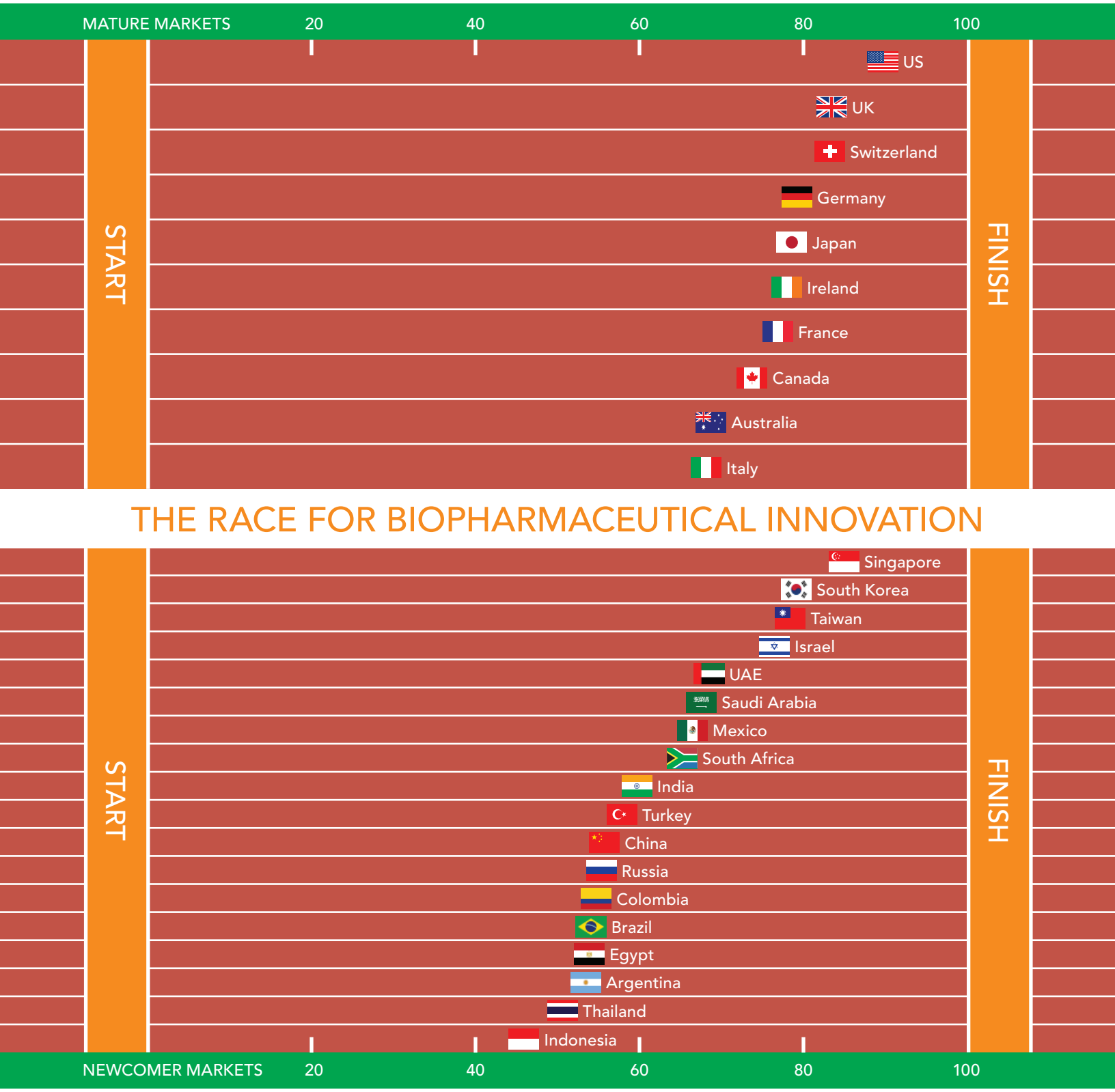
pugatchconsilium



THE RACE FOR BIOPHARMACEUTICAL INNOVATION

Biopharmaceutical Competitiveness & Investment (BCI) Survey, Third Edition, 2016

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

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LIST OF ABBREVIATIONS

API	Active pharmaceutical ingredient
BRIC	Brazil, Russia, India and China
BRICS	Brazil, Russia, India, China and South Africa
CETA	Comprehensive Economic and Trade Agreement
CTs	Clinical trials
FDI	Foreign direct investment
FTA	Free trade agreement
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
ICH	International Conference on Harmonisation
ICT	Information and communication technology
IND	Investigational new drug application
IP	Intellectual property
M&A	Mergers and acquisitions
NDA	New drug application
OECD	Organisation for Economic Cooperation and Development
PTE	Patent term extension
RDP	Regulatory data protection
R&D	Research and development
UNCTAD	United Nations Conference on Trade and Development
USTR	U.S. Trade Representative
WHO	World Health Organization


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EXECUTIVE SUMMARY

In the global race for biopharmaceutical investment countries' policy environments either enable or hinder their competitiveness for investment. Today who is sprinting ahead and who is trailing? What aspects of individual markets' environments are providing momentum and which are holding them back?

These questions are explored in the 2016 Biopharmaceutical Competitiveness Survey, a global executive opinion survey and index of economies' biomedical investment-attractiveness. 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.

In 2015 Pugatch Consilium released the second edition of the BCI Survey, which covered 15 economies, from major developed and high-income economies to some of the fastest growing emerging markets in the world.

This, the third edition, expands and enhances the BCI Survey in two main ways. First, the 2016 edition significantly expands the economies covered to 28 markets. On top of the 15 markets in the second edition, the third edition includes an even wider sample of developed and emerging economies, capturing many of the largest and most active biopharmaceutical markets worldwide. The table below lists the markets sampled in 2016.

Second, the BCI Survey has been developed into two separate surveys, one targeting "mature" markets and the other, "newcomer" markets. This division is based on sophistication of the health and biopharmaceutical system as well as extent of historical biopharmaceutical R&D and manufacturing capabilities. The two surveys address overarching necessary policy conditions in 5 categories, from scientific and clinical capabilities to quality of the regulatory framework, market access conditions and the intellectual property (IP) environment, as well as recent pertinent policy issues in the given group of markets. For example, newcomer market-specific questions cover basic standards such as existence of and compliance with Good Manufacturing Practice and pharmacovigilance, while mature market-specific questions cover topics like availability of fast-track approval pathways and special pricing schemes for breakthrough treatments. Based on a statistical analysis of the responses each market is assigned a quantitative score (out of 100) and compared with other markets in the relevant group, newcomer or mature markets. As such, economies are gauged in relation to other markets with similar levels of development, allowing for an even more fine-tuned snapshot of each market's attractiveness for biopharmaceutical investment.

Newcomer markets				Mature markets	
Argentina	Brazil	China	Colombia	Australia	Canada
Egypt	India	Indonesia	Israel	France	Germany
Mexico	Russia	Saudi Arabia	Singapore	Ireland	Italy
South Africa	South Korea	Taiwan	Thailand	Japan	Switzerland
Turkey	UAE			UK	US

BCI 2016 Overall Scores

Newcomer Markets

Asian Tigers lead in attractiveness for biopharmaceutical investment, while the BRICS and remaining APAC lag behind

Key Finding #1: Bigger is not better and the policy environment matters

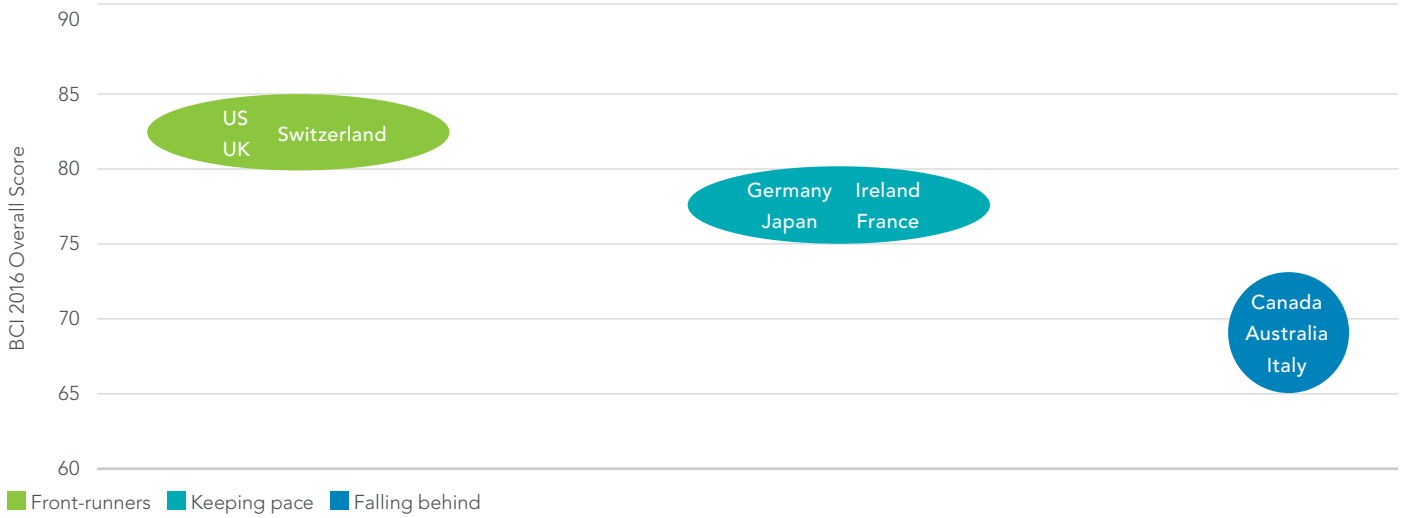
Looking at newcomer markets, the top scoring group of economies is comprised of relatively small markets compared to the rest of the sample. This suggests that market size alone does not determine an economy's global competitiveness in biopharmaceuticals. Rather, the policy environment matters a great deal for biopharmaceutical investment decisions. Economies with policies supporting biopharmaceutical innovation and investment are much more likely to actually secure investment compared to economies employing policies that are viewed as drawbacks by the biopharmaceutical innovators.

Key Finding #2: A biopharmaceutical R&D "ecosystem" best promotes investment

Enhancing a wide range of policies that are important for biopharmaceutical innovation and investment – from scientific and clinical capabilities, technology transfer platforms and a high-quality regulatory framework to a supportive market access environment and robust IP protection – is what sets economies apart in terms of attractiveness for investment. In the BCI, top performing economies score relatively highly across the board – in most, if not all, of the five categories. In contrast, economies lagging behind in competitiveness often demonstrate weaknesses in several different policy areas.

Mature Markets

The most competitive markets provide supportive conditions across the board, while strategic gaps exist in the least competitive



Key finding #1: Competition is fierce – A pro-innovation environment is essential for maintaining an advantage

Mature markets that score in the top half of mature markets are those that demonstrate a trend of prioritizing innovation within the biopharmaceutical policy ecosystem. These economies rely most on market-based instruments and models that reward innovation within the pricing and reimbursement system and promote technology transfer. They also seek to provide a highly streamlined regulatory framework, advanced IP protection and favorable tax conditions (with some exceptions).

In contrast, mature markets employing policies that dilute support for innovation are rated as comparatively less attractive for investment. Policies that detract from investment include additional administrative costs and delays for approval of new products and clinical trials. They also include the use of price controls and other cost containment measures that do not adequately reflect the long-term health and socioeconomic contribution of breakthrough treatments. Finally, barriers to securing patent protection and enforcing it on the ground, approaches that discriminate against patent holders and RDP frameworks that are out of sync with international standards also often affect those mature markets scoring in the bottom of the BCI.

Key finding #2: Support for pioneering R&D gives economies an additional edge in attracting investment

Mature markets scoring at the top have typically introduced policies aimed at incentivizing R&D into novel areas and targeting particular areas of unmet need, such as rare diseases or personalized medicine. Very often such policies are directed toward a range of elements, including development of relevant skills, infrastructure and technologies; dedicated regulatory pathways that ease and support testing and approval of products for new R&D areas; targeted R&D tax breaks and special market access arrangements that account for smaller patient groups and allow for real-world knowledge development. Economies that fall towards the bottom of the mature markets provide less of these incentives and measures for cutting edge R&D.

Biopharmaceutical policy focus: What gives economies an edge and what holds them back?

While each market operates in a unique macroeconomic and policy environment, several markets face common challenges and hurdles to improving their ability to compete for biopharmaceutical investment. Similarly, markets that are rated as more attractive for investment tend to exhibit a number of the same characteristics and incentives within their biopharmaceutical policy environments.

1. Policies detracting from innovation and investment: Intellectual property challenges

Compulsory licensing

In the area of IP protection, on top of wider gaps in enforcement, consideration and actual issuing of compulsory licenses for medicines significantly deteriorates investment conditions in a given market.

- For example, executives in Colombia noted that the Colombian government's consideration of a compulsory license on a key cancer drug that has no reported shortages and where a price reduction is already in place puts Colombia at a distinct disadvantage in terms of securing new investment.

- Executives in Indonesia are concerned about a further deterioration in existing investment conditions there due to a draft patent law that would permit wider use of compulsory licensing through new requirements for local manufacturing of patented products and associated technology transfer.

Barriers to biopharmaceutical patenting

In addition, executives found as a particular challenge a rise in patenting criteria that discriminates against biopharmaceutical inventions, whether through legislation, court decisions or administrative rules.

- India's IP regime, including Section 3(d) requiring biopharmaceutical inventions to show "enhanced efficacy", continues to affect its investment environment and has inspired look-alike bills in Brazil, Indonesia and South Africa, where executives also noted barriers to investment as a result of gaps in IP protection.

- Executives in Brazil also found that the government's policy of dual examination of pharmaceutical patents by both the patent office and drug regulatory authority has further contributed to difficult IP conditions.

- In Canada, executives raise concerns over the heightened patent utility requirement and deviation from international standards, as well as legislation allowing for release of confidential business information.

2. Policies detracting from innovation and investment: Regulatory challenges

Inadequate biosimilar pathways

As biosimilar markets expand, development of specific regulatory frameworks for the approval of biosimilars generally heighten a market's investment attractiveness. Nevertheless, where these do not take full account of the differences between biologics and chemical-based drugs in line with international standards – and as such can introduce significant public health and commercial risks for companies – they tend to downgrade markets' attractiveness from the perspective of executives.

- The fact that Colombia's biosimilar pathway is out-of-sync with WHO guidelines and international standards, particularly the lack of clinical data requirements in its "third pathway" for "non-comparable" biosimilars, presents significant risks to biopharmaceutical innovators.

- Local executives indicate that India's current draft biosimilar guidelines deviate from WHO guidelines and international standards in several areas (including in relation to the scope and timing of clinical trials and criteria for reference products and manufacturing sites) and if implemented as such could detract from India's investment competitiveness.

Clinical trial approval: Red tape and delays

Clinical research is a crucial and high-value type of biopharmaceutical investment, and executives particularly underscore the ease of obtaining approval for clinical trials – including the timeframe for approval – as a crucial factor in an economy's attractiveness for investment.

- Executives observe that significant delays and additional administrative requirements for approval of clinical trial applications hold China back from fully and effectively attracting global clinical trials.

- Although executives cite Colombia's recent announcement of a substantial reduction in the clinical trial approval timeframe as a very positive development, implementation is required (along with important improvements to other aspects of the environment) to promote stronger confidence in the market in this area.

3. Policies detracting from innovation and investment: Localization barriers

Localization policies that require investment in the local biopharmaceutical sector or establish punitive incentives to invest often end up deterring investment from biopharmaceutical innovators rather than encouraging it, reflected in a number of the BCI markets.

- Turkey's requirement for on-site Turkish GMP inspections for international products, leading to significant market approval delays, along with additional discriminatory treatment of foreign and innovative products reduces its competitiveness for investment in the eyes of executives.

- High barriers to foreign companies' participation in public sector drug procurement and proposed requirements for sharing sensitive commercial information as part of the market authorization process applicable to innovative and foreign companies are contributing factors to Thailand's weak level of competitiveness relative to many other emerging markets.

4. Market-based incentives enhance investment attractiveness

On top of a balanced policy environment in line with international best practices and adequately supporting biopharmaceutical innovation, countries that are the strongest competitors when it comes to biopharmaceutical investment also provide a range of market-based incentives, including a cutting edge science base, dedicated platforms and funding for R&D partnerships between local and foreign companies and tax measures.

- Executives note that a focus on developing human capital and infrastructure needed for biotech innovation has aided South Korea in developing a relatively strong capacity for biologics R&D, manufacturing and commercialization, especially in the area of biosimilars.

- In relation to Taiwan, executives highlight government efforts to strengthen the science base and level of private sector R&D in the biomedical field – for instance through a new biotech development strategy within the wider Productivity 4.0 plan – noting that if implemented, these efforts may yield significant dividends in terms of attracting biopharmaceutical investment.

- Singapore is cited as an economy with a clear and ongoing openness to and support for collaboration between local research institutions and the biopharmaceutical industry, including via its numerous "bioclusters".

1 MEASURING BIOPHARMACEUTICAL INVESTMENT ATTRACTIVENESS

Investment in biopharmaceutical innovation today represents one of the most high value areas of investment economies can secure. The 2016 BCI Survey builds on previous editions of the BCI Survey to measure the relative attractiveness of economies to investment from biopharmaceutical research-based companies.

1.1 The value of biopharmaceutical investment in the global economy

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 2015 global life sciences R&D spending was estimated at around $166 billion, with biopharmaceutical R&D investment by PhRMA member companies estimated at over a third of that (around $59 billion).[2] These figures place 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 pharmaceuticals manufacturing were valued at $50 billion globally as of 2014, with this figure rising to $114 billion in 2015.[5] Moreover, "greenfield" FDI – foreign investments with no pre-existing operations or infrastructure – by pharmaceutical companies amounts to over $13 billion globally (as of 2013).[6] Additionally, by some estimates life sciences industries generate close to 4.5 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, biopharmaceutical 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]

1.2 Demystifying biopharmaceutical investment

What does biopharmaceutical investment refer to? Investment in the biopharmaceutical sector is sometimes understood in a limited manner, involving, for instance, manufacturing operations or launch of a product, but in fact, biopharmaceutical 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 biopharmaceutical field:

1. Research and development
   First, the bulk of biopharmaceutical 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 biopharmaceutical 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 biopharmaceutical R&D process and product pipeline.

