No.F.1-1/2019-Admn-II/DRAP
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
3rd Floor, Kohsar Block, Pakistan Secretariat
***

Islamabad, the 30th June, 2026

Subject: **COMPLAINT AGAINST SERIOUS THREAT TO PUBLIC HEALTH DUE TO DEFICIT OF FEDERAL INSPECTOR OF DRUGS (FIDS)**

Kindly refer to Transparency International – Pakistan, Karachi letter dated 13TH March 2026 and Prime Minister's Office UO dated 12th June, 2026 on the subject above and to enclose herewith a **detail brief** regarding the subject matter for information and perusal.

(SIBGHATULLAH)
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BRIEF ON FEDERAL INSPECTORS OF DRUGS (FIDS) HIGHLIGHTED BY TRANSPARENCY INTERNATIONAL.

1. The Drug Regulatory Authority of Pakistan (DRAP) is established under the DRAP Act, 2012, to regulate Therapeutic Goods, including pharmaceuticals, biologicals, medical devices, alternative medicines and Health products.

2. As per mandate, DRAP is regulating licensing, registration / enlistment, Pharmacovigilance, Clinical trial oversight, allocation of controlled drugs and quality assurance, while sale, storage and distribution is regulated by Drugs control wings, Provincial Health Departments.

3. Federal Drug Inspectors (FIDs) are the enforcement arm of DRAP primarily for inspection of manufacturing unit of Therapeutic Goods. There are mainly two types of Regulatory Inspections carried out by DRAP:-

    a. For grant or renewal of Manufacturing & Import Licenses, DRAP constitute Panel of Inspectors to conduct inspection including the expert members of Statutory Boards, Technical Officers of DRAP having relevant experience and training.

    b. For follow-up and Post Market Surveillance Inspections, DRAP has adopted Risk Based Inspection System (RBIS) model where the frequency of inspections is governed by the risk profile of the manufacturer and product being manufactured.

4. DRAP is actively harmonizing its inspection systems and Good Manufacturing Practice (GMP) procedures with international best practices. To ensure a quality system for the inspectorate that meets global benchmarks and in alignment with this strategic roadmap 2026-30, DRAP has developed a comprehensive Risk-Based Inspection System (RBIS) and detailed human resource assessment has been completed, which concludes that a minimum of 42 notified inspectors are required to provide effective regulatory oversight of therapeutic goods manufacturers.

5. In May, 2024, DRAP initiated the process of 18 Federal Inspectors of Drugs (FIDs) notification for approval of Federal Government. However, only nine (09) FIDs were notified by the Federal Government vide SRO 1585(I)/2025 dated 22nd August, 2025.

6. DRAP initiated the recruitment process for 10 Deputy Directors/FIDs. However, Policy Board, in its 63rd Meeting on December 10, 2025, directed that *de-novo* recruitment process due to litigations and subsequent consideration of the matter by the M/o NHSR&C, the process has been significantly delayed beyond the period of 120 days as mentioned in Establishment Division's O.M. No. 53/1/2008-SP dated 04.06.2024 and

No.F.2-7/2026-Admn-II/DRAP
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
3rd Floor, Kohsar Block, Pakistan Secretariat
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Islamabad, the 3nd June, 2026

Subject: **COMPLAINT AGAINST ALLEGATION OF LACK OF CLEAR DEFINITION OF ALTERNATIVE MEDICINES IN THE DRAP ACT 2012 RESULTING IN AMBIGUITY IN DRAP UPCOMING DRAFT RULES ON ALTERNATIVE MEDICINES**

Kindly refer to Transparency International – Pakistan, Karachi letter dated 17th April, 2026 and Prime Minister's Office UO dated 31-05-2026 on the subject above and to state that there is no overlapping jurisdiction between the divisions of DRAP with respect to 'drugs' and 'alternative medicines'. Clauses (a) and (h) of sub-section (1) of Section 4 of the Drug Regulatory Authority of Pakistan Act, 2012 **(Annex-I)** clearly delineate the functions of the Division of Pharmaceutical Evaluations and Registration, and the Division of Health and OTC Products, as follows:

"(a) Director Pharmaceutical Evaluations and Registration.- He shall be incharge of the Division of Pharmaceutical Evaluations and Registration which shall be responsible for the evaluation, assessment and registration of Pharmaceuticals drugs for human beings, animals and to perform other functions connected therewith and assigned by the Board;
(h) Director Health and OTC Products (non-drugs).- He shall be incharge of the Division of Health and OTC Products (non-drugs) which shall be responsible for the assessment, licensing and registration of Alternative Medicines such as Ayurvedic, Chinese, Unani and Homeopathy, enlistment or registration of nutritional products and food supplements for human beings, animals and to perform other functions connected therewith;"

2. Furthermore, the issue of including 'alternative medicines' within the definition of 'drug' under Schedule-I of the DRAP Act, 2012, and the regulation of 'alternative medicines' through the Alternative Medicines and Health Products (Enlistment) Rules, 2014 promulgated under section 23 of the said Act, was extensively deliberated by the High Court of Sindh, Karachi in the Azfar Laboratories case [C.P. No. D-2329 of 2017], reported as PLD 2018 Sindh 448 **(Annex-II)**, and by the Lahore High Court in the Dawakhana Hakim Ajmal Khan case [W.P. No. 3973 of 2017], reported as 2020 PLD Lahore 899.

ANNEX-I

DRUG REGULATORY AUTHORITY
OF PAKISTAN

Drug Regulatory Authority of Pakistan Act, 2012

(Act No.XXI OF 2012)

(As amended till Februaary, 2022)

(ii) "Alternative Medicine" means a product used exclusively in Homeopathic, Unani, Ayurvedic, Biochemic, Chinese or other traditional system of treatment;

(iii) "Appellate Board" means an Appellate Board constituted under Section 12 for the disposal of appeals against the decisions of the Licensing Board or the Registration Board or Pricing Committee;

(iv) "Authority" means the Drugs Regulatory Authority of Pakistan established under Section 3;

(v) "Biologicals" means biological drugs as defined in Schedule-I;

(vi) "Board" means the Policy Board of the Authority constituted under Section 9;

(vii) "CEO" means the Chief Executive Officer of the Authority appointed under Section 5;

(viii) "Chairperson" means the Chairperson of the Board;

(ix) "civil servant" means a civil servant as defined in the Civil Servants Act, 1973 (LXXI of 1973);

(x) "decision" includes an order, determination or direction of the Authority or the Board made in accordance with laws, rules and regulations;

(xi) "Director" means director of a department of the Authority;

(xii) "drug" means drug as defined in Schedule-I;

(xiii) "fee" means fee prescribed by the Board for any service;

(xiv) "Fund" means the Drug Regulatory Authority of Pakistan Fund created under Section 19;

(xv) "health and OTC Products (non-drugs)" include probiotics and disinfectant, nutritional products, food supplements, baby milk and foods, medicated cosmetics, medicated soaps and medicated shampoos;

(xxvii) "pharmaceutical evaluation" means the assessment of a detailed pharmaceutical dossier submitted for the registration of a therapeutic good;

(xxviii) "pharmaceutical dossier" means a set of documents, as specified in Schedule-I;

(xxix) "prescribed" means prescribed by rules or regulations under this Act;

(xxx) "Prohibitions" means Prohibitions as specified in Schedule-II;

(xxxi) "regulation" means the regulations made under this Act;

(xxxii) "Registration Board" means a Registration Board constituted under Section 7 sub-section (u) of this Act to regulate the grant of registration to therapeutic goods;

(xxxiii) "rules" means the rules made under this Act;

(xxxiv) "Secretary" means Secretary of the Board;

(xxxv) "Schedule" means Schedule to this Act; and

(xxxvi) "Therapeutic goods" includes drugs or alternative medicine or medical devices or biologicals or other related products as may be notified by the Authority.

CHAPTER-II
AUTHORITY AND BOARD

3. Establishment of the Authority.— (1) As soon as may be, after the commencement of this Act, the Federal Government shall, by notification in the official Gazette, establish an Authority to be known as the Drug Regulatory Authority of Pakistan, to carry out the purposes of this Act.

(2) The Authority shall be a body corporate having perpetual succession and a common seal, and may sue and be sued in its own name and, subject to and for the purposes of this Act, may enter into contracts and may acquire, purchase, take, hold and enjoy moveable and

under the Act, and for testing or research of drugs and to perform other functions connected therewith. The Division will also perform the functions related to post marketing surveillance and shall be responsible for the evaluation, co-ordination and monitoring of safety, efficacy and quality of registered drugs and inactive materials including the clinical and toxicological study, drug recalls and with drawls, and to perform other functions connected therewith;

(d) *Director Medical Devices and Medicated Cosmetics.*--He shall be incharge of the Division of Medical Devices and Medicated Cosmetics which shall be responsible for the assessment, enlistment or registration of medical devices and medicated cosmetics, medicated shampoos and medicated soaps for human beings, animals and to perform other functions connected therewith;

(e) *Director Biological Drugs.*--He shall be incharge of the Division of Biological Evaluation and Research which shall be responsible for the evaluation, assessment, registration and licensing of Biologicals for human beings, animals and to perform other functions connected therewith including all the functions of national control authority for biologicals as required for the prequalification by World Health Organizations of locally manufactured human biological drugs;

(f) *Director Controlled Drugs.*--He shall be incharge of the Division of Controlled Drugs which shall in consultation with the Federal Government be responsible for regulation and allocation of quota of narcotic drugs, psychotropic substances and precursor chemicals and to perform other functions connected therewith;

(g) *Director Pharmacy Services.*--He shall be incharge of the Division of Pharmacy Services which shall be responsible for the development and promotion of pharmacy services and to perform other functions connected therewith;

(h) *Director Health and OTC Products (non-drugs).*--He shall be incharge of the Division of Health and OTC Products (non-drugs) which shall be responsible for the assessment, licensing and registration of Alternative Medicines such as Ayurvedic, Chinese, Unani and Homeopathy,

(a) has a post graduate degree in Pharmacy or medicine with an age not less than 45 years or more than 56 years, with a minimum of twenty years experience in management or pharmaceutical field or regulatory affairs, in public sector, or if no such person of aforesaid qualifications is available in the public sector, then a person possessing above qualifications and experience from the private sector;

(b) the tenure of appointment of CEO shall be for a period of three years, extendable on the recommendation of the Board for one year only; and

(c) the CEO shall exercise general Control and supervision over the affairs of the Authority and shall ensure the provisions of the Act, the rules, and that the regulations, policies and directions of the Board are properly executed;

(2) The CEO shall discharge such duties and perform such functions as are assigned to him by or under this Act or as may be prescribed by the Board and in particular shall,—

(a) keep in custody the records and seal of the Authority;

(b) submit plan of work and budget estimates of the Authority for approval of the Board; and

(c) submit to the Board, in accordance with the rules and regulations reports on the activities of the Authority.

(3) The CEO shall also have the power to,—

(a) supervise the activities connected with the execution of programs for training, research, institutional consultancies, and other services;

(b) authorize expenditure provided for in the budget in accordance with the rules and regulations;

(c) re-appropriate funds within the approved budget;

(d) delegate his powers to appropriate levels of management subject to such conditions as he may deem fit;

(iii) regulation for the advertisement;

(iv) drug specifications and laboratory practices;

(v) prosecution and appeals under this Act and the Drugs Act, 1976 (XXXI of 1976) relating to Federal subject;

(vi) regulation and allocation of quota of narcotic drugs, psychotropic substances and precursor substances (chemicals) in consultation with Federal Government;

(vii) regulation for pricing and mechanism for fixation of prices of various therapeutic goods under its ambit;

(viii) determining standards for biological manufacturing and testing;

(ix) implementation of internationally recognized standards such as good laboratory practices, current good manufacturing practices, good distribution practices, cold chain management, bioequivalence studies, stability studies, anti-spurious codes, clinical trials, biosimilar evaluations, and endorsement and systematic implementation of World Health Organization, International Conference on Harmonizations and Food and Drug Administration guidelines etc.;

(x) regulation, enforcement and monitoring of advertisement rule and ban on false advertisement;

(xi) manufacturing of active pharmaceutical ingredients in all its forms; and

(xii) use of central research fund.

(d) co-ordinate, monitor or engage, in conjunction with other organizations, Provincial Governments and international agencies, in training, study or project related to therapeutic goods. The Authority may engage any individual or counsel to advise or work for managing national and international opportunities for training, education, seminars, conferences etc., with a view to improve capacity building;

(p) prepare annual budget to be approved by the Board;

(q) to monitor and regulate the marketing practices, so as to ensure rational use of drugs, and ethical criteria for promotion of therapeutic goods in line with international practices;

(r) develop working manuals, guidelines, references, materials and procedures in order to improve the working environment of offices etc., set up under the Authority;

(s) prescribe, regulate or implement measures and standards on matters related or connected with the Authority;

(t) develop, issue, adopt, and enforce the standards and guidelines to ensure safety, efficacy, and quality of therapeutic goods with rational use at reasonable price;

(u) perform licensing, registration, pricing and appellate function thereof;

(v) co-ordinate with Provincial Governments and International agencies for smooth implementation of laws, capacity building and training of the regulatory staff;

(w) develop standard operating procedures, manuals, guidelines for transparent working of offices and conduct quality audits for conformance of the same;

(x) establish system of cost recovery to ensure financial autonomy and efficient functioning of the authority without becoming burden on the Government; and

(y) perform and carry out any other act, duty or function as may be assigned to it by the Policy Board and the Federal Government for furthering the provisions of this Act.

8. Delegation of powers.— The Authority may with the approval of the Board, by general or special order in writing subject to such conditions or limitations, delegate any of its powers and functions to any of its officers as it may deem appropriate.

Provided further that the expert member shall himself attend the meeting and shall not send a representative;

(4) No act or proceeding of the Board shall be invalid by reason only if the existence of a vacancy in the constitution of the Board.

(5) Notwithstanding the composition of the Board constituted by the Federal Government under sub-section (1), the Board may increase or decrease the number of its members and prescribe the qualifications and procedure for their appointment.

10. Meeting of the Policy Board.— (1) The meetings of the Board shall be convened by the Secretary of the Board with the prior approval of the Chairperson. In case of absence of the Chairperson, the members present may elect the Chairperson for that meeting.

(2) The meetings of the Board shall be held at twice a year or more as and when required. A special meeting may also be called at any time to deal with any urgent business.

(3) Save as hereinafter provided, the Board shall make regulations for the conduct of its business.

(4) A simple majority of the total membership shall constitute the quorum for a meeting of the Board and in case of equality of votes, the Chairperson or the person presiding over the meeting shall have a casting vote.

(5) All decisions or determinations taken by the Board shall be recorded in writing.

(6) The Board meeting shall be called by giving an advance notice of at least seven days.

11. Functions of the Board.— (1) The Board shall have the following functions, namely:—

(a) frame the policy and provide guidelines based on global and regional trends to the Authority and monitor the implementation and performance of the guidelines and of the functions of the Authority ensuring good governance and accountability;

(b) monitor and supervise all the functions of the Authority;

(c) approve the Budget of the Authority; and

shall be deemed to have been incurred, entered into, acquired or engaged to be done by for the Authority.

(4) All suits and other legal proceedings instituted by or against the said offices before their integration shall be deemed to be suits and proceedings by or against the Authority and may be proceeded or otherwise dealt with accordingly.

