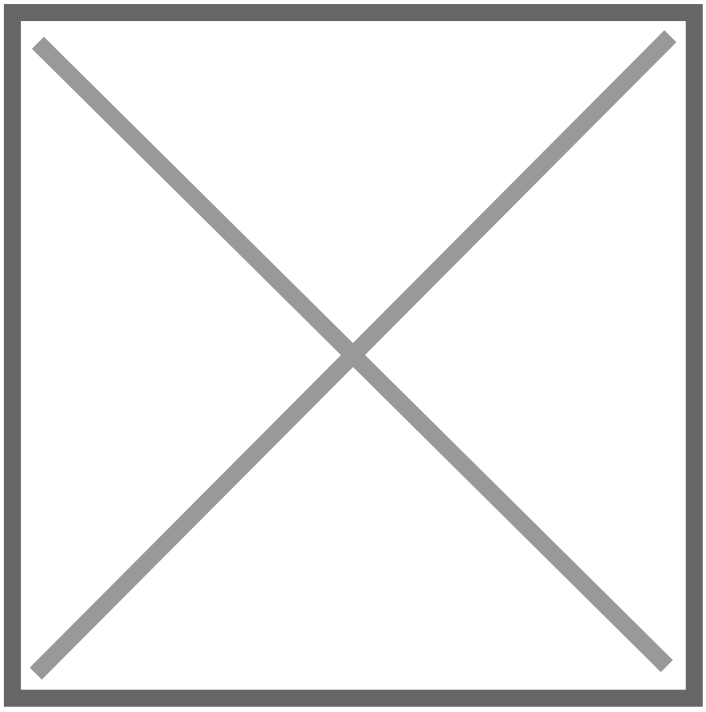
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On Death Bed

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Apathetic regulators run the industry to the ground

On Death Bed

India's globally acclaimed vaccine industry is gasping for its breath.

The Biospectrum Industry Forum was a platform to voice the predicament of the vaccine industry and look at the emerging opportunities in the biopharma space.

Myriad developments are now taking place in the biotech industry both for the good and for the bad. To get down to facts and statistics, the biotech industry as estimated by the Biospectrum-ABLE survey 2008, stood at $2.5 billion in 2007-08 with the appreciation in the rupee being a blow to the industry. Coupled with this is the latest threat to vaccine manufacturers in the face of WHO (World Health Organization) giving an ultimatum of October 2008 to the Indian regulators (the Drug Controller General of India and its accredited testing institution in Kasauli, Himachal Pradesh) to revamp the regulatory system failing which, they will be forced to derecognize the National Regulatory Authority (NRA), represented by these two organizations. This has come in the event of three public units being shut down resulting in many applications put on hold. In a country, where only 10 percent of the children are vaccinated, this can snowball into a serious issue. The other side of the picture for India is the biopharma space, which holds a lot of promise in the future.

Keeping these two key issues in mind, Biospectrum hosted an industry forum in Mumbai with the sole purpose of getting collective views of the vaccine and biopharma players and bringing out the opportunities and challenges that lie therein. While Bio-Rad Laboratories was the principal sponsor for the event, the UK Trade & Investment was the support sponsor. The event was divided into two panel discussions. While the first panel discussion deliberated on the issues related to the Indian vaccine industry, the second panel session ruminated on the potential markets as well as the challenges facing the biopharma industry. Giving context to the forum, N Suresh, Group Editor of BioSpectrum said, "The industry forum was an exercise to highlight the biotech industry's concerns to the regulators and policy makers. We hope to draw the attention of the Government on the issues concerning the vaccine players."

Discussion 1: Issues Facing the Vaccine Industry

The first panel discussion with Biospectrum editor, N Suresh as the moderator, consisted some of the prominent names from the vaccine industry--Dr Cyrus Poonawalla, Chairman, Serum Institute of India, Pune, Dr Krishna M Ella, CMD, Bharat Biotech, Hyderabad, KV Balasubramanium, MD, Indian Immunologicals, Hyderabad, Dr Masood Alam, CEO, Chiron Panacea

Vaccine and Country Head of Novartis, Mumbai and Dr Arvind Lali, Professor, UICT, Mumbai.

The deliberation that followed was three dimensional in the sense that the view points of all the three segments--the public sector, MNCs and the Indian companies were sought.

Tracing the genesis of the problem, Dr Poonawalla said, "About 18 months ago, we were first given the indication that the WHO was extremely disturbed at the state of affairs in India, especially the NRA. Some public sector (PSU) vaccines companies were shut down as their facilities were extremely pathetic. The PSU facilities are pathetic, there is no accountability, their GMP has been 30-40 years old and above all there is no money for renovation. The issue here is that if no concrete steps are taken then WHO would derecognize the NRA of India which would have a global impact for Indian vaccine manufacturers and naturally for some of the private companies their livelihood will be threatened. The second issue was the functioning of the NRA--their surveillance, licensing issue policies and clinical trails were questioned. Hence WHO will now send a Canadian team that would guide NRA and lay down the rules which it must follow and if the WHO is satisfied that the NRA has good technical staff and its house is in order then only will it withdraw the temporary stay on new licensing of vaccines from India."

