Indian Scenario on the Medical Diagnostics Business and Future Perspectives –An Overview

P. K. GHOSH

Department of Biotechnology, Ministry of Science & Technology, Government of India, Block 2 (7-8th Floor) CGO Complex, Lodi Road, New Delhi 110 003.

The growth of diagnostics market is related to the prevalence and the incidence of diseases, the attitude of medical profession towards diagnosis, the per capita income and the paying capacity of individuals, Government policy towards national health programmes, the status of the Indian diagnostic industry (which supplies the products) as well as with the extent of medical facilities available, specially in terms of pathological laboratories established throughout the country. India is burdened with a large number of communicable as well as non-communicable diseases. Besides, increase in the population growth is also creating enormous strain on the economy. In this context, simple, specific easy-to-use, inexpensive diagnostic kits for detection of diseases as well as the physiologically active proteins, peptides and hormones assumes great relevance and significance.

Table 1 indicates the incidence of some common diseases in India as of 1990 and as projected for the year 2000 AD. No precise data are available for the incidence of cancer and hormonal and metabolic disorders. Currently, there has also been wide-spread concern over the spreading of AIDS, specially in the metropolitan cities, which is also not yet correctly ascertained. In short, the status of incidence of diseases in India is very high.

Albeit, Indian population is suffering from many diseases (some of them have been mentioned above), there is a steady and sustained growth of per capita G. N. P. During the period from 1980-81 to 1988-89 the per capita GNP registered an annual growth rate of 11-12% at current price level. The increased budgetory provision for national health programmes gradually automatically emphasis on the diagnosis of diseases before initiating specific therapeutic treatment. Moreover, a sizable portion of the population, currently estimated at about 160 million, utilises 50% of the national product itself. The real private market for the sophisticated expensive diagnostics is thus substantially large, which can absorb the reasonably high cost of diagnosis. In this manner application of diagnostics would increase and consequently the market would grow substantially.

The real diagnostic market projected for the past 4 years has been outlined in Table II. The table also indicates the pharmaceutical market during the

corresponding year. It is observed from the Table II that the diagnostic market is increasing rapidly and the growth rate is found to be more than 25 % per annum.

In monetary terms, in the developed world, the Diagnostic market bears a ratio of about 6–7% to the Pharma market. Based on the data of 1987 and 1990 the relative linkage of Diagnostic market to Pharma market both in India and the world has been worked out and placed in Table-III. It will be seen that while the Diagnostic market is about 6-7% of the Pharma market on global basis, in India the Diagnostic market is currently only about 1.15% of the Indian Pharma market. This further indicates that the Indian Diagnostic market holds substantial potential for future growth and in future there would be increased emphasis on diagnosis before starting therapy.

There are a large number of hospitals in the country and also a very large number of pathological laboratories as indicated in Table-IV & V respectively. These data clearly demonstrate that there is already existing a large supportive infrastructure for the proper usage of diagnostics.

Moreover, the Government of India from its various agencies specially from the Department of Biotechnology is promoting the development of diagnostic market vigorously with a view to diagnose early the diseases as well as the physiological status of the body so as to enable the medical profession as well as the patients to take the appropriate steps at the earliest for prophylatic as well as therapeutic treatment. In view of these facts the attractive diagnostics market in the country is expected to grow at a much faster rate.

The current diagnostics market (1991–92) is estimated to be of the order of Rs. 55 crores. However, looking at status and pattern of the diseases, increased concern of the Government as well as large section of the population for the need of diagnostic aid for prevailing diseases, physiologically active proteins, hormones, parasites, bacterials etc. future market will be very high.

The costs of diagnosis are however, not yet affordable. In order to give an inkling of the current cost of diagnostic tests, I have illustrated the cost of various tests of normal pregnancy in table VIII. It is observed that more than Rs. 100/- is the current cost to the examinee. The table also indicates the cost of a test to the private laboratories. One can observe that the private laboratories are over-charging their clients. The clients are further distressed if there are histories of previous complications, as the number of test increase substantially. Table-VIII would indicate the cost to the examinee family, if the woman had histories of previous miscarriages. The cost of an examination

exceeds, Rs. 1,000 approximately. If the patients are to be tested for infection status against dreaded diseases e. g. Acquired Immuno Deficiency Syndrome (AIDS), the costs are phenomenally high. Presently though the cost of single AIDS tests vary between Rs. 25 to 50 per test, the Clients are charged by the pathological laboratories from Rs. 350 to Rs. 1000 for serological examinations. The cost of diagnosis is thus out of reach to common poor people. It is therefore, a challenge to the Scientists and Entrepreneures as well as to the society to devise simple, easy-to-use cost effective, laboratory based as well as "do-it-yourself-kits" for the benefits of the common man.

