



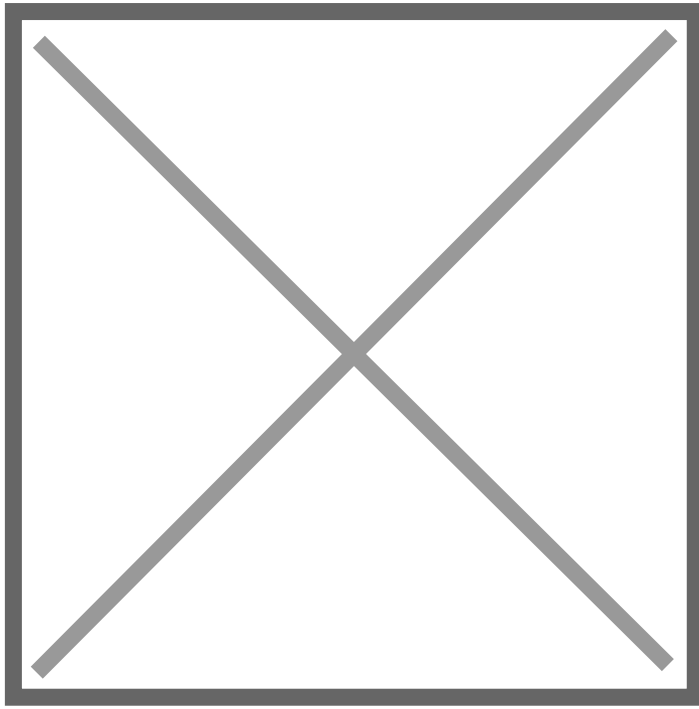
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Demand for animal biologicals on the rise

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Demand for animal biologicals on the rise

Although India has been exporting animal biologicals, in some areas it is looking at imports to meet the growing demand. The potential is huge as the animal biologicals market is growing at the rate of 15 percent against animal healthcare market of seven percent. With government support, the private sector is keen on entering this space to bridge the gap between supply and demand.

Only humans can benefit from medical biotechnology is a myth. Now even animals stand to benefit. As against another myth that animals are being exploited by applying biotechnology on them. Researchers and scientists are working to produce biotech products for the well-being of animals. And they have been successful in developing many animal biotech products. The health of all animals including companion, better known as pets, can be significantly improved through the use of biotech vaccines, such as the rabies vaccine, and new diagnostic tests that can identify things such as feline HIV. Domestic farm animals can greatly benefit from biotechnology through vaccines and diagnostic tests. Improved breeding programs enhanced by biotechnology can drastically improve herd health by eliminating hereditary diseases. Reproduction and breeding techniques influenced by biotechnology, such as in vitro fertilization, artificial insemination can even save endangered species by restoring shrinking populations.

Government Initiatives

Animal wealth in India has increased manifold and animal husbandry practices have changed to a great extent following the introduction of newer technologies particularly for crossbreeding and upgradation of indigenous breeds. More recently, with the liberalization of trade after the advent of World Trade Organization's Sanitary And Phytosanitary (SPS) agreement, the chances of ingress of exotic diseases into the country have increased. For ensuring disease-free status and to be compatible with the standards laid down by the Office International des Epizooties (OIE) - World Animal Health Organization, major health schemes have been initiated to support animal health programs in the states.

Further, in order to control the economically important livestock diseases and to undertake the obligatory functions related to animal health in the country, the Central government is implementing a centrally sponsored macro-management scheme called "Livestock Health and Disease Control". The scheme is being implemented with an outlay of Rs 525 crore. The Scheme has several components - Assistance to States for Control of Animal Diseases (ASCAD), National Project on Rinderpest Eradication (NPRE), Foot and Mouth Disease Control Program (FMD-CP) and Professional Efficiency Development (PED).

During 2005-06, the department of animal husbandry, ministry of agriculture, allocated about Rs 99.95 crore for livestock health. The outlay includes Rs 55 crore for animal disease control, Rs 7 crore for National Project on Rinderpest Eradication,

Rs 2.95 crore for professional efficiency development and Rs 35 crore for Foot and Mouth Disease Control Program.

