

Giant French Lab Creates Cheaper Drugs for Brazil and South

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In his address to the closing plenary session of BioVision - the World Life Sciences Forum - Jean-Francois Dehecq, Chairman and CEO of France-based sanofi-aventis, set out the guiding principles of his Group's strategy in its Policy of Access to Medicines in the "Southern Countries."

At a time when 80% of the world's population has little or no access to the most basic medicines, particularly in the Southern countries in which there are no public healthcare systems, the sanofi-aventis Group has pledged concrete action to make access to healthcare a key element of its strategy.

In order to meet this major public health challenge, sanofi-aventis is committed to making products available to populations of the Southern countries at tiered prices, geared to the incomes of the populations concerned.

"With innovative, profit-generating products and large-scale industrial facilities, the Group can play its part in this public health initiative by providing concrete responses for the Southern countries," stated Jean-François Dehecq.

The Group has identified six therapeutic areas for which concrete solutions can be envisioned: five curative therapeutic fields - malaria, leishmaniasis, sleeping sickness, tuberculosis and epilepsy - as well as the preventive field of vaccines.

In conjunction with UNICEF, GAVI (Global Alliance for Vaccine and Immunization) and the Vaccine Fund, Sanofi Pasteur, the vaccines business of the sanofi-aventis Group, practices a tiered pricing policy on a large number of vaccines: oral polio vaccine, measles, Diphtheria-Tetanus-Polio, antimeningococcal vaccine, Measles-Mumps-Rubella, yellow fever and Diphtheria-Tetanus-Polio - Haemophilus influenzae B.

"These initiatives are part of a pro-active strategy rooted in the long heritage that makes up the sanofi-aventis Group today: Sanofi-Synthelabo, Rhone-Poulenc, Roussel, Merieux, Lepetit, Pasteur, Hoechst..." added Mr. Dehecq.

"Most of all, however, this is our duty as the world's third largest pharmaceutical group, founded on strong innovation, determination to maintain competitive industrial facilities and continued support for mature products," he concluded.

Malaria

A specific program known as Impact Malaria has been rolled out, focusing on four key areas:

- * Research & Development of new families of compounds
- * Setting up new therapeutic strategies based on existing products
- * Making suitable products available at tiered pricing
- * Setting up training, education and communication programs about the disease.

R&D

In the Group's Research division, in partnership with universities and the Inserm units in Lille, Montpellier and Toulouse, three new projects are currently under evaluation.

New therapeutic strategies

WHO recommends use of an artemisinin derivative in combination with a standard antimalarial drug to treat malaria attacks. The Group chose a co-formulation of artemisinin+amodiaquine known as Arsucam which is now licensed in over 15 African countries. Although presented in co-blister format, this product meets clinicians' requirements with formats suitable for adults, children and infants.

In order to improve use of the treatment and patient compliance, however, the sanofi-aventis Group recently signed an agreement with DNDi (Drugs for Neglected Disease initiative) to co-develop a fixed-dose combination of the two active ingredients in a single tablet, thereby reducing the treatment from eight tablets per day to just three tablets per day for three days.

Making suitable products available at tiered prices

All these medicines are or will be available at a "no profit no loss" price to the public sector, international organizations fighting malaria, non-governmental and religious organizations.

Africa also has a private market operating through retail drugstores which have always stocked both standard-priced products and products at "no profit no loss" prices, as part of the access-card to antimalarials (CAP) program.

By bringing down pharmacists' and wholesalers' margins, the price of antimalarial drugs can be reduced by over 70%. Families with limited resources are issued with cards by pharmacists entitling them to buy these products at the lowest prices.

The program is currently in operation in Cameroon, Gabon and Madagascar and is set to be extended to Sub-Saharan Africa.

Information, education and communication programs

Antimalarial drugs are only a part of the fight against the disease. Education and general information about the disease, how it is transmitted and how to fight the proliferation of vectors also represent the added value that the Group can provide "at the end of the line," to patients.

Leishmaniasis

This transmissible parasitic disease, carried by a small fly named the phlebotomine sandfly, exists in three forms: cutaneous leishmaniasis, mainly present in the Middle East and Mediterranean basin, mucocutaneous leishmaniasis, present throughout Latin America including Brazil, and visceral leishmaniasis, or Kala Azar, present in the Indian subcontinent, Brazil, Ethiopia, Eritrea and Sudan.

There is no prophylactic treatment available. Sanofi-aventis produces two curative treatments: Pentamidine (pentamidine mesylate) and Glucantime (meglumine antimoniate).

Sanofi-aventis produces 5 million ampoules of Glucantime a year. The Group is pursuing a volume-oriented policy and centralizing its production in order to substantially reduce the cost of the drug to certain countries so that a greater number of sufferers can be treated.

