GOVERNMENT OF INDIA
SCIENCE AND TECHNOLOGY
LOK SABHA

UNSTARRED QUESTION NO:1419
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Production of Recombinant Vaccines
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Will the Minister of SCIENCE AND TECHNOLOGY be pleased to state:

a. whether the Government has any programmes for the production of recombinant vaccines indigenously; and
b. If so, the details and the present status thereof?

Answer

MINISTER OF STATE FOR SCIENCE & TECHNOLOGY AND EARTH SCIENCES
(Y.S. CHOWDARY)

(a & b) The Department of Biotechnology (DBT), M/o Science & Technology is supporting various R&D projects for development of recombinant vaccines such as Cholera, Dengue, Malaria, Tuberculosis etc. Under the aegis of Vaccine Grand Challenge Programme and INDO-US Vaccine Action Programme, the first indigenous live attenuated rotavirus vaccine called ROTAVACÂ® has been developed.

Further, the status of the R&D projects supported by the Department is as follows:

(i) Cholera Vaccine : DBT has supported development of an oral live recombinant cholera vaccine in India at National Institute of Cholera & Enteric Diseases (NICED), Kolkata The construct has been developed into a clinical product following cGMP by Shantha Biotechnics Pvt. Ltd. Phase I/II have been completed and the vaccine found to be safe and highly immunogenic. A large scale protection field trials are on anvil.
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(ii) Dengue Vaccine: The work has been supported at International Centre for Genetic Engineering & Biotechnology (ICGEB), New Delhi. Two promising candidates have been tested for protective efficacy in mice and continue to hold promise. The same needs to be further tested in primate models.

(iii) Malaria Vaccine: R&D activities have been supported at ICGEB for development of a recombinant combination blood stage vaccine for Plasmodium falciparum malaria (JAIVAC 2) and to develop a receptor blocking malaria vaccine against Plasmodium falciparum based on a novel combination of three blood stage antigens (JAIVAC 3). These studies are under exploratory phase and team is identifying the combination of antigens for development of vaccine candidates.

(iv) Tuberculosis Vaccine: Department has supported development of recombinant BCG85C strain at University of Delhi, South Campus. The team has succeeded in generating the BCG mutants, however, animal studies need to be undertaken.

2. Biotechnology Industry Research Assistance Council (BIRAC), a not for profit, Public Sector Undertaking of DBT, has supported projects for the production of recombinant vaccines like HPV, Pneumococal, H1N1 and Influenza. The status of these projects is as follows:

(i) HPV Vaccine : The vaccine development supported at M/s Serum Institute of India Ltd., Pune completed pre-clinical studies and the HPV vaccine supported at M/s Gennova Biopharmaceuticals Limited, Pune, is ready for pre-clinical studies.

(ii) H1N1 vaccine : The Pandyflu H1N1 vaccine developed by Panacea Biotec Ltd., New Delhi has been marketed.

(iii) Influenza vaccine: The research is at exploratory stage by Cadila Pharmaceuticals Ltd., Ahmedabad.

(iv) Pneumococcal Vaccine: The preclinical studies of 15 valent Pneumococcal conjugate Vaccine has been completed by Tergene Biotech Pvt. Ltd., Secunderabad is ready for clinical trials. Another 15-valent pneumococcal conjugate vaccine by Panacea Biotec Ltd., New Delhi is at exploratory research stage.
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