



MEASURING THE GLOBAL BIOMEDICAL PULSE

The Biopharmaceutical Investment & Competitiveness
(BCI) Survey – 2015

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LIST OF ABBREVIATIONS

API	Active pharmaceutical ingredient
BRIC	Brazil, Russia, India and China
BRICS	Brazil, Russia, India, China and South Africa
CETA	Comprehensive Economic and Trade Agreement
CTs	Clinical trials
FDI	Foreign direct investment
FTA	Free trade agreement
High-income economies	World Bank classification including: Canada, Ireland, Israel, Russia, Singapore, Switzerland, UK and U.S.
ICH	International Conference on Harmonisation
ICT	Information and communication technology
IND	Investigational new drug application
IP	Intellectual property
M&A	Mergers and acquisitions
Middle-income economies	World Bank classification including: Argentina, Brazil, China, India, Mexico, South Africa and Turkey
NDA	New drug application
OECD	Organisation for Economic Cooperation and Development
PTE	Patent term extension
RDP	Regulatory data protection
R&D	Research and development
ROI	Return on investment
UNCTAD	United Nations Conference on Trade and Development
USTR	U.S. Trade Representative



EXECUTIVE SUMMARY

Investment in biomedical innovation today represents one of the most high value areas of investment economies can secure. In 2014 global life sciences R&D spending was estimated at around \$200 billion, with investment by leading research-based biopharmaceutical companies at over a quarter of this figure. Today, economies seeking to attract biomedical investment are competing on a global scale, with developed and emerging economies vying for this investment side by side. But how do governments and economies improve their competitiveness and secure a larger piece of global biomedical investment? A growing body of data suggests that on top of market size, demand and costs, economies' competitiveness for biomedical investment is positively linked to the local policy environment – all of the laws, regulations and initiatives in place affecting biopharmaceuticals.

Thus, for developed and emerging economies alike that have targeted biomedical investment as being of strategic importance to national economic development and growth, there is a pressing need to understand and map the state of the biomedical investment environment in a given economy.

The Biopharmaceutical Competitiveness and Investment (BCI) Survey – Purpose and methodology

Various tools exist for mapping the biomedical policy ecosystem, including those that measure investment competitiveness more generally; those that focus on particular sectors; and those that measure specific policy areas. One aspect that, thus far, has been missing from the existing body of data is the on-the-ground perspective of the investment attractiveness of a given economy specific to the biomedical sector – its biomedical “pulse”. The Biopharmaceutical Competitiveness and Investment (BCI) Survey, a global survey-based index of economies' biomedical investment-attractiveness, aims to fill this gap.

The BCI Survey provides a comparatively more in-depth, holistic and focused barometer of the biomedical environment in a given economy than, on the one hand, more general measures, and on the other hand, more policy-specific measures. In addition, by taking a “bottom-up” approach the BCI enables a unique and highly relevant snapshot of economies' biomedical competitiveness. Indeed, the respondents to the BCI Survey – country managers and their teams – often have a candid and accurate understanding of how different aspects of the local policy environment factor in when discussing whether to allocate further resources in the economy.

The BCI Survey examines the entire ecosystem in which biomedical innovation takes place by examining the following major areas:

- ability to leverage scientific capabilities and infrastructure;
- state of the clinical environment, from test tube to patient;
- quality and efficiency of biomedical manufacturing and logistics operations;
- soundness and effectiveness of the biomedical regulatory framework;
- healthcare financing; and
- overall market and business conditions.