The Indian Diagnostics industry is not very large although it is growing quite fast. Presently, there are about 30 relatively large companies which are engaged in diagnostics business. The major producing companies of diagnostics with specializations in product areas are shown in Table IX.

India has a large number of trained man-power. Several well-equipped R & D laboratories have been established by the Government. The policies of the Government are encouraging and supportive. Indigenous capabilities have been developed to produce polyclonal as well monoclonal antibodies, isolate and purify antigens, produce antibody conjugates (with enzymes), substrates and coat latex particles on small-scale. However, there is still major inclination towards the imports of monoclonals, antibody conjugates, enzymes, agglutination particles, microtitration plates and micropipette tips by the industry in preference to their procurement from indigenous sources. This situation is primarily due to the less reliabilities of the indigenous materials. Moreover, certain categories of materials like pure enzymes (Alkaline Phosphates, Horse-raddish Peroxidase etc.), polystyrene based latex particles etc. are not available indigenously. In addition, the prevalent fiscal concessions extended by the Government on the imports of certain categories of complete diagnostic kits do not encourage the setting up of basic manufacturing facilities for these range of products in India. These situations need to be appropriately corrected to make the foundations of the Indian Diagnostic Industry stronger based on indigenous capabilities.

The current market is based on import intensiveness. At present almost all the immunodiagnostic kits are imported. However, the Government through its various agencies have promoted research at several institutes. This is bound to pay rich dividends for the development of immunodiagnostic tests for a large number of diseases. Already, techniques for detection of six conditions (including pregnancy) have been developed and transferred to Industry.

(Table-X). Immunodiagnostic tests for a number of conditions are under various stages of development as indicated in Table-XI. It is anticipated that 10-15 diagnostic kits will be marketed during the next 5 years and we will be able to compete with other imported similar kits.

As regards the spectra of diagnostic tests, the clinical chemistry tests have been developed to a large extent and several manufacturing units have been set up in the country which are producing reagents and chemicals including instruments required for diagnostics purpose. Diagnostics based on immunoassay including formats of latex agglutination, ELISA, EIA, RIA, IHA, etc. are of recent origin and much attention has been paid by the Government as well as the industry during the past 4 years to promote this market segment. Diagnostics based on nucleic acid probes are latest in the scenario and have not yet been commercially introduced although kits in research have been used in certain laboratories during the recent time. Table-XII gives the break-up of the current market (1990) of various ranges of products in the country.

It will be seen from the above that the current time is the most conductive to the setting up of new production units in the country. As indicated earlier, the current rate of growth of the business is very high and there is a large private as well as Government market for the products. The infrastructure is also supportive. The Government is offering encouragement to the entrepreneurs by extending various supports including fiscal incentives. The R&D base in the country is also strong and there is a large pool of trained man-power. Industrialists should take advantage of the current situation and develop basic manufacturing units in a phased manner. In this connection, the author feels that the real assets of a large pool of trained manpower and expensive R&D infrastructure already available in the country are not optimally utilized. There is also inadequate emphasis and appreciation on the standardisation of input and output materials as well as finished products. Therefore, if the existing assets and facilities are used to standardise indigenous raw materials like antigens, antibodies, conjugates, enzymes, monoclonals, plastic microtitration plates, micropipettes, other plastic containers, and also the finished products (in terms of sensitivity, specificity and stability), it would be possible to make packages of several production technologies into value-added products which would be internationally very competitive, and would open up new avenues for exports.