For control of major livestock and poultry diseases by way of prophylactic vaccination, the required quantity of vaccines are produced in the country at 26 veterinary vaccine production units. Of these, 19 are in the public sector and seven are in the private sector. Import of vaccines by private agencies is also permitted as and when required. According to the annual report 2004-05 of the department of animal husbandry, ministry of agriculture, a network of 26,540 polyclinics, hospitals and dispensaries and 25,433 veterinary aid centers, supported by about 250 disease diagnostic laboratories, are functioning in the states and union territories for quick and reliable diagnosis of diseases.

The Department of Biotechnology (DBT) has also been funding many projects on animal biotechnology. During 2004-05, the DBT renewed 25 ongoing projects and 12 completed projects were also reviewed for their achievements. Besides it looked into proposals for 31 new projects for financial support. There is also a proposal to set up an autonomous institution for animal biotechnology.

Biotechnology provides new tools for improving animal health and increasing livestock and poultry productivity. This technology helps in increasing production of milk and meat. As noted earlier, biotechnology has potential applications in the management of several animal diseases such as foot and mouth disease (FMD), classical swine fever and bovine spongiform encephalopathy. The most important biotechnology-based products consist of vaccines, particularly genetically engineered or DNA vaccines.

The improvements in these areas come from the enhanced ability to detect, treat and prevent diseases and other problems. Additionally, feed from biotech crops are better designed to meet the dietary needs of different farm animals, improve feed efficiency and reduce waste. Just like other assisted reproduction techniques such as artificial insemination, embryo transfer and in vitro fertilization, cloning can also significantly improve animal breeding programs and decrease the occurrence of hereditary diseases and improve the health of animals.

Biotech-based products to treat heartworm disease, arthritis, parasitic infections, allergies and heart disease as well as vaccines for rabies and feline HIV are used by veterinarians regularly. Companion animals benefit greatly from vaccines and diagnostic tests based on biotechnology. Gene therapy has also been used to help restore sight to blind dogs as well as for melanoma, canine lymphoma and bone cancer. Some biotech companies offer DNA sequencing of pure bred animals, such as dogs, for identification purposes. Gene therapy for diseases of pet animals is a fast developing area because many of the technologies used in clinical trials humans were developed in animals and many of the diseases of cats and dogs are similar to those in humans.

Institutions Involved in Manufacturing

A list of institutions
involved in
manufacturing
vaccines and other
biological products
for use on cattle

~ Institute of
Animal Health &
Veterinary
Biologicals,
Biological Products
Div, Calcutta
Institute of
Veterinary
Biologicals,
Lucknow

~ Indian
Veterinary Research
Institute (IVRI),
Biologicals Products
Div, Izatnagar

~ Institute of
Veterinary
Preventive
Medicine, Ranipet

~ Regional
Veterinary Biological
Unit, Jaipur

~ Punjab
Veterinary Vaccine
Institute, Ludhiana

~ Orissa
Biological Products
Institute,
Bhubaneswar

~ Institute of
Veterinary Biological
Products, Pune

~ Institute of
Animal Health &
Veterinary
Biologicals, Mhow

~ Institute of
Animal Health &
Veterinary
Biologicals,
Thiruvananthapuram

~ Institute of
Animal Health &
Veterinary
Biologicals,
Bangalore

Transgenic technologies are used for improving milk production and the meat in farm animals as well as for creating models of human diseases. Transgenic animals are used for the production of proteins for human medical use. Biotechnology is applied to facilitate xenotransplantation from animals to humans. Genetic engineering is done in farm animals and nuclear transfer technology has become an important and preferred method for cloning animals.

