SUPREME COURT OF INDIA

Indian soaps toiletries makers Association

Vs.

Ozair Husain

C.A.No.5644 of 2003

(G.S.Singhvi and Sudhansu Jyoti Mukhopadhaya JJ.)

07.03.2013

JUDGMENT

SUDHANSU JYOTI MUKHOPADHAYA, J.

1. These appeals have been preferred by the appellants against the judgment dated 13th November, 2002 passed by the Division Bench of the Delhi High Court in a Public Interest Litigation (Civil Writ Petition No.837 of 2001) whereby the High Court held that the consumer has the fundamental right to know whether the food products, cosmetics and drugs available for human consumption are of non-vegetarian or vegetarian origin and ordered as follows:

2. In so far as cosmetics are concerned, the same must be treated at par with articles/packages of food for the purpose of disclosure of their ingredients.
Till such time the requisite amendments are carried out, we direct as under:-

> (1) Where a cosmetic or a drug other than life saving drug, as the case may be, contains ingredients of non- vegetarian origin, the package shall carry label bearing the following symbol in red colour on the principal display panel just close a proximity to name or brand name of the drug or cosmetic:-
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> (2) Where a cosmetic or a drug other than life saving drug, as the case may be, contains ingredients wholly of vegetarian origin, the package shall bear the following symbol in green colour on the principal display panel just close in proximity to name or brand name of the drug or cosmetic:-

(3) Where a cosmetic or a drug other than life saving drug has ingredients of vegetarian of non- vegetarian origin, a declaration shall be made in writing on the package indicating the nature of the origin of the product.

(4) The Director General of Health Services/Drugs Controller General, Government of India, shall issue a list of Life Saving Drugs within a period of two months."

2. The Public Interest Litigation was filed by the respondent claiming the right of a consumer of cosmetics, drugs and articles of food to the full disclosure of ingredients of such product whereby a clear indication as to its origin (vegetarian/non-vegetarian) is made. The High Court referring to the constitutional rights guaranteed under Articles 19(1)(a), Articles 21 and 25 of the Constitution of India held:

"……..It seems to us that to enable a person to practise the beliefs and opinions which he holds, in a meaningful manner, it is essential for him to receive the relevant information, otherwise he maybe prevented from acting in consonance with his beliefs and opinions. In case a vegetarian consumer does not know the ingredients of cosmetics, drugs or food products which he/she wishes to buy, it will be difficult for him or her to practise vegetarianism. In the aforesaid context, freedom of expression enshrined in Article 19(1)(a) can serve two broad purposes – (1) it can help the consumer to discover the truth about the composition of the products, whether made of animals including birds and fresh water or marine animals or eggs, and (2) it can held him to fulfil his belief or opinion in vegetarianism."

"…..In this view of the matter, we have no hesitation in holding that Article 21 grants freedom to an individual to follow and to stick to his opinions, and for pursuing such a course he had right to receive information and also a right to know the ingredients or the constituents of cosmetics, drugs and food products."

"……In view of the aforesaid discussion, we are of the view that it is the fundamental right of the consumers to know whether the food products, cosmetics and drugs are of non- vegetarian or vegetarian origin, as otherwise it will violate their fundamental rights under Articles 19(1)(a), 21 and 25 of the Constitution. Accordingly, we answer the main question in the

affirmative. Since there is a constitutionally guaranteed right of the consumers to the full disclosure of the ingredients of cosmetics, drugs and articles of food, answers to remaining questions (ii) and (iii) necessarily are required to be answered in the affirmative. We, accordingly, answer the questions (ii) and (iii) also in the affirmative……"