(5) Notwithstanding anything contained in any contract or agreement or in the conditions of services,—

(a) every employee of the said offices under the Federal Government immediately after the commencement of this Act shall be required to exercise an irrevocable option either to continue in the present pay and service structure as a civil servant or to opt for absorption in the Authority within a period of thirty days from the date of commencement of this Act;

(b) all employees who opt to be included in the Authority under its rules shall be governed by this Act and the terms and conditions so prescribed;

(c) no health personnel who opts to be governed under this Act shall be entitled to any compensation because of such transfer; and

(d) the terms and conditions of service of all officers and staff employed in the Drug Regulatory Agency of Pakistan under Ordinance (I of 2012) before the commencement of this Act shall not be varied to their disadvantage under the Authority.

16. Experts, consultants and advisers not to be civil servants.— The experts, consultants, employees or advisers employed by the Authority shall be governed by the terms and conditions of their appointment and shall not be deemed to be civil servant within the meaning of Civil Servants Act, 1973 (LXXI of 1973).

17. CEO and officers etc., to be public servants.—The CEO. officers, employees, experts and consultant of the Authority shall, when acting or purporting to act in pursuance of any of the provisions of this Act, be deemed to be public servants within the meaning of Section 21 of the Pakistan Penal Code (Act, XLV of 1860).

(f) proceeds of any investments made by the Authority which are not required for immediate use. All investments to be made by the Authority shall be with the approval of the Board;

(g) proceeds from any other service rendered by the Authority, including Inspection Services, foreign or local, or sale of any publication; and

(h) Central Research Fund collected from the pharmaceutical industry.

(3) At the end of each financial year, the balance sheet shall be prepared and any un-spent remaining amount and all other collections including Central Research Fund shall be securely invested only in Government schemes in order to achieve self-sufficiency of the Authority.

(4) A separate pension endowment fund shall be established for the payment of pensions of employees recruited in the Authority.

20. Fees and other charges to be levied by the Authority.—(1) The Authority shall levy and collect such fees, in respect of any of its functions at such rates as may be determined, from time to time by the Authority, with the approval of the Policy Board, in accordance with rules.

(2) The Central Research Fund fee shall be deposited in the non-lapsable sub-account of the Authority to be utilized as per existing rules.

(3) The existing Central Research Fund kept with the Federal Government shall be transferred to the Authority immediately after the notification of establishment of the Authority.

21. Budget.—(1) The Authority shall, in respect of each financial year prepare on such date as may be prescribed a statement of the estimated receipts and expenditure, including the revised and estimated budgets, requirements of grant-in-aid from Federal Government, and foreign exchange for the next financial year for consideration and approval of the Board. Any foreign exchange requirements within the overall annual approved budget by the Board shall be sent to Federal Government for appropriate provision and allocation.

(2) It shall not be necessary for the Authority to take prior approval from the Government to spend money from its own generated funds, and shall practice financial freedom as the Board deem fit for furtherance of its functions.

(2) The Federal Government may require the Authority to furnish:-

(a) any return, statement, estimate, statistics or other information regarding any matter under the control of the Authority;

(b) a report on any subject related to the Authority; and

(c) a copy of any document in the custody of the Authority;

(3) The Authority shall expeditiously comply with such directions.

26. Power to call for information.—The Authority may call for any person, involved directly or indirectly, and reasonably believed to having such information in his control or possession which is required for carrying out the purposes of this Act. The person so called upon to provide such information shall do so within the period prescribed by the Authority and in case of failure to do so he shall be punished by imposition of such penalty which may not exceed one hundred thousand rupees.

27. Offences, penalties etc.—(1) The offences shall be such as specified in Schedule-III.

(2) The prohibition specified in Schedule-II shall be punished in accordance with Schedule-III.

28. Offences by companies etc.—Where the person guilty of an offence under this Act or the Drugs Act, 1976 (XXXI of 1976), is a company, corporation, firm or institution, every director, partner and employee of the company, corporation, firm or institution with whose knowledge or consent the offence was committed shall be guilty of the offence.

29. Cognizance of offences.—Cognizance of offences shall be taken by the Inspector in the manner specified in Schedule-IV.

30. Complaints.—(1) Any aggrieved person may file a written complaint with the Authority against contravention of any provision of this Act or any law specified in Schedule-VI.

(2) The Authority shall, on receipt of a complaint cause it to be investigated as may be prescribed and provide an opportunity to the complainant as well as the person against whom such complaints has been made. The Authority may, on completion of investigation, take any

37. Employment under the Authority to be employment under the Federal Government.— Every employment under the Authority shall, for the purpose of Pakistan Essential Services (Maintenance) Act, 1952 (LIII of 1952), be deemed to be employment under Federal Government and the said Act shall have effect accordingly.

38. Act X of 2012 not to apply to the Authority.— Nothing contained in the Industrial Relation Act (X of 2012), shall apply to or in relation to the Authority or any of the officers and employees of the Institute.

39. Co-operation with international organizations.— The Authority may, subject to the prior approval of the Federal Government, co-operate with any foreign authority or international organization in the field of health on the terms and conditions of any program or agreement for co-operation to which such authority or organization is a party, or pursuant to any other international agreement made or after the commencement of this Act.

40. Repeal and Savings.— (1) The Drug Regulatory Agency of Pakistan Ordinance, 2012 (Ordinance I of 2012) is hereby repealed.

(2) Notwithstanding the repeal of the Drug Regulatory Agency of Pakistan Ordinance, 2012 (Ordinance I of 2012) by sub-section (1),-

(a) any license to manufacture or any registration or maximum retail price fixed for sale issued thereunder to any person, or for the revalidation of an license or registration issued earlier under the Act, for which an application has been made to the Licensing Board, Registration Board, and Drug Pricing Committee as the case may be within the specified time, shall continue to be valid;

(b) any license for import or export or sale of drugs issued thereunder to any person, shall, unless it expires earlier under the terms thereof, continue to be valid for such periods as the Federal Government, may by notification in the official Gazette, specify in this behalf.

(3) All such actions of the Federal Government as mentioned in sub-section (2) since 20th April, 2010 shall be deemed to have validly made under this Act.

41. Policy Directive of Federal Government.— (1) The Federal Government may issue policy directives in accordance with the law and Constitution to the Board in respect of any of its

(i) bacterial vaccines including live, killed whole cell, protein sub-unit, polysacchrid or glyco-conjugate, toxin derivatives, and rDNA biotechnology developed.

(ii) viral vaccines including live, inactivated, sub-unit, DNA, conjugated;

(iii) polyvalent combinations of vaccines containing combination of vaccines defined in e (i) and d(ii).

(f) toxins and venoms including snake venoms, scorpion venoms etc;

(g) immunostimulanls of biological origin including BCG vaccine for immunotherapy;

(h) biotechnology products which are primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology or other processes involving site specific genetic manipulation techniques.

(i) human interferons, natural hormones, recombinant antibodies, monoclonal antibodies and derivatives gene therapy products;

(2) "Biological Drugs (Finished form)", are Biological Drugs that are defined in sub-section (1) above and are manufactured, packed by the manufacturer under his responsibility of quality assurance and is further released by the National Control Authority or the National Control Laboratory of the country of origin under the World Health Organization's Lot Release system of evaluation.

(3) "Biological Drugs (Ready-to-fill form)", are Biological Drugs that are defined in sub-section (1) above but are manufactured at one site in the form of a "Ready-to-fill Bulk" but are transferred to another site for final filling, labeling, packaging and quality control of the finished form. No further formulation or dilution of the Ready-to-fill bulk is allowed in this case of manufacture. The final product is released by the Pakistan's National Control Laboratory for Biologicals under the World Health Organization's Lot Release system of evaluation.

(4) "Biological Drugs (Concentrated form)", are Biological Drugs that are defined in sub-section (1) above that are manufactured at one site but are stored in the form of Concentrated-Bulk of the active ingredient at controlled temperatures. Such Concentrated-Bulk may be transferred to any other site under temperature controlled conditions for further dilution,

(a) master formula;

(b) all ingredients both active pharmaceutical ingredients and inactive excipients added with their safety profile data;

(c) complete manufacturing procedure of the drug, biological or medical device;

(d) quality control steps and procedures at each level of raw material selection, in-process testing, finished drug testing, and stability testing;

(e) clinical trial data and published reports about the safety and efficacy of the drug;

(f) complete details of manufacturing plant and equipment, quality control laboratories and equipment;

(g) ware-houses capacities and facilities; details of human resources available and the latest cGMP report shall also be part of this document set;

(h) any other information required by the registration board for establishing the safety, efficacy, bioavailability, bioequivalence, or biosimilarity of the drug.

2. DRUG includes,—

(a) 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, including substance used or prepared for use in accordance with the Ayurvedic, Unani, Homoeopathic, Chinese or biochemic system of treatment except those substances and in accordance with such conditions as may be prescribed;

otherwise applied to human body or part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of any such articles; except that such term shall not include soap.

SCHEDULE-II

[See Section 2(xxx)]

PROHIBITIONS

A. Import, manufacture and sale of therapeutic goods:

(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 therapeutic good;

(ii) any counterfeit therapeutic good;

(iii) any misbranded therapeutic good;

(iv) any adulterated therapeutic good;

(v) any substandard therapeutic good;

(vi) any therapeutic good after its expiry date;

(vii) any therapeutic good which is not registered or is not in accordance with conditions of registration as disclosed in the registration dossier and that has undergone pharmaceutical evaluation;

(viii) any therapeutic good 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 specified, recommended or suggested in the labeling thereof; or

(x) any therapeutic good in contravention of any of the provisions of this Act or rules made thereunder;

(ii) in the case of an imported drug, by the manufacture or importer of that therapeutic good or if the therapeutic good is imported through an indenter by such indenter; and

(iii) apply an incorrect batch number to a therapeutic good.

(2) Nothing in Paragraph (1) shall apply to the manufacture of small quantities of any therapeutic good for the purpose of clinical trial examination, test, analysis or personal use in small quantities.

[3][(3) No person shall himself or by any other person on his behalf sell or offer for sale, any drug in the finished form over and above the maximum retail price as may be fixed by the Federal Government or determined under the provisions of the Drug Pricing Policy, as notified by the Authority.

Explanation.- For the purpose of this paragraphs, the drug shall also include biologicals.]

B. 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,—

(a) any therapeutic good;

(b) any substance used or prepared for use in accordance with the Ayurvedic, Unani, Homoeopathic, Chinese or Biochemic system of treatment or any other substance or mixture of substances as may he prescribed;

(c) any remedy, treatment or offer of a treatment for any disease.

Explanation.--For the purpose of this entry "Advertise" means to make any representation by any means whatsoever for the purpose of promoting directly or indirectly the sale or disposal of therapeutic good, 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 or such other institution offering treatment.

[3] Added vide Notification No. S.R.O 913(I)/2017 dated 6th September, 2017.

(a) imports, manufactures for sale or sells any counterfeit therapeutic good; or

(b) gives to the purchaser a false warranty in respect of any therapeutic good sold by him that the therapeutic good does not in any way contravene the provisions of Schedule II 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 therapeutic good sold, or stocked or exhibited for sale, by him, whether the container or a label or in any other manner, a warranty given in respect of any other therapeutic good; or

(d) imports, manufactures for sales or sells any therapeutic good under a name other than the registered name; or

(e) exports, imports, manufactures for sale or sells any therapeutic good with which any substance, which should not actually be its component, or has been mixed or packed it 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, or with fine which may extend to five lakh rupees or with both.

(3) *Obstruction of Inspector.*--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 one lakh rupees, or with both.

(4) *Contravention of rules.*--Subject to the provisions of Clauses (1), (2) and (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 one lakh rupees, or with both.

(5) *Penalty for subsequent offence.*--Whoever having been convicted of an offence under Clause (1) of Schedule-Ill is convicted for a subsequent offence under that

relating to the import or export of therapeutic goods or the manufacture for sale, or sale, of a therapeutic good which is not for the time being registered or for the manufacture for sale of which a license 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 Registration Board or Licensing Board as the case may be, institute a prosecution for a contravention of any other provision of this Act and The Drugs Act, 1976 (XXXI of 1976).

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

(a) an offence punishable under Schedule-III other than an offence mentioned in Clause (1) of that Schedule shall be non-cognizable, and

(b) no Court other than a Drug Court established under The Drugs Act, 1976, (XXXI of 1976) shall try an offence punishable under this Act and Drugs Act, 1976 (XXXI of 1976);

(c) nothing contained in this Schedule 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 Act or The Drugs Act, 1976 (XXXI of 1976) or to require the transfer to a drug Court of any case which may be pending in any Court immediately before the establishment of Drug Court.

SCHEDULE-V

[See Section 2(xvi)]

POWERS OF INSPECTORS

(1) Subject to the provisions of this Schedule and of any rules made in this behalf, an Inspector may, within the local limits for which he is appointed, and in any

(h) lock and seal any factory, laboratory, shop, building, store-hose or godown, or a part thereof, where any therapeutic good is or is being manufactured, stored, sold or exhibited for sale in contravention of any of the provisions of this Act, the Drugs Act, 1976 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 Licensing Board, the Registration Board, as the case may be, specify, any person in charge of any premises from removing or dispensing of any therapeutic good, 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 Paragraph (f) to (j) shall be exercisable only by an Inspector specifically authorized 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 Paragraph (h) may be exercised by an Inspector not authorized as aforesaid where the contravention is of a provision which requires a license to be obtained for the manufacture, storage or sale of drug.

(2) The provisions of the Code of Criminal Procedure, 1898 (Act V of 1898), insofar as they are not inconsistent with the provisions of this Act and The Drugs Act, (XXXI of 1976), shall apply to searches and seizures made under this Act.

PROCEDURE FOR INSPECTORS

(1) Where an Inspector seizes any therapeutic good or any other article under this Schedule he shall tender a receipt therefore in the prescribed form.

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 this Schedule,--

(a) he shall as soon as practicable ascertain whether or not the therapeutic good contravenes any of the provisions of this Act and, 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 therapeutic good 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 Schedule-IV, 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 or The Drugs Act, 1976.

(6) The Provincial Inspector on finding any contravention of this Act or the Drugs Act, 1976 (XXXI of 1976) 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 contraventions.

(7) The Federal Inspector on finding any contravention of this Act or the Drugs Act, 1976 (XXXI of 1976) for which he is authorized shall unless otherwise directed, always refer the case to the 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.

SCHEDULE-VI

[See Section 2(i)]

(1) The Drugs Act, 1976 (XXXI of 1976).

(2) Rules made under the Drugs Act, 1976 (XXXI of 1976).

ANNEX-II

P L D 2018 Sindh 448

Before Munib Akhtar and Omar Sial, JJ

Messrs AZFAR LABORATORIES PRIVATE LIMITED through Directors and others---Petitioners

Versus

FEDERATION OF PAKISTAN through Secretary Ministry of National Health Services and 4 others---Respondents

Constitutional Petition D-2329 of 2017, decided on 26th February, 2018.

(a) Constitution of Pakistan---

----Arts. 142 (b) & 144---Constitution (Eighteenth Amendment) Act (X of 2010), Preamble---Legislative powers---Scope---Provisions of Constitution (Eighteenth Amendment) Act, 2010, omitted Concurrent List but still left three competences as concurrent: criminal law, criminal procedure and evidence--- Some of the entries from Concurrent List were shifted to Federal List and changes were also made to some of the entries otherwise to be found in the latter; there are (a) enumerated competences set out in Federal List, which are exclusive to the Federation; (b) three enumerated competences which are concurrent; and (c) a whole host of non-enumerated competences which are exclusive to the Provinces---Parliament, in ordinary course can only make laws in respect of the competences on Federal List and the three which are still concurrent (There are also certain legislative powers expressly conferred on Parliament under various Articles of the Constitution)---Federation, in certain exceptional circumstances, can also acquire power to make laws in respect of non-enumerated competences exclusive to the Provinces---One of such instances has been set out in Art. 144 of the Constitution.

