



CRA Insights: Life Sciences

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Policies that encourage innovation in middle-income countries

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) asked Charles River Associates (CRA) to evaluate the policies that host governments of middle-income countries use to encourage investment in innovative activities and the implications for future innovation policy.¹ Drawing on interviews with policymakers, international and domestic companies, and academics, we assess the innovative activities in middle-income countries, the degree to which these activities can be associated to public policy in eight case study countries, and conclude with six lessons that appear to be critical for success.

Innovative activities take place in a larger number of countries: an existing trend

Biopharmaceutical innovative activities² are still highly concentrated in high-income countries; however, there is a clear trend toward growth of these activities in middle-income countries. Indeed, between 2005 and 2010, the research and development (R&D) spend by the Pharmaceutical Research and Manufacturers of America (PhRMA) members increased by 455% in Asia-Pacific (excluding Japan), 112% in Latin America, and 303% in India.

Early-stage research is undertaken by international pharmaceutical companies working closely with leading academic centres in research hubs. These have historically focused on regions such as Boston and San Francisco in the US, London-Cambridge in the UK, Uppsala and Munich in Europe, and Singapore. In middle-income countries, however, China stands out as the home to 12 R&D centres. Additionally, a small number of R&D hubs are already established in India, Brazil, Russia and Indonesia.

The trend toward biopharmaceutical innovative activities in middle-income countries is even clearer when looking at later stages of the R&D process. Indeed, clinical research is undertaken in many

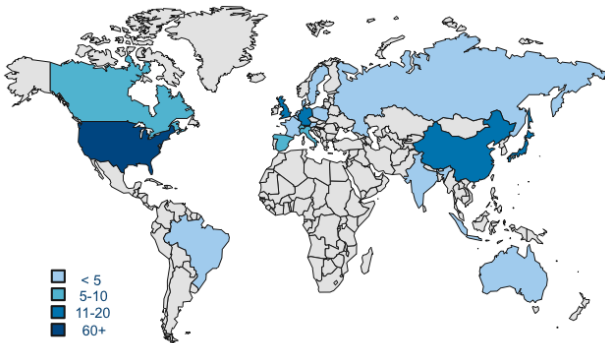
¹ The complete report can be accessed [here](#).

² CRA defines biopharmaceutical innovation as a multi-phased process, beginning with lab-based research leading to patentable inventions and then moving into the stages of clinical research, leading to commercially viable products from which society gains a benefit in terms of improved health. Innovative activities can be measured in terms of inputs such as investment or the number of people employed or outputs such as patents, products in development, or products ultimately commercialised.

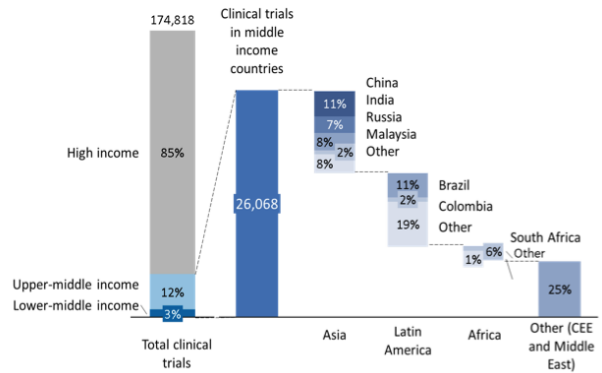
locations, with middle-income countries now hosting 15% of the clinical trial activity taking place within high- and middle-income countries. China, India, Russia and Brazil have captured the largest number of trials within middle-income countries.

Figure 1: Location of innovative activities in each stage of the R&D process

Location of R&D hubs by international companies



Total of clinical trials in high and middle-income countries



Source: CRA analysis. The location of R&D hubs is based on public information of IFPMA members as of August 2012. The number of clinical trials is based on www.clinicaltrials.gov.

