pugatchconsilium

MEASURING THE GLOBAL BIOMEDICAL PULSE

The Biopharmaceutical Investment & Competitiveness (BCI) Survey – 2015

This report was commissioned by the Pharmaceutical Research and Manufacturers of America (PhRMA). The views represented here are those of the authors only.

CONTENTS

CONTENTS (continued)

TABLES AND FIGURES

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.

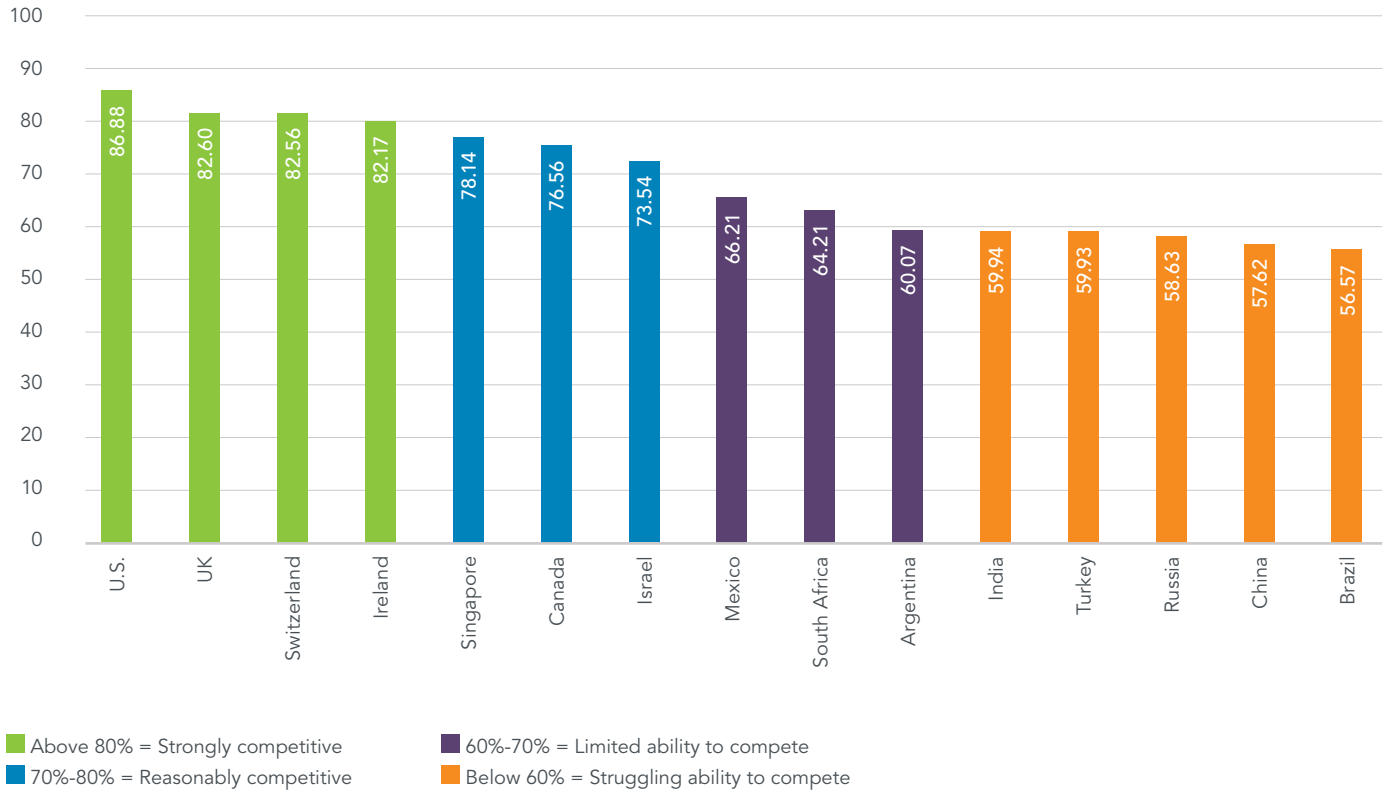
BCI 2015 – Headline results

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.

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.

- **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.

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.

1 MEASURING BIOMEDICAL INVESTMENT ATTRACTIVENESS

1.1 The value of biomedical investment in the global economy

Investment in biomedical innovation today represents one of the most high value areas of investment economies can secure. Development of, and access to, new medicines and health technologies is essential for meeting increasingly greater demand created by growing and ageing populations and medical challenges across the globe. What is more, biomedical investment generates all of the economic and welfare benefits of a knowledge-based field, from high-tech capacity building to homegrown innovative activities that lend to globally competitive domestic industries.

In terms of investment, the life sciences sectors are among the highest and diverse spenders worldwide, investing in areas ranging from scientific research to manufacturing all the way to medicines access schemes and treatment guidelines.[1] Having said that, a large portion of this spending is concentrated in research and development (R&D). In fact, in 2014 global life sciences R&D spending was estimated at around $200 billion, with biopharmaceutical R&D investment by PhRMA member companies at over a quarter of that (around $51 billion).[2] These figures places life sciences at the top of R&D spenders worldwide, second only to the Information and Communications Technology (ICT) industry.[3] And on a micro level, the biomedical and biopharmaceutical sectors spend more than double the amount on R&D per employee compared to the ICT sector.[4]

A significant portion of spending on biomedical manufacturing and wider operations also entails in-depth investment and high-value employment growth. According to a recent study by UNCTAD, cross-border mergers and acquisitions in the life sciences field were valued at over $40 billion globally as of 2013.[5] Moreover, "greenfield" FDI – foreign investments with no pre-existing operations or infrastructure – by pharmaceutical companies amounts to over $13 billion globally.[6] Additionally, by some estimates life sciences industries generate close to 4 million jobs in the U.S. alone (in the sector directly as well as in supporting sectors such as distribution and logistics).[7]

And though navigating significant headwinds in certain areas, particularly with patent expirations taking place on several key products, biomedical investment continues to grow at a dynamic pace, not least in terms of macroeconomic headline figures. One recent study of the global biopharmaceutical industry found that gross value added grew at an average rate of 6% per year during the period 2006-2012.[8] It also identified an average annual growth of employment worldwide of over 3% over the last 5-8 years.[9]

Today, economies seeking to attract biomedical investment are competing on a global scale, with developed and emerging economies vying for investment side by side. Though, in general, developed countries still lead (with the exception of China) in terms of overall market size and level of investment,[10] emerging markets outperform developed markets in their strong growth rates. One 2014 report on global spending on medicines cited at least 5-10% higher average annual growth rates in pharmaceutical spending over 2014-2018 among the BRIC economies than the average growth rates projected in developed markets (with a wide range of growth rates within each group).[11] An UNCTAD study found cross border M&A deals in pharmaceuticals among emerging and developing economies has quadrupled in 10 years (since 2005) to now reach near 20% of global deals.[12]

1.2 Demystifying biomedical investment

What does biomedical investment refer to? Investment in the biomedical sector is sometimes understood in a limited manner, involving, for instance, manufacturing operations or launch of a product, but in fact, biomedical investment comprises a whole host of activities undertaken by companies and other organizations that contribute economic value in a given economy.

In general, there are three different forms or phases of investment that are typically undertaken in the biomedical field:

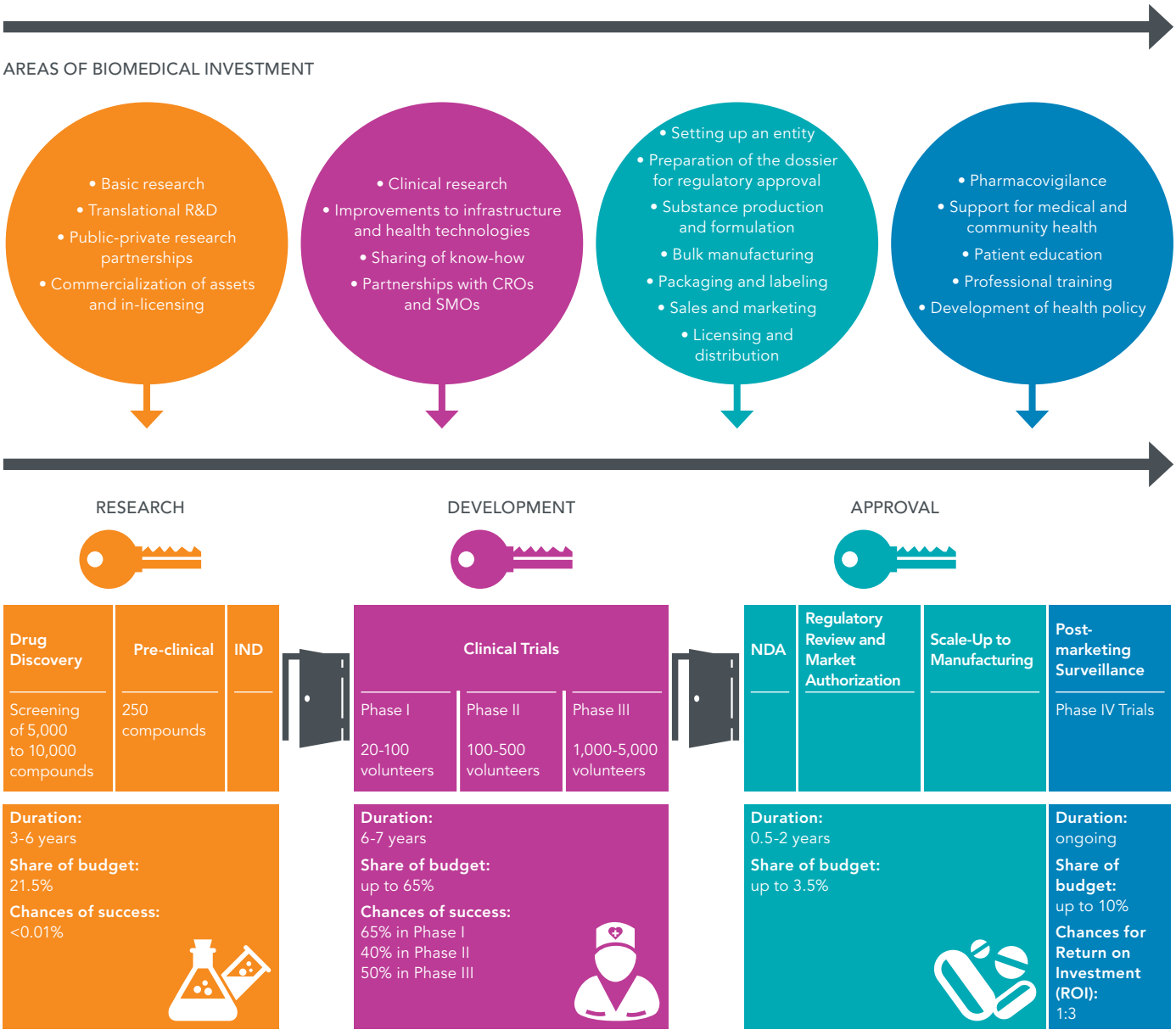
1. Research and development
   First, the bulk of biomedical investment is likely to take place in research and development, from basic research to translation of new discoveries into tangible medicines and health technologies, as well as clinical testing of these new products. This phase includes research partnerships between local firms, research institutes or clinical research organizations and large multinational research-based companies. It also involves commercialization of assets and know-how, including licensing-in of new technologies and molecules by companies that are involved in later stage or "downstream" development of products.

2. Manufacturing
   Second, companies are also likely to make significant investments in biomedical manufacturing operations, including bulk production, formulation, tableting and packaging. Specifically, manufacturing operations can range from basic or secondary activities, such as packaging and labeling, to more advanced or primary activities, such as production of active pharmaceutical ingredients (APIs) or other product substances, and formulation of these ingredients into a product.

3. Commercial and market access operations
   Finally, companies may undertake a range of commercial operations, including setting up an entity, sales and marketing, licensing and distribution and arrangements for regulatory approval. This phase also may also involve a number of activities promoting safe and effective use of a drug, such as development of health policy, support for medical and community health, patient education, professional training and participation in pharmacovigilance activities.

Figure 1 illustrates the full range of investment activities that may take place in a given economy across the biomedical R&D process and product pipeline.

FIGURE 1 The range and value of biomedical investment across the biomedical R&D pipeline



Source: Pugatch Consilium; adapted from PhRMA[13] and Nature

1.3 Increasing competitiveness?

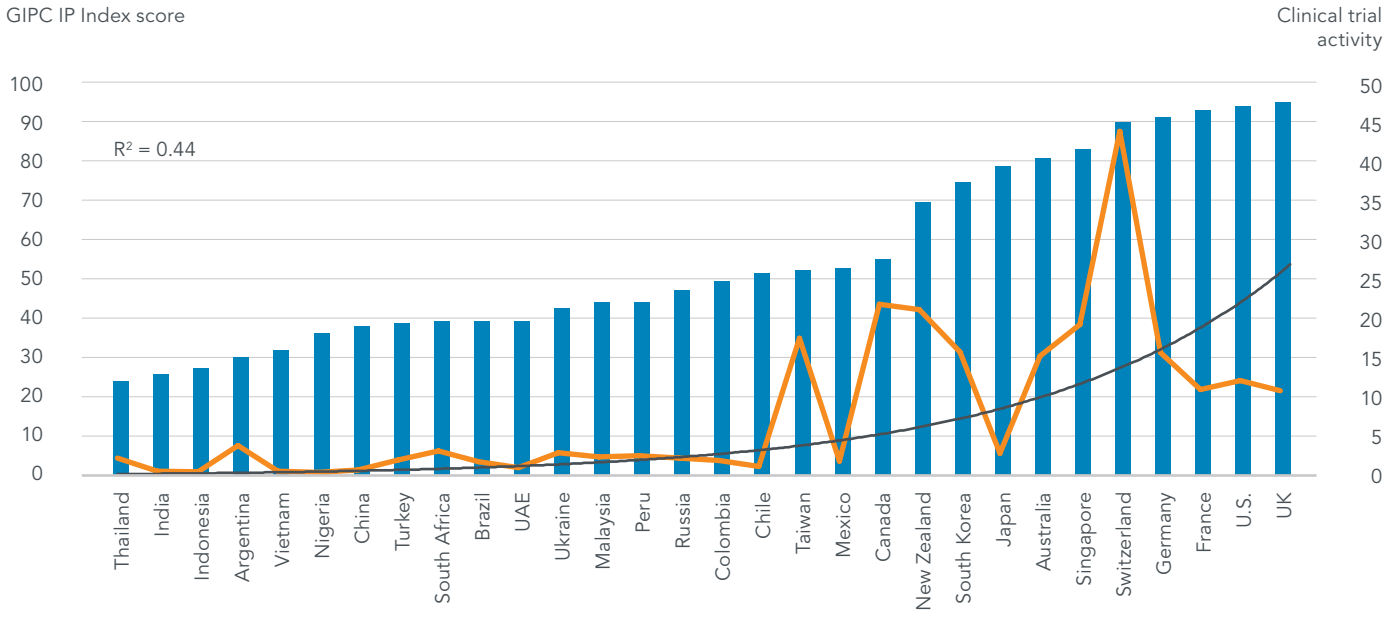
In this context, how do governments and economies improve their competitiveness and secure a larger piece of global biomedical investment? A growing body of data suggests that on top of market size, demand and costs, economies' competitiveness for biomedical investment is positively linked to the local policy environment – all of the laws, regulations and initiatives in place affecting biopharmaceuticals. In other words, whether or not an economy provides, for instance, support for basic research, strong life sciences-related intellectual property (IP) rights, robust regulatory standards, streamlined processes and a fair price, matters for its ability to attract biomedical investment.

To illustrate, one policy area demonstrating this link is IP protection and the effect of an economy's IP environment on the number of clinical trials hosted there (as a proxy for biomedical investment). Figure 2 indicates that economies with weak IP environments tend to host on average 9-10 times fewer clinical trials than countries scoring in the upper half of the index.[14] In fact, regression analysis of the data suggests that strength of IP protection can explain over 40% of clinical trial intensity – which is significant given that a number of other factors are also typically considered important for attracting clinical trials (such as adequate capabilities and resources).[15]

IP protection is just one element of a wide range of policies needed to create a biomedical innovation and investment "ecosystem" – the total policy environment impacting an economy's attractiveness for investment.[16]

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. This includes identifying which policies are in place in different areas, which are not and how biomedical investment is affected in these areas.

FIGURE 2 Association between level of IP protection and clinical trial activity (as measured by the annual rate of new clinical trials, 2009-2013)



GIPC IP Index score (standardized to 100), 2015, life sciences-related indicators

Clinical trial activity (standardized per million population), average annual rate 2009-2013

Source: GIPC (2015); Clinicaltrials.gov

1.4 The context, rationale and scope of the BCI Survey

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. Generally speaking, key measures of broad competitiveness and innovation rely on a combination of hard data and surveys. Of the existing broader tools, the World Economic Forum's Global Competitiveness Index is arguably the world's most cited measure of economic development and competitiveness.[17] Based largely on survey questions and socio-economic data, the index captures a range of aspects, from strength of institutions, access and quality of infrastructure, health and primary education to level of business sophistication and innovation. The Global Innovation Index, co-published by Cornell University, INSEAD and the World Intellectual Property Organization, ranks economies based on innovation capabilities and enabling frameworks and actual innovative activities.[18] This index is a meta-analysis of a wide array of existing international databases of macroeconomic and societal statistics as well as relevant global survey data, such as the World Bank's annual Doing Business report.[19]

Sector specific measures of investment competitiveness also exist, including those that measure the biomedical sector particularly. An important measure of the biomedical environment is the Scientific American Worldview Scorecard, which ranks economies' performance in biotech innovation in seven categories, ranging from education and the workforce to institutional frameworks and political stability.[20] Similar to the above cited competitiveness and innovation indices in certain respects, the scorecard relies on existing metrics, primarily quantitative, that capture economies' ability to generate biotech innovation (which includes but is not limited to biomedical innovation).

Finally, there are tools that zero in on specific aspects of the biomedical investment environment, such as IP protection. For example, the U.S. Chamber's GIPC IP Index includes categories and indicators specific to the life sciences, such as indicators relating to enforcement of biopharmaceutical patents and existence of a legal basis for regulatory data protection.[21]

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 relies on statistically established survey modeling tools, including those used in the Global Competitiveness Index and Doing Business report, but refocuses them on the biomedical field. In total, the BCI 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, though still with results in a quantitative format, 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.

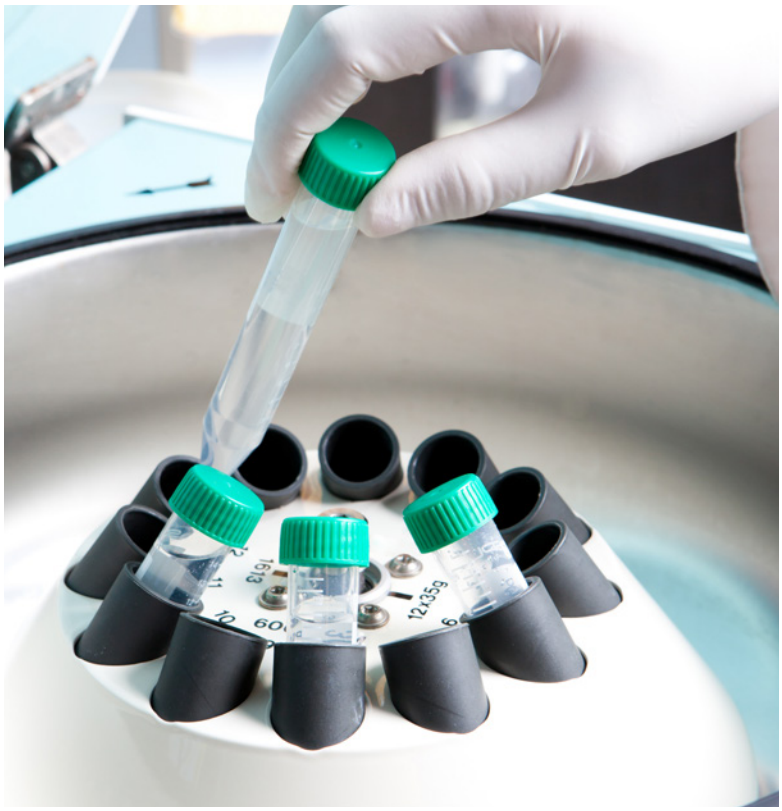
Using statistical analysis respondents' answers are translated into a quantitative score, which is used to benchmark economies' performance and overall attractiveness for investment (a full description of the BCI methodology is provided in section 4).

1.5 The 2015 BCI Survey

The BCI was first conducted as a pilot survey in 2012 and subsequently published in the 2012 *Scientific American Worldview*. The first edition covered 11 developed and emerging economies.

This, the second, global edition of the BCI widens the scope of coverage to 15 economies:

- Argentina;
- Brazil;
- Canada;
- China;
- India;
- Ireland;
- Israel;
- Mexico;
- Russia;
- Singapore;
- South Africa;
- Switzerland;
- Turkey;
- UK; and
- U.S.



The sample of economies in the 2015 BCI Survey is intended to reflect a range of key biopharmaceutical markets in terms of different levels of economic development, size and geographical spread. For instance, using the World Bank's classification system, this edition of the BCI comprises 8 high-income economies (only one of which, Russia, is not an OECD member) and 7 middle-income economies.[22]

In addition, the sample covers five geographic regions (adapted from the World Bank classification system[23]):

- **North America:** U.S. and Canada;
- **Latin America:** Argentina, Brazil and Mexico;
- **Europe:** Ireland, Russia, Turkey, Switzerland and UK;
- **Middle East & Africa:** Israel and South Africa; and
- **Asia:** China, India and Singapore.

The BCI captures a wealth of data and observations concerning major areas of the biomedical environment, providing new insights on policy strengths and challenges in the sampled markets. The insights generated by the BCI may be of value in several different ways and for different stakeholders. The BCI provides a common, numeric and global measure of biomedical competitiveness that may be used by governments, biomedical companies and other organizations to understand and compare economies' performance on a like-for-like basis. As a quantitative measure of investment attractiveness the BCI may also be used to analyze the relationship between various policy inputs and investment outputs. In addition, on an individual economy basis the BCI scores shed light on the particular areas for improvement in a given economy in terms of the total biomedical ecosystem as well as specific areas/categories within the ecosystem. As such, the BCI is an evidence-based platform for supporting efforts to strengthen the biomedical policy environment at the national, regional and global levels.

2 THE METHODOLOGY AND PROCESS OF THE BCI

The BCI is a survey-based index composed of two parts: 1) a survey completed by respondents; and 2) statistical analysis and translation of the responses into a quantitative score. This section will describe the components of the survey and the process of obtaining responses and define the methodology used to calculate the scores.

2.1 The composition of the BCI Survey

The BCI Survey is composed of 50 questions and asks seven questions in each of seven major categories applicable to the economy in which the respondent operates. The full text of the survey may be viewed in the Appendix to this report.

1. Part A – Leveraging Scientific Capabilities & Infrastructure
   The questions in this category assess the quality of personnel, technologies and facilities in biopharmaceutical research forums in the economy, and the ability to leverage these to translate discoveries into products.

2. Part B – Clinical Environment – from Test Tube to Patient
   The questions in this category assess the ability of research institutions in the economy to conduct necessary clinical research in a high quality and efficient manner.

3. Part C – Manufacturing & Logistics – Quality & Efficiency
   The questions in this category assess the ability to manufacture and distribute biopharmaceutical products efficiently and to a high standard in the economy.

4. Part D – Soundness & Effectiveness of the Regulatory Framework
   The questions in this category assess the ability of the regulatory system in the economy to ensure that only high quality, safe biopharmaceutical products enter the market, yet do so in a timely manner.

5. Part E – Health Care Financing
   The questions in this category assess the ability of new biopharmaceutical products to access the market via the pricing and reimbursement system in the economy in an efficient manner and at an acceptable price.

6. Part F – Effective Intellectual Property Protections
   The questions in this category assess the ability to fully realize required terms of intellectual property protections for biopharmaceutical products.

7. Part G – Overall Market Conditions
   The questions in this category assess the degree to which general political, macroeconomic and bureaucratic conditions facilitate or hinder biomedical investment in the economy.

Each category is designed to evaluate respondents' views of an economy's performance in a different area of the ecosystem in which the biomedical innovation life cycle takes place. In all, the survey seeks to provide a comprehensive, relevant and accurate picture of an economy's performance at different segments of the biomedical "pipeline", and hence its attractiveness for investment.

For each question, respondents rate an economy's performance in relation to a certain benchmark. Figure 3 gives examples of the benchmarks used in three survey questions. In Question 9, a high level of commitment to clinical research by hospitals across the country provides the benchmark. For Question 34, consideration of both cost and value of medicines in determining drug coverage acts as the benchmark. Finally, in Question 38, the ability to obtain meaningful remedies for the infringement of IP rights represents the benchmark for the response.

FIGURE 3 Sample questions from the 2015 BCI Survey

Question 9
How easy is it to recruit and maintain volunteers for participating in clinical trials in your country?

Very difficult (greatly lacking in volunteers; adverse public perception) ☐	Relatively difficult (volunteers are available but in insufficient numbers; officials anxious about public perception) ☐	Relatively easy (some limitations in the ability to secure long-term participation; public perception generally positive or not a factor) ☐	Easy (high level of success in recruiting and maintaining candidates; positive public perception) ☐

Question 34
To what extent is public reimbursement in your country based on the value of medicines and not only on their cost?

Not applicable (public reimbursement is not available) ☐	Not at all (reimbursement is based only on cost) ☐	To some extent (reimbursement is based mostly on cost but takes value into account) ☐	To a great extent (reimbursement is based on consideration of both the value of the product as well as price) ☐

Question 38
In your view, how effective are civil and criminal remedies for infringement of intellectual property rights in your country?

Highly ineffective (framework for litigation and penalties does not exist) ☐	Fairly ineffective (framework exists but is generally not implemented or enforced) ☐	Fairly effective (framework is generally implemented and enforced but with key exceptions) ☐	Very effective (including compensation, injunctions and penalties; ability to challenge validity of a patent) ☐

Source: BCI Survey (2014)

In order to capture specific nuances of economy performance, respondents select from a scale of four answers for each question. This scale ranges from the lowest possible performance to the highest possible performance (i.e., the benchmark), but the exact scale varies for each question. This design gives respondents a framework for gauging their views, but in a way that minimizes constraining their answers as much as possible.

2.2 Execution of the 2015 BCI Survey

The 2015 BCI Survey was distributed primarily to general managers of multinational research-based biopharmaceutical companies operating in the 15 sampled economies – in other words, experts in the field and on-the-ground practitioners with deep knowledge of the local biomedical investment environment in a given economy.

When asked about the utility and accuracy of the BCI, the overwhelming majority found the BCI to be a useful tool for assessing the biomedical ecosystem. In the view of 92% of respondents, most, if not all, of the questions covered relevant elements of an economy's attractiveness for biomedical investment.

2.3 Calculation and classification of scores

To score the responses, each question accounts for a total of two points, which means that with seven questions per category a maximum score of 14 exists for each category. The final category, a single question that captures a respondent's overall impression of country performance, receives a maximum score of 2. The four answer options for each question correspond to scores of 0.5, 1.0, 1.5 and 2.0 – ranging, in order, from the options reflecting the poorest to the highest performance. Based on the analysis of all 50 responses, each economy receives a score for each category as well as an overall score, out of a maximum of 100.

