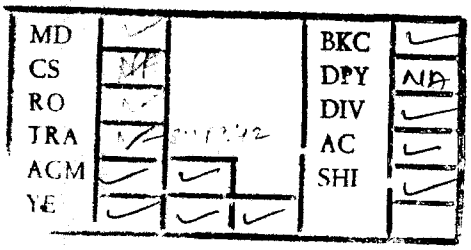

QUALITY. FOR LIFE.

CHEMINOR DRUGS LIMITED

Annual Report 1996-97

'Ask yourself:
Am I more of a
maintenance engineer
keeping today's business
humming along, or an architect
imagining tomorrow's
businesses ?'

C.K. Prahalad
and Gary Hamel,
Competing for the Future.

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EAGLE VISION

Quality - For life.

I distinctly remember an incident of almost 20 years ago, when I was actively involved in process development. One of the laboratory chemists working on the process informed me over the phone that he got good yield of the product but it had impurities and was not passing the melting point. The product in development was Metronidazole. I suggested to him immediately that he should wash it in weak solution of Ammonia, because I knew that the impurity was soluble in Ammonia. That indeed became a very elegant process for production of Metronidazole.

Years later, when we produced Ibuprofen by a totally new and independent process, we have surpassed the inventor's purity levels. When a German trader asked us to match the quality of the inventor's product, I jokingly said, if you are really serious about that, we will have to add some impurities to our Ibuprofen.

QUALITY. That's what we said we would produce. We would produce a standard that would not just be the best that our customers got in India. It would be the best anyone got in the world.

The danger with using the word Quality as the philosophy to drive our business was that one ran the risk of being misinterpreted. Misinterpreted to the extent that Quality would always be associated with a numerical purity level that our output would be driven to achieve. So we redefined Quality. We said it would be a standard that would reflect in everything we did. A standard that would reflect in the way we conceived the range of our products, the manufacturing processes developed for these products, the cost at which we produced these products, the speed at which we produced, the manner in which we waged war on waste and the financial value that we delivered to our share owners.

More importantly, Quality standards keep changing and become more stringent as time passes. We are constantly on the move to meet these more exacting standards.

Cheminor, as an organisation, reflects precisely this obsession. Its standards are ahead of their time in India. Its most important products are approved for sale in the USA. Its manufacturing facilities and infrastructure at these facilities compare only to the best in the world. Even the most demanding multi-national companies are delighted at the manufacturing practices and the quality assurance systems, such as documentation, training and validation, followed at Cheminor's facilities. These competence of Cheminor are a direct result of having Quality as the under current of our business.

Quality at Cheminor is not an address; it is a never-ending journey. It will never be a statistic to be secreted away in files; but the driving force for relieving pain.

For finding cures.

For life.

Dr. K Anji Reddy
Chairman

'DROP IN PROFITS
is a short-term aberration'

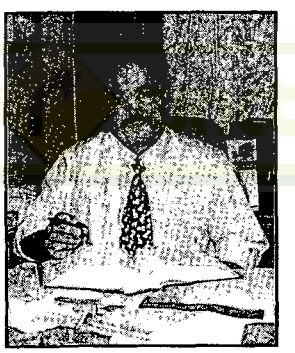
The Managing Director analyses Cheminor's present performance and strategy for the future.

Q : A number of observers are going to be disappointed with Cheminor's performance in 1996-97.

A : So are we. However what is important is that concerned as we are about the lower profits, we perceive this to be a short-term aberration. In fact, we expect the situation to correct itself strongly in 1997-98.

Q : What reasons would you ascribe for the drop in profits ?

A : The principal reason was that the deal with Hoechst Celanese came to a premature end during the course of the year. This took nearly Rs 30 cr. off our turnover. Apart from the loss in anticipated profit, we took a hit on account of the inventories that we had to hold and the prohibitive cost of finance incurred in the process. We have filed a suit to recover these damages.



Q : Is that the only reason behind the drop ?