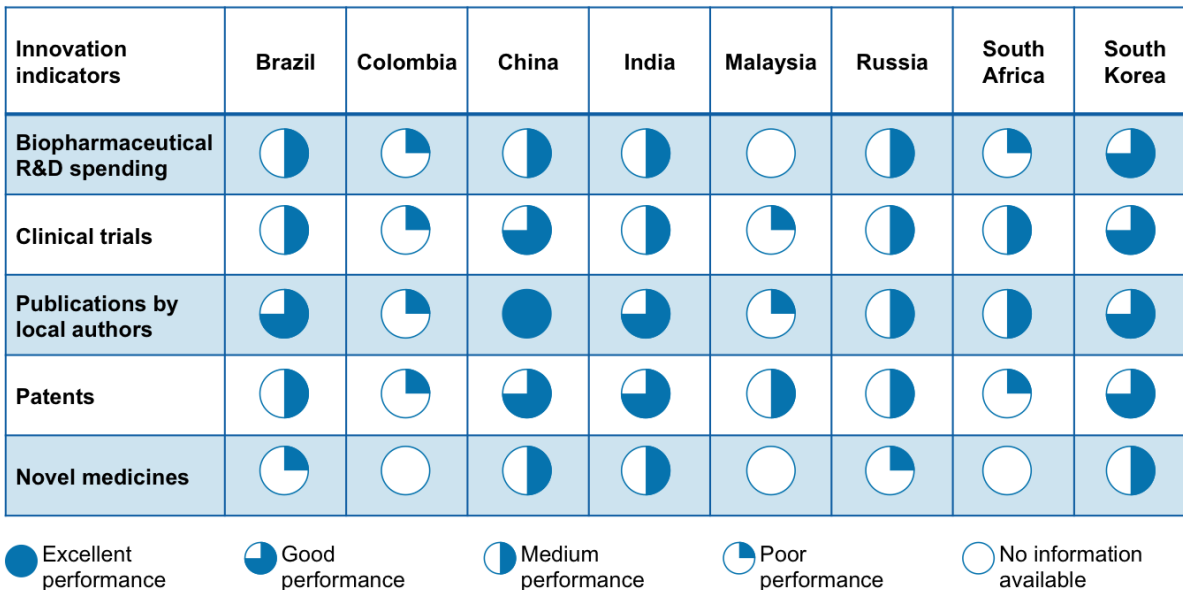
Innovation in middle-income countries: success to date

To understand what stimulates and drives innovation in middle-income countries, we selected eight countries representing different regions (Brazil, Colombia, China, India, Malaysia, Russia, South Africa and South Korea) that have been relatively successful in developing innovative activities to date and that have used a range of different policy approaches. We developed case studies for these countries to illustrate the different levels of progress in the development of innovative activity and the degree to which this success can be attributed to the policies employed.

There has been considerable progress in all of these countries in developing some elements of innovative activity in the biopharmaceutical industry over the last decade, but the extent of progress varies significantly:

- South Korea's biopharmaceutical R&D spending is the highest but this is increasing in Brazil, China, India and Russia.
- The number of clinical trials has increased in China and South Korea although even in these countries the number of Phase I trials remains relatively low.
- China, South Korea, India and Brazil have a high and increasing number of scientific articles focusing on the life sciences.
- South Korea, China and India have patented and commercialised some locally developed novel medicines.

Figure 2: Relative performance of the case study countries in selected measures



Source: CRA analysis

Factors that can successfully encourage innovative activities: lessons from the case studies

1. *To develop innovative activity (particularly early-stage research), governments must have a consistent long-term policy to support innovation in life sciences and that policy must be implemented effectively.*

All the case study countries have developed long-term policies regarding innovation in the pharmaceutical industry. These differ in terms of focus, when they were applied (and if they were implemented) and their short-term objectives. Given how recent some of these plans are it is difficult to draw strong conclusions about which of these have worked most successfully, but it is clear that there must be a consistent policy if it is to provide the right signals regarding the future.

South Korea, which first initiated its innovation policy in the 1980s, demonstrates the value of consistently placing priority on developing a biotechnology industry, initially by investing in basic research and then through policies to encourage commercialisation.

2. *The capabilities required to undertake different parts of the pharmaceutical industry value chain are different and hence so are the policy initiatives needed to support the development of those capabilities.*

Although sharing some common components, the mix of policies that are needed to encourage early-stage research and clinical trials differ. Countries have different characteristics in terms of population and market size as well as their comparative advantage in innovation. The policy priorities should therefore depend on the types of innovative activity that the country is trying to encourage and the country's existing capabilities.

