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Chronicling 365 days of Modi govt: Major highlights

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The National Democratic Alliance government led by the Prime Minister, Mr Narendra Modi completed one year on May 26, 2015. A year before on the same day, there was euphoria over new governance and progress that could possibly usher in India as a result of a majority stable government after a long time. Having been underestimated for long, the biotech sector was no different with the industry leaders and associations expressing optimism on change of fortunes. A galore of demands too was spoken of. So, have even few of these met or the challenges remain the same? This is a question which may get answered while we take a look at the few decisions taken by the government.

Even though the review of policies so far have not been on the massive, most agree that the style of governance has witnessed a sea change. Launch of new programmes such as 'Make in India' and Swach Bharat' has exhibited the government's will to bring in change. These have found good connect with the industry leaders who have lauded such initiatives.

For the health sector, the highlight of the year was certainly the release of the draft National Health Policy that recognised the relevance of medical technologies for a robust healthcare delivery system. The 'Make in India' campaign runs on science and technology, research and development, new processes, precision technology, innovation and skill and has tremendous potential to showcase talent of Indians working in life science domain and beyond.

As per Dr Manu Jaggi, chief scientific officer, Dabur Research Foundation, "Modi government has taken some proactive steps in last one year, which has had a positive impact on the pharma industry. Allowing up to 100 percent FDI in medical devices in the pharmaceutical sector is a positive move. This is likely to attract more investments and boost the domestic manufacturing. Provision of essential medicines at lower rates is also a welcome step from which many will benefit. In the last one year, more than 300 life saving medicines which are used to treat life threatening diseases have been brought under drug price control by the Modi government."

Dr Kiran Mazumdar Shaw, chairperson, Biocon feels that national interest is foremost. In one of her tweets, she mentioned, "Partisan politics must stop and focus should be on important national needs. GST is an urgent need of the hour."

"Science and technology is of strategic importance to India's future leadership. India needs to step up its investment in research and translational innovation. We must identify key areas in which to build world-class scientific and technological excellence, for example, genomics, nanoscience, analytics, synthetic biology, information technology, space technology etc.," wrote Dr Shaw in Forbes India magazine. She has also asked the Modi government to look at incentivising innovation and IP creation is important for India's future growth prospects. "Enabling entrepreneurs to propel ideas into sustainable businesses will add value to our economy in the long run. The government should give R&D a boost by providing a 10-year tax holiday on products developed indigenously, provide tax breaks for venture funding, and allow zero duty on R&D equipment."

Soon after the new government took over, the process of charting out a new regulatory pathway for vaccines was started by the Central Drugs Standard Control Organization (CDSCO) which constituted three core working groups from within the industry each for strategy, technical operations and technical post approval each with its designated chairman and member secretary who will take the things forward in a time bound manner. The new initiative is an outcome of the interaction between the vaccine manufacturers and importers in the country with the Drug Controller General of India (DCGI) on January 15, 2015 at the FDA Bhawan, in New Delhi. The dialogue between regulator and industry on various issues, challenges, opportunities in respect of manufacturing of priority vaccines including import of vaccines and regulatory pathways i.e to promote a legal, regulatory and administrative framework for the safety of vaccines at national and international levels. With a great potential to emerge as country's key industrial contributor, the vaccine businesses has not been fully able to evolve due to regulatory hiccups.

Mr R K Suri, chief executive-biologicals, Panacea Biotec, mentioned, "It was indeed a new chapter on the anvil in the Indian regulatory space where the regulatory team under the able leadership of the DCGI, Dr GN Singh was clearly eager to translate the vision of our prime minister, Mr Narendra Modi to take India on the leadership level in the Vaccine map of the world in next 5-6 years."

Report card oozes optimism:

Healthcare

âˆ? National Health Policy-2015

The Ministry has formulated the Draft National Health Policy, 2015 and placed it in public domain on 30th December, 2014 for wide stakeholder consultation. The feedback received from the stakeholders is presently being analysed. The aim of the National Health Policy 2015 is to inform, clarify, strengthen and prioritize the role of the Government in shaping health systems in the country. This covers investment in the health sector, organization and financing of healthcare services, prevention of diseases and promotion of good health through cross sectoral action, access to technologies, developing human resources, encouraging medical pluralism, building the knowledge base required for better health, financial protection strategies and regulation and legislation for health.

