

## New government: India's leading biotech voices speak

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With the new government in place in the country now, expectations are soaring high across various industry segments.

Industry experts and stalwarts are keeping a keen watch on every move the new government is making to keep its promises. The nation's Biotechnology sector, neither, is an exception.

With unresolved and long-pending turmoil and hurdles over regulations, investments, and clinical trials, the industry is fully geared, pinning its hope on the new government. But then, there are industrialists who believe that the government alone cannot solve the industry's crises.

According to Dr G S Krishnan, regional president-India, Novozymes South Asia, areas like regulatory, biodiversity and environmental concerns require serious fillip and revamp to witness giant leaps in business opportunities.

"The Industry needs decision makers to support the industry's development with faster approval process, if we have to be on par with the other developing world. It is definitely BT after the IT boom, which will also be the key to India's economic growth which is far more sustainable," he added.

This new government is also expected to prioritize overall support to the biotech segment helping India compete with the global markets by playing a leadership role.

Dr Krishnan also opined that the government can play a pivotal role in supporting key traditional polluting industries for faster adoption of sustainable biotech solutions and by enforcing environment regulations which are already in place, thereby sustaining the economy in the long run.

"It is also imperative that a special committee is set up to address biofuel segment development in the interest of reducing dependence through oil imports in line with the rest of the world, and reducing our current account deficit significantly. We can take advantage of the abundant agricultural residues available in this country. They can be put to better use and evolve a policy which will support inclusive growth, supporting farmers and also generate employment in rural areas," he commented.

Then there are others who want reduced interest rates on borrowed capital, creating a climate for investment in the segment.

Said Dr Ajay Bhardwaj, CEO, Anthem Biosciences, "It is important to remove the stigma of India being a difficult place for getting simple things done. Also, reduction in rampant corruption in government agencies is crucial for development. In fact, it is a daunting task to deal with government. Making land and buildings reserved for biotechnology industries at affordable rates is much needed. The lobbying ability of Biotechnology enterprises with the government is limited. We are still at the margins. ABLE needs to get more diversified and professional to take up the challenge of representing this nascent industry."

Dr Bhardwaj also wants the new government to treat investments in biotech on par with the IT sector. "The IT sector has innumerable duties and tax exemptions compared to biotech. It is important to open doors for international investments in biotechnology. This technology has to be embraced and not feared. However, misguided and misinformed NGOs hold too much sway over policy," he commented.

Post election results, on May 17, 2014, Dr Kiran Mazumdar-Shaw, CMD, Biocon, in her blog, under the title, 'Reviving the Indian Growth Story', wrote, "If the new government is serious about delivering on its promise of a better life for every single Indian, its No. 1 priority should be to navigate the country towards a path of sustainable and inclusive economic growth. The new government that comes to power will have to move quickly to de-bottleneck projects and revive investment sentiment in the country. India desperately needs to be seen taking corrective actions to regain its lost glory by creating an enabling ecosystem that paves the way for a double digit growth."

According to her, the new government needs to take critical steps to revive the Indian economy through smarter regulations for ease of doing business, efficient taxation system, removing bottlenecks for boosting the flow of foreign capital, generating high-skilled jobs, introduction of universal healthcare program and focusing on science and technology, and incentivizing innovation.

Dr Mazumdar-Shaw also wrote, "There is no scope for complacency as significant challenges face the country. Projects worth over \$100 billion were shelved or abandoned in FY14, the highest in the past 18 years, due to policy uncertainty and pending regulatory clearances, according to CMIE."

Avethagen's founder and CMD, Dr Viloo Morawala Patell, sums up her expectations in just one line. "It is funding, funding and funding, and allowing R&D companies to list on the stock market."

For some of them, the existing confusion over clinical trials regulation in the country seems to be a mammoth burden that the new government mandatorily needs to solve immediately.

Dr Jagadish Mittur, head, Biotech Facilitation Cell in KBITS, Department of IT, BT and S&T, Government of Karnataka, expressed, "We need an atmosphere of fearlessness in supporting innovation and creativity. Lack of large capitals and coordination in prioritized research need to be addressed quickly by the new government. There should also be accountability in place on research spending. Most of all, the commotion over the requirement of GM technologies to solve India's hunger, malnourishment and farmers issue has to be resolved."

Hyderabad-based Indian Immunologicals' deputy managing director Dr K Anand Kumar said that streamlining the regulatory approval process for vaccines is crucial, since the current situation takes four long years for human vaccine approvals and six years for veterinary vaccines.

