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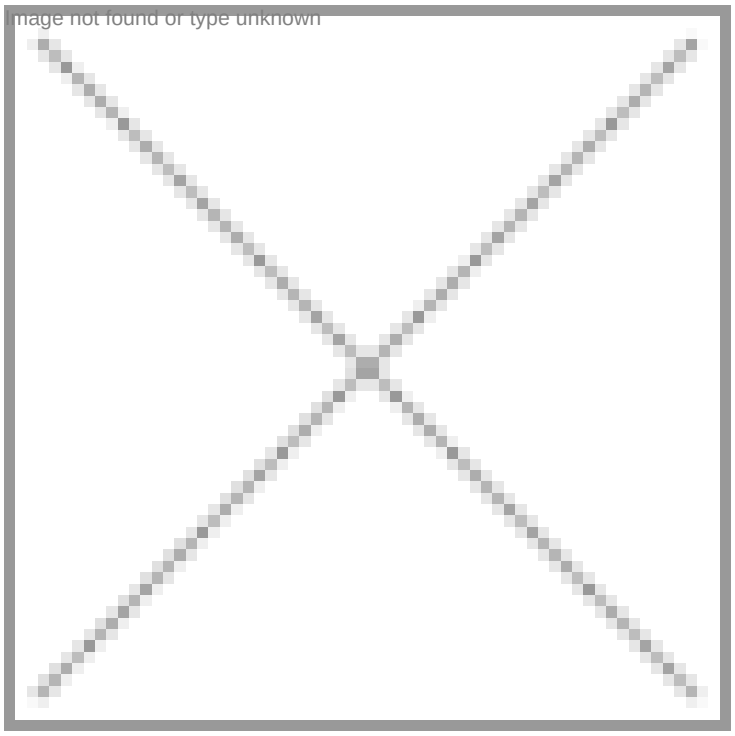
Poor funding crippling R&D

14 July 2006 | News



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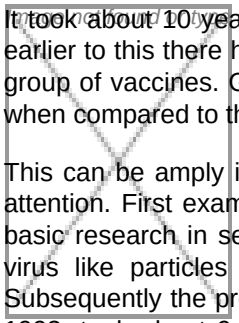

Varaprasad Reddy
MD, Shantha Biotechnics Ltd

It took about 10 years for India to emerge as a vaccineâ€“manufacturing hub for modern recombinant vaccines. Of course, earlier to this there have been Indian manufacturers who were well established in manufacturing traditional vaccines like DTP group of vaccines. Given the complexity in identifying and developing a vaccine candidate, ten years is not a very long time when compared to the history of global leaders in recombinant vaccine development and manufacture.

This can be amply illustrated from the history of development of two of the vaccines, which are currently attracting a lot of attention. First example is that of Human Papilloma Virus (HPV) vaccine for prevention of cervical cancer in women. Early basic research in several institutions worldwide, over a span of 10 years (1982-1992) had established that self assembled virus like particles (VLPs) of recombinant HPV L1 protein are the most appropriate candidates for a HPV vaccine. Subsequently the pre-clinical to clinical translation process for HPV vaccines by two leading companies, which began around 1993, took about 9 years to reach fruition. Same is perhaps the case with the development of the other vaccine, namely Rotavirus vaccine, for which again proof of concept information was available by as early as 1993 and further product and manufacturing process development followed by clinical testing have lead to the vaccine commercialization. It goes beyond saying that most of the crucial information for making both these vaccines was already patented or was being patented simultaneously.

Vaccine development

The history of development of vaccine for malaria or tuberculosis is long drawn, proven to be very tough and elusive. For a successful malaria vaccine, it is felt that inclusion of several antigens is required. The malaria vaccine initiative (MVI, a non-profit initiative at PATH), envisages evaluating dozens of vaccine candidates that have been identified and patented over the past decades by a variety of investigators. Further, a good adjuvant also may be needed. Therefore the MVI aims at forging in several partnerships and alliance to bring together different antigens, adjuvants and platforms together for bringing in a successful vaccine. Obviously, resolving patent issues will also be a major task. The issues with the development of an efficacious TB vaccine are also going to be similar and Aeras Global TB Vaccine Foundation is very active in this vaccine development.

Therefore the complexities that have to be faced by Indian companies for the development of any of the new generation vaccines including a TB or malaria vaccine are going to be much more. First, one has to steer clear of IPRs. Second, there doesn't seem to be substantial basic research to fall back on. Third, these being major public health issues, the support from government in terms of action plans and policies is not very forthright. Finally, getting into the development of these vaccines has to be in a mission mode and is investment intensive for a small to medium size company to sustain.

Other players

Besides our company in India, the other companies seriously working on vaccines are Serum Institute of India at Pune, Bharat Biotech International Ltd, Biological Evans and Indian Immunologicals Ltd at Hyderabad. All these companies are engaged in developing new vaccines like rotavirus, rabies, and malaria. To my knowledge, no initiative has taken place for development of vaccine against TB.

Research funding

There is an immense gap for research funding. Our venture capitalists in the country are not matured enough to invest into R&D on acceptable terms. Government support for R&D is very meager and the quantum of money they disburse to any company for R&D purpose is not exceeding $1â€“1.5 m. You will appreciate that any R&D for a new or even generic product will be in the range of $25â€“30 m.

Apart from this, one of the options would be to get involved in any of the global initiatives for new generation vaccines, if it ultimately leads to bringing in cost effective efficacious vaccine into our country. This would also need support and mediation of the government. Finally, in addition to the above-mentioned issues, lack of talented pool in some of the key areas is also a major concern. There is a dearth of quality and number of technically competent personnel available to the industry.