1.3 Increasing competitiveness?

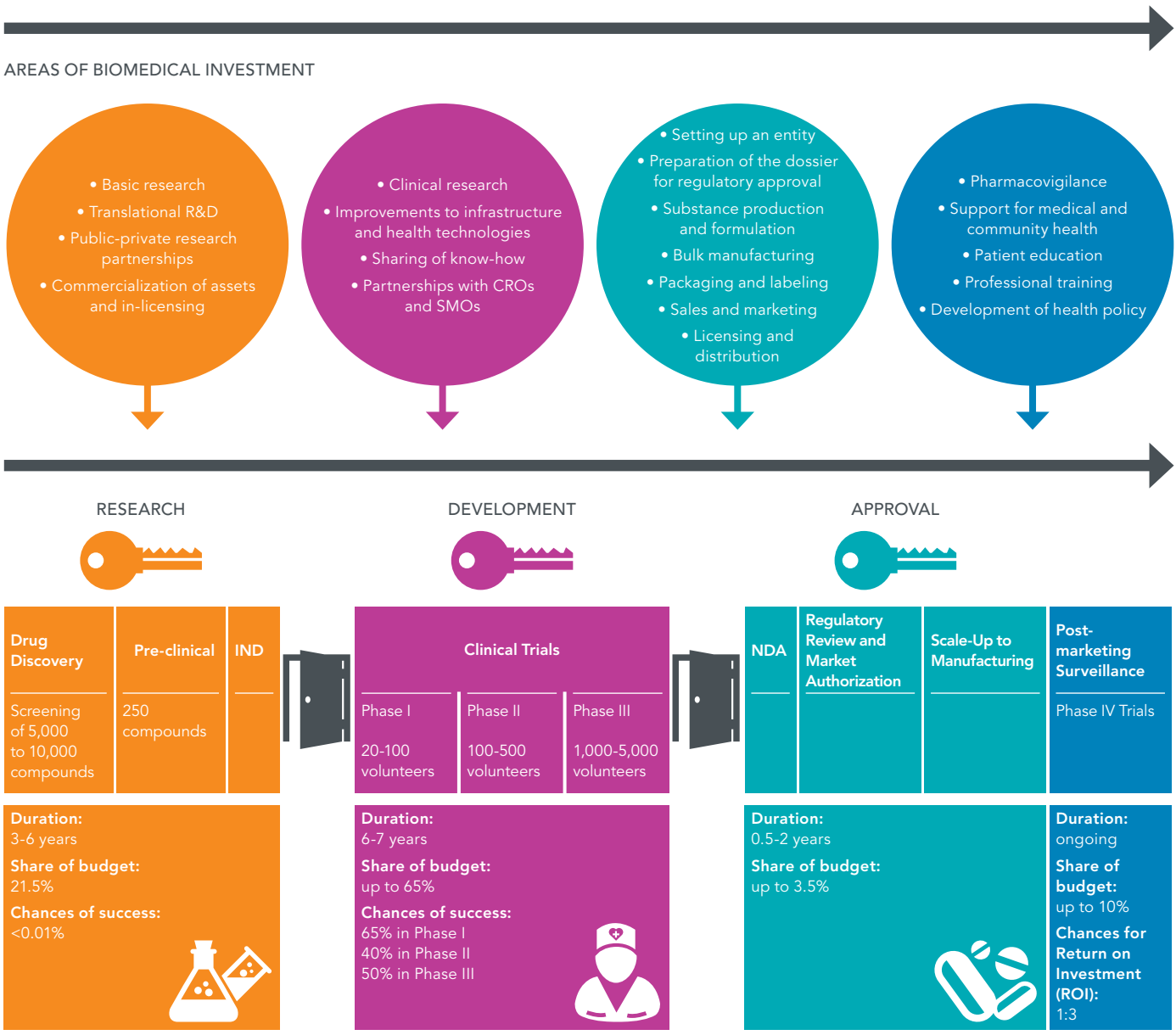
In this context, how do governments and economies improve their competitiveness and secure a larger piece of global biopharmaceutical investment? A growing body of data suggests that on top of market size, demand and costs, economies' competitiveness for biopharmaceutical investment is positively linked 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 biopharmaceutical 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 biopharmaceutical 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.[10] 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).[11]

IP protection is just one element of a wide range of policies needed to create a biopharmaceutical innovation and investment "ecosystem" – the total policy environment impacting an economy's attractiveness for investment.[12]

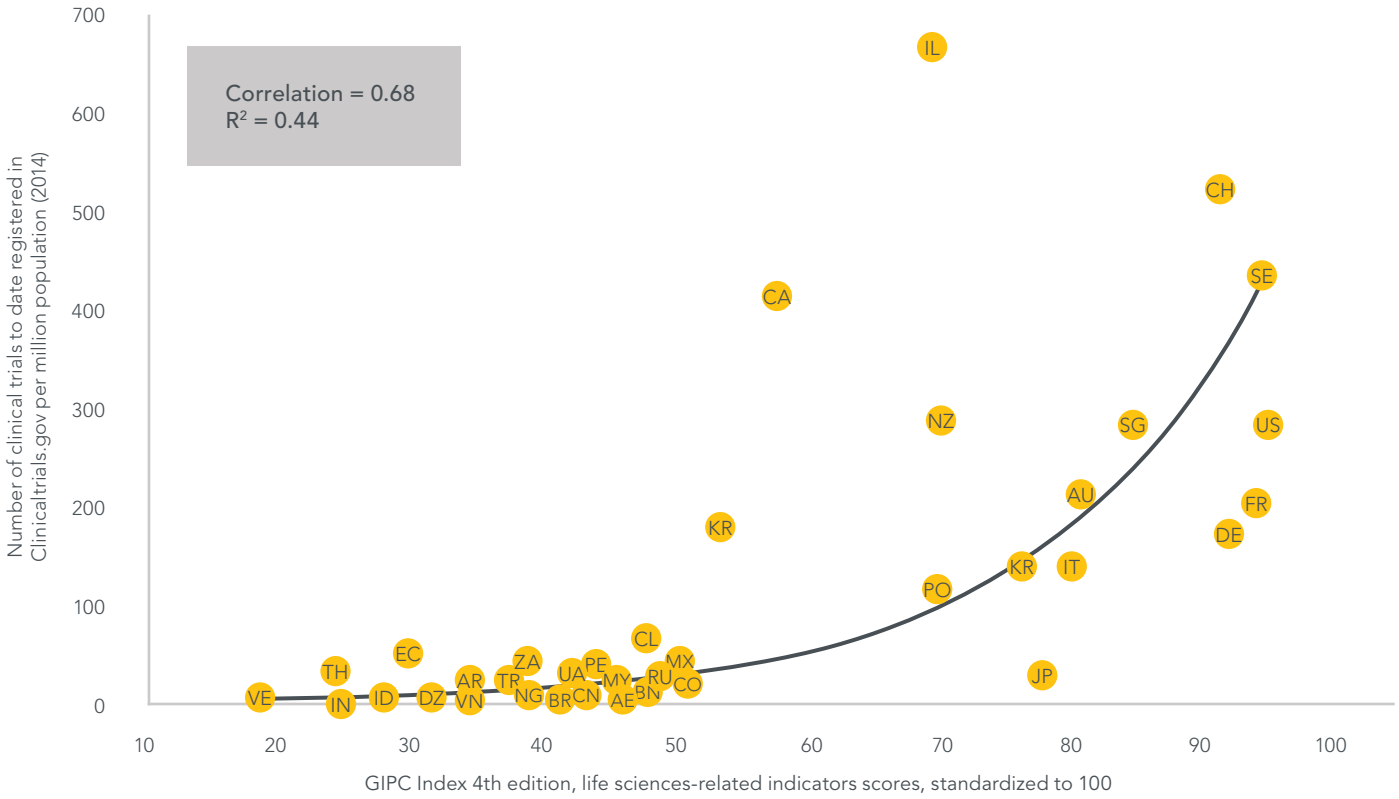
Thus, for developed and emerging economies alike that have targeted biopharmaceutical investment as being of strategic importance to national economic development and growth, there is a pressing need to understand and map the state of the biopharmaceutical investment environment in a given economy. This includes identifying which policies are in place in different areas, which are not and how biopharmaceutical investment is affected in these areas.

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



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

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



Source: US Chamber of Commerce (2016); Clinicaltrials.gov

1.4 The context, rationale and scope of the BCI Survey

Various tools exist for mapping the biopharmaceutical 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.[14] 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.[15] 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.[16]

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.[17] 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.[18]

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 biopharmaceutical sector – its biomedical "pulse". The Biopharmaceutical Competitiveness and Investment (BCI) Survey, a global executive opinion survey and index of economies' biopharmaceutical 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 biopharmaceutical field. In total, the BCI provides a comparatively more in-depth, holistic and focused barometer of the biopharmaceutical 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' biopharmaceutical 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 biopharmaceutical 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;
- soundness and effectiveness of the biopharmaceutical regulatory framework and quality of biopharmaceutical manufacturing;
- market access conditions and healthcare financing; and
- strength of intellectual property protections pertaining to biopharmaceuticals.

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 the following section).

In doing so, the BCI captures a wealth of data and observations concerning major areas of the biopharmaceutical 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 biopharmaceutical competitiveness that may be used by governments, biopharmaceutical 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 biopharmaceutical 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 biopharmaceutical policy environment at the national, regional and global levels.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2 THE METHODOLOGY AND PROCESS OF THE BCI 2016

The BCI is a global executive opinion survey and index of economies' biopharmaceutical investment-attractiveness. The BCI is composed of two parts: 1) a survey completed by multinational biopharmaceutical executives; 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 third edition of the BCI expands and enhances the BCI Survey in two main ways. First, the 2016 edition significantly expands the economies covered to 28 markets. On top of the 15 markets in the second edition, the third edition includes an even wider sample of developed and emerging economies. The economies represented in this edition are members of the G20 plus nine additional markets selected on the basis of their contribution to world GDP and trade and relative size of the biopharmaceutical market. As such the 28 markets included in the BCI in 2016 capture many of the largest and active biopharmaceutical markets worldwide. Table 1 lists the markets sampled in 2016.

Second, to capture the wide range of markets included in this edition the BCI Survey has been developed into two separate surveys, one targeting "mature" markets and the other, "newcomer" markets. This division is based on sophistication of the health and biopharmaceutical system as well as extent of historical biopharmaceutical R&D and manufacturing capabilities. The two surveys have been collected, scored and analyzed separately.

Condensed into 25 questions each (from 50 in 2015), around 60% of the questions in both surveys are the same or similar, addressing overarching necessary policy conditions in five categories:

1. 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.[19] 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.[20] For instance, federal funding aimed at fundamental

TABLE 1 Economies covered in the BCI 2016 by market group

Newcomer markets				Mature markets	
Argentina	Brazil	China	Colombia	Australia	Canada
Egypt	India	Indonesia	Israel	France	Germany
Mexico	Russia	Saudi Arabia	Singapore	Ireland	Italy
South Africa	South Korea	Taiwan	Thailand	Japan	Switzerland
Turkey	UAE			UK	US

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.[21]

In this light, the questions in this category assess the quality of personnel, technologies and facilities in biopharmaceutical research forums in the economy; the extent of collaboration between public and private research partners; and the ability to leverage these to translate discoveries into products.

2. Clinical Research Conditions & Framework

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.[22]

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.[23]

In this light, the questions in this category assess the ability of research institutions in the economy to conduct clinical research in a high quality and efficient manner.

3. The Regulatory System – Drug Approval, Quality Assurance and Pharmacovigilance

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.[24] Conversely, a strong regulatory environment creates the conditions for the production and sale of high quality products and technologies.[25] 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).[26] 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.[27]

In this light, 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.

4. Market Access & 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.[28] 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.[29]

In this light, the questions in this category assess the ability of new biopharmaceutical products to access the market via the pricing, reimbursement and procurement system in the economy in an efficient manner and at an acceptable price.

5. Effective IP 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.[30]

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.[31]

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.

In this light, the questions in this category assess the ability to fully realize required terms of intellectual property protections for biopharmaceutical products.

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

In addition, each survey covers policy issues that are pertinent to the given market group,

FIGURE 3 Sample questions from the 2016 BCI Survey

Question 10 in newcomer market survey (Question 9 in mature market survey)
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 11 in mature market survey
To what extent do designated fast-track pathways for priority innovative biopharmaceutical products exist in your country?

None (such pathways do not exist at the moment) ☐	Basic (framework for a fast-track pathway(s) exist but are not actually operational or effective) ☐	Satisfactory (designated fast-track pathways are in place and are being used) ☐	Excellent (fast-track pathways are fully operational and produce concrete results in terms of the ability to introduce priority products to the market) ☐

Question 24 in newcomer market survey
In your view, how effective are civil and criminal remedies for infringement of intellectual property rights and battling counterfeit medicines 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, seizures and penalties; ability to challenge validity of a patent) ☐

Source: BCI Survey (2016)

newcomer or mature. For example, newcomer market-specific questions cover basic standards such as existence of and compliance with Good Manufacturing Practices and pharmacovigilance and presence of delays between market approval in a given market and approval by the FDA or EMA. Mature market-specific questions cover topics like the availability of fast-track approval pathways and special pricing and reimbursement schemes for breakthrough treatments and new research areas.

The full text of both surveys may be viewed in the Appendix to this report.

As in 2015 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, 1 common to each survey; 1 from the newcomer market survey and 1 from the mature market survey. In Question 10 (Question 9 in the mature market survey), an adequate independent capacity for review and approval of new biopharmaceutical products in line with international standards provides the benchmark. The benchmark used in Question 11 in the mature market survey is the availability of designated fast-track pathways with demonstrated success in enabling the timely introduction of priority innovative products. For Question 24 in the newcomer market survey, the benchmark is the existence of a regulatory mechanism that ensures timely and effective patent enforcement.

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 2016 BCI Survey

The 2016 BCI Survey was distributed primarily to general managers of multinational research-based biopharmaceutical companies operating in the 28 sampled economies – in other words, experts in the field and on-the-ground practitioners with deep knowledge of the local biopharmaceutical 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 biopharmaceutical ecosystem. In the view of over 90% of respondents, most, if not all, of the questions covered relevant elements of an economy's attractiveness for biopharmaceutical investment.

2.3 Calculation and classification of scores

As in 2015, based on a statistical analysis of the responses, each market is assigned a quantitative score (out of 100). However, in 2016 each market is only compared with other markets in the relevant group, newcomer or mature markets. As such, economies are gauged in relation to other markets with similar levels of development, allowing for an even more fine-tuned snapshot of each market's attractiveness for biopharmaceutical investment.

For both surveys, to score the responses each question accounts for a total of 4 points. The four answer options for each question correspond to scores of 1, 2, 3 and 4 – ranging, in order, from the options reflecting the poorest to the highest performance. Based on the analysis of responses to all 25 questions, each economy receives a score for each category as well as an overall score, out of a maximum of 100. As a result, the 2016 results for economies that were included in the 2015 BCI Survey may be compared to their 2015 results in terms of the share of the total possible score overall and in a given category.

Based on category and overall scores, economies are classified into levels of competitiveness in the global "race" for biopharmaceutical investment and innovation relative to the other sampled markets in each group. Newcomer markets 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 45 and 85):

1. Pace-setters
   Economies with an overall score above 75;

2. Catching their stride
   Economies with an overall score between 60 and 75;

3. Trailing
   Economies with an overall score between 50 and 60; and

4. Struggling to compete
   Economies with an overall score below 50.

Similarly, mature markets are divided into three groups:

1. Front-runners
   Economies with an overall score above 80;

2. Keeping pace
   Economies with an overall score between 75 and 80; and

3. Falling behind
   Economies with an overall score between 65 and 75.

This score spread and classification system is similar to ones used in other indices, even if the themes are different. For instance, the 2016 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.[32]


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3 OVERALL FINDINGS OF THE 2016 BCI SURVEY

3.1 Newcomer markets

Overall results

Figure 4 presents the overall results for the 18 newcomer markets covered in the 2016 BCI Survey.

Key Finding #1: Bigger is not better and the policy environment matters

As Figure 4 indicates, the "Asian Tigers" lead in attractiveness for biopharmaceutical investment, while the BRICs and remaining Asia Pacific economies lag behind. Looking at the groupings of economies, the top scoring group is comprised of relatively small markets compared to the rest of the sample. This suggests that market size alone does not determine an economy's global competitiveness in biopharmaceuticals. Rather, the policy environment matters a great deal for biopharmaceutical investment decisions. Economies with policies supporting biopharmaceutical innovation and investment are much more likely to actually secure investment compared to economies employing policies that are viewed as drawbacks by the biopharmaceutical innovators.

Key Finding #2: A biopharmaceutical R&D "eco-system" best promotes investment

Enhancing a wide range of policies that are important for biopharmaceutical innovation and investment – from scientific and clinical capabilities and a high-quality regulatory framework to a supportive market access environment and robust IP protection – is what sets economies apart in terms of attractiveness for investment. In the BCI, top performing economies score relatively highly across the board – in most, if not all, of the five categories. In contrast, economies lagging behind in competitiveness often demonstrate weaknesses in several different policy areas.

FIGURE 4 The race for biopharmaceutical innovation: Who is sprinting ahead and who is trailing among newcomer markets? - BCI 2016 Overall results

TABLE 2 BCI 2016 scores and classification, Newcomer markets: Year on year change compared to 2015

Newcomer Markets	Change in Score as a Share of Total Possible Score, 2015 to 2016
Singapore	Score Rose
South Korea	2016 only
Taiwan	2016 only
Israel	Score Rose
UAE	2016 only
Saudi Arabia	2016 only
Mexico	Score Remained the Same
South Africa	Score Remained the Same
India	Score Remained the Same
Turkey	Score Fell
China	Score Fell
Russia	Score Fell
Colombia	2016 only
Brazil	Score Fell
Egypt	2016 only
Argentina	2016 only
Thailand	2016 only
Indonesia	2016 only

Trends in biopharmaceutical competitiveness: Pack mentality?

Comparing the 2016 BCI Survey results with the 2015 results, a number of striking trends are visible among the newcomer markets. As Table 2 indicates, globally, scores have largely fallen (or in a few cases remained the same) compared to last year, suggesting that the biopharmaceutical R&D environment in many newcomer markets has deteriorated over the past year. Economies with lower scores compared to last year – Argentina, Brazil, China, Russia and Turkey – display policy challenges across the biopharmaceutical R&D eco-system, particularly at the market access, regulatory and IP levels, that have remained unaddressed or have accelerated.

Table 2 also underscores a wider trend, that economies are moving in packs in distinctly different directions. Those falling in the bottom half of the sampled economies continue to prioritize and pursue policies that hinder biopharmaceutical innovation and investment. In contrast, economies in the top group largely appear to be on a more positive policy trajectory, seeking to further strengthen key areas supporting biopharmaceutical R&D and overall, avoiding policies that strongly deter investment. A handful of economies – Mexico, South Africa and India – on balance remained stable in 2016, both making improvements to their policy environments but also maintaining or introducing barriers to investment in certain respects.

