Pharmaceutical Companies Talk to The Daily Star

Rhone-Poulenc Rorer Bangladesh Ltd.

1 Currently in the market we have 154 presentations of 82 brands. They are 100 per cent effective, and meet the worldwide quality criteria of our parent group.

2 Yes, we have growing market for our product. Our brands currently in the market are:

ANTI-INFECTIVE
1 ANTISEP
2 ASCABIOL
3 BIPICLOX
4 BITOXIL
5 BITRIM
6 FIAMBUTOL
7 FICILLIN
8 FICLOX
9. FIMOXYL
10 FIONICOL
11 FIRAZIN
12 FIRIFAM
13 FISAT
14 FISOVIN
15 FLAGYL
16 FRAMYCORT
17 GYNOPE
18 INH
19 MACROCIN
20 MEBEN
21 METRONID
22 NIVAQUIN
23 NOTEZINE
24 ORACYNK
25 PALUTHER
26 PENV
27 PEFLACINE
28 PEVARYL
29 PEVISON
30 RIFAZID
31 ROVAMYCINE
32 SECNIDAL
33 SEFRAD
34 THIOZID
35 CEFTRIAXONE
36 FIMOXYCLAV
37 FLUCLOXACILLIN
38 FIPROXIN

ANTI INFLAMMATORY
39 FICLON
40 INFLAM
41 PROFENID
42 ORUVAIL

CNS
42 IMOVANE
43 LARGACTIL
44 AVOMINE
45 STEMETIL
46 BUTAPAN
47 CETALGIN
48 FICLOZAM
49 FITAMOL
50 FIZEPAM
51 GENASPRIN
52 MOTILON
53 SPASMONIL

ONCOLOGY
54 CAMPTO
55 GRANOCYTE
56 TAXOTERE

RESPIRATORY& ALLERGY
57 INTAL
58 AZMACORT
59 TILADE
60 BANISTYL
61 NASACORT
62 COFEREX
63 MEPADIS
64 PHOLOCODINE
65 PHENERGAN
66 SALBUTAL
67 DIPHEN

THROMBOSIS
68 CLEXANE

CARDIOVASCULAR
69 AMIZIDE
70 BETANOL
71 CARDOPHILINE
72 FICARD
73 FODOPA
74 PILACTONE

OTHERS
75 ANTHISAN
76 ASINAR
77 CAPCIPAN
78 GLUCOTAB
79 FIDAPLEX INJ
80 FOLFETAB
81 VITAMINB 12 INJ
82 FLAXEIDIL

3 Currently we have a market share of about 11 per cent of the total pharmaceuticals market in Bangladesh.

4 Intal, Tilade, Fimoxyl, Sefrad, Ficlox, Inflam, Asinar,Texotere, Clexane, Flagyl, Phenargan, Oracyn K, Stemetil, Rovamycine.

5 It varies according to therapeutic class. Majority of the products is under the drug control price and the others are fixed and approved by the drug administration committee depending on various factors (Raw materials, etc.).

7 We only sell to licensed chemists and druggists. As it is illegal, we do not sell any drug without a doctor's prescription. But in many cases, for inadequate Health Care Manpower and poor economic condition of the general people, some products are sold directly over the counter.

8 Drug Administration exercises their strict regulations on the manufacturers for producing quality drugs. However, they do not have adequate manpower to monitor the same in the market place. Spurious drugs, products of doubtful quality, unregistered drugs may be sold in this situation.

9 The pharmaceutical industry in our country is developing. Compared to the other industries, the growth in this sector has been consistent for the past several years. In fact the industrial growth in Bangladesh has consistently been led by the Pharmaceutical sector. The international companies operating in Bangladesh account for more than 35 per cent of the pharmaceutical business in Bangladesh. Among the top 20 companies of Bangladesh 7 are multinationals. Almost all the life-saving imported products and new innovative molecules are channeled into and marketed in Bangladesh through these companies. These companies ensure a high level of quality and standard in everything they do — manufacturing at the highest level of Current Good Manufacturing Practices (CGMP) standards, rigorous quality control and following strictly the code of marketing practices.
Multinational companies either directly or indirectly are contributing largely towards raising the standard of healthcare through enabling local health-care personnel to gain access to recent international data, supporting continuing education programmes, arranging lecture tours of eminent international experts.

