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INDUSTRY HIGHLIGHTS

Focus on Generics Policy

Drugs in Parliament
and
Regular Items

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The Generics Policy

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The issue of substitution of brand names by Generic names is active in the national and international pharmaceutical politics for many years. Some developing countries have tried to create a workable generics policy to generate a perpetual generics market through the Governmental action, but such attempts have not been generally successful in the entire spectrum of pharmaceuticals business in any country. However, generic names have shown some consumer acceptance in certain range of products, the nature of which varies from country to country. In our country though the generics concept has emerged in certain areas of pharmaceuticals, it is yet at a very low key.

The generics issue was studied for the first time by the Hathi Committee at some length during 1974-75, which broadly concluded that:

(*i*) brand names lead to high promotional costs and consequently high prices of formulations.

(*ii*) medical students generally receive their education on drugs under the generic names and therefore, generics prescription should be preferred.

The Committee made several recommendations, important among them were:

(*i*) Brand names for drugs, marketed in India, should be abolished in a phased manner and a beginning of generic names may be made by starting with the drugs identified by the Committee.

(*ii*) New drugs, first introduced into the country should *not* be allowed to be marketed under brand names.

The New Drug Policy statement of March 1978 on brand names, embodies specifically the above recommendations, with some modifications, in the Policy Paragraphs 71.1 to 71.6 and 99 and 100 (Annexure-I). In line with the Policy, the Ministry of Commerce and Civil Supplies have instructed the Registrar of Trade Marks (effective from 16.3.79) not to register any trade mark for new single ingredient formulation when introduced for the first time in India for consumption within the country. The Ministry of Health and Family Welfare have, by a Notification (dt. 17-1-1981), amended Rule 96 of the Drugs & Cosmetics Rules, 1945 so as to implement the embodiment of the New Drug Policy in

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respect to brand names (Annexure-II). The Ministry of Industry is not allowing the incorporation of any brand names for any drug (bulk as well as formulation) in licences issued under I (D&R) Act in accordance with the New Drug Policy. All these government actions are set out to distinctly implement the embodiment of the New Drug Policy. However, success of the generics policy is a matter, which only the future will decide.

In order to understand the various aspects of the generics vs. brand names issue, the important factors which go into the system have to be understood. Generally three main segments, namely, the Government (the regulatory body) the Industry (the manufacturers) and the Users (the doctors, the chemists and the consumers) have to be understood at great length in order to predict if the generics policy would be useful and meaningful in the long run.

The Government: The basic driving force of the Government to implement the generics policy arises out of the decision taken in the Parliament in this regard in March, 1978. The Government through the Ministries of Chemicals and Fertilizers, Health, Commerce, Industry and the State Governments have been trying in various ways to implement the generics policy to its maximum level.

1. It is generally believed that marketing in generic names requires less of marketing expenditure and, therefore, such products could be marketed at a cheaper price. Although the Drugs Price Control Order, 1979 is supposed to bring at par the selling price of equivalent formulations, the process could only fix the maximum allowable limits of selling. While the marketes of the branded products generally take advantage of the limit usually upto the maximum level, the marketers of the generics do not take the full advantage which ultimately results in the appearance of cheaper generic products.

2. Generics are believed to be therapeutically equally effective when compared with equivalent branded products. Although the Government have not adopted any specific measures for assuring the quality of the generics in particular, the State Drug Control Administration in every state is vigilant and is constantly examining/ascertaining the quality of every pharmaceutical product manufactured in the state.

3. Certain companies, mostly the multi-national, have specialised marketing techniques. The corporate objectives of such companies are to maximise their profits by every means. Therefore, irrespective of whether their products are superior in effectiveness and quality or not, they adopt various tempting methods and sophisticated selling techniques such as claims of superior bio-availability, minimum bacterial count on products, etc. While such scientific means as the bio-availability, minimum bacterial count etc. have their importance in certain range of products, they are by no means parameters for generalisation for every range of marketed products. In the process, the real worth of the product is masked by exaggerated claims of such selling methods and prescribers and the users get carried away and form thrusted opinion of superiority of such products. Such impression of superiority of certain product gets propagated through the users/prescribers.