BCI 2015 – Headline results

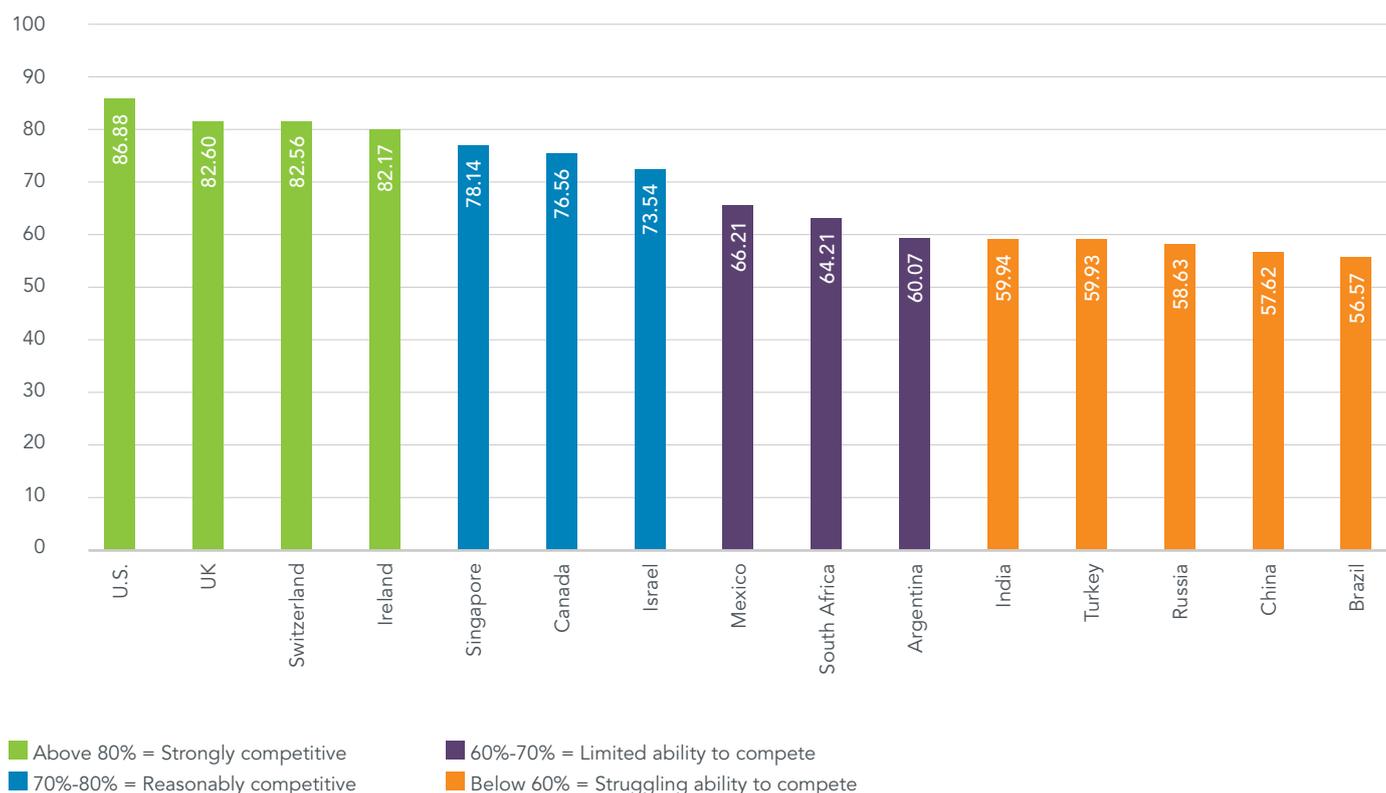
The 2015 BCI Survey covers 15 economies in total, from major developed and high-income economies to some of the fastest growing emerging markets in the world. The figure on the next page summarizes the overall scores for all 15 markets, ranks them in order of their scores from highest to lowest and categorizes them based on their biomedical investment attractiveness.

The overall scores exhibit a relatively clear division by income and development. All high income economies bar Russia score above 70 out of 100, with six of these seven achieving at least 75% of the total possible score. Having said that, some economies exhibit significant weaknesses in critical areas. For example, Canada represents an outlier among developed high-income economies. Although Canada has attractive aspects to its biomedical environment

(such as robust regulatory system and generally international standard manufacturing capacity), what is notable is how far below other high-income economies its overall score falls, despite in some cases having a much larger market. Canada’s relatively low score is primarily due to a mediocre life sciences IP environment that deviates from international norms in important aspects of patenting and enforcement; an overly restrictive pricing and reimbursement environment; and delays in the regulatory system. These elements present major hurdles to investment and the biomedical environment overall.

For middle income economies the challenges are equally stark. The most dynamic economies with the greatest market potential and some of the lowest R&D costs included in the BCI Survey are still at the bottom of executives’ perception. For example, all BRIC economies

Overall BCI scores and ranking by economy



plus Turkey score less than 60 out of 100, with their biomedical investment environments characterized as “struggling to compete” relative to the other sampled economies. Though each market has its own specific challenges, common threads exist across all five particularly in the areas of regulatory quality and efficiency, ability to secure a fair price and protection of biopharmaceutical IP rights.

