Novel approaches to vaccine development in lower-middle income countries

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Abstract

Purpose – The purpose of this paper is to identify, analyze and describe the novel approaches that affect vaccine development in lower-middle income countries (LMICs).

Design/methodology/approach – The vaccine market in LMICs currently focuses on traditional Expanded Program for Immunization vaccines instead of new ones. Unlike the successful introduction of those traditional vaccines, the introduction of new vaccines appears to be very slow, mainly due to financial issues. This paper systematically reviews a set of published papers on vaccine development and analyzes them against a specific region-setting framework.

Findings – Public–private partnership alone could not ensure long-term vaccine sustainability. Several factors that encourage domestic vaccine development were identified. The findings demonstrate that the regulatory approach of hybrid collaboration and market opportunity strategies can be a major breakthrough for domestic vaccine development in LMICs.

Research limitations/implications – Further research is required to include qualitative and quantitative methods for policy analysis, as all of the discussion in this research focused on literature reviews. The authors did not discuss how strategic decisions are affected from a political perspective and this needs to be specified in future research. Think tanks, considerably and fundamentally, affect policy ideas and decisions. However, important breakthroughs continue to be made at the same time.

Social implications – The development of vaccines in LMICs is expected to be a mechanism to overcome the inadequate access to vaccines in those countries, as solving this problem requires tackling issues from both the supply and demand sides.

Originality/value – This is a literature review that creates recommendation and approaches for domestic vaccine development in LMICs. This review aims to encourage LMICs to produce their own vaccines for sustainability of the vaccine access through vaccine development lifecycle, instead of expecting donor that provides funding and vaccines (vaccine access) in certain period of time. Donor is not always the solution for the problem, since vaccine development requires finance to function infrastructure. There are many efforts in revoking this, including World Health Organization through several reports; however, this effort still has many doubts. Therefore, the article would like to try to see this as a viable solution from the policy perspectives, with several examples to make recommendations more practical.

Keywords Public health, Health policy, Health law or regulation, Public health regulations, Vaccines or vaccination, Political strategy

Paper type Literature review

Introduction

Without a doubt, vaccination is the most effective method for preventing diseases and protecting public health. Immunization achievements after the introduction of the Expanded Program of Immunization (EPI) have been impressive, in particular, its role in global efforts for the eradication of polio and the control of measles. In general, there are six traditional EPI vaccines against six diseases, which include the BCG (tuberculosis), DTP (diphtheria, tetanus, pertussis), measles and polio (poliomyelitis), which are then
expanded to Hepatitis B and Haemophilus influenza type b (Hib) vaccines as basic EPI vaccines building on traditional schedules (www.who.int/immunization/research/implementation/optimize_schedules/en/). They are used routinely all over the world, particularly in least-developed countries, where disease burden is high. In the 2000s, new vaccines such as the human papilloma virus and rotavirus vaccines were introduced. These new vaccines have been a part of the EPI vaccines in high-income countries (HICs), but not in lower-middle income countries (LMICs) due to the high price of vaccines and lack of research and development (R&D) of domestic pharmaceutical manufacturers to produce the vaccines (Greenwood, 2014). In addition, there are burden of infectious diseases in LMICs for which vaccines do not exist, and recently a threat of emerging infectious diseases (EIDs) to health security that primarily affect LMICs needs the availability of vaccines (Almond and Medaglini, 2017; Plotkin et al., 2017).