This situation is beneficial to the few companies who market them. But it is not beneficial to the country as a whole, since the process pushes back the concept of equitable distribution status to equivalent products. The driving force of such marketing efforts could be greatly reduced by disapproving brand names. All the marketing techniques concentrate upon creating an image of the 'Brand' name before the prescribers/users. In the absence of a brand name, the marketing efforts of a company get greatly diluted before the prescribers/users, since the latter knows the product by only one name which is the generic name. This results in minimising the impact of diverse marketing techniques on him.

4. It is obivious that the Government is concerned about the large number and the diverse composition of formulations currently being marketed, a substantial portion of which is considered irrational and is not commensurate with prescribed dosage requirements. The driving force in the introduciton of odd packs arose because of various reasons, important among them could be the adoption of newer selling methods, better profitability expectations, etc. In the process the market got flooded with unmanagably large number of packs in almost equal number of diverse brand names. According to one estimate the current number of packs in the market exceeds 20,000. It may be worth remembering that the number of active ingredients (bulk drugs) used is of the order of 400 only. Ideally, therefore, the most effective single ingredient medicines formulated out of such drugs could be only equal to this. Since, however, the same drug may be in several forms—e.g. oral-solids (in the form of tablets, capsules, granules, powders, etc.), liquids (syrups, elixirs, tinctures, etc.), injectables (intramuscular as well as intravenous), sprays like—aerosols etc.—besides having variations in dosage administration for children and adults, the number of single ingredient formulations has increased to some extent. However, this would not take the number of single ingredient formulations in various finished dosage forms to any substantially large number. And that is what the country really needs for medication. There is, however, no denying of the fact that certain multi-ingredient formulations are novel and that the benefits derived out of such formulations are more than the separate and individual use of each of the single ingredients. However, such special multi-ingredient formulations may not be in very large numbers. There is a strong view that more effective monitoring and control could be exercised if the number of formulations introduced into the market is less. This would also help extending prompt justice to the formulators in revising their prices in the event of any variation in the prices of input materials. While several factors require to be considered for solving such an intricate issue, parameters such as rationalisation of dosage forms, unanimity in the presentation, adoption of set packaging norms, abolition or restriction of brand names specially for single ingredient formulations, foregoing marketing rights in favour of more efficient formulators etc., are more important ones. All these factors except the last one could be brought together with a common denominator if brand names are sacrificed in favour of the generic names.

The Industry: The manufacturers who market their products in brand names believe that they have set standards for their products which are higher than the minimum required by law. According to them compulsory generic prescription will strangle the manufacturers' incentive to achieve product excellence and quality standards above the minimum legal requirements. They believe that manufacturers who basically compete on price alone may not be in a position to maintain high standards. They also believe that no regulatory machinery (like the Government) can assure quality, safety and therapeutic efficacy of all generic drugs.

1. The Industry also feels that by allowing the usage of brand names the pharmaceutical products are made to carry the manufacturers' assurance of quality and reliability.

2. The manufacturers are of the view that since brand name exists in every other industry there is enough ground that the same should exist in the pharmaceutical industry as well.

3. The manufacturers also feel that patients will not get drugs of appropriate quality if brand names are abolished. According to them introduction of formulations in generic names may lead to introduction of sub-standard and spurious drugs.

4. They also feel that patients will be at the mercy of the chemist/pharmacist since the latter is free to supply equivalent generic drugs. The Industry feels that if the chemist is unscrupulous he may be tempted to offer the drug of a manufacturer who gives him the highest margin of discount/profit, and highest margin could be offered by manufacturer of spurious and sub-standard drugs only.

5. The Industry also feels that under generic prescription, it is difficult to fix the responsibility on the manufacturer for the damage done to the patients by consuming a generic drug, as it is impossible to identify the manufacturer.