âˆ? Mission Indradhanush

The Ministry of Health & Family Welfare has launched "Mission Indradhanush", depicting seven colours of the rainbow, to fully immunise more than 89 lakh children who are either unvaccinated or partially vaccinated; those that have not been covered during the rounds of routine immunisation for various reasons. They will be fully immunised against seven life-threatening but vaccine preventable diseases which include diphtheria, whooping cough, tetanus, polio, tuberculosis, measles and hepatitis-B. In addition, vaccination against Japanese Encephalitis and Haemophilus influenza type B will be provided in selected districts/states of the country. Pregnant women will also be immunised against tetanus.

The first round of the first phase started from 7 April 2015-World health Day- in 201 high focus districts in 28 states and carried for more than a week. This will be followed by three rounds of more than a week in the months of April, May June and July 2015, starting from 7th of each month. The 201 high focus districts account for nearly 50% of all unvaccinated or partially vaccinated children in the country. Of these, 82 districts are in just four states of UP, Bihar, Madhya Pradesh and Rajasthan and account for nearly 25% of all unvaccinated or partially vaccinated children of the country. 4.7 lakh children have so far been fully immunised. The children immunized under Mission Indradhanush are in addition to the children who are immunized under the Universal Immunisation Programme. Total of 297 districts will be targeted in the second phase to commence from September 2015.

âˆ? India Newborn Action Plan (INAP)
India loses about 7.5 lakh newborns (< 28 days) every year primarily due to prematurity, sepsis and asphyxia. The India Newborn Action Plan (INAP) was launched in September 2014 to end all preventable newborn deaths and still births to a single-digit by 2030. The present neonatal mortality rate is 28 per thousand live births.

âˆ? National Deworming Day
According to WHO estimates, 24.1 crore children in the age group 1-14 year (68 percent of the total cohort) are at risk of parasitic intestinal worm infections that impair physical growth and cognitive development. The ministry observed the first National Deworming Day on 10 February 2015, followed with mop-up activities till 14 February 2015. It was implemented in 277 districts covering 11 States/UTs across 4.7 lakh schools and 3.67 anganwadi centers.

âˆ? Maternal and Neonatal Tetanus Eliminated (MNTE) from the country
Total of 32 States/UTs have been validated for Maternal and Neonatal Tetanus Elimination (MNTE) and the formal communication from WHO has been received. For the remaining four states of Nagaland, Meghalaya, Dadra & Nagar Haveli, and Jammu & Kashmir, field visits have been conducted by the joint team of WHO and UNICEF and the parameters for MNTE validation were found to be satisfactory. However, the formal communication from WHO is expected in two months.

âˆ? Decision to introduce new vaccines
In a bid to protect the children from more vaccine preventable diseases, new vaccines are proposed to be introduced as part of India's Universal Immunisation Programme (UIP). The Injectable Polio Vaccine will be introduced in October 2015. This will benefit 2.7 crore children every year. 20 high burden districts have been identified in Assam, Uttar Pradesh and West Bengal for adult JE vaccination in the age-group of 15-65 years. Rotavirus vaccine implemented to full scale would save approximately 1 lakh lives every year. Measles Rubella vaccine eliminates measles and its campaign will be carried out after appropriate planning and will cover 45 crore children.

âˆ? Kala-Azar Elimination by 2015
Action Plan for elimination of Kala Azar by 2015 launched in UP, Bihar, West Bengal and Jharkhand. This will benefit approximately 116.57 million population in the four states. The Action Plan includes active search, new drug regimen, coordinated Indoor Residual Spray (IRS) etc. First round of Indoor Residual Spray with DDT insecticide started in 33 districts of Bihar, 4 of Jharkhand and 11 in West Bengal. In addition, new non-invasive diagnostic kit has also been launched.

âˆ? Drug resistant survey for 13 TB drugs launched
The Health Ministry launched the biggest ever drug resistant survey in the world for 13 TB drugs in September 2014. The results are expected in a year's time. The nationwide drug resistance survey (DRS) will provide the Revised National TB Control Programme (RNTCP) with a better estimate on the burden of Multi-Drug Resistant Tuberculosis in the community. As part of the survey, the samples will be subjected to susceptibility testing for 13 anti-TB drugs (5 first line drugs and 8 second line drugs).
In addition, under the Revised National TB Control Programme there has been rapid expansion of diagnostic facilities including highly sensitive molecular test at 119 facilities across various states for diagnosis of Multi-Drug Resistance TB and TB among HIV and pediatric patients. The baseline second line Drug Susceptibility Testing has been initiated in six states- Gujarat, Tamil Nadu, Kerala, Maharashtra, Karnataka and New Delhi.