10 The export market is in an infant stage. We have to explore the export market by stressing on quality. Certification of the international pharmaceutical bodies will help to raise the export market. There are opportunities to export particularly in CIS and other regional countries like Nepal, Vietnam, Bhutan, Myanmar, Sri Lanka, Pakistan. Some of the local companies are exporting in these countries.
RPR is currently exporting manufactured products from Bangladesh to Sri Lanka, Myanmar, Hong Kong and Philippines and also have been selected for export to European countries in near future. Among these countries Myanmar is very price sensitive on the other hand Hong Kong and ASEAN countries market prefer high quality products. Raising export in these countries completely depends on our competitive advantage. Through our competitive advantage if we can meet the specific requirement of these countries then there is a possibility. For example, in Myanmar if we can supply product in a very low price and with standard quality then we can expand our export. Again in Hong Kong, Singapore and other Southeast Asian countries product quality including packaging has to be up to international standard. Besides these, an exporter has to have a good distributer in the exporting country who can promote the product with a very good image.

11 The Rhône-Poulenc group has taken on hand CGMP upgrade and capacity expansion projects at the factories at Tongi and it is expected that these projects will be completed by 1999. After completion of these projects, RPR's manufacturing facilities will become most modern and uniquely conforming to the world standards regarding CGMP and other practices.
Government's role should be to ensure strickness and fairness in regulatory activities like registration, quality monitoring, environmental issues etc. Price should be de-regulated and left to the market forces.

12 Office of Drug Administration:
The regulatory authority or the drug administration of the Ministry of Health should provide a clear set of guidelines and policies. The documentation and registration requirements should be more transparent and specific and be updated in line with global changes. It should be an independent body outside the control of the Ministry of Health.

The long delay in organising meetings of the Drug Control Committee (DCC) cause delays in new product launches which is critical for international companies. There have been only about 5 or 6 meetings of the DCC in the last two and a half years. Due to delay in registrations, local competitors gain time to develop branded generic alternatives of these research molecules through patent piracy thus reducing the market attractiveness for the foreign investors. Moreover, in absence of the original product, quality and efficacy of these generies cannot be compared. The DCC meetings need to be organised more frequently in order to remove the back-log.
Registration of pharmaceutical products requires Free Sales Certificates (FSCs) from the country of origin and 2 other developed countries. As a result of global changes such as the formation of the European Union (EU), it has now become difficult to obtain 3 separate FSCs since under the EU, the system of single European Registration has been introduced. Further, the epidemiology in the developed countries is essentially different from that in a developing tropical country. Thus, a product essential in Bangladesh may not be available in 3 developed countries or even in the country of origin. Therefore the system of certification through FSCs needs to be reviewed.
Sometimes a change in regulatory board membership affect previously taken decisions by the board. Inadequacy of their organisation in terms of human resources, their development, training and also other resources and facilities are apparently the limitations of the Directorate of Drug Administration.
Complication with regard to duty assessable value:
Although the Directorate of Drug Administration certifies that pharmaceutical raw and packaging materials' duties should be based on the C&F prices approved in the "block-list", disputes on the duty assessable value arise frequently with the customs authority. The "block-list" price should be considered as a basis for all such imports, because it is approved by the most competent and relevant government agency.
Pricing issues:
Locally manufactured products: The Government wisely de-controlled the pricing of all but 117 so called essential molecules through introduction of a system of "indicative price".
It is interesting to note that, even with de-control, prices have not shot up since market forces and healthy competition is keeping prices at an affordable level. However, the prices of these 117 products need to be reviewed periodically at the request of individual companies based on international prices of raw materials and devaluation of Taka against Dollar. The list needs also to be reviewed to further deregulate the prices of some products.
Imported finished products: For imported finished products, a fixed percentage of markup is applied on the C&F price to arrive at the Maximum Retail Price (MRP), irrespective of whether they are within the list of 117 molecules or not.
* This directly contradicts the Government's move towards de-control.
* Again, with the margins available with fixed-markup system, it is virtually impossible to cover costs of local marketing and distribution.
* This in all probability could encourage some importers to tamper with the C&F prices to recover costs.
We firmly believe that in line with all de-controlled local products, pricing of imported products should also be decontrolled and local marketers be allowed to fix their own prices based on actual operational cost, and market competitiveness.
Uniform Pricing or Open Pricing: Pricing is one of the variables in the marketing strategy. So it is up to the company how they want to price their product. Through the open pricing system we believe, ultimately the consumers get the benefit. It brings open competition and as a result consumers get a competitive price.
But a uniform price will affect the pharmaceutical market. While the Government can not fully subsidise the medicines it is our responsibility to supply the essential products at a reasonably low price. This can be achieved through a reduction of duties and exemption of taxes. In a neighbouring country (Pakistan) 10 per cent sales tax has been abolished on imported raw materials and packaging. This tax exclusion led to an average 4 pert cent fall in retail prices. Our government might take this kind of step to boost up the pharmaceutical industry and at the same time provide medicines at an affordable price.
Price control also discourages investment in GMP upgrades, because the entrepreneurs does not have the possibility to recover the costs of such investment through price adjustments.
Discrimination between local and international companies:
International companies are not allowed to manufacture oral vitamins and antacids which together constitutes more than 10 per cent of the Bangladesh Pharmaceutical market. This is a discrimination, which contradicts with the current Foreign Private Investment Act.
Although these formulations were classified as "simple" products, any expert in the field would be able to testify that these products require stringent stability and microbiological controls in their manufacturing and quality assurance methods. That is why, this discrimination needs to be removed and international companies should be encouraged to produce quality vitamins and antacids in Bangladesh.
Obligation on purchase of local raw materials:
Of late, we are obliged to purchase raw-materials (RM) which are manufactured locally. This obligation is against the principles of World Trade Organisation. In addition:
* Local RMs are not favourably priced vs international competition. In fact, even foreign materials are available at a lower price in the international market.
* The quality of the local RMs do not always meet all quality specifications of international companies, particularly in respect of physical properties, which is very important.
Under the Drug Control Ordinance 1982, foreign companies who have no investment in Bangladesh have been barred from entering into "under-licence" agreements with local partners.
We believe this should immediately be re-considered in the face of the following:
* Such arrangements will encourage optimal utilisation of the capacities and improve efficiency. Presently there is ample idle capacity remaining unutilised.
* It is in the interest of the local industry to have such operations for their own development and expertise. If we look today at the leading companies of Bangladesh, it is very much apparent that past foreign collaboration with multinational companies with "under-licence" agreement has contributed largely to their development and expertise.
We therefore recommend that the prohibition of "under-licence" manufacturing be immediately waived to pave the way in this important sector linked directly to the health of the population.
Inclusion of FICCI representative in various committees of Ministry of Health:
* In absence of our representatives many a time we have encountered problems arising out of communication gaps. Such complications unnecessarily complicate the business environment and send wrong signals to international investors.
* The participation of FICCI could help introduce an international perspective in the deliberations of the committees and members firms could contribute to the development of the sector as well as transfer of technology to the local industry.