6. The Industry points out that a new drug is discovered by sustained research for long years. The research and development expenditure on drugs by certain companies in developed countries is enormously high and manufacturers are not willing to carry out research on products until and unless they are assured that the money so spent is recoverable through the introduction of effective drugs whenever discovered. These organisations feel that out of various ways of protecting the proprietory right of the products so introduced by them, permission to allow the introduction of the product under brand name is one. Restriction or denial to market such research products in brand names would hinder the introduction of such effective drugs into the country. And the new drugs might come to the country only very late at a time when much more efficacious drugs have already been discovered elsewhere.

The Customer: The customers of the pharmaceuticals industry include the prescribing physicians, the chemists/pharmacists and the ultimate users of the medicines. The users are either individuals or organised purchasers like the Government or the private organisations.

1. Physicians are usually conservative in their approach to the issue of any drastic change in the present system where their authority is going to be weakened/shifted.

2. In so far as the chemist /pharmacists are concerned, they have so far played a very minor role in the choice of the medicines for the patient. Practically the only role these professional groups play is to advise the ultimate consumer on over-the-counter medication, on request. Even here they are not fully free to do so for the threat of being prosecuted for practising medicine.

3. The individual customer who is the ultimate user of the medicine is a vast section of people comprising people with high literary to people with no education. Unfortunately the latter part being predominantly large, no useful response is expected from the masses in general. The very small section of the population having above average education are, however, usually quite open to accepting generics prescription. Besides, those persons who are on long term maintenance therapy and who pay for their drugs may also support the generics prescription since these are going to cost less. However, at present, the degree of acceptance of generics among the individual consumers is difficult to assess. A nationwide sample survey among the educated class could only bring out some status on the issue.

4. For the customers belonging to the group of organised purchasers like the Government, who are always constrained to reduce the cost of health care system, the generics is an important means to reduce the cost of drugs required for maintaining the public health since purchase under generics are normally cheaper.

5. The semi-private and the private customers belonging to the group of organised purchasers like various public sector undertakings, the nationalised banks, the State Trading Corporation, the Indian Airlines etc. as well as other purely private group of people like the executives in the various industries and private institutions etc. have not in general come forward to support the generics' policy. In the system practised in the reimbursement scheme, the authorised physicians usually choose the medicine for their clients. Such authorised physicians are usually greatly influenced by the large companies in their prescribing habits. These large companies are almost exclusively in the habit of promoting products in the brand names.

Discussion: The claim of the industry that they set standards for their branded products higher than the minimum required by law is not always true. Usually the knowledge on various aspects including the manufacturing technique, the bio-availability, etc. for various drugs (formulations) discovered long ago and introduced into the country for several years (more than 20 years) is not a secret and it becomes almost a common knowledge to people in the business.

For such drugs the claim to have standards higher than the minimum required by law is rather exaggeration. Wherever a drug appears in the pharmacopoeia it is usually belieyed that adequate knowledge on the drug has already been gathered and, therefore, there is nothing very special

which any manufacturer can claim for such drugs.

● On the contention of the industry that introduction of brand names would lead to the induction of substandard and spurious drugs in the market it may be stated that the Hathi Committee in its report had stated that "there have been no instances where a product marketed under generic name has ever been reported to be spurious." The Hathi Committe concluded that "branding of products promotes a tendency to prepare misbranded or spurious products."

● The fear of the industry that the patients would be at the mercy of the chemists/pharmacists rather than under the supervision of the prescribing doctors if the prescription is of a generic product seems to be stretching the issue far beyond relevance. It could also be argued that the ethics of every prescribing doctor might not be of equal standard and, therefore, the fear that a qualified chemist/pharmacist would act less responsibly to a prescription does not seem to be tenable.

● There is, however, a strong point in favour of the Industry when they are arguing for the right of introducing brand names for products discovered for the first time in India or abroad, and which are being introduced for the first time in India. It is believed that each discovery involves massive R&D efforts in terms of manpower and money, which every company can not afford. There has, therefore, to be a method of adequate compensation for R&D efforts and, thus recognition of brand names for such new products for some minimum period should be allowed, since this is also considered to be a method of compensation.

