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Challenges await the new government

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Challenges await the new government

From a regulatory stand point, there has been a fair amount of unease in the lifesciences sector in India. The top priority of the government must be to cross the barriers and make the industry confident. Here we look at the top hurdles that the new dispensation will have to cross:

Sustained policymaking

The industry-policymaker-academia relationship will have to be further strengthened. The trust deficit and dis-satisfaction of the industry will have to be removed through continuous deliberations and identification of problem areas. "I expect the new government to spend about 4-5 billion per annum on strengthening the infrastructure in regulation, enforceability of quality controls, IP and also other infrastructure requirements that are currently not in place. There has to be a separate channel at customs for import of all materials related to R&D or atleast a separate cell which can fast track such processes. In addition, it would be useful to have a 5 year policy for S&T. Every single approval needs a clear path of progression with a time line. We need to win back investors to India." Mr PM Murali, president, Association of Biotechnology Led Enterprises said.

Intellectual property

Another big fight where the government will have to step in, is the one between multi-national pharma companies versus home grown companies. The issues on intellectual property rights have caused lot of bad blood between the two. Mr Tapan Ray, independent pharmaceutical industry analyst and consultant, feels that the new government must not give into the

pressure of multi-national pharmaceutical companies who might lobby for amendments in the intellectual property rights act. "India is the largest foreign supplier of generic medicines to America, having over 40 percent share in its $ 30 billion generic drug and Over-The-Counter (OTC) product market. Thus, expecting that the Indian government would wilt under pressure, the 2014 'Special 301 Report' of the US Trade Representative (USTR) on Intellectual Property Rights (IPR) has retained India on its 'Priority Watch List', terming the country as violator of the US Patents Law," he wrote in his blog on May 25, 2014.

Streamline regulations

From undefined research guidelines in stem cells and genetically modified crops to a single window regulator, there needs to be clear understanding of the requirements. In case of the clinical trials scenario, where there has been a total blackout for last year (only few approvals), the government will have to seriously address the issues and replace the lack luster style. A balance between the protecting the rights of recruited subjects while providing clear norms for the conduct of trials is the dire need of the hour. At the core of the issue lies the lack of regulations which are stable and do not undergo changes time and again. The requirement of dealing with multiple regulatory authorities, both at the central and state level adds to the complexity of doing business.

Infrastructure development

The Federation of Indian Chambers of Commerce and Industry (FICCI) is of the view that it is important for the coming government to provide support and work towards empowering the entire innovation ecosystem. As per Ms Shobha Mishra Ghosh, senior director, FICCI, "One of the primary mandates of the new Government should be to trigger, transform and tend biotech startups to convert innovative research in public and private sector into viable, competitive products and enterprises. There is a need for partnership between industry and government, especially for the biotechnology sector particularly in vaccines, biosimilars and regenerative medicine, and institutionalizing policies that enable faster market entry at lower costs, without compromising product quality, safety and efficacy. Enhancing innovation and improving market access for biotech products are one of the many defining goals of healthcare reforms.

Expanding industry and promoting entrepreneurship

Industry cannot be expanded in size unless there are new companies. Dr J N Verma, managing director, Lifecare Innovations feels that startups and MSMEs need higher level of financial support for both pre-clinical and clinical development of biotech/biopharma products. "Withdrawing partial funding schemes will not do any harm as large companies can pursue their goals without partial funding and MSMEs cannot proceed despite such partial grant-in-aid. To encourage entrepreneurship, it would immensely help to create insurance schemes in case young entrepreneurs fail in their endeavour. Such insurance schemes can be created with adequate safeguards to minimise abuse," says Dr Verma.

FDI in pharma

Industry experts believe that the FDI in pharma issue should be once for all settled now. Whether it has to be routed through the greenfield or brownfield, decision should be taken clearly. "The FDI debate which has been under discussion for the last many months will need to be addressed. The criteria for approval of brownfield investments must be very clearly articulated. The removal of the non-compete clause poses a threat to companies wishing to operate in niche areas," mentions Mr Utkarsh Palnitkar, partner and head, Advisory and Life Sciences, KPMG India.

Increased funding

There is a need to enhance budgetary support to science and technology in general and biotechnology in particular, given the food and health needs of the country's growing population. Continuous flow of funds and setting up venture capital funds remain the need of hour for the sector. The agri-biotech industry association, ABLE-AG wants the government to double investment in agricultural research including much higher outlay to biotechnology research and product development. According to Dr N Seetharama, executive director-ABLE-AG, "For biotechnology to prosper, it is important that all government departments work in much greater harmony than seen at present, and avoid duplication of efforts. Emphasis should be placed on ex-ante analysis of publicly funded projects. Government should also increase its capacity to independently and transparently assess impact of specific technologies, and ensure synergistic effects of those technologies."

Ending tax terror

Increase in weight tax deduction from 200 to 250 percent and extending its applicability to activities like clinical trials, tax rebates, grants for advanced skills development programs, exemption from excise or custom duties on life saving medicines as well as on their raw materials and also on capital goods and consumables, CRO's and diagnostic kits. Additionally, the rate of Central Excise duty on bulk drugs which is 10 percent may be brought down at par with drug formulations which is 5 percent.

No to red tapes

Some believe that the government should concentrate on facilitating fast and timely commercialization of technology rather than giving paltry financial support. Dr M Kuppusamy, managing director, Tergene Biotech, Hyderabad, believes that the new government must delink funding for biotech industries from the ambit of DBT and DST and their involvement should be restricted to proof of concept and basic research. There should be a separate agency to fund technology translation and commercialization of science and technology."

Drug pricing

The drug price control organization's (DPCO) restrictions on private sector drug manufacturing must be removed. The government can stipulate prices for its own purchases but allow the market forces to determine the prices of medicines. The current policy framework has created a large number of substandard manufacturing facilities where the quality of medicines is sub-optimal.

Hurdles galore:

â– Functional Biotechnology Regulatory Authority of India (BRAI) bill.
â– Streamlining clinical trial regulations and clarity on stem cell research.
â– Decision on FDI in pharma.
â– Commercialisation of GM crops.
â– Active sustainable industry-government relationship.
â– Segregate biopharmaceuticals (biologicals and biosimilars) pricing from chemical drugs.
â– Institutionalizing policies that enable faster market entry at lower costs, without compromising product quality, safety and efficacy.
â– Enhancing innovation and improving market access for biotech products are one of the many defining goals of healthcare reforms.
â– Ensure the skilled manpower through improved university programmes.