"……In so far as food products are concerned, adequate provisions have been made for informing the consumers as to whether or not the article of food is vegetarian or non- vegetarian. As regards drugs and cosmetics, necessary amendments have not been made in the relevant statutes. In so far as life saving drug is concerned, there is a view point that the information: whether or not it is derived or manufactured, wholly or partly, from an animal, should not be disclosed since it is meant to fight disease and save life. In other words, a patient, who is suffering from serious ailment, which can be fatal if a life saving drug is not administered to him, need not be informed in his own interest as to whether or not the drug contains part of any animal as it is conductive to preservation of life and, therefore, in tune with Article 21 of the Constitution, this also means that he should not have a choice in the matter of administering life saving drug to him. In many cases patients are unconscious and they have to be put on life saving drugs. In any event they cannot exercise an informed choice in the matter of selection of drugs. In the circumstances, therefore, the aforesaid view must prevail in case of life saving drugs. This limited exception will apply only to life saving drugs. It needs to be clarified that all drugs do not qualify for being treated as life saving drugs. Drugs which are not life saving drugs must stand at part with the food products and must disclose whether or not they are made of animal, whether in whole or in part.

In so far as cosmetics are concerned, the same must be treated at par with articles/packages of food for the purpose of disclosure of their ingredients."

3. The appellant Union of India is afraid of serious paradox in so far as drugs are concerned. According to the learned senior counsel, it is not possible to distinguish as to which drug is a 'Life Saving Drug' or otherwise; under a given circumstance and condition of patient, a drug which ordinarily may not be treated as a 'Life Saving Drug', can be used as a Life Saving Drug. In some other case it may be general. Thus, it is not possible to demarcate the drugs as life saving or otherwise. Therefore, the direction issued by the High Court to the extent it requires Union of India to prepare a list of Life Saving Drugs would neither be appropriate nor

proper, particularly when there is no definition of 'Life Saving Drug' in pharmacology of the modern system of medicines.

4. It was further contended that every drug is considered to be useful in either saving or prolong the life by curing, mitigating or preventing diseases. Given that every disease has the eventuality of taking life if not properly treated in time, the identification of 'Life Saving Drug' will depend upon identification of different situations when they are required.

5. Further, according to the learned counsel for the Union of India, the direction of the High Court for affixing Red Label which is symbolic of danger on drugs and cosmetics is inappropriate particularly when a Cosmetics Sectional Committee had recommended the use of 'Brown' colour for labelling certain cosmetic products. He also placed reliance on the report submitted by the 'Drug Technical Advisory Committee' constituted under Section 5 of the Drugs and Cosmetics Act wherein the reason was shown for not providing any identification as to 'ingredient of non-vegetarian origin'.

6. Learned counsel appearing on behalf of the appellant-Indian Soaps Toiletries Makers Association (hereinafter referred to as the 'Association') submitted that it is neither practicable nor desirable to give any identification as to ingredients of 'vegetarian' or 'non- vegetarian' origin. It has no relevancy as the use of cosmetics has nothing to do with the vegetarian or non- vegetarian origin ingredients; they are not 'food products' and are not meant for ingestion. It was submitted that it is difficult to identify the origin of non-vegetarian ingredients, as it is very difficult to know the basic source from which such ingredient is derived.

7. The following arguments were also advanced on behalf of the Association:

> (a)Unlike food items, generally cosmetic items are not ingestible. Every single dictionary definition of words "vegetarian" "non- vegetarian" relate to food or the act of eating. Therefore, the sentimental feeling that is brought upon by the consumers for any edible items are not applicable to cosmetic items. The rationale, i.e. emotional, religious, cultural, sentimental, health values which necessitate different treatment in terms of vegetarian and non-vegetarian for food items coming from animal and non-animal sources respectively does not hold good for cosmetic items (i) on account of its external application and (ii) on account of long held and general awareness amongst consumers about cosmetic composition.

b) Unlike the food industry where the processing of food takes place near to the primary produce or a step away from the primary produce center and not many intermediary stages are involved before the final food item is packed for consumption, cosmetic industry is far removed from the stage of raw material sources. Cosmetics are manufactured from a significantly large number of raw materials which in turn contain composite ingredients while food items are manufactured generally from 4 to 5 basic raw materials.