A : There were frequent changes in the production schedule of Ranitidine because of capacity expansion at the facility. We lost an estimated Rs 10 cr. in sales as a result. Besides, the manufacture of D+acid, an intermediate for Diltiazem, was shifted from our Pedadevulapalli plant to the Vizag plant and that transition took a longer time than we expected. Because of this, we lost sales worth Rs 5 cr.

Q : A number of shareholders fear that this might be the start of a long-term decline for Cheminor.

A : Their fear is misplaced for one reason : we are presently working with world-class assets at the low end of the market and over the coming years we are going to begin the evolution towards the high end of the market. Once the block buster patents start expiring from 1997-98 onwards we expect to see a considerably bigger generics market opening for us. From 1999-2000, I expect that Cheminor's formulations business will take off. What is reassuring is that we have a carefully-designed strategy to capitalise on the emerging scenario in the pharmaceuticals industry instead of going blindly towards it. This gives us the confidence that a decade from now we will not only be around but be a more profitable and much more powerful player.

Q : What strengths does Cheminor have to emerge from the trough ?

A : For the services we provide to our customers, we are among the most competitive in the world. This should not be confused with 'cheapest'. We offer products at a slightly higher price in the developed and quality conscious markets. Cheminor also has solid strengths in terms of technology development, manufacturing systems and human resources. These enable us to cater to the stringent demands of the developed markets, which are willing to give us our due - in terms of a price premium. To this extent, the bottomline of 1996-97 is not indicative of our future.

Q : In what way ?

A : We have continued making investments in assets without a corresponding immediate return. We haven't started selling the products for which we have built facilities. From the second half of 1997-98 we expect to start doing distinctly better when some of these products start hitting the market as their erstwhile patents begin expiring. We should hit nearly Rs 200 cr. in turnover in 1997-98. But the year after that should be a big one when product introduction accelerates.

Q : There is a danger that Cheminor might be living much of its existence in the future.
A : Absolutely. We have to keep balancing the present with the future. I keep telling others at Cheminor that we must survive the present to be able to succeed in the future. We keep repeating that if things are not good, that if the market is not giving us a better price, we must find it from within by increasing operational efficiencies. In fact, if one draws out the threats facing the company, then grappling with the present must surely be one of them.

Q : Any other threats ?
A : Our over-reliance on regulated markets is one. The challenge lies in how we can move over to the non-regulated markets of the moment - 50 per cent are in Asia - around the time they become stringent in terms of expectations. There is also the threat of a product recall or a failed FDA inspection because once word gets around in the global markets that one has failed in even one area or a single product, the general tendency is to stay off that company. This sets the concerned company back by years.

And then there is always the threat of a patent extension. We may have spent years and money in product development but if one is not going to be able to launch it, not only would it result in a loss in anticipated revenues but also gives competitors a chance to catch up.

Q : What is Cheminor's strategy to meet the challenges of the industry ?
A : Moving up the value chain. We expect to enter into a couple of relationships for regulatory work and marketing of our finished dosages. Through these tie-ups we will be able to participate in the market place with an end product without building a full-fledged marketing team. We will share the label as well as the profits. Nobody in India has done this and I am certain that this will liberate the company's fortunes.
More importantly, we are confident that we have the right strategy to succeed in a what is becoming a highly sophisticated pharma industry environment. We have identified the right products to work on, we have developed the right processes which are non-infringing, we are very strong in documentation and analytical development and our compliance with cGMP is respected. Over the next five years we expect that the last leg in our supply chain will have achieved the right critical mass. That is when we will start in terms of building a marketing organisation for our finished dosages business, in developed markets to sell directly.

Q : What are your immediate priorities in 1997-98 ?
A : To continue improving the quality of our products and our overall service. To penetrate the developed markets with a couple of products as soon as the patents expire and thereafter keep pushing the volumes that would be instrumental in pulling the company out of the trough in 1997-98.