Market scenario

According to reports, the worldwide sales of biotech-based products for use in animal health generated \$2.8 billion in 2003 (out of a total market for animal health products of \$18 billion). The share of biotechnology-based products and services in 2004 was \$4.1 billion out of the total animal healthcare market of \$21 billion. This is expected to grow to \$5.1 billion by the year 2005 in a total animal healthcare market of \$23 billion. Animal biotechnology market is projected to be worth \$12.5 billion by the year 2010. According to USDA, there are different licensed biotech products available for animals. These products include veterinary vaccines, biologics and diagnostic kits. The animal health industry invests more than \$400 million a year in research and development.

According to KV Balasubramaniam, managing director, Indian Immunologicals Ltd, the global animal biological market is one sixth of the animal health market of \$18 billion. And it is growing at 7 percent against the animal health market growth rate of 2 percent. In India, the animal healthcare market is Rs 1000 crore growing at the rate of 10 percent. The major segments include cattle (45 percent), poultry (40 percent), canine (6 percent), sheep (4 percent) and others (5 percent). The animal biological market in the country is one fifth of the health market (Rs 200 crore) but it is growing faster than the health market at 15 percent. Segments in animal biologicals include cattle 42 percent, poultry (45 percent), canine (7 percent), sheep (3 percent) and others (3 percent).

There is relatively higher growth of vaccines in animal health market in India due to new initiatives undertaken by government for control of animal diseases, progressively more emphasis on prophylaxis. Strong domestic industry with technology capabilities and sound cost structure has supported the growth of animal biologicals market. Hence Balasubramaniam said, "We see more of exports (Rs 20 crore) with little of imports (Rs 10 crore)."

However, Prof S Krishnaswamy, chairman and managing director, Animal Biotech (Bangalore) Ltd, said, "Typically there are not many biotech products in India for animal healthcare application. The total market for pharma products for animal health is about Rs 1000 crore as per the ORG report. But most of these are antibiotics, anti-bacterials, vitamins and minerals. A GMO product developed by Sumitomo - somatotrophin (Bovine Growth Hormone) was introduced in India but there were no takers owing to high cost.

Sharing similar views, Alok Gupta, country head, life sciences and biotechnology, YES Bank Ltd, said, "The animal health care market is about Rs 1000 crore with growth rate of 8-10 percent. Besides specialized companies like Intervet India, Fort Dodge, an animal health division of Wyeth, ABIC, Merial, Venkateshwar Hatcheries, Serum Institute, big pharma companies such as GlaxoSmithKline, Pfizer, Novartis, Zydus Cadila, Alembic, Intas, Wockhardt have presence in the animal health care market."

Prof S Krishnaswamy further said, "The other sector in animal biotech market is vaccines that is primarily for poultry and foot and mouth vaccine for cattle. These are produced by companies in private sector and vaccines for large animals are mainly produced by government agencies. The size of the vaccine market is over Rs 400 crore. Venkateswara Group and Srin Biologicals dominate poultry vaccine market. They have a captive market. Other important vaccine manufacturers are Indovax located at Hissar that has collaboration with Vineland, USA."

Rajiv Gandhi, managing director, Hester Pharmaceuticals Ltd, which is mainly into poultry vaccines but eager to enter animal biologicals space, said, "Licensed biotech products for animals would include vaccines, enzymes, and growth promoters. Vaccines for poultry, dogs, cattle are manufactured in India besides many which are imported."

According to Gandhi, the Indian poultry vaccine market is about Rs 150 crore. Manufacturers of poultry vaccines include Hester Pharmaceuticals (market share 10 percent), Venkateswara Hatcheries (group company of Western Hatcheries - 50 percent) and Indovax (9-14 percent). Imported vaccines meet the rest. Intervet does imports from parent company, American Home Products and Zydus Sarabhai from ABIC, Israel. He said, "Except one or two types of poultry vaccines, all are locally manufactured."

Sharing his views on animal healthcare market, Gandhi said, "The animal healthcare industry in India has been increasing. In 2000 it was about \$200 million, \$215 million in 2003, \$230 million in 2004 and in 2005, it is estimated at \$246 million.