c) Unlike food items where the analysis mechanism is reasonably established through PFA Act ad Rules, the analysis of cosmetic products by its sheer complexity is difficult, which difficulty gets compounded on account of non-availability of technology, large number of ingredients coming in from different sources. In the absence of such technology being available the requirement of indicating symbols on labels would be impractical and would lead to chaos and confusion in as much as cosmetics with animal origin ingredients would carry vegetarian symbol or vice versa, and thus it will defeat the very purpose for which such requirement is intended.

d) Unlike food products which are normally manufactured and consumed in India, barring a few exceptions, the cosmetic industry competes with international products both in terms of import as well as exports and consequently, requiring the industry to put such a label without any technology being available for making such distinction would not only add enormous cost on the industry but also place the Petitioners members at disadvantage in competing with international cosmetic products. Such labelling without any technology for analysis is also likely to be challenged against the Petitioner's members who instead of promoting and encouraging exports from India would be left with fighting legal battles at enormous cost and at the cost of foreign exchange.

8. According to the appellant-Association, the High Court failed to appreciate that cosmetic formulation is complex in nature as compared to drugs or the food products. The appellant-Association relied on following facts to justify their finding:

(1) There are as many as 66 dosage forms in cosmetic formulations as listed in one of the standard reference books- The Chemistry Manufacture of Cosmetics by Maison deNavaree, Allured Publishing.

2) Schedule S of Drugs Cosmetics Act recognizes 29 of such types of cosmetics.

3) Each type of formulation has wide choice of 12,000 ingredients approved by CTFA or INCI directory of ingredients and are safe for use in cosmetic products.
Ref.: CTFA on-line web site.

4) In fact, some of the INCI ingredients are mixture of ingredients in various proportions of similar compounds. For example, commonly used CARBOMER is a homopolymer of acrylic acid cross linked with allyl ether of pentaerythritol, allyl ether of sucrose or allyl ether of propylene. It has 7 different technical names based on different grades, 32 trade names and 7 trade name mixtures.

5) Mostly a perfume is component of cosmetic preparation. The perfumes are proprietary formula by itself and are mixture of several ingredients. Each ingredient of perfume could be synthetic, natural or animal in origin. Example – Musk perfume is trade secret composition. It may contain any number of ingredients coming from any source as synthetic, natural or animal origin. Generally perfume contains 10-100 different ingredients.

6) All of these ingredients are purified several times to reach the acceptable form as required by INCI requirements. At this stage it is at least 4th or 10th step of purification, wherein original starting material can not be traced back to even ppb level. Example – Fatty acid based surfactants from plant origin or purely synthetic or animal origin.

7) In case of food and drug related formulae, there is list of limited excipients or additives. In case of drug formulae, mostly the excipients are only a few and are published monographs in official pharmacopoeia. In case of food, the formulae are simple and contain very few ingredients being declared on the pack. So the origin is very easy to verify.

8) Cosmetic formulae are far more complex to drug formulae. The source of thousands of ingredients being used in multiples of combination in the cosmetic formulae, make the task extremely difficult to check and certify the origin of ingredients used.

9. It was also contended that the power of determination of labelling requirements including their contents is vested with the Union of India's authorities such as the Drug Technical Advisory Board. In such case the High court ought not to have given a finding to provide certain mark on the labelling of the drugs and cosmetics based on vegetarian or non-vegetarian origin.

10. Learned counsel appearing on behalf of the respondent submitted that almost 60% of the population in India is vegetarian, over 50% of it is illiterate and over 90% public cannot read English. The Public Interest Litigation for disclosure of the ingredients of the products was filed to safeguard the interest of such innocent consumers and to ensure that such products bear an easily recognizable symbol to know whether it has any animal ingredient. The consumers have a right of informed choice between the products made or derived from vegetarian and those made or derived from non-vegetarian ingredients.