âˆ? National AIDS Control Programme
66 new targeted interventions have been established taking the total to 1,818 that provide HIV prevention services to female sex workers, injecting drug users, migrants, truckers, etc. Computerized Inventory Management System launched to strengthen the supply chain management system of Anti-Retroviral Drugs, enhance efficient use of the drugs and minimize wastages across the country.

âˆ? Six new AIIMS
Work has been expedited on the 6 new institutes equivalent to All India Institute of Medical Sciences (AIIMS) at Raipur, Bhopal, Patna, Bhubaneshwar, Rishikesh and Jodhpur. During the last one year, the hospital work has begun and all the 6 new AIIMS are providing high-end clinical care besides the MBBS teaching activities. In addition, 9 new AIIMS one each at Andhra Pradesh, Maharashtra, West Bengal, Uttar Pradesh, Jammu & Kashmir, Punjab, Tamil Nadu, Himachal Pradesh and Assam are proposed to be set up.

âˆ? Women health
"Women's health, hygiene & nutrition" is the current focus under DBT's women's societal upliftment programme of DBT. The department has supported major programme on cervical cancer screening, genetic disorder & counseling, pregnancy-related complications, breast cancer screening & post-operative care. A project for awareness, counseling, screening & education to

prevent genetic and congenital disorder has been implemented in West Bengal and a web based portal (www.genomegyan.com) on genetics has been developed to popularize it as a subject among medical students and physicians.

Vaccines and diagnostics are under key focus in Modi government.

Rotavirus vaccine launched
The first indigenously developed and manufactured Rotavirus vaccine 'Rotavac.' from an Indian strain 116E was launched by the PM Modi on March 9, 2015. The indigenously developed vaccine will boost efforts to combat infant mortality due to diarrhoea. ROTAVAC developed in collaboration with Bharat Biotech under the Public-Private Partnership mode is efficacious in preventing severe rotavirus diarrhoea in low-resource settings in India. The NTAGI of M/o Health & FW has approved introduction of the vaccine in EPI in a pilot mode.
Celiac Disease Diagnostics kit was commercially launched by Dr Jitendra Singh, the then Minister for Science and Technology, Government of India, at an event held in the ICGEB, New Delhi, on October 28, 2014. These kits have been developed through a collaborative, multi-institutional, inter-disciplinary approach funded by the Department of Biotechnology, Ministry of Science & Technology, Government of India.

Agriculture:

In order to implement the long pending demand of technology driven agriculture, the concerned ministry has launched 'Mera Gaon, Mera Gaurav' scheme involving agricultural experts of agricultural universities and ICAR institutes for effective and deeper reach of scientific farming to the villages. A group of experts will be associated with one particular village to create awareness and adoption of new technologies including farm investment, loans, availability of inputs and marketing. All the scientists from ICAR and agricultural universities will participate in this initiative.

Indian Institute of Agricultural Biotechnology is being established at Ranchi (Jharkhand). Also, National Research Centre on Integrated Farming System is to be established at Motihari, Bihar. A new Central Agricultural University has been planned at Barapani, Meghalaya and Post Graduate Institute of Horticulture is to be established in Amritsar. IARI has initiated its outreach programme to further expand the PG education by offering courses in Horticulture and Agricultural Engineering in collaboration with ICAR-Indian Institute of Horticultural Research, Bengaluru and ICAR-Central Institute of Agricultural Engineering, Bhopal respectively. Agriculture and Technology Foresight Centre (ATFC) is to be established to foresee the coming changes in agricultural sector and plan accordingly.