Regional patterns: Leaders and laggards

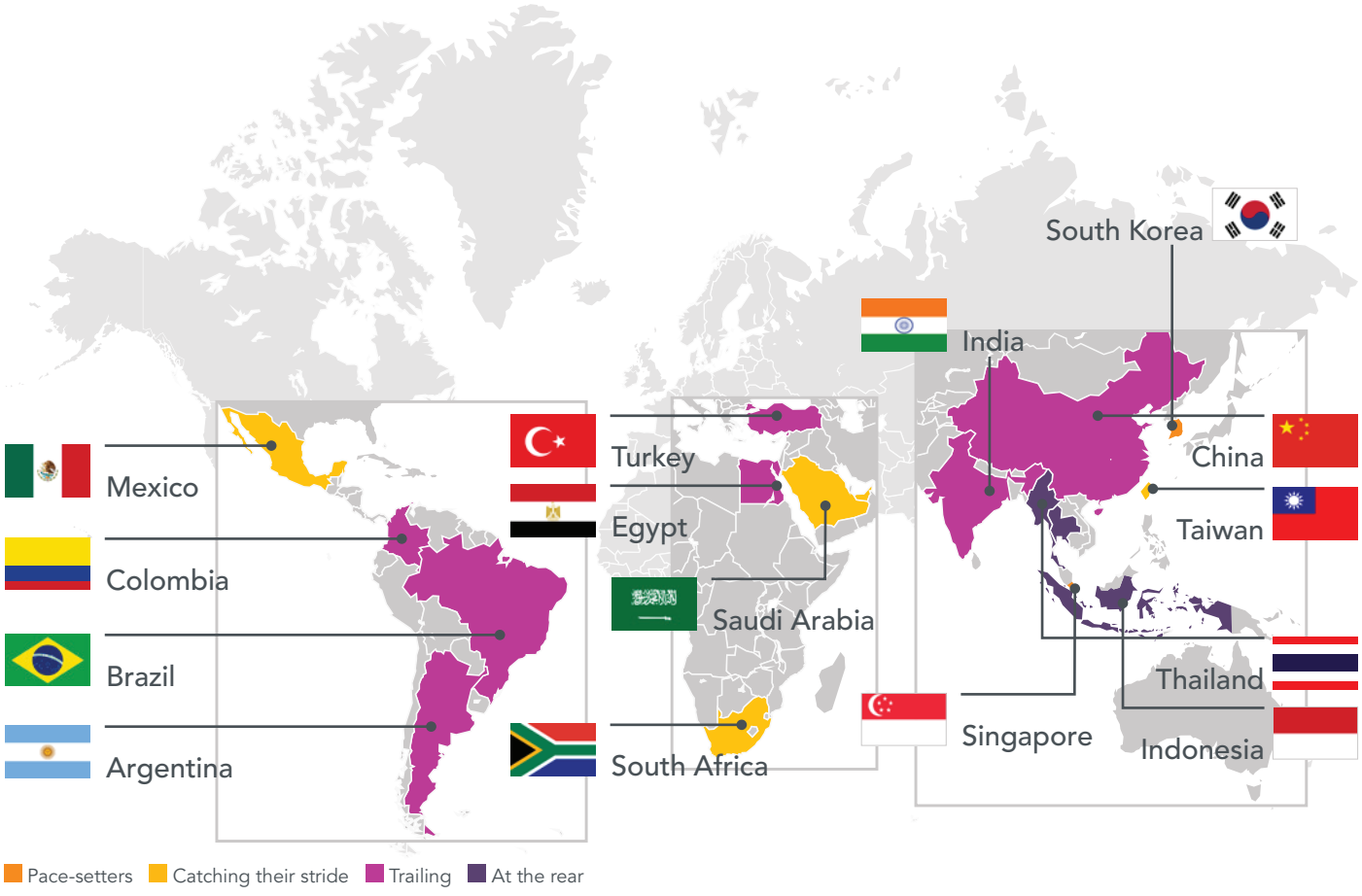
Among the regions represented in newcomer markets included in the 2016 BCI certain economies stand out as models for the rest of the given region. These markets are rated as more attractive for investment by biopharmaceutical executives and provide more supportive biopharmaceutical ecosystems compared to other economies in their respective regions. As Figure 5 suggests, within the sampled markets in Latin America Mexico stands out as being relatively more competitive. One factor enhancing Mexico's competitiveness includes the introduction of a more integrated market authorization procedure with shorter timelines. Mexico has

also implemented improvements to its national IP environment including availability of patents for biopharmaceuticals and RDP (though further strengthening of patent enforcement and RDP to biologics are cited by executives as needed to reach the standards of the most competitive markets globally).

Singapore, Taiwan and South Korea lead the Asia Pacific region, having for a number of years provided targeted support to biopharmaceutical innovation through investment in R&D, high quality science education and infrastructure and special platforms for technology transfer and industry-academic collaboration. Though executives note that room for improvement exists, the regulatory framework and IP environment in these markets are also perceived by and large as streamlined and in line with international standards.

Within the Middle East and Africa, the UAE emerges as a leader. Over the past several years, the UAE has developed a fairly strong regulatory capacity, including review and approval of medicines, quality control and pharmacovigilance and introduced relatively supportive tax conditions for innovators and greater resources for R&D. In addition although key gaps exist in relation to biopharmaceuticals, national IP protection is seen as relatively effective.

FIGURE 5 BCI results among select newcomer markets by region



Biopharmaceutical policy focus: What gives economies an edge and what holds them back?

While each market operates in a unique macroeconomic and policy environment, several markets face common challenges and hurdles to improving their ability to compete for biopharmaceutical investment. Similarly, markets that are rated as more attractive for investment tend to exhibit a number of the same characteristics and incentives within their biopharmaceutical policy environments.

Policies detracting from innovation lead to decreased market confidence from biopharmaceutical innovators

1. Intellectual property challenges

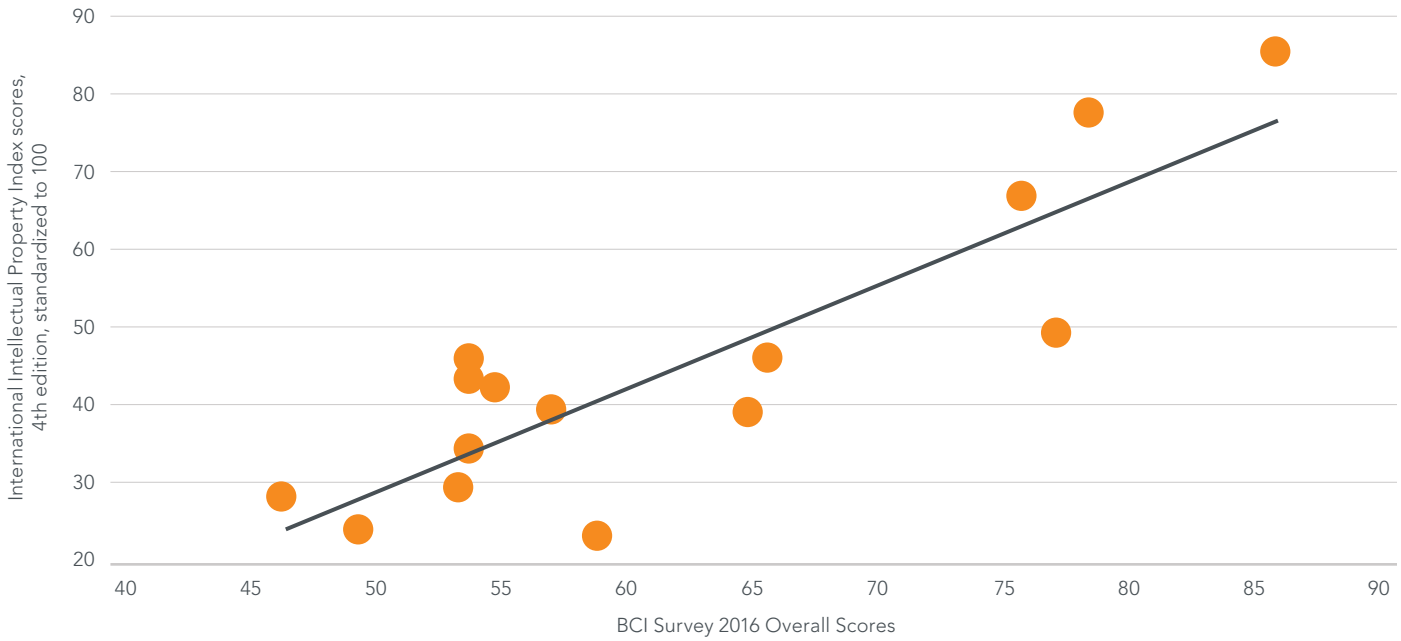
Compulsory licensing

In the area of IP protection, on top of wider gaps in enforcement, consideration and actual issuing of compulsory licenses for medicines significantly deteriorates investment conditions in a given market.

National IP environments and biopharmaceutical competitiveness

The national IP regime and level of IP protection figures significantly in economies' global competitiveness for biopharmaceutical investment. Comparing the BCI 2016 scores with a standard global measure of national IP environments, the International IP Index, economies rated as most attractive for investment to biopharmaceutical innovators also tend to score at the top in the International IP Index. Conversely, economies considered to be less competitive overall also display lower scores on the IP Index.

FIGURE 6 BCI 2016 and International IP Index, 4th edition scores, Newcomer markets



Source: Pugatch Consilium; US Chamber (2016)

- For example, executives in Colombia noted that (though at the time of publication a declaration of public interest was issued instead) the Colombian government's consideration of a compulsory license on a key cancer drug that has no reported shortages and where a price reduction is already in place puts the Colombia at a distinct disadvantage in terms of securing new investment.

- Executives in Indonesia are concerned about a further deterioration in existing investment conditions there due to a draft patent law that would permit wider use of compulsory licensing through new requirements for local manufacturing of patented products and associated technology transfer.

Barriers to biopharmaceutical patenting

In addition, executives found as a particular challenge a rise in patenting criteria that discriminates against biopharmaceutical inventions, whether through legislation, court decisions or administrative rules.

- India's IP regime, including Section 3(d) requiring biopharmaceutical inventions to show "enhanced efficacy", continues to affect its investment environment and has inspired look-alike bills in Brazil, Indonesia and South Africa, where executives also noted barriers to investment as a result of gaps in IP protection.

- Executives in Brazil also found that the government's policy of dual examination of pharmaceutical patents by both the patent office and drug regulatory authority has further contributed to difficult IP conditions.

2. Regulatory challenges

Inadequate biosimilar pathways

As biosimilar markets expand, development of specific regulatory frameworks for the approval of biosimilars generally heighten a market's investment attractiveness. Nevertheless, where these do not take full account of the differences between biologics and chemical-based drugs in line with international standards – and as such can introduce significant public health and commercial risks for companies – they tend to downgrade markets' attractiveness from the perspective of executives.

- The fact that Colombia's biosimilar pathway is out-of-sync with WHO guidelines and international standards, particularly the lack of clinical data requirements in its "third pathway" for "non-comparable" biosimilars, presents significant risks to biopharmaceutical innovators.

- Local executives indicate that India's current draft biosimilar guidelines deviate from WHO guidelines and international standards in several areas (including in relation to the scope and timing of clinical trials and criteria for reference products and manufacturing sites) and if implemented as such could detract from India's investment competitiveness.

Clinical trial approval: Red tape and delays

Clinical research is a crucial and high-value type of biopharmaceutical investment, and executives particularly underscore the ease of obtaining approval for clinical trials – including the timeframe for approval – as a crucial factor in an economy's attractiveness for investment.

- Executives observe that significant delays and additional administrative requirements for approval of clinical trial applications hold China back from fully and effectively attracting global clinical trials.

- Although executives cite Colombia's recent announcement of a substantial reduction in the clinical trial approval timeframe as a very positive development, implementation is required (along with important improvements to other aspects of the environment) to promote stronger confidence in the market in this area.

3. Localization barriers

Localization policies that require investment in the local biopharmaceutical sector or establish punitive incentives to invest often end up deterring investment from biopharmaceutical innovators rather than encouraging it, reflected in a number of the BCI markets.

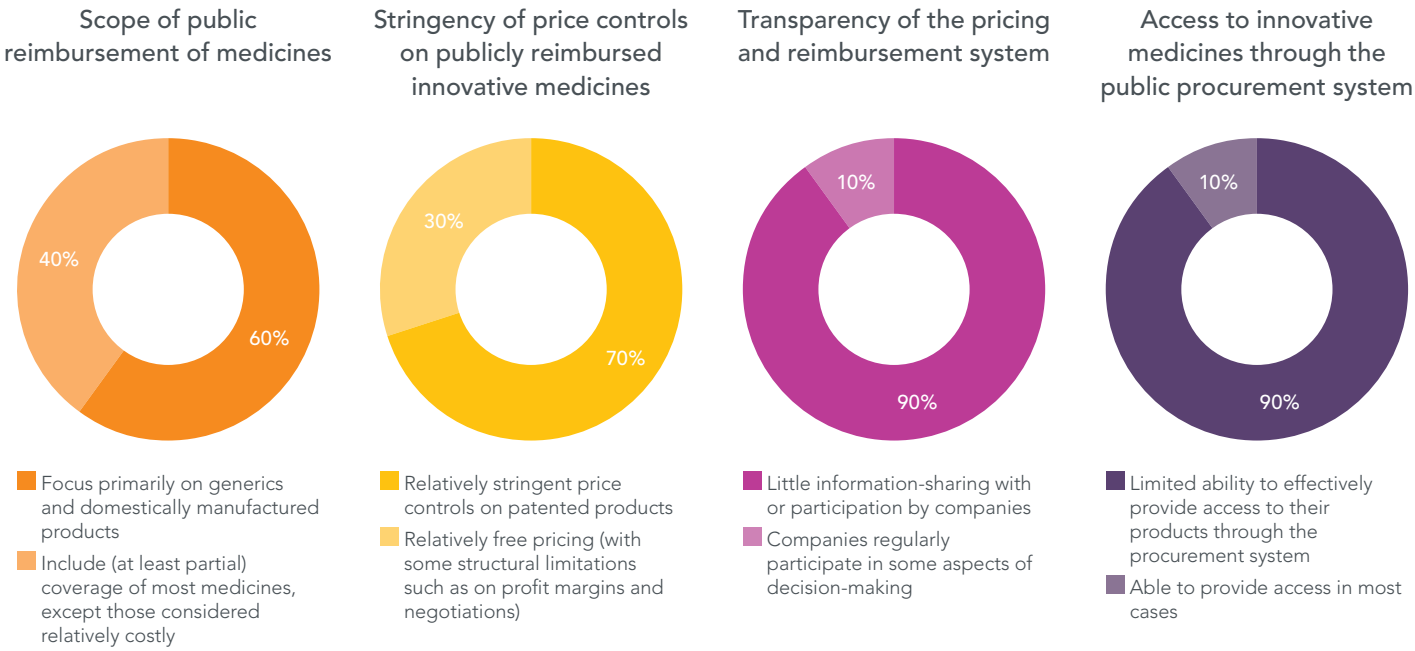
- Turkey's requirement for on-site Turkish GMP inspections for international products, leading to significant market approval delays, along with additional discriminatory treatment of foreign and innovative products reduces its competitiveness for investment in the eyes of executives.
- High barriers to foreign companies' participation in public sector drug procurement and proposed requirements for sharing sensitive commercial information as part of the market authorization process applicable to innovative and foreign companies are contributing factors to Thailand's weak level of competitiveness relative to many other emerging markets.

Spotlight on executives' views: Challenges around market access and financing limit economies' overall attractiveness for investment

Newcomer markets scoring in the lower half of the BCI exhibit a number of fundamental challenges for innovators in accessing the market that detract from their overall competitiveness. Executives cite difficulty obtaining inclusion in public formularies and tenders and strict and arbitrary price cuts that heighten market uncertainty as some of the barriers they tend to face in these markets.

FIGURE 7 Biopharmaceutical executives' views on market access & financing among select newcomer markets

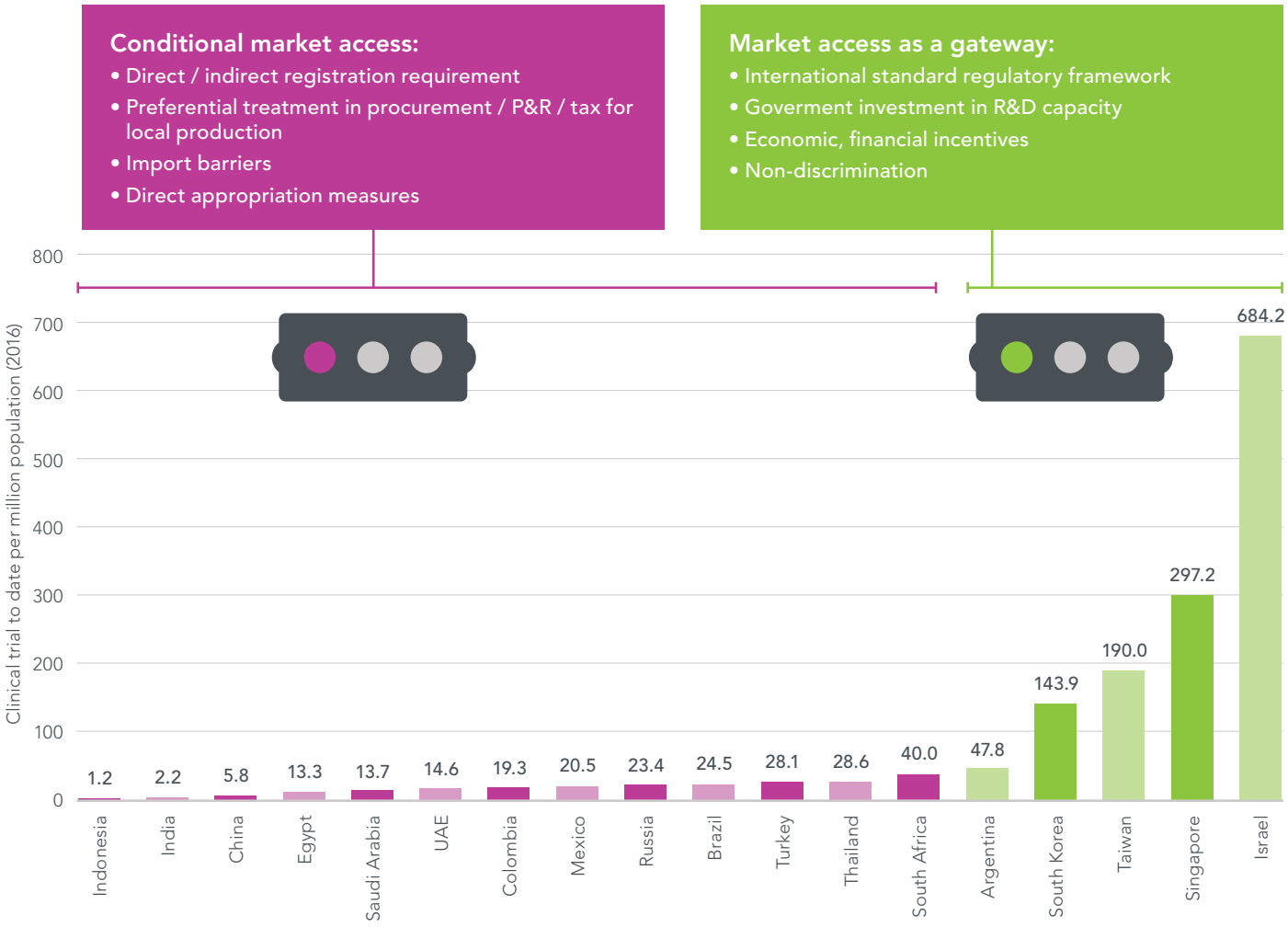
Among newcomer markets falling into the bottom half of the 2016 BCI Survey, based on the average response per market in the following areas:



Pitfalls of localization barriers and success of positive non-discriminatory incentives for investment and innovation – Localization policies and clinical trial intensity

Localization barriers do not have the desired positive impact on biopharmaceutical FDI. The clearest indication that localization barriers have not succeeded is the low level of clinical research (one proxy of high-level and sustained biopharmaceutical investment) in economies with such barriers in place. These negative results stand in stark contrast to the success of markets that focus on creating an enabling environment through positive non-discriminatory incentives and policies.

FIGURE 8 Clinical research and localization regime, BCI newcomer markets



Source: Pugatch Consilium analysis; Clinicaltrials.gov (2016); World Bank (2016)

Market-based incentives enhance investment attractiveness

On top of a balanced policy environment in line with international best practices and adequately supporting biopharmaceutical innovation, countries that are the strongest competitors when it comes to biopharmaceutical investment also provide a range of market-based incentives, including a cutting edge science base, dedicated platforms and funding for R&D partnerships between local and foreign companies and tax measures.

- Executives note that a focus on developing human capital and infrastructure needed for biotech innovation has aided South Korea in developing a relatively strong capacity for biologics R&D, manufacturing and commercialization, especially in the area of biosimilars.
- In relation to Taiwan, executives highlight government efforts to strengthen the science base and level of private sector R&D in the biomedical field – for instance through a new biotech development strategy within the wider Productivity 4.0 plan – noting that if implemented, these efforts may yield significant dividends in terms of attracting biopharmaceutical investment.
- Singapore is cited as an economy with a clear and ongoing openness to and support for collaboration between local research institutions and the biopharmaceutical industry, including via its numerous "bioclusters".