11. The questions involved in this case are:

(i) Whether under Article 226 of the Constitution of India the High Court has jurisdiction to direct the manufacturers of drugs and cosmetics to display a particular symbol in their packages to identify the ingredients of ' non-vegetarian' or ' vegetarian' origin; and

(ii) Whether it is practicable and desirable to display any identification as to the origin of the non-vegetarian ingredients in the packages of drugs and cosmetics.

12. Before discussing the relevant provisions of the Drugs and Cosmetics Act, 1940 and the Rules framed thereunder, it is relevant to notice that with a view to prevent adulteration of food stuff and bringing uniformity of laws in the country, the Prevention of Food Adulteration Act, 1954 was enacted. Later on when it was felt that the "consumer of food products" should know whether any article of food contains whole or any part of animal including birds, fresh water or marine animals or eggs or product of any animal origin, the Government of India by notification dated 4th April, 2001 enacted the Prevention of Food Adulteration (Fourth

Amendment) Rules, 2001 amending Rule 32 and Rule 42 of the Prevention of Food Adulteration Rules, 1955 and introduced symbol and colour code of vegetarian and non- vegetarian food products. Under clause (b) of amended Rule 32 of the Prevention of Food Adulteration Rules, 1955, it was made compulsory to make declaration whether article of food contains any non-vegetarian ingredients by a symbol and colour code so stipulated for the said purpose, to indicate that the product is a non-vegetarian food. The symbol of non-vegetarian food on every food product package was introduced by inserting clause (16) of sub-rule (ZZZ) of Rule 42 of the Prevention of Food Adulteration (Fourth Amendment) Rules, 2001. The amendment came into effect from 7th March, 2001.

But no such provision has been made to indicate whether any ingredient of any drug or cosmetics is of non-vegetarian origin.

13. "The Drugs and Cosmetics Act, 1940" was introduced to regulate the import, manufacture, distribution and sale of drugs and cosmetics including its package.

"Drug" as defined in Section 3(b) of the Drugs and Cosmetics Act, 1940 reads as follows:

"3(b) "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 diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

ii) such substances (other than food) intended to affect the structure or any function of human body or intended to be used for the destruction of 6(vermin) or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

(iii) all substances intended for use as components of a drug including empty gelatine capsules; and

iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or

animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board ;

'Cosmetic' is defined in Section 3(aaa):

"3(aaa) "cosmetic" means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic."

14. Under Section 5 of the Drugs and Cosmetics Act, 1940 a "Drugs Technical Advisory Board" is to be constituted to advise the Central Government and the State Governments on technical matters arising out of the administration of the Act and to carry out other functions assigned to it by the Act. The Board consists of the Director General of Health Services; the Drugs Controller of India; the Director of the Central Drugs Laboratory; the Director of Central Research Institute; the Director of Indian Veterinary Research Institute, the President of the Medical Council of India; the President of Pharmacy Council of India; etc. The Central Government is also required to establish a 'Central Drugs Laboratory' under the control of a Director under Section 6 'for analysis and test of samples of drugs'. Under Section 7, the Drugs Consultative Committee is constituted to advise the Central Government, the State Governments and the Drugs Advisory Board on any matter tending to secure uniformity throughout India in the administration of the Act. Under Section 8 standards of quality in relation to drugs and cosmetics have been prescribed. Chapter III deals with the definition of 'misbranded drugs'; 'adulterated drugs'; 'spurious drugs'; 'misbranded cosmetics'; 'spurious cosmetics' etc.

Under Section 16, it is mandated that the quality of a drug should comply with the standard as set out in the Second Schedule. Similarly, the quality of a cosmetic should comply with such standard as may be prescribed by the Central Government.

