



Are domestic vaccines manufacturers in ASEAN markets a threat or an opportunity for successful market entry?

Selling vaccines in the region places commercial considerations alongside humanitarian obligations

Vaccines are the most cost-effective healthcare intervention, as they prevent disease rather than curing it. Benefits offered to individuals and healthcare systems are clearest in low resource countries, but the healthcare market gap between need and access/affordability also exists in the vaccines field.

Since the declaration of the UN Millennium Development Goals (MDG) in 2000, vaccines access has improved globally. The fourth goal MDG4 challenges the global community to “reduce by two thirds, between 1990 and 2015, the under-five mortality rate”. Multiple causes of childhood mortality are vaccines-preventable, such as pneumonia, diarrhoea and infectious disease outbreaks.

Since its foundation in 2000, the Global Alliance for Vaccines and Immunisation (GAVI) has facilitated the introduction of essential vaccines throughout the least developed countries, such as pentavalent vaccine (DTP-Hib-HepB) in 65 countries. GAVI has not limited itself by handing out vaccines to recipient countries, but is driving co-responsibility through co-funding of vaccines.

One of GAVI’s strategic objectives is shaping the vaccine marketplace. By 2011, 5 out of 10 vaccines manufacturers that were awarded contracts were based in emerging markets. This means that those vaccines producers now meet WHO global quality standards. These trends will accelerate, as more National Regulatory Authorities (NRAs) become WHO-certified and thus their national vaccines become eligible for international tenders. With the certification in March 2012 of the Chinese SFDA regulatory system, the country’s vaccines manufacturers can now submit their vaccines for review at WHO and thereafter bid on tenders globally.

The development of a globally-competitive domestic vaccines industry

The market entry hurdles for the vaccines business differ significantly from those in other sectors of the pharmaceutical industry. The vaccines clinical development process is more predictable, as the focus of development using traditional technology is to stabilise and render harmless antigens and induce an antibody response in healthy individuals. It is not facile, but neither is it as challenging as finding the right antagonist for a receptor in small molecule drug research.

Since vaccines are a business of scale, two key market hurdles need to be overcome: high-capital investments in buildings and maintenance of vaccines

manufacturing plants, and committed, long-term vaccines buyers. Where a government commits to long-term strategic investments in vaccines, both hurdles become addressable. Governments with the vision and dedication to building a national vaccines plan can raise the funds and know-how needed to build what needs to be built, while guaranteeing a reliable buyer for the vaccines.

What does this mean for vaccines in the Association of Southeast Asian Nations (ASEAN) region?

The ASEAN region comprises Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar (Burma), the Philippines, Singapore, Thailand and Vietnam and represents the largest grouping in Asia after China and India. The region is in the process of setting up the ASEAN Economic Community (AEC), which by 2015 will “transform ASEAN into a single market and production base, a highly competitive economic region, a region of equitable economic development”. This is a reflection of the member states’ increasing interdependence and will create a market of 600 million people.

The ASEAN countries are aspiring to improve regional trade through harmonised regulations. However, countries have disparate economies and growth potential. For example Cambodia, Myanmar and Laos are eligible for GAVI funding, while the advanced economies of Singapore, Malaysia and Brunei have healthcare access.

Unlike the other countries in the region, Indonesia, Thailand and Vietnam are producing traditional vaccines domestically, with each pursuing its own priorities. Their capabilities have been developed and built with the assistance of donors and NGOs, or as JV with industry.

Vietnam - comprehensive domestic coverage

Vietnam is targeting comprehensive domestic vaccines coverage, aiming to bring capabilities throughout traditional vaccines into the country. These capabilities are shared over three government-backed institutes, with each institute building up its own specialties. While exporting beyond Vietnam’s borders could be an option, further adaptations to meet WHO global standards are necessary, such as the WHO certification of the Vietnamese NRA and the GMP certification of production sites, which are time- and resource-intensive changes.

Indonesia - from domestic to regional provision

The state-owned company PT Biofarma is a producer



of vaccines, sera and diagnostic products. Founded to serve the local market, Indonesia has been looking beyond this. Biofarma was the first ASEAN-based vaccines manufacturer to achieve WHO prequalification status, enabling participation in UNICEF tenders for DTP, DTP-HepB, HepB, measles and oral polio vaccines.

Beyond traditional vaccines, Indonesia's exposure to H5N1 influenza and its resulting contributions to global flu outbreak monitoring have driven further vaccines developments. Through a technology transfer from the Biken Institute of Japan, together with WHO, BioFarma is now working towards producing 20 million doses of pandemic flu vaccines. This will not meet domestic demand, but is a better starting point than other countries have.

Thailand - a bold vision for growth

Thailand has held vaccines capabilities in small scale settings since 1953 with the set-up of a BCG vaccine production at Queen Saovabha Memorial Institute (QSMI). Most recently, Thailand has embarked on a National Vaccines Strategy, aiming not just to become self-sufficient but also to meet regional needs.

GPO-Mérieux, the JV between the Thai government and Sanofi-Pasteur, is unique in the ASEAN region: GPO-Mérieux is manufacturing innovative vaccines that meet regional needs. Sanofi-Pasteur's Japanese encephalitis vaccine (JEV) has been developed through regional clinical development and transfer of all manufacturing steps after bulk vaccine production to its Thai facility.

Regional perspective

The ASEAN countries can be viewed as forming three clusters: the producers, the recipients and the purchasers:

- The producers (Vietnam, Thailand and Indonesia) constitute the three vaccines hubs in the region. They are developing portfolios that fit national or at most regional needs, based on fill-finishing bulk vaccines or in some cases upstream capabilities. Near-term the threats that they pose to multinational corporations (MNCs) with a differentiated portfolio are limited
- The recipients (Laos, Cambodia and Myanmar) rely on donor-funded vaccines and NGO facilitated implementation of vaccines programmes. In the near-term the opportunity for MNCs to meet these needs remains limited to bidding on international tenders and supplying according to those price requirements
- The purchasers (Philippines, Malaysia, Brunei and Singapore) are locally funded and allowing for market-appropriate formulations, eg halal compatible vaccines, these countries are able to buy for government and self-funded markets supplies as needed by immunisation schedules. Coverage beyond the traditional vaccines is an additional opportunity in these countries.

The impact of domestic vaccines companies on multinational firms interested in ASEAN

With a 12 million annual birth cohort, ASEAN represents a significant opportunity for vaccines producers and their needs are only partially met. Domestic vaccines companies were set up to deliver traditional vaccines for routine childhood vaccinations and are still, largely, confined to this remit. In recent years, as the capabilities and processes improved to WHO quality standards, these vaccines are beginning to reach donor-funded markets in the region and beyond. Therefore, to dismiss ASEAN based vaccines manufactures as pursuing only their national markets is too simplistic.

As such, access to endemic and non-traditional vaccines is an unmet need throughout the ASEAN region. While national governments are deliberating on cost/benefit of adding further vaccines to their routine immunisation schedules MNCs need to be present to explain the value propositions of their products. Nevertheless, the burgeoning middle classes already offer opportunities for private market vaccines sales.



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