The rising burden of infectious diseases is the major factor driving the growing demand for vaccines. Despite the value of vaccines in public health, the market for vaccines is comparatively small due to their uses for prevention, not for repeat uses in patients, and impacts on reducing transmission in society. Nevertheless, the revenue growth opportunity in vaccines is promising. Its market force is dominated by the public sector through procurement agencies or governments and there are a limited number of manufacturers (WHO, 2011). The development of vaccines in LMICs is expected to be a mechanism to overcome the inadequate access to vaccines in those countries, since solving this problem requires tackling issues from both the supply and demand sides (Oyston and Robinson, 2012). World Health Organization (WHO) approach of enhancing domestic production through technology transfer is arguably an effective strategy to resolve the problems facing sustainable access to vaccines (WHO, 2011). When Gavi, the Vaccine Alliance, excluded LMICs with a threshold of about US$ 1500 in gross national income (GNI) per capita, LMICs have deemed it necessary to provide access to more affordable vaccines in their domestic markets (Gilchrist and Nanni, 2013; Keith et al., 2013; Saxenian et al., 2015) since in LMICs, affordability is more important than the cost-benefit analysis of new vaccines (Oyston and Robinson, 2012; Keith et al., 2013). Therefore, to promote needs-driven innovation, there are calls for governments to provide a contribution to overall R&D efforts in the form of direct funding, tax cuts and prioritization of public health needs (Oyston and Robinson, 2012; Reid and Balasegaram, 2016) and also a consistent policy including policies on government, foreign and private investment, price control, technology transfer, education, networking and collaboration market (WHO, 2011).

This research aims to develop novel approaches that can be implemented in practice to advocate for LMICs to promote their own vaccine development for vaccine access. Within this context, barriers and facilitators to vaccine development are identified to see this as a viable solution and to enable policy makers to intervene in an efficient manner to overcome doubts, and how some of the possible risks can best be managed.

Methods
A review of published literature was done to identify, analyze and describe novel approaches that affect vaccine development in LMICs. A fishbone (Ishikawa) diagram was used as the analytic framework and assessment tool for listing probable facilitators and barriers to the development of new vaccines with four aspects: public–private partnership (PPP), manufacturing capability, market-related factors and policy approach (Figure 1).

Literature searches related to stimulating vaccine development to provide access to new vaccines in LMICs were performed using keywords and their common synonyms, which are “lower-middle income countries,” “novel approaches” and “vaccine development.” Several bibliographical databases were selected for a systematic search, including JSTOR, Proquest and ScienceDirect and the Google search engine. Only studies published in English were selected.
Results

*Is PPP the best way to provide access to new vaccines?*

The interest in establishing PPPs comes from the demand in infrastructure and limited available public funds to address unfulfilled public health needs (Buse and Walt, 2000). PPPs develop and represent a strong lever to encourage collaborative vaccine development. PPPs have, in several ways, been remarkably successful in providing LMICs with the access to new vaccines (Gilchrist and Nanni, 2013; Keith et al., 2013; Almond and Medaglini, 2017; Walton, 2017). Determining who owns the intellectual property (IP) rights to new vaccines is critical. However, PPPs are able to provide appropriate approaches to handle IP issues such as the open-collaboration approach (open sharing of research), the partnership-focused approach (a restricted access to research) and the hybrid approach (negotiable access) (Stevens et al., 2016).

Some examples of PPPs are provided in Figure 2, which are chosen from the participants who attended the 17th Developing Countries Vaccine Manufacturers' Network (DCVMN) meeting in 2016 (Pagliusi et al., 2017).
meeting in 2016 (Pagliusi et al., 2017). These PPPs mainly operates in the field of vaccines for EIDs and are separated into categories at specific stages of a vaccine’s lifecycle, leading to a number of options for LMICs to engage with according to their needs. Amongst these PPPs, Gavi, the Vaccine Alliance, appears to be the most popular PPP, incorporating key agencies, governments, manufacturers, private sectors and civil societies involved in immunization and vaccine development in LMICs. Gavi supports LMICs with GNI per capita below threshold of US$1,500 to benefit from Gavi’s funding and technical support, to address low coverage and unequal access to life-saving vaccines during a certain period. Further, Gavi’s market-shaping strategies aim to provide low-price forecast vaccines to manufacturers that have partnered to supply the Gavi’s market and supported its long-term plan (Gilchrist and Nanni, 2013; Keith et al., 2013; Saxenian et al., 2015; Gavi, 2016a, b).