TABLE 3 BCI 2016 scores and classification, Mature markets: Year on year change compared to 2015

Mature Markets	Change in Score as a Share of Total Possible Score, 2015 to 2016
US	Score Remained the Same
UK	Score Remained the Same
Switzerland	Score Remained the Same
Germany	2016 only
Japan	2016 only
Ireland	Score Fell
France	2016 only
Canada	Score Fell
Australia	2016 only
Italy	2016 only

3.2 Mature markets

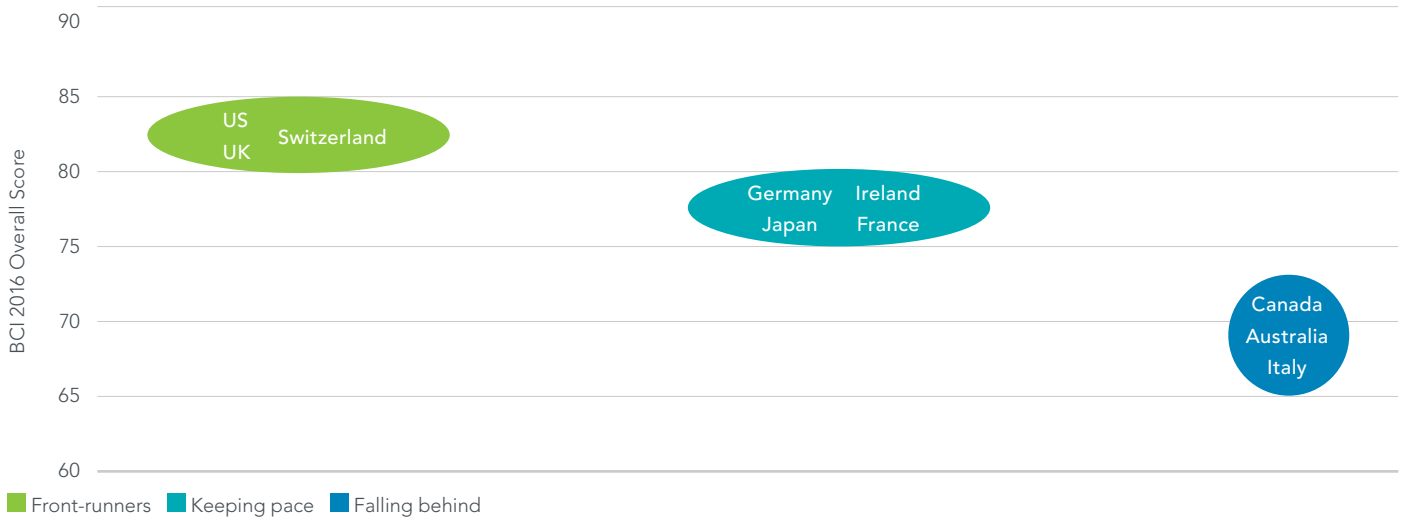
Overall results

Figure 9 present the overall results for the 10 mature markets covered in the 2016 BCI Survey.

Key finding #1: Competition is fierce – A pro-innovation environment is essential for maintaining an advantage

Mature markets that score in the top half of the 2016 BCI – including those that have remained at the top from the 2015 to 2016 editions – are those that demonstrate a trend of prioritizing innovation within the biopharmaceutical policy ecosystem. Generally speaking, these economies rely on more market-based instruments and models that reward innovation within the pricing and reimbursement system and promote technology transfer. They also seek to provide a streamlined regulatory framework, strong IP environment and tax conditions that are relatively favorable to innovators and multinational companies (with some exceptions).

FIGURE 9 The race for biopharmaceutical innovation: Who is sprinting ahead and who is trailing among mature markets? - BCI 2016 Overall results



Fast-track regulatory pathways, new funding and research networks for cutting edge R&D contribute to economies' investment attractiveness

Streamlined registration pathways for priority drugs targeting unmet needs and new disease areas can ease the regulatory process, reduce costs for innovators and ensure cutting edge treatment reach patients as quickly as possible. Dedicated funding for R&D in these disease areas and platforms for collaboration between different R&D entities facilitate key steps in the drug development process. These factors all contribute to supporting biopharmaceutical innovation and investment.

For example, the Japanese government's Sakigake Strategy, launched in 2014, provides support for pre-clinical and clinical research targeting cancer and orphan drug treatments through public-private coalitions and networks, improvements to infrastructure and fast-track review.[33] The strategy created a new clinical innovation network and coordinating agency, the Agency for Medical Research and Development, aimed at increasing collaboration among hospitals, companies and government agencies and improving data sharing through building patient registries.[34] The strategy also seeks to streamline regulatory approval for breakthrough treatments and prioritized therapeutic areas to bring down average approval timelines to six months.[35]

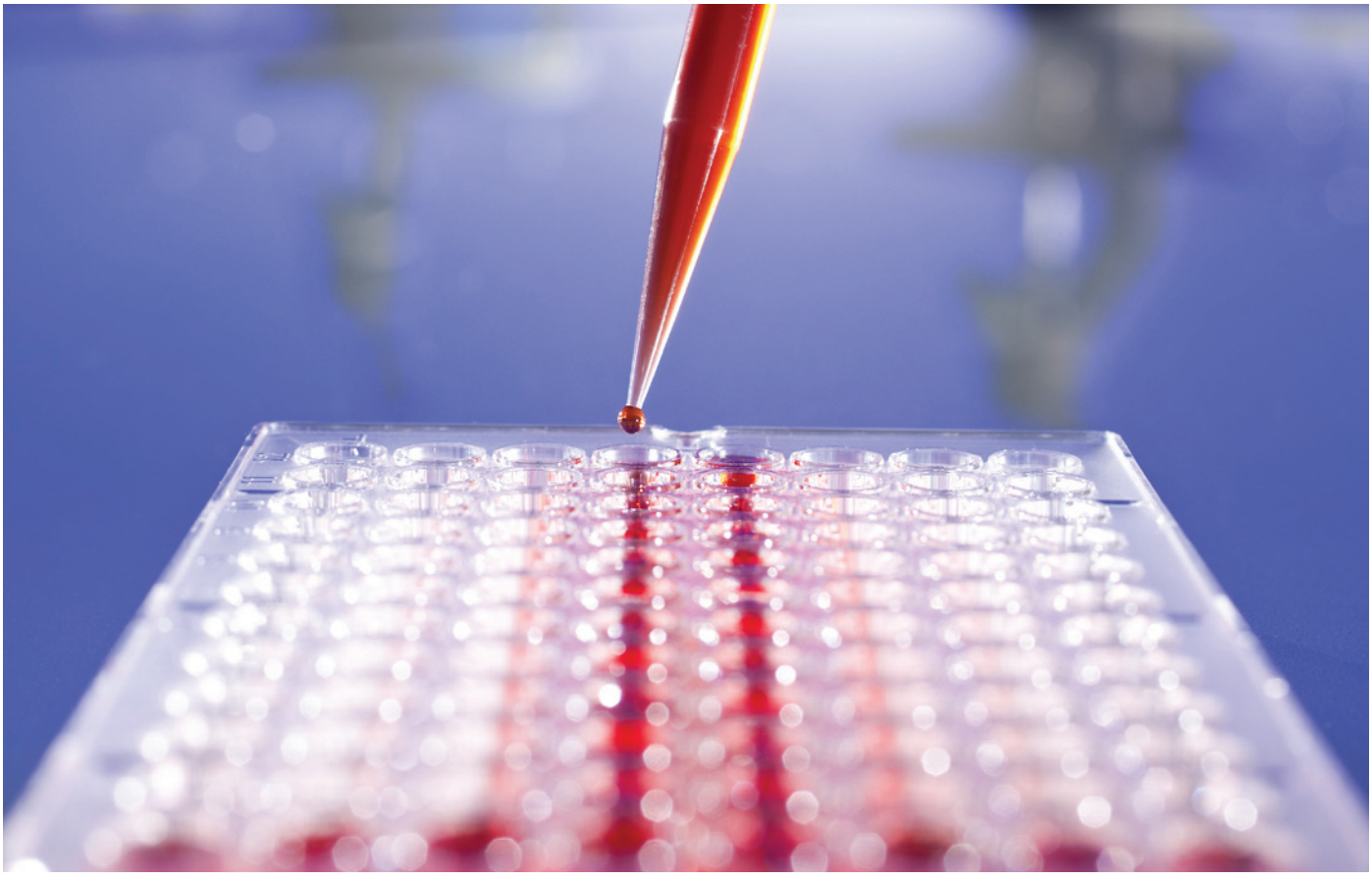
FIGURE 10 Enabling conditions for R&D into priority areas among mature markets: Stop or go?

Economy group	R&D: R&D capacity for new areas and unmet needs	Regulatory: Designated fast-track pathways for priority innovative products	Market access & financing: Adequate price for breakthrough treatments	Market access & financing: Alternative market entry agreements for non-reimbursed products	Market access & financing: Tax environment attractive for R&D	Intellectual property: Pro-innovation IP environment
Front-runners, average	Highly competitive	Highly competitive	Somewhat competitive	Somewhat competitive	Highly competitive	Highly competitive
Keeping pace, average	Highly competitive	Somewhat competitive	Somewhat competitive	Somewhat competitive	Somewhat competitive	Highly competitive
Falling behind, average	Somewhat competitive	Limited competitiveness	Somewhat competitive	Somewhat competitive	Somewhat competitive	Limited competitiveness

In contrast, economies employing policies that dilute support for innovation are rated as comparatively less attractive for investment. Policies that tend to detract from investment include red tape and additional costs and delays for approval of new products and of clinical trials. They also include the use of price controls and other measures that do not fully reflect the long-term contribution to patients and society of breakthrough treatments providing significant therapeutic value compared to existing treatments. Barriers to securing patent protection and enforcing it on the ground, approaches that discriminate against patent holders and RDP frameworks that are out of sync with international standards are additional policies eroding economies' investment environments.

Key finding #2: Support for pioneering R&D gives economies an additional edge in attracting investment

Mature markets scoring at the top in the 2016 BCI have typically introduced policies aimed at incentivizing R&D into novel areas and targeting particular areas of unmet need, such as rare diseases or personalized medicine (see Figure 10). Very often such policies are directed toward a range of elements, including development of relevant skills, infrastructure and technologies; dedicated regulatory pathways that ease and support testing and approval of products for new R&D areas; targeted R&D tax breaks and special market access arrangements that account for smaller patient groups and need for development of knowledge about new products. Economies that fall towards the bottom of the mature markets provide less of these incentives and measures for cutting edge R&D.

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4 ECONOMY-SPECIFIC FINDINGS AND PROFILES

Introduction

The section presents a summary and analysis of each individual economy's overall and category scores. The section is divided into newcomer markets and mature markets, with profiles in each sub-section presenting the results of the respective survey.

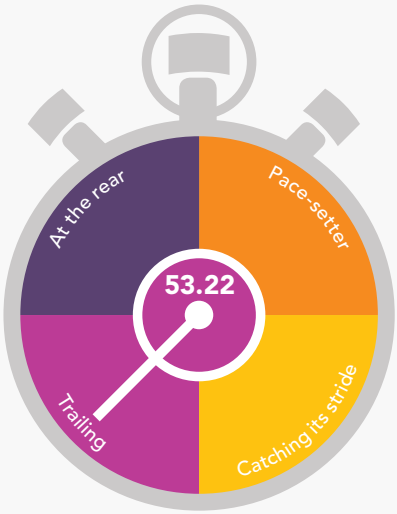
Each profile first displays the overall BCI score and classification for the economy. In each, a given economy's performance per category is also shown, presented in relation to the top scoring economy in each sampled group – Singapore among newcomer markets and the U.S. among mature markets. In their profiles, Singapore and the U.S. are compared to the average score of the top 5 economies in their respective market group.

Each profile also provides a comparative analysis of the economy's overall score and performance by category (in terms of share of the total possible score), shown in relation to: a) for the 15 economies included in the 2015 BCI, the economy's share of the total possible score overall and by category in 2015; and b) for economies added to the sample in 2016, the average overall and per category scores among the given market group.

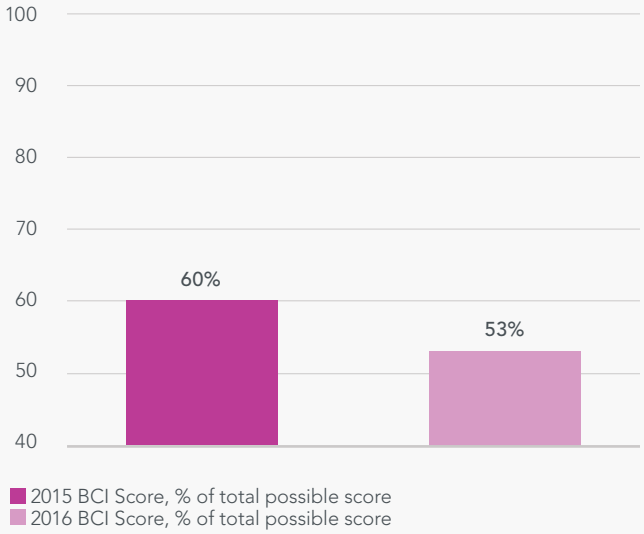
Finally, drawing on BCI responses and comments, a more in-depth analysis and explanation of the economy's BCI scores is provided. This section includes the key strengths and weaknesses identified by executives.

ARGENTINA

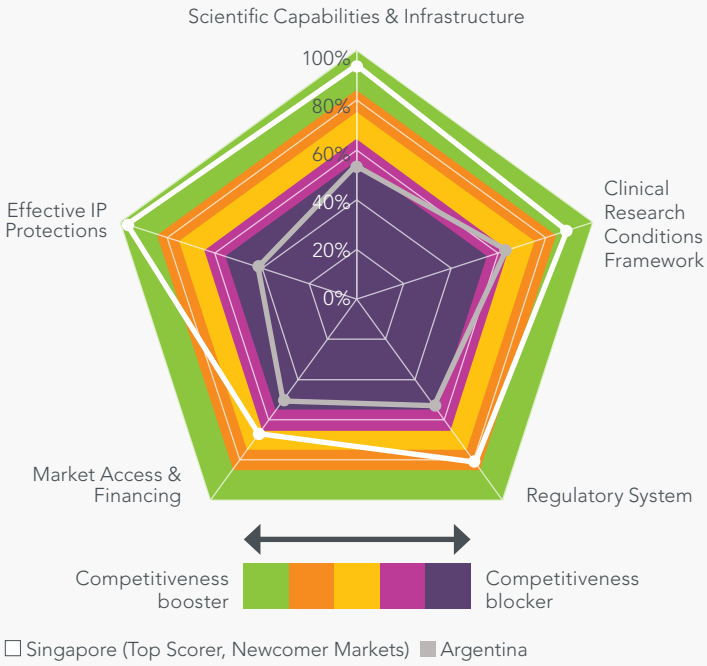
BCI Survey 2016 – Overall Scores



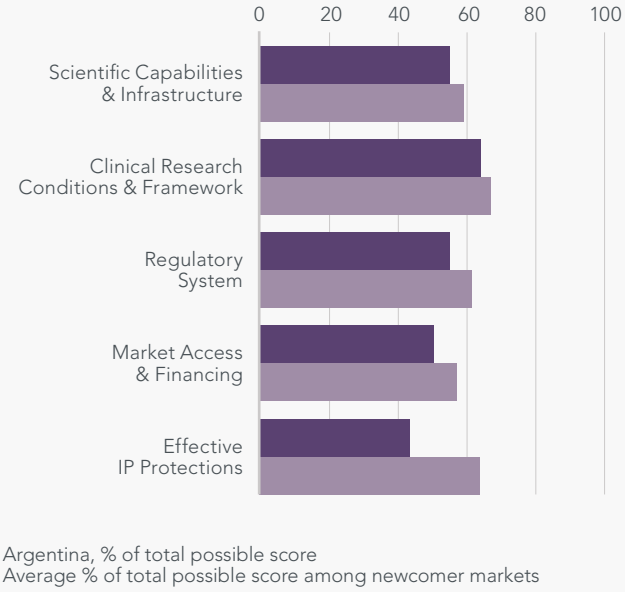
2015 vs. 2016



BCI Survey 2016 – Category Scores



Comparison to Newcomer Markets



BCI Results In Depth: What helps and what hinders Argentina's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✘ Though scientific training is viewed as generally adequate, executives increasingly feel gaps in financial support and R&D investment that would support domestic development of biopharmaceutical know-how.
- ✘ Executives also identify collaboration between the biopharmaceutical industry and research institutions as a key area for improvement, building on recent government efforts to create biomedical R&D platforms.

Clinical Research Conditions & Framework

- ✔ Clinical research capabilities are present in some cases, though there is significant room for development.
- ✘ Approval times for clinical trials seen as an impediment to clinical research.

The Regulatory System

- ✘ Gaps are noted in the implementation of the biopharmaceutical regulatory framework, particularly for biosimilars.
- ✘ Compliance with quality control and pharmacovigilance standards is seen as inconsistent.

Market Access & Financing

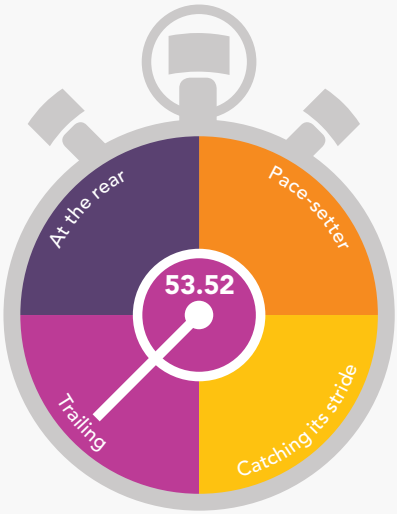
- ✘ Though universal coverage exists, executives cite recent cuts to reimbursement and preferential treatment for lower cost, locally manufactured medicines in the wake of the global commodity crisis.
- ✘ Drug pricing is viewed as lacking transparency, with inconsistent updates to the pricing framework.

Effective Intellectual Property Protections

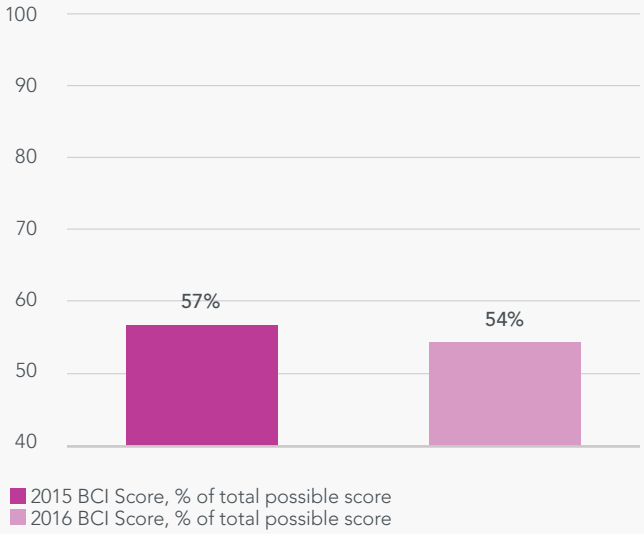
- ✘ IP protection for biopharmaceutical products is currently seen as weak, both in terms of the length and scope of protection afforded.
- ✘ Executives note that Argentina does not have an effective regulatory mechanism for enforcing biopharmaceutical patents or regulatory data protection.