There should be representative of FICCI in all relevant committees formed by the Ministry. We would special emphasis on the following committees:
1. Drug Control Committee
2. Drug Control and Technical Sub-Committee
3. Pricing Committee
4. Pricing Technical Sub-Committee
5. Standing Committee on import of raw materials and finished products
6. New projects evaluation committee
The selection of representatives from any professional or trade organisation should be done carefully so that there are high quality inputs rather than a representation of narrow self-interests.

13 Our key therapeutic areas —
Anti-infectives: RPR has strong presence in anti-infective area. This category of products contributes 60 per cent of its turnover and occupies 21 per cent of the total anti-infective market. Major products in this area are — Flagyl, Fimoxyl, Ficlox, Sefrad, Peflacine, Oracyn-K, Rovamycine, Macrocine Rifazid etc.
These drugs are usually used to treat a variety of infections caused by bacteria. Among the common infections are tonsillitis, bronchitis, boils, furanculosis, tuberculosis, gonorrhoea, typhoid, amoebic and bacillary dysentery, nephritis, cystitis, bone and joint infections and so forth.
Anti-inflammatory
Analgesics: RPR has a leading place in this therapeutic area and occupies highest market share of 18 per cent in this therapeutic class and its turnover contribution is 10 per cent. RPR products in this class are Oruvail, Profenid, Profenid CR, Inflam and Ficlon.
These category of products are used to treat various types of rheumatic diseases and other painful musculoskeletal disorders and in the management of post operative pain.
Cardiovascular Products: RPR has also a range of cardiovascular products which include Clexane, Betanol, Fidopa, Amizide, Pilactone and Ficard. They occupy 8 per cent of the total cardiovascular market.
These products are used to treat various cardiovascular diseases such as hypertension, angina, cardiac arrhythmia's and so on.
Respiratory and Allergy: RPR has a major presence in this therapeutic area with a number of products like Phenergan, Banistyl, Intal, Salbutal, Nasacort, Tilade etc. Some of these products such as Tilade offers a new approach in the treatment of Asthma and have significant advantage over the conventional therapies.
C&S Products: RPR has also a number of products in this therapeutic class that include Imovane, Largactil, Avomine, Stemetil, Butapan, Spasmonil ,Cetalgin, Fitamol, Motilon, Fizepam etc.
These products are used in variety of ailments related to neurological disorders, such as schizophrenia, vomiting, insomnia, spasmotic disorders, febrile conditions. These products contribute 10 per cent of the total sales of the company.
Anticancer: RPR's present top priority is on oncology products. It is now investing heavily in the research and developments of modern anticancer products and has already developed few innovative products. Taxotere is one such product which offers a significant advancement in the treatment of breast cancer, a most common cancer type in the females. The product is approved by FDA in the USA and is already marketed in all developed countries. The product has been registered in Bangladesh and is available for the patients suffering from breast cancer.
Vaccines: RPR Bangladesh also markets a range of vaccines for the prevention of some deadly diseases like rabies, tetanus, typhoid, meningitis manufactured by PasteurMerieux Connaught a separate division of Rhone-Poulenc and a world leader in marketing biological products.