Education:

Hike in Research Fellowships
The NDA Government has fulfilled the much awaited demand of research scholars by revising the fellowships for various categories such as Junior Research Fellows, Senior Research Fellows and Research Associates. Across the board hike in fellowship amount is at least 50 percent more than what was existing. The hike was made effective from October 01, 2014. Junior Research fellowship was hiked from Rs 16,000 to Rs 25,000. Senior Research Fellowship was hiked from Rs 18,000 to Rs 28,000. Research Associateship was hiked from Rs 22,000, Rs 23,000 and Rs 24000 to Rs.36,000, Rs38,000 and Rs 40,000 respectively.
Knowledge Involvement in Research Advancement through Nurturing (KIRAN) programmme was launched in the year 2014 to bring gender parity in science through nurturing the research career of women scientists. The programme is aimed at providing opportunities to women scientists who had a break in their career primarily due to family responsibilities. The programme includes women-exclusive schemes and encourages them to foster their career by undertaking research not only in science & engineering but also for societal benefit besides making a career through entrepreneurship.

Technical Research Centres
Finance Minister during his budget speech 2014-15 had announced setting-up of five Technical Research Centres (TRCs) in the existing autonomous institutions of the Department of Science & Technology. A detailed road-map has been prepared by the Department for setting-up of these centres. Necessary approvals are being obtained for these centres. TRCs are expected to speed-up the technology transfer and commercialization process of the research work being carried out by these autonomous institutions.

North East remains a priority area
The twining programme of DBT has supported nearly 400 R&D projects, leading to more than 200 papers published in peer reviewed journals, and more than 450 young scientists of NER trained in advamced biotechnology. Every year approximately 70-80 projects under this flagship programme are being supported to NER. Also, the setting up of "DBT-NER Centre for Advanced Animal Diagnostics and Services on Animal Health and Diseases (ADSAHD) was announced on February 17,

2015. With a view to recognize promising mid-career scientists in NER, a programme of awarding Unit of Excellence grant to them has been initiated so as to enable them to pursue their innovative research in frontier areas of biotechnology. So far, 12 Units of Excellence have been established during the year.

Enhanced Innovation Ecosystem:
Under the DBT, for a well-defined Innovation Ecosystem for product development - a Public Sector undertaking, Biotechnology Industry Research Assistance Council (BIRAC) has been set-up, supporting nearly 300 companies and 100 young entrepreneurs for innovation, research and product development. Further, the Biotechnology Translational research and industry academia partnership has promoted through 3 Biotech clusters, 8 Biotech Parks and 13 Bioincubators. Also, 16 Centers of Excellences have been created as a flexible model of long-term support for highly innovative, basic and translational research to create high quality state-of-the-art facilities for R&D.
Biotechnology Industry Research Assistance Council Ace Fund (BIRAC Ace Fund) which is an equity fund for accelerating entrepreneurs was announced by science and technology minister, Harsh Vardhan during BIRAC Foundation Day event in Delhi recently.

Clinical research

The clinical research which was in shambles a year before is also slowly catching up. "Over the last few months, several steps have been taken by Indian regulators to bring clinical research in India back on track. We now need to restore confidence among all the stakeholders that robust and streamlined guidelines and systems are in place in the country for conducting clinical research," mentioned Ms Suneela Thatte, president, Indian Society for Clinical Research (ISCR) adding "Thousands of patients are desperately waiting for new therapies and drugs to enter the market, and we, as clinical research professionals, have an enormous responsibility to fulfill this need. We are fully committed to working with everyone across the clinical research spectrum to create an enabling environment which encourages scientific and ethical clinical research so that patients can have better and quicker access to new treatments."

According to Dr Geeta Shroff, founder & medical director, Nutech Mediworld & India's leading stem cell expert. "During his first term in office, Modi has shown interest in stem cell research as it evident from his visit to various institutes across the country and abroad to access progress being made in stem cell research and genetics. He has reiterated the need for supporting "Indian discovery science" in order to boost national economy. Given the focus on creation of research and development in his budget, the Modi government has taken the first step to ensure that the healthcare sector gets back its confidence to grow and help in nation building."

Indeed there needs to be separate policies for stem cells as they are not drugs hence should not be treated as such. It is also important that opinion of stem cell experts (those that have published and patented stem cell related work) be taken while drafting policies and not to be limited to governmental organizations.

Dr Manu Jaggi draws attention to few other priority issues needed to be addressed, He explains, "Despite some of the drugs being banned internationally, a large number of drug combinations are widely sold in India without the necessary regulatory approvals,. We need to align our policy on this with other western countries. There is lack of transparency regarding government's strategy on the IPR. Despite India being TRIPS-compliant, this is sending a false signal. Further, the government is yet to share the new IPR policy."