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FOOD AND DRUGS INDUSTRY IN INDIA "AN OVERVIEW"

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This paper discusses the present Government policy, regulatory and business trends in food and pharmaceuticals Industry in India. These sectors of industry provide multifarious opportunities to potential investors in this Sector, both domestic and foreign. As several policy initiatives are undertaken by the Government of India since liberalization in August 1991, the industry sectors have witnessed unprecedented growth in most of the segments.

Introducing India's Food Industry

The **food industry** is the complex, global collective of diverse businesses that together supply much of the food energy consumed by the world population.

The food processing industry is one of the largest industries in India. It is ranked fifth in terms of production, consumption, export and expected growth. Food Processing Industry is widely recognized as a 'sunrise industry' in India having huge potential for uplifting agricultural economy, creation of large scale processed food manufacturing and food chain facilities, and the resultant generation of employment and export earnings. India has enormous growth potential from its current status of being the world's second largest food producer to be the world's number one producer.

Food Processing Industry is of enormous significance for India's development because of the vital linkages and synergies that it promotes between the two pillars of the economy, namely Industry and Agriculture. Food processing covers a spectrum of products from sub-sector comprising agriculture, horticulture, Plantation, animal husbandry and fisheries. Essentially, the food industry involves the commercial movement of food from field to fork.

While India has an abundant supply of food, the food processing industry is still nascent: only two per cent of fruit and vegetables; and 15 per cent of milk produced are processed. Despite, of this the processed food industry ranks fifth in size in the country, representing 6.3 per cent of GDP. It accounts for 13 per cent of the country's exports and 6 per cent of total industrial investment. The industry size is estimated at US$ 70 billion, including US$ 22 billion of value added products. This sector has been attracting FDI across different categories.

Food Basket

- One of the world's largest food producers, India produces 600 million tonnes of food grains every year. Its granaries had a buffer stock of nearly 50 million tonnes of food grains (wheat and rice) in 2003-2004.
- The second largest exporter of rice and fifth largest exporter of wheat in the world, its agricultural exports account for nearly 14.2 percent of its total export figures.
- India ranks first in the world in production of cereals and milk. It is the second largest fruit and vegetable producer and is among the top five producers of rice, wheat, groundnuts, tea, coffee, tobacco, spices, sugar, and oilseeds.
- India is the seventh largest producer of fish in the world and is ranked second in inland fish production.

With the overwhelming success of the Green and White Revolution, India is now fervently poised for the Food Revolution that will ensure agricultural diversification and large investments in food processing. The entries of multinationals, aggressive rise of commodity branding and low cost of technology are changing the economics of the Indian food industry. The rise of aggressive regional players making forays into categories where entry barriers are low and a boom in Indian Fast Moving Consumer Goods (FMCG) markets and the rising need for these products are the key reasons for this growth in food business.

In Store…The Indian food market is approximately Rs 2, 50,000 crore ($69.4 billion), of which value-added food products comprise Rs 80,000 crore ($22.2 billion). Despite food production in the country is expected to double by the year 2020. With food production expected to double by 2020, large investments are already going into food and food processing technologies, skills and equipment.

The Confederation of Indian Industry (CII) has estimated that the food processing sector has the potential of attracting Rs 1,50,000 crore (US$ 33 billion) of investment in 10 years and generate employment of 9 million persons. The Government has formulated and implemented several Plans and Schemes to provide financial assistance for setting up and modernizing of food processing units, creation of infrastructure, support for research and development and human resource development in addition to other promotional measures to encourage the growth of the processed food sector.

A Goldman Sachs report ('Dreaming with BRICs: The Path to 2050') states that among Brazil, Russia, India and China, India will grow the fastest over the next 30 to 50 years by leveraging its demographic advantages and through continued development. At its present rates of growth, the burgeoning market in the country "would be adding nearly one France every 3.5 years and one Australia every year".

Food processing industries in India-Regulatory Framework

Different laws govern the food processing sector in India. The prevailing laws and standards adopted by the Government to verify the quality of food and drugs is one of the best in the world.

Multiple laws/regulations prescribe varied standards regarding food additives, contaminants, food colours, preservatives and labelling. In order to rationalize the multiplicity of food laws, a Group of Ministers (hereinafter referred as "GoM") was recently set up to suggest legislative and other changes to formulate a modern, integrated food law, which will be a single reference point in relation to the regulation of food products. The food laws in India are enforced by the Director General of Health Services, Ministry of Health and Family Welfare, Government of India (GOI).