However, there are some doubts whether Gavi is beneficial for LMICs due to issues such as financial sustainability of immunization programs and opportunity for long-term purchase of low-cost vaccines from Gavi’s market, Gavi itself has another issue with sustainability of the vaccine manufacturers (Gilchrist and Nanni, 2013). Gavi’s current strategies have been shifting from fostering innovative products based on market analysis and forecasting, and strengthening collaboration with industries to focusing on preparing countries to finance themselves (Saxenian et al., 2015; Gavi, 2016a, b). Several countries that have reached the end of Gavi’s funding continue facing obstacles because they are still reliant on the support provided by other organizations. Even though Gavi has been seeking commitment from manufacturers to maintain Gavi prices for all Gavi graduated countries, there is no guarantee that the country is able to purchase these vaccines for long-term sustainability (Saxenian et al., 2015). Those bring out that a PPP’s acceptance is still debated.

Gilchrist and Nanni (2013) criticized that Gavi focused more on new vaccines that were mainly developed by large pharmaceutical manufacturers than on those that were already available in LMICs, which were more likely to be more appropriate and affordable for these countries, whereas Gavi has come up with strategies to increase the number of low-cost vaccine manufacturers as options to LMICs to improve vaccine access. This likely leads to reliance issues and the expectation of a return on investment (ROI). International purchasing agencies, i.e. Gavi, UNICEF and the Global Fund, would only purchase vaccines that have been prequalified by WHO. Factors that determine the WHO’s prequalification include the evidence of efficacy, safety, quality and good manufacturing practices, regardless of the fact that the vaccine has already gone through a Drug Regulatory Authority (DRA) assessment in its country of origin (Ahonkhai et al., 2016).

In terms of low-cost vaccines, Gavi has not always succeeded in providing low-cost vaccines, i.e. pentavalent and rotavirus vaccines. Gavi failed to negotiate the price of those vaccines to a level that was as low as traditional vaccines, even though it took several years to negotiate (Gilchrist and Nanni, 2013). Vaccines developed in HICs would likely be inaccessible in LMICs if they are offered at a uniform price, since manufacturers expect to benefit from increased revenues and profits. A pricing strategy that aims to improve access to lower-cost vaccines in LMICs (tiered pricing) has several drawbacks, including difficulties in maintaining sustainable low prices, no clear allocation for R&D costs, reducing the power of the government and further raising concerns of a non-target country gaining access to cheaper vaccines through a black market (Oyston and Robinson, 2012; Keith et al., 2013).

Ensuring that LMICs can successfully end their dependence on donor aid and achieve self-sufficiency is the optimal way to sustain vaccination efforts. A PPP should enable the public sector to expand on infrastructure, public assets or services. Katz (2013) criticized how countries that offered foreign aid to help countries in need neglect the poor infrastructure of these countries. The author of the book The Big Truck That Went By: How the World Came to Save Haiti and Left Behind a Disaster emphasized the critical concept of
having a good cooperation between those offering foreign aid and the governments of countries in need in order to accomplish the ultimate goal that had been set and to avoid a situation of unclear plans, disparities in aid distribution or discrepancies between what they did and what they actually wanted to achieve. A PPP is supposed to collaborate with the government in order to overcome challenges and to enhance the effectiveness of the foreign aid, and not just provide funding within a certain period of time, by having clear plans as is defined in the agreements to achieve the goals and sustain what was achieved (OECD, 2008).

Another dimension of partnership is the level of commitment to a culture of mutual trust. Katz’s published book indicated concerns of a climate of mistrust associated with corruption in past collaborations. Since a PPP constitutes the main driving force dealing with major constraints on public resources and fiscal space, it may become vulnerable to corruption. Various types of corrupt practices may include bribes in order to get a tender’s decision or authorization, or to reduce the costs imposed by the government in the form of taxes, fees and regulations; conflict of interests during the agreement process; neglect of normal pre-defined procedures and criteria; and irregularities in the procurement cycle (COBARZAN and HAMLIN, 2005). Since channels for corruption exist throughout the partnership process, at this stage, COBARZAN and HAMLIN (2005) indicated that enhancing efficiency and transparency by establishing codes of conduct is the top priority for public sector reforms.