TABLE–I : Estimated Incidence of some Common Diseases in India

Diseases	Estimated Incidence (Nos. in million)	
	1990 AD	2000 AD
COMMUNICABLE		
Tuberculosis	14	15
Leprosy	8	9.5
Amoebiasis	240	285
Diarrhoea (Total bouts/Year)	444	526
Typhoid Fever	40	48
Helminthiasis	320	340
Filariasis	42	50
Respiratory Tract Infection		
(a) Upper Tract	80	95
(b) Lower Tract	12	15
(c) Combined	30	35
Malaria	40	19
Veneral Diseases	47	61
NON COMMUNICABLE DISEASES		
Heat diseases	26	38
Hypertension	38	55
Rheumatic diseases	3.5	4
Anaemia	17.9	223
Diabetes	19	25

Source : From "A Report on the Indian Drug Industry 1980-2000 AD " The Indian Drug Manufacturers Association, Bombay), 1981.

TABLE–II: Diagnostics and pharma market in India

Year	Diagnostics market (Rs. million)	Pharma Market (Rs. Million)	Diagnostics market as % of Pharma market
1987	200	23500	0.85
1988	235	26900	0.87
1989	320	31900	1.00
1990	410	35600	1.15

Source : Indian Pharma Market from "Report on the Working Group on Drugs and Pharmaceuticals for the 8th 5 year Plan", GOI, Min, of Industry (Dept. of Chem. and Petrochemicals) New Delhi, 1989, page 2.

TABLE–III : Pharma and Diagnostic Markets India *VS* World

Year	India/World	Pharma market (US $ million)	Diagnostic market (US $ million)	Diagnostics market as % of Pharma market
1987	India	1822	15.4	0.85%
	World	117540	7710	6.56%
1990	India	2094	24.1	1.15%
	World	156450	10700	6.84%

Source : World Pharma and Diagnostic markets from various published sources; Indian figures worked out by taking the dollar to rupees exchange rates prevailing in 1987 and 1990.

TABLE–IV : Hospitals and Beds in India : 1987

Particulars of No. of hospitals & beds	Urban (Nos)	Rural (Nos)	Total
No. of Hospitals in India	6637 (69%)	2966 (31%)	9603
No. of beds in Hospitals	484494 (84.5%)	89084 (15.5%)	573578
No. of Hospitals with more than 100 beds	1065	148	1213

Source : Directory of Hospitals in India (Central Bureau of Health Intelligence, Directorate General of Health Services, Min. of Health and Family Welafre, New Delhi) 1988, Page 2-23.

TABLE–V : Pathological Laboratories in India and Daily work Load 1990

Estimated No. of Laboratories	No. of Tests carried out daily
75 to 100	More than 400 to 2000
325 to 400	Between 300 to 400
1300 to 1500	Between 150 to 300
2500 to 3000	Between 50 to 150
6300 to 7000	Betrween 10 to 50
2500 to 3000	Less than 10
Total 13000 to 16000	

Source : Estimated by the author based on feed-back information from various sources.

February–May, 1992

TABLE–VI : Estimated Potential Number of Tests Currently Required

Particulars	Estimated current No. of tests required (potential) per annum (Nos. in million)
Early pregnancy	50–60
Tuberculosis	15–20
Leprosy	2–5
Typhoid Fever	3–5
Amoebiasis	20-25
Diarrhoeal Diseases (Rota virus, *E. coli*, etc.)	5–10
Filariasis	20–25
Hepatitis B	3–5
AIDS	3–5
Malaria	20–25
Veneral Diseases	3–5
Rheumatic Diseases	2–3
Cancer	1–1.5
Hormone Tests (Sex hormones,T3, T4, etc.)	1–1.5
Ovulation Tests	2–3
Total	150–199

Source : Estimated by the author.

TABLE–VII : Cost of Normal Pregnancy

Particulars	Price Charged by Private Labs. per Test (Rs.) 1991	Cost of a Test to the private Lab. (Rs.) 1991
Tests for the Women		
Pregnancy Confirmation (Latex Agglutination)	040 – 060	9–12
Haemoglobin	015 – 020	2-08
Blood Pressure	002 – 005	–
Blood Grouping	25 – 030	5-09
Blood Sugar	05 – 030	0.5–01
Cost to the Examinee	087 –145	

Source : Estimated by the author based on market information.