There are various food laws applicable to food and related products in India :-

- Prevention of Food Adulteration Act (PFA), 1954 and Rules (Ministry of Health & Family Welfare).
- The Standards of Weights and Measures Act, 1976, and Standards of Weights and Measures (Packaged Commodities) Rules, 1977
- Agriculture Produce (Grading & Marking) Act (Ministry of Rural Development).
- Essential Commodities Act, 1955(Ministry of Food & Consumer Affairs).
- Fruit Products Order (FPO), 1995.
- Meat Food Products Order, 1973 (MFPO).
- Milk and Milk Products Order, 1992.
- The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 and Rules 1993.
- The Insecticide Act, 1968.
- Export (Quality Control and Inspection) Act, 1963.
- Environment Protection Act, 1986.
- Pollution Control (Ministry of Environment and Forests).
- Industrial Licenses.
- BIS Act, 1986.
- VOP (Control) Order – 1947.
- SEO (Control) Order -1967.

The Prevention of Food Adulteration Act (PFA), 1954 focuses primarily on the establishment of regulatory standards for primary food products, which constitute the bulk of the Indian diet. The Central Committee for Food Standards, chaired by the Director General of Health Services, is the decision making entity. The appeals process, however, is cumbersome and time consuming. All imported products must adhere to the rules as specified in the regulation, including the labeling and marking requirements.

The Standards of Weights and Measures Act, 1976 and Standards of Weights and Measures (Packaged Commodities) Rules, 1977 are legislative measures are designed to establish fair trade practices with respect to packaged commodities. The rules prescribe that the basic rights of consumers regarding vital information about the nature of the commodity, the name and address of the manufacturer, the net quantity, date of manufacture, and sale price are provided on the label. There are additional mandatory labeling requirements for food items covered under the PFA. The Department of Consumer Affairs in the Ministry of Consumer Affairs, Food, and Public Distribution is the regulatory authority and enforcement agency.

The fruit and vegetable processing sector is regulated by the Fruit Products Order, 1955 (FPO), which is administered by the Department of Food Processing Industries. The FPO contains specifications and quality control requirements on the production and marketing of processed fruits and vegetables, sweetened aerated water, vinegar, and synthetic syrups. All such processing units are required to obtain a licence under the FPO and periodic inspections are carried out. Processed fruit and vegetable products imported into the country must meet the FPO standards.

Meat Food Products Order, 1992 administers the permissible quantity of heavy metals, preservatives, and insecticide residues for meat products. This order is equally applicable to the domestic processors and importers of meat products. However, its implementation is weak due to unorganized production in the domestic market and fewer imports.

Milk and Milk Products Order, 1992 order regulates the production, distribution, and supply of milk products; establishes sanitary requirements for dairies, machinery, premises; and sets quality control standards for milk and milk products. Standards specified in the order are also equally applicable to imported milk products.

The Destructive Insects and Pests Act, 1914, and Plants, Fruits, and Seeds (Regulation of Import in India) Order, 1989 regulate imports of planting seeds into India, and prohibit imports of seeds for sowing and planting materials without a valid permit. The implementing agency is the Directorate of Plant Protection, Quarantine, and Storage under the Department of Agriculture and Cooperation, Ministry of Agriculture.

After the enactment of the proposed Food Safety and Standards Bill, 2005 in India, the food processing sector would be governed by only one law and one regulator, instead of presently applicable 15 different laws. With the simplified mechanism growth in the food-processing sector would kick-start, which is needed to ensure higher growth for the agriculture sector.

Policies and Regulations

Since liberalization several policy measures have been taken with regard to regulation & control, fiscal policy, export & import laws, taxation, exchange & interest rate control, export promotion and incentives to high priority industries. Food processing and agro industries have been accorded high priority with a number of important reliefs and incentives.

At present,no industrial license is required for almost all of the food & agro processing industries except for some items like: beer, potable alcohol & wines, cane sugar, hydrogenated animal fats & oils etc. and items reserved for exclusive manufacture in the small scale sector. Items reserved for Small Scale Industry (hereinafter referred as "SSI") include pickles & chutneys, bread, confectionery (excluding chocolate, toffees and chewing-gum etc.), rapeseed, mustard, sesame & groundnut oils (except solvent extracted), ground and processed spices other than spice oil and olioresins, sweetened cashew nut products, tapioca sago and tapioca flour.

In order to boost the food processing sector, the Centre has permitted under the Income Tax Act a deduction of 100 per cent of profit for five years and 25 per cent of profit in the next five years in case of new agro processing industries set up to package and preserve fruits and vegetables. Excise Duty of 16 per cent on dairy machinery has been fully waived off and excise duty on meat, poultry and fish products has been reduced from 16 per cent to 8 per cent.