A new feature of partnership is needed to shift the dependence of governments with the PPPs into capacity building, i.e. the transfer of technical knowledge to reduce technical risk. A hybrid model of a PPP that was introduced by Jensen and Wu (2017) is a potential way to engage governments and private sectors to work on and monitor projects together in accordance to the interests of the public. Aside from avoiding the barriers that would arise if a sector stands alone, the hybrid model is expected to build technical competence, enabling private sectors to provide public services. The principle of a hybrid collaboration to establish more equal partnerships is expected to make impact on vaccine development which constitutes a more comprehensive attempt to offer a coordinated, predictable and transparent collaboration. A joint effort between the PATH and WHO with financial support from the BMGF to provide appropriate technologies to the Serum Institute of India to develop an affordable meningitis A vaccine is of a real life example of successful collaboration (WHO, 2011; Kulkarni et al., 2015; Tiffay et al., 2015).

Manufacturing challenges for sustainable supply in LMICs

The manufacturing of new vaccines is a lengthy, costly and complex process that produces a product largely derived from discoveries, to develop processes and analytics with uncertainty at each phase of development, a high level of quality control at every stage of the process and compliance with a wide range of assays. This would require investment both to encourage R&D for new vaccines and to increase manufacturing capacity (Waye et al., 2013; Plotkin et al., 2017). Unfortunately, the cost for a pharmaceutical manufacturer to create one vaccine including R&D, manufacturing and trials to test efficacy and distribution is unlikely to be publicly transparent. Several published papers drew on a number of estimates for the R&D costs of a single vaccine, indicating an estimated cost of $200m to $2bn (Serdobova and Kieny, 2006; Oyston and Robinson, 2012; Keith et al., 2013). The development would eventually lead to the expectation of maximizing profits, as an ROI for R&D (Almond and Medaglini, 2017; Gordon and Robertson, 2017). In fact, the cost of vaccines includes not only R&D, but also supply chain and service delivery costs. Thus, the ROI involves economic benefits of implementing vaccination programs, taking into account treatment costs and productivity losses. This ROI, on average, results in 16 times the costs and 44 times in benefits when societal costs are included (Mihigo et al., 2016). The issue of a high level of demand along with a low purchasing power in exclusive countries with a vaccine targeting a small population is another limitation that could impact vaccine development.
(Almond and Medaglini, 2017). A range of government investment in R&D would be to potentially resolve the issues of access to vaccine and a sufficient return to manufacturers. Governments in China and India have investment policies to establish research institutes, increase investment, build infrastructure and promote collaborations, leading them from imitation to innovation countries (Ding et al., 2011; Government of India, 2011; The National Bureau of Asian Research, 2011; Parry, 2014; WHO, 2017a, b).

It is most desirable to develop the most promising candidates in terms of their potential public health impact and safety. Determining the forecasts for the uptake of new vaccines in LMICs should address in-country public health needs, and cannot simply follow those that are introduced in HICs (Oyston and Robinson, 2012; Gilchrist and Nanni, 2013). However, the existing mechanism for forecasting the demand of a vaccine and for ensuring sufficient supply is not satisfactory since LMICs lack local epidemiological data, an adequate healthcare system and immunization coverage (Keith et al., 2013). Viral diversity and the sporadic and unpredictable nature of the way many infectious diseases spread are other challenges to forecasting innovative vaccines. To advance vaccine development pipeline in LMICs, the following forecasting approaches can be applied to plan a candidate vaccine to move forward with the development process:

1. the adoption of existing life-saving vaccines aiming to reduce the uncertainty of a human’s response, rather than a novel vaccine candidate that may cost hundreds of millions of dollars and may take more than a decade to develop;

2. the adoption of vaccines that have proven that their benefits outweigh the risks during the research phase; and

3. the adoption of vaccines in the individual country’s pipeline, including regional and global forecasts.

