**IN THE HIGH COURT OF SINDH, KARACHI**
**CP D-4387 of 2014**
**and connected petitions**

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Date Order with signature of Judge

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Present: **Munib Akhtar and Omar Sial, JJ.**

For hearing of main case

Dates of hearing: 12, 13 and 26.09 and
03, 04, 05, 11, 13, 17 and
19.10.2017

Counsel for petitioners:

Mr. Munir A. Malik, Mr. Atif Chaudhry,
Mr. Agha Faisal, Ms. Amber Lakhani,
Ms. Sathi M. Ishaq, Ms. Zara Vayani,
Mr. Khalid Mehmood Siddiqui, Mr.
Sameer Ghazanfar, Ms. Saify Ali Khan,
Ms. Rozina Issa, Advocates

Counsel for respondents:

Mr. Salman Talibuddin, Additional Attorney
General a/w Ms. Alizeh Bashir Advocate and
Mr. Asim Mansoor Khan, DAG

Mr. Shabbir Hussain Shah, Additional Advocate
General Sindh a/w Ms. Maryam Atta Malik, Advocate

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

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**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 18$^{th}$ 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 "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 food 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 CP 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 the 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 humans 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 CP 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 to grant legislative competence to Parliament to make a law in respect of "drugs and medicines". It 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 the same 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 s. 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 operated on the constitutional plane and had to be read and applied as such. Referring to the non-enumerated competences which were exclusive to the Provinces and which, according to learned counsel, constituted a residuum of 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 CP 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 s. 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, one 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 18$^{th}$ 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 s. 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 CP 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 to 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 discernable 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 maximlist 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 s. 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 more so 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 expansive. 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 s. 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 the 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):<br><br>"drug" includes [I] all medicines for internal or external use of human beings or animals, and all substances intended to be used for or in the treatment, mitigation or prevention of disease in human beings or animals, [II] other than medicines and substances exclusively used or preparcd for use in accordance with the Ayurvedic or Unani systems of medicine; | S. 2(g)(i):<br><br>“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 beings or animals or the restoration, correction, or modification of organic functions in human beings or animals, [II] not being a substance exclusively used or prepared for use in accordance with the ayurvedic, unani, homoeopathic or biochemic system of treatment [III] except those substances and in accordance with such conditions as may be prescribed; | Schedule I, para 2(a):<br><br>DRUG includes [I] any substance or mixture of substances that is manufactured, sold, stored, offered for sale or represented for internal or external use in the treatment, mitigation, prevention or diagnosis of diseases, an abnormal physical state, or the symptoms thereof in human beings or animals or the restoration, correction, or modification of organic functions in human beings or animals, [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 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 specifically 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 to 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 & Palkhivala'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 DRAP 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 s. 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, fungi, 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 promotion and well being of humans and animal health | any substance or mixture of substances … 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 …. |

It will be seen that both definitions apply equally to humans and animals. The words “therapeutic, 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 2014 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 s. 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 shall 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 s. 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:
CP Nos. 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, 5237/2017 and 5892/2017.

c. There will be no order as to costs.

JUDGE

JUDGE