ROLLER-COASTER BUSINESS

Big changes and upheavels are predicted

It is a time of ironies. Even as the pharmaceutical industry worldwide inches towards an increasingly regulated scenario for protecting intellectual property over the coming decade - which means that opportunities are likely to reduce for a number of existing players - the opportunity in reality is likely to be greater than ever before.

CONFUSED ? *It's like this : companies that have survived by copying patented drugs will need to evolve alternative strategies once patent protection gets enforced in currently unregulated markets. Therein lies the threat. Meanwhile, over the coming decade a number of block buster drugs are going off-patent creating perhaps the biggest expansion in the generics market ever. Therein lies the opportunity.* The global size of the pharmaceutical industry is estimated at $ 290 billion.

Over the next three years upto the turn of the century, products worth $ 10 billion are likely to lose their patent protection. The market for generics (see glossary) is expected to grow significantly : studies indicate that the market share once commanded by the patented drugs will erode a hefty 75 per cent in the first year. This will rise to as high as 90 per cent over a two to three year period. Meanwhile, the generics market is expected to grow 15 per cent each year. In the US, the largest pharmaceutical market in the world, the generic component is expected to double from the existing 40 per cent of the market by the turn of the century. By the year 2000, it is estimated that three out of every four oral prescriptions dispensed in the US will be generic. Why should this happen ? For a number of reasons. The increasing role of Healthcare Management Organisations is one.

Because of the vast number of patients covered under such schemes, these HMOs command significant bargaining power when dealing with medical suppliers. Being cost -conscious, HMOs are increasingly tilting towards generics. As a result, the market for generics is expanding rapidly. Correspondingly, in a number of European countries, the state health system funded welfare spending to the extent of 90 per cent earlier. Now with the state becoming more cost-conscious there is a transition to cheaper generics, thereby increasing the scope for this alternative industry.

For companies intending to eat market share in this exploding generics market, the factors critical for success is going to lie in the ability to develop the generic (or the bulk active which is the raw material for the generic) well before the patent expiry, get the relevant regulatory approvals comfortably early enough to forge the right marketing alliances.

More importantly, companies will need to accelerate the development of a number of such products to beat the short life cycle of a number of these generics inevitably characterised by falling prices. Companies who can master their timing and product mix are the companies most likely to emerge as winners in one of the biggest pharmaceutical opportunities of our time.

Cheminor is responding to this emerging global scenario by setting up a generic manufacturing plant of international quality to sell in the regulated markets. This will enable the company to add value from intermediates and bulk actives upwards.. It has embarked on the development of a number of products whose patents are expiring a few years from now. The marketing alliances entered into by Cheminor will enable it to be in the market at the right time.

THE 'Q' FACTOR

A state of mind at Cheminor Drugs

Quality is the umbrella philosophy of Cheminor Drugs. However, 'Quality' as we understand it is not confined to one segment of our production or any single aspect of our business. It is a comprehensive statement of our intent. It is reflected in everything that we do. These are some of the major drivers of Cheminor's business and the quality obsession that makes them important contributors to the company's international presence.

PRODUCT QUALITY : This is the pivot around which Cheminor's entire business revolves - and something that Cheminor's clients have begun to take for granted. The bottomline is that we must reach a purity level which matches that of the innovator's product. The company has reached a level of competence where it can deliver whatever purity standards required of it by its international clients. *In the manufacture of Naproxen, for example, the pharmacopoeial standards permit an impurity level of two per cent; Cheminor has delivered a purity standard of much less than 0.30 per cent*

MANUFACTURING AND QUALITY SYSTEMS : An increasing number of buyers the world over want to be assured that what they are buying has a high purity level, and also that the manufacturing and quality assurance systems that Cheminor follows are reliable, consistent and reproducible. The company's processes and systems are comfort-inducing to its customers and conforming to the current good manufacturing practices (cGMP). This has been achieved by a ceaseless systems orientation and internal checks and controls and developing validated processes. *Cheminor has dedicated people for quality assurance at its plants and at the corporate quality assurance centre. They work as the internal audit team with standards as demanding as that of the regulatory agencies. Recent USFDA inspections of Cheminor's facilities were successfully completed without issue of any form 483.*