The speed of adoption would be strongly influenced by a country’s profile, which underpin the strategy of forecasting pertaining to the demographic, health system and financial situation of each country (Keith et al., 2013; Hardt et al., 2016). Research-related relationships between pharmaceutical manufacturers and academia are of critical importance in translating the discoveries of basic biological research into new therapies. Most of the basic research upon which vaccine development depends on continues to be carried out by universities and laboratories, with pharmaceutical manufacturers assuming the later stages of vaccine development and bringing them to the market. Manufacturers have to find academics in their own country and approach universities and scientists within pharmaceutical manufacturers who are working with other scientists around the world. Manufacturers that expect to survive must actively aggregate and integrate knowledge from across the world, for example, through the merging of two or more research institutions that develop the same products (Almond and Medaglini, 2017).

A regulatory policy on vaccine development typically possesses an array of regulatory powers needed to regulate the safety and efficacy criteria to overcome major scientific hurdles, even if the current vaccine pipeline looks promising. Forecasting demand for a vaccine is particularly challenging because of the uncertainty surrounding the key characteristics of a future vaccine that often remains at the time of vaccine approval (Gordon and Robertson, 2017). The understanding of previous research can help suggest the development of new vaccines in the country, even though the potential public health impact cannot be estimated simply from a large double-blind randomized clinical trial (Mahoney, 2014). Under these circumstances, drug regulators are caught between the need for evidence and the need for access to vaccines (Mahoney, 2014). In spite of the great need of having evidence in the vaccine development process, an adaptive licensing approach would be an acceptable strategy that can accelerate access to vaccines.
A regulatory approval would come in stages in parallel with marketing, either by time-limited conditional approval or indication limitation. This regulatory pathway is considered applicable for a novel tuberculosis vaccine with experiences likewise in a new tuberculosis drug and meningococcal group B vaccine (Rustomjee et al., 2014).

Creating market to LMICs’ vaccines

Clearly, access to vaccines requires some concepts in strategic marketing approaches that a particular country can consider, pursue and apply. An innovation will remain a novelty and not offer any impact on public health if it fails to achieve widespread use (no access to the vaccine). The vaccine market has distinct features since a market in which both buyers and sellers have significant market power (supply and demand) and subject to the standard medical practices of each country (Gordon and Robertson, 2017; www.who.int/immunization/programmes_systems/procurement/market/en/). The use of a particular vaccine is influenced by the opinions of professional bodies, medical associations and peer reviews. At this point, a policy intervention plays a key role in disseminating and legitimizing innovations with the intention of influencing the behavior of professionals at the individual or group level and introducing vaccines into healthcare systems.

The diffusion of new vaccines is feasible when knowledge is spread throughout the world and knowledge gaps are overcome. A policy intervention may disseminate the innovation from LMICs targeting HICs to address an unmet need in HICs, which is known as reverse innovation (DePasse and Lee, 2013). HICs benefit from this reverse innovation due to the more favorable conditions in the environment of an LMIC, such as low cost of production, acceptance of new technology, manufacturing sustainability, fewer regulations and the availability of product alternatives. DePasse and Lee (2013) adopted from Roger’s (2003) theory and introduced a model of reverse innovation that could be adopted by LMICs to fulfill the vaccine needs of HICs, by identifying common issues in LMICs and HICs, disseminating the innovation within LMICs, then crossing over to the HICs’ setting and finally being implemented by the HICS. The acceleration of the spread of innovation (reverse innovation pipeline) contributes to a product value advantage (i.e. effectiveness, cost efficiency) relative to existing alternatives, consistency with existing goals in the context of local policies or social systems, complexity of the innovation (simple to understand and use), easily experimental innovation on a limited basis and visible outcomes to be observed (Rogers, 2003; DePasse and Lee, 2013). To achieve this strategy, it is important to expand the health system network which consists of policy makers, entrepreneurs, health system leaders and researchers, including WHO-led initiatives that aim to identify problems in LMICs and HICs; get funding; and bridge the gaps and measure global reverse innovation activity (DePasse and Lee, 2013).

