as may be necessary for any such laboratory to perform its functions;
- (b) prescribe specifications, including the strength, potency, purity, quality or other property, of any drug, and the methods of test or analysis to be employed in determining whether a drug is of required specifications;
- (c) prescribe the maximum proportion of any poisonous or other substance which may be added to or contained in any drug, or extracted or omitted therefrom; prohibit the import, manufacture, sale or stocking or exhibition for sale or distribution of any drug in which that proportion is exceeded and specify substances which shall be deemed to be poisonous;
- (d) specify the drugs or classes of drugs for the import or export of which a licence is required; the testing of such drugs, and prescribe the form and conditions of such



- licences, the authority empowered to issue the same, and the fees payable therefor:
- (e) prescribe the places at which any specific drug or drugs may be imported, prohibit their import at any other place, and control their import through any specified agency;
  - (f) prescribe the evidence to be supplied, whether by accompanying documents or otherwise, of the quality of drugs sought to be imported, the procedure of officers, of customs in dealing with such evidence and the manner of storage at places of import of drugs detained pending admission;
  - (g) prescribe the forms of licences for the manufacture for sale of drugs or any specified drugs or class of drugs, the form of application for such licences, the conditions subject to which such licence may be issued, the person under whose signature the same be issued and the fees payable therefor;
  - (h) require the date of manufacture and the date of expiry of potency, to be clearly and truly stated on the label and container of any specified drug or class of drugs and prohibit the sale, stocking or exhibition for sale or distribution of the said drug or class of drugs after the expiry of a specified period from the date of manufacture or after the expiry date and prescribe the manner of disposal of such drug or class of drugs;
  - (i) prescribe the conditions to be observed in the packing in bottles, packages and other containers of drugs and prohibit the sale, stocking or exhibition for sale or distribution of drugs packed in contravention of such conditions;
  - (j) regulate the mode of packing and packaging, including its size, dimensions, fill and other specifications, the material used therefor and mode of labelling packed drugs and prescribe the matters which shall or shall not be included in such labels or on the leaflets accompanying the drugs;
  - (k) require that the non-proprietary or chemical or accepted scientific name or the proprietary name of any specified drug or any ingredient thereof shall be displayed in the prescribed manner;
  - (l) prescribe the requirements and conditions in respect of good practices in the manufacture and quality control of drugs;
  - (m) prescribe conditions for distribution of samples for sales promotion of drugs;

- (n) prescribe the procedure for introduction in Pakistan of a new drug;
- (o) prescribe terms and conditions of members of the Central Licensing Board and the Registration Board;
- (p) prescribe types of registration of drugs, the form of application for such registration, the conditions subject to which such registration may be granted, the manner of registration and post-registration and surveillance and deregistration of registered drugs and the fees payable therefor;
- (q) prescribe conditions for registration of indentors, importers, wholesalers and distributors within Pakistan and any establishment within any foreign country engaged in the manufacture for export of a drug and prescribe conditions providing effective and adequate means, by arrangement with the Government of such foreign country or otherwise, to enable the licensing authority or the Registration Board to determine from time to time whether drugs manufactured in such establishment, if imported or offered for import into Pakistan, shall be refused admission where the public interest so requires;
- (r) prescribe the form of warranty for manufactured drugs;
- (s) specify offences in relation to which the stock of drugs, articles or things shall be liable to forfeiture under this Act;
- (t) prescribe the qualifications, and regulate the procedure for exercise of powers and performance of functions, of Federal Inspectors;
- (u) prescribe the laboratories to which the Federal Inspectors shall submit samples of drugs taken for the purpose of test and analysis and the form and procedure for submitting the report of such test and analysis and the fee payable therefor, where so required;
- (v) prescribe measures for securing and maintaining supplies of drugs at reasonable prices, conditions to be met in respect of manufacture, production, pricing, keeping, movement and disposal of drugs and to fix prices, commissions, discount of the manufacturer, wholesaler, distributor, retailer or any other dealer of drugs, to control giving of bonus in cash or kind or in any other manner to any of the said parties and for collecting or calling for any information, statistics, records or books with a view to regulating the matters aforesaid;

- (w) specify drugs which may be advertised and the conditions subject to which such drugs may be advertised;
  - (x) prescribe conditions subject to which small quantities of drugs may be imported or manufactured or exported for the purpose of examination, test or analysis, clinical trial or personal use; and
  - (y) prescribe any other matter which is to be, or may be, prescribed by the Federal Government.
- (3) The power to make rules conferred by this section shall, except on the first occasion of the exercise thereof, be subject to the condition of previous publication.