(b) Constitution of Pakistan---

----Art. 141---Legislative power---Extent---In matters relating to legislative competences a broad approach is preferable.

(c) Constitution of Pakistan---

----Art. 144---Power of Parliament---Object, purpose and scope---One principal purpose behind Art.144 of the Constitution is to ensure that there is one law that seamlessly applies across provincial boundaries as a unified whole.

(d) Constitution of Pakistan---

----Arts.144 & 199---Drug Regulatory Authority Act (XXI of 2012), Ss.32 & 40---Alternative Medicines and Health Products (Enlistment) Rules, 2014---Legislative Powers---Parliament legislating for Provinces---Principle---Petitioners were aggrieved of applicability of Drug Regulatory Authority Act, 2012, on various products as manufactured, sold, used or imported by them and assailed the legislative competence of Parliament after Constitution (Eighteenth Amendment) Act, 2010---Validity---Parliament was to apply maximlist approach---Law enacted by Parliament under Art. 144 of the Constitution could at any time be amended or repealed by Provincial Assembly in

relation to its own Province---If an Assembly, that had passed a resolution that was in scope apparently less than the one couched in the broadest terms, was dissatisfied with the law enacted by Parliament, it could at any time take necessary action either by amending the law to tailor it to its own resolution or repealing it altogether---Parliament was competent to enact Drug Regulatory Authority Act, 2012, it could have repealed Drugs Act, 1976, as in force in all Provinces---Parliament had chosen not to do so and by S.32 of Drug Regulatory Authority Act, 2012, it was specifically provided that it was in addition to and not in derogation of Drugs Act, 1976---Such provision and the continued existence of Drugs Act, 1976, could be taken to mean that Drug Regulatory Authority Act, 2012, itself could not be enforced or given effect in all Provinces on its own terms as therein provided---Neither Parliament's competence under Art.144 of the Constitution nor the manifestation of the same in the shape of Drug Regulatory Authority Act, 2012, was so circumscribed---Drug Regulatory Authority Act, 2012, was the controlling statute, operating seamlessly as one unified law that had applied trans-provincially across all Provincial boundaries and not Drugs Act, 1976, operating in each Province as territorial bound provincial legislation---High Court directed the authorities to give hearing to petitioners in respect of each product or substance as to whether the product/substance had come within the scope of Alternative Medicines and Health Products (Enlistment) Rules, 2014, or Drug Regulatory Authority Act, 2012, especially with reference to the definitions---Constitutional petition was disposed of accordingly.

Pakistan International Freight Forwarders Association v. Province of Sindh and others 2017 PTD 1 and C.P. D-1313/2013 ref.

(e) Alternative Medicines and Health Products (Enlistment) Rules, 2014---

----Sindh Pure Food Ordinance, 1960 (VII of 1960), S. 2 (9)---"Food supplements"---Scope---Food supplements etc. as defined in Alternative Medicines and Health Products (Enlistment) Rules, 2014, come within the meaning of 'drug' as used in Drug Regulatory Authority Act, 2012---If any product comes within the definition contained in Alternative Medicines and Health Products (Enlistment) Rules, 2014, then the same falls outside the ambit of Sindh Pure Food Ordinance, 1960.

Munir A. Malik, Atif Chaudhry, Agha Faisal, Ms. Amber Lakhani, Ms. Sathi M. Ishaq, Ms. Zara Vayani, Khalid Mehmood Siddiqui, Sameer Chazanfar, Ms. Saify Ali Khan and Ms. Rozina Issa, for Petitioners.

Salman Talibuddin, Additioal Attorney General along with Ms. Alizeh Bashir and Asim Mansoor Khan, DAG for Respondent.

Shabbir Hussain Shah, Additional Advocate General Sindh along with Ms. Maryam Atta Malik for Respondent.

Sohail Muzaffar, Kafil A. Abbasi, Kashif Nazir, Ghulam Hyder Shaikh, Ms. Masooda Siraj for Departmental Respondents.

Dates of hearing: 12th, 13th and 26th September, 3rd, 4th, 5th, 11th, 13th, 17th and 19th October, 2017.

ORDER

MUNIB AKHTAR, J.---By this common judgment, we intend disposing off the petitions mentioned in para 51 below. The petitions arise under and in relation to the Drug Regulatory

Authority of Pakistan Act, 2012 ("DRAP Act"). The core issue is whether, as the petitioners contend, the DRAP Act cannot, does not and should not apply to various products as manufactured, sold, used or imported by them, including Unani medicines, prescriptions and preparations, food supplements, animal feeds etc. The questions that the petitioners raise to press the core issue fall into two sets. One set sounds on the constitutional plane, primarily with reference to Article 144 of the Constitution, under which the DRAP Act has been enacted by Parliament. The other set comprises essentially of questions regarding the interpretation of various provisions of the DRAP Act. One important plank on which the petitioners rest their case is the relationship of the DRAP Act with earlier legislation, the Drugs Act 1976 ("1976 Act"). This law therefore also needs to be examined. In addition, certain rules framed under the DRAP Act, being the Alternative Medicines and Health Products (Enlistment). Rules, 2014 ("2014 Rules") need to be considered.

2. Learned counsel for the petitioner in CP D-4387 of 2014 submitted that the DRAP Act was challenged in relation to the legislative competence of the Federation to enact the same in its applicability to the Province of Sindh. Learned counsel submitted that even if the statute were found to be competently enacted certain provisions thereof violated Articles 18 and 25. In addition the 2014 Rules were also challenged as being ultra-vires the DRAP Act. By way of background, learned counsel submitted that the initial legislation in respect of drugs was the Drugs Act 1940 ("1940 Act") enacted under the Government of India Act, 1935 ("GOIA"). Referring to various legislative entries in the lists contained in Schedule VII of the GOIA, learned counsel submitted that the aforesaid Act was passed under S. 103 of the GOIA. (We may note here that this section is in all material respects the same as Article 144 of the present Constitution.) Referring to post-Independence developments as well as the Indian Constitution, learned counsel submitted that there was no entry as such in relation to "drugs and medicines" in the earlier constitutional dispensations, and it was for the first time that such an entry came to be found as entry No.20 of the Concurrent Legislative List of the present Constitution. It was with reference to this entry that the Drugs Act 1976 ("1976 Act") was enacted by the Federation, which statue also repealed the 1940 Act. Learned counsel submitted that after the 18th Amendment whereby the Concurrent List, including entry No.20, was omitted the 1976 Act passed to the exclusive Provincial domain. With reference to the DRAP Act, learned counsel submitted that three Provinces, being Sindh, KPK and the Punjab Assemblies passed resolutions under Article 144 whereupon first an Ordinance was promulgated and, ultimately, the DRAP Act enacted, the latter receiving the President's assent on 12.11.2012.

3. Learned counsel referred to the date on which the Provincial Assemblies passed the resolutions aforesaid (being 15.02.2012 in all three cases) and to the definition in S.3(g) of "drug" as contained on that date in the 1976 Act. Learned counsel submitted that the petitioners whom he represented dealt with Unani medicines and preparations, as practitioners of Tibb, i.e., the Unani system of medicine. Referring to the resolution passed by the Sindh Assembly, it was submitted that it only allowed Parliament to make a law constituting a drug regulatory authority and nothing more or further. It was submitted that such authority could only regulate what was a "drug" as on the date of the resolution, which necessarily meant that it could only regulate drugs that came within the definition contained in the 1976 Act. As regards the DRAP Act, learned counsel accepted that the petitioners' medicines and preparations did come within the definition of "drug" therein contained. However, it was contended that the petitioners' products did not come within the meaning of "drug" as contained in the 1976 Act. On such basis it was contended that, at least insofar as this Province was concerned, Parliament while acting under Article 144 could only enact a law establishing a drug regulatory authority but could not alter the meaning of "drug", whereas this was exactly what the DRAP Act purported to do. Therefore, the definition contained in the latest statute was ultra vires the powers that had been conferred by the resolution of the Sindh Assembly on Parliament. What learned

counsel contended, more generally, was that those portions of the DRAP Act that did not come within the scope of the resolution of the Sindh Assembly could not be enforced in this Province. The net result, as we understood the case, was that the petitioners' Unani medicines and preparations could not be regulated by and under DRAP Act.

4. Referring to various provisions of the DRAP Act, learned counsel submitted that allopathic medicines and drugs on the one hand and Unani medicines and preparations on the other constituted two separate and distinct categories or classes. They represented two distinctly different systems of medicine. It was submitted that to impose one and the same regulatory regime in terms of the DRAP Act on these two classes, that ought to be regarded as distinct and separate, was in violation of the rights of the petitioners under both Articles 18 and 25 of the Constitution. Insofar as the 2014 rules were concerned, learned counsel referred to various rules thereof to submit that the regulatory regime set up for or "alternative medicines" (as defined in, s. 2(ii) of the DRAP Act and which included the Unani system of treatment) was ultra vires the parent statute. It was submitted that the various bodies, committees, inspectorates etc constituted under the 2014 Rules failed to recognize that allopathic medicines and Unani medicines represented the output of two distinct and separate systems, which could not be handled in one unified manner. More precisely, the methodology and practices of the allopathic system could not be imposed on the Unani system, as had purportedly been done under the 2014 Rules. Thus, according to learned counsel the petitioners were entitled to suitable relief and he prayed accordingly.

5. Learned counsel appearing in CP D-1684 of 2014 submitted that the petitioner therein was a manufacturer and user of Unani medicines and a practitioner of that system. Learned counsel reiterated the submissions already made as to how the Unani system was entirely different and distinct from the allopathic system. Learned counsel submitted that Unani medicines did not come within the scope of the 1976 Act and in this regard referred also to the Unani, Ayurvedic and Homeopathic Practitioners' Act 1965, which regulates the practitioners of the Unani system. It was submitted that the DRAP Act had been enacted with ulterior motives to defeat and frustrate the rights of the practitioners of the Unani system. In addition, learned counsel made submissions with regard to the 2014 Rules that were substantially the same as noted above. As regards the resolutions passed by the three Provincial Assemblies, learned counsel drew attention to, and placed reliance on, the difference between the language of the resolutions passed by the Punjab Assembly and the Sindh Assembly. It was emphasized that insofar as this Province was concerned, only a drug regulatory authority could be set up by the law to be enacted by Parliament under Article 144 and reference in this context was made to S.32 of the DRAP Act.

6. Learned counsel who appeared for the petitioners in CP D-6262 of 2016 and others referred to the definition of "alternative medicines" as given in the DRAP Act on the one hand and the definition of "drug" contained in the 1976 Act on the other. Learned counsel submitted that the products which were imported and/or otherwise dealt with by the petitioners were food, dietary or health supplements and they could not and did not come within the definition of "drug" as contained in the 1976 Act. It was submitted that in fact those supplements were simply "food" and this came within the scope of the Pure Food Ordinance 1961. Learned counsel referred to the definition of "food" as therein contained and also the description and characteristics of the foods supplements etc. which were the subject matter of the petitions by referring to material placed on record. It was submitted that in fact earlier many food supplements were registered as drugs under the 1976 Act but they were de-notified by the Federal Government in 1985. Learned counsel submitted that after the 18th Amendment when, as noted above, "drugs and medicines" became an exclusive Provincial subject and the DRAP Act came to be enacted, the petitioner's products did not come within the meaning of "drug" as set out in

Schedule-I to the DRAP Act. Nonetheless, the 2014 Rules were sought to be enforced in respect of food supplements etc. and the petitioners' products were included therein. Learned counsel emphasized, referring to Article 144 and the resolutions passed by the Assemblies, that the 1976 Act was the controlling statute and there could be nothing in either the DRAP Act or the 2014 Rules that could go beyond what was contained in the former statute. Insofar as that food supplements etc. were sought to be brought within the ambit of the DRAP Act by including the same under the aforementioned Schedule-I, learned counsel submitted that the provisions thereof were ultra vires the legislative competence granted to Parliament under Article 144.

7. Learned counsel in C.P. D-5892/2017 submitted that the petitioner's products were meant for animals. Though they were included in Schedule-I to the DRAP Act and thus also stood included in the 2014 Rules, learned counsel submitted for substantially the same reasons as already noted that this could not be so and these provisions traveled beyond the legislative competence of Parliament, as conferred in terms of Article 144. In support of his case learned counsel also relied upon a Punjab law, the Punjab Animals Feed Stuff and Compound Feed Act 2016.

8. Learned counsel appearing in CP D-4421 of 2017 submitted that products imported by the petitioner were food supplements and in support of this contention referred to various documents and material on the record to show the nature and characteristics of the said products. For substantially the reasons already advanced it was submitted that the petitioner's food supplements did not and could not come within the scope of the DRAP Act.

9. Learned counsel who appeared in CP D-1921/2017 submitted that the subject matter of this petition was various types of animal feed products. Learned counsel adopted the submissions earlier made and emphasized that the DRAP Act could not be made applicable to animal feed products. It was submitted that the petitioner's products did not need to be enlisted in terms of the 2014 Rules. The products were imported by the 'petitioner and the Customs Department was insisting on such enlistment. Learned counsel submitted that the petitioner's products did not come within the scope of Schedule-I to the DRAP Act. It was submitted that feed for animals was different from food for humen especially as regards the administration of it. Explaining his point learned counsel submitted that the product had to be used according to certain measures. It was submitted that different standards were used for drugs for animals on the one hand and drugs for humans on the other. Learned counsel submitted that the animal feed as was the subject matter of the petition had no therapeutic effect. It was contended that there had to be a differentiation between animal feed which had therapeutic effect, which could be regulated, and that which had no such effect, and could not be so regulated. In failing to draw this distinction the 2014 Rules were in excess of the DRAP Act insofar as an attempt was being made to apply the same to the petitioner's products. Referring to certain definitions in the 2014 Rules learned counsel submitted that the products of the Petitioner did not come within the definitions of "therapeutic claim" and "health related purpose" but that in any case these definitions were broader than the scope of the DRAP Act and hence ultra vires accordingly.

10. Learned counsel in C.P. D-4421/2017 submitted that the subject matter of this petition were food and dietary supplements etc., which were not sold as drugs but rather simply and only as food. It was submitted that these products did not come within the definition of drugs and, therefore, could not be regulated by the DRAP Act.

11. The learned Additional Attorney General, relying on entries Nos. 3, 27, 39 and 59 of the Federal List submitted that the regulation of drugs as well as the manufacture thereof was a federal subject. The learned AAG submitted as regards Article 144 that although there was some variation in the language used in the three resolutions, the effect and substance was nonetheless the same namely

"drugs and medicines" competence to Parliament to make a law in respect of
was submitted that before the enactment of the DRAP Act, an Ordinance in substantially the same terms had been promulgated on 16.02.2012, i.e., one day after the resolutions were passed. This Ordinance was ultimately replaced by the DRAP Act. Referring to the material placed on record the learned AAG contended that the Sindh Assembly was well aware of the draft of the Ordinance and what was requested by Parliament as regards the enactment of a federal law on the subject. It was submitted that all the Provinces were fully on board at all material times in this regard and well appreciated and accepted the need for country-wide legislation. Thus the extent and scope of the proposed federal legislation was well within the knowledge of the Sindh Assembly. This was also the case for the other Assemblies. All the resolutions were passed on the same day. Thus, the learned AAG contended, the resolution of the Sindh Assembly had to be read in the same manner and to the same effect, and had thesame scope, as the resolutions of the Punjab and KPK Assemblies. The DRAP Act was therefore very much applicable and. enforceable as it stood in this Province.