The Act deals with disclosure of the name of the manufacturer of a drug, cosmetic and its agent under Section 18A. The Central Government is also empowered under Section 26A to prohibit manufacture, etc., of drug and cosmetic in public interest. The conditions to be observed in the packing in bottles, packages, and other containers of drugs or cosmetics including

regulating the mode of labelling of packed drugs or cosmetics prescribed by the Central Government by framing a Rule under Section 33 which reads as follows:

"33.Power of Central Government to make rules. —(1) The Central Government may after consultation with, or on the recommendation of, the Board and after previous publication by notification in the Official Gazette, make rules for the purposes of giving effect to the provisions of this chapter: Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.

(2) Without prejudice to the generality of the foregoing power, such rules may—

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(i) prescribe the conditions to be observed in the packing in bottles, packages, and other containers of drugs or cosmetics, including the use of packing material which comes into direct contact with the drugs]and prohibit the sale, stocking or exhibition for sale, or distribution of drugs or cosmetics packed in contravention of such conditions;

(j) regulate the mode of labelling packed drugs or cosmetics, and prescribe the matter which shall or shall not be included in such labels;"

15. Part XV of the Drugs and Cosmetics Rules, 1945 relates to labelling, packing and standards of cosmetics. The list of ingredients, present in concentration of more than one per cent is required to be listed in the descending order of weight or volume under sub-rule (7) of Rule 148. Rule 149A is a special provision relating to toothpaste containing fluoride whereunder it is mandatory to mention the content of fluoride on the tube and the carton apart from the date of expiry.

Rule 97 relates to 'labelling of medicines' :

“97. Labelling of medicines--- (1) The container of a medicine for internal use shall—

(a) if it contains a substance specified in Schedule G, be labelled with the words ‘Caution: it is dangerous to take this preparation except under medical supervision’ – conspicuously printed and surrounded by a line within which there shall be no other words;

(b) if it contains a substance specified in Schedule H be labelled with the symbol Rx and conspicuously displayed on the left top corner of the label and be also labelled with the following words:-

Schedule H drug-Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only’;

(c) if it contains a substance specified in Schedule H, and comes within the purview of the [Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985)] be labelled with the symbol NRx which shall be in red and conspicuously displayed on the left top corner of the label, and be also labelled with the following words:-

Schedule H drug -“Warning:-- To be sold by retail on the prescription of a Registered Medical Practitioner only’;

(d) if it contains a substance specified in Schedule X, be labelled with the symbol XRx which shall be in red conspicuously displayed on the left top corner of the label and be also labelled with the words : -

Schedule X drug -“Warning:-- To be sold by retail on the prescription of a Registered Medical Practitioner only’;

(2) The container of a embrocation, liniment, lotion, ointment, antiseptic cream, liquid antiseptic or other liquid medicine for external application shall be labelled with the word in capital ‘For External use only’.

(3)The container of a medicine made up ready only for treatment of an animal shall be labelled conspicuously with the words ‘Not for human use;

for animal treatment only' and shall bear a symbol depicting the head of a domestic animal.

(4) The container of a medicine prepared for treatment of human ailments shall if the medicine contains industrial methyllated spirit, indicate this fact on the label and be labelled with the words :-

"For External Use only".

(5) Substances specified in Schedule X in bulk form shall bear a label wherein they symbol as specified in sub-rule (1) shall be given conspicuously in red letters."
Whereas Rule 105 relates to packing of drugs, including sizes meant for retail sale as prescribed in 'Schedule P'. For other drugs, a separate packing has been prescribed under Rule 105A read with 'Schedule X'.

16. The Drugs and Cosmetics Act, 1940 or the rules framed thereunder do not mandate mentioning or displaying symbol of ingredients of non- vegetarian or vegetarian origin. The manufacturer or others are not required to mention 'vegetarian' or 'non-vegetarian' on the label of drugs or cosmetics.

The Central Government is vested with the power under the Drugs and Cosmetics Rules, 1945 to amend the 'label of the drugs and cosmetics' in consultation with the Drugs Technical Advisory Board. Without fruitful consultation with the Drugs Technical Advisory Board, no amendment can be made or suggested to change the label of the drugs and cosmetics.