14 People know about our product through the doctors. Advertisement in the media is not allowed due to the restriction of Drug Administration but sometimes we advertise in professional (medical) publications only.

OPSONIN Chemical Industries Ltd

1 We manufacture around 100 products comprising 215 formations. 40% of total products are life saving. All products assure BP & USP standard efficacy.

2 Yes.

3 We control around 8-10% of total market share.

4 Ranitid, Diclofen, Cisarid, Metryl, Hysomide, Cirpox, Doxin, Histal, APA, Opsovit, Keflin, Moxin, Cephran, Traxon etc. we sell more and are more popular.

5 Range is Tk. 0.25 to Tk. 350.00 which are identical to approved price of Drug Administration.

6 Yes. But VAT on life saving drugs may further be reduced for greater benefit of poor patients.

7 No. It is not legal.

8 Yes.

9 Present pharmaceutical state is very encouraging. We can ensure self sufficiency in this sector by the present state. Still import of identical finished products can be reduced and export facilities can be redesigned for better encouragement. Encouragement for pharmaceutical bulk drugs and other accessories manufacturing may be increased by the government.

10 At present we are exporting to Yemen. And 25 products are being exported. Approximately 1 crore taka worth of medicines are exported to Yemen so far. Product registration process are going on in a few countries like Burma, Philippines, Pakistan, Russia etc. Product registration cost is much higher in some countries especially in Russia. Single product registration cost is about 10-12 thousand US$ in Russia.
But our other sister concerns like M/s Global Capsules Ltd. & Opso Saline Ltd. export in a bigger dimension to many countries like Pakistan, Iran, Syria, Malaysia, Indonesia, Burma, Philippines, Yemen, South Africa, Kenia, Tanzania, Russia, Germany, USA etc. with a turnover of around 12 crore taka. In the case of Global Capsule Ltd. 70% of capacity production are being exported.

11 Government can increase export facility with benefit. Extensive promotion may be done through EPB. Embassies in the countries concerned can play the vital role of promotion and monitoring of exports.

12 For export, whenever we register any product to any country, the product registration cost involves 1,000 to 10,000 US$ for a single product. Butin our country importers register any single product with only 100 US$. This difference must be minimised for greater national interest.
Duty structure and product registration system should be identical with India, Pakistan etc. to compete globally. As for example India, Pakistan impose 85% import duty on empty Gelatin Capsule and disposable syringe. But in our country Government impose 15% duty on imported disposable syringe and 30% duty on imported empty hard gelatin capsule. So proper protection is not maintained for locally produced items.

13 All the products are essential for our country. It is introduced as per essential advancement of pharmaceutical science all over the world and specification of WHO and endorsed by Drug Administration and Ministry of Health. As a result it is proven to be essential.

14 We promote the products to the registered physicians. As per prescription demand, we sell the products to the authorized chemists and druggists around the country. We advertise it only in the doctors forum.

Drugs and Doctors

by Dr Sabrina Q Rashid

IN Bangladesh you don't need a doctor when you are sick — sounds strange, but it is true! All you need is a drug store or pharmacy. For it is a custom here that when a person is first taken ill he will go straight to the salesman of the drug store and tell him about his ailment, even though a doctor may be there within the shop or just nearby. When all drugs are available over the counter, without doctor's prescription, why waste money on a doctor? But what the people do not understand is by saving a small amount of doctor's fee, they may be doing a greater damage to their own health and well being. First of all the salesman has little medical or pharmacological education, how can he then prescribe medication? But most of our people have faith on him! It is only when after repeated 'treatments' by the salesman, they fail to get well or even get worse, do they think of going to the doctor. This is a very wrong system. But it is widely prevalent in our country, though not in any developed country.