12. The learned AAG submitted that traditional medicines, which included medicines prepared under the Unani system, had always been within the meaning of the drugs as contained in the 1976 Act. In support of this submission the learned AAG submitted that on its true and proper reading, S.3 (g)(i) of the 1976 Act fully established that Unani medicines etc were well within the meaning of "drug" as therein contained. Insofar as food supplements and the other products involved in the various petitions were concerned, with the passage of time it was recognized that they also had to be regarded as drugs. Thus, it was contended, the definitions of traditional/alternative medicines and food supplements as contained in the DRAP Act only reflected the changes in approach and thinking that had come about between 1976 and 2012. The learned AAG submitted that these were developments that had taken place internationally. Referring to material placed on record the learned AAG submitted that the definitions and scope of the DRAP Act built on what was already within the scope of 1976 Act. Reliance was also placed on certain case law in this regard.

13. Insofar as the grievance of the petitioners who practiced in the Unani system, that they were not appropriately represented on the bodies and committees established in terms of the 2014 Rules, the learned AAG submitted that this was incorrect. There was no discrimination or violation of any right that inhered in these petitioners nor had any damage been caused to any of their interests. As regards food supplements, learned counsel submitted that they in fact also came within the scope of s. 3(g)(i) of the 1976 Act and sought to establish this from the material placed on record by the relevant petitioners in their petitions. The learned AAG further submitted that in its essence what the DRAP Act sought was enforcement of certain WHO guidelines that had been issued by that UN Organization in respect of traditional medicines and placed on record various documents and material in this regard. Reference was made to various provisions of the DRAP Act where specific reference is made to the WHO. Relying in particular on section 7 of the DRAP Act the learned AAG submitted that it gave statutory recognition in municipal law to the convergence between international guidelines on the one hand and national and local regulations on the other in order to ensure that there was harmony and uniformity in this regard. Reference in this context was also made to the statement of reasons and objects when the Bill that eventually became the DRAP Act was introduced in Parliament. The learned AAG, with reference to animal feeds and to the specific facts of the petitions where such substances were the subject matter, submitted that the substances were artificial and not natural and therefore came within the drugs both under the 1976 Act and the DRAP Act. By way of illustration, the learned AAG referred to one type of animal feed which was meant for cattle and which comprised of seaweed. It was submitted that seaweed would not normally be regarded as food for cattle in this country and that here it had to be regarded as a drug within the meaning of the aforesaid statutes.

14. Insofar as Article 144 was concerned, the learned AAG also compared the same with Article 147 of the Constitution. It was contended that in terms of Article 144 once a Province resolved to entrust a legislative competence in its exclusive domain to Parliament that meant that the whole of the legislative field become open to the latter. In other words, the learned AAG contended that Article 144 operated on an "all or nothing" basis. This was precisely what had happened in the present case. The entire legislative field of the erstwhile entry No.20 being open to it, Parliament had properly and competently enacted the DRAP Act, which was applicable as such in all the Provinces. For all of these reasons it was submitted that the petitions were without substance and ought to be dismissed.

15. The learned Additional Advocate General Sindh submitted that the primary question was whether Parliament could now legislate in respect of traditional medicines and food supplements. It was submitted that the DRAP Act was properly enacted in exercise of the powers conferred under Article 144. However, the learned AAG emphasized that this statute could only have been enacted if the Provincial Assemblies had passed resolutions under the aforementioned Article since, if Parliament could itself have enacted the law as submitted by the learned Additional Attorney General, there would have been no need to invoke this Article. With reference to the reliance placed by the learned Additional Attorney General on entry No.3 of the Federal List, the learned AAG submitted that Parliament did have the power to give force in municipal law to international treaties, etc., but if the subject matter of the same related to a legislative competence exclusive to the Provinces, as soon as a Provincial Assembly made a law then to the extent of any inconsistency the federal law had to give way. The learned AAG submitted that in its pith and substance the DRAP Act related to the legislative competence of "drugs and medicines" and none other and it had been enacted only by reason of Article 144. Thus, according to the learned AAG, entry No. 3 had no application to the case at hand.

16. Referring to the resolutions passed by the Provincial Assemblies and in particular to that of the Sindh Assembly, the learned AAG submitted that it too covered the whole of the legislative competence and was not circumscribed in the manner as contended by learned counsel for the petitioners. The learned AAG further submitted that although the resolution referred only to "drugs" it was sufficiently brought to include within its competence "medicines" as well. Without prejudice to this submission and in order to properly present the case of the Province, the learned. AAG submitted, in opposition to what had been submitted by the learned Additional Attorney General, that a resolution under Article 144 could even grant power over part of a legislative competence. In other words, his case was that it was not an "all or nothing" matter as submitted on behalf of the Federation. Furthermore, the learned AAG submitted, if the resolution related only to a part of a legislative field and Parliament enacted a law beyond the grant, the said law would be incompetently made to the extent of the overreach. However, the learned AAG emphasized that such was not the position at hand and the DRAP Act, as enacted was fully applicable in this Province as well. The learned AAG submitted that the nature of the subject was such that it required a unified approach which justified the resolution of the Sindh Assembly being given a broad meaning and scope. It was submitted that the context in which the resolution came to be passed, and the intent of the Assembly in passing the same, were relevant for purposes of interpreting it and determining its scope and extent. On such basis the learned AAG submitted that the narrow and restricted meaning urged on behalf of the petitioners and the resultant limitations placed on the scope of the DRAP Act were incorrect and did not apply.

17. With regard to food supplements the learned AAG submitted that while the DRAP Act in its pith and substance related to "drugs" and not "food", the food supplements which were the subject matter of the various petitions came in the former and not the latter category. According to the learned AAG, "food" was something else and different from drugs. Reference was made to various provisions

of the Sindh Food Authority Act, 2016. In this context the learned AAG submitted that it was immaterial whether the food supplements would be regarded as drugs or not under the 1976 Act. It was the DRAP Act that controlled and it applied in terms as just stated. It was prayed that the petitions be dismissed.

18. The right of reply was exercised. Learned counsel for the petitioner in CP D-4387/2014 submitted that the resolutions of the Provincial Assemblies Referring to the non-enumerated competence which were exclusive to the Province and which, according to learned counsel constituted a residuum legislative power, it was submitted that they were not legislative fields at all. In fact, they were only the residuum once the enumerated powers had been properly identified. They could thus be regarded as a "topic" or an "item" and Article 144 applied accordingly. Learned counsel referred to the 1940 Act and its position in India, where it still applied though in much amended form. Some of the provisions of the 1940 Act, as amended, were referred to and compared with certain provisions in the 1976 Act and the DRAP Act with regard to the definition of drugs. Learned counsel submitted that "drugs" was not a separate or independent legislative competence but rather a part of the legislative competence of "public health". It was emphasized that the 1976 Act continued to remain in the field in un-amended form and that, therefore, when the Sindh Assembly passed its resolution it could only have been to allow Parliament to set up a regulatory authority that regulated and gave effect to this law and not to any provisions of enlarged scope, independently of the 1976 Act.

19. Continuing with his submissions learned counsel submitted that after the 1976 Act became a provincial law on account of the omission of the Concurrent List, the executive authority in relation thereto also devolved on the Provinces. However, the Provinces were unable to properly exercise this authority and that was the context in which the resolutions were passed. It was submitted that when so understood the scope of the Sindh Assembly became obviously limited only to allowing Parliament to set up a regulatory authority and not beyond that. What was sought by means of the resolution was effective enforcement of the 1976 Act and nothing more. It was submitted that the conferment of power under Article 144 was in the nature of a delegation, and such delegation and hence the resolution of the Sindh Assembly had to be strictly construed. Learned counsel compared and contrasted the resolution of the Sindh Assembly with the one passed by the Punjab Assembly. It was contended that the use of the word "drugs" in the Sindh Assembly resolution was not in any constitutional sense but only in the statutory sense, i.e., meaning drugs as defined in the 1976 Act. Reference was also made to the Sindh Allopathic System (Prevention of Unauthorized Use) Act, 2014. It was submitted that it was only if the law enacted by Parliament under the resolutions could, in its pith and substance, be relatable to the competence of "public health" that it could be regarded as properly made. With regard to entry No.3 of the Federal List relied upon by the learned Additional Attorney General, learned counsel submitted that it had no application in the present case, since no international treaty or agreement as such was involved. The WHO guidelines relied upon did not constitute any such treaty or agreement. As regards the applicability of the DRAP Act in this Province, learned counsel emphasized that if it was, as contended for, beyond the resolution of the Sindh Assembly then insofar as this Province was concerned it had to be regarded as circumscribed accordingly. In this regard the continuous silence or inaction of the Sindh Assembly did not mean that it had accepted the situation created by Parliament through the DRAP Act.

20. Learned counsel who appeared in C.P. D-6262/2016 also exercised the right of reply. It was submitted that the DRAP Act had to be regarded as nothing but an elaboration of the 1976 Act and, therefore, that which was not drugs in terms of the former could not be so regarded in terms of the latter. It was submitted that food supplements were not drugs even under the DRAP Act. In fact, they were what was there described as "non-drugs". They also did not come within "therapeutic goods", as

defined in the DRAP Act. It was emphasized that food supplements were covered by the food laws and not by legislation relating to drugs and medicines. The Punjab Agricultural Food and Drug Authority Act, 2016 was also referred to. It was submitted, without prejudice, that even if food supplements could be regarded as therapeutic that did not in or itself constitute them as drugs.

21. We have heard learned counsel as above, examined the record and considered the case-law. The core issue has been identified at the beginning of the judgment. We start with the first set of questions, which relate to the constitutionality of the DRAP Act as enacted under Article 144. This Article originally had two clauses, of which the second was omitted by the 8th Amendment in 1985. The remaining clause also underwent certain changes in the 18th Amendment. As it now stands Article 144 provides as follows:

> **"144. Power of Majlis-e-Shoora (Parliament) to legislate for one or more Provinces by consent.** (1) If one or more Provincial Assemblies pass resolutions to the effect that Majlis-e-Shoora (Parliament) may by law regulate any matter not enumerated the Federal Legislative List in the Fourth Schedule, it shall be lawful for Majlis-e-Shoora (Parliament) to pass an Act for regulating that matter accordingly, but any act so passed may, as respects any Province to which it applies, be amended or repealed by Act of the Assembly of that Province."

Of the two changes made by the 18th Amendment, one was necessitated by the omission of the Concurrent List, and need not detain us. The other, which will require some comment, was that originally Article 144 applied only if two or more Provincial Assemblies passed the necessary resolutions. By the 18th Amendment, the word "two" in the marginal note and at the beginning of the Article was substituted by the word "one". Thus, now even if one Provincial Assembly passes the relevant resolution, the Article can be invoked. Of course, the law made by Parliament in terms of Article 144 can only apply in such of the Provinces as have passed the resolutions.

22. Article 144 had its predecessors in earlier constitutional dispensations. It was to be found as section 103 in the Government of India Act, 1935 ("GOIA"), as Article 107 of the 1956 Constitution and as Article 140 of the Interim Constitution. (The 1962 Constitution, as always the odd man out, had its own peculiar arrangement in Article 131.) In all the earlier dispensations, the Article could only be invoked if resolutions were passed by two or more Provincial Assemblies. Otherwise, the provision was the same in all material respects as Article 144. The position in India is rather different. Article 252 of the Indian Constitution provides as follows:

> **"252. (1)** If it appears to the Legislatures of two or more States to be desirable that any of the matters with respect to which Parliament has no power to make laws for the States except as provided in articles 249 and 250 should be regulated in such States by Parliament by law, and if resolutions to that effect are passed by all the Houses of the Legislatures of those States, it shall be lawful for Parliament to pass an Act for regulating that matter accordingly, and any Act so passed shall apply to such States and to any other State by which it is adopted afterwards by resolution passed in that behalf by the House or, where there are two Houses, by each of the Houses of the Legislature of that State.
>
> (2) Any Act so passed by Parliament may be amended or repealed by an Act of Parliament passed or adopted in like manner but shall not, as respects any State to which it applies, be amended or repealed by an Act of the Legislature of that State."

23. What is the nature of the power that can be exercised by Parliament once Article 144 is invoked? This requires some brief comments on the division of legislative powers under the federal

structure of our Constitution. The Constitution divides legislative power into legislative competences. These can be classified in two ways. One categorization is the distinction between those competences which are enumerated or otherwise specifically set out (either in the legislative list(s) or otherwise), and those which are not. The second categorization is as to the nature of the power over the legislative competences, i.e., is it exclusive or concurrent? These characteristics of legislative power are of course not an innovation of the present Constitution. The antecedents lie in the GOIA, which itself drew inspiration from the experience of the Imperial Parliament in relation to the Canadian and Australian constitutions. All constitutions, starting from the GOIA and including the Indian Constitution, have had legislative lists and these characteristics in one form or another. Before proceeding further, submission made by learned counsel for the petitioners may be dealt with. It was submitted that insofar as the "residual" non-enumerated powers were concerned, they did not constitute specific legislative fields or competences. With respect, we are unable to agree. It is misconceived to regard the non-enumerated legislative powers as a residuum where competences cannot be distinguished, one from the other. For example, when the 18th Amendment omitted the Concurrent List and most of its entries became non-enumerated powers exclusive to the Provinces, they did not disappear into some undifferentiated mass of legislative power. They remained what they had been before: distinct and discrete legislative fields. It must also be remembered that the constitutional dispensation in force immediately prior to the date (14.08.1973) that the present Constitution came into effect was the Interim Constitution. This, following the pattern of the GOIA, had three lists and the exclusive provincial list (List II) contained 54 legislative entries. Inasmuch as these did not find their way into the Lists of the present Constitution, they became non-enumerated competences on 14.08.1973. They did not thereby fuse into one mass in which the individual competences ceased to be distinguishable. Thus the huge swathes of legislative power that are exclusive to the Provinces comprise of specific and discrete legislative fields or competences, which are known with particularity. Any submission to the contrary cannot be accepted.

24. The present Constitution of course had two Legislative Lists on its commencement. The competences listed in the Federal List were exclusive to the Federation, those on the Concurrent List were common, and those which were not enumerated were exclusive to the Provinces. (Of course, the Federation has always had the exclusive power to legislate in respect of non-enumerated competences for such areas as do not form part of any Province, being primarily the Islamabad Capital Territory and FATA. This point is only stated this once but should always be kept in mind.) The 18th Amendment omitted the Concurrent List but still left three competences as concurrent: criminal law, criminal procedure and evidence (see Article 142(b)). Some of the entries from the Concurrent List were shifted to the Federal List and changes were also made to some of the entries otherwise to be found in the latter. The net result is that now there are (a) enumerated competences set out in the Federal List, which are exclusive to the Federation, (b) three enumerated competences which are concurrent, and (c) a whole host of non-enumerated competences which are exclusive to the Provinces. In the ordinary course Parliament can only make laws in respect of the competences on the Federal List and the three which are still concurrent. (There are also certain legislative powers expressly conferred on Parliament under various Articles of the Constitution but this aspect need not detain us.) In certain exceptional circumstances, the Federation can also acquire power to make laws in respect of the non-enumerated competences exclusive to the Provinces. Article 144 sets out one of those instances. (The others are to be found in the Emergency provisions, but need not be considered here.)