● The belief of the authorities that generic products are comparatively cheaper was proved by ascertaining the facts. Data were collected for the selling prices of important drugs including antibiotics, analgesics, steroids, anti-T. B drugs and anti-dysentery drugs which were sold in generics as well as in brand names (Annexure-III), from among the leading producers. It was found that by and large generics were cheaper than equivalent branded products.

● The Government is committed to implementing the generic policy as embodied in the New Drug Policy, 1978. The multipronged efforts of the Government have resulted in effecting a small go for the generics in certain areas. Annexure-IV shows the trade attainment of a few products marketed in generic names by reputed manufacturers. In would be of interest to note that the market of most of such products is on the increase.

● The data in Annexure-IV reveal that the drugs which are being marketed under generic names like Insulin, Tetracycline, Oxytetracycline, Benzyl Penicillin, Benzathine Penicillin, Sulfadimidine, Sulfaguanidine, Sulfadiazine, A. P. C., Analgin, Prednisolone, etc. are having substantial sales. Almost all such drugs are in use in the country for more than twenty years and are considered to be comparatively old ones. Relatively new drugs have, however, not shown much impact in the trade sales in generic names.

● Although certain formulations marketed under generics have shown

some progress, the overall picture of the trade sales compared to total trade sales of 'generics' is still at a low profile. Roughly the trade sales of generics during 1978-79 (Sept.-Aug.) constituted nearly 1.7% of the total trade sales, while during the following year (Sept , 79 -Aug, 80) it increased to about 1.9%.

● There are at present 137 companies in the organised sector and about 3,000 companies in the small scale sector. The sales turnover of formulations marketed by these companies during 1979-80 amounted to Rs. 1,150 crores. While all these companies contributed in their own way in the selling of drugs, a few (120 to 150) were really more important in terms of their market share in the overall business. A private organisation conducting a monthly survey of trade sales of 150 important companies in their report for the month of August, 1980 indicated the annual trade sale-value at Rs. 607.80 crores (Sep., 79 to Aug., 80). The first 30 companies accounted for about 66.4% of the total trade sales. Since these companies contributed substantially to the market share it was considered necessary to examine if such companies marketed any generic product. Answer to this question was important since this would directly tell us whether or not companies having substantial hold in the market had accepted the concept of generic marketing. It was revealed that of these 30 companies, only 12 had at least one generic product in their price list. The remaining companies had no generic product at all in their price list. This clearly indicates that the willingness of the large companies to participate in the generics business has not been universal. Some incentive will be required to be given to pharmaceutical producers for adopting generics business.

● The sale of formulations to the various institutions during the last two years is estimated at about Rs. 220-250 crores annually, a substantial portion of which is believed to be sold in generics. Institutional sales is highly competitive and is not much influenced by the opinion of the prescribing doctors. Exemption of generics from excise duty, while branded products are levied 12.5 per cent, is an important incentive to generics to get favour in institutional sales. A few patent and proprietory formulations containing one or more of the ingredients such as Quinine and its salts, Dapsone, INH, PAS and salts, Insulin, Iodochlorohydroxy quinoline, Diiodohydroxyquinoline, Emetine, Dehydroemetine, Ethionamide, Cycloserine, Pyrazinamide, Thiacetazone, Morphazinamide, Chloramphenicol, Penicillin, Streptomycin, Dihydrostreptomycin, Ethambutol, Chloroquin, Amodiaquin, Primaquin, Pyrimethamine, Mepacrine, Rifampicin, Clofazimine, Tolbutamide, Metronidazole, D. C. Citrate, Piperazine and its salts, and tetracycline are however exempted from any excise duty.

● For support of the doctors in generics prescription/usage it would be more appropriate to approach socially conscious and younger generation which will appreciate the advantages and the benefits of the generics compared to the branded products. The chemists/ pharmacists have also to be given greater freedom so that they put to use their accumulated knowledge acquired in the preparation for the profession.