Based on category and overall scores, economies are classified into levels of biomedical investment competitiveness relative to the other sampled markets. For overall scores, economies are divided into four groups, with the upper and lower ends based on the distribution of the scores (which follows a typical bell curve pattern in which the scores are concentrated in a certain score range, in this case roughly between 55 and 85):

1. Strongly competitive
   Economies with an overall score above 80;

2. Reasonably competitive
   Economies with an overall score between 70 and 80;

3. Limited ability to compete
   Economies with an overall score between 60 and 70; and

4. Struggling to compete
   Economies with an overall score below 60.

This score spread and classification system is similar to ones used in other indices, even if the themes are different. For instance, the 2015 Index of Economic Freedom classifies sampled countries into five categories within a spread of 60 points, with the top group ("free" countries) consisting of countries with scores of 80-100, and the remaining four groups divided by scores of 70-79, 60-69, 50-59 and 40-49, respectively.[24]


40/0.65
160/0.17

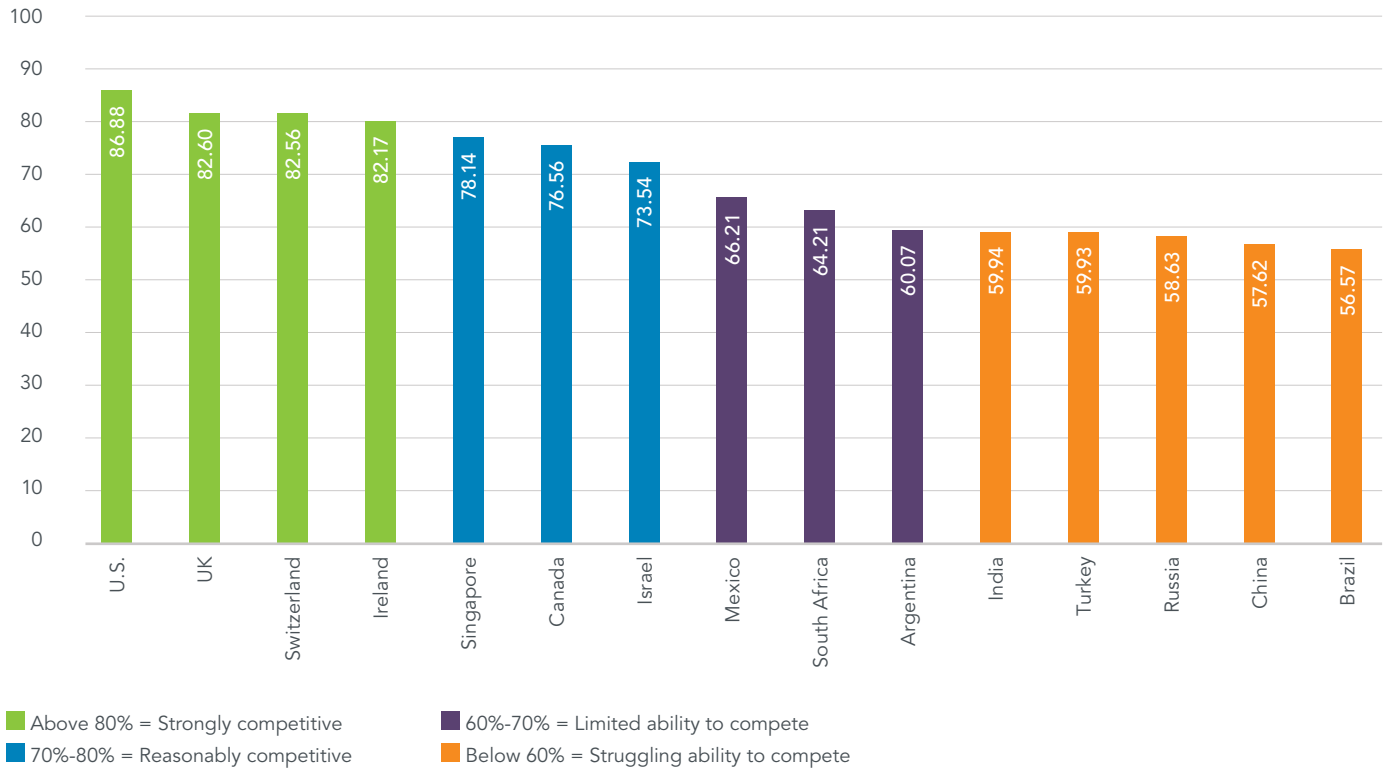
3 OVERALL FINDINGS OF THE 2015 BCI SURVEY

3.1 Overall economy scores

Figure 4 below summarizes the overall scores for all 15 markets covered in the 2015 BCI, 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 clear division by income, with an even split between the seven high-income and eight middle-income economies. High-income economies all score above 70 out of 100, with six of these seven achieving at least 75% of the total possible score. Having said that there is a significant range of close to 15 points between the high-income economies. The U.S., UK, Switzerland and Ireland, respectively, have the highest overall scores, and their biomedical environments fall into the category of "strongly competitive" relative to the other sampled economies. These four economies place at the top of the sample in most, if not all, categories. All four boast excellent and effective scientific research systems, regulatory frameworks that meet the highest international standards, pricing and reimbursement systems that provide comparatively better opportunities for market access and generally positive market conditions. Still, while the U.S. and UK particularly excel in the quality, scope and effectiveness of the scientific research system as well as clinical research capabilities, Ireland and Switzerland lead the pack in manufacturing capacity. The U.S. and Switzerland dominate the charts in terms of providing effective IP protections. It also worth mentioning that, not surprisingly, these economies have reached these levels of success predominantly through use of market-based,

FIGURE 4 Overall BCI scores and ranking by economy



pro-innovation policies and initiatives, including policies aimed at biomedical products.

Still, the top four performers all experience challenges in certain areas that do not permit their overall scores to rise to 90% of the total possible score or above. For instance, the U.S.' public pricing and reimbursement system (including the Medicare and Medicaid programs) is fragmented and sometimes difficult to navigate effectively. With fairly stringent price controls on both public and private drugs, local executives in the other three economies say that the government at times is missing the link between investment, research and market access in a timely manner and at a fair price. In addition, both the U.K. and Ireland still experience some gaps in effective translation and commercialization of research into new products as well as undermine market access incentives through heavy use of parallel importing of medicines. Across the four markets, high operational costs also cut into their attractiveness somewhat and all could benefit from greater regulatory streamlining.

The composition of the second group of high-income economies – comprised respectively of Singapore, Canada and Israel – is in some ways surprising. Positively, two "newly" developed economies, Singapore and Israel achieve scores not far below the top performers globally, with Singapore even scoring above Canada. For the past 25 years Singapore has worked to put in place state-of-the-art biomedical programs and initiatives, as well as strengthened its legal and regulatory framework, with the aim of stimulating homegrown biomedical talent and attracting FDI and technology transfer. In turn, Singapore has relatively strong capabilities in R&D and manufacturing, with most of the necessary regulatory frameworks and safeguards in place and in line with international best practices. Moreover, IP protection today is generally on par with world-leading standards. Israel's success in growing its biomedical attractiveness can be attributed in part to R&D capacity building and the strengthening of its biopharmaceutical IP regime, including improvements to its patent term restoration framework and the extension of RDP. In terms of scientific capabilities, Israel's score is 20-30% higher than emerging markets and in manufacturing and logistics, 10-20% higher.

In contrast, in the BCI Canada represents an outlier among high-income economies. Although Canada has many 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. Canada's score is a full 10 points under the top performer, the U.S., and significantly below the other high-income economies – despite in some cases having a much larger market. Canada's low relative 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.

Figure 5 isolates high-income economies' (with the exception of Israel) scores for three categories (IP Protections, Regulatory Framework and Healthcare Financing) to examine the ability to obtain timely and effective market access and exercise exclusivities derived from IP in these economies. Looking at the average score for all 3 categories, Canada clearly places in the bottom of the group, reflecting the above mentioned challenges.

Looking at the bottom half of the sampled BCI economies in terms of scores, what is also striking is that the most dynamic economies with the greatest market potential and lowest costs still bring up the rear. All BRIC economies (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.

Despite holding strong aspirations for growing its biopharmaceutical and biotech sectors, Brazil still has a long way to go to reach its potential for investment. In the view of local executives, the economy's regulatory system is fraught with delays and red tape. Widespread, draconian price

controls hinder market access. Moreover, the IP system, particularly the patenting process, is bureaucratic and generally ineffective.

Though biopharmaceuticals are one of the Russian government's strategic innovation priorities, Russia lacks many of the framework conditions necessary to achieve its industrial and innovation objectives. From the perspective of local executives there is only rudimentary quality control of biomedical products across most clinical and manufacturing phases – leaving the market largely out of sync with international standards. The market access environment is challenging and enforcement of IP rights and anti-counterfeiting actions are quite weak.

India possesses the foundation and potential for becoming a hub of biopharmaceutical innovation – but currently faces several major structural barriers to moving up from the bottom ranks in biomedical competitiveness. Local executives particularly noted the presence of major regulatory deficiencies and bottlenecks and very limited coverage of medicines, even with costs driven down. In addition, they highlighted major gaps in India's biopharmaceutical IP protection that render the system overall ineffective.

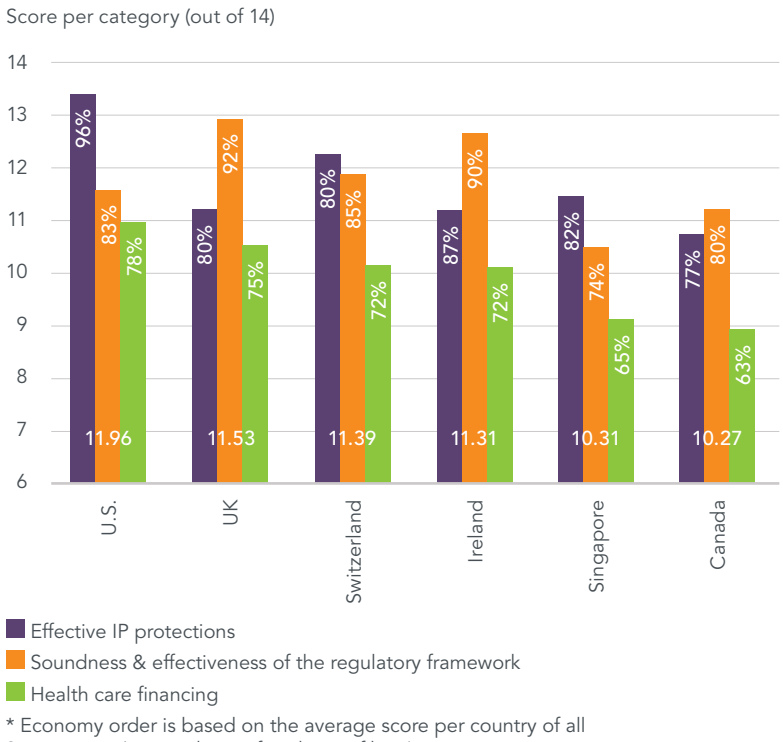
Vying for the second or third position globally in terms of biopharmaceutical market size, China's very low ranking for its biomedical ecosystem comes as somewhat of a surprise. Though improvements to the actual legal and regulatory framework affecting biomedical innovation are taking place in certain areas, in local executives' experience IP enforcement and actual available remedies remain fledgling. In addition, local executives face long approval delays and arbitrary regulatory processes as well as holes in quality control across the biomedical pipeline.

Despite the Turkish government's stated intention to grow the local innovative biomedical sector and a relatively low-cost environment, its policy environment hinders, rather than facilitates, a change of direction. Local executives cite increasingly stringent (and by some counts, protectionist) registration and market access requirements. They also confront major gaps in enforcement of patents and effective RDP. Though a manufacturing base exists, capacity for production of high quality active ingredients is missing, as are homegrown R&D capabilities.

Figure 6 summarizes several of the challenges in three of the above emerging markets – China, India and Turkey – identified by local executives in their responses to the BCI Survey.

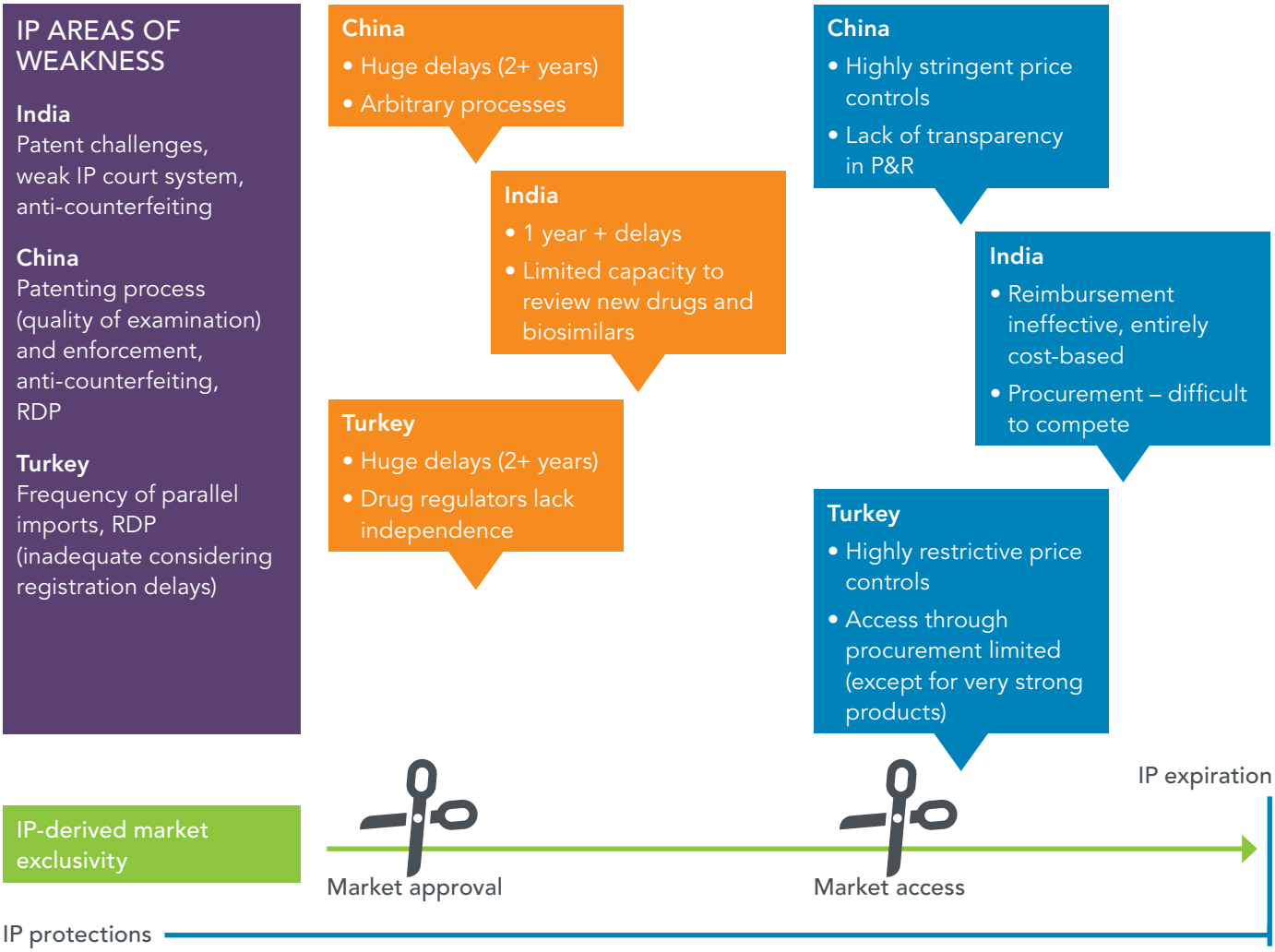
This is not to say that the BRICs and Turkey do not possess several attractive aspects of their biomedical environments – not only in terms of low costs and high market demand, but also the existence of basic capabilities as foundations for further growth – and hence hold future potential. Nevertheless, in regard to emerging markets, the BCI overall scores and the above discussion underscore that size, costs and growth potential are not the only factors when it comes to biomedical investment attractiveness. Rather, the policy environment does in fact matter for drawing biomedical FDI in-flows into these economies. In economies such as the BRICs, where policies affecting aspects of the biomedical environment present substantial challenges

FIGURE 5 Comparing biopharmaceutical market access across high-income economies*



* Economy order is based on the average score per country of all 3 categories (seen at base of each set of bars).

FIGURE 6 Market access challenges in emerging markets: Feedback from executives



across many fronts – which in many cases outweigh incremental improvements made to different areas of the ecosystem – local executives also rank these economies as struggling to be competitive for biomedical investment from their companies. Figures 7 and 8 highlight two areas in which challenging policies erode the biomedical ecosystem in emerging economies and impact investment attractiveness (in other words, are linked to lower relative BCI scores).

Finally, the three economies falling into the category of "limited ability to compete" – Mexico, South Africa and Argentina – exemplify middle-income economies that while imposing problematic conditions in certain areas, also have certain strengths that make these economies relatively more attractive compared to the bottom group. For instance, Mexico possesses foundational capabilities in scientific research and biopharmaceutical manufacturing as well as a basic level of quality control. At the same time, innovative drugs are placed at a disadvantage in the market access stage; substantial challenges in IP enforcement are present; and key gaps exist in the quality control of advanced products such as biosimilars.

FIGURE 7 What does the BCI tell us about IP policy and innovation?

How supportive the IP policy is in a given country speaks to trends across the board towards biopharmaceutical innovation, and future development and access to new medicines.

With a lack of IP rights specific to biopharmaceuticals and a challenging enforcement environment, India also demonstrates a weak level of innovation. BCI respondents cited inadequate attention from the government to developing a culture of biopharmaceutical innovation, building life sciences capabilities and translating basic research into tangible health technologies.

In contrast, Israel's strengthening of its IP regime in recent years – including improvements to patent term restoration and extension of data exclusivity – and a parallel rise in its BCI score on IP between 2012 and 2015 have enabled other areas of the environment to improve. For instance, in terms of scientific capabilities, Israel's score is 20-30% higher than emerging markets and in manufacturing and logistics, 10-20% higher.

FIGURE 8 What does the BCI tell us about mandatory localization policies?

Localization requirements do not constitute part of a policy mix that attracts biopharmaceutical investment. Countries that introduced heavy-handed localization requirements in 2014 tend to score at the bottom of the BCI (below 60% of the total possible score, categorized as "struggling to compete").

Moreover, on a category basis, the BCI shows that countries opting for localization requirements actually lack an environment that can support local R&D and manufacturing, whether mandated or not. Rather, in many cases, the policy environment in different areas actually impedes localization.

To illustrate, China has recently raised requirements for local clinical trials, yet in the BCI local executives cite huge clinical trial approval delays and arbitrary processes that make local clinical trials difficult to actually conduct. In Russia, proposed increases to local manufacturing requirements are incongruent with the currently low level of local manufacturing capacity (with BCI respondents noting crucial holes manufacturing standards such as GMP compliance). Similarly, Turkey requires 51% of the total cost of production to be derived from local materials/labor for products with local generic alternatives yet domestic manufacturers do not have adequate capabilities for high-quality production of APIs.

South Africa boasts a relatively strong interest in and the human capital available for clinical research and, while its manufacturing capabilities are basic, they are seen as mainly being of high quality. Nevertheless, South Africa presents difficult market access and IP environments, local executives face severe regulatory delays and regulatory capacity is weak for new and/or advanced products.

For its part, Argentina has an adequate foundation in scientific capabilities and fairly good compliance with international standards in research and manufacturing (with some exceptions). Drug coverage is also seen as being fairly strong in Argentina. Still, regulatory processes are affected by significant delays and lack of independence, and innovative drugs are often de-prioritized in the pricing and reimbursement system. Moreover, local executives view the IP system as largely ineffective in terms of available protections and actual remedies, on top of legal and political instability.

The following subsections will examine the BCI results on a category by category basis.

3.2 Scores for Part A – Leveraging Scientific Capabilities & Infrastructure

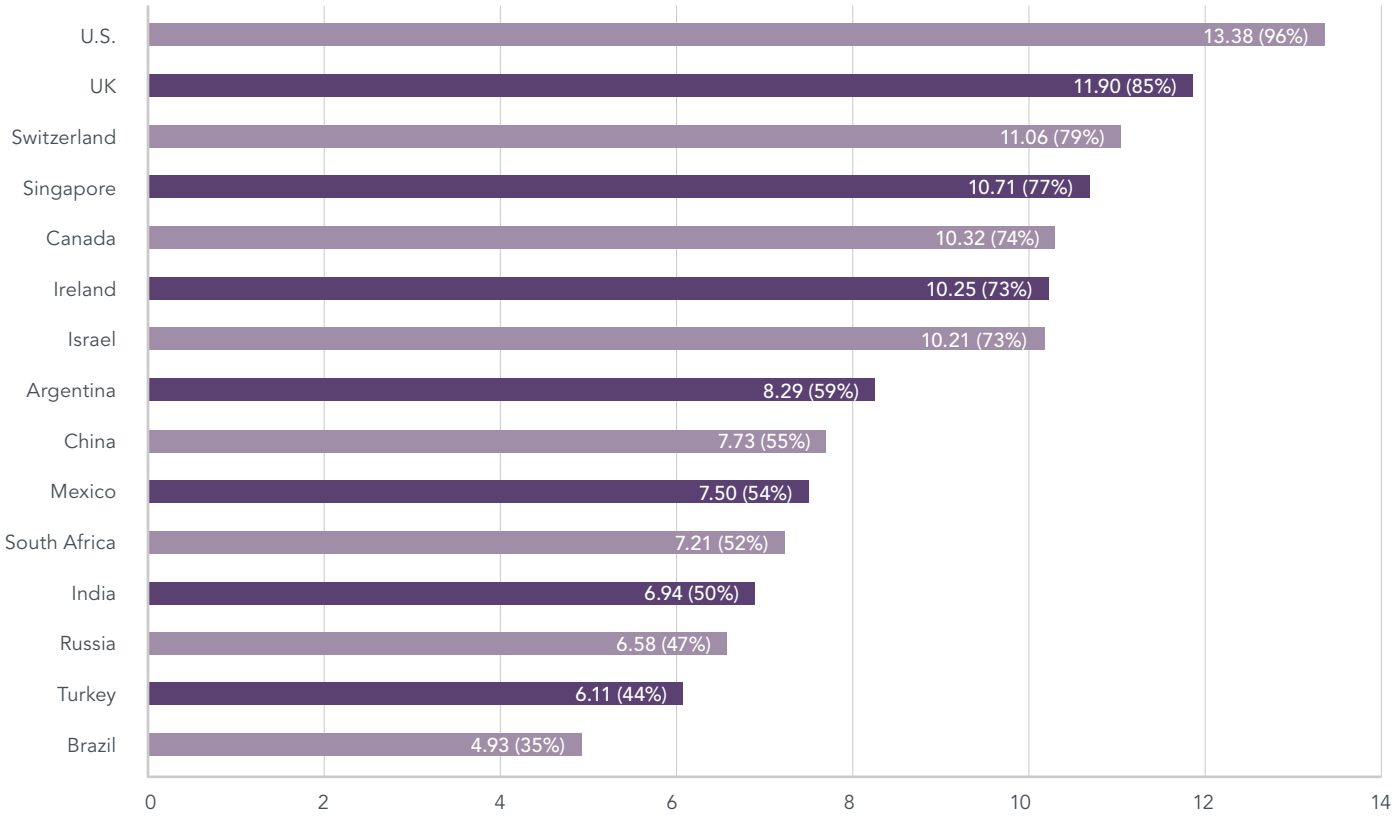
The biopharmaceutical innovation system is driven by several science and technology "push factors", including investment in biopharmaceutical R&D, a steady source of cutting edge advances in the life sciences and a sustained supply of physical and human resources available and utilized for biopharmaceutical innovation.[25] Specific elements that are often identified are: a sufficient quantity of highly-skilled biomedical professionals and researchers; scientific infrastructure; the presence of research clusters; technology transfer frameworks and financial support for R&D, including both public and private investment.[26] For instance, federal funding aimed at fundamental biomedical research by universities and public research institutions has been identified as a key element of biomedical discovery in the U.S., and a basis for drug development.[27]

Figure 9 summarizes the total scores for the first category, Part A – Leveraging Scientific Capabilities & Infrastructure. The category consists of seven questions, with a maximum possible score of 14.

The results in this category are marked by significant gaps in capabilities between economies. Among those in the top tier in terms of overall score, the U.S. and UK also do very well in terms of scientific capabilities and infrastructure, with the U.S. achieving close to 100% of the total possible score.

Switzerland and Ireland, along with the second tier – or the remaining 3 high-income economies – all perform slightly below, with scores between 60

FIGURE 9 Economy scores for Part A – Scientific Capabilities & Infrastructure



and 80% of the total possible score. The key issue cited by BCI respondents that holds this group back is the need to enhance commercialization and translation of research into actual products.

The middle-income economies in the sample all fall into the bottom half, with scores under 60% of the total possible score. Brazil brings up the rear by a large margin, its score less than half of the average high-income economy. Economies in this group, and particularly Brazil, demonstrate significant weaknesses and deficiencies in the scope and quality of the scientific research system vis-à-vis biomedical R&D, as well as lack a culture and structure for translating research into new technologies.

TABLE 1 Economy scores for Part B – Clinical Environment

	Ranking	Category score	% of possible score
High per capita intensity of clinical trials			
1	Singapore	11.21	80%
2	U.S.	11.13	79%
3	Canada	11.07	79%
4	UK	10.70	76%
5	Israel	10.64	76%
6	Switzerland	10.56	75%
7	Ireland	10.34	74%
Low per capita intensity of clinical trials			
8	Mexico	10.21	73%
9	Turkey	10.11	72%
10	South Africa	10.00	71%
11	Russia	9.67	69%
12	Argentina	9.36	67%
13	India	9.17	65%
14	China	7.92	57%
15	Brazil	7.86	56%

3.3 Scores for Part B – Clinical Environment – From Test Tube to Patient

Conducting clinical trials is part of an extensive process for determining which compounds out of hundreds under investigation may be further developed and eventually brought to market, and in what manner. Clinical research enables companies and drug regulators to ensure that new drugs will be safe and effective for use. It also often uncovers novel applications of medicines and medical devices or facilitates tailoring drugs to different populations. Furthermore, it provides a wide number of social and economic benefits to patients, health systems and national economies, including advance access to innovative drugs, opportunities for local participation in cutting edge research and clinical standards and improvements to infrastructure.[28]

From an investment perspective, biomedical companies seek clinical trial sites in which they can conduct trials both in a way that would bring them value, as well as provide the most effective means of collecting data. Therefore, companies consider a wide range of factors when deciding to conduct clinical trials in a given economy. These factors include: the characteristics of the population related to the specific product to be tested; the availability and willingness of the population to participate throughout the duration of the trial; the infrastructure of local hospitals and research centers; the ability of physicians and supporting medical staff to carry out clinical trials and work with international organizations; the ease of the regulatory system, including approval of clinical trials; and the costs of performing the trials in the economy.[29]

Table 1 summarizes the total scores for the second category, Part B – Clinical Environment – From Test Tube to Patient. The category consists of seven questions, with a maximum possible score of 14.