Quoting the latest report of CLFMA of India, an Association of Livestock Industry, Dr Ashish Mohapatra, general manager - sales, Intervet India said, "The animal healthcare market is Rs 1,350 crore. There are 250 companies in this space. The market is growing at 8-10 percent. Although biologics contribute about 15 percent (i.e. about Rs 200 crore) of the animal healthcare market, it is growing at the rate of 25 percent. The biologics market can be mainly classified into poultry vaccine, (63 percent), cattle (FMD vaccine - 24 percent) and vaccine for companion animals (13 percent). Poultry contributes Rs 128 crore, cattle sector (Rs 47 crore) and pet animals sector (Rs 25 crore). Besides the private sector, there are many organizations in co-operative or public sectors. These are running at no profit—no loss basis. "However, Bharat Tandon, chairman, CLFMA of India said, "The Indian animal biological market is about Rs 400-500 crore. The major contribution is from the public and cooperative sectors. The public sector mainly consists of the government institutes as all the state governments have one or two veterinary institutes to manufacture the basic vaccines for large animals like sheep, goat and cattle. These institutes supply animal biologicals at very nominal price or free to farmers. Hence it is difficult to calculate the exact size of the animal biologicals market. Besides there are companies in private sector too. It accounts to about Rs 200 crore."

"In large animals the leading names include Indian Immunologicals, Intervet, and BAIF group. In poultry space we have VH group, Hester Pharmaceuticals, Indovax, and in the companion sector, the leading names include Intervet, Serum Institute, GlaxoSmithKline, the Sarabhai. Most of the vaccines for pets are imported and supplied through distributors. The market is small compared to the other two segments. The market is picking up and growing at the rate of 10-12 percent," said Bharat Tandon.

Besides vaccines, according to USDA, animal biotech products include bacterins and bacterial extracts, antibody products, vaccines with bacterins/bacterial extracts/toxoids, diagnostic products, antitoxins and bacterin-toxoids.

Veterinary Biological Products

No. of licensed veterinary biological products available globally include:

~ Vaccines (155)

~ Bacterins and bacterial extracts (106)

~ Antibody Products (19)

~ Vaccines with bacterins/bacterial extracts/toxoids (185)

~ Diagnostic products (86)

~ Antitoxins (8)

~ Bacterin-Toxoids (54)

~ Toxoids (11)

~ Miscellaneous (11)

Source:
www.aphis.usda.gov

Molecular diagnosis is another area that is assuming an important place in veterinary practice. Polymerase chain reaction and its modifications are considered to be important. Fluorescent in situ hybridization and enzyme-linked immunosorbent assays are also widely used. Newer biochip-based technologies and biosensors are also finding their way in veterinary diagnostics.

"Other areas of 'biotech' products include feed enzymes and probiotics. Recent entrants in this space include Advanced Biochemicals and Lumis Biotech who are into feed enzymes. There are many formulators and leading among them is Bangalore-based Vetcare. Wockhardt, Dabur are also vet product formulators. Natural Remedies, Himalaya and a few others make botanicals, plant-based bioproducts but these are not biotech products. Future products should include hormones (GMO), DNA vaccines and transgenic products from animal sources," said Prof. S Krishnaswamy.

In India, we find more of fundamental/basic vaccines for poultry and large animals such as FMD Vaccine, Gumboro vaccine-IBD, new castle disease vaccine, mareks vaccine, rabies vaccine and canine multi component vaccine and not other biologicals including the diagnostic kits. Balasubramaniam of Indian Immunologicals said, "Therapeutic and diagnostic products are almost non-existent in India."

Bharat Tandon, chairman, CLFMA of India, informed, "The market for diagnostic kits for animals in India has picked up but price is the main reason for the sluggish growth. Besides we don't have more experts to do the tests. However, a few professors at veterinary colleges and government doctors who do private practice, are doing the tests. Their number is also limited and restricted to a few regions like coastal Maharashtra, Gujarat and Andhra Pradesh."