17. Earlier a proposal was made by certain persons to amend 'the Drugs and Cosmetics Rules, 1945' so as to mention the words "vegetarian" and "non-vegetarian" on the labels of the drugs and cosmetics. After fruitful deliberations, the Drugs Technical Advisory Board in its 48th Meeting held on 8th July, 1999 rejected the proposal as quoted hereunder:

"AGENDA ITEM NO.3

PROPOSAL TO AMEND DRUG COSMETIC RULE

1945 TO REQUIRE MENTION OF WORDS

V(VEGITAIAN) AND NV(NON VEGITARIAN) ON

LABELS OF DRUGS/COSMETICS

Ministry of Social Justice and Empowerment nominated Shri Devdas Chhotray, Joint Secretary, Ministry of Food Processing and Shri S.R. Khanna, representative from an NGO, VOICE for acquainting the Board Members with their views on this subject. Sh. Chhotray, explained regarding his Ministry's concern about the killing of animals and consumer's right for information. He stated that some consumers may like to avoid use of any product containing material from animal source if they have recourse to such information and this need of consumer requires to be respected. It was, therefore, proposed that the provision for labelling V and NV on every food/drug product depending on its vegetarian or non vegetarian aspects may be introduced in the Drugs Cosmetics Rules.

Dr. S.R. Khanna, also, in detail stressed upon consumers rights to such information and desired a mandatory provision to indicate the source of drug in terms of V and NV.

The Chairman explained that while respecting the consumers rights to information the issue of V NV markings need to be examined in wider perspectives of medical treatment an critical importance of certain drugs products like vaccines, harmones, Biotech products etc. which are of life saving nature and could be traced to animal origin. (Unlike food, drugs are not taken by choice or for the purpose of gratification). He, however, suggested that in the context of general understanding of vegetarianism such drugs where macroscopic portion of animal tissues like animal blood, liver extract etc. are present in oral preparations may be considered by the Board for marking NV on the label of such drugs.

1. Prof. Jindal opined that the drugs may be labelled to indicate their source i.e. synthetic source, Bio Source and animal source. This suggestion was, however, not found practicable.

2. Prof. Kokato and Mrs. Muthuswamy representatives of ICMR felt that what may be appropriate in case of food may not necessarily be appropriate in case of drugs which are prescribed for relief from disease conditions and many a times in life threatening situation. To introduce the concept of

Vegetarian and Non Vegetarian by marking V or NV in drugs may not be in the overall interest of the consumers.

3. Sh. Praful Seth agreed with the views of Chairman about the possibility of considering the proposal for a limited number of non critical drugs that is oral tonics etc. having obvious animal tissues. He also explained that alternate formulations are also available and the physician may advice/educate consumers about it.

4. Prof. S.D. Seth, and Sh. R.Anand Raj Sekhar, opined that if at all proposals to mark NV has to be considered it may be discussed only for non-essential drugs.

5. Dr. Prem Agarwal, representative of IMA opposed any move to bring in the concept of V/NV in the field of medicines and also stated that it would not be rational to further classify drugs essential or non-essential for the purpose of marking NV on the labels.

6. The Drugs Controller, Karnataka, was in agreement to the extent of marking NV on non-essential drugs taken orally and containing obvious animal tissues but did not favour the concept of making V or NV in the field of drugs.

7. The president MCI, Dr Ketan Desai was of opinion that marking products as NV is not relevant for medicines and no attempt should be made to differentiate them as essential and non-essential once. The proposal may be considered for food products and not for drugs.

8. Dr. Bhargava, representatives of Medical Council of Indian, Dr. Gupta, Director, CDR Lucknow and Mr. M.V. Kumar, expressed strong views against, introducing the requirement for marking drugs products with NV.