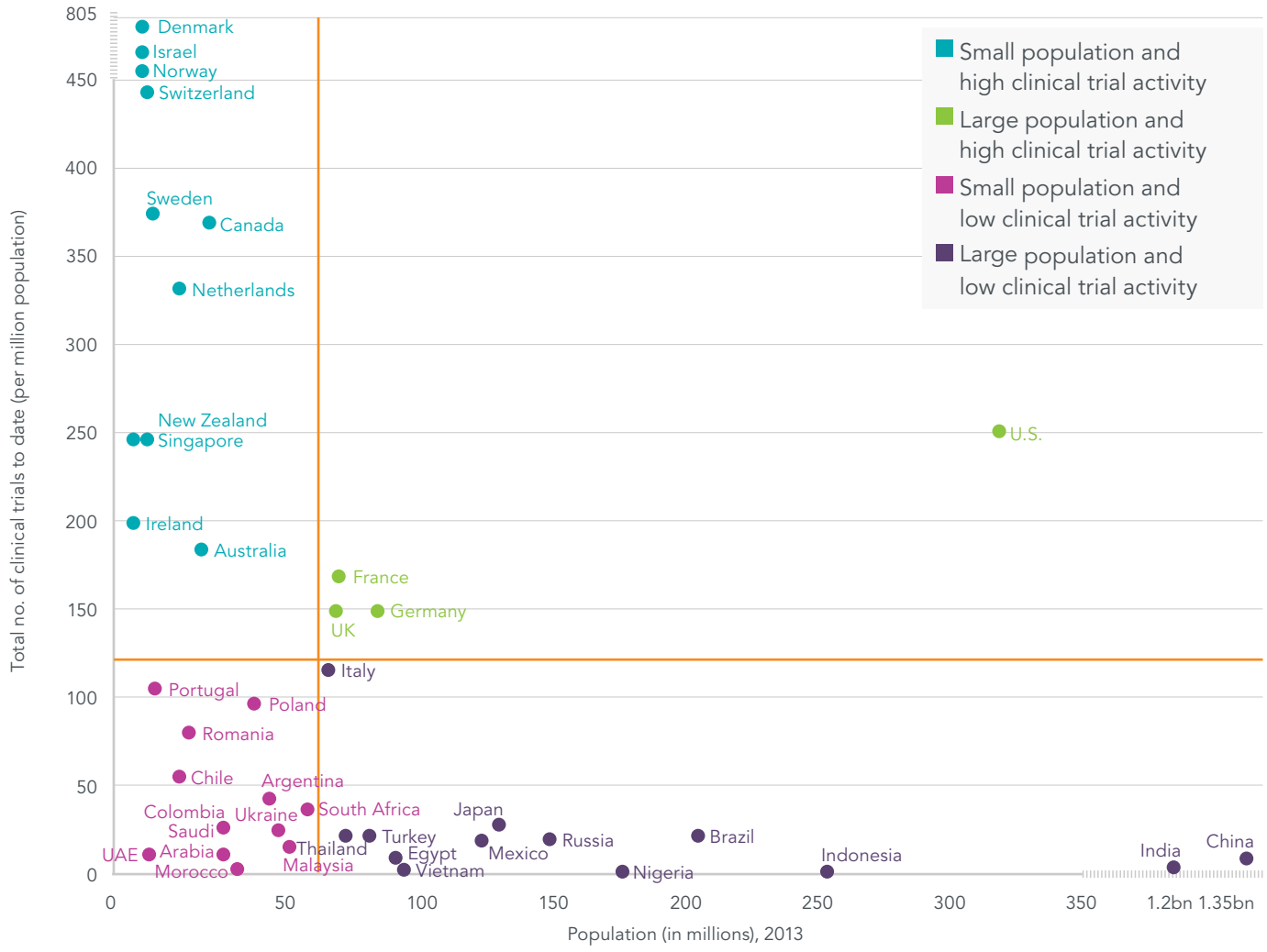
Table 1 shows a fairly clear divide in BCI scores for Part B – Clinical Environment between economies with a high intensity of clinical trials and those with a low intensity (as seen in the below Figure 10). In other words, economies placing in the top half of the BCI sample actually see a relatively high clinical trial intensity in terms of per capita number of clinical trials taking place in the economy, while economies placing in the bottom half see a relatively low clinical trial intensity.

Moreover, while they present lower relative operational costs, economies in the bottom half of the sample (including India, China and Brazil) display significant clinical trial approval delays and burdensome regulations that bring down their scores. The above suggests that although the cost of clinical research plays a role in economies' competitiveness and attractiveness as clinical trial destinations, in most cases approval delays and red tape hold more weight in investment decisions.

3.4 Scores for Part C – Manufacturing & Logistics – Quality & Efficiency

Having a strong manufacturing base, especially one that can handle production of large and/or complex molecules, is critical for biomedical investment in the area of manufacturing. Of particular importance to investment is the ability to access needed permits and materials (whether they are imported or produced locally) as well as ensure that products manufactured in the economy meet international standards of safety, quality and efficacy. The latter is safeguarded through a number of regulatory standards, including implementation of Good Manufacturing Practice (GMP) across an economy's

FIGURE 10 Per capita clinical trial intensity (based on number of clinical trials to date per million population) vs. population in selected countries



Source: Pugatch Consiium (2014); Clinicaltrials.gov, World Bank (2013)

manufacturing plants and adequate quality control of imports, exports and internal supply chains. Finally, local capacity, expertise and infrastructure for the manufacturing operation itself are essential.

Research-based companies are likely to limit investment in a market where the above standards are not practiced.[30] Conversely, where a high quality and efficient manufacturing system does exist, these companies are more likely to invest a portion of their operations, laboratories, factories, etc. in the economy, and employ local scientists, technicians and clinicians there. In this way, cutting edge technologies, know-how and overall capacity for innovation and industrial growth is further built up in the economy.[31]

Table 2 summarizes the total scores for the third category, Part C – Manufacturing & Logistics – Quality & Efficiency. The category consists of seven questions, with a maximum possible score of 14.

TABLE 2 Economy scores for Part C – Manufacturing & Logistics

	Ranking	Category score	% of possible score
1	Ireland	13.17	94%
2	Switzerland	13.00	93%
3	UK	12.60	90%
4	Singapore	12.29	88%
5	U.S.	12.00	86%
6	Canada	11.54	82%
7	Israel	11.29	81%
8	South Africa	10.50	75%
9	Turkey	10.18	73%
10	India	10.00	71%
11	Mexico	9.64	69%
12	Brazil	8.79	63%
13	China	8.62	62%
14	Argentina	8.50	61%
15	Russia	7.58	54%

In this category, there is a fairly large range in score, with a clear divide between high-income and middle-income economies. Economies scoring at the top possess modern manufacturing capabilities and processes meeting the highest international standards. High-income economies that score below 90% of the possible score, such as the U.S. and Canada do so mainly because of the presence of some red tape associated with importing raw materials and obtaining manufacturing permits noted by BCI respondents.

Middle-income economies, particularly the BRICs, score 20-40% lower than the high-income economies in the sample, showing that they still have a ways to go to provide effective, globally competitive manufacturing environments. Russia scores at the very bottom, based on its lack of GMP compliance and inadequate review of locally manufactured products as well as difficulties experienced in securing manufacturing permits, all cited as concerns by BCI respondents. Mexico is also an economy that places lower than expected considering its position in overall scores, particularly because of gaps in quality control of warehousing and distribution services.

3.5 Scores for Part D – Soundness & Effectiveness of the Regulatory Framework

The regulatory environment in a given economy plays an important role in shaping incentives for investment and establishing adequate levels of quality and safety for biomedical products. Inadequate approval standards may promote the presence of substandard drugs in the market, which could affect demand for high quality drugs and discourage investment in new products.[32] Conversely, a strong regulatory environment creates the conditions for the production and sale of high quality products and technologies.[33] While complying with these standards may impose substantial costs on manufacturers it also gives patients and health care providers confidence that new biomedical products are safe and effective.

High regulatory standards tend to refer to those which assess the quality, safety and efficacy of products to a high level, according to the

International Conference on Harmonisation's (ICH) standards and require a system for monitoring products once they are in the market (known as pharmacovigilance).[34] These standards vary depending on the type of product, whether it be a completely new drug application (NDA), a generic or a biosimilar, with generic approval needing to include bioequivalence testing and biosimilar approval a higher standard that goes beyond bioequivalence testing.[35]

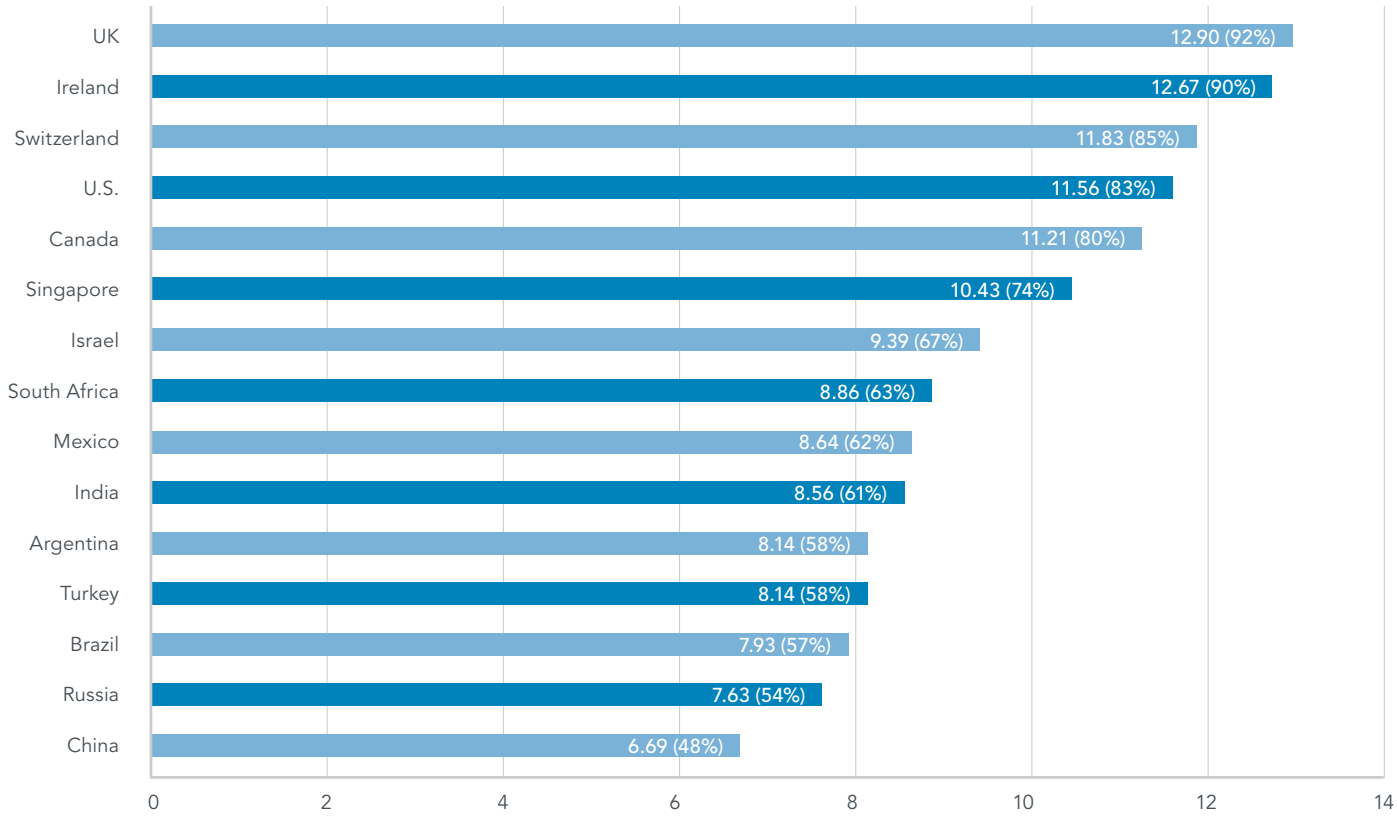
Figure 11 summarizes the total scores for the fourth category, Part D – Soundness & Effectiveness of the Regulatory Framework. The category consists of seven questions, with a maximum possible score of 14.

In terms of soundness and effectiveness of the biomedical regulatory framework, the scores in this category are a fairly strong reflection of the overall BCI scores. The top two tiers are composed of the same economies as in the overall scores, with Canada falling into the second tier largely due to delays in the review and approval of biomedical products. Though scoring slightly lower, Singapore also performs to a satisfactory level, showing that its overall score and relatively strong performance in investment attractiveness is not only due to building capabilities but also improving regulatory standards.

Economies placing around 60% (plus or minus 5%) of the total possible score tend to have in place basic regulatory frameworks that are generally or in certain cases in line with international standards. However, these markets often do not have the capacity for high quality review of advanced or cutting edge products, such as biologics or biosimilars.

Regulation of biomedical products in the economies placing in the bottom group, particularly China, not only display weak standards, but also very long market approval timelines and lack of a transparent and independent drug regulator.

FIGURE 11 Economy scores for Part D – Regulatory Framework



3.6 Scores for Part E – Health Care Financing

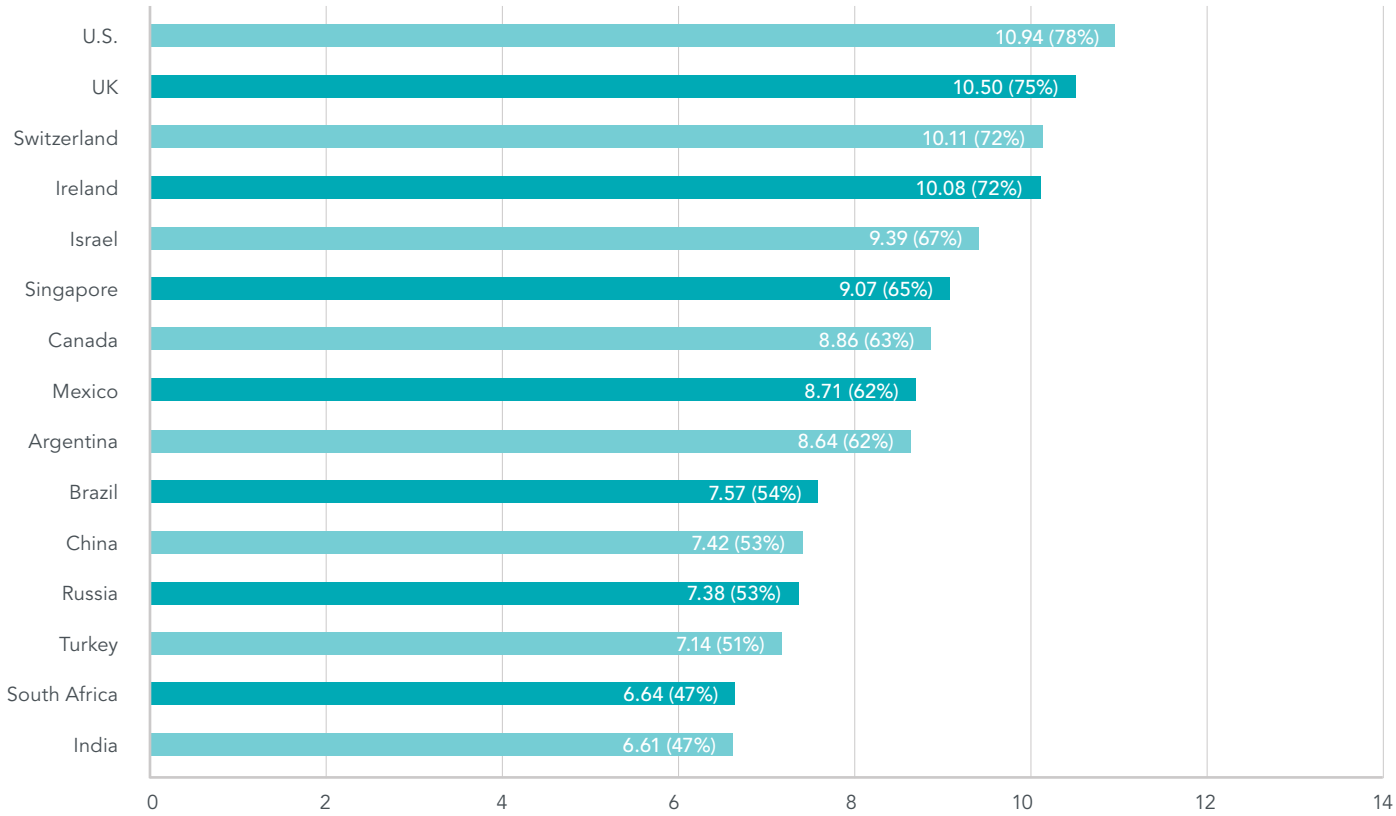
Most health care systems today have in place either direct or indirect mechanisms for regulating the pricing and reimbursement of medicines. In Europe this is frequently done directly through pricing and reimbursement negotiations between health ministries or government agencies and biomedical manufacturers. Prices are often determined through complicated formulas of internal and external reference pricing that compare the cost of medicines in a number of countries. Many countries have also adopted advanced systems of pharmacoeconomic and cost-effectiveness analysis and comparisons. In other more diversified health systems such as in the U.S., the price and cost of medicines is to a greater extent influenced by pure market factors. However, payers – be they public bodies or private health insurers – still set formularies and reimbursement guidelines.

The continued rise of health care costs in mature and emerging markets has put more pressure on health authorities and payers to limit future increases in health spending through different pricing, reimbursement and procurement policies. The manner and extent to which these policies are put in place can have a profound impact on the incentives for biomedical investment.[36] Academic research and modeling suggests that for biomedical products restrictive pricing and reimbursement policies limit and delay investment in a market, including new product launches.[37]

Figure 12 summarizes the total scores for the fifth category, Part E – Health Care Financing. The category consists of seven questions, with a maximum possible score of 14.

The range for this category, which covers the pricing, reimbursement and procurement environment in a given economy, is not too large – with just around a 30% difference between the top and bottom scores, and top being around

FIGURE 12 Economy scores for Part E – Health Care Financing



80% of the possible score. This suggests that these aspects of the environment are of particular concern to local executives and a challenge across the board, although clearly much more difficult in certain economies compared to others.

Economies scoring at the top, again matching the top tier in the overall BCI scores, tend to provide more comprehensive reimbursement for medicines and involve a valuation of medicines that, generally speaking, takes into account product value on top of cost.

Among established high-income economies Canada is a particular outlier in this category mainly on account of the use of restrictive price controls that limit market access and pose significant challenges in the eyes of local executives.

The BRICS and Turkey all score quite poorly at under 60% of the total possible score, reflecting some, if not all, of the following challenges: highly stringent price controls, poor coverage of medicines, arbitrary decision-making and procurement processes that place innovative drugs at a significant disadvantage.

3.7 Scores for Part F – Effective Intellectual Property Protections

Over the last decade a number of empirical studies have been published on the positive and cumulative effect of IP protection on investment generally. For instance, one OECD study found that a 1% change in the strength of a national IP environment (based on a statistical index) is associated with a 2.8% increase in FDI in-flows.[38]

In relation to the life sciences, IP rights play at least two major roles: 1) provide a guarantee of temporary market exclusivity that facilitates a return on investment and further re-investment in R&D; and 2) act as a platform for transferring technologies among R&D entities. Hence, a strong legal basis for IP protection as well as its enforcement in a given market assures biomedical companies and other investors that their IP assets will be protected from infringement as they develop, test and launch products in that market.

In particular, patents and other forms of exclusivity for biomedical products, such as regulatory data protection and special exclusivity incentives for the protection and production of orphan drugs, provide research-based companies with an incentive to invest vast sums in R&D and the discovery of new biomedical products and technologies. As suggested above in Figure 1, the research process for biomedical products is unique in its time, cost and high rate of failure. The market exclusivity period provided by IP rights gives firms the protection and incentive needed to recoup R&D investments made. Evidence suggests that many drugs and therapies would not have been discovered had it not been for the incentive and protection provided by these IP rights.[39]

Equally important for biomedical products is the on-the-ground enforcement of IP protections. Key concerns for biomedical investors are the extent to which the production and availability of infringing products, including counterfeits, are limited and deterred. The ability to control the manufacturing and sale of products protected by patents and trademarks within the country in which these rights are registered is also crucial in the biomedical sector. The adoption of a regime that permits parallel trade means that the legitimate owner of the rights relating to a product in a given country no longer has the exclusive right to operate in that economy and must now compete against commercial intermediaries which have imported the product from other markets.[40]

Figure 13 summarizes the total scores for the sixth category, Part F – Effective IP Protections. The category consists of seven questions, with a maximum possible score of 14.

Once again, in terms of IP protection for the life sciences, the distribution of scores is largely parallel to the overall BCI scores, suggesting that having strong and effective IP protection in place also represents a kind of gateway to promoting other areas of the biomedical ecosystem. Vice versa, economies with weak IP environments also tend to lack overall biomedical competitiveness.

This category is led by the U.S., which again scores close to 100% of the total possible score. Notably, the top tier also includes Singapore, who along with the U.S. and Switzerland, is known for having put in place a robust legal framework –

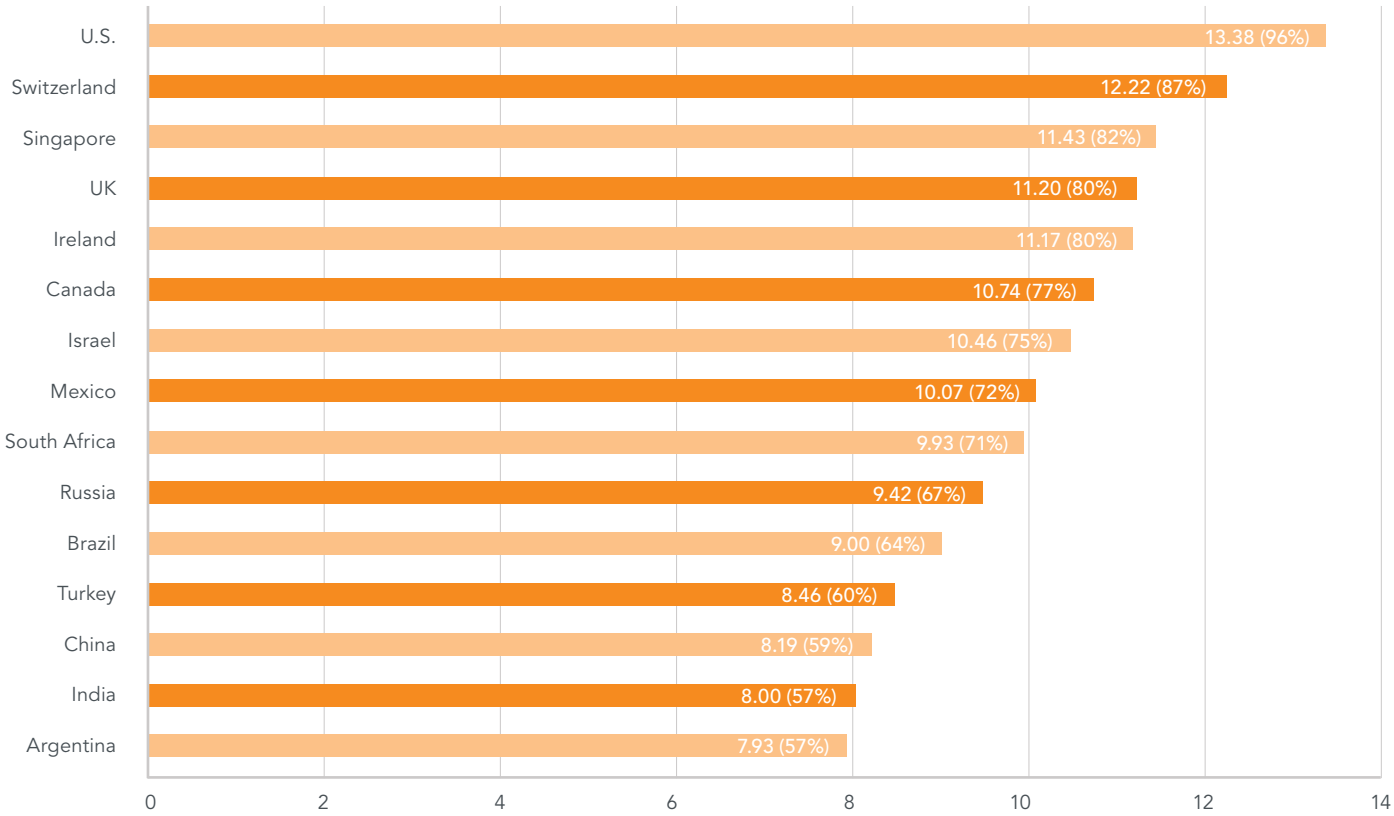
both overall and specifically for life sciences – and a track record of enforcing these rules across the judicial, administrative and police systems.

The UK, Ireland and Canada deviate from these standards in a few particular areas and as such score below the other high-income economies in the BCI. Local executives in the U.K. and Ireland raised concerns over the frequency of, and uncertainty introduced due to, parallel importing of medicines from other European markets. In addition, although, as mentioned, Israel has worked to put in place several of the key tenants of life sciences IP protection, it too faces some challenges with parallel importing.

Among established high-income economies, Canada ranks the least attractive in the group. Its scores are particularly low on questions that deal with IP "fundamentals", i.e. overall IP protection and enforcement. In addition, its life sciences patenting (including onerous patentability standards and lack of patent term restoration) as well as effective instruments for the enforcement of IP rights are out of sync with international best practices.

Finally, emerging markets largely hold the bottom positions in this category, with Argentina scoring the lowest. These economies tend to lack key elements of life sciences IP protection, such as RDP and patent term extension, as well as effective enforcement mechanisms for the IP rights that do exist. Ability to obtain meaningful remedies for infringement and effectiveness of anti-counterfeiting actions are considered particularly weak among these economies.

FIGURE 13 Economy scores for Part F – IP Protections



4 ECONOMY-SPECIFIC FINDINGS AND PROFILES

Introduction

The section presents a summary and analysis of each individual economy's overall and category scores.

Each profile first provides a summary of the economy's performance and key challenges and opportunities faced there based on the BCI Survey results.

The profile also displays the overall BCI score, ranking and classification for the economy as well as a comparative analysis of the economy's score, shown in relation to the average for: 1) high-income economies; 2) middle-income economies; and 3) the region to which the economy belongs.

Each profile also provides the economy's scores and ranking per category, presented in relation to its income group, region and the top scoring economy in the sample, the U.S.

Finally, drawing on BCI responses and comments, a more in-depth analysis and explanation of the economy's BCI scores is provided. This section includes the key strengths and weaknesses identified by local executives, both generally and per category.

ARGENTINA

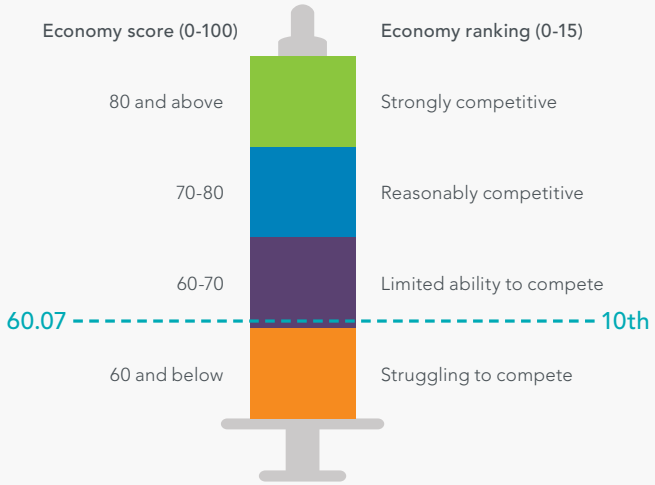
Market Overview – From the Lens of Local Executives

Local executives find the biomedical environment in Argentina to have relatively limited attractiveness, stifled by structural deficiencies and macroeconomic and political volatility. Within the BCI, Argentina achieves a similar level of attractiveness as the average middle-income economy and falls into the lower half considering only the Latin America region.

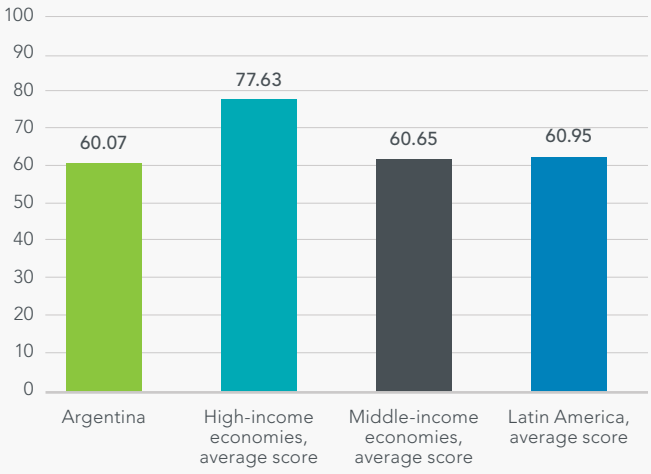
In particular, local executives have concerns with what they describe as a lack of development of biomedical specialties within the scientific research system and inadequate focus on translational R&D. Significant delays and gaps in institutional capacity are also seen as hampering the effectiveness and quality of the regulatory and IP systems. In the view of local executives, cost is often prioritized at the expense of rewarding value within the pricing and reimbursement system. Finally, weak market conditions – a poor economic, legal and business environment, and particularly, political instability – tend to affect Argentina's attractiveness to local executives more than the economy's market potential.

