The Brazilian vaccine manufacturers’ perspective and its current status

Akira Homma*


Received 2 February 2009; accepted 2 February 2009

Abstract

This article aims to give an overview of the current situation and perspectives for the Brazilian vaccine manufacturers, who play strong roles for developing countries in this field.

The research, development and production of immunobiologics in Brazil, especially vaccines for human use, is mainly supported by governmental institutions linked to the Ministry of Health as part of a strategy that prioritizes the public sector for access to vaccines and other biologicals that are regarded essential for the population.

As a result, 83% of the vaccines required in 2007 were provided by national vaccine producers and only 17% were imported, mainly to reference centers for special vaccines that were used for special patients. Moreover, the country has actively exported yellow fever vaccine since 2002 and meningitis AC vaccine since 2007, having covered more than 60 nations.

The perspectives have positively increased due to the government’s policy of making internal investments, not only to avoid the external dependence of products for public health, but also to strengthen the Brazilian industrial sector related to biotechnology.

© 2009 The International Association for Biologicals. Published by Elsevier Ltd. All rights reserved.

Keywords: Biotechnology; Health; Innovation; Vaccine manufacture

1. Introduction

The trilogy research, development and innovation in Brazil is receiving high priority as a governmental initiative, which adopted it as one of its main policies, as well as the decision to strengthen the country’s technological capacity.

This initiative involves the integration of research, development and innovation policies and the definition of priorities by the Ministry of Science and Technology, the Ministry of Development, Industry and Foreign Trade, the Ministry of Agriculture, Livestock and Supply and the Ministry of Health. This includes the ranking of subjects, new sources of financing (from the National Bank of Social and Economic Development), and the incentive to promote public–private partnerships.

Relative to biotechnology, there are 181 companies operating in the field of biosciences in Brazil, from which 39.4% are related to the health area (21.1% human health; 18.3% animal health) and 19.6% to inputs areas [1].

In this regard, it is important to identify three main actors focused on human health:

(a) The Immunobiological Technology Institute/Bio-Manguinhos, from the Oswaldo Cruz Foundation/Fiocruz

---

* Tel.: +55 21 3882 9305; fax: +55 21 2564 2344.
E-mail address: akira@bio.fiocruz.br

---

Abbreviations: Anvisa, the Brazilian NRA (Agência Nacional de Vigilância Sanitária); BNDES, Brazilian National Bank of Social and Economic Development; DT, diphtheria and tetanus; DTP, diphtheria, pertussis and tetanus; DTP + HB + Hib, diphtheria, hepatitis b, pertussis, tetanus and Haemophilus influenzae type b; DTP + Hib, diphtheria, pertussis, tetanus and Haemophilus influenzae type b; FINEP, projects and studies financier, from the Brazilian Ministry of Science and Technology; FNDCT, Technological and Scientific Development National Fund; FUNTEC, "Tecnopolis" Development Foundation; HBV, hepatitis b vaccine; HPV, human papilloma virus; IABS, International Association for Biologicals; INCQS, the Brazilian NRL (Instituto Nacional de Controle de Qualidade em Saúde); MoH, Ministry of Health; NRA, national regulatory authority; NRL, national regulatory laboratory; OPV, oral polio vaccine; PNI, Brazilian National Program on Immunization (Programa Nacional de Imunização); PROFARMA, support program to the development of the health industrial complex.

© 2009 The International Association for Biologicals. Published by Elsevier Ltd. All rights reserved.
(MoH), which develops and produces vaccines (such as: DTP + Hib, meningitis AC, OPV, triple viral, yellow fever), reagents for laboratory diagnosis (rapid test, Elisa, immunofluorescence for various diseases) and bio-pharmaceuticals (erythropoietin, interferon alfa 1b), especially for the national health programs;

(b) The Butantan Institute (São Paulo State laboratory), also in charge of developing and producing vaccines (DTP, DT, HBV, influenza) for the public system, and immune serum (anti-snake, anti-toxin); and

(c) Hemobrás (State enterprise), focused on the development and production of hemoderivatives (factor VIII, factor IX, albumin).

The Brazilian vaccine manufacturers’ perspective is very positive, because it relies on the National Immunization Program (PNI), which is considered one of the best and most complete among emerging countries. Due to its high vaccination coverage, the incidence of all vaccine-preventable diseases is very low, and there are neither poliomyelitis cases caused by wild virus since 1989, nor measles autochthonous cases since 2000, as per Fig. 1 (Incidence of poliomyelitis and immunization coverage with the OPV in the National Immunization Campaigns, Brazil, 1968–2005) and Fig. 2 (Incidence of measles and immunization coverage with the measles vaccine in national immunization campaigns, Brazil, 1980–2005).