● Many countries like ours had experimented in evolving a workable generics policy. It is understood that most of such efforts have not brought any significant results in any country except USA where generics sale is emerging as an important factor. Although quantifiable data are not available to appreciate the impact, it is a matter of great satisfaction to those who believe that drug sales in generics is going to be a tool for standardisation in the dosage, package and presentation, the systematisation of which will lead to the availability of cheaper and effective drugs.

Conclusion: In view of the above the following conclusion is apparent:

1. The concept of generics marketing has not yet been universally accepted among the leading manufacturers. Without their active participation there is not going to be much progress in the matter.

2. Although generic drugs are cheaper, they have not yet made substantial impact in the trade sales. Therefore, any drastic measure on the part of Government to forcibly direct the manufacturers to participate in the concept might not prove effective in the longer run. Since there is an element of obsolesence in drug industry, it could be useful to impose restrictions on the introduction of the marketing of single ingredient formulations based on drugs in use in our country for a long time, say more than 30 years. Marketeers could be asked to change over to the generic names for such single ingredient formulations in a phased manner since adequate returns from such products are believed to have already been realised by them.

3. Branded products, which are exempted from excise duty because they contain certain ingredients mentioned earlier should be levied an excise duty. More incentives to generics marketing have to be given if the generics policy is required to be implemented.

4. A stumbling block to the acceptance of generic drugs is that a large section of the population believes that in these drugs prescribed quality standards are not always maintained. No matter what the enforcement authorities might think about this issue, it is universally accepted that no government control can assure adequate quality standards for any product marketed. Traditionally the corporate objectives as well as the long-established culture of the manufacturers have to be relied upon in the matter. It is a fact that large companies having established reputation never play with the quality of the product they market. It is, therefore, of prime importance that besides strengthening the enforcement authorities in ensuring the quality standards of the products marketed, ways and means are to be evolved to make the reputed manufacturers actively participate in the generics policy of the Government.

5. Selling of drugs in the trade is an important area of specialisation which every company can not master. Drugs industry being the one directly responsible for the health care of the society, the normal marketing force of competition may not be deliberately allowed in certain areas where mass consumption is contemplated. Drugs which have been reserved for production in the public sector units only, are items of mass

consumption. Usually other manufacturers are not interested to invest in such items primarily because these are low profit earning items requiring substantial investment. Public Sector units being under full control of the Government, it is easy to direct them to market generic products. Moreover the public in general believes that the PSU's never compromise with quality. But PSU.s are poor marketeers. Government could do a great service to nation if the reservation policy adopted in the manufacture of bulk drugs could also be enforced to cover formulations based on such reserved bulk drugs. Such reservation would eliminate the scope of competition and, therefore, the difficulties in the marketability of such products would vanish, Government could simultaneously instruct marketing of such reserved formulations in generic names only. By this, there could be a substantial gain on the part of the Government in achieving two goals. This should, however, be restricted to single ingredient formulations only.

Annexure I—(Government Policy on Brand Names)

Government's Policy on Brand Names is embodied in Paragraphs 71.1 to 71.6 and 99 to 100 of the Drug Policy Statement of March, 1978 which are reproduced below:

71.1 Brand names shall be abolished in the first instance in respect of the following five drugs:
Analgin
Aspirin
Chlorpromazine
Piperazine and its salts such as adipate, citrate and phosphate
Ferrous sulfate

71.2 All single ingredient dosage forms of the above drugs shall be marketed only under generic names.

71.3 Drugs which are to be exported will be allowed to bear brand names.

71.4 This decision will be kept under constant review in the light of actual experience.

71.5 Drugs formulations marketed under generic names will also be subject to price control.

71.6 Such amendments as might be necessary would be carried out immediately in the relevant Acts like the Trade and Merchandise Act 1958 and Drugs and Cosmetics Acts/Rules.

99 All single ingredient drugs and drugs included in the Indian Pharmacopoeia other than those in respect of which brand names have been abolished shall bear labels displaying prominently the generic names. Brand names may be shown on labels in a less conspicuous manner.