### COMMENTS

Mere resemblance of label and outer packing of a carton would not be covered by definition of "counterfeit drug" as given in S. 3(f). Accused facing prosecution u/ss. 23, 24 in such case would be entitled to acquittal by accepting his application u/s. 249A, CrPC.<sup>246</sup>

Registration of case. Drug Inspector should make a report against contravention of Act to Provincial Quality Control Board for initiating criminal action. Case for contravention of Act cannot be registered at Police Station on report of Drug Inspector.<sup>247</sup>

Mere averment in FIR that accused was carrying contraband injections of Cholorampho for sale, would not make accused liable, u/ss. 23/27. Accused in such case would be entitled to bail.<sup>248</sup>

Recovery of Calcium Sandoz Syrup and cotton bandages which did not have surgical bandages, would be no offence when there is no proof that accused was selling these items as drugs. Accused in such case would be entitled to acquittal.<sup>249</sup>

**44. Power of the Provincial Government to make rules:** (1) The Provincial Government may by notification in the official Gazette, make rules in respect of the following matters, namely:--

- (a) the establishment of laboratories for testing and analysing drugs;
- (b) the qualifications and the procedure, for exercise of powers and performance of functions of Provincial Inspectors;
- (c) the forms of reports to be given by Government Analysts and the manner of application for test or analysis and the fees payable therefor;

<sup>246</sup> NLR 1996 CrLJ 399.

<sup>247</sup> NLR 1996 CrLJ 414.

<sup>248</sup> NLR 1996 CrLJ 414.

<sup>249</sup> NLR 1996 CrLJ 401.

- (d) the conditions to regulate sale or storage or distribution of drugs or any specific drug or class of drugs;
- (e) the offences against this Act or any rule in relation to which the stock of drugs shall be liable to confiscation and destruction under this Act;
- (f) the forms of licences for the sale or distribution of drugs or any specified drug or class of drugs, the authority empowered to issue the same, the form of applications for such licences, the fees payable therefor and the condition subject to which such licences may be issued;
- (g) the procedure to be followed by the Provincial Quality Control Board; and
- (h) any other matter which is to be or may be, prescribed by the Provincial Government.

(2) The power to make rules conferred by this section shall, except on the first occasion of the exercise thereof, be subject to the condition of previous publication.

<sup>250</sup>[44-A. **Delegation.**—(1) The Federal Government may, by notification in the official Gazette and subject to such conditions and limitations as may be specified therein, delegate all or any of its powers and functions under this Act, to the Provincial Government, or any other authority as it may deem fit.]

(2) Subject to sub-section (1), the Provincial Government may, by notification in the official Gazette, and subject to such conditions and limitations as may be specified therein, delegate all or any of its powers and functions under this Act to any authority as it may deem fit.]

**45. Repeal and Savings:** [(1) The Drugs Act, 1940 (XXII of 1940), the Drugs (Generic Names) Act, 1972 (XXIV of 1972), and the Drugs Ordinance, 1976 (IV of 1976), are hereby repealed.]

(2) Notwithstanding the repeal of the Drugs Act, 1940 (XXIII of 1940), by sub-section (1),---

- (a) any licence to manufacture for sale issued thereunder to any person, for the revalidation of which an application has already been made to the Central Licensing Board within the date specified by the Federal Government shall continue to be valid until orders are passed by the said Board in this behalf;

Inserted new section (44-A) by Drugs (Amendment) Ordinance, XXII of 1998, dated 23.12.1998.