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Vaccine makers pour their heart out

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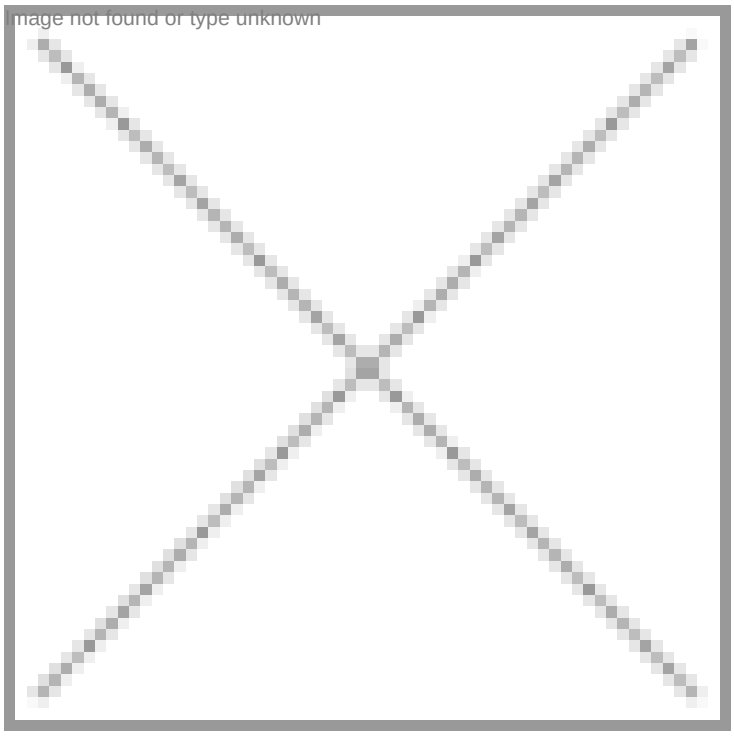

Vaccine makers pour their heart out

The vaccine manufacturers in the country, mainly the exporters, have been at the receiving end of a threat by the World Health Organization (WHO) to stop buying of their supplied vaccines. This was due to the shutting down of three public sector vaccine manufacturing units which were providing the testing facilities to the Indian drug regulatory agency. To understand this issue better and help forge a united front to take remedial action, BioSpectrum organized an Industry Forum on the issues facing the Indian vaccine industry in Mumbai on August 28, 2008. The Forum was sponsored by Bio-Rad and supported by the UK Trade and Investment agency.

The panel discussion was moderated by BioSpectrum Group Editor, Narayanan Suresh. The five panelists were: Dr Cyrus Poonawalla, Chairman, Serum Institute of India, Pune; Dr Krishna Ella, CMD, Bharat Biotech International, Hyderabad; Mr KV Balasubramaniam, MD, Indian Immunologicals, Hyderabad; Dr Masood Alam, CEO, Chiron Panacea Vaccine and country head of Novartis; and Dr Arvind Lali, Professor at UICT, Mumbai.

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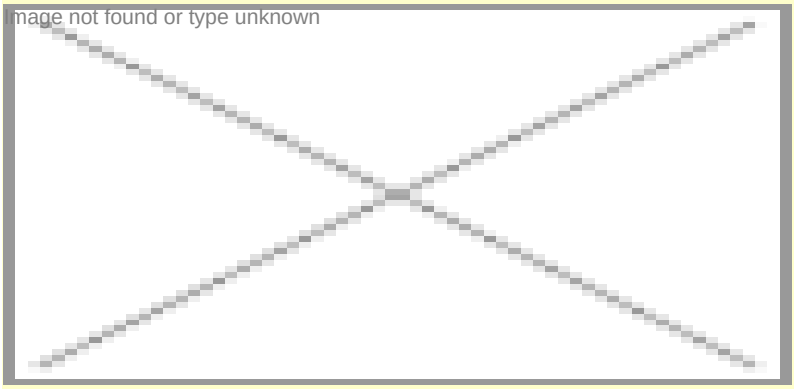

VACCINES PANEL (L-R):
Biospectrum Editor, N Suresh; Dr Krishna M Ella, CMD, Bharat Biotech, Hyderabad; KV Balasubramaniam, MD, Indian Immunologicals, Hyderabad; Dr Cyrus Poonawalla, Chairman, Serum Institute of India, Pune; Dr Arvind Lali, Professor, UICT, Mumbai; and Dr Masood Alam, CEO, Chiron Panacea Vaccine and Country Head of Novartis, Mumbai.

Highlights from panel discussions:

Suresh: What is the genesis of the problem and how will it impact the Indian vaccine industry?

Cyrus Poonawalla: About 18 months ago we were first given an indication by the WHO that after an inspection of the private sector and public sector organizations, particularly the biologicals, they were extremely disturbed by the lack of GMP at many of these units. The public sector companies which were shut down were in extremely pathetic conditions and the National Regulatory Agency (NRA--the combination of the Drug Controller General of India, Ministry of Health, and the three government units where drug tests are done) was being questioned for two-three months by the WHO and other health agencies. These agencies questioned the double standards which allowed top-class private facilities and public units which had poor facilities with no quality or accountability. They were also sad about non-allocation of government funds for the modernization of these public units.