Nevertheless, local executives do view Argentina as possessing certain key stepping-stones to building an innovative biomedical sector. These include an adequate general science base as well as basic regulatory standards in place for clinical research and biopharmaceutical manufacturing. Argentina is also regarded by local executives as providing fairly wide coverage of medicines, but a significant gap in access to innovative products still remains.

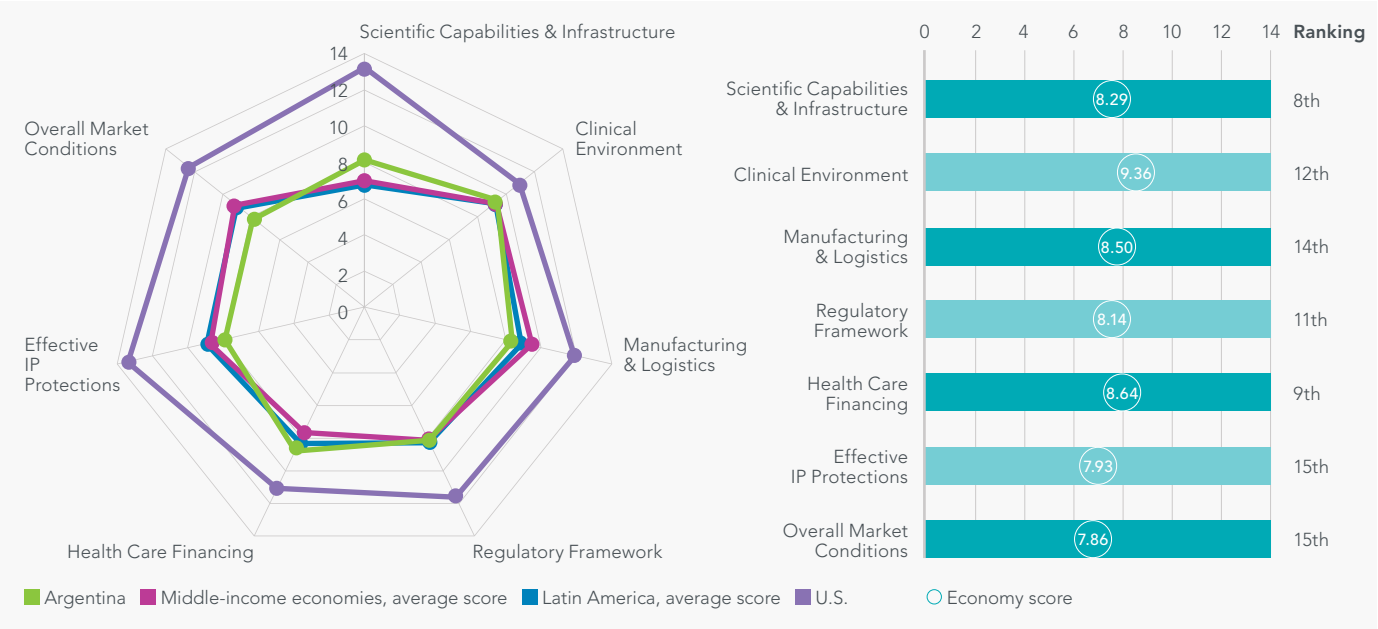
BCI Overall Results



Comparative Results – BCI Overall Scores



BCI Scores by Category



Map of the National Biopharmaceutical Environment – BCI Results in Depth

Key areas of strength

- ✔ Adequate foundation exists in scientific capabilities
- ✔ Fairly good compliance with international standards in research and manufacturing, with exceptions
- ✔ Overall drug coverage in place through public and supplementary channels (though key gaps on innovative drugs)

Key areas of weakness

- ✘ Regulatory processes affected by significant delays and lack of independence
- ✘ Innovative drugs often de-prioritized in pricing and reimbursement system
- ✘ Ineffective intellectual property system in terms of available protections and actual remedies
- ✘ Legal and political instability hinder existing market potential

Scientific Capabilities & Infrastructure

- Scientific education and training is viewed as relatively well developed.
- Key weaknesses were identified in the translation and commercialization of biomedical research.

Clinical Environment

- Cost and approval times for clinical trials seen as an impediment to research.
- Executives overwhelmingly agreed that adherence to global clinical standards takes place.

Manufacturing & Logistics

- Limited capacity exists for local production of high quality APIs.
- Controls on imported materials and quality assurance standards for warehousing and distribution perceived as of a reasonable standard in most cases.

Regulatory Framework

- Review of generics and biosimilar applications not regarded as meeting international standards
- Challenges were also identified in terms of approval times and institutional independence of health regulators.

Health Care Financing

- General coverage of medicines is seen as adequate, but special coverage of cutting edge drugs only available on a limited basis.
- Price controls are viewed as stringent and based mainly on cost rather than value, and transparency of pricing decisions as lacking transparency.

Effective IP Protections

- Available IP protections viewed as limited with considerable lack of enforcement.
- Very low levels of professional and institutional capacity for patent examination.

Overall Market Conditions

- Argentina market perceived as somewhat attractive in terms of demand and prioritization of innovative drugs.
- Concerns were raised over the rule of law, an unstable political environment and general lack of governmental support for the biopharmaceutical sector.

BRAZIL

Market Overview – From the Lens of Local Executives

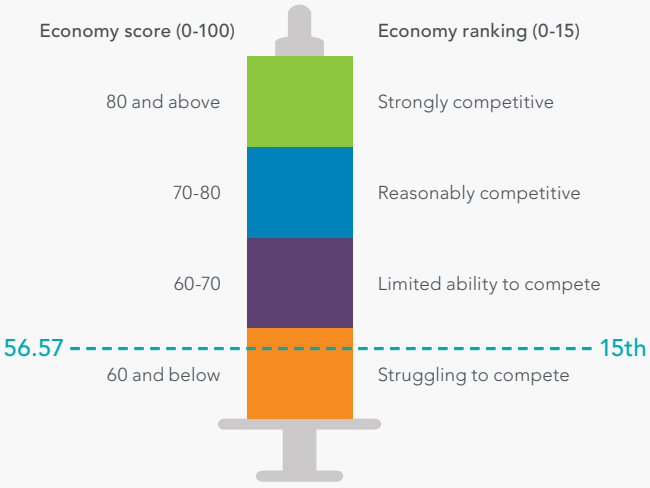
Local executives view Brazil's biomedical sector as struggling to compete with other key markets. Within the BCI, Brazil performs slightly worse than the average middle-income economy as well as other major Latin American markets.

In the view of local executives Brazil's key strengths lie in government support for improving research and development and for efforts to bring the biopharmaceutical regulatory framework in the areas of clinical research and manufacturing quality control in line with international standards.

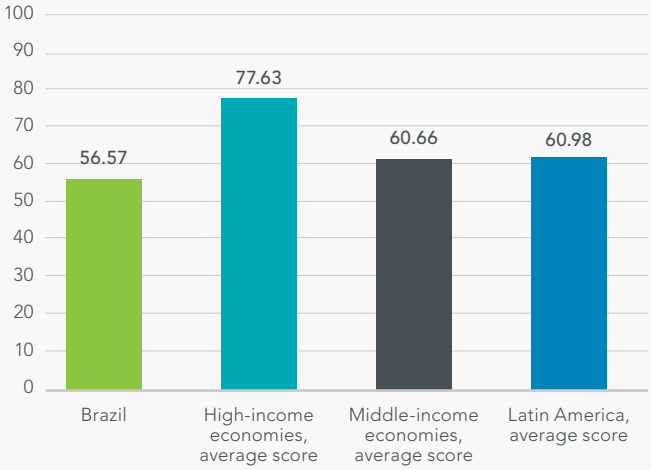
Despite these supporting factors, local executives find that important gaps remain in Brazil's biopharmaceutical environment that impede its ability to attract biopharmaceutical investment. They view scientific research and technology transfer as remaining relatively limited by international comparison, and stringent price controls and policies favoring generic drugs are seen as hindering market access. Across Brazil's regulatory and legal system as it affects biopharmaceuticals, local executives identified gaps in efficiency and expertise that are needed to operate effectively.

In 2014-15 the Brazilian government has recognized several similar gaps in the biomedical ecosystem, introducing legislation aimed at simplifying registration and removing barriers for commercialization of new products and technologies.[41] Recent efforts to reduce approval times for certain drug classes are also important steps towards resolving the existing barriers to competitiveness in Brazil.[42]

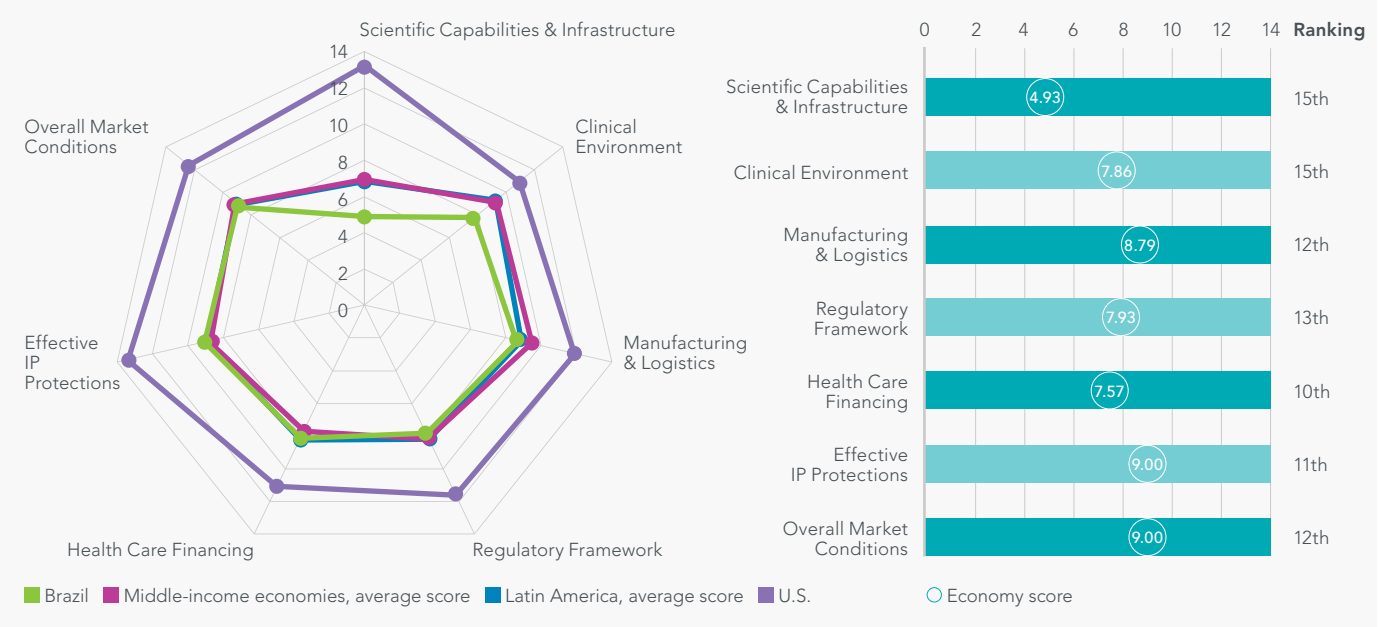
BCI Overall Results



Comparative Results – BCI Overall Scores



BCI Scores by Category



Map of the National Biopharmaceutical Environment – BCI Results in Depth

Key areas of strength

- ✔ Market considered overall attractive in terms of demand
- ✔ Fairly good compliance with global clinical trial standards
- ✔ Inspection of imported and exported materials/products generally adequate

Key areas of weakness

- ✘ Regulatory system fraught with delays and red tape
- ✘ Widespread, draconian price controls hinder market access
- ✘ Bureaucratic, ineffective patenting process
- ✘ Tax environment not business-friendly

Scientific Capabilities & Infrastructure

- Scientific research system is viewed as limited in scope and weak in quality.
- Significant distance is perceived between research institutions and the biopharmaceutical industry.

Clinical Environment

- Lengthy delays for approval of clinical trials approval are experienced.
- Clinical trials regulations are regarded as burdensome and ineffective.

Manufacturing & Logistics

- Respondents note that limited capacity exists for local production of high quality APIs.
- The process of obtaining manufacturing permits is seen as cumbersome.

Regulatory Framework

- The market approval process is viewed as exceedingly long and drawn out.
- The capacity for biosimilar approval is seen as limited and approval standards not in line with international standards.

Health Care Financing

- Pharmaceutical price controls in both the public and private sectors are considered to be highly restrictive.
- Local executives find that the pricing and reimbursement system lacks transparency.

Effective IP Protections

- The patenting process is perceived as overly bureaucratic and patent examiners lack sufficient expertise.
- Anti-counterfeiting actions are viewed as ineffective.

Overall Market Conditions

- The tax environment is not considered to be conducive to biopharmaceutical investment.
- The government is found to be somewhat unsupportive of business, including the biopharmaceutical industry.

CANADA

Market Overview – From the Lens of Local Executives

Though from a global perspective local executives find Canada's biomedical ecosystem to be reasonably competitive, they view it as continuing to be eclipsed in key areas by most other high-income economies.

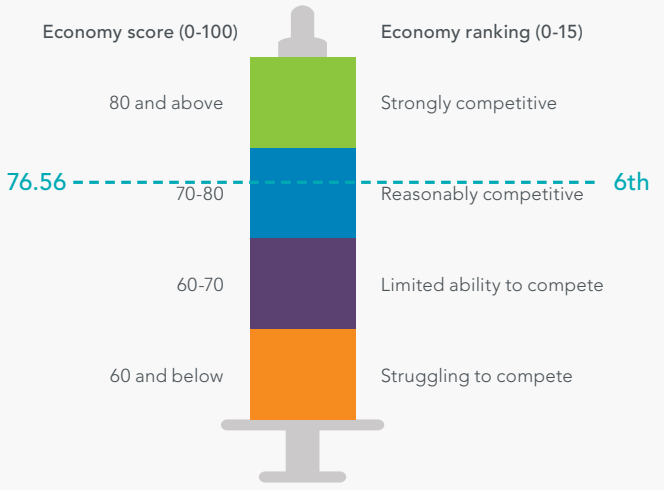
In a positive sense, they view Canada as having a well-established biotechnology base that has seen rapid growth in certain areas of research and manufacturing over the past two decades.

In addition, local executives have relatively high regard for Canada's biomedical regulatory system, noting generally strong quality control across the biopharmaceutical pipeline (though the timeframe for approval could be sped up).

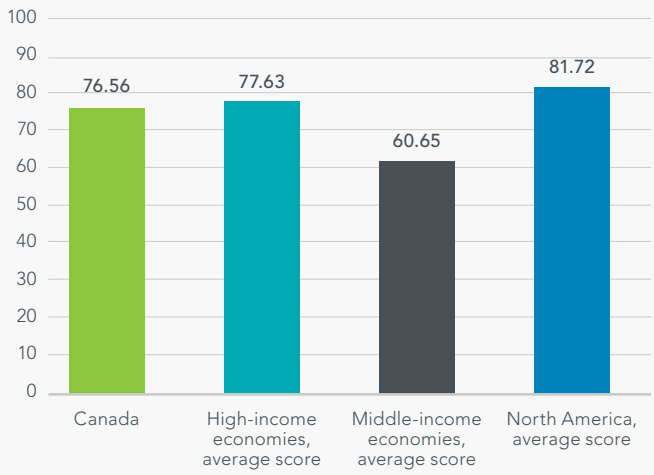
Still, local executives have several key concerns with the Canadian biomedical environment. Within the BCI, Canada's life sciences IP environment is an outlier among developed economies, ranking the least attractive in the group. Local executives cited the environment as being out of sync with international norms in areas of life sciences patenting and enforcement of IP rights. One particular challenge they raise is the recent trend toward judicial decisions that undercut global patentability standards and establish a distinct standard of utility, with many viewing this trend as eroding certainty and return on investment in the Canadian market. At the same time, local executives anticipate that aspects of the environment, such as lack of patent holder right of appeal and a term of patent term restoration, will improve upon adoption and implementation of the CETA trade agreement between Canada and the EU.[43]

Additional concerns raised by local executives include price controls limiting market access conditions for biomedical technologies and general lack of a business friendly environment.

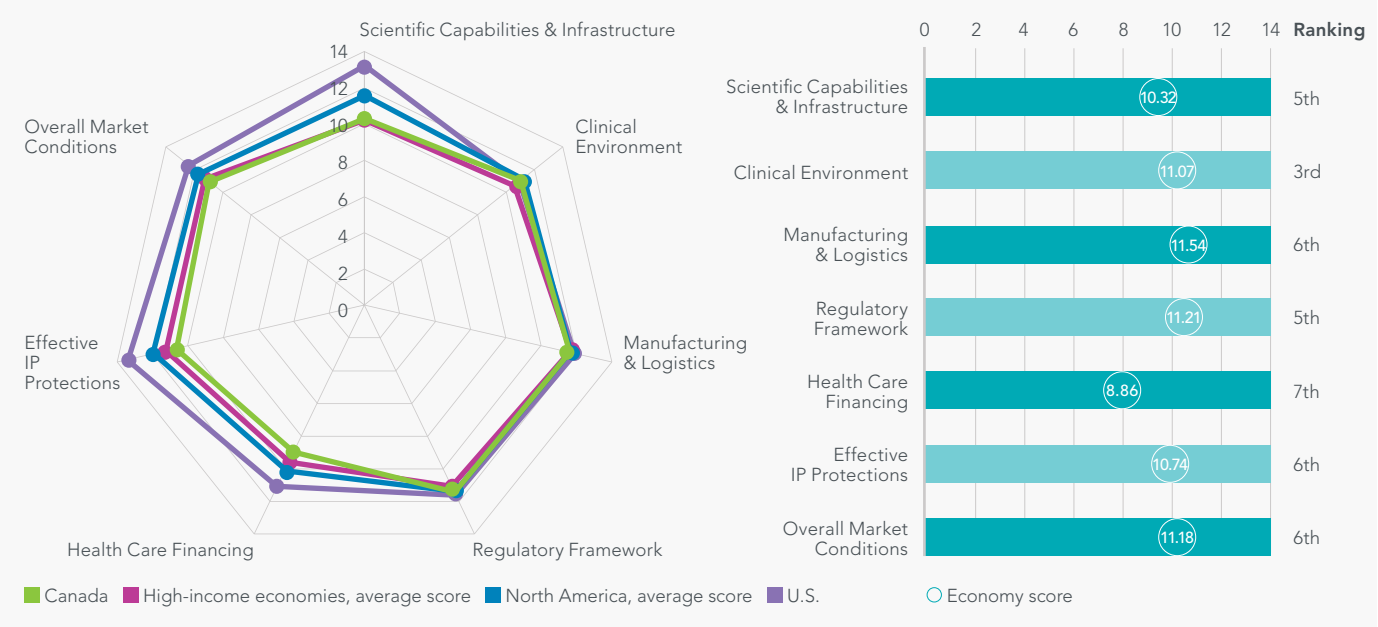
BCI Overall Results



Comparative Results – BCI Overall Scores



BCI Scores by Category



Map of the National Biopharmaceutical Environment – BCI Results in Depth

Key areas of strength

- ✔ High quality scientific and clinical research capabilities
- ✔ Regulatory standards in line with international best practices
- ✔ Quality control framework for manufacturing and distribution quite strong

Key areas of weakness

- ✘ Mediocre IP environment that deviates from international norms in patenting and enforcement
- ✘ Overly restrictive and somewhat hostile P&R environment
- ✘ Some delays in regulatory system
- ✘ High costs and remaining gap between industry and research institutions impede reaching full R&D potential

Scientific Capabilities & Infrastructure

- Scientific education viewed as of high quality, with a wide breadth of life sciences disciplines.
- Weaknesses were identified in the translation and commercialization of research into products.

Clinical Environment

- Clinical research perceived to be generally more expensive than other developed countries.
- Adherence and compliance to global clinical standards overwhelmingly seen as taking place.

Manufacturing & Logistics

- Manufacture, distribution and storage of biopharmaceuticals was overwhelming regarded as meeting the highest international standards.
- Some challenges were identified with regards to the importation of APIs and release of such materials by relevant authorities.

Regulatory Framework

- Drug regulators generally viewed as having a high level of competency in market approval.
- Concerns were raised regarding regulatory delays of over 1 year as well as proposed legislation allowing for release of confidential business information.

Health Care Financing

- Respondents had quite significant concerns with what was perceived as restrictive pricing of biopharmaceuticals.
- Executives also regarded decision-making within the P&R system as fairly arbitrary and noted difficulty competing effectively in public procurement.

Effective IP Protections

- IP fundamentals – biopharmaceutical IP protection, the patent system and enforcement – ranked as worst among developed countries.
- Respondents highlighted the heightened patent utility requirement, noting that patent case law is beginning to deviate from norms in other developed countries.

Overall Market Conditions

- Overall respondents found Canada to be a somewhat attractive destination for biopharmaceutical investment in the near future.
- However, concerns were raised over a general lack of governmental support for the biomedical sector.

CHINA

Market Overview – From the Lens of Local Executives

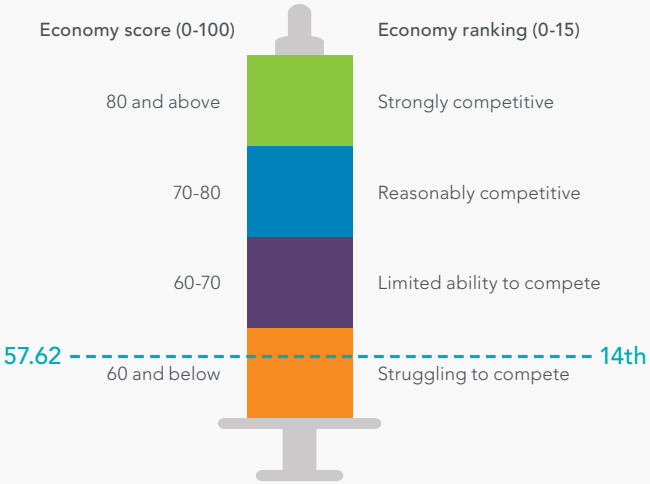
Though local executives view China as a low-cost, large market, they still categorize the environment there as struggling to compete for biomedical investment. Recognizing certain improvements to China's legal and regulatory framework that broadly affect biomedical innovation, nevertheless overall, local executives face several challenges in terms of specific biopharmaceutical policies and wider framework conditions that hold China back from achieving its full potential in biomedical investment.

Within the BCI, China performs below the average middle-income economies and significantly behind certain neighboring Asian economies.

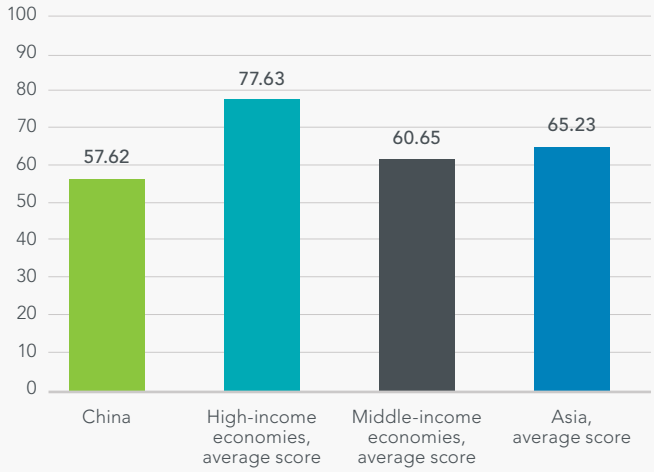
In the eyes of local executives, several factors deter China's biomedical investment attractiveness. These include lack of regulatory capacity, transparency and independence. They view regulatory processes as somewhat arbitrary and still unaligned with international standards in key areas, leading to severe regulatory delays. In addition, local executives note a continued de-prioritization of innovative and foreign medicines in market access channels. Though making incremental strides, they also find that China still has a long way to go to reach effective enforcement of IP rights, citing need to close gaps in the rule of law and to demonstrate a concrete decline in infringement activities. In terms of R&D, local executives say that much more is required in terms of building the scientific research base and infrastructure, as well as in terms of the mechanisms that would enable institutions to commercialize and develop biomedical discoveries into tangible products.

These impressions largely reflect policy trends in China in 2014-15. For example, on the one hand, registration delays have grown by a year on average due to new guidelines requiring that waivers for international clinical trials be approved in advance of a new drug application.[44] The same period has also seen heightened preference for domestically manufactured products in procurement, for instance in Tier III hospitals' purchasing of mainly locally produced medical devices.[45] At the same time, building the R&D base has attracted greater focus from the Chinese government, with an over 12% increase in science and technology spending announced in the 2015 central government budget, and close to $500 million allocated for biopharmaceutical development for infectious diseases allocated within the 2014 budget.[46]

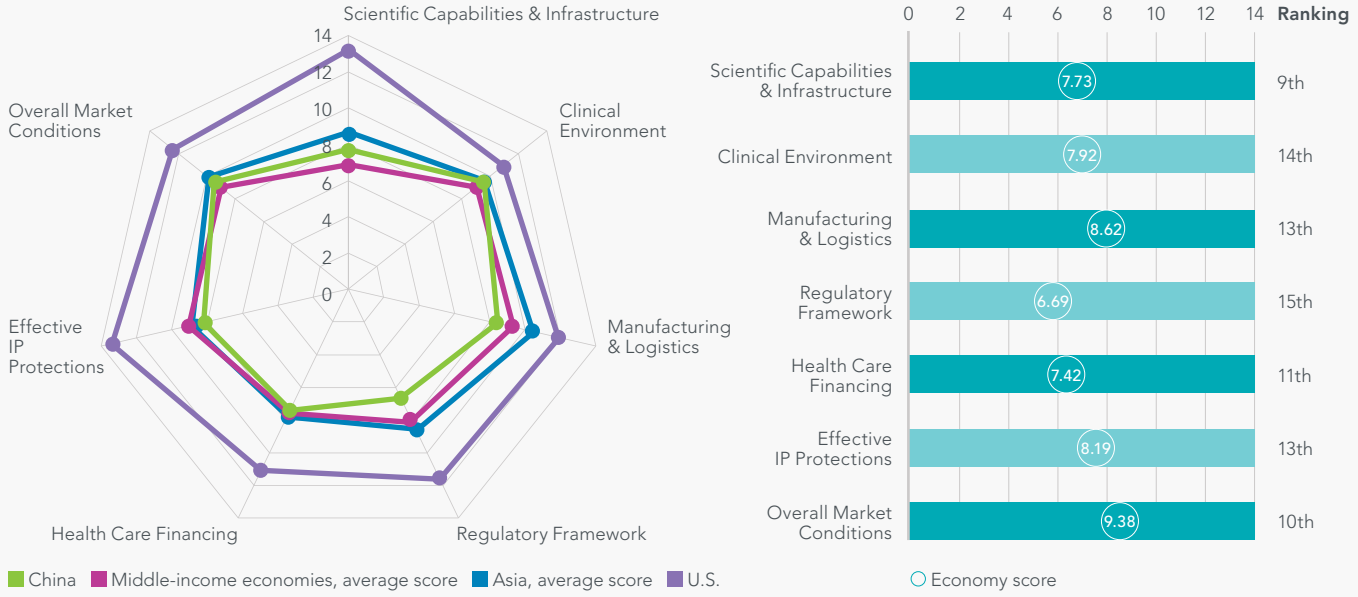
BCI Overall Results



Comparative Results – BCI Overall Scores



BCI Scores by Category



Map of the National Biopharmaceutical Environment – BCI Results in Depth

Key areas of strength

- ✔ Significant demand and market potential
- ✔ Relatively low operational costs
- ✔ Parallel importing of biopharmaceuticals is very limited

Key areas of weakness

- ✘ IP enforcement and remedies remain fledgling
- ✘ Long approval delays and arbitrary regulatory processes
- ✘ Holes in quality control across the pipeline
- ✘ Restrictive price controls represent major hurdles to market access

Scientific Capabilities & Infrastructure

- Lack of diversity in life sciences disciplines and research capabilities noted by respondents.
- Bottlenecks were also identified in the translational research phase and commercialization of ideas and research into tangible biopharmaceutical products.

