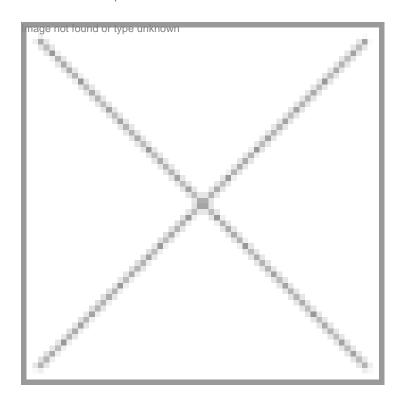
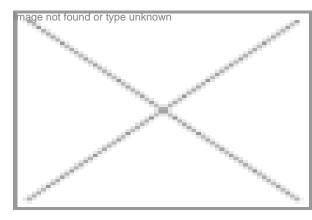


# A public sector success story

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Haffkine BioPharmaceutical Corporation Ltd, a BioSpectrum top 20 company, was the first in the country to successfully develop indigenous oral polio vaccine (OPV). The company has been increasing its turnover since 1997-98. Simultaneously it is also earning profits. In 2001-02 its sales reached a peak of Rs 86.2 crore against Rs 31 crore in 1997-98. And its profits have jumped from a mere Rs 9 lakh in 1997-98 to Rs 5.6 crore in 2001-02. Today the corporation is in a sound position as result of strategic planning and sustained efforts, which has resulted in appreciable increase in productivity and cost reduction. With the continued zeal and confidence of over 600 employees as well as the support of the Indian and Maharashtra government the corporation has been making profits and also announcing dividends to its employees every year from the past six years.

Initially set up as Plague Research Laboratory at Mumbai, it was later renamed as Haffkine Institute in 1925. In order to expand the production activities and to meet the growing demand for medicines and life saving drugs, Haffkine Institute was bifurcated by the state government in 1975 and the production activities were entrusted to Haffkine Bio-Pharmaceutical Corporation Ltd. Since then, the company has been playing a pioneering role in the development and production of a wide range of bacterial and viral vaccines Besides, the company has a farm and laboratory at Pimpri where antitoxins and sera for snake and scorpion venom, tetanus and diphtheria toxins are produced. It also formulates pharmaceutical products, disinfectants, ointments, injectables, syrups and mixtures at its unit at Mumbai. The company also has a well-equipped

animal house in Mumbai for breeding laboratory animals.

Its motto of "service to mankind in healthcare sector" has attracted many people to its campus during the pre- and post-independence era.

Haffkine BioPharmaceutical continues to focus on its core strengths since 1975, namely, oral polio vaccine, anti rabies vaccine and bacterial vaccines.

### Oral polio vaccine

The role of polio vaccine in protecting every newborn child against the dreadful disease has been long acknowledged. The erstwhile Haffkine Institute was the first to extend a helping hand with the supply of OPV for immunization of the masses. Instead of importing the vaccine from abroad as a finished product, it imported the concentrated bulk and blended the required vaccine for production in vials for mass scale immunization. This helped to save valuable foreign exchange. The company was the sole supplier of this vaccine in the country for many years. The production of OPV has been steadily increasing over the years till 1994. It was in 1996-97 that the Government of India took up the pulse polio immunization program on a national scale to eradicate polio in India. Accordingly, Haffkine increased the production of OPV to meet the demands of the Government. The company has also received orders for supplying OPV to UNICEF. The production of OPV is carried out in a well-equipped and modern state of art laboratory confirming to the WHO standards. The OPV batches are certified by an in-house quality control department and are also endorsed by the Central Drug Authority, Kasuali, in Himachal Pradesh before supply. The company has also obtained WHO-GMP certification for its OPV facility in1999.

In addition to OPV, Haffkine also manufactures Anti Rabies Vaccine (ARV) using sheep brain. The company now plans to come up with tissue culture ARV soon.

#### **Bacterial vaccine**

The bacterial vaccines manufactured at Haffkine are of the DPT group, namely, diphtheria, pertussis and tetanus (DPT). These components are produced individually and then mixed to give the required vaccines—DPT and DT absorbed on aluminium phosphate gel. Since the inception of the expanded program of immunization in 1978, Haffkine has been supplying increasing quantities of DTP vaccines. It has now proliferated into a key organization in the bulk biopharma production sector in India.

The corporation has come a long way, from the stationary culture method to the latest fermentation technology for processing all the three vaccines (DPT) in the group. The Indian Government has duly appreciated the participation of the corporation by way of grants through UNICEF.