TABLE–VIII : Cost of Pregnancy with Previous History of Miscarriage

Particulars	Price Charged by Private Labs. per Test (Rs.), 1991	Cost of a Test to the Private Lab. (Rs.) 1991
Test for the Women		
Pregnancy Confirmation (Latex Agglutination)	40-060	9-12
ELISA/CARD Test	90-100	25-50
Haemoglobin	15–020	2-8
Blood Pressure	2–005	–
Blood Grouping	25–030	5-9
Blood Sugar	5–030	0.5-1
Urine (Routine)	5–010	0.10-0.30
Urine (Culture)	50–060	10-15
Ultra Sound	250–300	
TORCH	450-550	60-80
Tests for the Husband		
VDRL	30–050	10-15
Cost to the Examinee Family	962-1215	

Source : Estimated by the author based on market information.

February–May, 1992

TABLE–IX : Major Producing Companies with Specialisation in Product Areas

Companies		Specialisation in product areas
M/s. Ethnor Ltd.	–	Blood Grouping Sera
(Ortho Diagnostic system)	–	IHA Tests
	–	Clinical Chemistry
M/s. Span Diagnostics, Surat	–	Latex Agglutination tests
	–	ELISA kits for Hepatitis B
	–	Clinical Chemistry
M/s Hoechst India (Behring	–	IHA Tests
Diagnostics), Bombay	–	Latex Agglutination tests
	–	ELISA kits for Hepatitis B
M/s. Miles India, Bombay	–	Urine Test strips
	–	Blood Glucose test strips
	–	Clinical Chemistry
M/s. Bhaba Atomic Research Centre, Bombay	–	All Radio labelled products
M/s Ranbaxy Diagnostics, Delhi	–	Latex Agglutination tests
M/s. Cadila Laboratories Ltd.,	–	ELISA kits for Filariasis
Ahmedabad	–	Blood Grouping
M/s. Trans Asia, Delhi	–	Clinical Chemistry
	–	blood grouping sera
M/s. Lupin Diagnostic Ltd., Bhopal	–	Immunoglobulins, conjugates
	–	Immunodiagnostics
M/s. NR Jet Pharmaceuticals Ltd. Bombay	–	Clinical chemistry
	–	Latex immuno assays
M/s. Boehringh Knoll Ltd., Bombay	–	Clinical Chemistry
M/s. Stangen Diagnostics, Hyderabad	–	Clinical Chemistry
	–	Serological products
M/s. Accurex Diagnostics, Bombay	–	Clinical Chemistry
M/s. J. Mitra & Co., Delhi	–	Clinical Chemistry

Source : Based on Market Studies by the Author.

TABLE–X :MOUs Signed Between Institutes & Industries

– Early pregnancy detection.
– Filariasis detection.
– Hepatic Liver Abscess detection
– Typhoid Fever
– Malaria
– Blood Grouping Sera

Source : Department of Biotechnology, Govt. of India, New Delhi.

TABLE–XI : Diagnostic Tests in the Pipe-Line : 1991

– Tuberculosis including Tubercular meningitis
– Leprosy
– Hepatitis A
– Hepatitis B
– Encephalitis
– Leishmaniasis
– Rotaviral gastroenteritis
– Acquired Immunodeficiency Syndrome
– Streptococcal Infection
– Escherichiosis
– Shigellosis
– Aspergillosis
– Candidiasis
– Toxoplasmosis
– Filariasis
– Schistosomiasis

Source : Department of Biotechnology, Govt. of India, New Delhi.

TABLE–XII : Current Market of Different Classes of Products : 1990

	Classes of Products	Estimated Turnover (Rs. in million)	Turnover value as % of Total (%)
1.	Clinical Chemistry Tests	185	45.1
2.	Infections disease testing AIDS Hepatitis-B Strep. B Malaria Rubella Mumps Measles Amoebiasis Toxoplasmosis Typhoid	56	13.7
3.	Physiological Status of body Fluid and non-infections diseases. Pregnancy Immune-disorders Cancer Hormones Allergies	107	26.1
4.	Haematology including Blood grouping Blood banking Coagulation	62	15.1
	Total	410	100.0

Source : Estimated by the author based on Market Studies.