PRICE : Cheminor believes in giving the best possible quality to its customers at the most competitive price. 'Competitive' is not to be confused with the cheapest. Cheminor strongly believes that it doesn't sell products, it sells peace of mind; it sells a product of the highest quality along with the necessary regulatory and environmental compliances. For this comprehensive package, the price quoted by Cheminor is highly attractive from a buyer's point of view. *Cheminor believes that buyers will become increasingly demanding on comprehensive assurances and prefer to buy only from those companies that can give them - in exchange for a better price to the supplying company.*

DEVELOPMENTAL CYCLE TIME : The time taken to develop a new product is a critical factor in Cheminor's business. This is why : if a product takes considerably long to develop, the company might miss the most opportune time in which to launch it. Cheminor's systems ensure that it is one of the fastest companies in the world to research and develop a product. Being early developers gives Cheminor's clients the opportunity of filing for the necessary approvals, much earlier, with their respective regulatory authorities. *The comprehensive package delivered by Cheminor covers product development, analytical method development, impurity profiling, synthesis of impurities and structure elucidation along with stability studies. For this range of exhaustive services offered by Cheminor, the time taken to develop the product is one of the lowest in the world. Ranitidine was developed in six months. The company launched Doxazosin after exhaustive polymorph studies within a year of starting work on the product. Development of an intermediate for the bulk active Flurbiprofen would normally have taken most companies 12 months; we did it in five. We feel that this is a feat that few companies in the world would*

'Quality is pride of workmanship'
- J. Edwards Deming

be able to match.

TIMING : When a product is launched is critical to its success. This is so because the market for generics is highly active for the first couple of years following the expiry of the patent. Studies have shown that prices of generics start tapering off thereafter. If the generic company misses this boat, it loses a major marketing opportunity. To be able to synchronise the commercial launch with the patent expiry, the company needs to start working on the generic drug a few years in advance. This helps it enlist as a primary source of supply to finished dosage manufacturers. *Cheminor starts working on generics seven to eight years before the patent expiry. This helps the company to submit its generics for approval well before its prospective competitors, helping it forge the right marketing alliances in the process. Even though the patent for Doxazosin will expire only in 1999, Cheminor was the first company in the world to supply developmental quantities of the bulk active to a client who has already begun his work on the finished dosage.*

RETURNS : Cheminor is committed to deliver robust growth and a strong financial value to its shareowners. This will be enabled by the vertical integration from intermediates to bulk actives to formulations. This integration also gives Cheminor a proper insight into the business which increases the company's intangible strengths.

RESULT : For its size and breadth of products on offer, Cheminor's vertical integration solution for value-addition makes it unique in the global pharmaceutical industry. The integration is designed to generate robust cash flows that can be reinvested in to the business period.

THE FUTURE

C H E M I N O R

A unique international play

With the increasing genericisation of the pharmaceutical industry over the coming years, the following factors are likely to influence the survival and success of the players.

TIMING : A company intending to manufacture a generic will need to commercially launch the day the patent expires. *Cheminor is well equipped in this area. For instance, Cheminor sought - and received - approvals for the commercialisation of Ranitidine (form one) before the patent expires in July 1997. This expertise enables the company to launch its product the day the innovator's drug goes off-patent.*

PRODUCT MIX : To be successful, a company needs to select the right product mix. *Cheminor's product selection is based on criteria such as: product, process and formulation patent evaluation, timing, market information on the potential value and volumes, whether it will be able to handle the chemistry of the product, the chances of genericisation of the product and the anticipated profitability. Cheminor's product list includes 21 of the top 50 drugs in the world.*

ALLIANCE : The selection of an alliance partner is important. The alliance partner should be one with a strong presence in the market so that substantial business is generated for the vendor.

INTEGRATION : The company with an effective control over its entire supply chain not only delivers a more dependable