Clinical Environment

- Clinical trial approval delays were cited as being a major impediment to research.
- Cost was viewed as less of an obstacle compared to developed economies.

Manufacturing & Logistics

- Quality of local biopharmaceutical manufacturing and distribution as well as ease of importing materials were reported as key challenges.
- The obtaining of manufacturing permits was viewed as being difficult and at times unpredictable.

Regulatory Framework

- Respondents overwhelmingly saw the very long approval times as a severe drawback.
- Significant concerns were raised regarding regulatory capacity, particularly for review of new medicines, and reference made to arbitrary decision-making processes.

Health Care Financing

- Respondents had quite significant concerns with what was perceived as stringent pricing of biopharmaceuticals as well as lack of transparency on reimbursement decisions.
- Access to innovative medicines through public and private mechanisms was generally viewed as being partial or incomplete.

Effective IP Protections

- Enforcement of IP rights perceived as weak, with availability of effective remedies limited and measures against counterfeiting inadequate.
- Respondents overwhelmingly viewed parallel importing as being non-existent or very limited.

Overall Market Conditions

- Respondents found China's current and future market potential to be strong in terms of level of unmet need and ability to spend on health care.
- However, significant concerns were raised over corruption, the basic legal framework and the general lack of governmental support for the research-based biomedical sector.

INDIA

Market Overview – From the Lens of Local Executives

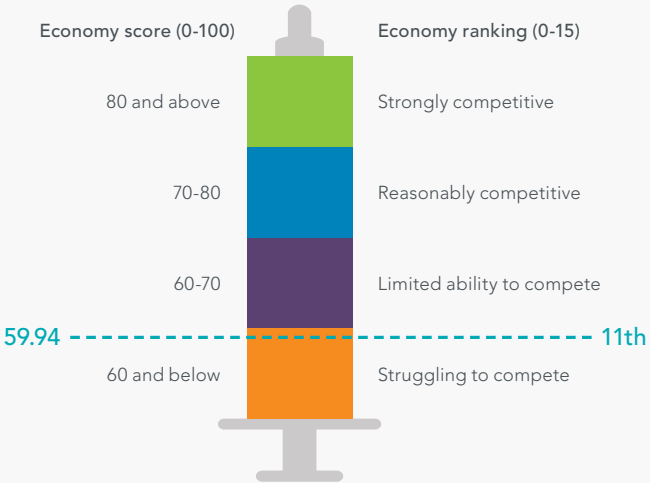
While valuing India's large, low-cost market and its foundation in manufacturing and contract research, local executives still find that India places in the bottom ranks in biomedical competitiveness.

Within the BCI, India performs slightly below other middle-income economies and significantly behind certain Asian economies, though not China. Acknowledging India's capabilities and global competitive advantage in the production of generics and APIs – and parallel to this, incremental regulatory improvements – local executives still find that regulatory deficiencies accompanied by delays and corruption seriously undermine the regulatory system. Specific areas cited for improvement relate to approval, monitoring and quality control of complex drugs. Inadequate access to medicines also remains a significant concern among local executives, not least due to weak coverage of health care and pharmaceuticals. Indeed, at 4.1%, health spending as a percentage of GDP is the lowest among all countries covered in the BCI[47] and India's per capita spending on medicines brings up the rear worldwide.[48] Moreover, only around 14% of new medicines launched globally in 2008-2012 were made available in India as of 2013.[49]

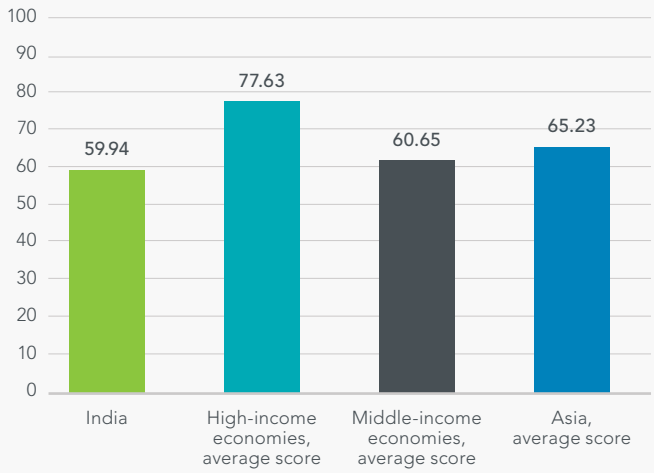
Crucial gaps in biopharmaceutical IP protection, which have historically represented a major challenge to innovators seeking to operate in India, continue to be felt by local executives. They underscore a high level of uncertainty and antagonism within certain parts of the system towards the very areas in which India's future innovation potential may lie, such as incremental innovation. Enforcement is also mentioned as being problematic, with drawn-out litigation and difficulties securing meaningful and timely remedies. In this same context, local executives note that an underlying preference for local industry persists – felt in government-industry relationships generally and particularly when it comes to market access.

Yet at the same time, there is greater government support for biomedical investment and innovation under the new Modi government. The current "Make in India" campaign and 2014-15 government budget provide for numerous national and state-based tax incentives aimed at pharmaceutical and biotech R&D and manufacturing as well as public investment in research institutions.[50] In addition, the new draft National IP Rights Strategy lays the basis for necessary improvements to the system, including recognizing existing gaps in IP protection, with the stated aim of improving India's global competitiveness.[51]

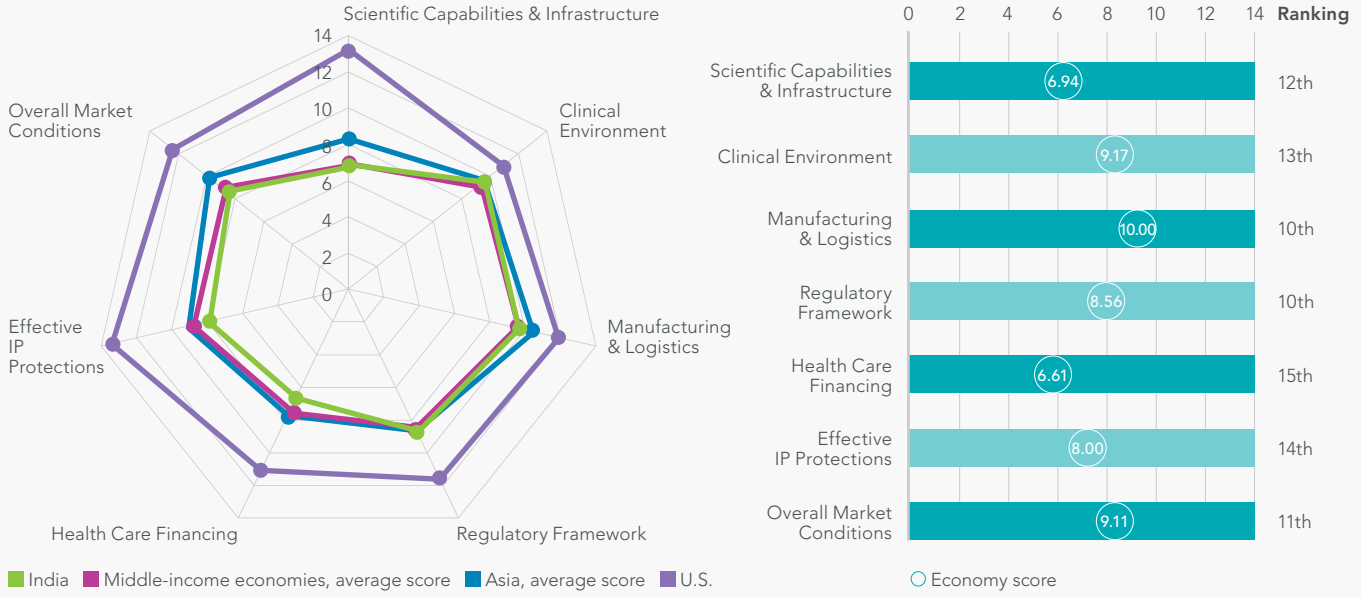
BCI Overall Results



Comparative Results – BCI Overall Scores



BCI Scores by Category



Map of the National Biopharmaceutical Environment – BCI Results in Depth

Key areas of strength	Key areas of weakness
✔ Relatively low operational costs	✘ Major regulatory deficiencies and bottlenecks
✔ Global competitive advantage in API production	✘ Limited coverage of medicines even with costs driven down
✔ Solid base of general scientific education and training	✘ Biopharmaceutical IP protection overall ineffective
✔ Market potential expected to grow over the medium-term	✘ Significant lack of dedicated basic and translational R&D

Scientific Capabilities & Infrastructure

- Life sciences disciplines viewed as undiversified and infrastructure at a basic level.
- Significant weaknesses were identified in the translation and commercialization of research and the lack of innovation clusters and incubators.

Clinical Environment

- Regulation of clinical research seen as problematic in some areas, with approval times cited as a major impediment.
- The relatively low cost of clinical research was viewed by many respondents as one of India's attractive characteristics.

Manufacturing & Logistics

- Respondents cited difficulties in obtaining of manufacturing permits.
- Quality control of local warehousing and distribution as well as of imported materials were also reported as key challenges.

Regulatory Framework

- Some concerns were raised in relation to drug regulators' capacity to review new drugs and biosimilars as well as to gaps in the pharmacovigilance system.
- Respondents overwhelmingly saw long approval times as an impediment.

Health Care Financing

- Respondents had quite significant concerns with the limited access to products through public reimbursement as well as private mechanisms.
- A strong focus by public authorities on cost rather than value of biopharmaceuticals is perceived across pricing, reimbursement and procurement.

Effective IP Protections

- Concerns weighing most on respondents were the prevalence of drawn-out patent challenges and lack of expertise in biopharmaceutical IP.
- Respondents also highlighted the limited framework for regulatory data protection and for anti-counterfeiting.

Overall Market Conditions

- Current market demand seen as limited but with good potential for growth based on unmet medical need.
- Corruption in the health care and pharmaceutical sector perceived as fairly common.

IRELAND

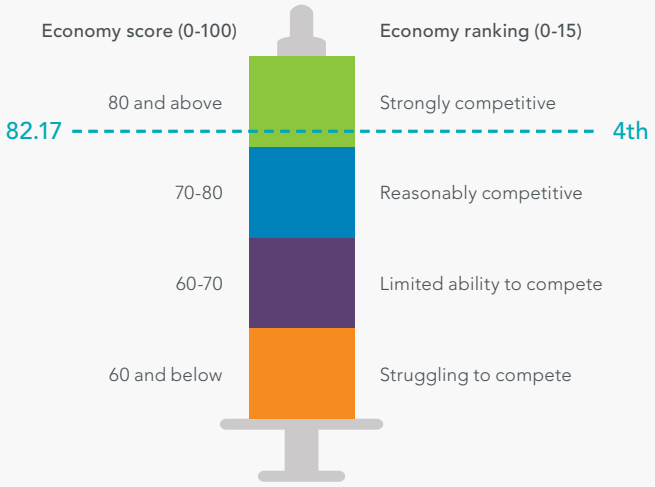
Market Overview – From the Lens of Local Executives

Local executives find Ireland to be a strongly competitive biomedical market. Within the BCI, on the whole Ireland performs above the average high-income economy.

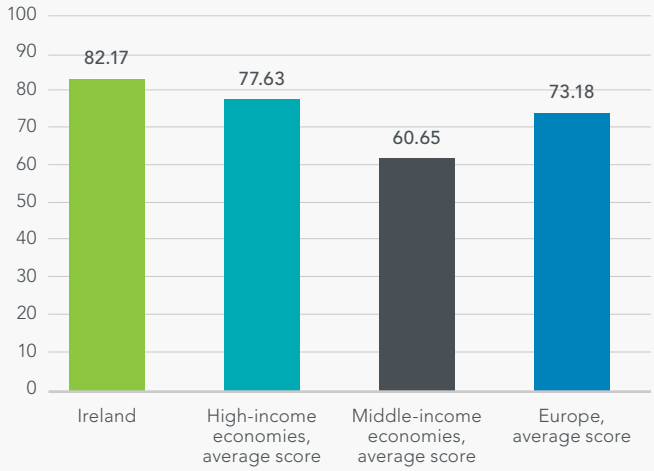
Broadly speaking, local executives have a relative high regard for Ireland's biopharmaceutical manufacturing capabilities and system. In addition, they view the IP and regulatory framework as, for the most part, in line with international standards. They also ranked Ireland near the top for its business-friendly policies, in particular the low corporate income tax rate of 12.5% and a wide range of R&D tax credits available to companies based in the country.

Local executives do cite a few key bottlenecks in Ireland's biomedical ecosystem. Despite dedicated investment in R&D, local executives noted a lack in actual translation and commercialization activities as well as high costs of research in certain areas, though they mention the field of oncology as particular growth area. Specific challenges in the IP system that they do face relate to the prevalence of, and market erosion caused by, parallel importing. In addition, while highlighting wide coverage of medicines and health technologies and a relatively accessible procurement system, they find that conditions are significantly weakened by price controls and what they consider to be an undervaluation of innovative products by pricing authorities.[52]

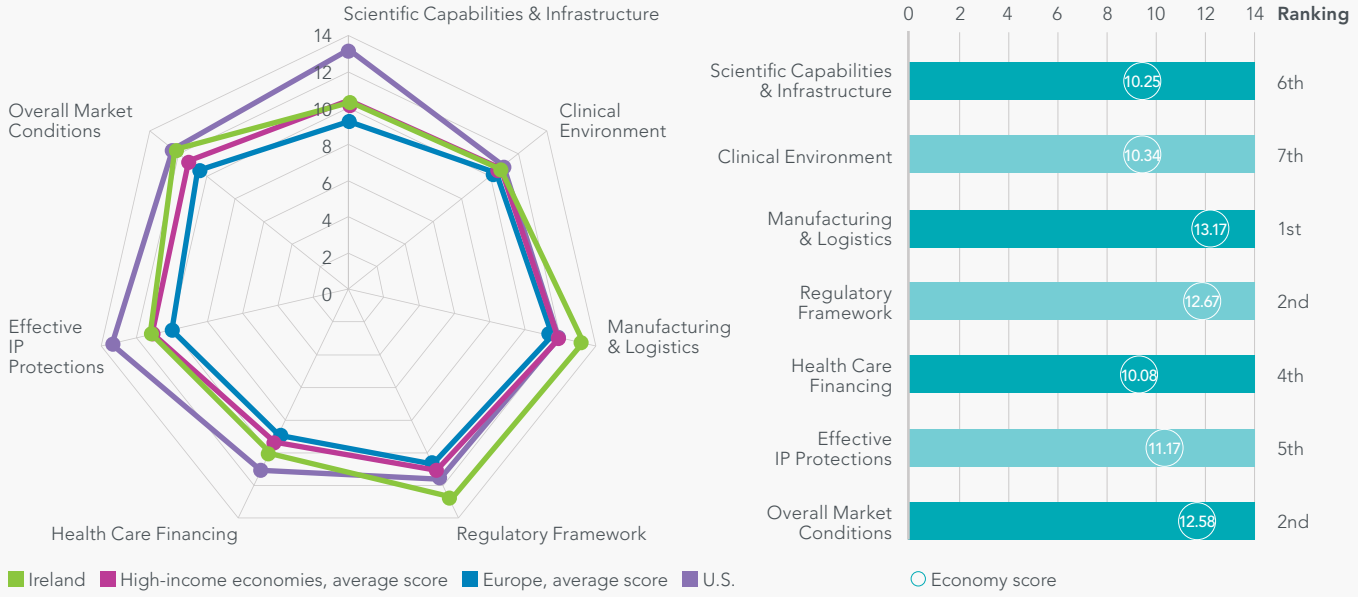
BCI Overall Results



Comparative Results – BCI Overall Scores



BCI Scores by Category



Map of the National Biopharmaceutical Environment – BCI Results in Depth

Key areas of strength

- ✔ Framework conditions overall supportive
- ✔ Top ranked manufacturing capacity
- ✔ Generally high quality regulatory standards and processes
- ✔ Coverage of medicines through public reimbursement fairly comprehensive

Key areas of weakness

- ✘ Difficult pricing environment
- ✘ Market access undermined by parallel imports
- ✘ Future market potential weakened slightly by high costs
- ✘ Gaps in effective translation and commercialization of biomedical research

Scientific Capabilities & Infrastructure

- Scientific and research capabilities were viewed as being relatively strong with room for improvement in diversification of research areas.
- Although a high level of interest for translating research into new products is perceived, actual translation and commercialization is viewed as only partially successful.

Clinical Environment

- Clinical capabilities were generally viewed as being adequate.
- Cost was cited as an impediment to research.

Manufacturing & Logistics

- Respondents viewed the overall quality of biopharmaceutical manufacturing and distribution throughout the supply chain as being excellent.
- Some lack of consistency in quality of import inspections was reported.

Regulatory Framework

- Health and market authorization regulators are regarded as having the highest level of competency and capability.
- Some concerns were raised over health technology evaluations and a perceived lack of clarity in some areas.

Health Care Financing

- Respondents generally viewed access to medicines through public reimbursement channels as being quite comprehensive.
- Local executives note a disconnect between the government's emphasis on innovation and the ability to secure timely access at a fair price.

Effective IP Protections

- Ireland's biopharmaceutical IP environment was generally regarded as effective and strong.
- However, respondents cited parallel importing as a major barrier.

Overall Market Conditions

- Overall respondents found the Irish market to be an attractive destination in the near term.
- However, potential of the market over the longer term was seen as limited.

ISRAEL

Market Overview – From the Lens of Local Executives

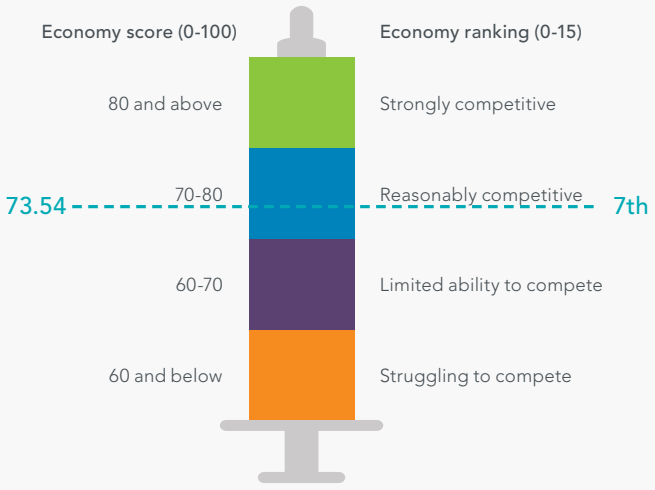
Despite its small size, local executives are relatively pleased with the Israeli biopharmaceutical market, finding Israel to be more attractive than emerging markets in the sample when taking into account the entire biomedical ecosystem.

Local executives identified several key strengths in Israel. They view the relative scale of early stage R&D as well as clinical research as quite attractive. The general ability to manufacture pharmaceutical products is also seen as strong and to the highest international standards. In addition, the regulatory, market access and legal frameworks related to the biopharmaceutical ecosystem are viewed as relatively supportive, compared to emerging markets. Local executives also ranked Israel's biopharmaceutical IP environment as comparatively high, just below leading developed countries.

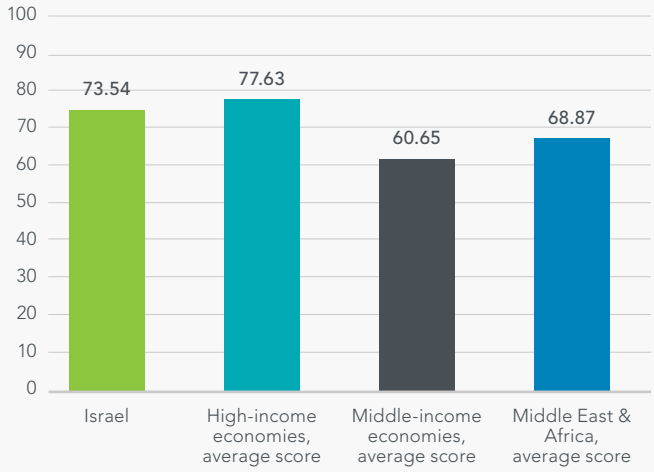
These views correspond to recent policy changes as well as other measures of biomedical investment. As one example, as part of a 2010 agreement with the U.S. Israel strengthened IP provisions in the areas of patent term extension, regulatory data protection and publication of patent applications.[53] By 2014, the government of Israel had effectively implemented these changes and was removed from the USTR's Special 301 Watch List.[54] Today Israel has one of the highest per capita levels of clinical trials globally, and is a world leader in medical device patenting (also in per capita terms).[55]

Still, remaining gaps raised by local executives include a need to intensify efforts towards translation of biomedical R&D into actual products and to streamline aspects of the regulatory system, specifically in market approvals and release of manufacturing permits. In addition, they face challenges with Israel's pricing and reimbursement system, which they perceive as incentivizing prioritization of cost over value. They also say that, at times, the biopharmaceutical industry lacks key incentives and support from the government, on top of facing pockets of instability in the political system.

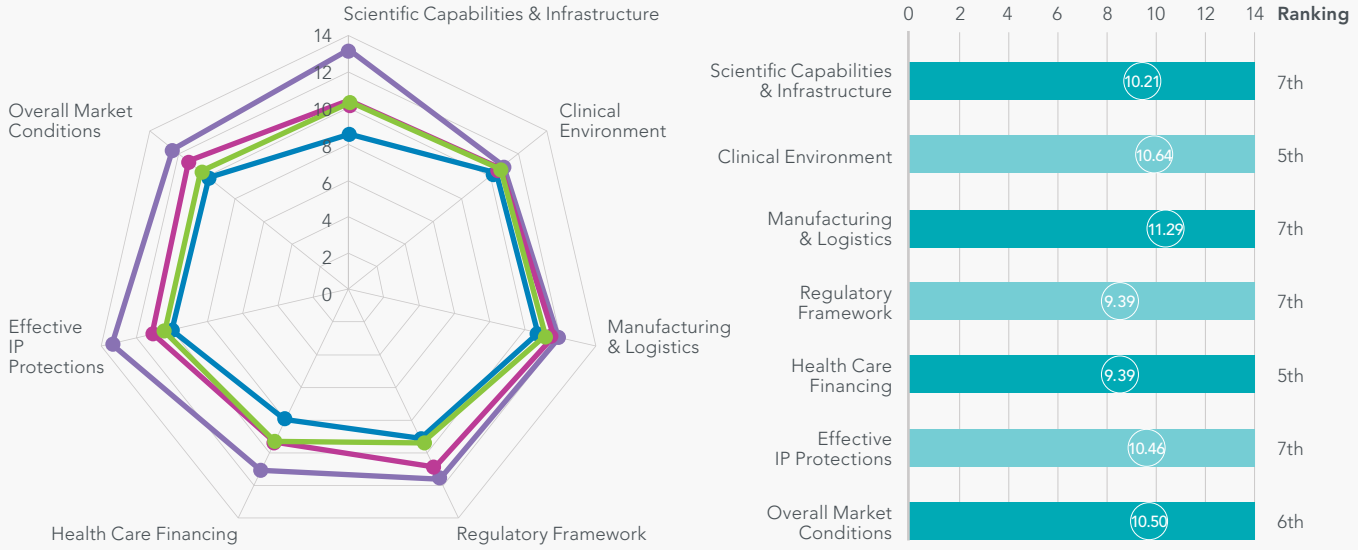
BCI Overall Results



Comparative Results – BCI Overall Scores



BCI Scores by Category



Map of the National Biopharmaceutical Environment – BCI Results in Depth

Key areas of strength

- ✔ Robust and relatively diverse biomedical and clinical research system
- ✔ Overall strong capacity and standards for high quality manufacturing
- ✔ Generally high availability of medicines including innovative products
- ✔ Generally effective and high standard IP system

Key areas of weakness

- ✘ Somewhat challenging pricing environment
- ✘ Limitations in capacity for new drug and biosimilar approval
- ✘ Burdensome regulatory delays
- ✘ Greater government goodwill and incentives for industry required

Scientific Capabilities & Infrastructure

- Scientific and research capabilities were viewed as being relatively strong, including across different biomedical specialties.
- Strong interest identified in translating research into new products, though gaps remain in actual commercialization.

Clinical Environment

- Clinical capabilities were generally viewed as being very high and in line with international best practices.
- Concerns were raised over long approval times and costs of clinical research.

Manufacturing & Logistics

- Overall quality of biopharmaceutical manufacturing and distribution throughout the supply chain viewed as being of a high standard.
- Concerns were raised over slight bottlenecks in obtaining permits for manufacturing.

Regulatory Framework

- Respondents consider key areas for improvement to be in the approval of new medicines and biosimilars, as well as shortening of approval times.
- Health and drug regulatory authorities were overwhelmingly viewed as independent from political interference.

Health Care Financing

- Respondents view access to medicines through public reimbursement and supplementary channels as fairly comprehensive.
- Price controls in place for public reimbursement as well as in the private marketplace perceived as stringent.

Effective IP Protections

- Biopharmaceutical IP environment seen as relatively robust with particular strengths in the patenting process and enforcement mechanisms.
- However, respondents cited gaps in anti-counterfeiting actions as a concern.

Overall Market Conditions

- Israel regarded as a very attractive destination for biopharmaceutical sales in the near term, though longer term market potential viewed as less certain.
- Tax environment and government support for the innovative biomedical sector could be enhanced.

MEXICO

Market Overview – From the Lens of Local Executives

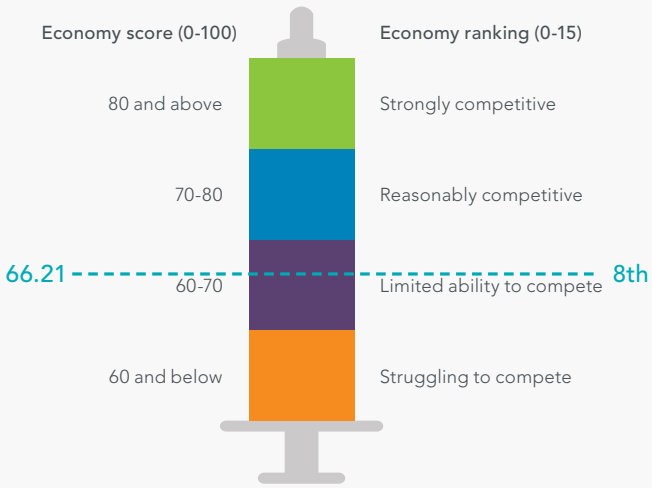
Though local executives view Mexico as more attractive than the average middle-income economy and other major markets in Latin America, they still identified significant concerns that limit its global competitiveness for biomedical investment.

According to local executives, key drivers of its relative competitiveness are the low-cost environment and what they cite as foundational capabilities and basic best practices in place in terms of R&D, clinical research, manufacturing and regulatory control.