Key findings

While the overall results of the BCI Survey as well as the individual categories within the Survey provide deep and rich insights on all aspects of the sampled economies’ biopharmaceutical ecosystem, several major findings stand out:

General insights

- Gaps still exist between leaders and laggards**
In the global competition for biomedical investment certain economies perform much better than others in the eyes of local biopharmaceutical executives. In the BCI, a more than 30% difference in score exists between the top ranked economy, the U.S., and the bottom, Brazil.
- Markets with pro-innovation environments rank as the most attractive for biomedical investment**
Economies with policy environments that, by and large, support investment and innovation score in the top half of the BCI. In contrast, economies displaying key gaps in policies and conditions needed for biomedical innovation tend to score in the bottom half.
- Performance in different aspects of the biomedical ecosystem are linked**
With a few exceptions, economies ranked as attractive in one category of the BCI are also ranked in the upper half of the survey in other categories. Conversely, economies with weak scores in one area are often classified as struggling in other areas of the BCI too.

Topical insights

- Intellectual property protection matters to executives on the ground**
Biopharmaceutical IP protection and enforcement is a key area of concern among local executives. BCI respondents consistently cited challenges with patent office backlogs, availability of remedies for infringement and anti-counterfeiting actions as being problematic, especially among emerging markets.
- Improving regulatory standards is just as important as building capabilities for strengthening investment attractiveness**
Economies that perform well in the overall BCI scores tend to have not only strong scientific capabilities but also, in the view of local executives, robust regulatory frameworks for biopharmaceuticals. At the same time, economies rated at the bottom of the BCI are also those that demonstrate weak standards for new drug and biosimilar approval, considerable market authorization delays and lack of transparency.
- Inadequate quality control and red tape hold many markets back from providing effective, globally competitive manufacturing environments**
Despite the relatively low cost of operations and market potential, emerging markets are not viewed as favorably by local executives as developed markets in the area of manufacturing. Emerging markets score 20-40% lower than developed markets in terms of manufacturing standards and processes.
- The market access environment is fundamental to investment attractiveness**
Health care financing and market access represent significant challenges on the ground globally and strongly affect overall attractiveness of a given market. Local executives consistently cited and ranked economies poorly on issues surrounding pricing, reimbursement and procurement.



- **Economies with greater overall attractiveness tend to have higher quality biomedical research systems**

Gaps in scientific research capacity are palpable, especially in emerging markets. In addition, even if they present lower cost environments discrepancies in regulatory standards, capacity and efficiency ultimately mean that emerging markets continue to be less attractive as clinical research destinations in the view of local executives.

- **Certain developed markets present surprising challenges**

For example, as mentioned, in the area of IP protection Canada is an outlier among developed economies, ranked by local executives as the least attractive in the group and scoring a full 20% below the top developed market. Additionally, local executives classified Canada's pricing and reimbursement system as being stringent, rating the market access environment below leading developed economies.

Key market-specific challenges

- **Emerging markets still have a long way to go to improve their attractiveness for investment**

Notwithstanding low costs and considerable market potential, the BRICs plus Turkey still fall into the bottom group of the BCI in overall score and in most categories. What particularly holds these markets back are gaps in effective IP protection, difficult market access environments, regulatory delays and weak quality control standards.



Tying it all together – What the BCI Survey tells us about global flows of biopharmaceutical investment

Policy matters. If there is one message that stands out clearly from the BCI Survey it is that public policies relating to the biomedical ecosystem matter greatly to the relative attractiveness of a given economy for investment. While the policy strengths and weaknesses differ from economy to economy, the executives and managers on the ground are clear in their message that the policy trajectories taken by government officials and regulators have a real and significant impact on the investment decisions and recommendations that these executives and managers make.

This is particularly the case for emerging markets – the BCI Survey results underscore that size, costs and growth potential are not the only factors when it comes to biomedical investment attractiveness. In economies such as the BRICs, where policies affecting the biomedical environment present substantial challenges – which in many cases outweigh incremental improvements made to different areas of the ecosystem – local executives also rank these economies as struggling to compete for biomedical investment from their companies. Nevertheless, the BCI also confirms that when markets take major steps to improve key elements of the biomedical environment, investment will follow.