25. In order to properly appreciate the nature of Article 144, it has to be clearly understood that the legislative competence thereby conferred on Parliament does not become a concurrent power. A concurrent legislative competence is one in relation to which either legislature, acting independently

and of its own volition, without anything more and subject only to any applicable rules of precedence, has the power to make laws. In this sense, the competence "belongs" independently to each legislature. (It must also be remembered that it is only the legislative field that is concurrent and not the laws made with reference thereto by the respective legislatures.) The position under Article 144 is different. The legislative competence is exclusive to the. Provinces and can be exercised by the Federation only by "invitation", i.e., only if the necessary resolution(s) are passed. The competence continues to remain "exclusive" to the Provinces in the sense that any Provincial Assembly may, in relation to its own Province, at any time amend or repeal the law made by the Federation, i.e., "curtail" or "withdraw" the "invitation". This was also the position in the earlier constitutional dispensations. It will be seen that the position in India is strikingly different. There, clause (2) of Article 252 has the effect of removing the legislative area extended to the Union under clause (1) from the States' domain. To the extent that a law is made it is in effect "surrendered" to the Union. But it does not thereupon become exclusive to the Union. As clause (2) makes clear, any law made by the Indian Parliament in terms of clause (1) can be altered or repealed only by following the procedure laid down in the latter clause, i.e., by the necessary resolutions being passed by the States. All of this creates a rather complicated situation, but none of this is relevant for Article 144.

26. It follows from the foregoing that even when Parliament makes a law under Article 144, the constitutional nature of the competence does not change: it remains exclusively within the Provincial domain. It is, in other words, provincial legislation that has been made by the Federation. One important point that must be considered here is whether in making a law in terms of Article 144, Parliament can also include in the statute provisions that relate to legislative competences that are within the Federation's own domain. In other words, in such a statute can there be a commingling by Parliament of provisions that derive constitutional validity from on the one hand the powers granted under Article 144, and on the other are exclusive to the Federation or concurrent? In our view, the answer has to be in the affirmative. As discussed in the next para, one reason why a provision such as Article 144 exists is to enable a law to be made that, though relating to a competence exclusively provincial, transcends provincial boundaries and does so seamlessly as one unified whole. That ability of course is one of the defining characteristics of federal legislative power, since in respect of matters that lie in the Federal domain by right Parliament can make laws for the whole of Pakistan or any part thereof. It would be unduly restrictive of the purpose and intent behind Article 144 if Parliament, while making the law for which it has been given power cannot include therein provisions that relate to matters in the Federal domain as of right. Secondly, a provincial law made subsequent to the law made by the Federation under Article 144 may override or impliedly repeal the latter. This follows directly from the express provision that the Provincial Assemblies may amend or repeal the law made by Parliament. The power of express repeal necessarily carries with it the power of implied repeal, and to override. Thirdly, the Federation, in exercising the power to make a law under Article 144 has the power to repeal or override, either expressly or impliedly, an existing provincial law. However, here a distinction, following from the nature of the grant, may have to be made. Article 144 provides that once Parliament is granted the power to 'regulate' a "matter" exclusive to the Provinces, it may then by law 'regulate' "that matter accordingly". ("Matter" obviously means a legislative competence.) Clearly, the law made by Parliament can repeal (expressly or impliedly) or override any existing provincial law in respect of the "matter" for which power has been granted. But what of existing provincial laws relating to "matters" other than those in respect of which the grant is made? If there is a conflict between any of those laws and the one made by Parliament, which will prevail? In our view, even here the law made by Parliament should ordinarily be regarded as having the normal effect that a subsequent law has on previous legislation. However, that may not necessarily always be the case. This point, which does not arise here, must be regarded as being left open. But, be that as it may, it

must be understood that it would not be the case of a federal law overriding a provincial law. The constitutional nature of both laws is provincial and the applicable rules would apply accordingly.

27. One question that arises in relation to Article 144 is, why have such a provision at all? If the federal structure of the Constitution envisages competences being either exclusive or concurrent, why provide for a situation where Parliament may be asked by one or more Provincial Assembly to enact legislation that is exclusively provincial (or Parliament may request for such a grant)? It must be admitted that the reason why "one" Provincial Assembly may wish to invoke Article 144 is not clear. However, why two or more Assemblies may wish to do so (or why the Federation may make a request in this regard) is more readily discernable. The reason lies in the territorial limitation of provincial legislation. As Article 141 makes clear a Provincial Assembly can only make laws for its Province or any part thereof. When the provincial boundary is reached so is the extent of the provincial law. (This general statement is subject to certain modifications and exceptions, principally in the area of taxation. But we are here concerned with the general rule.) Now, it may be that a matter that comes within the exclusive provincial domain does need to be dealt with in a trans-provincial manner. In other words, even if each Province could be induced to make substantially (or even identically) the same law, such laws would each operate only within their own territorial boundaries. This may not suffice. It may be that the law, as a unified whole, needs to transcend those boundaries. Each Province, acting on its own, cannot achieve this result. Hence, Article 144. By empowering Parliament, the Federation is enabled to make a law that would operate across (and cross) provincial boundaries in a unified and seamless manner. And it may be that in order to make this fully effective Parliament needs to include in the statute it enacts under Article 144 provisions that relate to competences that are by right in its own domain, either exclusively or concurrently. This commingling may be more than incidental. It may be a necessary ingredient and essential element in the successful operation of the law. But it must be remembered that all of this will be true only of the law actually made by Parliament under Article 144. It will not apply in respect of any existing provincial legislation even if the law made by Parliament is enacted to interact, or run and be applied in tandem, with such provincial legislation. That other law would remain territorially bound. As will be appreciated, this has obvious implications for how the DRAP Act interacts with the 1976 Act. It will be convenient therefore to pause here in our analysis of Article 144, and take a look at the current position of the latter statute.

28. The 1976 Act was enacted as federal legislation when the Concurrent List was extant and it is, correctly, common ground that in its pith and substance it related to entry No. 20 of that List ("drugs and medicines"). The 1976 Act repealed and replaced the Drugs Act, 1940 ("1940 Act"). Interestingly, that statute had been enacted under the GOIA by the federal legislature in exercise of powers conferred under section 103, i.e., the constitutional progenitor of Article 144. As explained elsewhere (see Pakistan International Freight Forwarders Association v. Province of Sindh and others 2017 PTD 1, para 49), on the commencement of the present Constitution the 1940 Act had to be examined under Article 268 simply as a existing law in its own right and without regard to its provenance under any previous constitutional dispensation. On being so considered it was clearly relatable in its pith and substance to the aforementioned entry No. 20. It thus fell in the federal domain and became federal legislation. The repeal of this Act by the 1976 Act was therefore simply one federal law replacing another. What became of the 1976 Act when the 18th Amendment came to pass? Entry No. 20 was omitted along with the Concurrent List, and this legislative competence became exclusively provincial though now non-enumerated. How was now the 1976 Act to be regarded? In a recent decision of this Court (in C.P. D-1313/2013 and others, order dated 12.02.2018), a Division Bench had to consider the Companies Profits (Workers' Participation) Act, 1968 ("1968 Act"). That had, as an existing law on the commencement of the Constitution been found relatable to

entry No. 26 of the Concurrent List and had therefore passed to the federal domain. This entry also stood omitted along with the Concurrent List. Therefore, the post-18th Amendment position of the 1968 Act was, for present purposes at least, no different from the 1976 Act. It was held as follows:

> "23. Entry No. 26 of the erstwhile Concurrent List had provided as follows: "Welfare of labor; ....". In our view when the 1968 Act is considered ... it was, in its pith and substance, relatable to "welfare of labor" and hence to entry No.26. Thus, being an existing law relatable to an entry on the Concurrent List, it stood allocated to the Federation and operated as a federal law. When the 18th Amendment omitted the Concurrent List ... [w]hat happened to the 1968 Act? The legislative competence to which it related had moved.... The 1968 Act necessarily followed suit. It therefore "fractured" into provincial legislation. Instead of being one unified federal law applying as such over the whole of Pakistan, it now applied as provincial legislation in each of the four Provinces, and as a law in the federal domain in the Capital by reason of Article 142(d). Of course, no doubt that when the 18th Amendment came into force it applied identically all over Pakistan. But it must be clearly understood that this was not because it so applied in any unified sense as being one law relatable to the legislative competence of one legislature, i.e., Parliament. It so applied simply because on "fracturing" it passed (obviously in exactly the same form and shape) to each of the Provinces as provincial legislation, and continued to apply in the Capital on the same terms. Put differently, it was as though each Province had enacted exactly the same law for itself exercising its exclusive legislative competence, and the Federation had done the same for the Capital in terms of Article 142(d). Instead of there being one law, there were now five laws. Now, as is well known the territorial extent of legislation by a Provincial Assembly is limited to that province (see Article 141) and that of federal legislation under Article 142(d) to the Capital (and such other territory as does not form part of a province). Therefore, in that sense the 1968 Act had not merely "fractured"; it also "receded" from being one unified all-Pakistan law into five separate and distinct laws that, albeit identical, applied in their own respective territories. To the extent that the 1968 Act continued as federal legislation, it was only by virtue of Article 142(d) and there also only confined to the Capital. The fact that when the 18th Amendment came into force the 1968 Act continued to apply all over the country should not obscure the crucial constitutional change that had taken place, both as regards the territorial operation of the "fractured" statute as well as the legislatures to which it now stood allocated."

The 1976 Act, in like manner, "fractured" and "receded". It became provincial legislation and hence territorially bound. It now so operates in this and all other Provinces. It must be kept in mind that this position has remained unaltered, and is unaffected by the enactment of the DRAP Act under Article 144. Whatever may be the relationship of, and interaction between, the two laws, the 1976 Act does not now transcend or cross provincial boundaries in the manner of the DRAP Act.

29. Reverting to Article 144, it is invoked when the necessary resolution is passed by a Provincial Assembly. How is such a resolution •o be interpreted and applied? Chapter XVI of the Rules of Procedure of the Provincial Assembly of Sindh, 2013 ("Assembly Rules") deals with the resolutions mentioned in the Constitution and specifically provides for a resolution under Article 144. The Chapter, which comprises of only one rule (Rule 136) is essentially procedural in nature and provides, in sub-Rule (4) that "[a]fter a resolution has been moved, it shall be dealt with, as far as possible, in accordance with the rules contained in Chapter XV". The latter Chapter deals with resolutions "on matters of general public interest". Rule 125 provides for the form and content of a resolution that can be moved under this Chapter, and would therefore appear to relate, mutatis mutandis, to a resolution under Chapter XVI. Rule 125 is largely concerned with procedural aspects, being essentially a check

list of "do's and don'ts". The Assembly Rules do not therefore provide any substantive assistance. In our view, a resolution moved in terms of Article 144 ought not to be regarded as though it were a statute. Thus, it would be inappropriate to apply the rules of statutory interpretation to such a resolution. Without intending any disrespect, this is all the more so because it would not be incorrect to suggest that it is possible (and may well be probable) that the resolution will not have been drafted with the precision usually associated with legislative drafting. At the same time, it cannot be treated as loosely as would a resolution on a matter of "general public interest". A resolution under Article 144 does, after all, have legal, indeed constitutional, consequences. In our view, when considering a resolution under Article 144, three questions at least need to be asked:

(a) Is a legislative competence discemable in the resolution? It should be kept in mind that more than one legislative competence may be involved.

(b) In respect of the legislative competence(s) under (a), does the resolution cover the whole of the legislative field(s) or only a part thereof?

(c) Is the resolution a standalone measure adopted by the Assembly or is it in tandem with resolutions passed or to be passed by other Assemblies?

In addressing these questions a broad and expansive, as opposed to narrow and pedantic, approach should be adopted. This is line with what is the subject matter of the resolution: a legislative competence. It is well established that in matters relating to legislative competences a broad approach is preferable. Furthermore, in addressing the second question, the third must be kept in mind because if the resolution is not (or is not to be) a standalone measure that in our view will definitely have an effect on how the second question is to be approached and answered. This aspect, which is central to the case presented by the petitioners, must now be considered in some detail. Before doing so, it may be noted that the learned Additional Attorney General had argued that a grant under Article 144 had to be on an all-or-nothing basis, i.e., either the whole of the legislative competence had to be made available to the Federation or none at all. With respect, we are unable to agree. There is nothing in Article 144 that requires this or prevents the resolution(s) from dealing with only a part of a legislative field. It will be convenient to first set out the resolutions on the passing of which the DRAP Act came to be enacted. As noted in the third preamble to the DRAP Act, resolutions were passed by the Sindh, Punjab and Khyber Pakhtunkhwa (KPK) Assemblies. Each Assembly passed the resolution on the same day, 15.02.2012. They were in the following terms (as set out in para 11 of the memo of petition in CP D-4387/2014):

> Sindh Assembly: The Provincial Assembly of Sindh hereby authorizes the Parliament of Pakistan to enact a law regarding establishment of a Drug Regulatory Authority.
>
> Punjab Assembly: The Provincial Assembly of the Punjab resolves that the Majlis-e-Shoora (Parliament) may by law regulate matters relating to drugs and medicines in terms of Article 144 of the Constitution of the Islamic Republic of Pakistan.
>
> KPK Assembly: Resolution no 693 passed under section 144 of constitution has authorized the Parliament to prepare the rules and regulations regarding drugs and Medicines.

It has been contended by learned counsel for the petitioners that the Sindh Assembly only authorized Parliament to set up a regulatory authority and no more. Inasmuch as (according to them) the DRAP Act goes well (indeed, way) beyond that it is ultra vires Article 144 at least insofar as the operation of the statute in this Province is concerned.

30. The first question, whether the resolution refers to a legislative competence, raises few difficulties. Obviously, unless it can be answered affirmatively the resolution must fail since there would then be no "matter" in respect of which Parliament could be said to have been empowered. In the present case, there can be no doubt that a legislative competence is identifiable in the resolutions, being the erstwhile entry No. 20, "drugs and medicines". In our view this is the only legislative field involved. Furthermore, it is a competence that exists independently and on its own. With respect, we are unable to agree with the submissions that this competence is in some sense a sub-category of a 'general' competence of "public health" and it is the latter that applies. The competence as noted exists and clearly is the only one involved. The second question lies at the heart of the controversy now under consideration. Looking at the resolutions, there can be no doubt that the resolution of the Punjab Assembly appears to be stated in the broadest terms. It brings the entire legislative competence within the scope of Article 144 and hence within Parliament's power when enacting the law. Prima facie, the resolution of the Sindh Assembly appears to be more narrowly focused. The KPK Assembly's resolution could be regarded as either co-terminus with that of the Punjab Assembly's or falling somewhere between the resolutions of the other two. Had the Sindh Assembly resolution been a standalone measure, it could have been regarded as bringing not the whole of the legislative competence within the scope of Article 144 but only a part thereof, with Parliament's power circumscribed accordingly. But there is also the third question to consider. Having regard to the material and record placed before us, we are of the view that it would be inappropriate to regard the three resolutions as standalone measures. It is clear that the three Assemblies acted, and intended to act, in tandem, and the resolutions were so passed. How does this affect consideration of the second question? The question now to be addressed may be restated as follows. If two or more Assemblies pass resolutions in tandem but the scope of the resolutions appears to vary, one from the other; then to what extent can Parliament enact a law in respect of the legislative competence entrusted to it under Article 144?