"The WHO is concerned more about how a product was made right from the beginning and the checks that went on it rather than the final product and that was totally lacking especially in the public sectors who have not upgraded their facilities in the last 40 years. They became sick units and the same can happen to private companies who are forced to supply at these prices."

While Dr KV Balasubramanium agreed to the point, he brought to light another basic problem, about the very structure of the regulatory framework, "There is no independence of the NRA which reports to the Ministry of health. There are also a multitude of agencies for vaccine players. So there is no independent regulatory authority as such in the country."

Dr Alam said, "Here the gatekeeper himself is questioned and unless these regulatory issues are resolved, we cannot move forward and regulators must move in an accelerated way to solve these issues. We have the technology but no good testing labs." The complexity was in been accountable to multiple regulations and agencies.

Dr Ella gave a different perspective, "There are pricing complications. Today the price of a vaccine is lower than a bottle of mineral water and if we do not have funds where do we have the resources. In India we work in a pressure cooker like environment."

At this hour, innovation and a decent pricing model system is needed. Dr Lali said, "We have to build vaccines at a decent price and building processes which are far more innovative today--innovations both at the molecular engineering level and process engineering level and education can bring about innovation for which there is no interest."

The clamor by panelists hence was the formation of an association for all the vaccine players. This association would be independent, they would check and inspect facilities to maintain high quality standards, cross certify and maybe in the future come out with an accreditation. Also the independence of the NRA is the need of the hour while the issue of pricing could be sorted out only when the industry becomes aware about the economics of the segment and for that again an association of vaccine players was of crucial importance.

Dr Poonawalla condemned the lack of political will in the country to increase the immunization levels of India's poor people. He highlighted the coverage of vaccination in India was much less than that in many African countries and even Bangladesh. "Resources are not an issue for the country. It is the utter lack of commitment to ensure the health of the nation, " he lamented.

Discussion 2: Biopharma Potential and Challenges

With Dr Shrikumar Suryanarayan, Director General, ABLE as the moderator, this session explored the issues relating to entering new markets, particularly the biopharma market, in depth and plan for the future. Panelists for this session included Dr Niranjan Kumar, Senior Vice President, Wockhardt Biotech, Auragabad, Brad Crutchfield, Global Vice President, Life Science Business Bio-Rad Laboratories, Hercules, California, Dr Arvind Lali, Professor, UICT, Mumbai, Ramani Aiyer, Chief Scientific Officer, Actis Biologics, Mumbai, Chirag Mehta, Head Strategy and R&D, Intas Biopharmaceuticals, Ahmedabad and Dr KG Rajendran, Head, Knowledge Cell, USV, Mumbai.

The session focused on the importance of innovation and how to bring alive innovation and its relevance. Above that innovation could only be brought about through bright leaders who could change the mindset of the Government. The

panelists were unanimous that the element of entrepreneurship was much needed in the industry. Said Crutchfield, "India has a competitive edge over China but at the same time it needs to be innovative. Even if you have innovation you need to employ people who are employable, polish the education system here to drive programs to encourage people to join life sciences. Biotech in the future will affect everything that is around." Aiyer agreed to the fact that the pipeline for talent was not there in universities and colleges. "People might know how to handle an HPLC but they should be innovative enough to see that what is the next step."

At this hour, lack of competency was a major problem facing the biopharma sector and as Dr Kumar put it, "Lack of competency arises from the fact that people are given work but not given the time and leadership driving them is also lacking." This is coupled with acute lack of infrastructure. "Dr Rajendran said, "Students have not seen basic infrastructure when they were in college and when they come to the industry they do not understand the dynamics." Dr Kumar too voiced the same opinion where he mentioned, "The Government invites us to start off with projects but then ultimately we have to go through a lot of problems like for example they cut off our water supplies and for a biopharma companies water is needed 24x7. Systems are also not in place." In this situation there is a major disconnect between the kind of research conducted by universities and what the industry actually needs.

With biosimilars being the buzz, the billion dollar question is "Can India pull it through and can it cash on to the opportunity considering its aversion to risks?" To which Mehta while laying out a business model said, "We have to be innovative but here innovation means that we need to be a little structured in terms of letting go of things which in turn will make you think new innovative ideas. We have to be business oriented. As far as regulations in biosimilars are concerned we are just 70 percent there. We do not have commercial expertise; we are just good at academics." Also Indian biopharma companies lacked a good distribution network. India at the same time has an edge even over China because biosimilars unlike generics has a huge timeline and hence for those companies wishing to make quick profits, biosimilars is not the ideal route. So there are three business models--one is a product oriented model where you have a biosimilar product and sell it outside and then we have an innovation-incubation model where we bring in innovation from outside and the third is the CRAMS space.

At this point, the industry opined the panelists, is young, and it needs a holding hand like the Government who has all the funds. The problem here is not the lack of money but the lack of spending money and lack of awareness about costs and hence the whole exercise for the industry now is to change the mindset of the Indian Government given the immense potential India has as a biopharma destination.

Nayantara Som

Note: A detailed report on the two issues will be published in the subsequent issues of BioSpectrum.