Sleeping sickness

In 2001, the Group signed a five-year US\$ 25 million partnership agreement with WHO.

There are three planks to the program:

* Supply of drugs: the three active drugs currently available to fight the disease are produced by the Group:

- Pentamidine (pentamidine mesylate)
- Arsobal (melarsoprol)
- Eflornithine (difluoromethylornithine)

* Disease monitoring and control: screening must be systematic and is carried out by mobile teams touring the populations. Over \$1.5 million is devoted to this plank of the program every year, with:

- An increase in the numbers of mobile teams visiting villages in remote areas where the disease is endemic.
- Mapping of the areas with a high concentration of cases and monitoring of the geographical spread of the disease.
- Regional and cross-border cooperation between various national programs: 19 countries have already benefited from these actions.

* Research and Development: there is a clear need for new medicines, and above all for treatments that are more easily administered. These R&D efforts are being carried out in conjunction with the Special Program for Research & Training in Tropical Diseases (TDR) and WHO.

Sanofi-aventis is the only industrial partner engaged in the fight against this disease.

Tuberculosis

Sanofi-aventis is a key supplier of Rifampicin (one of the basic treatments for tuberculosis). The Group is committed to making Rifampicin affordable on retail markets in the Southern countries by restructuring and streamlining its industrial policy.

More specifically in South Africa, sanofi-aventis markets a combination of four anti-tuberculosis drugs in a single tablet, Rifafour (rifampicin + isoniazid + ethambutol + pyrimethamine). The combination makes for better patient compliance with treatment. After approval by WHO, this product could be distributed in other countries.

As with malaria, education and awareness concerning the disease play a crucial role. In South Africa, sanofi-aventis has joined forces with the Nelson Mandela Foundation and local health authorities in launching a program to train DOTS (Directly Observed Treatment Short-course) supporters - reflecting the fact that one of the keys to successfully fighting this disease is ensuring full compliance with the course of treatment (which lasts six months on average).

The partnership initiated in South Africa will enable nine training centers to be built (one per province), of which four are already operational. By completion, the program will have produced 100,000 trained DOTS supporters, enough to monitor 1 million patients. This program, for which the Group provided \$15 million in funding, will be completed in 2008 and its ambition is to serve as a model for other countries where the disease is endemic.

Epilepsy

There is little awareness of this disease in Southern countries, although it poses a major public health problem. In many countries, the physical symptoms associated with the disease mean that the sufferer is seen as bewitched or possessed by spirits, as a result of which they are marginalized or even excluded from their communities.

Before epileptics can be treated, health workers have to be made aware of the existence of the disease and how it can be managed. Only then can effective treatment be instituted.

Sanofi-aventis has launched a training program in Mali in collaboration with the NGO Sante Sud. Once the training is complete, valproic acid will be made available to health workers at a "no profit no loss" price. This is a pilot program that will subsequently be extended to other Southern countries.

Vaccines

Sanofi-aventis, through Sanofi Pasteur, is the leading producer of vaccines worldwide.

Vaccination made it possible to eradicate smallpox, a scourge that has taken a heavy toll in human life. Poliomyelitis should be the second disease to be eradicated in the near future.

Sanofi Pasteur is the leading producer worldwide of oral poliomyelitis vaccine, and is participating in this effort by donating 120 million doses to the eradication program (WHO-Unicef-Rotary).

A monovalent oral vaccine against type 1 polio - Monovalent Oral Polio Vaccine 1 or mOPV 1 - recently received approval in France. Once the vaccine is licensed by Egypt's National Organization for Drug Control and Research, a mass immunization campaign will be launched in Egypt, where only the type 1 virus remains in circulation. Since poliovirus types 2 and 3 have already been eliminated in Egypt, WHO is hoping to put an end to the transmission of polio by the end of this year.

A vaccine for dengue is currently being developed, with the aim of eradicating this disease endemic to Asia, Latin America, the Caribbean and Polynesia.

In 2006, an antimeningococcal vaccine active against the W-135 strain (present in sub-Saharan Africa and the Arabian Peninsula) will be made available to the health authorities at a price of less than \$1 per shot.

About sanofi-aventis

Sanofi-aventis Group is the world's 3rd largest pharmaceutical company, ranking number 1 in Europe. Backed by a world-class R&D organization, sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic disorders, central nervous system, internal medicine, and vaccines.

The sanofi-aventis Group conducts business in the U.S. through its affiliates Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals Inc.

Sanofi Pasteur, the vaccines business of the sanofi-aventis Group, sold 950 million doses of vaccine in 2004, making it possible to protect more than 500 million people across the globe, which is about 1.4 million per day. The company offers the broadest range of vaccines, providing protection against 20 bacterial and viral diseases.

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