31. Speaking generally, in such a situation at least three solutions are conceivable. The first is to take what might be called the maximalist approach. Here, the scope of the competence entrusted to Parliament would be determined by the resolution couched in the broadest terms, and the law so enacted would so apply in all the Provinces. The second is to take what might be called a minimalist approach. This is, obviously, the converse of the first approach. Here, Parliament's power to enact the law would be determined 'by the resolution most narrowly couched, and the law so enacted would so apply in all the Provinces. The third is to take what might be called a nuanced approach. Here, Parliament would have to enact a law that is so crafted that it takes into account the scope of each resolution and applies only to that extent in the Province concerned. Thus, e.g., the law may be so drafted that it applies (say) in whole in one Province but only in selective part or parts in the others. We have carefully considered these possible solutions. In our view, the last mentioned approach must be discarded as untenable. As noted above, one principal purpose behind Article 144 is to ensure that there is one law that seamlessly applies across provincial boundaries as a unified whole. To apply the third approach would be to, in effect, do away with Article 144: after all, each Provincial Assembly can, within its own Province, enact a law that applies in such manner as the provincial legislature deems appropriate. A law crafted by Parliament in terms of the nuanced approach would create a situation that would, in practical terms, be no different. This leaves the first two possibilities. A law enacted on the minimalist formula would apply the legislative competence in the full measure of the grant in the Province that passed the narrowest resolution, and in some measure of the grant in the other Provinces, though not of course to the extent as granted. A law enacted on the maximalist formula would apply the legislative competence in the full measure of the grant in the Province that passed the broadest resolution, but in relation to the other Provinces could be objected to on the basis that it has exceeded the scope of the grant.

32. Nonetheless, it is our view that the correct solution lies in applying the maximalist approach. Our reasons for coming to this conclusion are as follows. Firstly, and most importantly, a law enacted by Parliament under Article 144 can at any time be amended or repealed by a Provincial Assembly in relation to its own Province. If therefore an Assembly, that passes a resolution that is in scope apparently less than the one couched in the broadest terms, is dissatisfied with the law enacted by Parliament, it can at any time take the necessary action, either by amending the law to tailor it to its own resolution or repealing it altogether. Secondly, as noted above, it is possible (and if, with respect, we may say so, probable) that a resolution under Article 144 is not artistically crafted or drafted. Thus, it may well be that the resolution as apparently passed was in fact intended to have a broader scope and effect. Here again, the purpose behind passing a resolution under Article 144 must be kept in mind: it is to create a legal framework that transcends provincial boundaries. If, say, the minimalist approach is taken this objective may be defeated. Take the very case at hand. If the minimalist approach were to be adopted, that would mean that the law Parliament could enact would be limited in scope only to what the Sindh Assembly resolution appears to allow (at least as per the petitioners), namely the setting up of a drug regulatory authority. But, what would this authority regulate? An obvious answer could be: the 1976 Act, and this is in fact what was urged by learned counsel for the petitioners. But as already noted this law is now entirely provincial in nature. It cannot, and therefore does not, cross provincial boundaries. What purpose would be served in setting up a trans-provincial regulatory authority that can only apply a law (or rather four laws) that must in each case stop at the provincial boundary concerned? Some uniformity of approach and policy would undoubtedly be achieved, but the basic objective of having a law seamlessly crossing provincial boundaries would be lost. In this context, it is not without relevance to note that insofar as drugs are concerned, it was felt necessary to have such a legal framework in place right from the beginning, i.e., even under the GOIA when the 1940 Act was enacted in terms of section 103. Thirdly, it would not be appropriate for the Court to second guess a Provincial Assembly as regards the scope of its resolution under Article 144. The apparent scope of the resolution may appear to be less than what was actually intended, and therefore granted, by the Assembly. This is all the moreso because, as noted, a Provincial Assembly can, at any time, amend or repeal the law enacted by Parliament. In the present case of course the Sindh Assembly has done nothing to amend or undo the DRAP Act. During the course of his submissions, we specifically sought the assistance of the learned AAG Sindh on this point. His reply was that the resolution, when read properly, extended the whole of the competence in terms of Article 144 to Parliament. Even if the counter submission for the petitioners were correct, it would seem that the Sindh Assembly has accepted what Parliament has understood the scope of its resolution to be, and has accepted what Parliament has done in terms thereof by enacting the DRAP Act. In our view, the silence or lack of any action or response by the Provincial Assembly is not without significance. In fact, it seems to us to be a matter of considerable relevance, especially where the resolution is being passed in tandem with those of other Assemblies. Finally, also as noted above, in respect of resolutions under Article 144 the whole approach ought to be broad and expensive. A minimalist solution would run counter to this.

33. It is therefore our conclusion that in the present case, the scope of the legislative competence entrusted to Parliament in terms of Article 144 is governed by the terms of the resolution passed by the Punjab Assembly. Since that Assembly has allowed Parliament to make a law extending to the whole of the legislative competence, this so applies in respect of all the three Provinces. No exception can therefore be taken to the DRAP Act in relation to its applicability in this Province on the ground that it exceeds the terms of Article 144. In view of this conclusion, we are also unable to agree with learned counsel for the petitioners that all that the authority constituted under the DRAP Act can do in this Province is to give effect to or enforce the 1976 Act and no more. Indeed, on the view that we take of the 'matter, it was well within Parliament's competence that while enacting the DRAP Act it

could have repealed the 1976 Act as in force in all the Provinces. It has chosen not to do so, and by section 32(1) has specifically provided that the DRAP Act is in addition to, and not in derogation of, the 1976 Act. However, this provision and the continued existence of the 1976 Act cannot be taken to mean that the DRAP Act itself cannot be enforced or given effect in all the Provinces on its own terms, as therein provided. Neither Parliament's competence under Article 144 nor the manifestation of the same in the shape of the DRAP Act is so circumscribed. It is now the DRAP Act that is the controlling statute, operating seamlessly as one unified law that applies trans-provincially across all Provincial boundaries, and not the 1976 Act, operating in each Province as territorially bound provincial legislation. It follows that the challenge on the constitutional plane fails and must be rejected.

34. One argument advanced by learned counsel for the petitioners as regards the proper scope of the DRAP Act was that Unani medicines, preparations or substances were never regarded as "drugs" and hence never subjected to regulation in terms of the earlier legislation. The attempt to do so now was therefore impermissible. This submission was linked to the constitutional question by looking at the resolution of the Sindh Assembly on its own. It was submitted that insofar as this Province was concerned, Parliament could only enact a law that set up a drug regulatory authority and nothing else. The scope of what the authority could regulate was determined by the 1976 Act. Thus, it was only drugs within the meaning of the 1976 Act that could be regulated under the DRAP Act and nothing else. And, it was contended, drugs as therein defined did not include Unani medicines or substances. While this submission has been dealt with above and found wanting on the constitutional plane, it must now also be considered in the context of what is meant by "drug". Even when so considered, with respect, the submission is untenable. It will be pertinent to take a historical approach and compare the definitions of "drug" to be found in the 1940 Act, the 1976 Act and the DRAP Act. The definitions (as regards the later two laws, to he extent presently relevant) are set out below. To assist analysis, each definition is divided into "parts" which are identified by the use of Roman numerals in square brackets.

1940 Act	**1976 Act**	**DRAP Act**
S.3(b) "drug" includes [I] all medicines for internal or external use of human being or animals, and all substances intended to be used for or in the treatment, mitigation or prevention of disease in human being or animals, [II] other than medicines and substances exclusively used or prepared for use in accordance with the Ayurvedic or Unani systems of medicine:	S.2(g)(i) "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 disease, an abnormal physical state, or the symptoms thereof in human being or animals or the restoration, correction, or modification of organic functions in human being or animals, [II] not being a substance exclusively used or prepared for use in accordance with the	Schedule I, para 2(a) DRUG includes [I] any substance or mixture of substances that is manufactured, sold, stores, 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 being or animals or the restoration, correction, or modification of organic functions in human beings or animals [II] including substance used or prepared for use in accordance with the Ayurvedic, Unani, Homoeopathic, Chinese or biochemic system of treatment [III} except those substances and

	ayurvedic, unani, homoeopathic or biochemic system of treatment [III} except those substances and in accordance with such conditions as may be prescribed;	in accordance with such conditions as may be prescribed.

35. The first point to note is that all the definitions are inclusive and not exhaustive. When the 1940 Act is considered the definition fell into two parts. The first part defined what drugs were, and the second part excluded from this Unani medicines and substances. In the 1976 Act, the definition has three parts. The first defines what drugs are. The second part excludes from this Unani medicines and substances, but the third part allows such Unani substances to be brought back into the definition (and on such conditions) as may be. prescribed. The definition in the DRAP Act also has three parts. The first defines what drugs are. The second part expressly includes Unani medicines and substances, but the third part allows such Unani substances to be taken out of the definition (and on such conditions) as may be prescribed. When the definitions are considered in the foregoing terms, the progression of the law is clear. The first, and most fundamental, point is this: Unani medicines and substances were always within the scope of the main (i.e., first) part of the definition. If the second part in the case of the 1940 Act, and the second and third parts in the case of the latter statutes, had not been there, Unani medicines and substances would undoubtedly be drugs. It was nothing but the policy of the law that Unani medicines and substances were treated separately and distinctly, and this policy has changed over time. In the 1940 Act the policy was to take Unani medicines and substances out of the definition altogether without exception. In the 1976 Act this policy has been retained but subjected to the important rider that under prescribed conditions any Unani substance can be brought back into the definition. In other words the policy of rigid or absolute exclusion has been altered. It is immaterial for analytical purposes whether the rider was ever put into practice and if so to what extent. The crucial point is that part [III] of the definition in the 1976 Act represents a change in policy. In the DRAP Act, the policy has been reversed. Now, it is expressly provided (by part [II]) that Unani medicines or substances are indeed drugs. However, the rider in part [III] allows for any Unani substance to be taken out of the definition under prescribed conditions. When all of the foregoing is kept in mind, it is in our view incorrect to suggest, as submitted for the petitioners, that Unani medicines and substances have for the first time been brought within the definition of drugs. They were always there. They were always drugs. It was simply the policy of the law that treated them differently over time, and that policy has itself changed, its latest manifestation being as provided in the DRAP Act. Furthermore, the use of the word "includes" in part [II] of the definition in the DRAP Act should not cause confusion. It appears to suggest that something that was not there, or would not be there but for the words that follow, was being added to the definition of drugs. This is not so at all. It was because the policy of the 1976 Act was being reversed that the word was used. The use of this word in the definition simply reflects the past trajectory of the law's policy, and also the fact that the 1976 Act continues to remain on the Provincial statute books. This provides the context in which the use of this word must be understood. Now, it appears that the rider in part [III] of the definition in the 1976 Act was hardly, if ever, used. Thus, from 1940 to 2012 the practical position was that the policy was to keep Unani medicines and substances out of the definition even though, it must be reiterated, they would have been very much a part of it but for the exclusion. In 2012 the policy underwent a substantive change and was reversed. There is nothing inherent in Unani Medicines and substances that they did not or could not fall within the definition of drugs. We are

therefore, with respect, unable to accept the submissions that the DRAP Act has impermissibly brought about a situation that never existed before and could not exist. Since we have already held that the entire legislative competence of "drugs and medicines" has been granted to Parliament in terms of Article 144, the change brought about by the DRAP Act is constitutionally unexceptionable. It is not for the Courts to gainsay or defeat the policy that now finds statutory expression in the DRAP Act.

36. On the question whether Unani medicines or substances were drugs within the meaning of either the 1976 Act or the DRAP Act, learned counsel also referred to certain other clauses of the definition, being in particular S.3(g)(v) of the former and para 2(e) of Schedule I of the latter. These provisions are in fact substantially similar. We were also referred to certain provisions of the 1940 Act as applicable in India, where it continues to be in force though in much amended form. In our view, with respect, no purpose will be served in considering these provisions in any detail and we intend no disrespect to the assistance provided by learned counsel in this regard. In our view, the entire matter is fully addressed in terms as stated, with reference to the provisions set out above.

37. Insofar as the 2014 Rules are concerned, we are, with respect, not at all satisfied that the petitioners have been able to make out a case that the practitioners of the Unani system are being discriminated against or that their interests or rights are in any manner being violated by an application of the said Rules to them and their products. Learned counsel for the petitioners have argued that the allopathic and the Unani systems are different. That may well be so. But, in our view, the differences are not of such a fundamental nature that they cannot both be regulated by the same parent statute, the DRAP Act. After all, at the most basic and fundamental level, namely the definition of 'drugs", we have already seen that Unani medicines and substances were very much within the scope thereof except that up till 2012 they were kept out of the definition as a matter of policy. This policy has of course now changed. Allopathic medicines and substances have in any case always been within the definition. Thus, at the most fundamental point, both types of medicines and substances come within the rubric of the same law. Why that law should not be able to regulate the products of both the systems under Rules framed pecifically with reference, inter alia, to Unani medicines and substances is something on which, with respect, we cannot agree with learned counsel for the petitioners.

38. It follows from the foregoing that in our view the challenge mounted of the DRAP Act or the 2014 Rules in those petitions where the subject matter is the Unani system and/or Unani medicines and substances, must fail. We so hold.

39. We now turn to consider the matter of the food supplements, animal feed and other products (being in the case of one petition cosmetics). Since we have already concluded that the DRAP Act has been competently made under Article 144 and applies as such in all the Provinces, the submissions by learned counsel that it is only the 1976 Act that applies cannot be accepted. What needs to be considered is the submission that these types of products were never "drugs" within the meaning of the 1976 Act and ought not, therefore to be so regarded under the DRAP Act. As noted, it has been stated in relation to food supplements that at one time they were registered under the 1976 Act but were then de-notified by the Federal Government itself. We begin by noting that that the statutory meaning of a term, no matter how well settled it may be, does not control when the term is considered on the constitutional plane with reference to a legislative competence. As is well known competences are fields of legislative power which are to be interpreted and applied in the broadest terms. We are here concerned with the legislative competence of "drugs and medicines" with reference to which the DRAP Act has been enacted. The statutory meaning of "drug" in the 1940 Act and/or the 1976 Act cannot control the meaning of this term when considered on the constitutional plane. A classic

example, from taxes on income, will help illustrate the point. It is set out in Pakistan International Freight Forwarders Association v. Province of Sindh and others (2017 PTD 1. Though the immediate context there was fiscal legislation, the point made applies generally. It was stated as follows:

> "33. ... Firstly, it may be, that the taxing event, as manifested in sub-constitutional legislation even over a period stretching over many decades, is not the full scope or extent of the taxing power. A classic example is in relation to the power to tax income, contained in entry No. 47 of the present Constitution. Leaving aside the power to tax agricultural income (of which more later), the power to tax income as such has always vested exclusively in the Federation, and this goes back to even before the GOIA. Now, the scope of the taxing event in the legislation (starting with the Income Tax Act, 1922), as developed in judicial decisions given at the highest levels, was regarded as confined to revenue as opposed to capital. This distinction was regarded as fundamental to income tax law: revenue receipts could be brought to tax but capital receipts could not. Equally, expenditure that went to revenue account could be claimed as a deduction but capital expenditure could not. Therefore, when the Indian legislature sought to tax capital gains, such levy was challenged as falling outside the legislative entry and hence beyond the legislature's constitutional power. In a landmark judgment, Navinchandra Mafatlal v. Commissioner of Income Tax AIR 1955 SC 58, 26 ITR 758, the Indian Supreme Court dismissed the challenge. The late N. A. Palkhivala, perhaps post-Independence India's greatest tax lawyer (and of course, much else besides) had no doubt as to the correctness of this decision. The matter is put in the following terms in the latest edition (10th, 2014) of his justly renowned work on income tax law (internal citations omitted; emphasis supplied):
>
> "The Supreme Court held in Navinchandra Mafatlal v. CIT that the word 'income' in entry 54 in List I of the Seventh Schedule to the Government of India Act, 1935 should be given the widest connotation, in view of the fact that it occurred in a legislative head. conferring legislative power, and in that context, it did not bear the meaning as was ascribed to it in cases decided under the income-tax statutes but included capital gains. Consequently, the court held the levy of tax on capital gains under the 1922 Act to be intra vires the central legislature. There can be no question about - the Parliament's competence to levy a tax on capital gains under the Constitution." (Kanga & Pallchivala's The Law and Practice of Income Tax, Vol. I, pp. 1177-8)
>
> The same view has been taken in Pakistan. This decision underscores the danger of attempting to divine the extent and scope of a legislative entry, and especially a taxing competence, from the sub-constitutional manifestation of the taxing power, in terms of the taxing event as set out in the statute. At the same time, it affirms the autonomous nature of the power on the constitutional plane."