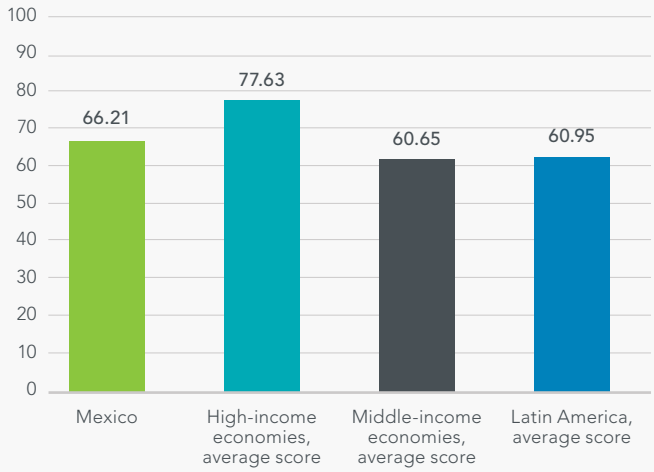
However, local executives underscore that much remains for improvement, especially when it comes to activities surrounding cutting edge and complex medicines and health technologies. In their view, significant gaps in effective R&D activities exist, both in terms of advanced biomedical research as well as in the fields of translation and commercialization. In addition, they consider that greater efficiency in regulatory and administrative processes as well as capacity building is needed, particularly in the review and tracking of advanced medicines. They also see the pricing and reimbursement system as favoring locally produced, low-cost generics. Moreover, while local executives cite advancements in the area of IP protection, especially in terms of the legal framework, they find that enforcement of these rights still falls well behind international standards. Finally, the business environment in Mexico is considered by local executives to be mixed, with generally good relationships between industry and government reported, but at the same time, lack of certain incentives such tax breaks.

The Mexican government has already recognized some of these gaps, in particular introducing initiatives aimed at streamlining regulatory processes and raising standards. Mexico's drug regulator, COFEPRIS, has recently taken steps to increase its capacity and efficiency through, for instance, fast-tracking applications that have previously been approved in the U.S., Canada and Europe and announcing efforts to reduce approval timelines for clinical trials. In 2012, COFEPRIS also introduced RDP for pharmaceuticals (though this has not been extended to New Molecular Entities and enforcement is still a concern).[56]

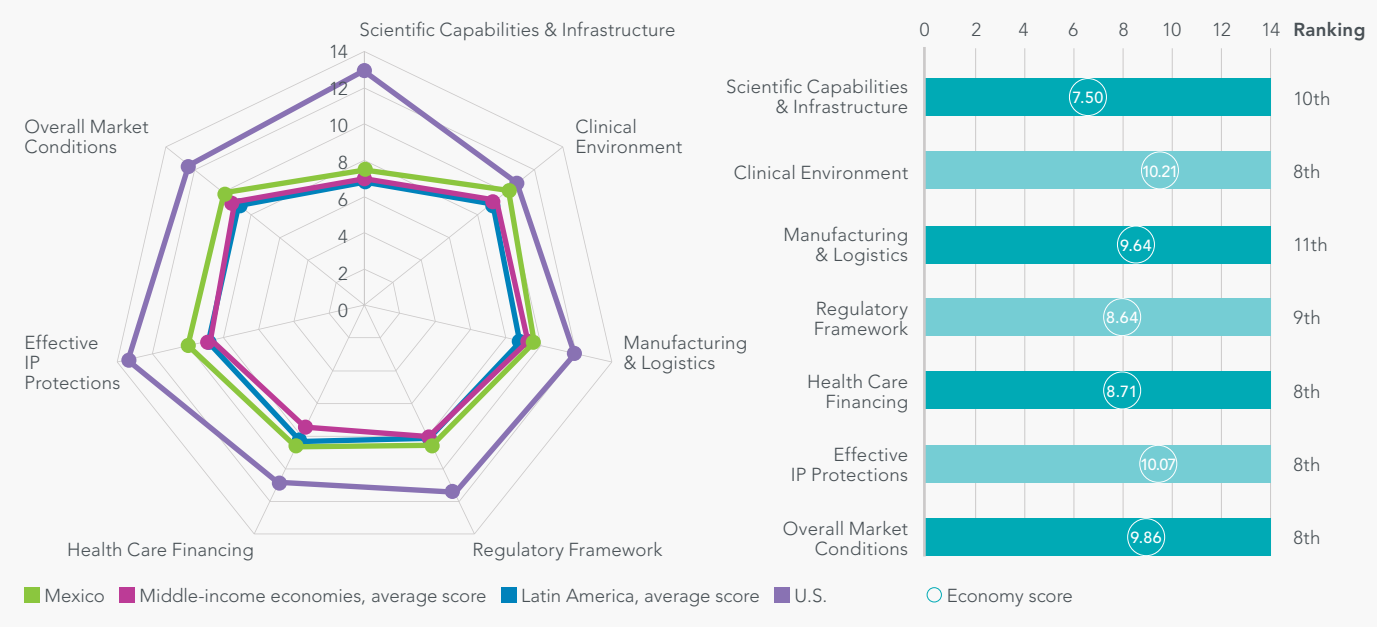
BCI Overall Results



Comparative Results – BCI Overall Scores



BCI Scores by Category



Map of the National Biopharmaceutical Environment – BCI Results in Depth

Key areas of strength

- ✔ Relatively low operational costs
- ✔ Basic manufacturing capacity present
- ✔ Implementation of regulatory best practices for basic products
- ✔ Scientific training in the country is good but could benefit from diversification

Key areas of weakness

- ✘ Innovative drugs placed at disadvantage in market access system
- ✘ Substantial challenges in IP enforcement
- ✘ Some deficiencies in quality control and approval of advanced local products (e.g. biosimilars)
- ✘ Need for greater industry incentives and streamlining of administrative processes

Scientific Capabilities & Infrastructure

- Scientific research standards viewed as being of average quality and lacking diversification in life science research.
- Concerns were raised regarding the ability to successfully translate biomedical research into commercialized products.

Clinical Environment

- Clinical research is considered to be relatively low cost and carried out in line with international standards.
- However, remaining red tape in the regulatory system governing clinical trials is viewed as somewhat challenging, though improvements are ongoing.

Manufacturing & Logistics

- Capacity to produce high quality APIs is considered to be limited.
- The system for approving products for export is seen as satisfactory (though not excellent).

Regulatory Framework

- The capacity of the health regulator to review new biopharmaceutical products and generics is seen as good, but capacity to review biosimilars limited.
- Local executives cited concerns over pharmacovigilance.

Health Care Financing

- Drug coverage narrow in certain areas, with reimbursement mainly provided for cheaper and domestically manufactured products.
- Access to the public market on the basis of medicines' value is seen as limited.

Effective IP Protections

- Biopharmaceutical IP protections are generally perceived to be acceptable, with specific concerns raised over scope of regulatory data protection.
- Enforcement of IP rights is seen as a major challenge, with anti-counterfeiting actions perceived as fairly ineffective.

Overall Market Conditions

- The tax environment is viewed as somewhat unattractive.
- However, local executives cite a good level of cooperation with government.

RUSSIA

Market Overview – From the Lens of Local Executives

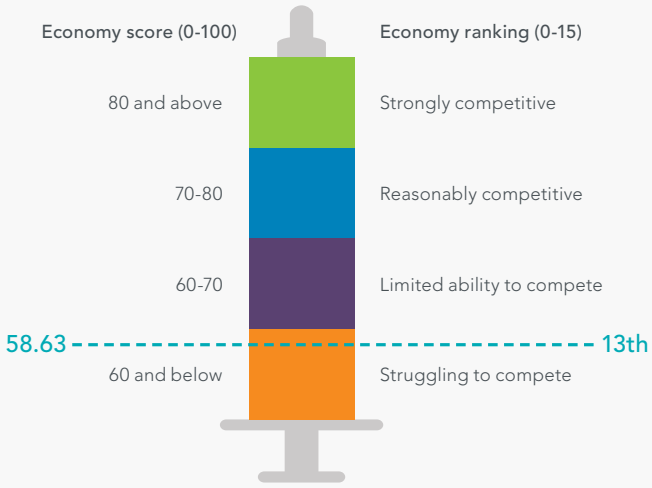
In terms of the total biomedical environment, local executives find Russia to be struggling to compete for biomedical investment. Within the BCI, Russia performs in the bottom group of the sample and far below other high-income economies.

Local executives raised several major challenges in the Russian biomedical sector. While they feel there is a growing interest in R&D within Russia, they note that in order to actually act there is substantial need for modernization across the scientific and clinical research system as well as for closing the gap between research institutions and the private biomedical sector. Lack of transparency and independence in government, and overall a high level of corruption, lends to quite challenging general market conditions. In terms of IP, in the view of local executives the system has improved somewhat as Russia has implemented its WTO commitments (such as the recent introduction of a 6 year RDP term), however they feel there is still a long way to go in terms of enforcement of the biopharmaceutical IP provisions introduced. The regulatory framework is viewed as fairly inefficient and standards out of sync with international standards in key areas such as GMP, market authorization of medicines and review of exports. Finally, local executives also find the market access environment to be difficult.

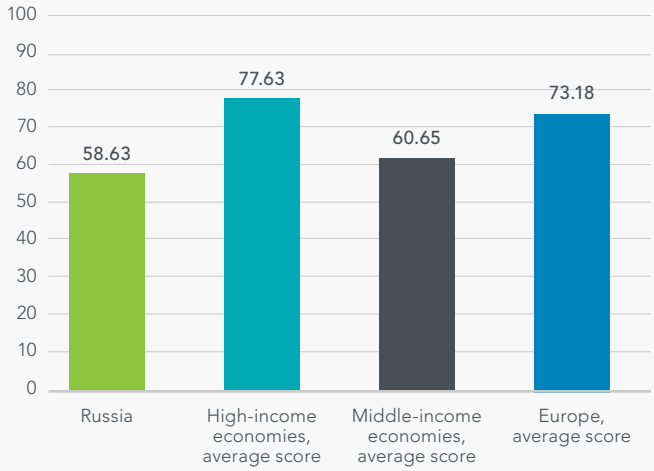
In several ways, these concerns reflect recent policy trends in Russia, including the mixed manner in which the government has sought to implement its strategic innovation priorities under its main innovation initiative, 2020 Strategy. In particular, to achieve its innovation targets the Russian government has primarily adopted policies protecting the local industry and requiring foreign companies to localize operations and know-how.[57] In 2015, discussions impacting the market access and IP environments are intensifying, including discussions on tightening preferences for local products, permitting compulsory licensing for use outside of established public health rationale, and introducing parallel importing as a cost-cutting measure.[58]

Nevertheless, in a positive sense, efforts within the scope of the Eurasian Union to harmonize Russia and other member states' biomedical regulatory framework with international standards in several key aspects represents a important opportunity for improving the biomedical ecosystem in Russia.[59]

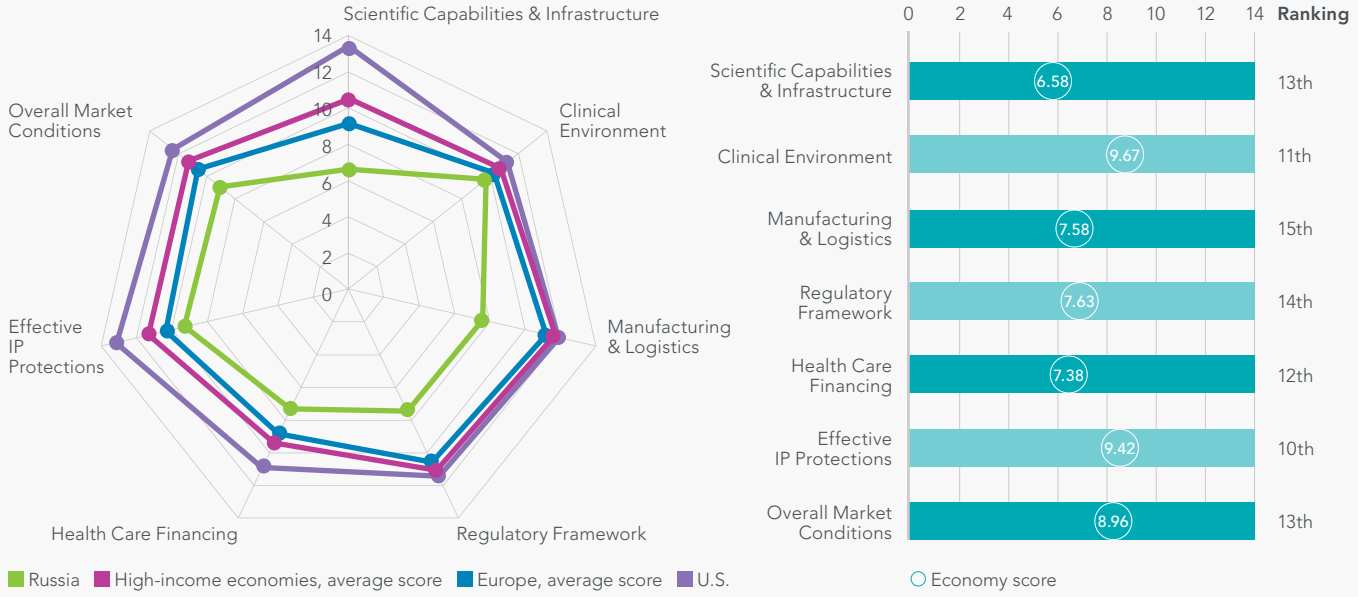
BCI Overall Results



Comparative Results – BCI Overall Scores



BCI Scores by Category



Map of the National Biopharmaceutical Environment – BCI Results in Depth

Key areas of strength

- ✔ Potential for near-term growth
- ✔ Currently low levels of parallel importing
- ✔ Relatively strong interest interest and willingness to participate in clinical research

Key areas of weakness

- ✘ Rudimentary quality control of biomedical products across all phases
- ✘ Challenging market access environment
- ✘ Enforcement of IP rights and anti-counterfeiting actions quite weak
- ✘ Scientific and biomedical research system is generally outdated and under-equipped

Scientific Capabilities & Infrastructure

- The scientific research system is viewed as basic and generally out of sync with current trends in biomedical research.
- From the perspective of local executives, research institutions are rarely successfully at commercializing their research.

Clinical Environment

- Recruitment of trial subjects for clinical trials is perceived to be relatively easy.
- Still, regulatory and operational capacity for clinical research see as limited.

Manufacturing & Logistics

- Severe gaps in GMP compliance among local pharmaceutical manufacturing sites are reported.
- Review of exports considered superficial and significant delays for manufacturing permits cited.

Regulatory Framework

- The state health regulatory agency is viewed as having limited capacity to review and approve pharmaceutical products.
- Pharmacovigilance systems in the country are perceived to be basic, with rudimentary reporting systems and inadequate response.

Health Care Financing

- Price controls on innovative medicines included on the Essential Drug List are seen as quite severe.
- The public reimbursement framework is considered to be fairly limited and access to the market through the procurement system very challenging.

Effective IP Protections

- The legal framework providing biopharmaceutical IP protection is generally viewed as acceptable at the moment, but significant concerns were raised over enforcement of these rights.
- Local executives were particularly pleased with the introduction of RDP under Russia's implementation of its WTO commitments.

Overall Market Conditions

- Russia is seen as a somewhat attractive location for marketing pharmaceutical products with satisfactory potential for near-term growth.
- Corruption in the health care and pharmaceutical sectors is perceived to be very common.

SINGAPORE

Market Overview – From the Lens of Local Executives

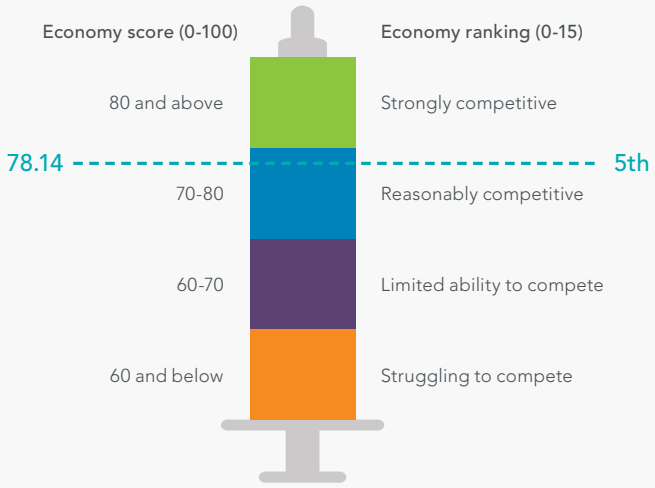
Local executives find Singapore's biomedical environment to be reasonably competitive, despite being a small and relatively new market. Within the BCI, Singapore is ranked just below the top high-income economies worldwide and considerably above major neighboring markets in Asia.

In the view of local executives, where Singapore does present certain challenges is mainly in relation to the local market. A key concern is the ability for innovative products to secure market access through the public reimbursement system, which they find to be weak and incongruent with the emphasis on investment and innovation in other aspects of the biomedical ecosystem.

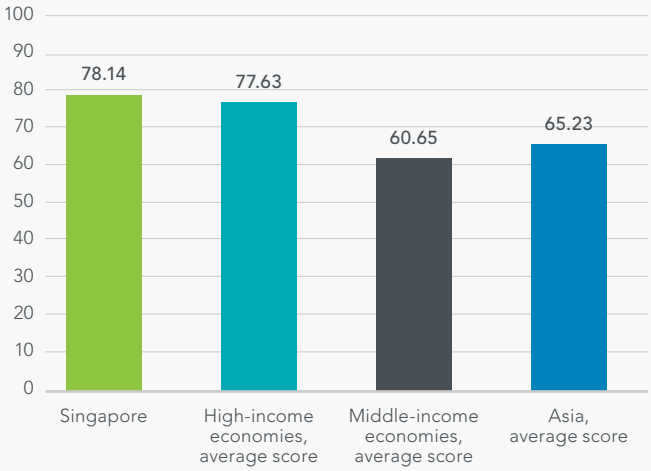
Nevertheless, the overwhelming sense from local executives is that Singapore has relatively strong capabilities in R&D and manufacturing, with most of the necessary regulatory frameworks and safeguards in place and in line with international best practices. They also consider IP protection to be generally on par with world-leading standards, though partly due to its geographical position Singapore still faces challenges in relation to export of counterfeit medicines. In addition, the general legal, political and business environment rank relatively highly in the BCI.

The fact that local executives are generally pleased with Singapore's biomedical ecosystem reflects dedicated and ongoing local efforts to create a pro-innovation and investment environment. Government programs, such as the Agency for Science, Technology and Research and the Translational and Clinical Research Flagship Programme, support biomedical R&D clusters around Singapore and facilitate collaborations between local universities/hospitals and international partners.[60] Initiatives to strengthen and update the legal and regulatory framework also continue, with for instance the national drug regulator a member of a global partnership aimed at enhancing and streamlining development and approval of new products.[61]

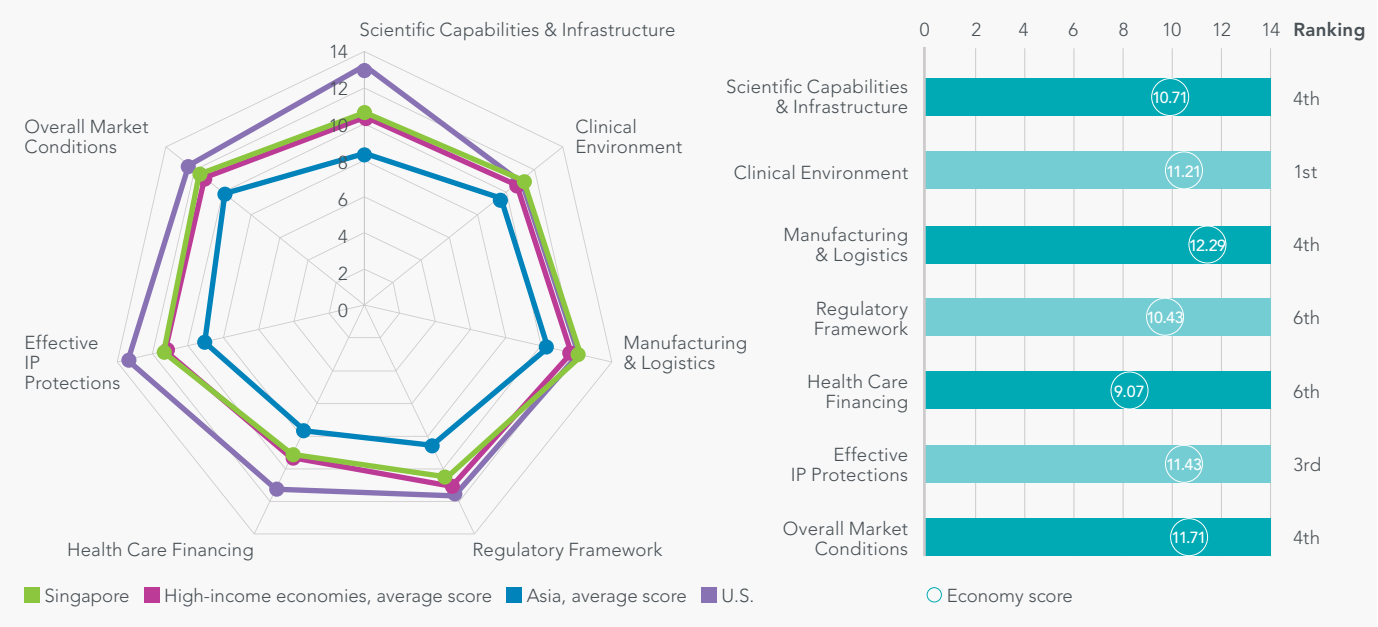
BCI Overall Results



Comparative Results – BCI Overall Scores



BCI Scores by Category



Map of the National Biopharmaceutical Environment – BCI Results in Depth

Key areas of strength

- ✔ Robust biopharmaceutical IP protection available
- ✔ Scientific and R&D capabilities quite strong in most areas
- ✔ Generally excellent quality control of medicines across all phases
- ✔ Generally positive overall market conditions

Key areas of weakness

- ✘ Innovative industry faces significant disadvantage in pricing and reimbursement system
- ✘ Some bottlenecks in the drug approval process
- ✘ Does not necessarily have a cost advantage over neighboring markets
- ✘ Slight slowing of market potential anticipated in the future

Scientific Capabilities & Infrastructure

- Respondents cited high quality scientific training and education and strong capabilities for biopharmaceutical R&D.
- They noted there is some room for improvement in the translation of research into commercial products.

Clinical Environment

- Local executives view the scientific and regulatory capacity for clinical research as being quite high.
- However, they report that it is relatively costly to conduct clinical trials in the country.

Manufacturing & Logistics

- Companies do not have issues importing necessary raw materials or other manufacturing components.
- The system for reviewing and approving products intended for export is seen as highly robust.

Regulatory Framework

- Market approval and post-marketing monitoring of medicines is generally considered to be on par with developed market standards, though regulation of biosimilars could be improved.
- Nevertheless, delays are reported in the drug approval process.

Health Care Financing

- Coverage of medicines is viewed as only partial and based primarily on cost, with particular gaps in the public system.
- Though respondents cite that drug prices are set relatively freely they find the pricing and reimbursement system generally to be quite arbitrary, with industry having little sway in decision-making.

Effective IP Protections

- IP protections specific to the biopharmaceutical industry are generally considered to be robust and in line with international standards.
- Respondents cite slight room for improvement in policing actions against counterfeiting of medicines.

Overall Market Conditions

- The legal framework is seen as excellent, with very low levels of corruption, and generally speaking there is strong support for business from government.
- Respondents expect market demand and potential to slow slightly in the next five years.

SOUTH AFRICA

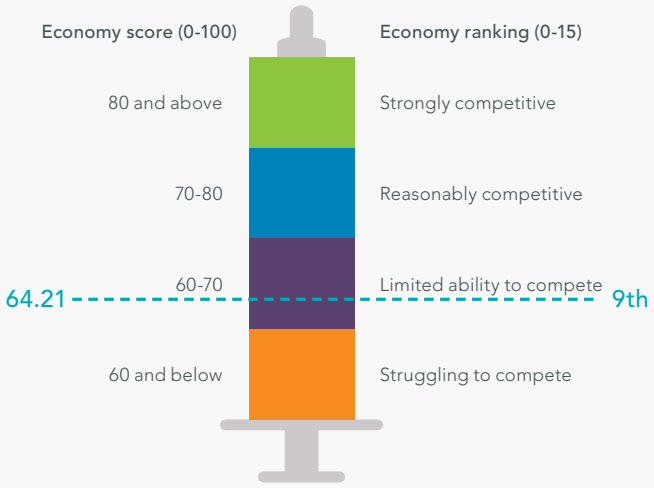
Market Overview – From the Lens of Local Executives

Local executives find South Africa to currently have limited ability to compete for global biomedical investment, though they cite the existing basic manufacturing and regulatory framework as supporting potential for future growth.

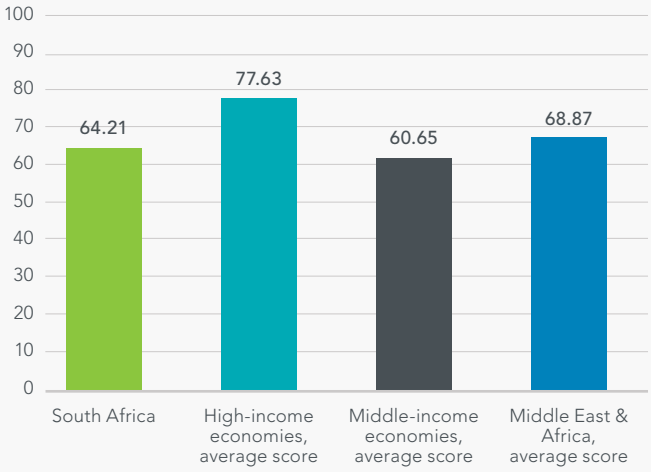
From local executives' standpoint, several major gaps must be closed across the biomedical ecosystem in order for South Africa to transition to a more innovative and attractive market that can satisfy domestic demand. The weakest links identified by local executives include limited scientific and biomedical research capabilities as well as manufacturing of cutting edge medicines. In addition, the market access system is viewed by local executives as very challenging – in fact, rated as one of the most difficult among the economies sampled in the BCI – with stringent price controls, narrow reimbursement for large segments of the population and a strong preference for generics. On top of weak capacity for review of state-of-the-art products, red tape and lack of regulatory transparency are a real concern across the biopharmaceutical regulatory system. Finally, local executives raised concerns about the IP system, particularly the lack of specific life sciences provisions and enforcement of these rights on the ground.

The South African government has recognized some of these same concerns and has initiated steps to boost its biomedical ecosystem. Its new Bio-Economy Strategy, launched in 2014, includes a pillar focused on health and the biomedical sector.[62] Among the pillar's key tenants are special funding dedicated to building the economy's ability to manufacture high-quality active pharmaceutical ingredients, vaccines and complete biopharmaceuticals. In another positive step, a recent parliamentary bill seeks to enhance mechanisms and resources for streamlining regulatory review and decision-making.[63] Still, not enough has been done to address several gaps, for instance in the area of IP; the Bio-Economy Strategy does not address incentives for investment through enhanced IP protection.