BRAZIL

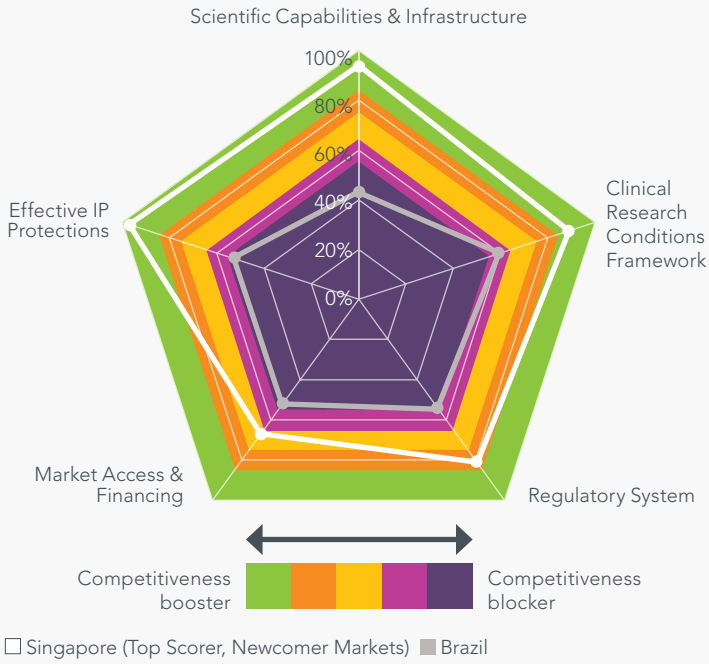
BCI Survey 2016 – Overall Scores



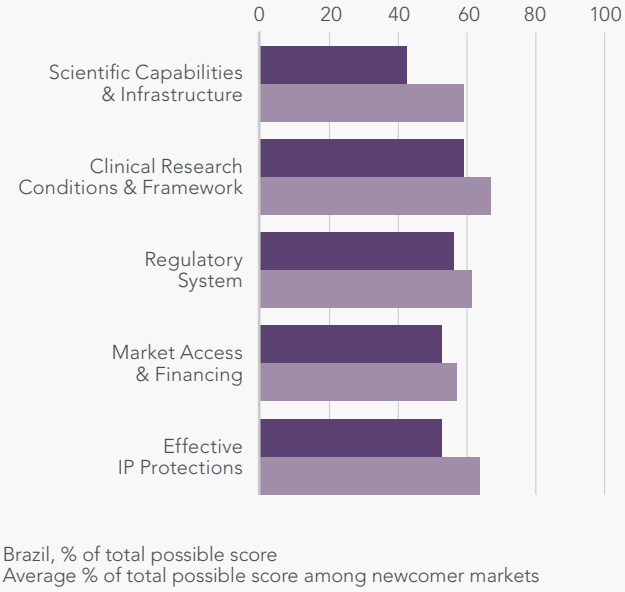
2015 vs. 2016



BCI Survey 2016 – Category Scores



Comparison to Newcomer Markets



BCI Results In Depth: What helps and what hinders Brazil's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✘ Scientific research system is viewed as limited in scope and weak in quality.
- ✘ While new measures aimed at reducing red tape in R&D collaboration are viewed as positive steps, overall collaboration between research institutions and the biopharmaceutical industry continues to occur a limited basis and remains held back by lack of transparency and forced partnership requirements.

Clinical Research Conditions & Framework

- ✘ Although efforts to streamline the clinical trial approval process are underway, executives continue to note long delays in scientific and ethical approval, particularly for biologic drugs.
- ✔ Clinical research capabilities among hospitals and CROs are viewed as fairly developed, with some room for improvement.

The Regulatory System

- ✘ The market approval process continues to be viewed as long and drawn out, lacking transparency and predictability.
- ✔ Drug review capacity is seen as adequate in certain areas (such as generic approval), though gaps are cited in relation to innovative drugs and to ensuring compliance with GMP among local manufacturers.

Market Access & Financing

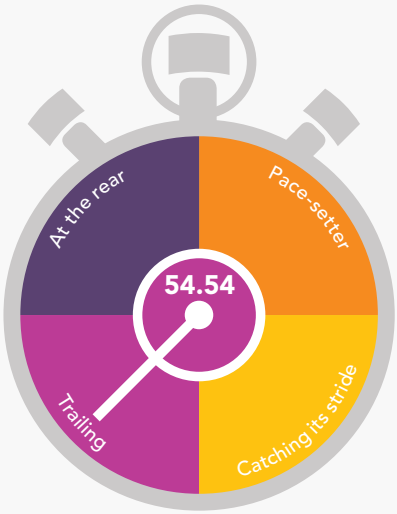
- ✘ Executives note that reimbursement and coverage of innovative drugs is limited and the reimbursement system increasingly convoluted and uncertain.
- ✘ Executives cite preferential treatment of local companies in the public procurement system and high taxes on imports as additional barriers to accessing the market.

Effective Intellectual Property Protections

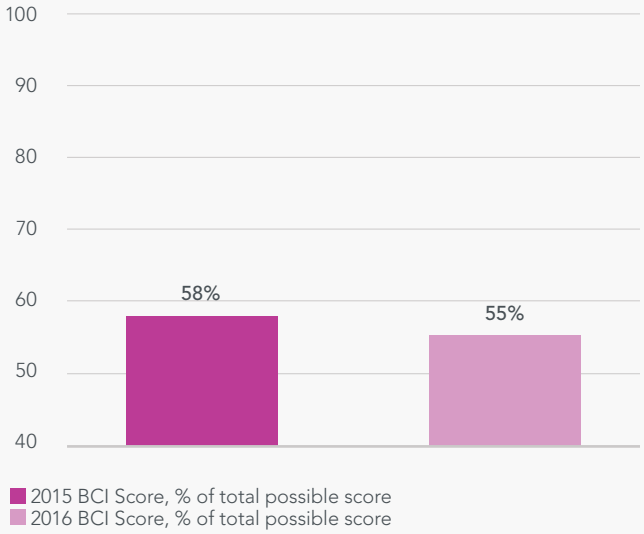
- ✘ Dual examination of patents by the patent office and the drug regulatory agency (ANVISA) and severe delays continue to undermine the biopharmaceutical patenting process.
- ✘ Gaps in the overall biopharmaceutical IP system and in the availability of effective remedies are also seen as impeding Brazil's attractiveness for investment.

CHINA

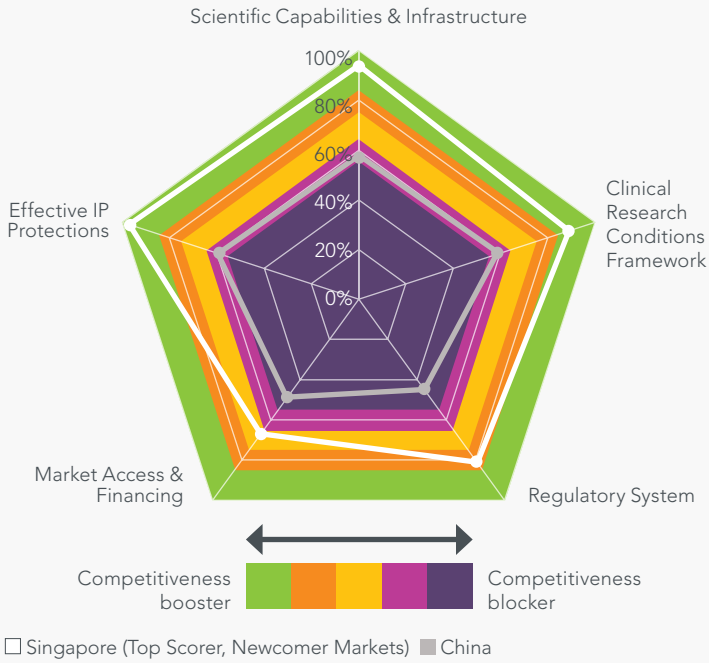
BCI Survey 2016 – Overall Scores



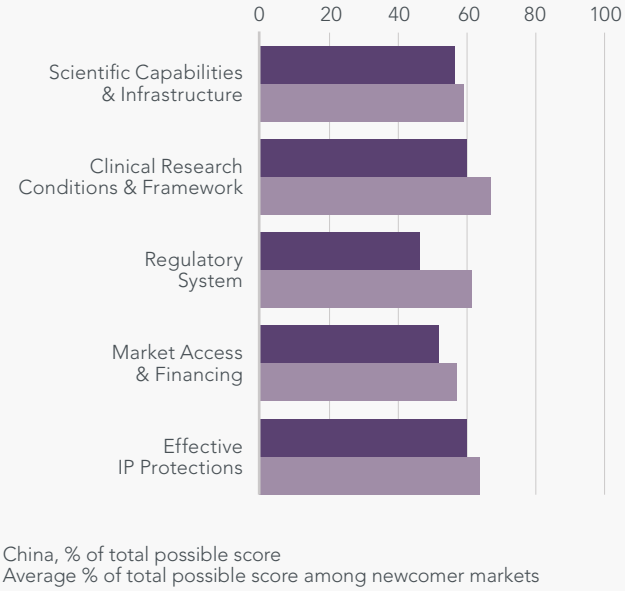
2015 vs. 2016



BCI Survey 2016 – Category Scores



Comparison to Newcomer Markets



BCI Results In Depth: What helps and what hinders China's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✘ Biopharmaceutical R&D capabilities are still perceived as being at a basic level.
- ✔ Although academic-industry partnerships are seen as occurring on a limited basis, executives note that the level of research collaboration is growing on the back of new bioclusters and measures streamlining technology commercialization.

Clinical Research Conditions & Framework

- ✘ Significant clinical trial approval delays (despite new measures reducing duplicative registration) and gaps in quality assurance and compliance with international standards are seen as persistent bottlenecks.
- ✔ Relatively low costs and availability of participants continue to be viewed as advantages.

The Regulatory System

- ✘ Executives overwhelmingly see the very long approval times as a major drawback, though efforts are underway to reduce delays.
- ✘ Concerns are raised regarding regulatory capacity and processes, although new measures strengthening biosimilars review and fast-track pathways for some innovative drugs are viewed as opportunities for strengthening the system.

Market Access & Financing

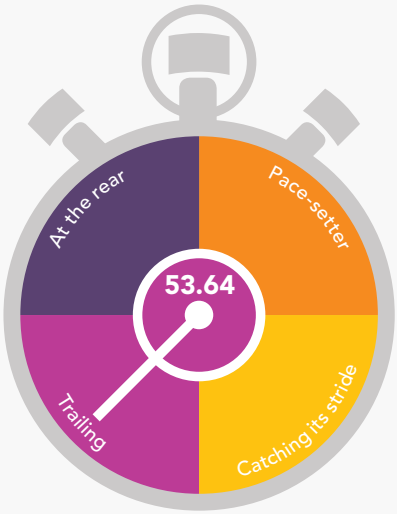
- ✘ Executives view trends towards more stringent price controls and limits to public hospital procurement of innovative drugs as hindering China's competitiveness.
- ✘ Overall, the public pricing and reimbursement system is viewed as lacking transparency.

Effective Intellectual Property Protections

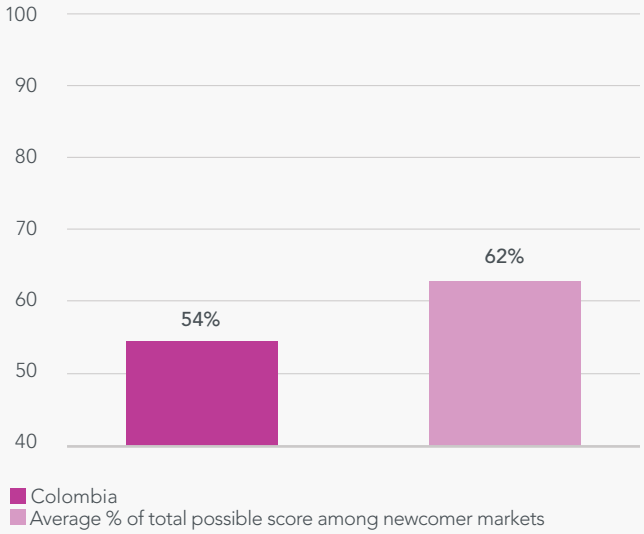
- ✘ Executives indicate that lack of clarity on patentability of biopharmaceuticals and the related evidentiary burden; RDP (particularly for products not first launched in China); and the patent linkage mechanism undermine investment.
- ✔ They note some improvements in civil and criminal remedies available for infringement.

COLOMBIA

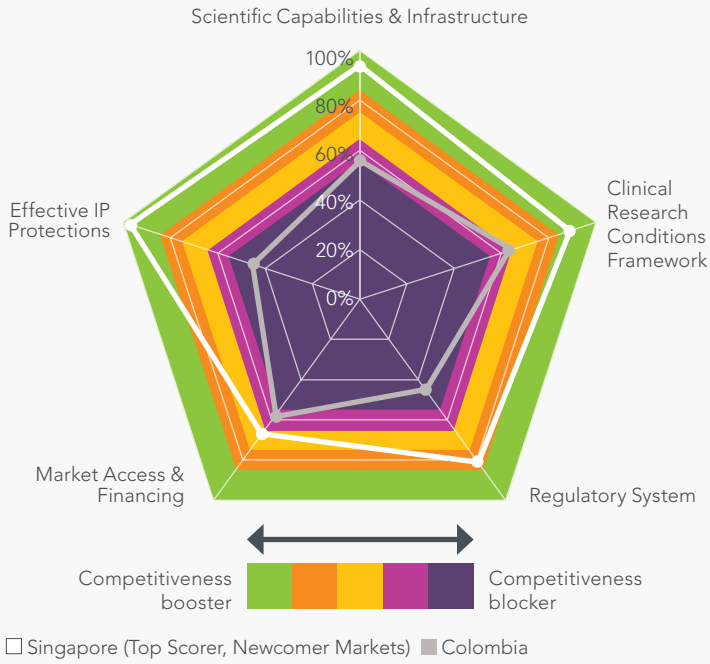
BCI Survey 2016 – Overall Scores



Comparison to Newcomer Markets



BCI Survey 2016 – Category Scores



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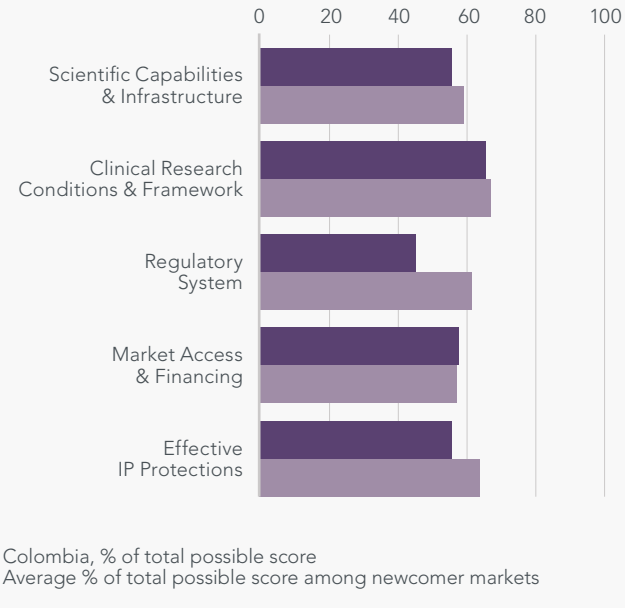


BCI Results In Depth: What helps and what hinders Colombia's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✘ The scientific research system is viewed as basic and lacking adequate investment, though recent measures aimed at strengthening capabilities represent potential steps forward.
- ✔ Executives note that while collaboration between research institutions and the biopharmaceutical industry only occurs occasionally, new initiatives to boost collaboration and technology transfer are welcome.

Clinical Research Conditions & Framework

- ✘ Although new measures to reduce clinical trial approval timelines are seen as positive steps, executives currently cite significant delays in approval.
- ✔ Clinical research capabilities among hospitals and CROs are viewed as fairly strong.

The Regulatory System

- ✘ The market approval process continues to be viewed as relatively long, with red tape and linking of registration with pricing decisions reinforcing delays and uncertainty.
- ✘ Overall, drug review capacity is seen as basic and limited, and lacking transparency.

Market Access & Financing

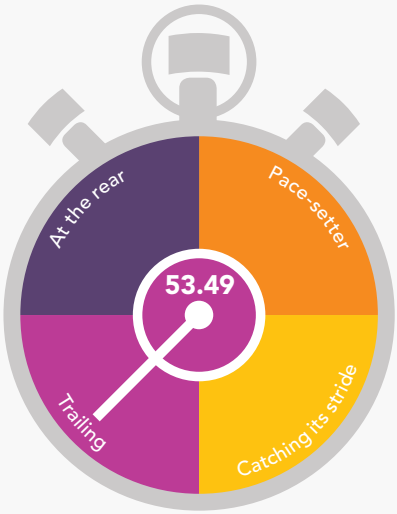
- ✘ Executives note that pricing and reimbursement decisions are frequently made on a non-transparent basis.
- ✘ What are perceived as fairly stringent price controls, in some cases without any input from the manufacturer, are viewed as also hindering investment.

Effective Intellectual Property Protections

- ✘ Gaps across the biopharmaceutical IP system, including ability to patent biopharmaceutical inventions, regulatory data protection and discussion on compulsory licensing, are seen as eroding Colombia's competitiveness.
- ✘ Possibility for dual examination of patents by the patent office and the Ministry of Health (MHSS) is seen as negatively impacting the biopharma IP environment in Colombia.

EGYPT

BCI Survey 2016 – Overall Scores



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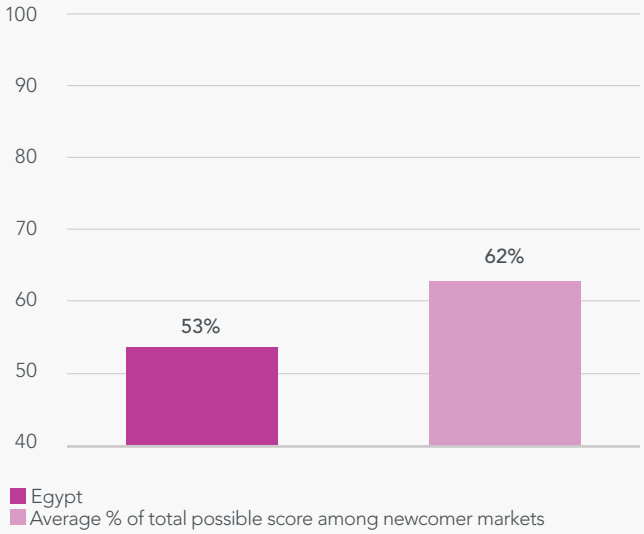
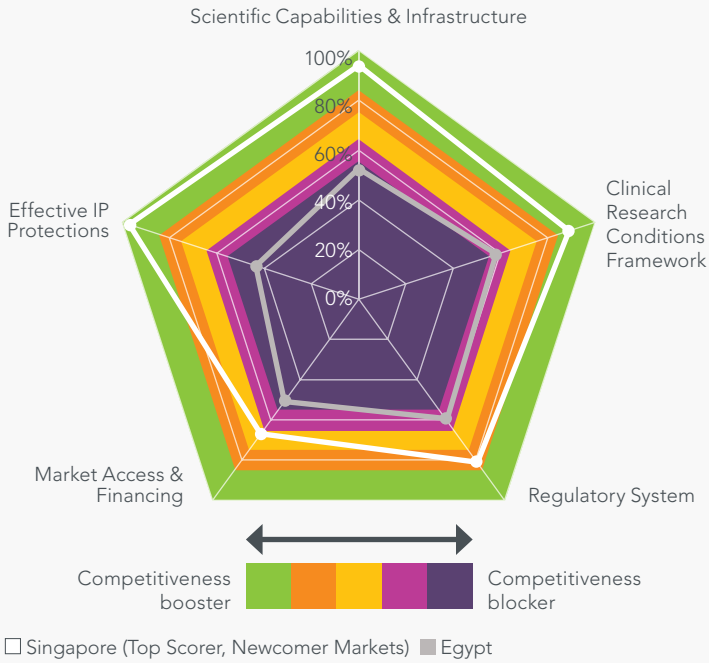
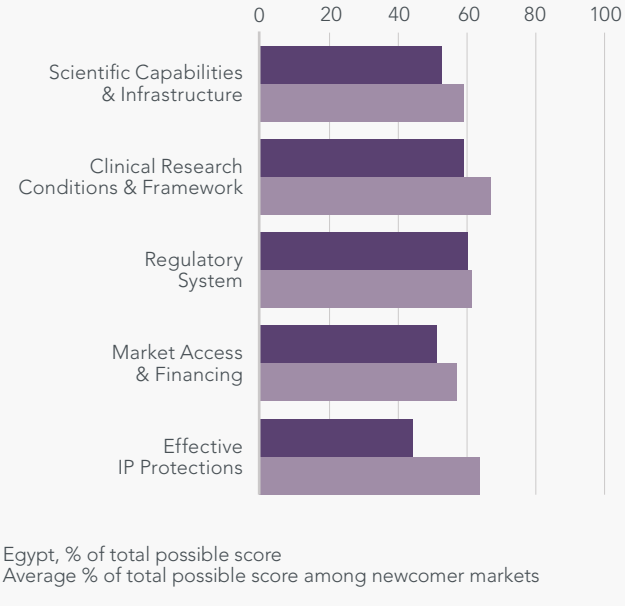


BCI Survey 2016 – Category Scores



Comparison to Newcomer Markets



BCI Results In Depth: What helps and what hinders Egypt's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Science base is seen as relatively well developed.
- ✘ Biopharmaceutical R&D capacity at a basic level, with limited though growing collaboration between research institutions and industry.