Thus, even if the petitioners are correct that prior to the DRAP Act, for years if not decades "drug" was not understood on the statutory plane as including products like food supplements, animal feeds etc, that is not decisive on the constitutional plane. How "drugs" were statutorily conceived in previous legislation cannot control or be determinative of how the term is used in the DRAP Act. With these principles in mind, we now turn to consider the statutory provisions of the DRAP Act and the 2014 Regulations in relation to food supplements, animal feeds etc.

40. Section 2(xii) of the D.RAP Act defines "drug" as meaning "drug as defined in Schedule I". The said Schedule comprises of four parts each of which contains descriptions that are stated inclusively and not exhaustively. The four parts are: biologicals, drugs, medical devices and medicated cosmetics. Each part, and in particular the first two, comprise of several paragraphs and/or

clauses of detailed description. It is therefore in the first instance the totality of all of these parts that are "drugs" within the meaning of the DRAP Act. Secondly, inasmuch as the said parts are not exhaustive the definition includes what could even otherwise come within the respective headings of biologicals, drugs, medical devices and medicated cosmetics. The first clause from the second part has been reproduced in the table above. We may note here that the DRAP Act occasionally refers to "drug" in a somewhat ambiguous manner. Sometimes the reference is to "drug" as meant in section 2 (xii), i.e., as encompassing the whole of Schedule I. However, sometimes the reference is to "drug" only as used in the second part of Schedule I. This distinction should be kept in mind.

41. The 2014 Rules contain a long series of detailed definitions, being no less than 90 in number. Of these, the following are of particular interest:

> "(xxxi) "Food supplements" or "dietary supplement" or "health supplement" or "Nutraceuticals" means products containing vitamins, pro-vitamins, multivitamins, minerals including a mineral salt, a naturally occurring mineral, metals and their salts, a lipid, including an essential fatty acid or phospholipids liproteins,amino-acids, proteins, fatty acids, carbohydrates, a mucopolysaccharide, plant or herbal material (or a synthetic duplicate of that kind), including plant fibers, enzymes, algae, fimgi, cellulose and derivatives of cellulose and chlorophyll, herbal preparation, resins, balsams, volatile oils, non-human animal material (or a synthetic duplicate of that kind) including dried material, bone and cartilage, fats and oils and other extracts or concentrates, a microorganism, whole or extracted, except a vaccine expressed juices, exudates etc., alone or their combinations and are presented in pharmaceutical dosage forms intended for health related purpose;
>
> (xxxiv) "health related purpose" means a therapeutic, curative, preventive, palliative, or cosmetic purpose or for promotion and well being of humans and animal health;".

42. If we reduce the first definition to such bare essentials as are relevant for present purposes, it may be restated as follows:

> "Food supplements" or "dietary supplement" or "health supplement" or "Nutraceuticals" means products containing [any of the listed and specified substances except those specifically excluded] alone or their combinations and are presented in pharmaceutical dosage forms intended for health related purpose;"

It will be seen that the definition has the following elements. Food or dietary supplements (as also of course health supplements and nutraceuticals) mean (i) any product containing any of the substances listed in the definition, (ii) whether alone or in combination, (iii) which are presented in pharmaceutical dosage forms, (iv) and are intended for a health related purpose. Focusing first on the last element that, as noted above, is itself defined. Thus, paring the definition down still further for a moment, a food supplement etc. is a substance that is intended for a health related purpose. When the definition of "health related purpose" is compared with the definition of drug in the second part of Schedule I, in our view, it clearly brings food supplements etc. within the scope of clause (a) (reproduced above). For ease of comparison, the definition of the former can be set out against the essential elements of the latter as follows in tabular form:

"health related purpose" means	**"drug" includes**
a therapeutic, curative, preventive, palliative, or cosmetic purpose or for	Any substance or mixture of substances... for internal or external use in the treatment, mitigation, prevention or diagnosis of

promotion and well being of humans and animal health	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 being or animals.....

It will be seen that both definitions apply equally to humans and animals. The words "therapeutict curative, preventive [or] palliative' in the first definition correspond to the words "treatment, mitigation, prevention or diagnosis of diseases, an abnormal physical state, or the symptoms thereof'. The words "cosmetic purpose or for promotion and well being" correspond to "restoration, correction, or modification of organic functions". This categorization is of course not intended to create watertight compartments; there is obviously also an overlap. But it serves to highlight the essential point, and our conclusion: a "health related purpose", as defined, and hence food supplements etc. are included in the definition of "drug". Therefore any product. that is intended for a "health related purpose" and contains a substance that comes within the list of the substances set out in the definition of food supplements, etc. is a drug within the meaning of the DRAP Act and this is so regardless of whether it is intended for human or animal use or consumption. In other words, the definitions in the 2614 Rules cover both what the petitioners refer to as food or health supplements as well as animal feed. The definitions as used in the 2014 Rules cannot therefore be regarded as beyond or outside the scope of the parent statute and hence ultra vires the DRAP Act.

43. But of course, that is not the end of the matter. There is also the third element to consider, i.e., the food supplements etc. must be "presented" in "pharmaceutical dosage forms". Before proceeding to consider this element, it must be noted that both the "presentation" and the "pharmaceutical dosage form" will be different for humans on the one hand and animals on the other. Furthermore, there will be sub-categories within these and also variations and differences (and perhaps even overlap) in the sub-categories. Therefore, what may be a "pharmaceutical dosage form" for one may not be so for another, and yet both may be within the definition. Turning to the words used in the third element, they are not as such defined in either the DRAP Act or the 2014 Rules. In our view "presented" means as presented (i) either to the final or actual consumer, or (ii) for the intended final or actual use. "Dosage forms" appear to vary according to the route of administration, i.e., how the substance is applied. For example, in a "topical" route of administration the dosage form may be either a lotion, cream, ointment, gel/jelly, powder, paste or transdermal patch. For our purposes, especially in relation to food supplements and animal feed, the "oral" route of administration is very relevant. As is to be expected the dosage forms here include a solution, emulsion, suspension, syrups, drops, tablets or capsules of various forms and types and generally anything that can be ingested. Injections are dosage forms administered by the parenteral route of administration. This listing is necessarily incomplete since we are here concerned only with matters of law but enough has been said to make the essential point, which is this: "dosage forms" encompass a wide variety and range. However, in order to come within the definition, the "dosage form" must be "pharmaceutical". This is clearly intended to have a technical meaning. It would therefore be inappropriate for us to attempt a description of what is meant by a "pharmaceutical dosage form" in general terms. At the same time, it cannot be denied that the lack of such a definition in the 2014 Rules does create an ambiguity, which can have important practical consequences. How we intend to deal with this matter is set out below.

44. When the foregoing analysis is applied to the facts of each petition that involves food, health or dietary supplements and animal feed, and the submissions that were made by learned counsel for the petitioners on the one hand and the learned Law Officers on the other our tentative assessment is

that prima facie the various products could well come within the Rules and the Act, especially on a combined reading of the definitions taken above from the 2014 Rules. They could therefore be drugs within the meaning of the DRAP Act. However, we recognize that for there to be a conclusive determination it is more appropriate to carry out a factual inquiry. It seems to us that perhaps such a determination cannot be made simply by looking at the material on the record (consisting largely of brochures, advertising claims, downloads from the Internet, etc.). It does seem to require a determination by the officers of the Authority constituted under the DRAP Act after giving an opportunity of hearing to the party concerned. We therefore intend to dispose off the petitions where the subject matter is food or dietary supplements or animal feed etc. in the manner set out below.

45. In one petition, the products involved appear to be cosmetics, and the petitioner there contends that they do not come within the meaning of "medicated cosmetics". It will be recalled that the latter constitute the fourth part of Schedule I to the DRAP Act and hence are drugs' as defined. For substantially the same reasons as given above in relation to food supplements, animal feed etc., we are of the view that a proper factual inquiry is required before it can be concluded whether or not the cosmetics in question are "medicated cosmetics".

46. Before concluding, it is necessary also to consider certain provincial legislation that was referred to by learned counsel. We were referred to two Punjab statutes in addition to the Sindh legislation. Now as already noted it is the hallmark of provincial legislation that it is territorially bound. Therefore, the effect of the Punjab statutes is limited to that Province. Whether, and if so to what extent, this law impacts on or interacts with the DRAP Act, is a matter to be decided in that Province and not here, i.e., by the Lahore High Court and not this Court. We do not therefore say anything with reference to the Punjab statutes.

47. Turning to the Sindh legislation, reliance was placed on the Pure Food Ordinance, 1960 ("1960 Ordinance"). Clause (9) of section 2 defines "food" in the following terms (as presently relevant):

> " "food" means any article used as food or drink for human consumption other than drugs, and includes-
>
> Explanation- An article shill not cease to be food by reason only that it is also capable of being used as a medicine."

Learned counsel appearing in those petitions where the subject matter was food, dietary and health supplements relied on the foregoing to contend that the substances were "food" and hence regulated by the 1960 Ordinance and not the DRAP Act. With respect, we are unable to agree. The definition on the face of it excludes "drugs" from the purview thereof. The latter term is not defined in the 1960 Ordinance, and must therefore, on the statutory plane, take its meaning from the controlling statute, which is now the DRAP Act. As we have seen above, food supplements, etc. as defined in the 2014 Rules come within the meaning of "drug" as used in the DRAP Act. Therefore, if the petitioners' products come within the definitions contained in the 2014 Rules (a determination yet to be made) then they would fall outside the ambit of the 1960 Ordinance. This statute does not therefore, with respect, provide assistance to the petitioners.

48. The Sindh Allopathic System (Prevention of Unauthorized Use) Act, 2014 was also referred to and relied upon. This statute, which has its antecedents in an Ordinance of 1962 essentially seeks to ensure that a person who is not a "doctor" or "dentist" registered under the Pakistan Medical and Dental Council Ordinance 1962 should not be able to hold himself out as such or to perform

procedures and operations without being so registered. It clearly has no relevance for the issues at hand.

49. This brings us to the Sindh Food Authority Act, 2016 ("2016 Act"). This defines "food" in s. 2 (g) as follows (as presently relevant):

> ""food" means any article used as food or drink for human consumption other than drugs, and includes- ...
>
> Explanation I.-An article shall not cease to be food by reason only that it is also capable of being used as drugs.
>
> Explanation II-In this clause, the word "drug" has the same meaning as is assigned to in the Drugs Act 1976 (XXXI of 1976)"

This definition is similar to that found in the 1960 Ordinance. However, there is one crucial difference for present purposes. The second explanation expressly defines "drug" as having the same meaning as in the 1976 Act. Reference must also be made to section 59, which contains an overriding provision in the following terms: "The provisions of this Act shall have effect notwithstanding anything contained in any other law for the time being in force". Prima facie, the 2016 Act may well have important consequences for the DRAP Act as applicable in -this Province. It therefore requires consideration, but at present that can be deferred. This is so because the statute, which is intended to repeal and replace the 1960 Ordinance, has apparently not yet come into effect. Section 1(3) provides that it shall come into force on such date as may be notified by the Provincial Government. It appears that no such date has yet been notified.

50. Reverting now to paras 44 and 45, in our view certain directions and orders are merited in relation to food, dietary and health supplements, etc, animal feed and medicated cosmetics. It is therefore directed as follows:

> a. Within 30 days of announcement of judgment the Authority under the DRAP Act shall issue proper guidelines, consistently with this judgment, as to what is meant by "pharmaceutical dosage forms". The guidelines shall deal separately with humans and animals and in each category provide for such sub-. categories as are deemed appropriate. The dosage forms and routes of administration and any other matters considered relevant or applicable by the Authority shall be properly set out in the guidelines. The Authority shall not, for purposes of complying with this para be entitled to rely on any order or determination earlier made or prior guidelines or directions, if any, issued by it or its officers. In other words, guidelines must be issued specifically with reference to this para. The guidelines shall be immediately and prominently posted on the opening webpage of the website of the Authority and shall be deemed issued for purposes of this para only when so posted.
>
> b. Simultaneously with posting the guidelines on its website, the Authority shall issue notice to each petitioner in the petitions to which this para applies. Such petitioner shall in respect of each product or substance be given a hearing as to whether the said product/substance comes within the scope of the 2014 Rules or the DRAP Act, especially with reference to the definitions considered in the paras herein above. The person shall be entitled to rely on such material, record or evidence as is considered relevant. The Authority shall then, by way of a reasoned order, issue a determination as to whether the 2014 Rules or the DRAP Act are applicable or not. Preferably, such determination shall be issued within 10 days of the

conclusion of the hearing. Any person aggrieved , by any such determination, in whole or in part, shall be entitled to seek such relief ,before such forum and in such proceedings as are appropriate.

c. Interim orders made in any petition to which this para applies shall continue but will lapse 30 days from the date on which the guidelines are posted as above or the date on which the determination is made, whichever is later. However, if a petitioner fails or refuses to appear before the Authority or attempts to delay or frustrate the proceedings or the conclusion thereof, the Authority may, at any time after the expiry of the aforesaid period of 30 days, so declare by an order in writing setting out its reasons for doing so, in which case the interim orders shall lapse immediately on the making of such an order.

51. In view of the foregoing, these petitions are disposed off as follows:

a. The following petitions are dismissed: CP D-4387/2014 and CP D-1684/2017.

b. The following petitions are disposed off in terms of para 50 herein above:

C.P.No.D-6532/2014, 2623/2016, 6262/2016, 6263/2016, 6264/2016, 6265/2016, 6310/2016, 6820/2016, 7134/2016, 7135/2016, 1135/2017, 1921/2017, 2329/2017, 424/2017, 4421/2017, 5237/29017 and 5892/2017.

c. There will be no order as to costs.

MH/A-43/Sindh

Order accordingly.

REGISTERED POST

ANNEX-III

IN THE LAHORE HIGH COURT, LAHORE

JIS WRIT

No. 2912 **Dated** 30 JUN 2021

From,

The Additional Registr
Lahore High Court, Lah

To,

3. Drug Regulatory Authority of Pakistani through Chief Executive Officer, Office at 2nd floor, Block-C. Pak Secretariat, Islamabad.

9. Provincial Task force for control & Elimination of Spurious for the Province through its convener Khawaja Imran Nazir, MPA, Punjab Assembly, Govt. of the Punjab.