*The medical infrastructure, population and requirements to serve local markets are driving clinical trial activity in **India, Brazil and Russia**. The strength of the academic research centres and the success of developing high-tech business parks clustering innovative companies in **China and South Korea** are seen as key to encouraging early-stage research.*

3. *There needs to be a high level of coordination between industrial and health policies.*

There is much discussion among policymakers and companies about whether there should be a focus on innovation for the global market or innovation for the domestic market. There are considerable differences in the case study countries in terms of whether they are focusing on global diseases (diabetes, cancer, cardiovascular) or diseases that are more prevalent in their markets. In either case, in order to encourage both early-stage research and clinical trials, a supportive domestic market (in terms of both the recognition of innovation and its subsequent reimbursement) is seen as important. A coordinated policy encompassing industrial and health policy is needed to support domestic innovation.

*The link between the growing market opportunity and the government's objective of developing an innovative sector is working together to make **China** a key location for innovation. There appears to be increasing recognition within the government agencies in **South Africa** that procurement of medicines needs to be aligned to industrial strategy.*

4. *Intellectual property is a necessary, but not sufficient, condition for developing indigenous research and a domestic innovative industry.*

The present innovation model is dependent on patents being observed to reward innovators who undertake risk in the innovation process. The impact of stronger intellectual property (IP) can be observed in many of the case study countries. For example, the level of IP protection influences the prioritisation of clinical trials in middle-income markets and the location of basic and preclinical research depends on the IP regime in the country. Although not sufficient, robust IP rules are required to encourage innovative activity.

*Most interviewees reported that the IP system was an asset in encouraging domestic innovative activity. Changes to strengthen the IP system in **Brazil** in 1997 were seen as significant in setting the foundation for innovative activity.*

5. *Sustainable innovation requires coordination among academia and the public and private sector.*

Once the basic infrastructure is developed, public investment in research is not enough to ensure a sustainable innovative product development and commercialisation industry. Partnership is vital for encouraging early-stage research that could lead to commercialised products. The reasons are twofold: 1) innovative activities and commercialisation tend to require a sustained, large amount of capital (as such public investment alone is often insufficient to successfully develop and commercialise innovative products) and 2) different capabilities are required to develop as compared to commercialise new drugs. The process is more efficient and successful when both public and private institutions work together.

*Innovative activity in **South Korea** only developed when private investment was encouraged. **South Africa** and **Brazil** have recognised the need to encourage partnership among academia, public research institutes and innovating private companies. In **China**, there are successful examples of public and academic capabilities and infrastructure (e.g., the Beijing Genomics Institute) supporting private innovation.*

6. *Policy in middle-income markets needs to reflect the changing global business model and the new opportunities this represents.*

Changes in innovative global pharmaceutical business models bring both opportunities and challenges for middle-income countries.

- *Developing product portfolios to penetrate growing markets:* Low growth in established pharmaceutical markets has created a need to look toward middle-income markets for additional revenue, hence the need to conduct clinical trial activities in those geographies to secure marketing approval.
- *The biologic and biosimilars opportunity:* New research is increasingly focused on biologic medicines that require different skills and capabilities. This is likely to be beneficial for some middle-income markets that have not invested as substantially in small molecule innovation; in others, this is likely to represent some additional hurdles.
- *Offshoring and outsourcing the value chain:* It has become standard practice for companies to relocate their manufacturing facilities to markets where the cost of production is lower. However, companies interviewed identified scientific capabilities (rather than cost) as the most important factor when choosing where to locate their innovative activities. The global industry is increasingly experienced in managing complex interactions among different suppliers in conducting early stage research and clinical trials. As middle-income countries develop their R&D capabilities, they will have greater opportunity to be part of international firms' innovation process.

*The advantages of outsourcing in **India**, refocusing on growth in **China** and the opportunities to develop biosimilar competitors in **Brazil** demonstrate the increased opportunities.*

Conclusions

To develop the range of innovative activities from basic research to clinical development, a complex mix of policies is needed. Components likely to be critical to the long-term successful development and expansion of innovative activity in middle-income countries include a consistent policy framework supporting innovation in life sciences, coordination between industrial and health policy, strong intellectual property and an environment that encourages partnership among the different stakeholders.

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