Clinical Research Conditions & Framework

- ✘ Quite significant delays and gaps in the clinical research regulatory framework cited as barriers to investment.
- ✔ Costs of clinical research rated as some of the lowest among newcomer markets.

The Regulatory System

- ✘ Executives note that though progress has been made to speed up regulatory approval, still further streamlining and transparency is needed.
- ✔ The pharmacovigilance framework is cited as one strength of the regulatory system.

Market Access & Financing

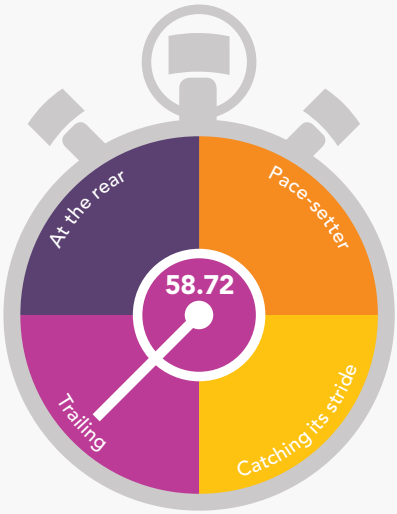
- ✘ Though reform efforts have occurred, price controls continue to be perceived as relatively stringent.
- ✘ What is seen as partial public reimbursement of medicines also hinders investment.

Effective Intellectual Property Protections

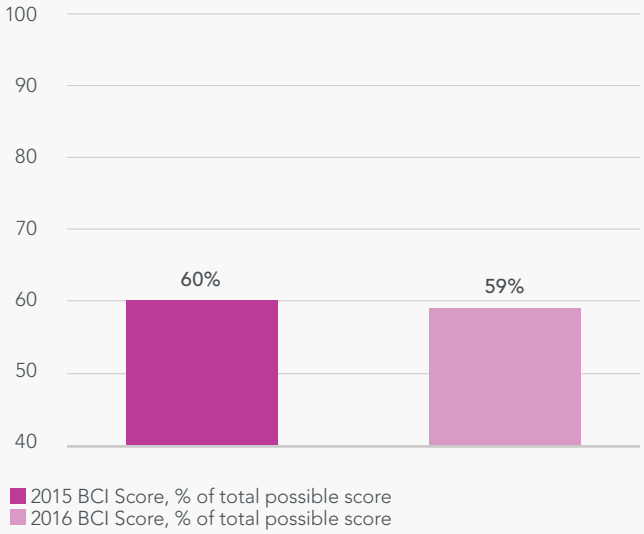
- ✘ Major gaps in biopharmaceutical IP protection and enforcement are considered to exist.
- ✘ Lack of RDP is particularly cited as limiting investment attractiveness.

INDIA

BCI Survey 2016 – Overall Scores



2015 vs. 2016



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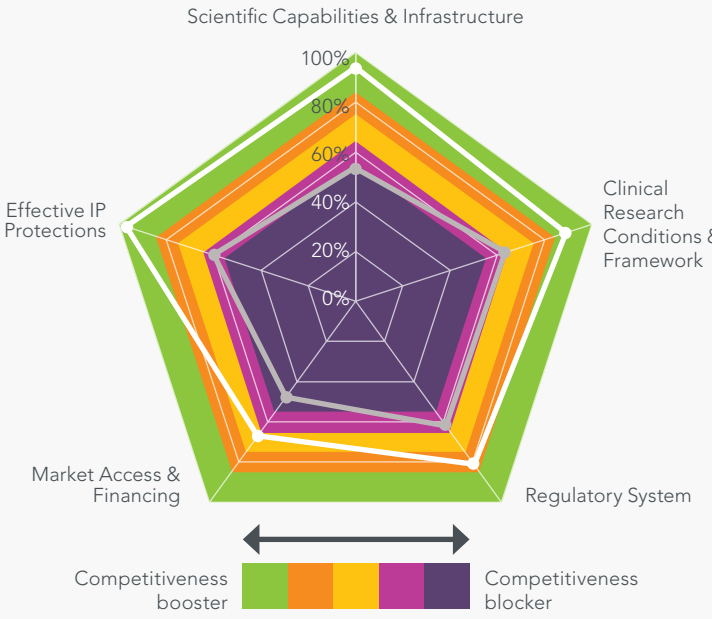
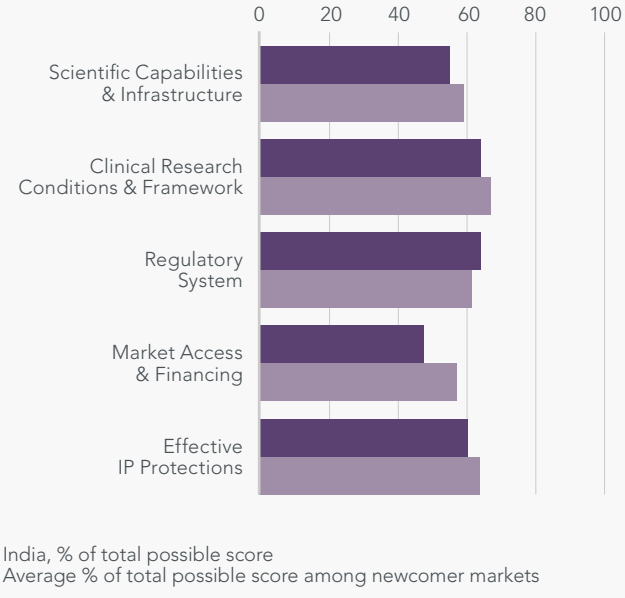


Comparison to Newcomer Markets



BCI Results In Depth: What helps and what hinders India's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ New biotech initiatives, funding and capacity building efforts are cited as positive steps, though overall R&D capabilities and infrastructure remain at a basic level.
- ✘ Despite new initiatives and bioclusters, actual collaboration between research institutions and the biopharmaceutical industry is seen as occurring infrequently.

Clinical Research Conditions & Framework

- ✔ The framework governing clinical trial approval and sponsor liability is described as having become more transparent and predictable in some respects, though challenges remain.
- ✘ Clinical trial approval times and some limits on the ability to secure participation in trials are cited as additional impediments to investment.

The Regulatory System

- ✘ Respondents view long approval times as a significant barrier to investment.
- ✘ Some gaps are raised in relation to drug regulators' capacity to review biosimilars and the regulatory framework guiding biosimilar approval.

Market Access & Financing

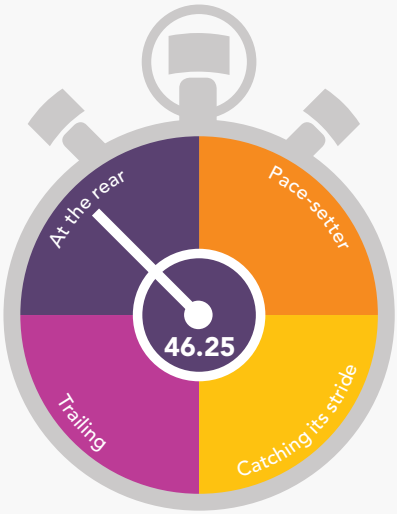
- ✘ Respondents had quite significant concerns with the limited access to biopharmaceutical products through public reimbursement and stringent price controls.
- ✘ A strong focus by public authorities on cost rather than value of biopharmaceuticals is perceived across pricing, reimbursement and procurement.

Effective Intellectual Property Protections

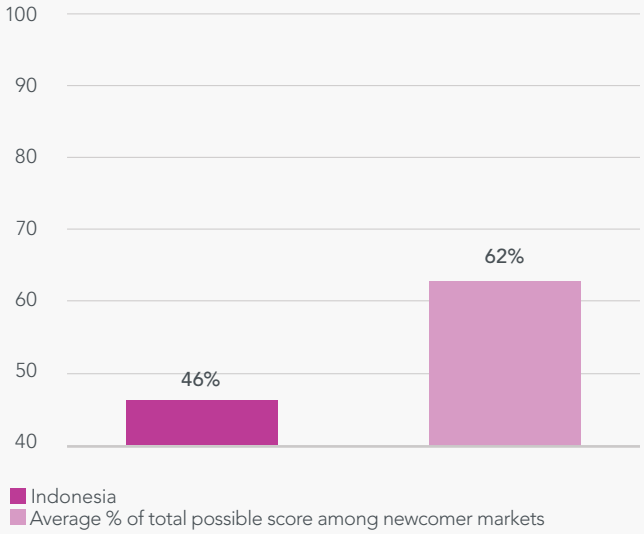
- ✘ The patent environment is seen as mixed, with concerns remaining over the ability to secure needed patents for biopharmaceuticals, the new National IP Rights Policy viewed as somewhat of a missed opportunity and potential improvements remaining largely at an aspirational level.
- ✘ Though efforts to reform are ongoing, executives cited the existing fragmented patent review system as an additional challenge hindering the patent system.
- ✘ Respondents also highlighted significant gaps in the availability of regulatory data protection.

INDONESIA

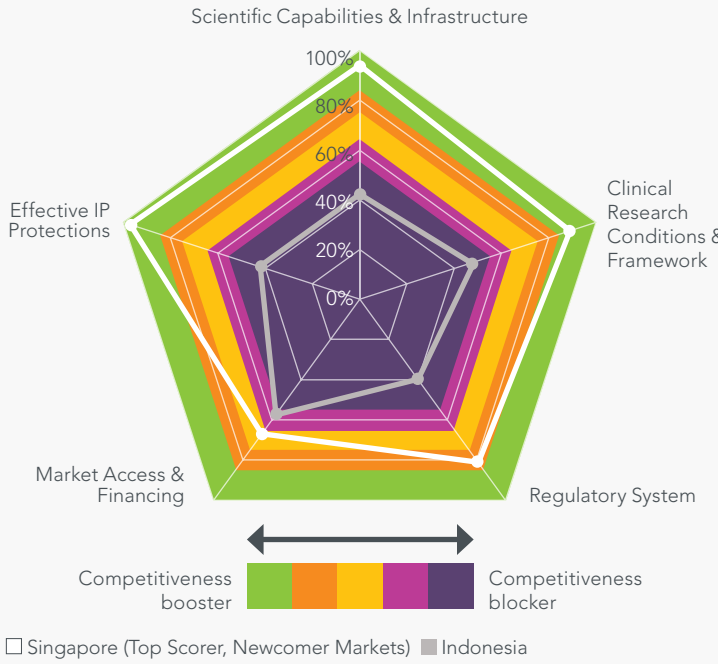
BCI Survey 2016 – Overall Scores



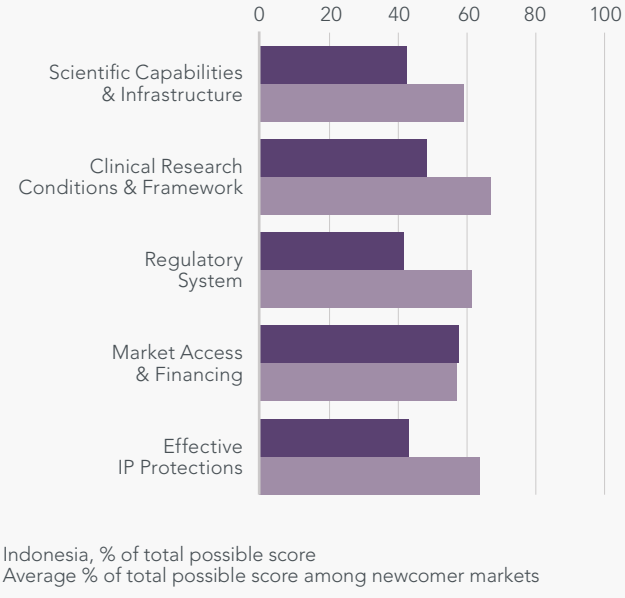
Comparison to Newcomer Markets



BCI Survey 2016 – Category Scores



Comparison to Newcomer Markets



BCI Results In Depth: What helps and what hinders Indonesia's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✘ The scientific research system is perceived as generally weak and underdeveloped, with low levels of spending on R&D compared to other G20 members, though pockets of investment from domestic companies exist.
- ✘ Collaboration between academic institutions and the biopharmaceutical industry is seen as occurring on a limited basis.

Clinical Research Conditions & Framework

- ✘ Executives cite limited institutional and operational capacity for conducting clinical trials and inconsistent compliance with global clinical trial standards.
- ✘ Significant backlogs and gaps in resources are noted in regards to approval of clinical trials.

The Regulatory System

- ✘ Approval timelines, costs and barriers rank as some of the most difficult among newcomer markets, including due to red tape, gaps in resources and domestic manufacturing requirements.
- ✘ Though efforts are underway to strengthen the system, executives indicate concern over the standards and capacity of the health regulator, National Agency of Drug and Food Control, for drug approvals, especially of biosimilars.

Market Access & Financing

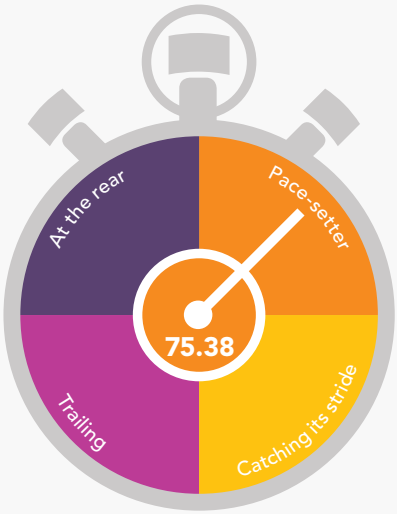
- ✘ Executives view reimbursement through the public system as limited, with significant hurdles to coverage of new health technologies.
- ✘ Executives find the public procurement system in many cases to be biased towards locally manufactured and generic products.

Effective Intellectual Property Protections

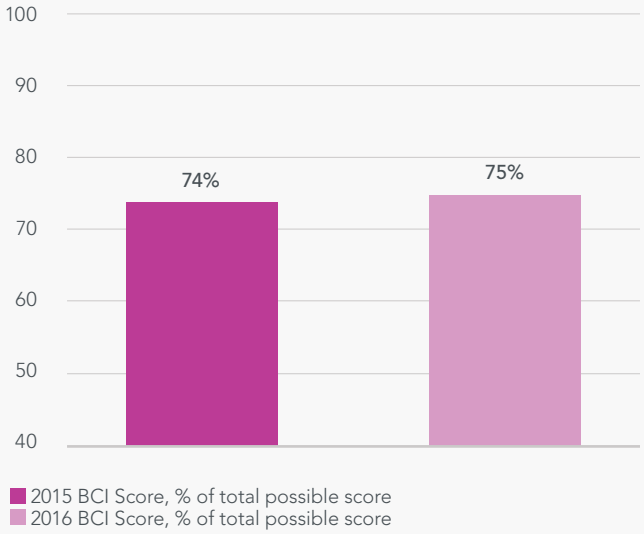
- ✘ Executives view major gaps in biopharmaceutical patent protection and enforcement, including proposed amendments, as significantly hindering Indonesia's investment attractiveness.
- ✘ Concerns are also raised over availability of regulatory data protection for biopharmaceuticals.

ISRAEL

BCI Survey 2016 – Overall Scores



2015 vs. 2016



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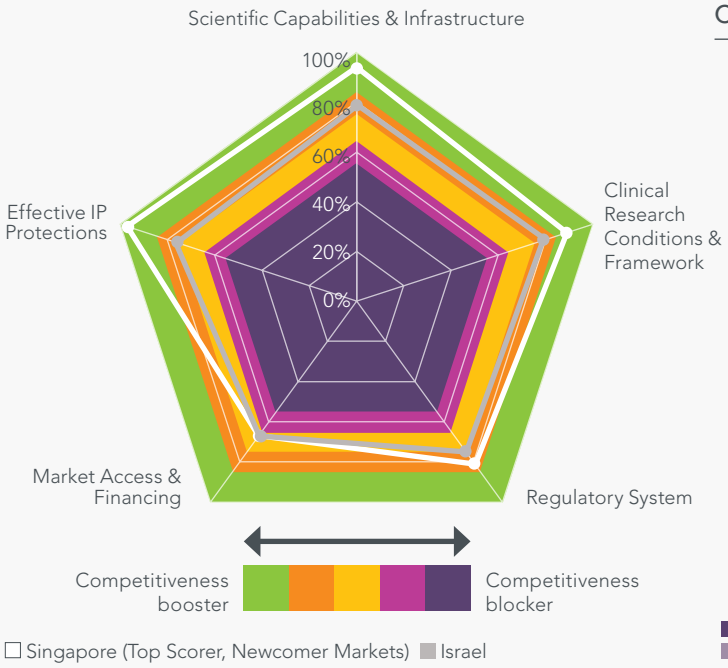
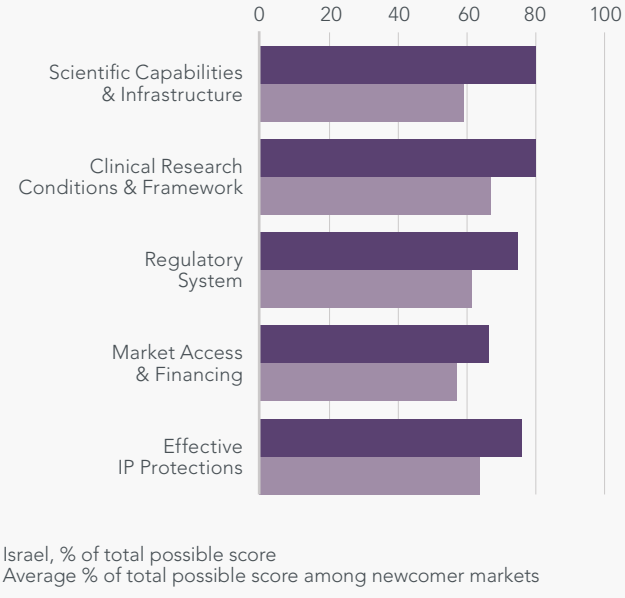


Comparison to Newcomer Markets



BCI Results In Depth: What helps and what hinders Israel's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Biopharmaceutical R&D is viewed as relatively strong, with some room for improvement in the area of scientific and laboratory research capabilities.
- ✔ Collaboration between research institutions and the biopharmaceutical industry is considered to occur regularly and be viewed as strategically important.