Brazil places a strong emphasis on vaccine production. The two main institutes, Fiocruz (founded as “Serotherapeutic Federal Institute”) and Butantan Institute, were created in 1900. Since then, both are continuously strengthening their structure and production activities. Since 1982, the only private multinational vaccine and antiserum manufacturer locally established, which had 90% of the market, stopped biological production activity in Brazil after the MoH’s request to strengthen their quality control system. For the private market, there are many multinational representatives importing vaccines and supplying them to private immunization clinics.

Brazil also has shown its strength as an immunobiologicals producer through the export of yellow fever and the meningitis AC vaccines after their pre-qualification by the World Health Organization, in 2001 and 2007, respectively. This international activity has now surpassed 60 countries and 100,000,000 doses [2].

2. Materials and methods

This article was developed through an analytical evaluation of official conferences, meetings and published papers in the related area [3–5] from the Brazilian Government, especially from the Ministry of Health and the Immunobiological Technology Institute of the Oswaldo Cruz Foundation (Bio-Manguinhos/Fiocruz).

The author himself has a vast experience in the immunobiologicals field, achieved during many years of activity at Fiocruz, where he currently holds the position of Bio-Manguinhos’ Director, at the Pan-American Health Organization and as member of international groups such as The Global Alliance for Vaccines and Immunization.

3. Results

Currently, the two players mentioned above, supply 83% of the demand of the Brazilian National Immunization Program regarding vaccines for human use (Fig. 3). Notwithstanding, the huge population (186 million people) and a cohort of 3.2 million births per year [6], the Brazilian government has decided to make investments in the national capability for development and production of vaccines and other biologicals, in order to avoid a large dependence on importation of these essential products for Public Health.

The strengthening of the technological capability for biological production is a result of continuous governmental investments to modernize facilities in research, development and innovation, as well as their support on technological transfer initiatives. Moreover, the export activities are creating
an expertise that projects Brazil into a new role as an international immunobiologics supplier. The government policy in this area, in addition to that mentioned in item 1, includes the strengthening of Regulatory Authorities, which provides assurance of the quality of the products used in the public health programs, through the NRL and NRA (INCQS and Anvisa, respectively). Brazil has a significant status as vaccine producer among developing countries vaccine manufacturers. More than a manufacturer, the country’s investments in various related areas are contributing to its establishment as a researcher, developer and bioscience innovator.

4. Discussion

Despite a very good position achieved by the Brazilian biological producers, there are many difficult challenges ahead.

One of the biggest challenges is the incorporation of new vaccines with very high prices (pneumococcus conjugate, meningococcal C conjugate, pentavalent DTP + HB + Hib and HPV, according to the Accelerated Growth Program pf the Brazilian Government) into the PNI, whose market reached approximately US$ 550 million (R$ 750 million) in 2008 [7], with free universal access, and production by the national laboratories.

It is clear that public and private partnership are needed in order to accelerate the development of new and important products for the MoH. Also, it is very important to explore a win–win situation to make possible technological transfer agreements for the relevant new products that are already on the market of developed countries.

On the other hand, the Brazilian government is establishing several new regulations to motivate and facilitate public and private interaction:

(a) Sectorial Funds (Health: Law no. 10.332, from Dec/19/2001, regulated by Decree no. 4.143, from Feb/25/2002; Biotechnology: Law no. 10.332, from Dec/19/2001 regulated by Decree no 4.154, from Mar/7/2002);
(b) Innovation Law (Law no 10.973, from Dec/2/2004, regulated by Decree no. 5.563, from Oct/11/2005);
(c) Law for incentives (Law no. 11.196, from Nov/21/2005: Tax incentives for companies that promote technological research and development of technological innovation; The company can choose between the original incentives of Law of Well or art. 19-A, introduced by Law no. 11.487);
(d) The Industrial, Technological and Export Policy (PITCE, launched on Mar/31/2004, which strengthens and expands the Brazilian industrial plant, through the improvement of the innovation capacity of the companies);
(e) Productive Development Policy (launched on May/12/2008 - http://www.desenvolvimento.gov.br/pdp);
(f) Economic subsidies to the companies from FINEP;
(g) FUNTEC/BNDES;
(h) PROFARMA, from BNDES, and the new PROFORMA II;
(i) Regulation of FNDCT.

The Brazilian MoH has also defined a list of priority products and medicines through the Law of Decree no. 978, from May/16/2008, which aims to stimulate the private and public enterprises.

Acknowledgements

The author would like to give special thanks to the 2008 IABS International Scientific Workshop organizers, who
invited him to present the Brazilian perspective and status as a vaccine manufacturer, and who inspired him to write this article; thanks also to Denise Lobo Crivelli, for her skill in putting the data together.

References