This could be very dangerous too in some cases e.g. if antibiotics are taken randomly and without following the dosage or course, it can lead to drug resistance. For this reason more and more antibiotics are losing their efficacy and therefore newer generation of antibiotics have to be produced and prescribed. These are very expensive but soon lose their efficacy too because of incomplete course taken and also not in proper dosage. Then some drugs need to be taken in a proper way eg. in full stomach and with added medication or they may cause irreversible damage to the stomach eg. Steroids and Anti-inflammatory drugs.

Proper duration of treatment and proper regime need to be followed in some eg. Ranitidine, Steroids, antibiotics etc. But in our country when a person feels a little uncomfortable after a fatty or heavy meal, he just gulps down one tablet of Ranitidine! This won't do. But it is going on abated. Therefore there should be a proper prescription sale coordination, as is so in most other countries. Also the salesman of the pharmacies must be a Pharmacist who at least understands what drugs are passing through his hands. Then again drugs from only licensed and proper companies should be allowed for sale in a Pharmacy. Once a Paracetamol syrup was produced by a spurious pharmaceutical company. Innumerable small children in the Shishu Hospital and other parts of the country started dying mysteriously of renal failure. On investigation by a Paedretician it was revealed that all these children had taken Paracetamol syrup of the same brand and had to pay with their innocent little lives. What negligence and callousness! How could such an inferior quality drug find its way into the market and into such a big children's hospital, thus leaving a trail of small dead bodies. What torture for the parents to lose their babies not by a sickness but by a medication!

After that incidence when my brother came from abroad with his family for vacation, he brought along with him more than a dozen different medicines only for their one month stay! He could not trust any Bangladeshi company! Even though I tried hard to convince him that drugs of our reputed companies are quite good and reliable but he had completely lost faith. Can you blame him for that? So this should be a lesson for all pharmaceutical cos., because if one of them causes a disaster such as this one, all will be affected and earn a bad name. So the quality control of the drugs of each and every company is a must. The reason for the little ones death was, one of the components of the syrup, di-ethyl glycol was of cheap quality and nephrotoxic. Well, un-licensed or new companies will always try to make quick profit by using cheaper and therefore lower quality ingredients. But, isn't there anybody to check these regularly?

Adulteration, in a country like ours is also so common in everything we consume, that drugs have an equally great chance of being adulterated too. We do hope that reputed companies keep a stern check on this. For the public, including the doctors are completely helpless in this regard. There is no way, whatsoever, for them to get any idea whether the drug is genuine or not. So this responsibility falls entirely on the cos. and the officials in charge. They must perform their duties. Some salines after infusion cause shivering and rigor in the patient. It can happen from the pyrogens that enter into the patient's blood stream via the saline. So the saline solution to be administered Intravenously must be 100% pyrogen free.

Sometimes patients tell the doctor that the same drug of one co. works better than that of another co. This should not be so, if the ingredients are the same and of same quantity in both. So this arises doubts regarding the quality in a doctor's mind. Quality control has many steps eg. proper formulation, suitable to a country's climate. Specific research is needed by each country as the climatic conditions vary from country to country. Then bioavailability of a medicine is a key factor in quality assurance. Poor bioavailability can lead to treatment failure. Proper production procedure must also be followed eg. mixing of the ingredients. Quality and therapeutic effect will deteriorate if these and many other such factors are not taken care of properly and up to the required standard.

Another thing that needs to be looked after with vigilance is the transport, storage and display of medicines on the shop shelves. Some drugs and all vaccines need to be kept at proper low temperature or they lose their efficacy. That is why in third world countries Polio is reported to have attacked some children even though they had been vaccinated. How pathetic indeed, for this disease has no treatment only prevention. Such drugs must be transported by special arrangements to distant clinics and shops from the factories. They must be supplied only to those who have a refrigerator. Many drugs don't need refrigeration but over-heating and direct sunlight falling on the medicine shelves do decrease their efficacy. So this must be checked properly.

The pharmaceutical companies should regularly see how their drugs are kept or stored by the shopkeepers and that the expired ones are removed timely from them. Otherwise it is them who will earn a bad name — not the shopkeepers or the doctors. Well, so much for the critical view! Now the good news is our drugs are way cheaper than those of developed countries. Probably because the money spent on research is included in theirs. Whereas our price is government controlled, considering our very low per-capita income.