

'India has provided answers to various viral epidemics'

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Dr Altaf Lal is the chief executive officer of MSD Wellcome Trust Hilleman Laboratories, a new enterprise jointly founded by UK-based premier research charity, Wellcome Trust, and US-based pharmaceutical company, Merck, with a not-for-profit mission to develop affordable vaccines for diseases common in the developing countries.

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In his long and distinguished career, Dr Lal's focus has been on vaccine and immunology research and global health policy. Prior to joining Hilleman Laboratories, he served from 2003-09 as the US health attaché and HHS regional representative for South Asia at the US Embassy in New Delhi. In an exclusive interview with BioSpectrum, Dr Lal speaks about the reasons behind the creation of the company, the uniqueness of the initiative, fundings, future outlook and much more.

Q What is the idea behind this programme and the joint venture?

Dr Lal: Hilleman Lab was established with the purpose to develop vaccines for developing countries. We identified needs that needed to be addressed and still continue to be unmet. One of these need is the need to optimize existing vaccines. The initiative started four-to-five months ago in October 2010. We chose to start this program virtually with Medicine in Need (MEND), a technology provider in Boston. We are in the process of developing a research lab at the Jamia Hamdard campus. Our plan is to move the entire research program from an external collaborator to Jamia. We are also utilizing the components of the existing vaccine from Merck, which is another external collaborator. All the work is being carried out at Boston. The work is in full swing and is expected to get completed by this year-end.

Q How do you explain the uniqueness of this programme?

Dr Lal: For the first time, a pharmaceutical company and charity organization are working hand-in-hand. Establishing a unique corporate in a country like India, where excellence in life sciences research has been achieved, we decided to take a different approach as compared to others. This is a separate entity and not part of Merck or Wellcome Trust. We will need many partners to be successful but we felt the initial governance of the joint venture was simplest if focused on two equal partners.

The area where nobody has paid attention in the past is that of optimizing the existing vaccines. The four new components in the existing vaccines that need to be optimized include heat stability, easy administration, reduction in package size and affordability. All these attributes combined together will make the vaccine useful from the perspective of the developing countries. The best part will be that there will be no requirements for cold chain and the cost to vaccinate a child also will reduce significantly.

Q Please tell us about the operational model and the fundings?

Dr Lal: The joint venture focuses on developing vaccines for the developing countries. Hilleman Labs will develop vaccines that can be sold at affordable prices in the world's poorest countries. It will explore a range of business models based on core support, project-specific grant funding and royalties and revenues received from intellectual property generated by Hilleman Laboratories. Any income received by Hilleman Labs will be reinvested to develop and deliver affordable vaccines to people in developing countries.

This 50:50 joint venture is a cooperative not-for-profit business model focusing on the immediate needs and the revenues generated will be put back into operations. The target contributions from each of the partners is 333 crore (\$72.5 million) for the first seven years. That amounts to 667 crore (\$145 million) in total from both sides for the period of initial seven years.

Q Which disease areas are being focused upon by Hillman Labs? Which are the other disease areas you will be focusing on?

Dr Lal: Currently, we have identified rotavirus as our priority area for optimization. The share holders have pledged that any royalties from innovations will be put back into the operations of Hilleman Labs.

Extensive discussions on other priority areas are on and, in the next six months, we will take the final call. However, the criterion remains the same, which is that it should be extremely important for the developing countries. We hope to develop a platform technology for oral vaccines and are also in the process of identifying other priority areas and conduct research to develop vaccines for oral routes.

We are currently working to meet the global needs. We have a strategic advisory board comprising eminent persons from all over the world. We want to develop the potential of vaccines to touch millions of lives. Whatever work we do is as per the India requirement, while also keeping other developing countries in mind. Manufacturing companies don't have to necessarily do much, as they will be handed over the dossier on each process that is to be followed. We will definitely look forward to the funding but at the same time, we will not ask for rebates from the government. We aspire that the countries which have grave issues regarding serious diseases should procure these vaccines.

Q Are you open to new collaborations with research organizations?

Dr Lal: We are open to new partnerships in R&D. When we do phase I and II for optimized rotavirus, we have to do the development and evaluation process. In that process, the government institutes can play an important role. The manufacturing partner will be required once the optimization of the vaccines is through.

Q How do you visualize the progress of biotech industry in India so far?

Dr Lal: The Indian government is doing the very good work to counter the various diseases. It is visible from the publications in this direction. India has provided answers to various viral epidemics. Few of the major companies, located especially in Delhi and Pune, have done tremendous work in the area. We are keen to make it more affordable and, some time in the future, we will fill the vacuum in the area.

We could have gone to Brazil or chosen other countries, but we preferred India because of the many good reasons, including existing rich programs in different research areas, government institutes doing extensive research, and the regulatory environment that is getting better by the day. However, the growth of the industry may have been a bit sluggish. In that context, I believe there might be a limitation in manufacturing and marketing but the progress in research has been tremendous. India and other countries should have harmonized systems. Making vaccines is serious business and these

should be tested vigorously. There is a strong need to synergize things and clarity in regulations should be there.

Q What is your future vision for the company?

Dr Lal: I would like Hilleman Labs to be the best vaccine company in the country. Using the platform technology, we are ready to optimize the existing vaccines to make them easy to administer, pack and transfer, and make it much more affordable.

Rahul Koul in New Delhi