Several factors that enable a domestic vaccine development were identified through two broad strategies known as push and pull mechanisms, to encourage and reward innovation at the same time (Mueller-Langer, 2013). Even though push factors impact the vaccine market through the manufacturer’s performance, however, pull factors are the most important for creating a secure market to direct consumer demand. The following possible pull factors for market strategy of vaccines could be identified:

- A commitment to product purchases (an advance market commitment) specifies clearly the number of doses to be purchased and the price, and is expected to fulfill the needs of a country (Webber and Kremer, 2001; Hecht et al., 2009; Mueller-Langer, 2013). Advanced market commitment provides a much-needed incentive by upfront commitment for manufacturers to invest in producing new vaccines. This has been implemented for the pneumococcal conjugate vaccine, and there are four manufacturers have made agreement with Gavi to supply this vaccine with a
maximum price of US$3.50 per dose (Cernuschi et al., 2011; Snyder Begor and Berndt, 2011). And recently, Gavi signed an agreement to buy the Merck’s Ebola vaccine once it is approved (www.gavi.org/library/news/press-releases/2016/ebola-vaccine-purchasing-commitment-from-gavi-to-prepare-for-future-outbreaks/).

- Procurement system in the vaccination strategy such as primary routine, catch-up, revaccination and national health coverage through one of, or a combination of, three sources: domestic production, direct procurement from a manufacturer or its agent and from existing procurement agencies such as UNICEF. Vaccine access in LMICs is increasingly becoming more affected by health financing models, which combines national budgets with public health insurance schemes and, to a lesser degree, private financing through voluntary insurance. Governments have a very strong incentive to become more active players in defining the structure of the overall healthcare system, both in the public and private sector (Luter et al., 2017).

- The promotion of a vaccine which targets professionals, who can provide information about new vaccines and contribute to the strengthening of primary care (Keith et al., 2013).

Push factors which affect the vaccine market by affecting the manufacturer’s ability of getting the vaccine to the market include:

- funding for stimulating the capacity of expansion of the vaccine, due to the availability of long-term commitments (Hecht et al., 2009; Mueller-Langer, 2013);
- information of the health sector’s procurement and supply would help the vaccine manufacturers prioritize markets (Webber and Kremer, 2001); and
- fast track regulatory review/priority review voucher (Webber and Kremer, 2001; Hecht et al., 2009) (Figure 3).

Ultimately, government intervention that aims to engage with the market is increasingly being seen as playing a critical role in vaccine access, by bringing together the best market opportunities locally and globally. There is a transition from vaccine suppliers in an LMIC’s domestic market to the suppliers of the global market, more recently from India and China, leading toward distribution of lower-cost vaccines compared to developed markets. This is attractive for countries that play a key role in the sale of vaccines with a rapidly expanding global market share (Roemer-Mahler, 2014; Luter et al., 2017; Pagliusi et al., 2017). Yet, while the potential may exist, the opportunities are not always realized. Therefore, it is important to understand the clusters of emerging markets, i.e. emerging economies (Buente et al., 2013), United Nations market (Luter et al., 2017; Pagliusi et al., 2017) and engagement with the private sector in other LMICs (Levin and Kaddar, 2011). To generate awareness in vaccine needs globally, the government may engage with international networks, such as DCVMN.
With 50 members and growing, DCVMN is now playing an important role in the international recognition of vaccine access, contributing for approximately 40 percent of UNICEF’s market (Luter et al., 2017; Pagliusi et al., 2017).