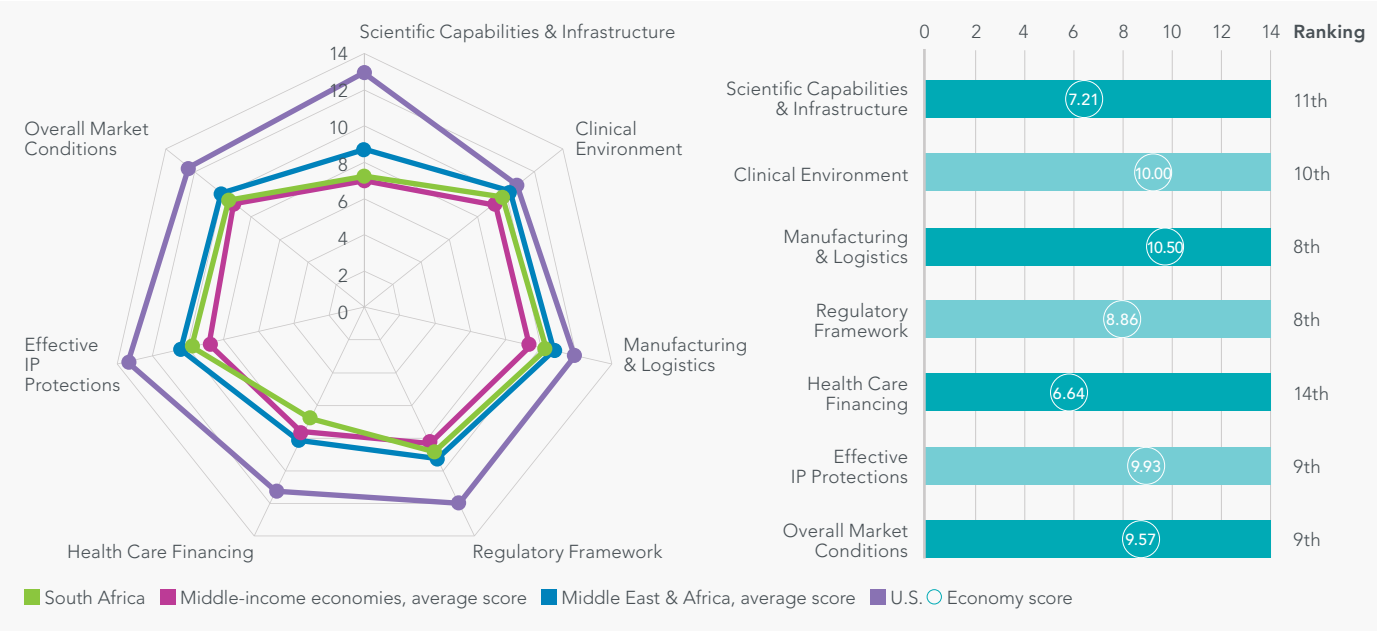
BCI Overall Results



Comparative Results – BCI Overall Scores



BCI Scores by Category



Map of the National Biopharmaceutical Environment – BCI Results in Depth

Key areas of strength

- ✔ Relatively strong interest in and manpower available for clinical research
- ✔ Manufacturing capabilities basic but mainly of high quality
- ✔ Legal environment seen as broadly effective

Key areas of weakness

- ✘ Very difficult market access environment
- ✘ Severe regulatory delays
- ✘ Regulatory capacity weak for new and/or advanced products
- ✘ R&D capabilities currently rudimentary

Scientific Capabilities & Infrastructure

- The scientific and biomedical research system is viewed as fairly weak, though respondents positively cited the government's new Bio-Economy Strategy as a sign that it is focused on encouraging R&D.
- They also noted that R&D at the institutional level is rarely translated into commercial products.

Clinical Environment

- Skilled capacity for and interest in clinical research is seen as relatively high.
- Nevertheless, concerns were raised over substantial delays in clinical trial approval as well as holes in governance of clinical research.

Manufacturing & Logistics

- Basic manufacturing operations are regarded as adhering to GMP standards and quality control of exports is considered to be high.
- The process to obtain permits for manufacturing is seen as cumbersome and unpredictable.

Regulatory Framework

- Market approval delays are cited as a major concern, taking in excess of 2 years.
- The standard of approval and monitoring of basic drugs is viewed as acceptable.

Health Care Financing

- Price controls for products in both the public and private markets are seen as highly restrictive.
- Public reimbursement and procurement, covering a majority of the population, is perceived as very narrow and focused on reimbursing low-cost generics.

Effective IP Protections

- Local executives are generally satisfied with basic levels of IP protection in South Africa.
- Areas cited as requiring improvement include specific rights targeting biopharmaceuticals as well as enforcement of IP rights through the administrative and court systems.

Overall Market Conditions

- Future market potential is viewed as somewhat behind the curve relative to other emerging markets.
- Respondents rated the legal environment quite highly, but business conditions are regarded as lacking in government incentives and support.

SWITZERLAND

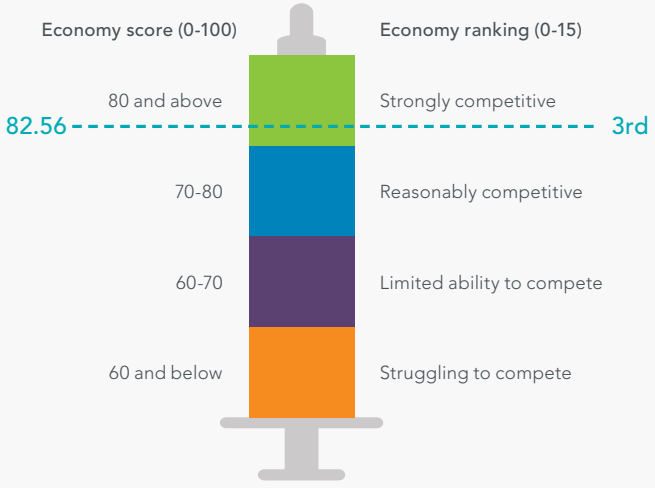
Market Overview – From the Lens of Local Executives

Local executives are generally pleased with the biomedical ecosystem in Switzerland and consider it to be strongly competitive vis-à-vis the global market. Within the BCI, Switzerland performs better than the average high-income economy, though not above the U.S. or UK.

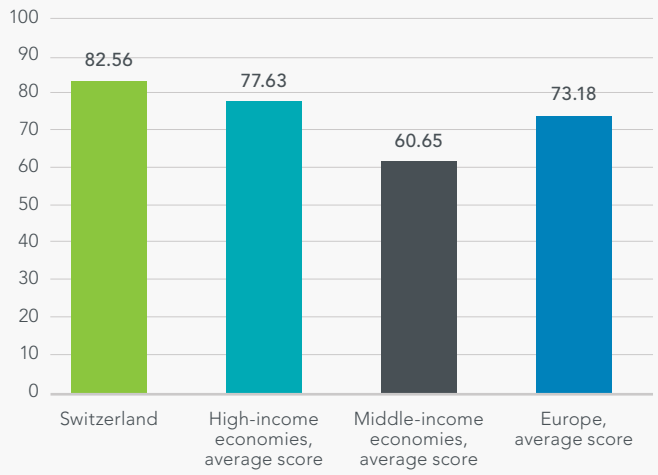
From the perspective of local executives, Switzerland has a generally well-rounded biomedical ecosystem. They cite a highly qualified and experienced workforce and cutting edge research infrastructure, though even more could be done to enhance collaborative R&D. Local executives consider Switzerland to have one of the best biomedical manufacturing sectors in the world, with diverse capabilities including in cutting edge processes and products, and all phases of manufacturing controlled in line with international standards. IP protections specifically relating to biopharmaceuticals are also viewed as outstanding, with Switzerland's BCI score for this category surpassing almost all the other markets in the sample.

Still, local executives identify a few bottlenecks in the system. The first is the ability to secure an adequate return on investment, with what they see as heavy price controls that limit fair prices for innovative medicines. Remaining concerns of local executives are largely related to functional aspects. They note that regulatory review and approval timelines could be tighter and more streamlined. In their view, high operational costs also at times limit the attractiveness of the market as an R&D destination.

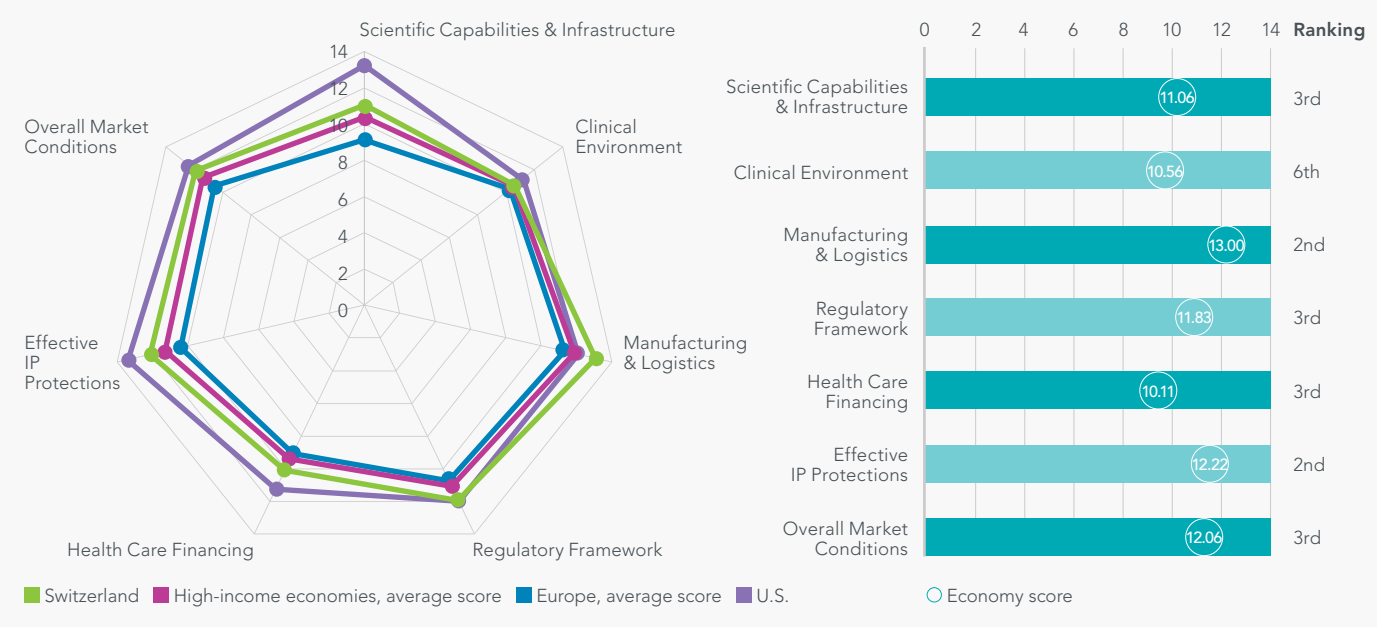
BCI Overall Results



Comparative Results – BCI Overall Scores



BCI Scores by Category



Map of the National Biopharmaceutical Environment – BCI Results in Depth

Key areas of strength

- ✔ Very strong and effective IP protections available
- ✔ Manufacturing processes meet the highest standards across the board
- ✔ Drug regulator possesses all necessary capabilities
- ✔ Top quality biomedical research system

Key areas of weakness

- ✘ High operational costs
- ✘ Significant regulatory delays
- ✘ Lack of a fair price for innovative medicines
- ✘ Need for greater transparency in P&R decision-making

Scientific Capabilities & Infrastructure

- The level of scientific and biomedical education and training in the country is viewed as excellent.
- Research institutions are generally seen as quite successful at commercializing their work but there is still some room for improvement.

Clinical Environment

- Compared to other markets, conducting clinical trials is considered to be very costly.
- Hospitals are regarded as well-equipped to carry out all phases of the clinical trial process, and are highly compliant with international clinical research standards.

Manufacturing & Logistics

- Quality control standards and capacity to meet these are viewed as being at a very high level across all major phases of manufacturing.
- Nevertheless, there were slight concerns regarding the ease of importing raw materials and components.

Regulatory Framework

- The health regulator is seen as having excellent capabilities for review and approval of all major product segments.
- The timeline for approving products, cited as over 12 months, is a matter of significant concern.

Health Care Financing

- Though coverage of medicines is perceived to be quite comprehensive, heavy price controls are seen as impeding market access for innovative medicines.
- Overall, pricing and reimbursement decision-making could be more transparent and HTA timelines better defined.

Effective IP Protections

- Respondents report that a very effective IP system is in place, both in terms of the legal framework and application on the ground.
- Slight concerns were raised over the frequency of parallel importing and comprehensiveness of anti-counterfeiting actions.

Overall Market Conditions

- Local executives cite a highly attractive tax environment for biopharmaceutical companies.
- They also note that government is generally supportive of the industry but areas exist where political and industry interests diverge.

TURKEY

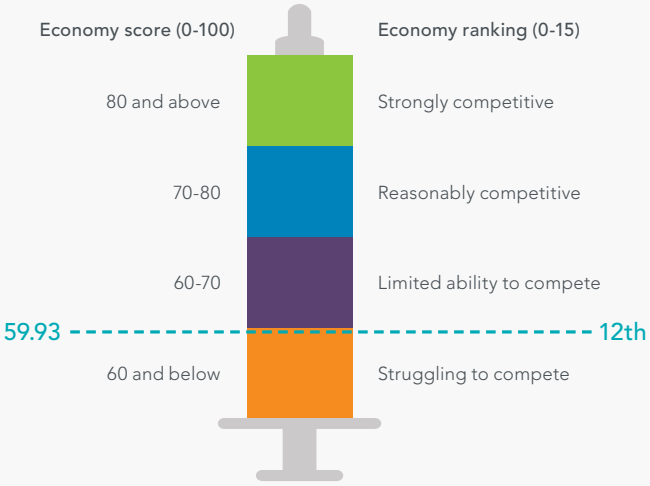
Market Overview – From the Lens of Local Executives

Local executives rank Turkey near the bottom globally in terms of biomedical investment attractiveness and, overall, have several major concerns with its biomedical ecosystem. Within the BCI Turkey performs below the average middle-income economy and significantly below its European counterparts.

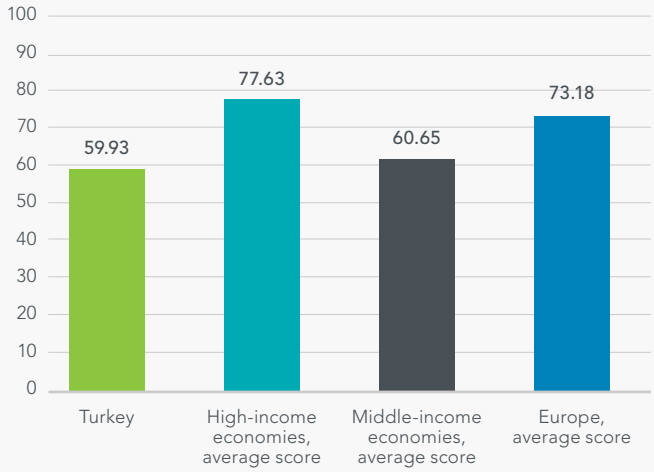
In particular, local executives identified the following challenges. In their view, the scientific and biomedical research system requires a substantial boost in scope and quality in order to build up and retain the local knowledge base. They consider Turkey to have entry-level manufacturing capabilities in place, but when it comes to advanced molecules and products they note significant gaps, such as in the production of high-quality APIs. Regulatory capacity is also viewed as fairly basic, with capabilities for new drug approvals as well as strategic areas, such as biosimilars, limited. Local executives note in particular that the system is held back by lengthy delays, in part due to complex rules governing GMP inspections (particularly difficult to fulfill for imported products). They also find the market access environment to be very challenging, rated as one of the most difficult among the markets sampled in the BCI. Gaps in IP protection noted by local executives focused on the ability to secure meaningful remedies for infringement as well as effective terms of RDP (which is based on the date of market authorization in Europe, despite delays in domestic drug approval). Finally, the business environment also ranked at the bottom of the group of economies in the BCI, with strong concerns from local executives over weaknesses in the legal framework and lack of business support.

To its credit, the Turkish government has introduced a handful of platforms aimed at supporting its objectives for the biomedical sector (which include reaching an industry value of $23 billion by 2023),[64] such as special economic zones known as technoparks that involve state funded infrastructure and tax incentives.[65] Nevertheless, several recent policy developments underscore local executives' concerns, and hinder, rather than facilitate, the government's industrial aspirations. As one example, 2014 requirements that over half of production of a given drug take place in Turkey for products with local generic equivalents – while at the same time failing to address domestic gaps in manufacturing capacity – adds further layers of discrimination against innovative drugs on top of those already identified by local executives.

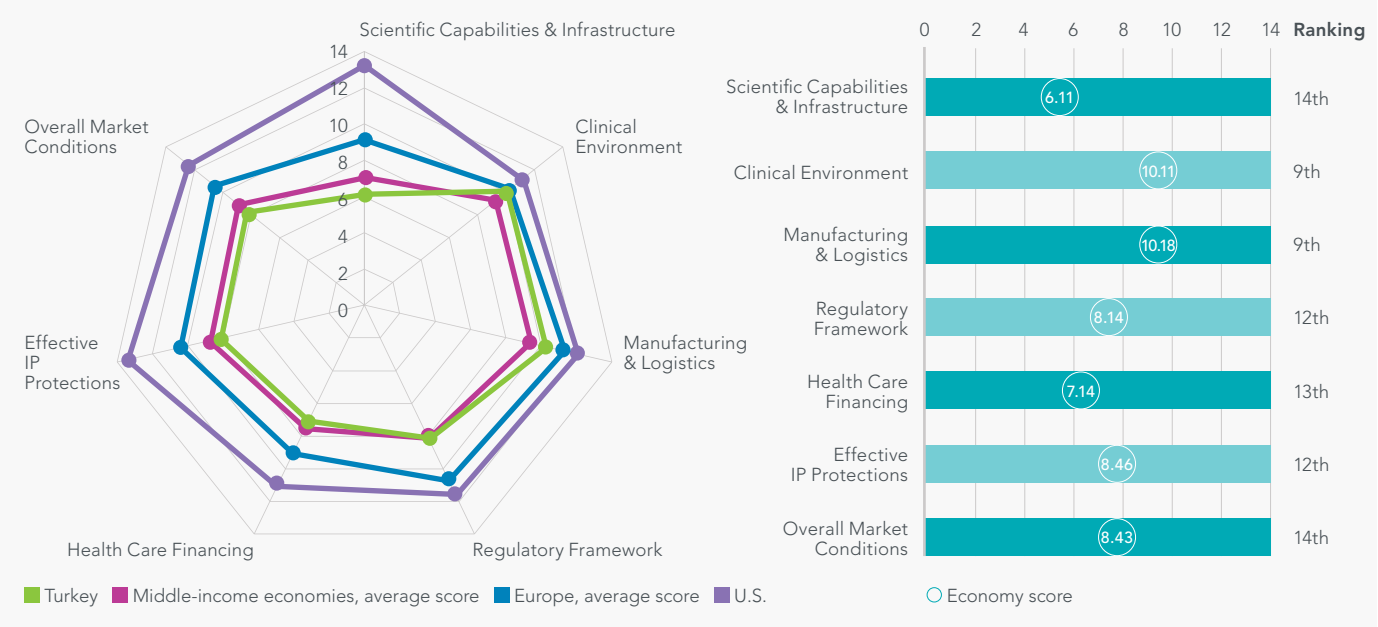
BCI Overall Results



Comparative Results – BCI Overall Scores



BCI Scores by Category



Map of the National Biopharmaceutical Environment – BCI Results in Depth

Key areas of strength

- ✔ Relatively low cost market
- ✔ Market approval capabilities strong in certain areas (generics)
- ✔ Stated desire to improve investment conditions

Key areas of weakness

- ✘ Increasingly challenging registration and market access requirements
- ✘ Major gaps in enforcement of patents and largely ineffective RDP
- ✘ Limitations to capacity for high quality manufacturing (such as APIs)
- ✘ Substantial lack in home-grown R&D capabilities

Scientific Capabilities & Infrastructure

- Scientific research system is viewed as undiversified and significantly affected by "brain drain".
- Commercialization and translation of research is perceived as very weak, though incentives schemes are in place to improve certain areas (such as biosimilars).

Clinical Environment

- Respondents cited considerable delays in clinical trial approvals.
- Compliance with global clinical trial standards is seen as fairly high and cost of conducting trials is low.

Manufacturing & Logistics

- Implementation of GMP is seen as mixed; gaps in ability to produce high quality APIs are noted.
- Warehousing and distribution quality assurance generally viewed as adequate.

Regulatory Framework

- Very long approval times (due to complex GMP inspection rules applicable to foreign plants) cited.
- Capacity/standards of biosimilar approval is considered below international standards.

Health Care Financing

- Local executives note that strict price controls and increasing reimbursement delays introduce huge uncertainty as to market access timeframe and ROI.
- Procurement system seen as challenging.

Effective IP Protections

- Civil and criminal remedies for IP infringement are seen as fairly ineffective, particularly on the ground.
- Local executives consider RDP to be very weak, given major market access delays in Turkey.

Overall Market Conditions

- Market demand, both current and future, is seen as relatively limited.
- Despite positive rhetoric from government, the business environment is viewed as poor and worsening.

UNITED KINGDOM

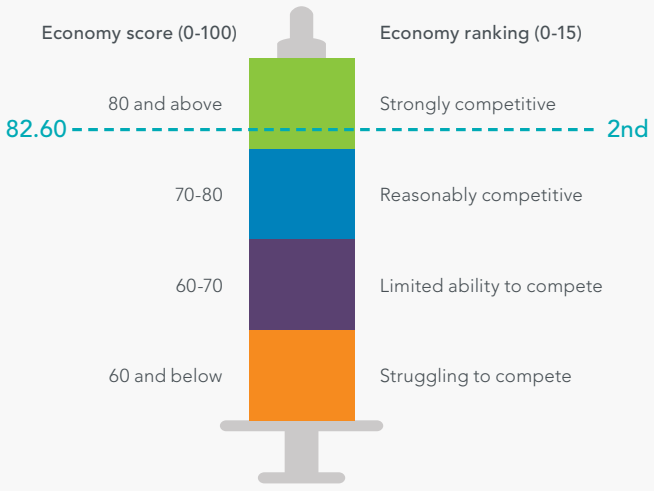
Market Overview – From the Lens of Local Executives

Local executives view the UK as a top global destination for biomedical investment and are relatively pleased with the biomedical ecosystem there. Within the BCI, the UK performs significantly above the average high-income economy, as well as above the U.S. in certain areas (such in manufacturing capacity and the regulatory system).

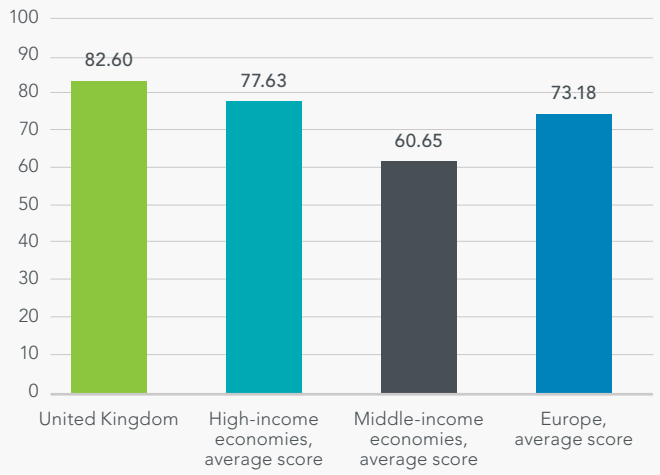
In the view of local executives, an active and ongoing commitment to biomedical innovation on the part of the UK government, on top of a robust and well-established legal and regulatory framework, are among key factors that have allowed the economy to continue to compete for high levels of global biopharmaceutical investment. An example of a recent policy initiative, in 2014 it implemented a "patent box" tax break that offers companies favorable taxes on income earned from IP generated in the UK.[66] Since implementing the new tax incentive the economy has reported a surge in biotech investment.[67]

However, local executives do note that remaining gaps and areas for improvement exist. In their view, there could be even greater efforts to promote horizontal research partnerships and actual development of new products and technologies. While they cite a strong clinical research system, in their experience this is slightly hampered by regulatory delays and high costs. An additional concern is that limited resources for drug purchasing, controlled by a single payer, a culture of slow adoption of new medicines and inadequate prioritization of cutting edge treatments tend to slow/hinder diffusion of innovative medicines in practice.

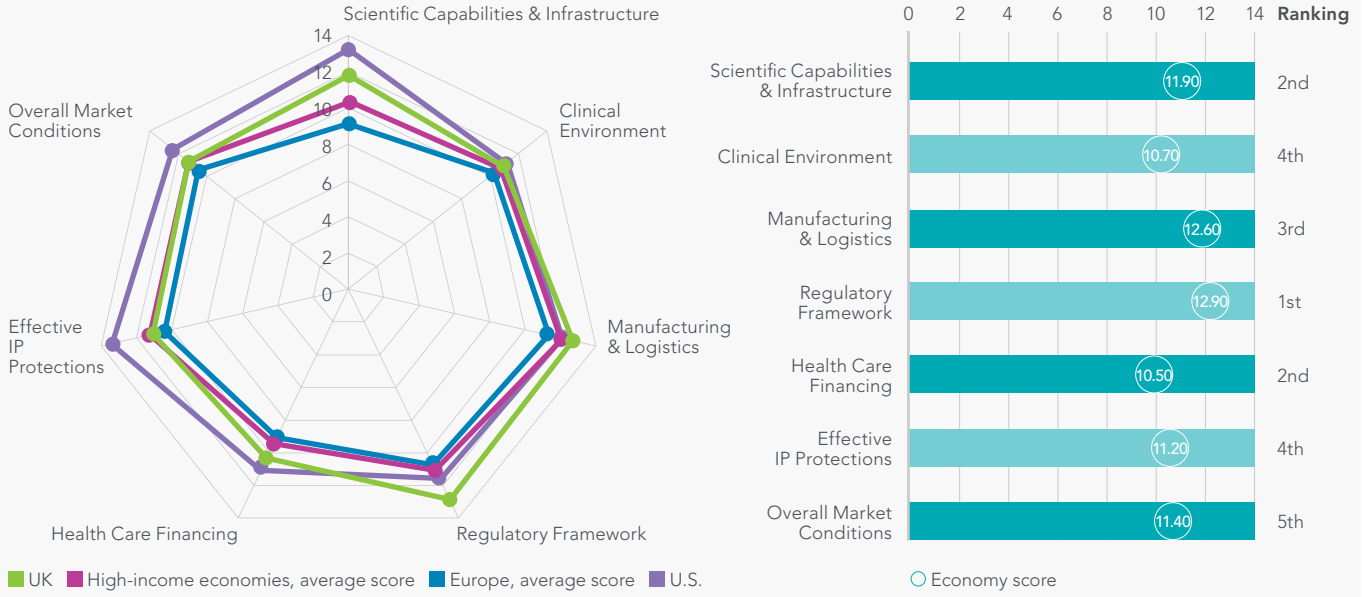
BCI Overall Results



Comparative Results – BCI Overall Scores



BCI Scores by Category



Map of the National Biopharmaceutical Environment – BCI Results in Depth

Key areas of strength

- ✔ Excellent manufacturing capacity
- ✔ Regulatory framework to highest international standards
- ✔ Leading scientific and biomedical research system with support from government
- ✔ IP system satisfactory

Key areas of weakness

- ✘ Some gaps in level of actual commercialization activities
- ✘ Relatively high operational costs
- ✘ Regulatory delays in certain areas
- ✘ Somewhat slow uptake of new medicines and somewhat limited market potential

Scientific Capabilities & Infrastructure

- Local executives cite frequent collaboration between research institutions and the biopharmaceutical industry.
- Nevertheless, they note that there is room for improvement in actual levels of translation and commercialization of basic research.

Clinical Environment

- The clinical research sector is viewed as highly developed and adhering to the highest standards.
- Conducting clinical trials is seen as being quite costly.

Manufacturing & Logistics

- Import and export control of pharmaceutical products is considered to be well-established and of high quality.
- Warehouse quality and distribution service standards are regarded as being in line with international standards.

Regulatory Framework

- The health regulator is seen as having excellent capacity to review the full range of drug submissions.
- There were slight concerns with delays in market approval.

Health Care Financing

- Respondents cited some lack of availability and use of new medicines due to limited resources and the single payer system, with supplementary coverage only partially accessible.
- Public sector price controls were mentioned as being somewhat problematic.