Clinical Research Conditions & Framework

- ✔ Clinical research conditions are viewed as being very high and generally in line with international best practices.
- ✘ Some concerns are raised over approval times and costs of clinical research relative to other newcomer markets.

The Regulatory System

- ✔ Quality control standards and compliance are seen as strong and mostly aligned with international standards.
- ✘ Respondents cite capabilities for approval of new medicines and additional streamlining of drug registration as key areas to further strengthen.

Market Access & Financing

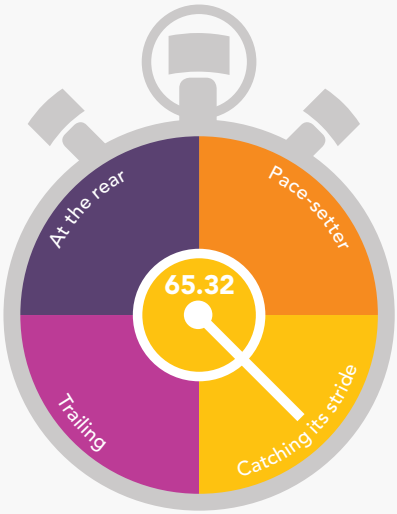
- ✘ Some barriers have been identified in relation to price controls and difficulty accessing the public procurement system for innovative products.
- ✔ Supplementary and private coverage schemes for reimbursement of medicines are considered to aid in improving access to cutting edge treatments.

Effective Intellectual Property Protections

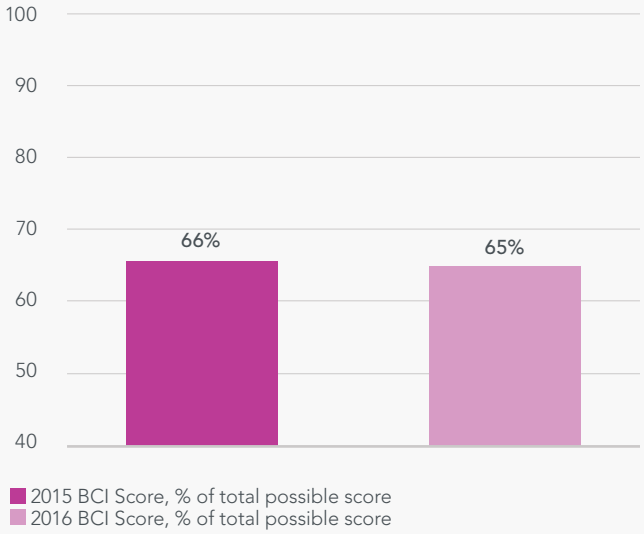
- ✔ Biopharmaceutical IP environment is seen as relatively robust.
- ✘ Some gaps were noted in relation to enforcement of biopharmaceutical patents and timely dispute resolution ahead of marketing of a potentially infringing product as well as regulatory data protection for biologics.

MEXICO

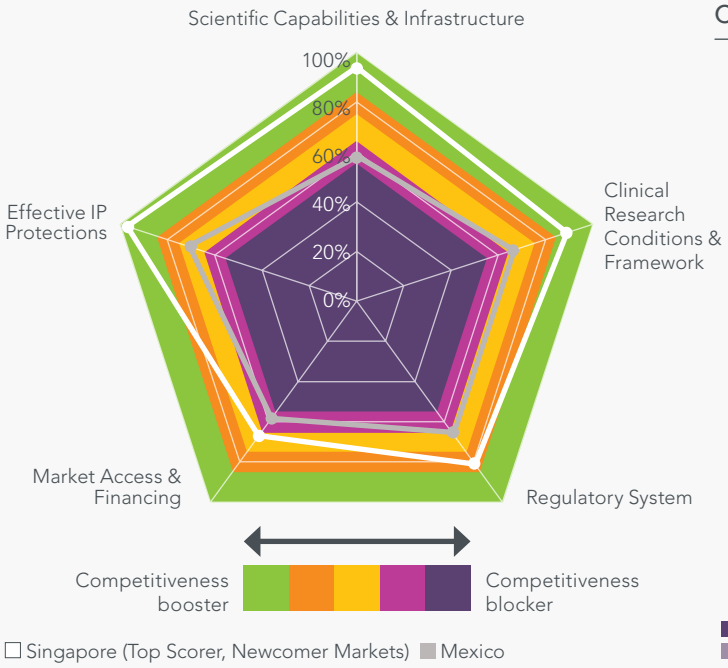
BCI Survey 2016 – Overall Scores



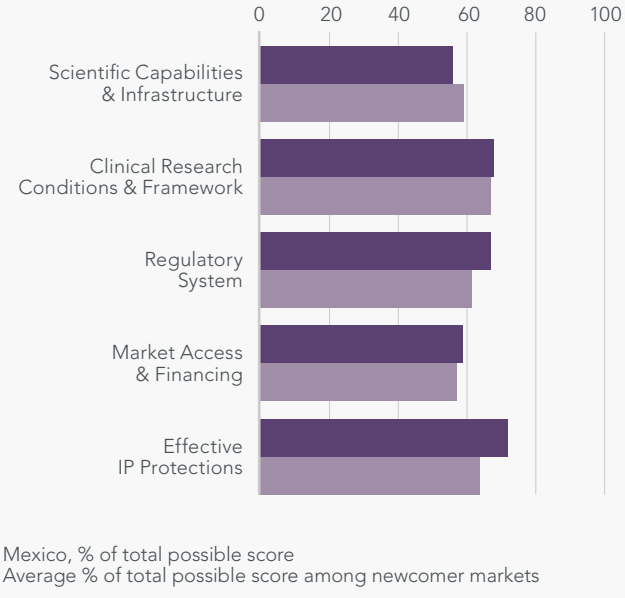
2015 vs. 2016



BCI Survey 2016 – Category Scores



Comparison to Newcomer Markets



BCI Results In Depth: What helps and what hinders Mexico's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✘ Overall biopharmaceutical R&D capabilities are viewed as basic and requiring greater support, although executives note that increasing R&D spending and training in the life sciences are growing priorities.
- ✘ R&D collaboration between the biopharmaceutical industry and research institutions is seen as only occurring on a limited basis.

Clinical Research Conditions & Framework

- ✔ Conducting clinical trials is considered to be relatively low cost and carried out in line with international standards, although executives noted that gaps in capacity for clinical research must be addressed for Mexico to secure greater investment.
- ✘ While executives note that the timeframe for clinical trial approval has improved, in practice and on average there is a still a ways to go to reach the government's target of 30 days.

The Regulatory System

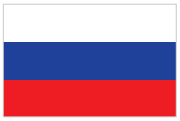
- ✔ Executives cite a stronger regulatory framework for biologics and improvements to market approval timelines, particularly for innovative drugs.
- ✘ Concerns continue to be raised over gaps in implementation of pharmacovigilance controls.

Market Access & Financing

- ✘ Drug coverage and reimbursement is viewed as narrow in certain areas, particularly for innovative products.
- ✘ The public procurement system is seen as fragmented and prioritizing cost over value, making it difficult for innovative products to compete effectively.

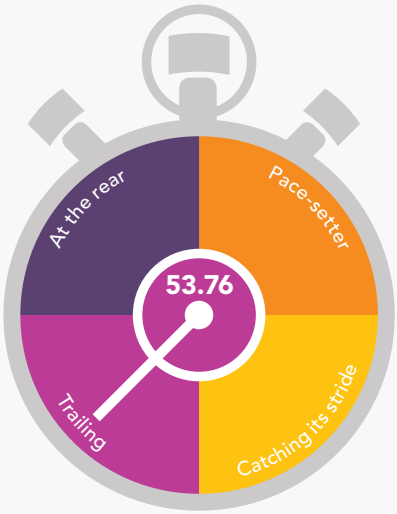
Effective Intellectual Property Protections

- ✔ Biopharmaceutical IP protections and the process of patenting are generally are perceived as adequate in some respects.
- ✘ Gaps in the regulatory patent enforcement mechanism and in the availability of regulatory data protection for biologics continue to present barriers to innovators.



RUSSIA

BCI Survey 2016 – Overall Scores



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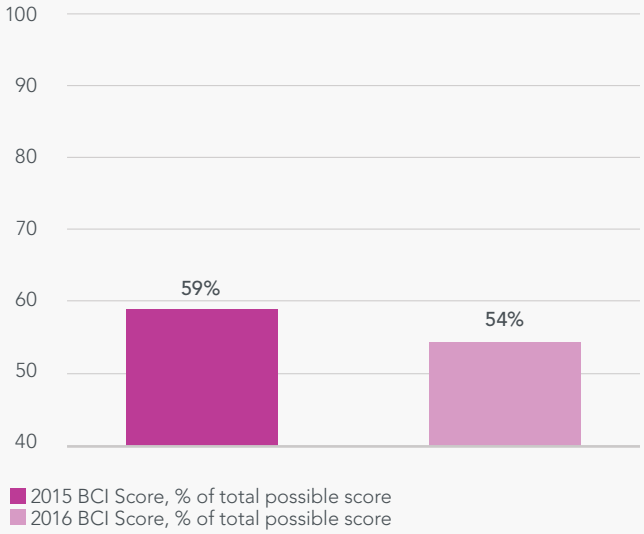
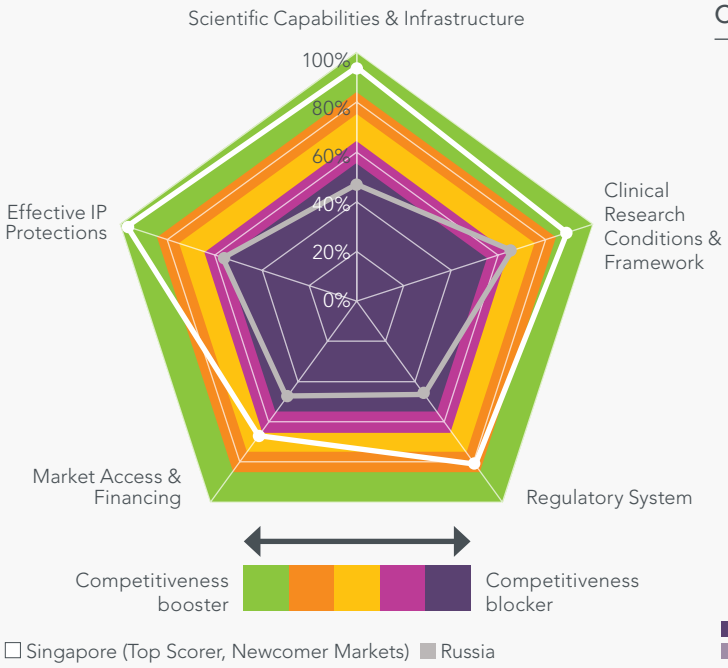
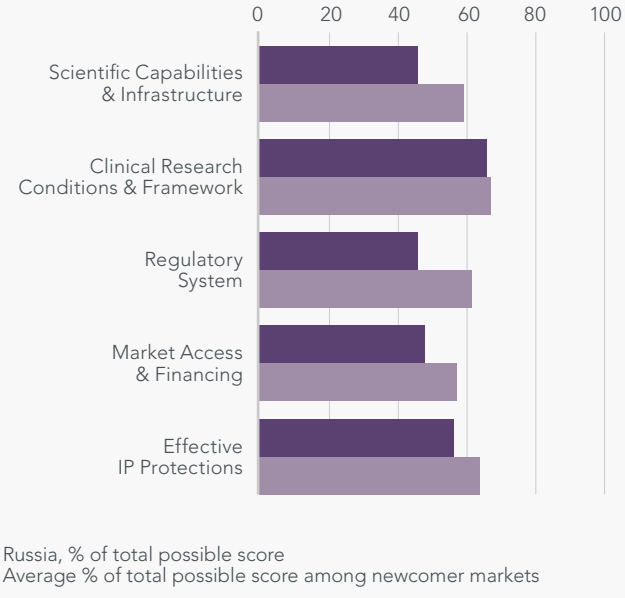


BCI Survey 2016 – Category Scores



Comparison to Newcomer Markets



BCI Results In Depth: What helps and what hinders Russia's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✘ Biopharmaceutical R&D capabilities are seen as basic with levels of R&D investment falling behind the curve.
- ✘ Actual levels of collaboration between the biopharmaceutical industry and research institutions continue to be viewed as limited.

Clinical Research Conditions & Framework

- ✔ Capacity for clinical research among hospitals and CROs is considered to be adequate.
- ✘ Despite 2015 legislation removing certain regulatory hurdles, overall clinical research regulations and requirements for local clinical trials for imported products continue to represent challenges for innovators.

The Regulatory System

- ✘ Executives view regulatory capacity and standards as underdeveloped, with long timeframes for approval.
- ✘ Ongoing delays to implementation of quality controls such as GMP and pharmacovigilance continue to present risks.

Market Access & Financing

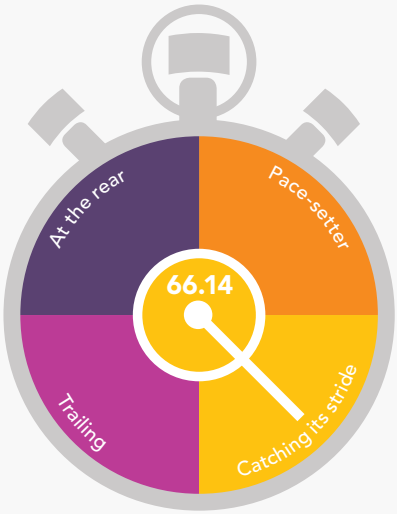
- ✘ Executives note that the considerable emphasis on cost within the pricing and reimbursement system, represents a growing barrier.
- ✘ Imported innovative drugs continue to face significant disadvantages and additional costs compared to locally produced drugs within the pricing and procurement systems.

Effective Intellectual Property Protections

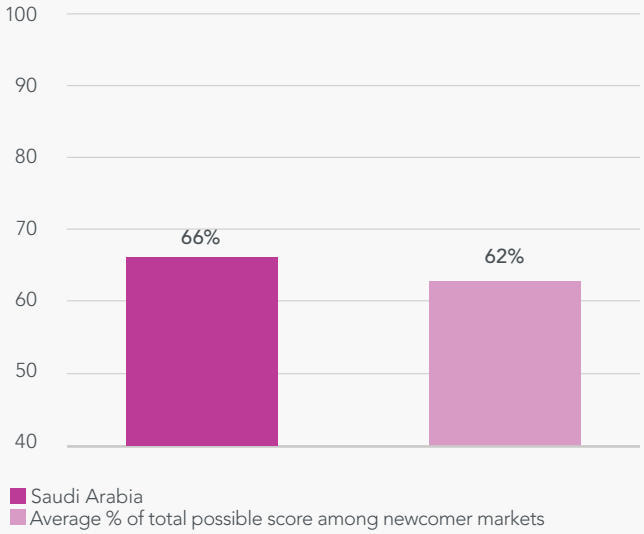
- ✘ Lack of effective enforcement of biopharmaceutical patents and other IP rights is a major concern.
- ✔ The patenting process for biopharmaceuticals is generally considered to be effective, although executives continue to monitor this area.

SAUDI ARABIA

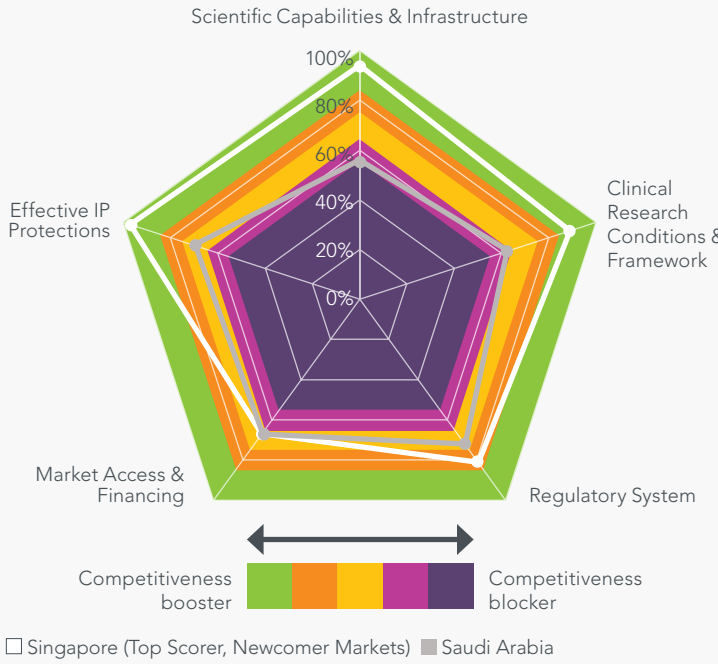
BCI Survey 2016 – Overall Scores



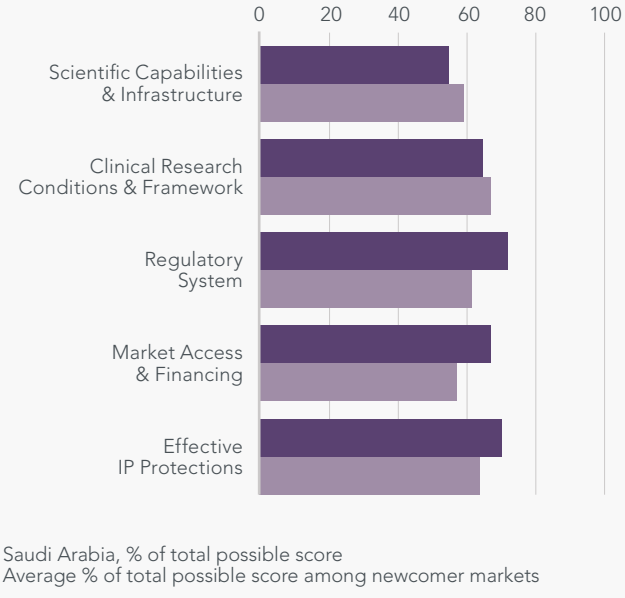
Comparison to Newcomer Markets



BCI Survey 2016 – Category Scores



Comparison to Newcomer Markets



BCI Results In Depth: What helps and what hinders Saudi Arabia's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✘ Executives note that scientific capabilities are currently nascent, though the country possesses significant potential.
- ✔ Recent government focus on investing in building the science base and improving R&D and advanced manufacturing capacity through industry partnerships is welcome, however must be implemented effectively.

Clinical Research Conditions & Framework

- ✔ Relatively good compliance with global clinical research standards is considered to be in place.
- ✘ Some difficulty in recruiting participants is noted.
- ✘ Executives find that improvements to clinical research capabilities/infrastructure (including expansion of CROs) and streamlining of clinical trial approval are needed.

The Regulatory System

- ✔ Drug approval frameworks are viewed as being of relatively high quality.
- ✘ Regulatory delays and burdensome procedures are seen as impeding investment.