Food Parks

In a bid to boost the food sector, the Government is working on agrizones and the concept of mega food parks. Twenty such mega parks will come up across the country in various cities to attract Foreign Direct Investment (FDI) in the food processing sector. The Government approved 105 proposals between January 2002 and May 2005 from foreign industrialists to set up food processing industries in India involving Rs.643.47 crore (US$ 144 million). The ministry has released a total assistance of Rs.105.22 crore (US$ 23 million) to implement the Food Parks Scheme. It has so far approved 50 food parks for assistance across the country. The Centre also plans Rs.100 crore (US$ 22 billion) subsidy for mega food processing parks.

FDI in Food Sector

Actual FDI inflow in food processing sector in 2004-05 and 2005-06 (till November, 2005) was Rs.332.00 crore. Automatic approval is granted for foreign investment upto 51% in high priority industries which include all food processing industries (except milk food, malted foods and flour) and all items of packaging for food processing industries. Investors need to file an application with the Reserve Bank of India (RBI) in the prescribed format and approval is ordinarily granted within 15 days. For foreign investment higher than 51% and for investments in industries outside the high priority industries, clearance has to be obtained from SIA. Applications are processed on a case by case basis on merit and usually SIA takes about 2 months for the process. Applications for setting up a 100% Export Oriented Unit is also required to be filed with the SIA. For setting up a unit in an Export Processing Zone (EPZ), application has to be filed with the Development Commissioner of the concerned EPZ. Foreign equity of upto 24% of the total shareholding is also being permitted in the small scale sector.

Under automatic procedures, foreign technology agreements are being permitted in respect of industries that are designated as high priority industries. The use of foreign brand names and / or trade mark of goods is also now being permitted freely. To provide access to international markets, majority foreign equity holding upto 51% equity is being permitted for international trading companies that are primarily engaged in export activities.

FDI in a company engaged in “cash and carry wholesale trading” is now permitted up to 100 % under automatic route. The present policy only permit FDI up to 100 % in Cash and carry wholesale trading, which is distinct from retail trading, involving sale to individual customers through normal retail outlets. Recently Government of India has allowed retail trading in single brand items. FDI is not allowed in any other agricultural sector / activity.

Fiscal Policy & Taxation

Wide ranging fiscal policy changes have been introduced progressively. Excise & Import duty rates have been reduced substantially. Many processed food items are totally exempt from excise duty. Custom duty rates have been substantially reduced on plant & equipments, as well as on raw materials and intermediates, especially for export Production. Corporate taxes have been reduced and there is a shift towards market related interest rates.

There are tax incentives for new manufacturing units for certain years, except for industries like: beer, wine, aerated water using flavouring concentrates, confectionery & chocolates etc. Indian currency (rupee) is now fully convertible on current account and convertibility on capital account with unified exchange rate mechanism is foreseen in coming years. Repatriation of profits is freely permitted in many industries except for some, where there is an additional requirement of balancing the dividend payments through export earnings.

Export Promotion

- Food processing industry is one of the thrust areas identified for exports. Free trade zones (FTZ) and export processing zones (EPZ) have been set up with all necessary infrastructure. Also, setting up of 100% Export oriented units (EOU) is encouraged in other areas. They may import free of duty all types of goods, including capital foods.
- Capital goods, including spares upto 20% of the CIF value of the Capital goods may be imported at a concessional rate of Customs duty subject to certain export obligations

under the EPCG scheme. Export linked duty free imports are also allowed.

- Units in EPZ/FTZ and 100% Export oriented units can retain 50% of foreign exchange receipts in foreign currency accounts.
- 50% of the production of EPZ/FTZ and 100% EOU units are saleable in domestic tariff area.
- All profits from export sales are completely free from corporate taxes. Profits from such exports are also exempt from Minimum Alternate Tax (MAT).

Custom clearance: Food items

Customs Department in India follows certain guidelines for custom clearance of food items which includes checks on the condition of the hold in which the products were transported, ensuring whether they meet the requirement of storage as per the nature of the products, and does not in any way cause deterioration or contamination of the products. Customs Department is also required to check the physical/visual appearance of goods in terms of possible damage and its compliance with labelling requirements under the Prevention of Food Adulteration Rules and the Packaged Commodities Rules. In addition,any imported food item, at the time of its import, should have a valid shelf life of not less than 60 % of original shelf life. The Customs Department ensures that the articles which do not meet this condition are not allowed clearance for home consumption.

Apart from the checks on all the consignments of edible/food products imported through Ports, Inland container Depots, Air Cargo Complexes, Container Freight Stations and Land Customs Station the samples of imported food products are required to be referred to the Port Health Officer for testing. For alleviating the difficulties of importers, it has been decided that pending receipt of the test repot, such consignments be allowed to be stored in warehouses under Section 49 of the Customs Act, 1962.