Effective IP Protections

- Heavy occurrence of parallel importing from other EU member states is viewed as a significant barrier to obtaining a return on investment.
- Generally, legal protection and practical enforcement are seen as being fairly effective.

Overall Market Conditions

- The government is considered to be a supportive partner of the biopharmaceutical industry.
- Future market potential is regarded as somewhat limited relative to other markets globally.

UNITED STATES

Market Overview – From the Lens of Local Executives

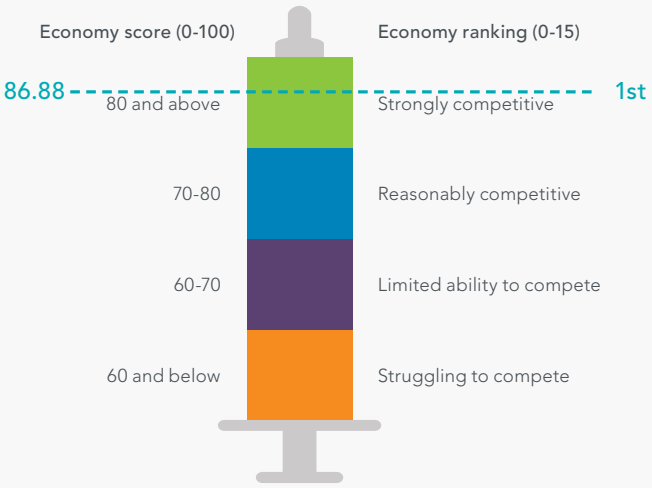
Local executives consider the U.S. to be the leading biopharmaceutical market in the world in terms of investment competitiveness. Indeed, the U.S. commands over half of global private biomedical investment each year.[68] Within the BCI, the U.S. is ranked number one, performing well above the average high-income economy and significantly above neighboring markets.

From the standpoint of local executives, the level of scientific and clinical research, training and infrastructure in the U.S. is unmatched and there are many opportunities to turn research conducted at the institutional level into commercial products. Additional key strengths they identify include a highly robust IP system and generally positive conditions in terms of the legal and political framework, with some exceptions. Also, although they view the pricing and reimbursement system as being somewhat fragmented, overall local executives characterize the U.S. market is one of the easiest to access effectively worldwide.

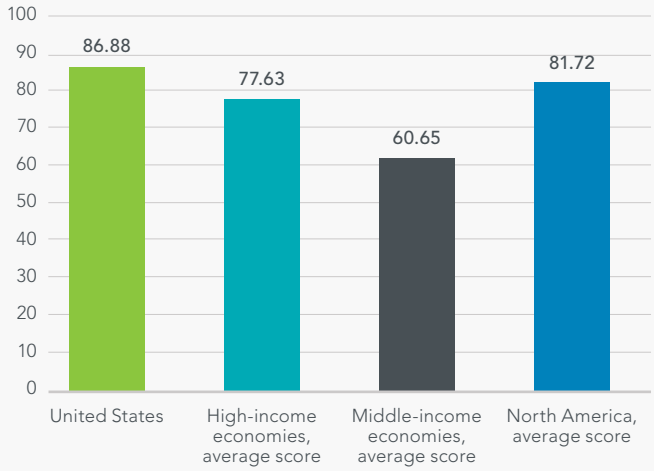
In the view of local executives, where the U.S. falls slightly behind other leading high-income economies is mainly in the areas of manufacturing and the regulatory framework (specifically in relation to the biosimilar pathway and to streamlining of manufacturing permits). Recent challenges surrounding patentability of biomedical products were also raised as concerns.

Yet, efforts are already underway to address some of these concerns and gaps in the U.S. biomedical ecosystem. For instance, among the more recent initiatives aimed at supporting the biomedical sector, and the U.S. innovation environment generally, the National Network for Manufacturing Innovation (launched in 2014) provides funding support to create public-private synergies aimed at enhancing advanced manufacturing capabilities in the economy.[69]

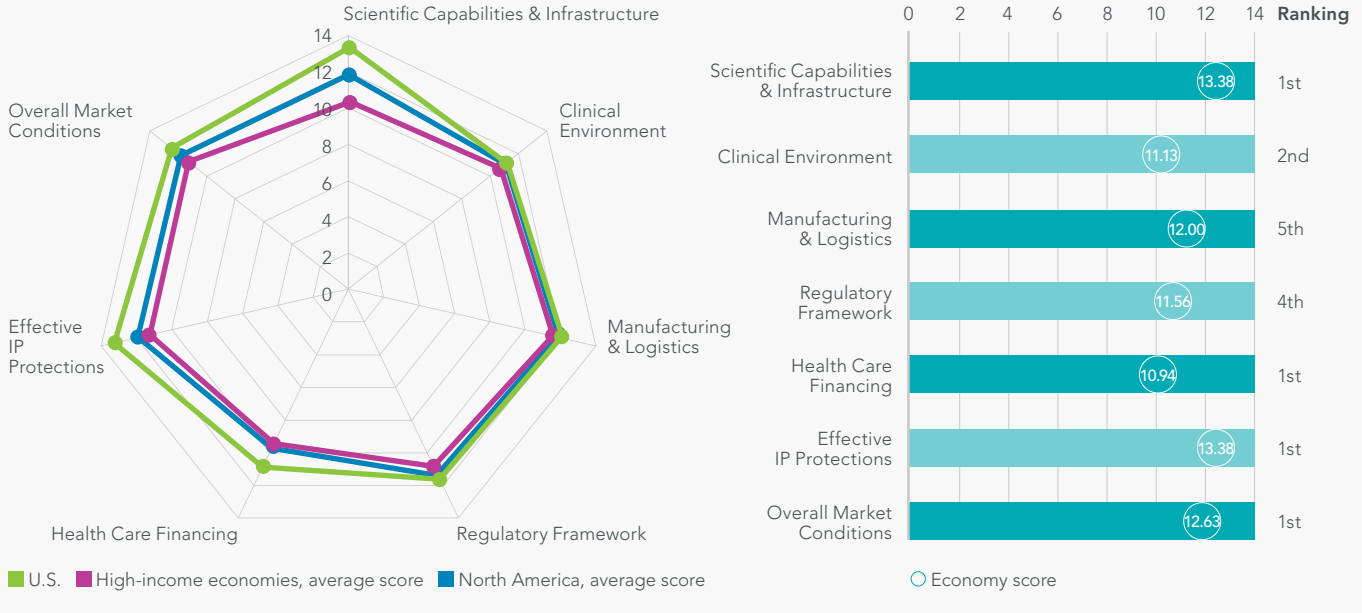
BCI Overall Results



Comparative Results – BCI Overall Scores



BCI Scores by Category



Map of the National Biopharmaceutical Environment – BCI Results in Depth

Key areas of strength

- ✔ Exceptional R&D capabilities
- ✔ Strong government support for biomedical sector
- ✔ Excellent IP protections
- ✔ Robust levels of unmet demand and market potential

Key areas of weakness

- ✘ Fragmented and sometimes challenging public pricing and reimbursement system
- ✘ High operational costs
- ✘ Regulatory streamlining needed in certain areas
- ✘ Tax environment for biopharmaceutical companies could be improved

Scientific Capabilities & Infrastructure

- Scientific research capabilities and the system as a whole are viewed as world beating.
- A strong culture and supporting legal framework for collaborative R&D and commercialization of research is cited, though conflicts of interest can be slight barriers at times.

Clinical Environment

- Hospitals and clinical research organizations are considered well equipped to carry out all phases of clinical trials to international standards.
- Compared to other countries the clinical trials environment is seen as costly.

Manufacturing & Logistics

- Broadly speaking manufacturing capabilities and standards are viewed as in line with global best practices.
- Respondents noted that the process of obtaining manufacturing permits could be better streamlined.

Regulatory Framework

- The health regulator is seen as independent and highly capable at handling drug approvals, with some room for improvement in biosimilar approval.
- Slight concerns were raised over market approval timelines.

Health Care Financing

- Price controls in the public sector are regarded as somewhat challenging and the public reimbursement structure highly fragmented, with various payers covering different segments of the population.
- Patients are seen as having excellent access to medicines through private sector markets.

Effective IP Protections

- The IP system is generally viewed as being of the highest standards.
- Patentability of biotech inventions and anti-counterfeiting actions could be enhanced.

Overall Market Conditions

- The corporate and biomedical tax environment is adequate but not top-notch.
- Current and future demand and market potential is regarded as quite strong.

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APPENDIX: 2015 BCI SURVEY TEXT

The following Appendix presents the survey questions submitted to BCI respondents and analyzed in the above report.

PART A – LEVERAGING SCIENTIFIC CAPABILITIES & INFRASTRUCTURE

The following questions assess the quality of personnel, technologies and facilities in biopharmaceutical research forums in your country, and the ability to leverage these to translate discoveries into products.

Question 1

How would you describe the overall level of your country in terms of its capabilities to engage in biopharmaceutical research and development?

Low (seriously behind other countries) ☐	Basic ☐	Significant (more than other countries, but still lacking in some areas) ☐	Excellent (top of the curve) ☐

Question 2

In your view, the level of scientific education and training in your country is:

Low (very basic and incomplete knowledge base) ☐	Basic (not sufficiently advanced to meet modern developments) ☐	Significant (more than other countries, but still lacking in some areas) ☐	Excellent (of the highest caliber across the board) ☐

Question 3

To what extent does the life science research system in your country include a wide range of disciplines relevant to biopharmaceutical research?

Basic (undiversified) ☐	Significant (touches upon various research areas, but not sufficiently diverse) ☐	High (is a diverse and multi-disciplinary system) ☐	Excellent (highly diverse and advanced system, with cutting-edge advances in different research areas) ☐

Question 4

How strong and effective is the level of collaboration in your country between research institutions and the biopharmaceutical industry?

Almost no collaboration ☐	Occurs occasionally ☐	Occurs frequently ☐	Occurs daily (is of a strategic interest) ☐

Question 5
To what extent are research institutions in your country interested in translating basic life science research into applications that can lead to the development of biopharmaceutical products?

No real interest (there is even antagonism towards this issue at times) ☐	Some interest (little concrete action) ☐	Active interest (some concrete actions) ☐	High level of interest (of high priority, with national support for concrete actions) ☐

Question 6
How successful are research institutions in your country at translating, transferring and commercializing biopharmaceutical research for the purpose of developing biopharmaceutical products?

Rarely successful ☐	Partially successful (for example, via licensing deals, joint venture and spin-off companies) ☐	Quite successful ☐	Very successful ☐

Question 7
To what degree do biopharmaceutical entities and research institutions in your country operate within the framework of innovation clusters, science parks and incubators?

Rarely ☐	Only in specific regions ☐	Frequently ☐	Part of the modus operandi (of a strategic national importance) ☐

PART B – CLINICAL ENVIRONMENT – FROM TEST TUBE TO PATIENT

The following questions assess the ability of research institutions in your country to conduct necessary clinical research in a high quality and efficient manner.

Question 8
How would you describe the readiness and capabilities of hospitals in your country to carry out clinical trials of different phases?

Low (limited capacity for conducting clinical trials) ☐	Basic (focusing mostly on post-clinical phases) ☐	High (strong capabilities for conducting clinical trials of different phases, but mostly final phase trials, i.e. phase III, are taking place) ☐	Excellent (of the highest caliber across the board; hospitals conduct and lead clinical trials in all phases and their standards are harmonized with global GCP standards) ☐

Question 9
How easy is it to recruit and maintain volunteers for participating in clinical trials in your country?

Very difficult (greatly lacking in volunteers; adverse public perception) ☐	Relatively difficult (volunteers are available but in insufficient numbers; officials anxious about public perception) ☐	Relatively easy (some limitations in the ability to secure long-term participation; public perception generally positive or not a factor) ☐	Easy (high level of success in recruiting and maintaining candidates; positive public perception) ☐

Question 10
Compared to other developed countries, how costly is it to conduct clinical trials in your country?

Financially unattractive (facilities and manpower are relatively expensive and difficult to access) ☐	Relatively costly ☐	Relatively less costly ☐	Financially attractive (high quality infrastructure and manpower are relatively inexpensive to secure) ☐

Question 11
In your view, what is the typical timeframe for obtaining approval for a clinical trial in your country?

More than 180 days or unpredictable ☐	90-180 days ☐	60-90 days ☐	30-60 days or less ☐

Question 12
How compliant are organizations participating in clinical trials in your country with global clinical standards and procedures?

Compliance is lacking ☐	Compliance varies ☐	Relatively compliant (with exceptions) ☐	Very compliant (across the board) ☐

Question 13
How would you describe the overall regulatory environment governing the conducting of clinical trials in your country?

Burdensome and ineffective ☐	Mixed (good in some areas and problematic in other areas) ☐	Fairly positive (with room for improvement) ☐	Effective and "user friendly" ☐

Question 14
How developed is the clinical research management (CRM) industry in your country?

Undeveloped ☐	Limited (in terms of presence and capacity) ☐	Fairly developed (with room for improvement) ☐	Highly developed (of the highest standard across the board) ☐

PART C – MANUFACTURING & LOGISTICS – QUALITY & EFFICIENCY

The following questions assess the ability to manufacture and distribute biopharmaceutical products efficiently and to a high standard in your country.

Question 15
In your view, to what extent do local pharmaceutical manufacturing sites in your country meet current good manufacturing practices (GMP)?

Compliance is lacking	Compliance varies	Relatively compliant (with exceptions	Very compliant (across the board)
☐	☐	☐	☐

Question 16
How robust is the system in your country for reviewing and approving products intended for export, in terms of quality, efficacy, and safety (typically provided by a certificate of pharmaceutical product)?

Very weak or non-existent (such a mechanism is effectively not available in our country)	Superficial (it is possible to export products manufactured in the country without regulatory review)	Relatively robust (the certificate or regulatory review signals a satisfactory level of quality, but with some reservations)	Highly robust (the certificate or regulatory review is a credible signal of quality)
☐	☐	☐	☐

Question 17
To what extent are pharmaceutical entities in your country able to produce high quality active pharmaceutical ingredients (APIs)?

No local capacity (APIs are imported)	Limited capacity (but only for local use)	Significant capacity (good domestic capacity, with some ability for export)	High capacity (full domestic capacity and internationally recognised as an exporter of APIs)
☐	☐	☐	☐

Question 18
How easy is it to import raw materials & components for pharmaceuticals into your country?

Very difficult	Frequently difficult	Fairly easy	Easy
☐	☐	☐	☐

Question 19
To what extent do authorities in your country control the release of imported raw materials and components?

Rarely or sporadically	On a limited basis (certain types of inspections exist, but they are not sufficiently robust)	Regularly (coverage of inspections is to international standards but quality is not consistent)	Frequently (according to accepted international standards)
☐	☐	☐	☐

Question 20
How would you describe the ease of obtaining permits relating to manufacturing in your country?

Very difficult (great deal of red tape and delay) ☐	Relatively difficult (possible, but still cumbersome and often unpredictable) ☐	Relatively easy (mostly transparent, but with limitations, e.g. lack of predictability, possible delays) ☐	Easy (straightforward, predictable and very professional) ☐

Question 21
How would you describe the quality assurance standards in warehousing & distribution services in your country?

Greatly lacking (storage and distribution operations are not accountable for quality assurance) ☐	Relatively low (basic and only sometimes enforced) ☐	Fairly high (international standards are generally in place and enforced, but with exceptions) ☐	High (international standards are enforced uniformly) ☐

PART D – SOUNDNESS AND EFFECTIVENESS OF THE REGULATORY FRAMEWORK

The following questions assess the ability of the regulatory system in your country to ensure that only high quality, safe biopharmaceutical products enter the market, yet do so in a timely manner.

Question 22
How would you describe the capacity of the health regulator in your country to review the data submitted to it for the approval of new biopharmaceutical products?

Very low (low capacity for independent review) ☐	Basic (most reviews based on prior approval in other countries; lacks significant capacity for independent review) ☐	Good (review based on prior approval in other countries as well as on independent review) ☐	Excellent (full capacity to conduct independent review) ☐

Question 23
How would you describe the capacity of the health regulator in your country to review and approve generic drugs (based on small molecules/chemical entities)?

No capacity (approval is automatic or not necessary) ☐	Limited (only bioequivalence tests are required) ☐	Reasonable (quality, safety and efficacy data is also required, but gaps remain in terms of phasing out substandard drugs) ☐	Excellent (regulatory framework requires approval according to the highest acceptable scientific standards) ☐

Question 24
How would you describe the capacity of the health regulator in your country to review and approve biosimilars (based on large molecules/biologics)?

No capacity (approval is automatic or not necessary, or only requires bioequivalence tests	Limited (preclinical and/or clinical testing is required for approval but only a minimal amount)	Reasonable (adequate preclinical and clinical testing is required and clearly defined in most cases)	Fully satisfactory (regulatory framework fully in line with WHO principles of biosimilar approval and standards are clearly defined across the board)
☐	☐	☐	☐

Question 25
In your view, what is the timeframe for the health regulator in your country to examine and approve a drug once it has received all available data?

Very long (takes 24 months or more, despite having data from prior approval in other countries)	Relatively long (takes 12 months or more)	Fairy short (takes 6-12 months)	Very short (takes no more than 6 months)
☐	☐	☐	☐

Question 26
How would you describe the pharmacovigilance system in your country?

Non-existent	Basic (rudimentary reporting system, frequent delays, inadequate response)	Relatively effective (adequate reporting system and response in most cases, yet lacking relative to other countries)	High-level (effective reporting system; rapid and comprehensive response)
☐	☐	☐	☐

Question 27
In your view, how independent is the health regulatory agency in your country?

Not at all (may be heavily influenced by financial interests and other political considerations)	Semi-independent (some influence from government)	Mostly independent (government has political influence on rare occasions)	Fully independent (operates solely on the basis of scientific and public health rationale)
☐	☐	☐	☐

Question 28
In your view, to what extent is the health technology evaluation and registration process systematic and well-defined in your country?

Not at all (procedures, processes & timelines are arbitrary & uncertain)	To a very limited extent (basic definition of process exists, but specific aspects are arbitrary)	To a large extent (most procedures are clearly defined, but with some exceptions, particularly for new or future product classes)	To a great extent (procedures & timelines are systematically and clearly identified)
☐	☐	☐	☐

PART E – HEALTH CARE FINANCING

The following questions assess the ability of new biopharmaceutical products to access the market via the pricing and reimbursement system in your country in an efficient manner and at an acceptable price.

Question 29
How comprehensive is the public reimbursement framework in your country?

Non-existent (there is no national or public reimbursement of pharmaceutical products) ☐	Partial (reimbursement is usually given to less costly and domestically manufactured products, i.e. focus is on generics) ☐	Relatively comprehensive (most medicines are reimbursed, but severe limitations are imposed on drugs which are considered relatively more costly) ☐	Fully comprehensive (reimbursement is given across the board, including the possibility of reimbursing costlier, innovative medicines) ☐

Question 30
In the absence of public reimbursement (or serious delays), to what extent are private or supplementary channels that allow patients to access biopharmaceutical products available in your country?

Not available (such channels do not exist in my country) ☐	Sporadically (mainly through out-of-pocket spending on individual drugs) ☐	Partially (supplementary coverage schemes are available, but mainly for certain income levels or disease areas) ☐	Frequently (the population can choose from various supplementary and commercial coverage schemes that allow access to a significant number of treatments) ☐

Question 31
How stringent are price controls on publicly reimbursed products in your country?
*If biopharmaceutical products are not publicly reimbursed in your country please select the first option.

Highly stringent (prices are determined by the state and are highly restrictive) ☐	Relatively stringent (price controls are imposed but to a limited extent) ☐	Moderate (companies are allowed to set their own prices, subject to structural limitations, such as profit margins and negotiations) ☐	Relatively free pricing (there are almost no limitations on how prices are set at the national level) ☐

Question 32
To what extent are prices of biopharmaceutical products consumed in the private sector set freely and not subject to price controls in your country?

Hardly at all (price controls exist for most products in the private sector) ☐	To a limited extent (price control mechanisms, such as reference pricing and price cuts, are prevalent, particularly for higher cost products) ☐	To a reasonable extent (no direct price controls are in place, but indirect measures, such as direct taxes and discounts/rebates, exist) ☐	To a great extent (manufacturers are generally able to set prices freely and are not subject to direct or indirect price controls) ☐

Question 33
How would you describe the transparency of the public pricing and reimbursement framework in your country?

Completely non-transparent (decisions take place behind fully closed doors; industry has little influence on or knowledge of the actual decision making process) ☐	Limited transparency (industry participates in negotiations but has only limited access to the basis of final pricing decisions) ☐	Quite transparent (industry routinely participates in decisions but is not privy to all aspects of the process) ☐	Fully transparent (rationale, data and personnel involved in decisions are entirely public information and are developed in collaboration with industry and key stakeholders, e.g. patients) ☐

Question 34
To what extent is public reimbursement in your country based on the value of medicines and not only on their cost?

Not applicable (public reimbursement is not available) ☐	Not at all (reimbursement is based only on cost) ☐	To some extent (reimbursement is based mostly on cost but takes value into account) ☐	To a great extent (reimbursement is based on consideration of both the value of the product as well as price) ☐

Question 35
To what extent does the public procurement system in your country allow your organization to effectively compete to provide patients access to your products?

Hardly at all (the process is heavily biased and/or providers/payers have all the negotiating power) ☐	To a limited extent (only in cases in which the product is very strong) ☐	To a reasonable extent (providers or other bid participants have an advantage some of the time) ☐	To a great extent (we are able to compete with other bids and/or negotiate with providers on an equal footing) ☐

PART F – EFFECTIVE IP PROTECTIONS

The following questions assess the ability to fully realize required terms of intellectual property (IP) protections for biopharmaceutical products.

Question 36
How effective are the IP protections associated with proprietary pharmaceutical products in your country?

Non-existent (high risk environment in which products are immediately deprived of protection) ☐	Ineffective (both in terms of the length and the scope) ☐	Relatively effective (reasonable length, yet the scope of protection is frequently challenged and disputed) ☐	Highly effective (both in terms of the length and scope of protection) ☐

Question 37
How effective is the process of patenting in your country?

Highly ineffective (complex and slow, with a very poor degree of professional examination capacity) ☐	Somewhat ineffective (a bureaucratic process with a fairly low level of expertise in the examination process) ☐	Fairly effective (professional, but with some exceptions) ☐	Highly effective (in line with current international standards; streamlined process for both domestic and international patents) ☐

Question 38
In your view, how effective are civil and criminal remedies for infringement of intellectual property rights in your country?

Highly ineffective (framework for litigation and penalties does not exist) ☐	Fairly ineffective (framework exists but is generally not implemented or enforced) ☐	Fairly effective (framework is generally implemented and enforced but with key exceptions) ☐	Very effective (including compensation, injunctions and penalties; ability to challenge validity of a patent) ☐

Question 39
To what extent does your country allow parallel importing of pharmaceuticals?

Extensively (pursued whenever possible; is core part of cost containment policies) ☐	Frequently (allowed in many cases) ☐	To a limited extent (only in special circumstances) ☐	Not at all ☐

Question 40
In your view, how effective are policing actions against counterfeiting in your country?

Highly ineffective (counterfeit products may be easily imported or exported, and penalties are not a deterrent) ☐	Fairly ineffective (borders are generally protected but there is limited action to address internal traffic of counterfeits) ☐	Fairly effective (action is taken at all points of access but key gaps in control remain) ☐	Very effective (comprehensive and thorough enforcement at all points of access, and penalties act as a sufficient deterrent) ☐

Question 41
To what extent is the biopharmaceutical industry able to provide information to patients on existing treatments in your country?

Not at all (information may only be given to physicians and/or in scientific publications) ☐	To a limited extent (very general information may be given about available treatments for a limited number to medical conditions, but are not allowed to refer to specific products) ☐	To some extent (information about the existence of available products to treat different medical conditions may be given, but without reference to names of product) ☐	To a great extent (information may be given on specific products, with reference to brand name, as long as such data is accurate and balanced, e.g. refers to limitations, risks etc.) ☐

Question 42
How effective are mechanisms in your country aimed at safeguarding clinical trial data (i.e. regulatory data protection)?

Non-existent (no such framework exists) ☐	Little effectiveness (the framework is very limited both in relation to term of exclusivity and scope) ☐	Partially effective (a framework exists but is mainly applicable only to new chemical entities) ☐	Very effective (the framework generally applies to all types of innovative medicines, including biologics and new indications) ☐

PART G – OVERALL MARKET CONDITIONS

The following questions assess the degree to which general political, macroeconomic and bureaucratic conditions facilitate or hinder biomedical investment in your country.

Question 43
In your view, currently how attractive is your country as a location for marketing biopharmaceutical products?

Very unattractive (unmet medical need is low or very specific; low purchasing power among population or healthcare system) ☐	Fairly unattractive (medical need mainly met by generic companies; limited purchasing power) ☐	Somewhat attractive (some unmet medical need, i.e. ageing population; significant purchasing power but with some restrictions on healthcare spending) ☐	Very attractive (large unmet medical need, including demand for treating ageing populations; relatively little restriction on ability to spend on healthcare) ☐

Question 44
How would you describe the future market potential of your country, i.e. in five years?

Low (very limited potential for sales and growth, as financing is lacking despite unmet medical needs) ☐	Medium (potential for growth but to a limited extent, despite unmet medical need) ☐	Satisfactory (good potential for growth in this market based on unmet medical need) ☐	Excellent (very strong potential with promising prospects for the future based on unmet medical need and willingness to invest in health) ☐

Question 45
In your view, how attractive is the tax environment for the biopharmaceutical industry in your country?

Highly unattractive (high corporate tax rate and no special tax-related incentives for businesses or R&D) ☐	Somewhat unattractive (neutral tax rate but few special incentives) ☐	Somewhat attractive (there are one or two major deterring factors relative to other markets, e.g. poor tax rate or lack of a certain incentive) ☐	Highly attractive (relatively low corporate tax rate and several different tax break schemes including for R&D and SMEs) ☐

Question 46
In your view, how robust is the legal framework in your country?

Very weak (missing certain fundamental components) ☐	Basic ☐	Fairly robust ☐	Excellent (robust framework) ☐

Question 47
In your view, to what extent is your country prone to corruption in the health care and pharmaceutical sectors?

Very prone (corruption is rampant) ☐	Somewhat prone (corruption is still accepted and fairly common) ☐	Slightly prone (legal framework is enforced most of time but with notable cases of corruption) ☐	Rarely prone (cases of corruption are extremely uncommon and immediately addressed) ☐

Question 48
In your view, how stable is the political environment in your country?

Highly unstable (unpredictable) ☐	Somewhat unsupportive; tends towards heavy-handed policies ☐	Generally supportive with some key established relationships with industry, but political interests run contrary at times ☐	Highly supportive; long standing positive relationship and understanding developed with industry ☐

Question 49
In your view, how business-friendly is the government in your country (especially with regard to the biopharmaceutical industry)?

Highly unsupportive of industry interests and market-based policies, and at times antagonistic ☐	Somewhat unsupportive; tends towards heavy-handed policies ☐	Generally supportive with some key established relationships with industry, but political interests run contrary at times ☐	Highly supportive; long standing positive relationship and understanding developed with industry ☐

PART H – GENERAL CONCLUSIONS

The final question assesses the overall attractiveness of your country to biopharmaceutical investment.

Question 50
Overall, would you recommend your country to your headquarters for additional near-term investment?

Not at this time	On a very limited basis	Yes, but with some reservations	Yes (as a top target for investment)
☐	☐	☐	☐

Before you finish the survey, we would be very grateful if you could provide us with some feedback by answering the following question:

To what extent has this survey reflected the overall factors that you would take into consideration before supporting an investment by your corporation in a given country?

Not at all (most of the questions and themes were not relevant)	Somewhat (the questions and themes were partially relevant)	Moderately (most questions were targeted appropriately)	Greatly (the survey was comprehensive in its coverage of relevant factors)
☐	☐	☐	☐

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