Policy approach to make R&D more effective in LMICs

Heightened awareness of local capability, as discussed previously, highlights a need to incorporate domestic vaccine development into national strategies for its feasibility, taking attributes of understanding barriers at the individual level. Policy approaches are deemed to be taken yielding relevant insights into the effective harness on vaccine development. These include:

1. A policy network consisting of stakeholders across various sectors and disciplines to provide technical information, mobilize finance, implement programs and enhance political support;
2. Maintaining a country’s sovereignty in spite of its interests in strengthening its capacity of developing novel vaccines and performing rapid prevention strategies;
3. Adaptive regulatory pathways to balance timely access with risks and benefits;
4. Regulatory assistance in the development of vaccines to prevent the vaccine from advancing beyond a certain stage;
5. Incentives for the development of novel vaccines that have emerged. The government has to play a role in initiating those incentives;
6. Prioritizing vaccines for overcoming public health issues.

The lack of consensus on the priority, public health value or feasibility of adding a new vaccine can delay policy decisions. Criteria for prioritization include demonstrated vaccine efficacy in the target age, geographic proximity to diseases, disease patterns and the vaccine’s availability, affordability, accessibility and its acceptability. IP is often highlighted as a barrier to vaccine development, requiring vaccine manufacturers to appropriately address agreements. However, the issues of availability, affordability, accessibility and acceptability require more attention since IP is just one tool for a vaccine’s access. One more approach is;

7. Determining priority and sustainable markets to meet short-term needs as well as to ensure sustainable access for vaccines in the long term.

The following framework, as shown in Figure 4, is proposed for creating an environment for the development of new vaccines in LMICs. A hybrid collaboration between a domestic vaccine manufacturer and either a PPP or academia or clinical research institutions develops an appropriate roadmap, guidelines and procedures. An integrated capacity building which supports vaccine development is the conceptual umbrella for this approach. Additional partners are necessarily needed as alternative donors to support relevant programs which are not accommodated by main donor. Specific role from the government in LMICs aside from implementing agreed programs is to increase policy coherence amongst those programs, while specific contribution from private sectors to the collaboration is to provide technology transfer aligning with IP rights management to facilitate the development of new vaccines in LMICs.

An adequate supply of a vaccine depends on the ability of a country to adopt new vaccine technologies; produce new vaccines according to national and global vaccine forecast and planning; prove their scientific advantages and distribute potentially useful affordable vaccines. These indicators for vaccine development were originally defined as
availability, affordability, acceptability and adoptability by Mahoney et al. (2007) in global access strategies. A government’s contribution by providing incentives that embrace and reward innovation would ensure a truly competitive market for new vaccines. At this stage, communication strategies are essential.

The development of dengue vaccine is an example of success of this kind collaboration between Instituto Butantan and US scientists, the Laboratory of Infectious Diseases at the National Institutes of Allergy and Infectious Diseases – National Institutes of Health. Each vaccine development gets regulatory support from ANVISA, a DRA with roles similar to FDA (Homma et al., 2013; Precioso et al., 2015).

Concluding perspectives
Making vaccines widely available on an equitable basis for health interventions is clearly a complex issue. A major goal of global partnerships is to ensure access and uptake of vaccines in LMIC; however, there are significant challenges to maintain sustainability and to reverse the vaccine availability gap. This review suggests potential options for domestic vaccine development in LMICs to ensure sustainable access as well as economic competitiveness. To achieve this, it may require establishing adequate policy strategies to explore and strengthen local capabilities. Hybrid partnership between government and vaccine manufacturers can obtain regulatory approval and establish market opportunities which can be a major breakthrough for vaccine development. Notably, the scope of collaboration should be increased, together with mobilized political will, providing hope for the domestic production of vaccines in LMICs.

References


WHO (2011), “Increasing access to vaccines through technology transfer and local production”, pp. 1-34.


WHO (2017b), “Indian policies to promote local production of pharmaceutical products and protect public health”.

Further reading

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