9. The mailer was discussed in great details and the other members did not favour any labelling of NV or V on the medicines.

In view of the above labelling of drugs “V/NV” or “from animal source” as proposed in the Agenda, was not accepted.” (Emphasis supplied).

18. A citizen has the right to expression and receive information under Article 19(1)(a) of the Constitution. That right is derived from freedom of speech and expression comprised in the Article. The freedom of speech and expression includes the right to receive information. [Refer : The State of U.P. vs. Raj Narain and othersl, (1975) 4 SCC 428; Secretary, Ministry of Information Broadcasting, Govt. of India and others vs. Cricket Association of Bengal and others, (1995) 2 SCC 161; P.V. Narasimha Rao vs. State (CBI/SPE), (1998) 4 SCC 626)]. But such right can be limited by reasonable restrictions under the law made for the purpose mentioned in the Article 19(2) of the Constitution.

19. It is imperative for the State to ensure the availability of the right to the citizens to receive information. But such information can be given to the extent it is available and possible, without affecting the fundamental right of others.

20. In the present case the appellant-Union of India had taken a plea that information relating to the ingredients of drug particularly those ingredients of non-vegetarian origin should not be given "in the interest of general public". A specific plea has been taken that it is not possible to distinguish the drugs whether these are life saving or otherwise.

21. In the given circumstances the condition of a patient may be such that a drug which is ordinarily not treated as a life saving drug may be essential to save the life. In such a case when drug becomes a life saving drug, it may not be desirable for the patient or his attendant to know the origin of the ingredients of the drug i.e. whether 'vegetarian' or 'non- vegetarian'. Such option cannot be left on the patient or his attendant if required to save the life or eradicate a disease.

22. The information about the origin of the ingredients of a drug or cosmetic, if claimed as a matter of right, a vegetarian can also claim information about the origin of a vegetarian ingredient, depending upon his food habit.

23. Food habit in India varies from person to person and place to place. Religion also plays a vital role in making such habit. Those who follow 'Jainism' are vegetarian but many of them do not eat some of the vegetarian food such as potato, carrot, onion, garlic etc. which are grown below the earth. Majority of Indians treat 'honey' and 'lactose' (milk derived sugar) as vegetarian but scientists treat them as 'non-vegetarian' products.

> Amongst the non-vegetarians a number of persons are 'eggetarian' i.e. those who only take one non-vegetarian product–egg. They do not eat other non-vegetarian food like animal, fish or birds. There are number of persons who treat egg as vegetarian food. Even amongst non-vegetarians, a large number of persons do not take beef or ham/pork because of religious belief. Many of the non-vegetarians do not eat snakes, insects, frog or bird. In individual case, the Central Government may feel difficulty in specifying the origin of a 'vegetarian' or 'non-vegetarian' ingredient, if a person wants to know the definite origin of such 'vegetarian' or 'non- vegetarian' ingredient on the basis of his food habit.

24. 'The Drugs and Cosmetics Rules' can be amended by the Central Government after taking into consideration any suggestion which the Drugs Technical Advisory Board may make in relation to the amendments of the said Rules. Earlier on a reference the Drugs Technical Advisory Board has already opined that the labelling of drugs as 'vegetarian' or 'non- vegetarian' or 'from animal sources' is not desirable and such proposal was not accepted.

25. The question arises as to whether in facts and circumstances noted above, the High Court was justified in issuing a writ of mandamus calling upon the Central Government to discharge its duty by amending rules. In A.K. Roy v. Union of India and others, (1982) 1 SCC 271, this Court considered the question whether the Court should issue a mandamus calling upon the Central Government to discharge its duty without any further delay and held:

> "The Parliament having left to the unfettered judgment of the Central Government the question as regards the time for bringing the provisions of the 44th Amendment into force, it is not for the court to compel the government to do that which, according to the mandate of the Parliament, lies in its discretion to do when it considers it opportune to do it. The executive is responsible to the Parliament and if the Parliament considers that the executive has betrayed its trust by not bringing any provision of the Amendment into force, it can censure the executive,….."