New Opportunities: In India

In India the Food Processing Industry is relatively nascent and offers opportunities for FDI. It accounts for Rs 1,280 billion (US$29.4 billion), in a total estimated market of Rs 3,990 billion (US$91.66 billion). There is a rapidly increasing demand for processed food caused by rising urbanization and income levels. To meet this demand, the investment required is about US$28 billion. Food processing has been declared a priority sector.

The outlay in the Food Processing Sector has been increased from US$19.5 million in 2004-05 to US$41.35 million the next year, more than twice the earlier amount. The government is also considering investing US$22.97 million in at least 10 mega food parks in the country besides working towards offering 100 per cent foreign direct investment and income tax benefits in the sector.

The Government has recently established Special Economic Zones with the purpose of promoting exports and attracting FDI. These SEZs do not impose duty on imports of inputs and they enjoy simplified fiscal and foreign exchange procedures and allow 100% FDI.

The Government is also moving towards introducing an integrated food law, which is expected to help meet the requirements of international trade and make the Indian food industry competitive in the global market. To harness the value-creating potential of agro processing, superior market mechanism and infrastructure are required to be created. State governments have already begun to actively encourage the creation of aggregators by encouraging companies to engage in agriculture marketing. It is believed that this may provide the basis to jumpstart private investment into cold chain and other supply chain infrastructure.

INDIAN PHARMACEUTICAL INDUSTRY

The Indian pharmaceutical industry has shown tremendous progress in terms of infrastructure development, technology base creation and a wide range of production. The country ranks fourth worldwide accounting for 8% of world's production by volume and 1.5% by value. It ranks 17th in terms of export value of bulk actives and dosage forms. Indian exports are destined to more than 200 countries around the globe including highly regulated markets of US, Europe, Japan and Australia. During 1999-2000, production of bulk actives (APIs) is estimated at US $ 860 million and value of Dosage forms is estimated around $ 3 billion (growth + 15%). The country is also showing excellent performance on the export front with the exports touching $ 1.5 billion during 1999-2000 as per provisional statistics. In the process, the pharmaceutical industry in India has achieved global recognition as a low cost producer and supplier of quality bulk drugs and formulations to the world.

India Patents Act of 1970 provided patenting of all processes and products in all areas excepting food, drugs and chemicals. Introduction of product patents in these three crucial areas indicates the sign of confidence and maturity of Indian industry particularly the emerging pharmaceutical industry. In fact, the new patent regime will help Indian pharma industry which has made large investments in drug research. It gives a chance to drug development by frontline companies with adequate safeguards to protect the interests of society.

REGULATORY FRAMEWORK-DRUGS SECTOR

Under the current Indian legal and regulatory regime, the manufacture, sale, import, exports and clinical research of drugs and cosmetics is governed by the following laws:-

- The Drugs and Cosmetics Act, 1940
- The Pharmacy Act, 1948
- The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954
- The Narcotic Drugs and Psychotropic Substances Act, 1985
- The Medicinal and Toilet Preparations (Excise Duties) Act, 1956
- The Drugs (Prices Control) Order 1995 (under the Essential Commodities Act.

There are some other laws which have a bearing on the manufacture, distribution and sale of pharmaceutical products in India. The important ones being:

- The Industries (Development and Regulation) Act, 1951
- The Trade and Merchandise Marks Act, 1958.
- The Indian Patent and Design Act, 1970
- The Factories Act.

The Drugs and Cosmetics Act, 1940 is a legislation brought in force to protect consumers interests. Provisions under this Act include punishments & fines for misbranding drugs, confiscating of such drugs (sec 14), prevention of the import of such drugs (sec10) etc. It prohibits the sale of such drugs under section 18. It also provides for the setting up of Central Drugs Laboratory for testing batches of drugs. The Act also prescribes strict standards that are to be followed by drug manufacturers and importers. It also clearly defines a misbranded drug under section 17. Section 13 clearly states that whoever contravenes any part of this Act will be punishable with imprisonment which may extend to one year, or with fine which may extend to five hundred rupees, or with both. If convicted again of the same offence then, in addition he shall be punishable with imprisonment, which may extend to two years, or with fine which may extend to one thousand rupees, or with both.

OPPORTUNITIES IN DRUGS SECTOR

The Indian pharmaceutical market has been forecast to grow to as much as US$ 25 billion by 2010 as per Organization of Pharmaceutical Producers of India (OPPI) estimates. However, Espicom's market projections forecast more modest but stable annual market growth of around 7.2 per cent, putting the market at US$ 11.6 billion by 2009.

With such a large number of drugs going out of patent by 2005, the opportunity of Indian industry is becoming bigger and bigger and the future is certain.