

Central Chairman, Pakistan Pharmaceutical Manufacturers' Association

Hamid Raza

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ICMAP: Please tell us briefly about your Association, its membership, role and activities?

HR: Pakistan Pharma Industry is very vibrant, dynamic and knowledge based industry, comprising of more than 700 units. The industry is going through a transition phase of modernization to cater local pharmaceutical requirements and to access more regulated market like Europe and USA. At present, the pharma industry in fulfilling more than 95 percent of domestic requirement. Our goal is to ensure availability of quality medicines to all at reasonable price and to enhance exports of the country by accessing more value added markets of Europe and USA.

ICMAP: How many multinational and local pharma companies are operating in Pakistan? Can you share some statistics of the industry and also the main impediments in its growth?

HR: Pakistan has over 700 large volume pharmaceutical formulation units, including those operated by 25 multinationals present in the country. The pharma industry meets around 95% of country's demand of finished dosage forms and 4-5% of Active ingredients. The industry has shown consistent growth, particularly over the last decade and trying to upgrade. Today most of pharma companies are following local Good Manufacturing Practices (GMP) laws, with a few in accordance with international guidance.

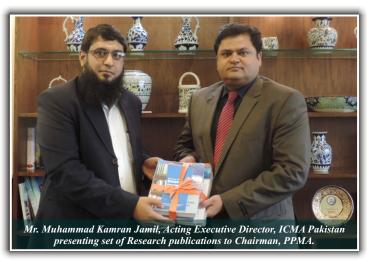


ICMAP: How do you compare the Pakistani pharma industry with the global pharma market in terms of domestic sales, exports, R&D investment, technology etc?

HR: Global spending on medicines has exceeded US\$ 1 trillion for the first time in 2014 and it is expected to reach almost US\$1.2 trillion in 2017. On the other hand, the Pakistan pharma industry sector market 3.2 billion and contributes 0.22% of total world pharma market. Annual growth is 11.11% which is more than the global growth of pharmaceutical industry.

ICMAP: What is the export potential of Pakistani Pharmaceutical Industry?

HR: There is lot of potential, however this industry need to be regulated properly with government's patronization. The total market of Pakistan is US\$ 3.2 billion whereas the global market till 2017 will be US\$ 1.3trillion. So, we are just contributing 0.22 percent of world pharma market. At present, Pakistan is exporting



Lanka, Afghanistan, Far East and African countries like Cambodia and Vietnam. The second category of countries includes ASEAN and few other countries of Africa. The third category includes those where regulations are quite stringent like USA and Europe. Hence, at initial stage, we should go for soft regulated countries. In second stage we

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around US\$ 20 million worth of medicines to 40 countries, including UK and Germany. I am sure we can explore the untapped global pharma market as we have the right dynamics.

Pharma is a science based industry and therefore whenever you apply to any country, even Africa, they ask for product documents from regulation authorities. In Pakistan, DRAP is the concerned regulator however we have to experience inordinate delays in getting the required documents for export purposes. The foreign importers do not wait for such a long time. In India, the regulator work in partnership with the pharma industry and as such India's exports is increasing. There is also an Export Promotion Council in India which works 24 hours and promotes their export of medicine around the world. Unfortunately, in Pakistan, the exporters have to face hurdles and delays from DRAP which is hampering our exports.

ICMAP: Which countries have more potential for export of medicines from Pakistan?

HR: We can classify the world into three different categories; one where there are soft regulations like Sri should move towards hard regulated countries and in the third stage, ultimately our medicine should go to US market which is around 38% of world market. There are huge chances of value addition. India is second supplier to US. If they can, why cannot we?

In USA, the cost of manufacturing is extremely high. Specifically, the manpower cost is too high in USA as compared to India and Pakistan. As such, USA imports generic products from India, Pakistan and China and produces value added drugs in their local market.

ICMAP: Pharma industry could not achieve its 'Vision-2020' for increasing medicine exports in 2015. What are the main reasons behind not achieving the target?

HR: The main reasons can be attributed to nonestablishment of an Independent Pharmaceutical Export Promotion Council (PEPC) and non-collaborations with USFDA, WHO, MHRA, TGA, Health Canada, etc to benefit from their expertise for boosting growth of Pakistani pharma sector by. PEPC should participate in international events to promote exports. The government should also provide support to pharma exporters by holding frequent



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meetings with them and resolving issues faced in target markets.

ICMAP: What are the major concerns of the pharma industry from the Health Ministry and DRAP, especially related to drug pricing policy?

HR: The pharma industry in Pakistan is facing discouraging and depressing environment. The industry is serving the nation better than any other industry in this country. The medicine prices are very low in Pakistan as compared to India, China and other countries. Our Industry is meeting almost 90 percent requirement of medicine and that too at lowest price. Had there been no pharma industry in Pakistan, the cost of medicine would have been 20% to 50% higher due to imports. The general public and the bureaucracy should realize the importance of this industry. This industry has one of the toughest regulations at every level, so much so that even after expiry of the product you are held responsible. If any of our employees make a mistake, I will be responsible.

As far as DRAP is concerned, they have done nothing for encouragement of the industry. They have their own politics and issues and one thing which is very important and it should be pursued at ministerial level that they do not notify for long time. If I have given an application in 2010, I did not receive any registration till date. So, where is my planning and speculation? In other countries like in India, if the registration process requires 30 days, they will not delay it till 31st day.