10. Provincial/Area Drug Inspector/Drug Controller, executive District Office Health, Lahore.

11. D.C.O District Chiniot, Officer Chairman Inspection Tea, District Chiniot.

12. Deputy Commissioner, Chiniot.

13. Commissioner Sargodha Division, Sargodha.

Subject:- **WRIT PETITION/ICA/CRL.ORG.NO.** 45190-20 ICA 45172/20 ICA 45173/20

VS

Memo,

In continuation of this Court's Letter No. _____ ***Dated*** _____ ***I am directed to say that the case cited on the subject has been disposed of. A copy of order dated*** 16/03/21 ***is enclosed herewith for necessary action. A copy of Petition on which the order has been passed is also enclosed herewith.***

Assistant Registrar (Writ-I)
For Additional Registrar (Judicial)

Form No:HCJD/C-121

ORDER SHEET

IN THE LAHORE HIGH COURT LAHORE
JUDICIAL DEPARTMENT

Case No: I.C.A. No. 45190/2020

M/s Nasir Dawakhana **Versus** Federation of Pakistan etc.

S.No. of order/ Proceeding	Date of order/ Proceeding	Order with signature of Judge, and that of parties of counsel, where necessary.
	16.03.2021	Nawab Saeed Ullah Khan, advocate for the appellants in ICA No.45190/2020 and ICA No.45172/2020. Mr. Saeed Akhtar Khan Khetran, advocate for the appellant in ICA No.45113/2020. Mr. Asad Ali Bajwa, Deputy Attorney General for Federation of Pakistan. Ch. Muhammad Zafar Iqbal, advocate for Custom Department/FBR. This order shall dispose of the instant appeal as well as ICA. No. 45172 of 2020 titled *"M/s Kanfuri Pharmacy Unani (Regd) versus The Federation of Pakistan etc"*, as well as ICA No. 45113 of 2020 titled *"M/s Aleem Dawakhana & Herbal Laboratories versus Federation of Pakistan etc"* as all have arisen out of one order. 2. Through these Intra Court Appeals under Section 3 of the Law Reforms Ordinance, 1972 impugned order passed by the learned Single Judge in Chambers dated 05.08.2020 has been challenged whereby legislative competence of Parliament to enact Drug Regulatory Authority of Pakistan Act,

2012 (XXI of 2012) hereinafter to be called **DRAP ACT, 2012** and the vires of the Rules made thereunder was upheld by dismissing the writ petitions of the appellants on merits. In the prayer clause the appellants made the following prayer:-

> *"It is, therefore, most respectfully prayed that the instant Intra Court Appeal may kindly be accepted impugned passed by Justice Ayesha A. Malik dated 05.08.2020 may kindly be set aside and the enactment is clearly violation of Constitution of Islamic Republic of Pakistan, 1973 in violation Chartered of United Nations as well as against the Gross Violation of Provisions of Article 4, 18, 25 of the Constitution of Islamic Republic of Pakistan, 1973, the Federal Government has having no authority to enact DRAP Act XXI of 2012 in violation of Article 147 of the Constitution of Islamic Republic of Pakistan, 1973. The act is stand repealed as laid down in Article 147 of the Constitution of Islamic Republic of Pakistan, 1973 after lapse of 60 days of the passing the first Resolution.*
>
> *It is further prayed that the appellant also seeks the Federal Parliament having no power to enact, The DRUG Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) Similarly the provisions of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) Particularly Sections 4, 7, 9(i) (ii) and Section 9(iii), Section 20(1) AND RULES OF (THE DRUG REGULATORY AUTHROITY OF PAKISTAN ACT, 2012) formed through S.R.O. 412-12014 (DATED 27.05.2014) are all illegal and unconstitutional Clause No. 1(a) section4-(viii) ix and 1(b) i.e. Section-9(g) paragraph (enlistment rule 2014, particularly rule 2(iii), 29 (i-x), 5(i) and 10 along with schedule may be declared unconstitutional, illegal, unlawful. Alternative medicines (health product rule of 2014) are illegal and violative of constitutions.*
>
> *It may also be declared that respondents may be restrained from making any coercive action against the appellant under SRO, No. 412 as well positions DRAP. Act, THE DRUG REGULATORY AUTHORITY OF PAKISTAN ACT, 2012 (XXI 2012) it is further prayed that all the shall not take any step derogatory to manufacture sale, storage and distribution of the Unani medicines in any manner or style whatsoever. That the ii of 1965 as well as drugs 1976 may be ordered to be operative and shall complied with terms and conditions.*
>
> *Any other relief which this honorable court deems fit and proper may also very graciously be granted."*

3. Learned counsels for the appellants contend that in order to legislate on the

subject of Drug Regulation by the Parliament falling in the Provincial Legislative list, a resolution required by the Provincial Assembly as laid down in Articles 144 and 147 of the Constitution under which the Federal Government can assume the legislative function within 60 days but such requirement of law was not fulfilled. Adds that since the powers of the President under 2(a) of Article 89 of the Constitution are to be laid before the National Assembly if it contains the matter specified in clause(2) of the Article 73, otherwise the law will stand repealed at the expiration of 120 days, therefore, at present it is no more a law. Also adds that the enactment is violative of Articles 4, 18 and 25 of the Constitution of Islamic Republic of Pakistan, 1973 as well as the Charter of United Nations.

4. Arguments heard. Record perused.

5. After hearing the learned counsel for the parties and perusing the record, it is straightway observed that the learned Single

Judge has concluded in paragraphs No. 48 and 49 reproduced as under for ready reference:-

"48. Therefore in view of the aforesaid:

(i) with respect to the issues on lack of guidelines on acceptable standards of evidence, DRAP is directed to devise guidelines setting out the acceptable standards of evidence required to support health related claims to prove quality, safety, efficacy and effectiveness of the product. Until guidelines are not available, DRAP should rely on international standards and make known the standards of evidence that the applicant is required to satisfy under the Rules. The acceptable standards of evidence should be publicized within 30 days either as per international practices or in terms of DRAP's Guidelines;

(ii) with respect to the Petitioners who claim that the products or entities do not fall under the DRAP's regulatory regime, a proper hearing should be given by DRAP, who should pass a speaking order as to whether the product or entity falls under the DRAP Act or Rules. Any person aggrieved of the order of the Authority order may file an appeal or seek remedy as required under the law;

(iv) with reference to the Petitioners who deal in hand sanitizers, in view of the Cabinet Decision dated 5.5.2020 and Notification dated 21.05.2020, during the period of declared emergency on account of the pandemic Covid19, DRAP should act accordingly;

49. To the extent of the challenge to legislative competence of Parliament and the vires of the Rules, the claims of the Petitioners are without merit, hence **dismissed**."

6. The legal position is that under Article 144 of the Constitution, the Provinces can delegate their powers in favour of the

parliament to legislate on the subject of drugs if such a resolution is passed, therefore, the Provincial Assembly of Punjab on 15.02.2012, Sindh on 15.02.2012, KPK on 16.02.2012 and Balochistan on 18.03.2012 have already passed the required resolutions. Article 144 of the Constitution is reproduced as under:-

> "144 **Power of [Malis-e-Shoora (Parliament)] to legislate for [one] or more Provinces by consent.**—(1) If [one] or more Provincial Assemblies pass resolutions to the effect that [Majlis-e-Shoora (Parliament) may by law regulate any matter not enumerated in [the Federal Legislative List] in the Fourth schedule, it shall be lawful for [[Majlis-e-Shoora (Parliament) to pass an Act for regulating that matter accordingly, but any act so passed may, as respects any Province to which it applies, be amended or repealed by Act of Assembly of that Province".

The other argument that the Province of Punjab had recalled/reduced the delegated authority through the Amendment Act, 2017 and of 2018, has not been supported by the learned law officer of the Province of Punjab, therefore, cannot be appreciated.

7. Besides, DRAP Act, 2012 applies trans-provincially, whereas **The Drugs Act, 1976** has a different scope which is not a statute giving the effect of a unified

controlling law. The two preambles are reproduced for the comparative reference:-

THE DRUGS ACT, 1976

"**Preamble**: Whereas it is expedient to regulate the import, export, manufacture, storage, distribution and also of drugs;"

DRAP ACT, 2012

"WHEREAS it is expedient to establish a Drug Regulatory Authority of Pakistan to provide for effective coordination and enforcement of the Drugs Act, 1976 (XXXI of 1976) and to bring harmony in inter-provincial trade and commerce of therapeutic goods;
AND WHEREAS it is expedient to regulate, manufacture, import, export storage, distribution and sale of therapeutic goods;
AND WHEREAS the Provincial of Khyber Pakhtunkhwa, Punjab and Sindh have passed resolution under Article 144 of the Constitution of the Islamic Republic of Pakistan to the effect that Majlis-e-Shoora (Parliament) may be law regulate the issue;"

8. As far as applicability of **DRAP Act, 2012** to import nutraceutical food and dietary supplements, infant milk and OTC Products as well as cosmetics, disinfectants and sanitizer together with Unani, Ayurvedic, Tibb, Herbal and Chinese medicines are concerned, Sindh High Court in case titled *Messrs AZFAR LABORATORIES PRIVATE LIMITED through Directors and others versus FEDERATION OF PAKISTAN through Secretary Ministry of National Health Services and 4*

others reported as **(PLD 2018 Sindh 448)**, (which has already attained finality) has discussed all these points and it was observed that the above products could fall within the meaning of "drug" under the DRAP Act, 2012 but for this a conclusive determination by the DRAP Authority, through a factual inquiry after hearing the concerned parties will be essential, by following the guidelines given separately for pharmaceutical dosage for human and animal use. Likewise, the petitioners who claim that they are specialized in Unani, Ayurvedic, Herbal and Chinese products having different and distinct sciences, need to be dealt with separately so as to exclude them from the definition of Alternative Medicine under **DRAP Act, 2012** will also be heard by the DRAP Authority before a final decision. Similar is the case with the manufacturer and importer of nutraceutical food and dietary supplements, infant milk, animal feeds and OTC Products alleging that their products are regulated

under different regimes so as to be called as drugs or medicines, or who are manufacturers, importers and distributors of cosmetics, disinfectants and sanitizers arguing that they are not used in treatment, mitigation, prevention or diagnoses of disease consumed rather applied, are also entitled to a thorough hearing.

9. Besides, DRAP was also authorized to ensure implementation of internationally recognized standards, especially implement-tation of guidelines issued by World Health Organization (WHO). Besides the other existing laws, are not quality, safety or health related with respect to Unani, Ayurvedic and Homoeopathic system of medicine or its products. Needless to mention that different regulatory regimes can co-exist within their own spheres, therefore, enlistment can also be made of different products. Besides, no significant argument was adhered requiring deliberation.

10. For the foregoing reasons, these Intra Court Appeal are hereby **dismissed**.

(MUHAMMAD QASIM KHAN)
CHIEF JUSTICE

(ALI BAQAR NAJAFI)
JUDGE

Shahzad

True Copy
In Case No.....
Examiner JIS (Writ Branch)
Lahore High Court, Lahore

Form No: HCJD/C-121

ORDER SHEET

IN THE LAHORE HIGH COURT, LAHORE,

JUDICIAL DEPARTMENT

I.C.A. No. 45113-2020

M/s Aleem Dawakhana Vs. Federation of Pakistan etc.

Sr. No. of order/ Proceeding	Date of order/ Proceeding	Order with signature of Judge, and that of parties or counsel, where necessary.
	16.03.2021	Mr. Saeed Akhtar Khan Khetrani, advocate for the appellant. Mr. Asad Ali Bajwa, Deputy Attorney General for Federation of Pakistan. Ch. Muhammad Zafar Iqbal, advocate for Custom Department/FBR. For the reasons recorded in our order of even date passed in connected **I.C.A. No. 45190-2020** titled **"M/s Nasir Dawakhana Vs. Federation of Pakistan etc."**, this Intra Court Appeal is also **dismissed** on merits. **(MUHAMMAD QASIM KHAN)** **CHIEF JUSTICE** **(ALI BAQAR NAJAFI)** **JUDGE**

A.Qadoos*

True Copy
In Case No.
Additional JIS (Writ Branch)
Lahore High Court, Lahore

Form No: HCJD/C-121

ORDER SHEET

IN THE LAHORE HIGH COURT, LAHORE,

JUDICIAL DEPARTMENT

I.C.A. No. 45172-2020

M/s Kanfuri Pharmacy Unani (Regd.) Vs. Federation of Pakistan etc.

Sr. No. of order/ Proceeding	Date of order/ Proceeding	Order with signature of Judge, and that of parties or counsel, where necessary.
	16.03.2021,	Nawab Saeed Ullah Khan, advocate for the appellant. Mr. Asad Ali Bajwa, Deputy Attorney General for Federation of Pakistan. Ch. Muhammad Zafar Iqbal, advocate for Custom Department/FBR. For the reasons recorded in our order of even date passed in connected **I.C.A. No. 45190-2020** titled **"M/s Nasir Dawakhana Vs. Federation of Pakistan etc."**, this Intra Court Appeal is also **dismissed** on merits. **(MUHAMMAD QASIM KHAN)** **CHIEF JUSTICE** **(ALI BAQAR NAJAFI)** **JUDGE**

A.Qadoos*

True Copy
In Case No.....
Examiner: JIS (Writ Branch)
Lahore High Court, Lahore

IN THE LAHORE HIGH COURT, LAHORE

I.C.A. No. 45190 /2020

In

Writ Petition No. 1998/2017

M/S NASIR DAWAKHANA, Gole Bazar Chanab Nagar, Tehsil Lalian District Chiniot through its Proprietor Nahkeem Abdul Sami Hami S/o Muhammad Rafi Nasir.

APPELLANT

VERSUS

1. The Federation of Pakistan, through Secretary Ministry of Health, Pak Secretariat, Islamabad.
2. The Secretary of Ministry of National Regulation & Service, constitution Avenue, Islamabad.
3. Drug Regulatory Authority of Pakistani through Chief Executive Officer, Office at 2nd floor, Block-C. Pak Secretariat, Islamabad.
4. National Council for Tib, a body established under the Unani/Ayurevedic and homeopathic practitioners Act, 1965, having its office at H-715 St No.22, Sector-1/8/2, Islamabad.
5. National Council for Homeopathic, A body established under Unani Ayurevedic and homeopathic practitioners Act, 1965, having its office at Fazal Town, phase-I, Airport Link Road, Rawalpindi.
6. Province of Punjab through the Provincial Secretary of Health Punjab, Civil Scretarirate, Lahore.
7. National Institute of Health. A body corporate established under the National institute of health

ordinance 1980 having its officer near Chak Shahzad, Off Mohra Nur Road, Islamabad.

8. Senate Standing Committee for Health through its Chairman, Islamabad.

9. Provincial Task force for control & Elimination of Spurious for the Province through its convener Khawaja Imran Nazir, MPA, Punjab Assembly, Govt. of the Punjab.

10. Provincial/Area Drug Inspector/Drug Controller, executive District Office Health, Lahore.

11. D.C.O District Chiniot, Officer Chairman Inspection Tea, District Chiniot.

12. Deputy Commissioner, Chiniot.

13. Commissioner Sargodha Division, Sargodha.

Respondents

APPEAL UNDER SECTION 3 & 4 OF THE LAW REFORMS ORDINANCE, 1972 AGAINST THE AGAINST IMPUGNED ORDER DATED 05.08.20 PASSED BY HONOURABLE SINGLE JUDGE OF THIS HONOURABLE COURT WHEREBY THE WRIT PETITION NO.1998/2017 FILED BY THE APPELLANT WAS DISMISSED.

Respectfully Sheweth:-

1. That the names and addresses of the parties as given in the head note of this writ petition are correct and sufficient for the purposes of issuing summons and notices by this Honourable Court, in this regard.

2. That through this ICA petition the humble appellant's challenge the validity of the drug