He sees clearing infrastructure bottlenecks, especially the lack of power availability as an important part of manufacturing vaccines. "Ironically, life-saving vaccine units face power cuts in Andhra Pradesh, whereas IT companies are exempt," he

lamented.

"The new government has to simplify the approval process for clinical trials without compromising on quality, safety and efficacy. Countries like the US and the UK have a separate regulatory body for veterinary products. India should adopt that. It is significant to provide incentives for both research and capital investments in the biotechnology sector," concluded Dr Kumar.

Dr V S Ravindran, CEO, Caprienzymes, strongly feels that the younger generation need to be given the right platform for the growth of the industry.

"Young-blooded entrepreneurs and start-ups in the country should be provided the right physical space in technology parks at subsidized rates. The new government needs to realize the importance of technology transfer and joint ventures along with industrial partnerships with academia and institutions. R&D activities desperately need support and transparency. In India, marine biotechnology needs much more attention, and the usage of chemical pesticides should be substituted by organic fertilizers and manures."

For many experts in the industry, 'regulation' seems to be on top of the mind which requires immediate attention. According to Ms Mahima Datla, the currently regulation related to new drugs is fragmented and spread across many ministries. "A restructuring of the CDSCO along with a consolidation between regulations related to food, GMO's and drugs needs to be seriously contemplated. There are many successful examples of this structure in most parts of the world. Building technical competence within such a consolidated structure would be equally important," she adds.

She also feels that another issue that needs more immediate attention is clinical trials.

"Clinical research is an absolutely critical step in the process of validating new drugs efficacy and safety and as such initiatives that raise the bar in terms of improving the quality of clinical research being conducted is welcome. At the same time, it is imperative that regulation in this area be streamlined and be formed in the context of encouraging innovation to occur. Our current regulations are counter-productive, not just for innovation but for affordability and access," says Ms Datla.

In the specific context of immunization, Ms Datla emphasizes the need to build on the success the country has demonstrated in Polio control, and focus on increasing the coverage of existing vaccines, and ensuring that children do not die from vaccine preventable diseases.

"Increasing the spend on health and reversing the alarming trend of reduction in budget allocations for immunization will need to be addressed in order to strengthen health systems and delivery and reduce childhood mortality," Ms Datla opines.

Some countries benefit from the fact that they have push-mechanisms, to stimulate innovation. Examples of this is where the governments invest significantly in research and innovation, thus having a robust pipeline emerging from academia and research institutes.

"In India, funding of scientific institutions has not translated to innovation and applicable health interventions, and we largely rely on innovation from external scientific institutions or industry," she continues. "Therefore, in the context of our country, mechanisms that generate demand for products and services, healthy policies related to FDI, pricing, and taxation have immediate relevance in stimulating innovation and investments in the biotech industry and these are the ones I hope the new government focuses on in order to facilitate growth."

According to Dr Mallik Sundaram, CEO & president, Mitra Biotech, the new government needs to form transparent policies regulations to create a friendly start-up environment to bring path-breaking technologies to the forefront.

"It is important to create and retain human capital which would be an asset. And developing a pipeline through premier educational institutions is crucial. It is also imperative to create an ecosystem conducive for funding through grants or investors for research and commercialization," commented Dr Sundaram.

He believes that creating a stringent framework to maintain optimal utilization of funds, and accountability by recipients should be made mandatory.

"Promoting working with educational institutions to encourage internships and update curriculum with recent advancements, leveraging more public-private partnerships and eliminating unnecessary red-tapism should be considered as pivotal tasks by the new government," ended Dr Sundaram.

Speaking for the Agri-biotech industry, Dr K K Narayanan, MD, Metahelix Life Sciences, said, "Regular functioning of GEAC and its sub-committees should be re-initiated. All the back-log of applications for GM crop trials or studies and commercialization should be disposed-off as soon as possible. It is significant to frame a clear policy regarding GM food crops which need to be allowed in the country. Also, the centre-state policy coordination mechanism needs to be made more effective."

Dr Narayanan also emphasized that the State-level NOC requirements for conducting field trials needs to be dispensed with. "The BRAI bill needs to be re-introduced after appropriate modifications," he added.

He also suggests that the new government initiate and launch a public outreach program to promote the correct understanding of biotechnology in agriculture to dispel misinformation and promote better understanding among the public at large.

"The government's subsidy should also be targeted at improving the adoption of new and productivity enhancing technologies that augment farmer's income," Dr Narayanan expressed.

"The new government seems to be keen on knowing the challenges, and is already taking measures to interact with all stakeholders. The industry organization, ABLE, can interact with the people concerned and also make formal representations, which I believe is already underway," he concluded.