26. The aforesaid decision was noticed and reiterated by this Court in Supreme Court Employees'Welfare Association v. Union of India and another, (1989) 4 SCC 187, and held:

> "51. There can be no doubt that no court can direct a legislature to enact a particular law. Similarly, when an executive authority exercises a legislative power by way of subordinate legislation pursuant to the delegated authority of a legislature, such executive authority cannot be asked to enact a law which he has been empowered to do under the delegated legislative authority."

27. In Bal Ram Bali and another vs. Union of India, (2007) 6 SCC 805, this Court discussed the separation of powers while dealing with the question of total ban on slaughter of cows, horses, buffaloes and chameleon. This Court held that it is a matter of policy on which decision can be taken by the appropriate Government and the Court cannot issue any direction to Parliament or to the State Legislature to enact a particular kind of law. The writ petition was held to be not maintainable with the following observation:

> "3. It is not within the domain of the Court to issue a direction for ban on slaughter of cows, buffaloes and horses as it is a matter of policy on which decision has to be taken by the Government. That apart, a complete ban on slaughter of cows, buffaloes and horses, as sought in the present petition, can only be imposed by legislation enacted by the appropriate legislature. Courts cannot issue any direction to the Parliament or to the State legislature to enact a particular kind of law. This question has been considered in Union of India v. Prakash P. Hinduja and Anr., (2003) 6 SCC 195, wherein in para 30 of the reports it was held as under:
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> "30. Under our constitutional scheme Parliament exercises sovereign power to enact laws and no outside power or authority can issue a direction to enact a particular piece of legislation. In Supreme Court Employees' Welfare Assn. v. Union of India, (1989) 4 SCC 187, it has been held that no court can direct a legislature to enact a particular law. Similarly, when an executive authority exercises a legislative power by way of a subordinate legislation pursuant to the delegated authority of a legislature, such executive authority cannot be asked to enact a law which it has been empowered to do under the delegated legislative authority. This view has been reiterated in State of J and K v. A.R. Zakki, (1992) Supp.1 SCC 548. In A.K. Roy v. Union of India (1982) 1 SCC 271, it has been held that no mandamus can be issued to enforce an Act which has been passed by the legislature...."

> 4. In view of the aforesaid legal position, we are of the opinion that this Court cannot grant any relief to the petitioners, as prayed for, in the writ petition. The writ petition is accordingly dismissed."

28. Learned counsel for the respondent-writ petitioner relied on the decision of this Court in Union of India vs. Association for Democratic Reforms and another, (2002) 5 SCC 294, and submitted that the "field has remained unoccupied this Court can issue such direction under Article 32 of the Constitution of India", but such submission cannot be accepted as it cannot be said that field has remained unoccupied as under the Drugs and Cosmetic Rules it is the Central Government which in consultation with the Drug Technical Advisory Board is empowered to decide whether any amendment is to be made in the relevant Rules showing the ingredients of vegetarian or non-vegetarian origin or to provide a symbol. In fact the issue in question was deliberated by the Central Government when such matter was referred to the Drug Technical Advisory Board which in its 48th Meeting on 8th July, 1999 rejected such suggestion.

29. In view of the discussions above, we hold that the High Court under Article 226 of the Constitution of India has no jurisdiction to direct the Executive to exercise power by way of subordinate Legislation pursuant to power delegated by the Legislature to enact a law in a particular manner, as has been done in the present case. For the same reason, it was also not open to the High Court to suggest any interim arrangement as has been given by the impugned judgment. The writ petition filed by Respondent being not maintainable for issuance of such direction, the High Court ought to have dismissed the writ petition in limine.

30. In the result, both the appeals are allowed and the order and directions issued by the High Court are set aside but there shall be no orders as to costs.