Now who is to be blamed for all this mess is a separate issue, but the issue here was that they were continuously giving negative reports and were threatening the health ministry that they would have to take the extreme step of derecognizing the NRA of India, which would negate the global recognition of the Indian vaccine manufacturers.

The second issue was the functioning of the NRA, their surveillance methods, licensing issue, policies and clinical trials and the general licensing policy. There were question marks over these issues too. The Indian government agencies relented for some time and agreed to an inspection by a Canadian team to guide them and lay down the rules which they must follow. It was agreed that if WHO was satisfied after this, it will temporarily lift the ban on Indian agencies.

Now how does it affect the industry as a whole? The WHO, apart from the threat of delicensing, which will be a disaster, will stay any new vaccine dossier applications.

Any vaccine that any company wants to launch or new entrants who want to come in and file their applications will be frozen till the NRA issue is solved. This is a very critical issue which the health ministry must look at seriously. This issue has been dragging on for the last 18 months. However, the ministry started to act only some five months ago.

Balasubramaniam: The basic problem here is that we have an NRA but there is no independence to the NRA as it reports to the ministry of health. If WHO has said that it will derecognize the NRA it is because there was a lack of authority for the functioning of the public sector units or other private sector units.

Another issue is that a multitude of agencies are involved in the regulatory process. We have the central CBSO and various state-level regulatory authorities. I can talk from my animal vaccine experience that even for an animal vaccine we do not have a permanent body which evaluates the vaccines to be introduced in the marketplace.

So the whole regulatory framework is not very clear, there is no independent regulatory framework. But I think we have to look at the larger issues and we have to look at long-term issues. I agree we must have vaccines which have high quality standards but then we have to address the basic issues and only then you will have a stronger regulatory system and you will

not have issues in future.

Today the government follows pre-qualifications approved by the WHO which is not reflected in the national situation. My organization has followed WHO standards and we have also been affected because some of our applications have been put on hold. So I hope that the government gets more serious about the issue and takes some long term steps to address this issue.

Alam: On one hand we are looking at coming up with value-added vaccines which can change the situation in India and then take it globally but here the gatekeeper is questioned and unless these issues are resolved we cannot move forward . And regulators must move in an accelerated way to solve these issues. If you have a vaccine to take it globally, you don't have a serology lab to test them. You have the technology but no facilities to test them and your regulatory filings get stuck.

Poonawalla: All these highlight the inadequacies of the NRA in testing and even releasing the existing products. The National Institute of Biologicals, which is going to be the central drug testing authority, has been set up near Delhi but it has not even taken up the issue. Even if they conduct a meeting, half of the members come late and half of them leave early. And the National Control Laboratory at Kasauli is incapable of handling issues with regards to the release of existing products.

Moreover inadequate manpower is another issue. They are transferred from these poor facilities to better ones in a year's time and if the facilities are improved, they can work on the new and existing products and we can really move forward.

Ella: UNICEF and WHO does not have testing facilities. So they say your testing facilities should be up to my standard. So they entrust the local governments to have a certified lab to meet their requirements. So we are the most victimized people because we are supposed to follow all the guidelines. Unlike biopharma, vaccines come under two different regulations not only in India but worldwide. I feel the reason for our problems is the vaccine manufacturers do not have an association. Today the cost of vaccines is cheaper than the price of a bottle of water. If we do not have funds where do we have the resources and now it is a handful of vaccine players. So there is also a pricing issue. There should be an association to represent ourselves. In India, we work in a pressure-cooker like environment, with jealous industry people. In fact I have been questioned by foreign delegates as to whether we have any association where we are represented.

Arvind: We have to build vaccines at a decent price using processes which are far more innovative today. Innovation is required both at the molecular engineering level and process engineering level. But where is this innovation going to come from? So one possibility is in investing on education. But what is the industry doing in terms of investing in education? Industry says we are not able to produce good graduates. But we say there is no industry participation.

Poonawalla: The WHO is concerned more about how a product is made right from the beginning and the checks that went on it rather than the final product and that is totally lacking especially in the public sector. The public sector could not upgrade its facilities in the last 40 years. As Dr Ella was pointing out because the vaccine cost which is given to them by the procurement agency is so mean that 10 doses of DPT vaccine is given at a price lesser than that of a bottle of water. The public sector has no choice. When they are giving an adjuvant toxoid vaccine at Rs 0.70 per dose, how can they manage GMP standards and they became sick and the same can happen to private companies who are now forced to supply at these prices to the government of India. The government's immunization programs will not be able to sustain and manage good manufacturing practices in the country. This has finally led to the complete ruination of the public sector vaccine manufacturing units.

Suresh: Can we bypass the NRA and get it tested in a lab abroad and then get it certified by WHO?

Poonawalla: Yes! but it is a complicated issue. The country of origin should approve it first. Indian vaccine companies never had to meet the hurdle of high expectations right from the beginning and got used to an easy way of life. It is quite easy to get your vaccine approved in Kasauli than in a Switzerland laboratory.

Even if government wants to follow WHO guidelines, you don't have people capable of doing that so you have to get people from Canada.

It is not something that the government can do, it is something that the private agencies have to do and get together and create an Indian association which is independent and they inspect the facilities of members and over a time build and do the accreditation and cross certify.

Ella: In vaccines QC and GMP is much more stringent than biopharma and testing is very complicated compared to biopharma.