If a new medicine does not come into the market, it will ultimately hurt the common men. Secondly, If a medicine is necessary for our people, then every firm should be allowed to manufacture it instead of giving registration to only few companies which is unethical practice and leads to polarization. If every pharma company is allowed to make medicine, this would lead to decline in prices in view of market competition and give advantage to common man. If you will allow permission to few firms and remaining firms will be on waiting list that will create frustration a lot. Right now, I am seeing a lot frustration regarding DRAP in industry. People are very anxious because they have million dollars investment and they are still in waiting list. A new registration creates a new employment and a new employment creates more business, but unfortunately the things are not moving that way.

In addition to the above, there are non-supportive export policies, lack of trade promotion programs, arbitrary regulations, weak government procurement policies which are all affecting pharma exports.

ICMAP: DRAP has allowed 8% increase in prices of different drugs based on raw material cost. What is the standpoint of PPMA on this increment in price?

HR: Raw material cost is not a major cost in most of the products in pharmaceutical industry. The major cost includes environment required for manufacturing, testing cost and implementing SOP's required for CGMP (Current Good Manufacturing Practices) and distribution and marketing cost. In few cases, the 8% could justify but in most products it should be rationalized.

ICMAP: Does the budget 2016-17 address concerns of the Pharmaceutical industry?

HR: No. Instead of providing any relief to pharma industry, the government has taken many decisions in the budget which go against the industry. For instance, restriction has been imposed on promotional expense which cannot exceed more than five percent. This is something very unnatural. A company cannot survive like this as we allocate good percentage on advertisements and other promotional means to increase profit. We have discussed this issue recently with Commerce Minster as well.

ICMAP: There is a myth that promotional expenses are undue expenses for doctors' awareness which compromises on patients' or consumers' rights. What do you say?

HR: You are right. There are malpractices like in any other industry or profession but our Association does not support such unethical practices. We always encourage ethical promotion which means telling about the features of product and its benefits to doctors and it then depends upon them to recommend or otherwise the medicines to their patients. We do recommend regulations to check such malpractices

ICMAP: What is the average industry expense on promotional activities?

HR: The average industry expense is around twenty percent plus and for new and smaller companies this is even higher. The pharmaceutical business is different from other sectors as our major cost is not raw material and packaging, rather it



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is selling and distribution. Sending of a medicine from Karachi to Gilgit or Swat involves innumerable costs related to transportation, free samples to doctors, hiring and training of sales team, advertising, promotion etc. For instance, if the price of a medicine is Rs. 100, it includes 15% retail margin and 10% to 12% distribution cost, hence actual price comes to around Rs. 70. Furthermore, pharmaceutical being a very peculiar industry, has to allocate substantial amount in maintain the faction environment, which even cost more than the material cost. For instance, in a pharma company, the air handing and air conditioning system need to operate 24 hours which is costly.

The general perception about the pharma industry that it is a big margin industry is altogether baseless. Pharma industry as compared to other businesses is a highly regulated industry all over the world. So much so that a pharma company cannot even select a plot for establishing its factory and develop a layout for which special permission is required from the government. All activities of a pharmaceutical company, from product manufacturing to selling in market is set by the regulatory authority.

ICMAP: For specific medicines you must be importing raw materials and due to high prices and other issues, such medicines become unaffordable for consumers in local market. How you tackle this?

HR: Yes, most of the raw material of pharma industry is imported from different countries. The domestic industry is at a nascent stage, catering to only 10% to 15% of raw material requirement of the pharma industry. The local raw material industry need to develop and expand for which the government should provide a conducive environment for growth.

ICMAP: The management accountants can be quite helpful in drug price-setting and ensuring better cost monitoring and effective control over drug prices? What do you say in this regard?

HR: Yes, the management accountants can be helpful for

NHCSR and DRAP for better cost monitoring and effective control. DRAP should take Cost and Management Accountants (CMAs) in consultation so that they can help them in better policy making and effective decision making.

ICMAP: To ensure transparency and cost effectiveness, do you think cost audit should be made compulsory in the pharmaceutical industry?

HR: Yes, cost audit should be made compulsory in the pharmaceutical industry in Pakistan to ensure transparency and cost effectiveness.

ICMAP: By profession, a good number of our members are associated with Pharma industry. What role do you think CMAs can play in reducing the cost of doing business of the Pharma industry?

HR: Management Accountant is the most important person in the pharma industry and the pulse of the company who tells us about our grey areas and helps us in taking right decisions about allocation of funds for promotion, reverse integration, consolidations, which are key decisions in a pharma business.

Management Accountants can play a very important role in any industry, especially the pharmaceutical industry by evaluating the forecasting, Activity based costing (ABC)), Batch related activities, actual over head costs, break even analysis, cash flow projections and future speculations. That can also help the management in making right and timely decisions.

ICMAP: How ICMA Pakistan and PPMA can jointly work for the revival of Pharma industry?

HR: PPMA and ICMAP can jointly work by signing a Memorandum of Understanding (MoU), organizing seminars, exchanging ideas and holding discussions on major issues of the industry.

The interview ended with a vote of thanks to Mr. Hamid Raza, Central Chairman, Pakistan Pharmaceutical Manufacturers Association (PPMA) who spared his valuable time and gave his candid views exclusively for this Journal - Editor