#### **Diversification drive**

The corporation established a subsidiary in 1977, the Haffkine Ajintha Pharmaceuticals Ltd at Jalgaon, in collaboration with Western Maharashtra Development Corporation Ltd. The subsidiary produces tablets, capsules, powders, ointments, etc, which are mainly supplied to the hospitals and Maharashtra government institutions. It has obtained WHO certification for certain pharmaceutical products also. The WHO certification has greatly helped the organization to increase its export turnover.

With a goal of manufacturing and supplying quality health care products at reasonable prices, Haffkine is also looking at new projects. The company plans to undertake new projects and enter business alliances aimed at producing new vaccines and upgrading the technology of the existing products. This will ensure its long-term survival and continued sustained growth.

Haffkine has successfully completed a lyophilization project a Pimpri for improving (confirming to GMP-WHO standards) and expanding the production facilities of anti-snake venom. It has initiated action for manufacturing anti rabies vaccines based on tissue culture (TCARV) with the transfer of technology from Pasteur Institute of India, Coonoor. It has already procured seed virus strain to manufacture TCARV and is creating necessary facilities for developing and manufacturing TCARV. It is also planning to restart the manufacturing of anti rabies serum, which is essential to prevent rabies. The corporation is considering the feasibility of undertaking other new projects like plasma fractionation, etc. To effectively meet the challenges posed by the increasingly competitive and market driven economic environment, Haffkine is laying greater emphasis on upgrading the manufacturing facilities so as to conform to the GMP standards of WHO. The company has already obtained

WHO certification for its OPV product and efforts are on to obtain the same for the other existing products.

To develop new products and to effect qualitative improvement in the existing ones, special emphasis is being placed on inhouse R&D efforts.

To implement these projects the company has envisaged a total capital expenditure of Rs 80 crore, which is proposed to be financed through additional equity infusion, internally generated funds and term loans from banks/financial institutions.

### Looking at brighter days

With the mission to serve mankind, Haffkine BioPharmaceutical has prepared an action plan. This aims to focus on the company's strengths, overcome the present weaknesses and take maximum advantage of the opportunities available while effectively face the threats of the external environment in order to ensure continued existence and sustained growth. The dedicated workforce, an able leader to guide the organization, strong implementable strategies will definitely help Haffkine BioPharma-ceutical to lead the path of profit in the years to come and serve mankind.

Narayan Kulkarni

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Medha Gadgil, who is heading Haffkine BioPharmaceutical Corporation as managing director, belongs to the 1983 batch of the Indian Administrative Services, where she was the topper amongst girls and secured the 6th rank in the all India merit list. Her interest in the health care sector led her to set up the Maharashtra State AIDS Control Society as project director in 1998. In an interview to BioSpectrum, she talked about her strategy to take Haffkine BioPharmaceutical to new heights.

Haffkine is doing very well compared to other public sector biopharma companies like Hindustan Antibiotics and Indian Vaccines Corporation. What is the secret of your success?

We have a history of over 100 years. We have been concentrating on our core strength, i.e., the Oral Polio Vaccine (OPV). Over 75 percent of our revenue is from this vaccine. We are the key suppliers of OPV to the Indian government for its immunization program. Besides, we are manufacturing anti sera for snake and scorpion venom, injectables, capsules, oral liquid products, antiseptics and pharmaceutical drugs through our subsidiary called Haffkine Ajintha Pharmaceuticals. Our success is mainly due to a combination of factors like strong government support, support from our dedicated employees and taking the right step/initiative at the right time.

India, being a signatory to the World Trade Organization treaty, will implement product patent regime by 2005. As Haffkine is producing bulk biopharmaceutical drugs with imported vaccines, what is your strategy for the product-patent regime?

We are importing the OPV from Indonesia, blending it and mass-producing it in Mumbai for the benefit of the general public. So far we have not thought about this. We will think about it and take it very seriously as to how to tackle this problem.

#### What is Haffkine's investment in R&D activities?

Haffkine BioPharmaceutical was bifurcated from Haffkine Institute in 1975 to manufacture vaccines in bulk. It is purely a manufacturing company. We continue to do so. I do agree that R&D is very essential for an organization. As of now Haffkine Institute is doing R&D work. We are exploring the possibility of investing in our own in-house R&D activities.

#### Is Haffkine exporting its biopharma products?

We are exporting serum vaccines to Sri Lanka where there is good demand for our sera products. At present we are selling OPV mainly to the Indian government for the immunization program. But we are working for an accreditation, once we get that we will export OPV to other countries.

## Are there any significant problems that Haffkine is facing and how do you plan to overcome them?

Right now we are in comfortable position but at the same time we are concerned about the future of the organization. The main problem for Haffkine is where to go from here? It is time for us to do some serious thinking. To sustain and grow in the industry we have to change the strategies that we have been following over the years. Now we are concentrating on working on new diversified projects.