Brighter outlook

There are about 30 companies in animal biologicals both in public and the private sector. However, only a handful of companies are exporting vaccines. Still in some areas, India has to look at imports to meet the demand. India has imported 445 kg of anti serum in 2004-05 and exported 71.9 kg in 2004-05. Similarly the country imported 1200 vials of insulin in 2004-05. In 2004-05, India imported vaccines to the tune of - 68,70,000 /700 (vials/unit/doses) and also exported 3,30,950 vials/unit/doses. (These figures are up to October 31, 2004). The opportunity is opening up further. The government has been making efforts to bridge the gap between supply and demand.

Dr S B Tatavarthy, deputy commissioner, department of animal husbandry, government of Maharashtra said, "There is manifold increase in the demand for vaccines after the Indian government launched a nationwide vaccination program and FMD control program to make "disease-free zones". The government institutes cannot fulfil the growing demand. Government agencies are supplying vaccines free of cost to the farmers."

Foot and Mouth Disease has been widespread in India, creating massive economic losses at all levels. Its existence in India is not only limiting beef export opportunities but also hitting the farmers hard as milk production in FMD infected animals is drastically reduced. So the government of India has earmarked FMD control as a top priority and has put in place livestock improvement programs. A FMD eradication program has been in place in the western part of the country, comprising mandatory vaccination of 40 million animals annually for a period of five years. Once completed, the region will be declared a "disease free zone". Eventually "disease free zones" will be extended to the entire country.

Biologicals and Manufacturers

Major animal biologicals available in India

• FMD vaccine (cattle & sheep)

• Gumboro vaccine-IBD (poultry)

• New castle disease vaccine

• Mareks vaccine

• Rabies vaccine (cattle & canine)

• Canine multi-component vaccine

Leading players in animal biologicals in India include:

• Fort Dodge

• Hester Pharma

• Indian Immunologicals Ltd

• Intervet

• Indovax

• Ventri Biologicals

• Zydus Cadila

To prevent economic losses due to FMD and to develop herd immunity in cloven-footed animals, FMD Control Program is being implemented in 54 specified districts of the country in the first phase with 100 percent central funding as cost of vaccine, maintenance of cold chain and other logistic support to undertake vaccination. The state governments are providing other infrastructure and manpower. Five rounds of vaccinations will be done during the tenth plan and the allocation for this is around Rs 200 crore. About 1500 lakh vaccinations will be carried during the five rounds of vaccination. About 270 lakh vaccinations have been carried out under this program during the first round in 2003-04 and about 550 lakh vaccinations are expected to be carried out in second and third round.

International players' presence in India

Intervet	Akzo	Nobel
(American Home Product)	Fort Dodge	
Cadila)	ABIC	(Zydus)
(Ranbaxy)		CEVAC
Merial		(Hester Pharma)
Factro		(Stellan)
TAD		(Indo Bio Care (IBC))

"Given the fact the current players are unable to fulfil the existing demand, there is an opportunity for 2-3 players in the market. This sector is a highly technical venture in terms of people and regulatory compliance. High entry cost barriers deters other small time players to enter this segment," said Gandhi of Hester Pharmaceuticals.

Elaborating further on the opportunity, Bharat Tandon said, "There is a gap in supply and demand for large animals mainly in FMD. Hence companies are looking at entering this space." However, he observed that the government agencies have an edge over private players in this space in terms of reach as they have a very good network to reach to the micro levels.

Gandhi believes that the animal biotech market has a good future. Reasons being, India is an emerging market. Demand for all products is going up. It is the biggest milk producer in the world and the fifth largest egg producer in the world. The current market in all sectors is becoming more competitive globally. India with a vast land mass and a huge population, does provide a good market.

Companies like Bharat Biotech, one of the leading names in human biologics, Brilliant Industries, mainly into pet vaccines, Venkateshwara Hatcheries and Hester Pharmaceuticals which is mainly into poultry vaccines are entering the large animal vaccine.

Narayan Kulkarni