

New challenges for national capability in vaccine technology: domestic technological innovation versus technology transfer

The Brazilian National Immunization Program (PNI) has been introducing technologically modern and high added-value vaccines into its routine immunization. While such vaccines have a positive impact on the country's health situation, they also overly pressure the Ministry of Health's budget. The technological capability of national vaccine manufacturers, mostly public institutions, has fostered the command over the production of vaccines included in the routine immunization schedule, except for the rotavirus vaccine, introduced in 2006. The latter was made possible thanks to the National Program for Self-Sufficiency in Immunobiologicals (PASNI), created in 1983, which invested in the expansion and modernization of vaccine manufacturing installations. Meanwhile, limited resources and attention have been focused on technological development and innovation. Currently, the main priority involves projects for the autochthonous development of vaccines, typically involving high risks and expenditures and which take more than ten years for a finished product to be obtained. The profit margins in the international vaccines industry have attracted interest by the multinational pharmaceutical companies. The latter are investing billions of dollars a year in development in order to keep ahead of the competition, launching new vaccines at high prices and protected by patents in the form of a monopoly. Only the more developed countries use these new vaccines. Recent examples include the pneumococcal, meningococcal C meningitis conjugate, hepatitis A, and HPV vaccines. This situation changes when similar products are launched, fostering competition, increased supply, and decreasing prices. The less developed countries only access these vaccines decades after they are originally launched. There is a collective effort among Brazilian national manufacturers, aimed at achieving domestic production of new vaccines within the lowest time frame and at the lowest cost possible in order to allow their inclusion in the immunization schedule. The Ministry of Health has thus been supporting technology transfer agreements for the local production of new vaccines. The National Immunization Program has recently introduced the triple viral (measles, mumps, and rubella), *Haemophilus influenzae* type B (Hib), and influenza vaccines. This strategy to achieve national production through technological agreements is made possible by the capability of national manufacturers, the size of the public market, and the thrust and energy of the National Immunization Program. Such conditions have attracted the attention of multinational vaccine producers, who identify Brazil as an attractive and promising market. Within this context, the Ministry of Health has used the government's purchasing power to make technology agreements possible. Meanwhile, in a synergistic and complementary process with such agreements, the Ministry is inducing projects for development and innovation. The National Biotechnology Policy and the INOVACINA program are initiatives in this direction. These two milestones define the priority vaccines, which allows inducing product-oriented development projects. Sources are being created to specifically promote these projects, while national manufacturers are reforming their management models by adopting tools for innovation. The scenario is promising, but it is crucial to guarantee that the policies and programs for this sector are maintained, in order for Brazil to achieve autonomy in the development and production of relevant vaccines for the country.

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