Market Access & Financing

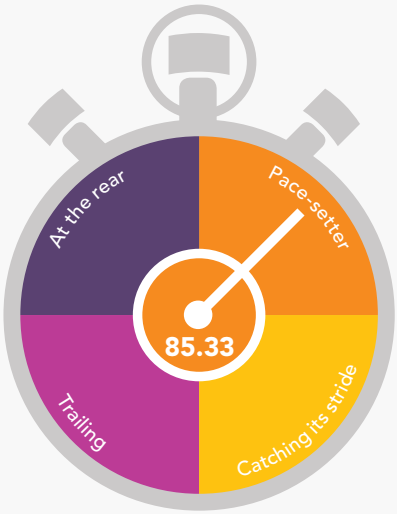
- ✔ Coverage of biopharmaceuticals though the public reimbursement system is perceived as generally strong.
- ✘ Price controls are viewed as somewhat stringent, with the pricing process lacking in transparency.
- ✘ Foreign ownership restrictions and manufacturing requirements can present barriers to the research-based industry.

Effective Intellectual Property Protections

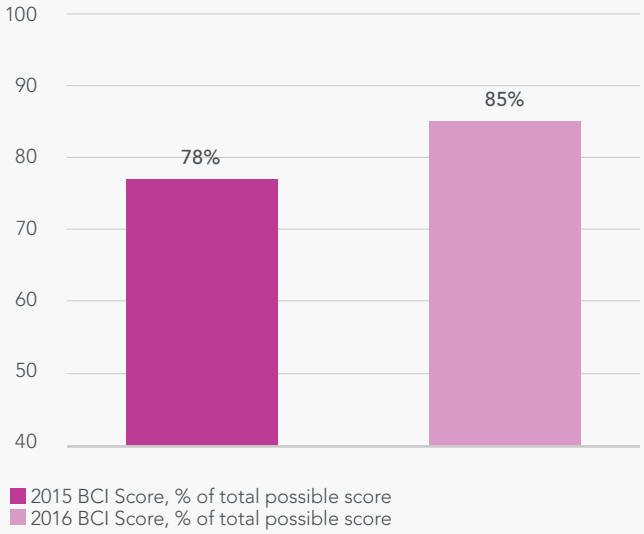
- ✔ The patent enforcement mechanism in place strengthens the investment environment in the eyes of executives, though greater implementation is needed.
- ✘ Executives note that RDP for biopharmaceuticals lacks in effectiveness.

SINGAPORE

BCI Survey 2016 – Overall Scores



2015 vs. 2016



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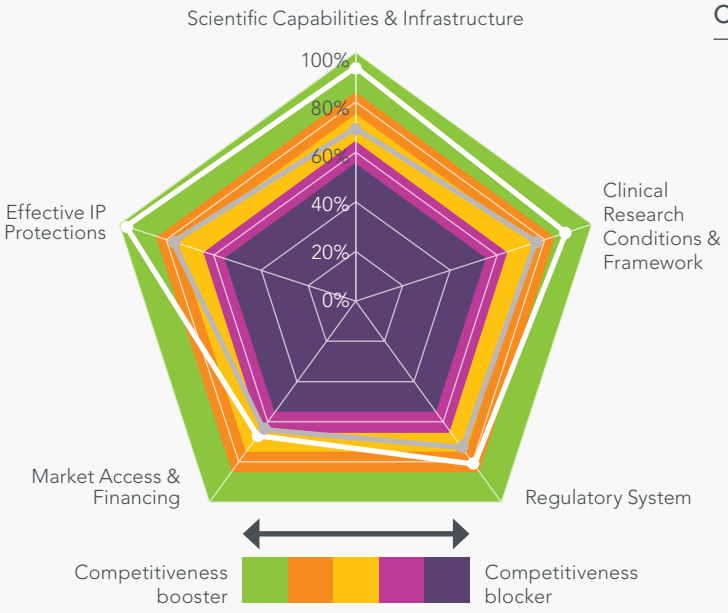
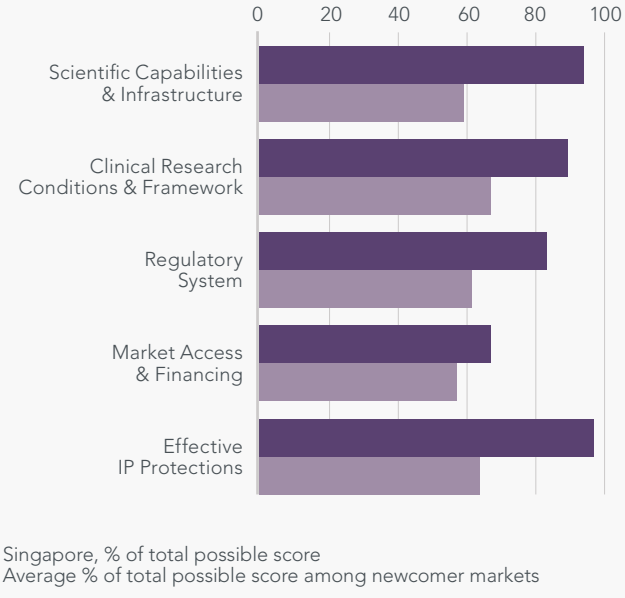


Comparison to Newcomer Markets



BCI Results In Depth: What helps and what hinders Singapore's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Respondents cite high quality scientific training and strong capabilities for biopharmaceutical R&D, with investment growing consistently.
- ✔ Collaboration between the biopharmaceutical industry and research institutions is seen as occurring routinely and considered of strategic importance in Singapore.

Clinical Research Conditions & Framework

- ✔ Local executives view the scientific and regulatory capacity for clinical research as being quite high.
- ✔ Recent strengthening of clinical research regulations has added further transparency and predictability to the system, particularly for biologic products.

The Regulatory System

- ✔ Market approval and post-marketing monitoring of medicines is generally considered to be on par with developed market standards.
- ✘ Some delays are reported in the drug approval process.

Market Access & Financing

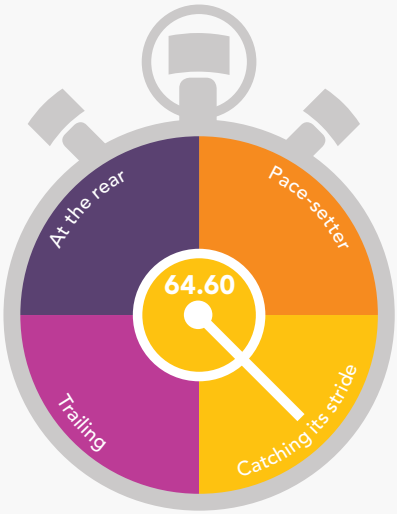
- ✘ Public reimbursement of medicines is only partial, and patient coverage of high-cost medicines represents a key barrier to access.
- ✔ Apart from this, relatively free pricing of biopharmaceuticals is seen as supporting broad market access.

Effective Intellectual Property Protections

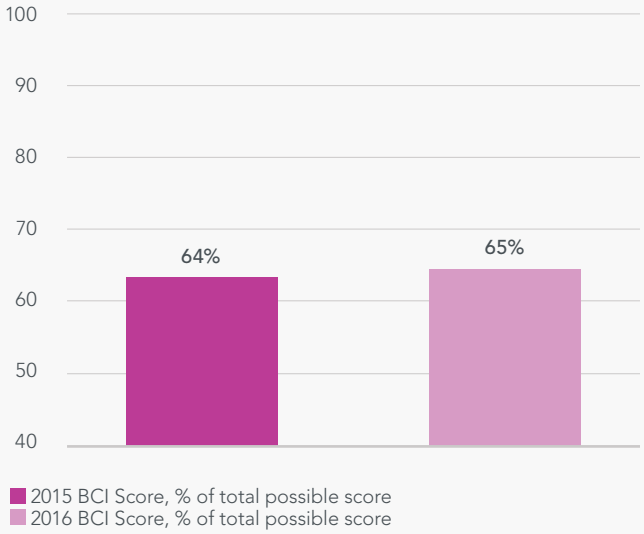
- ✔ Biopharmaceutical IP rights are generally considered to be robust and in line with international standards.
- ✔ Enforcement of these rights is recognized as being strong in most cases.

SOUTH AFRICA

BCI Survey 2016 – Overall Scores



2015 vs. 2016



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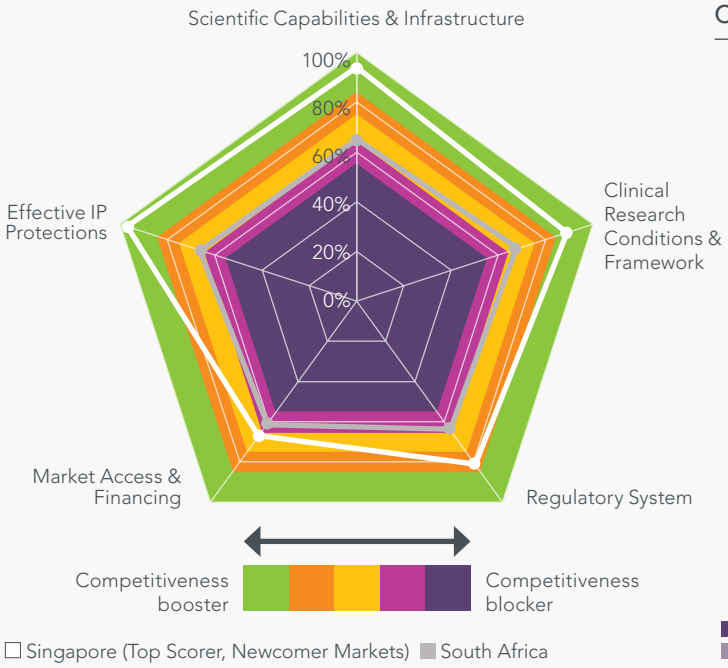
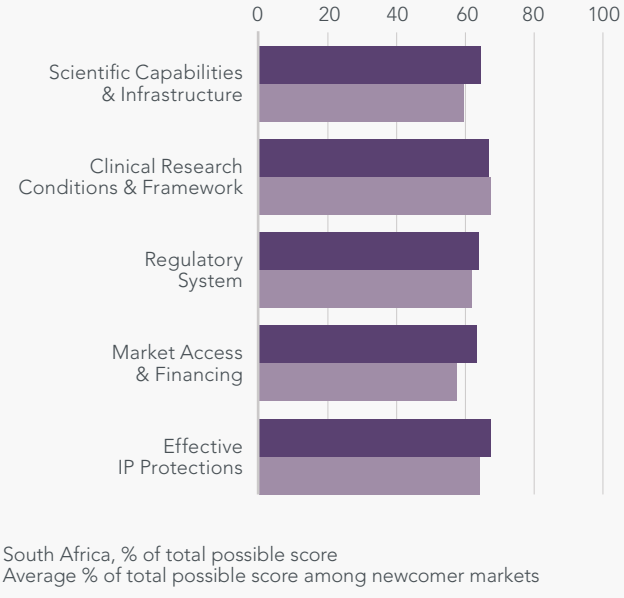


Comparison to Newcomer Markets



BCI Results In Depth: What helps and what hinders South Africa's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Incremental improvements to the science base (including government commitments to double R&D spending) are welcome, though still remain limited to certain areas.
- ✘ Collaboration between academia and industry requires much greater emphasis.

Clinical Research Conditions & Framework

- ✔ Compliance with global clinical research standards and growth of the CRO industry are seen as relative strengths.
- ✘ Approval delays hinder greater clinical trial intensity.

The Regulatory System

- ✘ Market authorization delays (3-4 years at present) continue to be cited as a major concern, but are expected to improve under the forthcoming independent drug regulatory agency, SAHPRA.
- ✔ Compliance with quality assurance standards and pharmacovigilance frameworks is considered to be relatively good.

Market Access & Financing

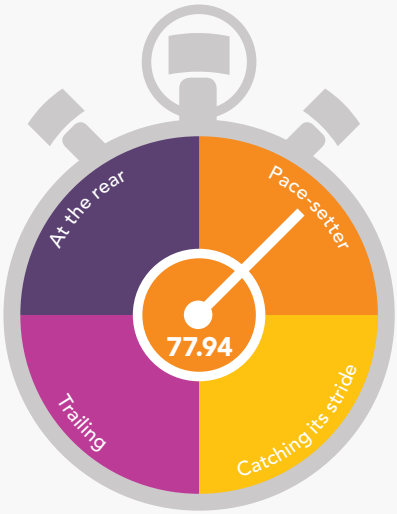
- ✘ Though perceived as somewhat less problematic, external reference pricing system and price caps are still viewed as limiting the market's competitiveness significantly.
- ✘ Barriers to market access are identified via the procurement system due to prioritization of cost over value and preferential treatment to local companies.

Effective Intellectual Property Protections

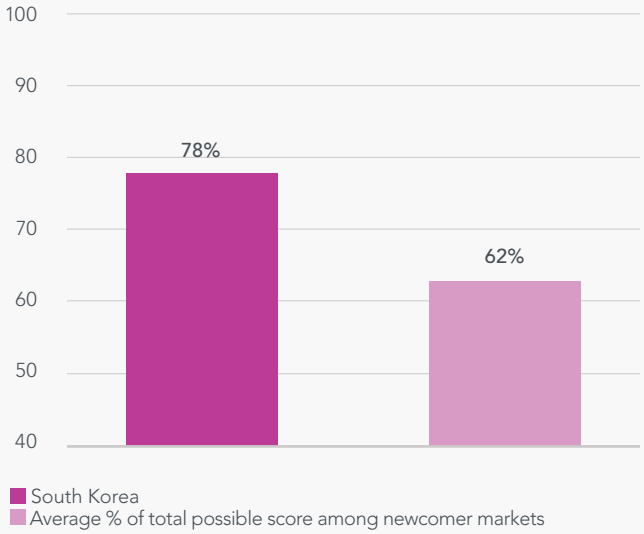
- ✘ Gaps in biopharmaceutical IP rights (including regulatory data protection and patent term extension) erode investors' confidence in the market.
- ✘ Draft patent amendments restricting biopharmaceutical patents further exacerbate uncertainty over IP.

SOUTH KOREA

BCI Survey 2016 – Overall Scores



Comparison to Newcomer Markets



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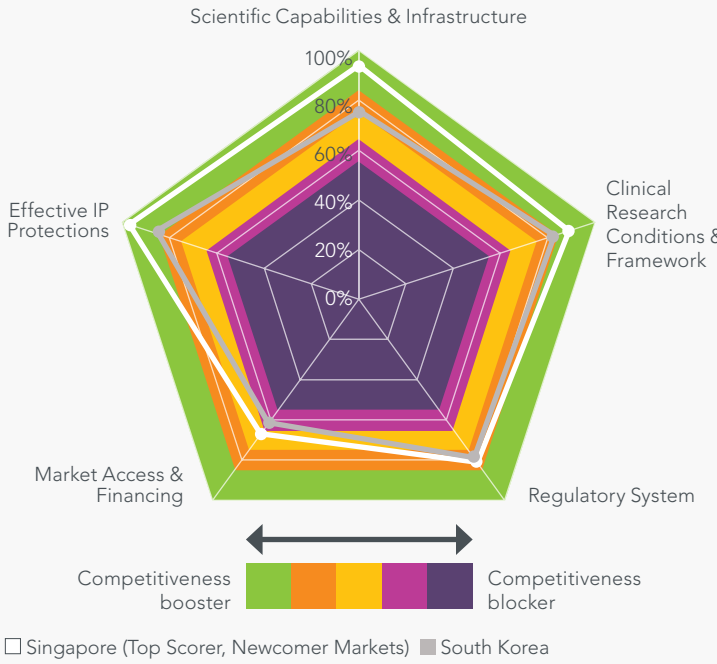

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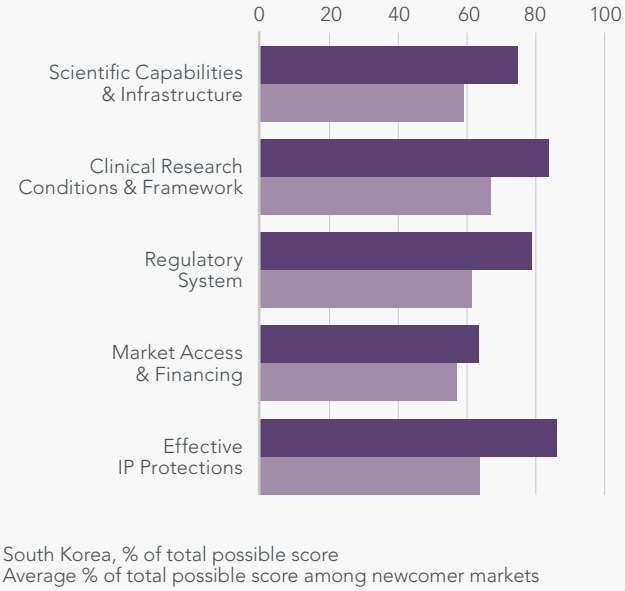


BCI Results In Depth: What helps and what hinders South Korea's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ The biomedical science base is considered to be relatively strong (with biosimilars identified as a key growth area).
- ✔ Local/multinational industry collaboration is seen as improving (e.g. Hanmi Pharma and Samsung Biologics), yet there is still a ways to go (including inadequate platforms and administrative support).

Clinical Research Conditions & Framework

- ✔ Clinical research capabilities (including staff, infrastructure and standards) are viewed positively.
- ✘ Timeframe for trial approval is an area that could be further enhanced in the eyes of executives.

The Regulatory System

- ✔ The regulatory environment is viewed as relatively strong, including capacity to review biopharmaceutical products and compliance with international standards of quality control.
- ✘ Regulatory delays are noted (particularly where local clinical trials are not available).

Market Access & Financing

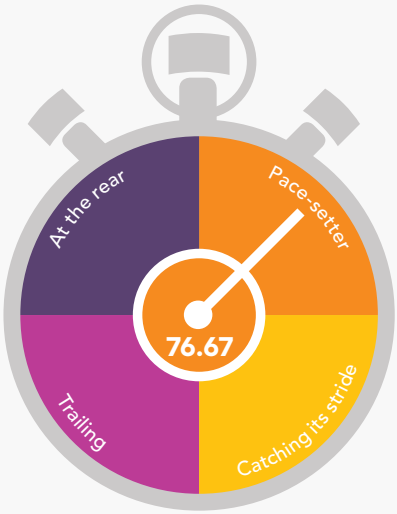
- ✘ What are perceived as fairly stringent price controls are imposed on innovative drugs, based primarily on cost.
- ✘ Executives note that greater transparency is needed, particularly for pricing of local versus imported innovative products.

Effective Intellectual Property Protections

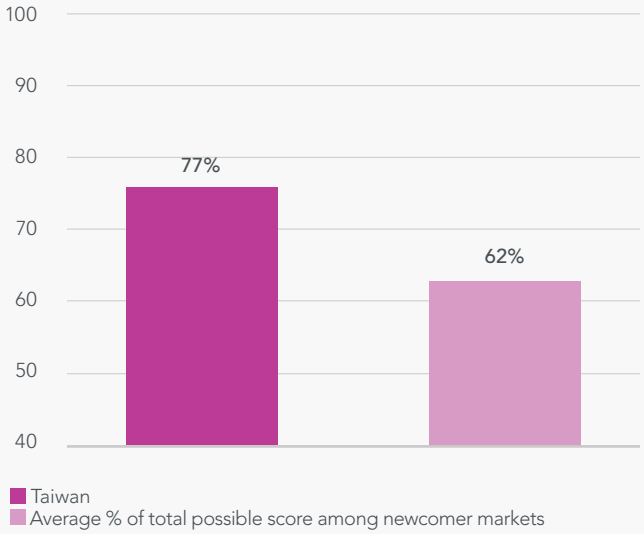
- ✔ Overall, a relatively strong biopharmaceutical IP environment is seen as being in place.
- ✘ Some challenges exist around patent linkage (including related to amendment of claims and uncertainty regarding remedies).

TAIWAN

BCI Survey 2016 – Overall Scores



Comparison to Newcomer Markets



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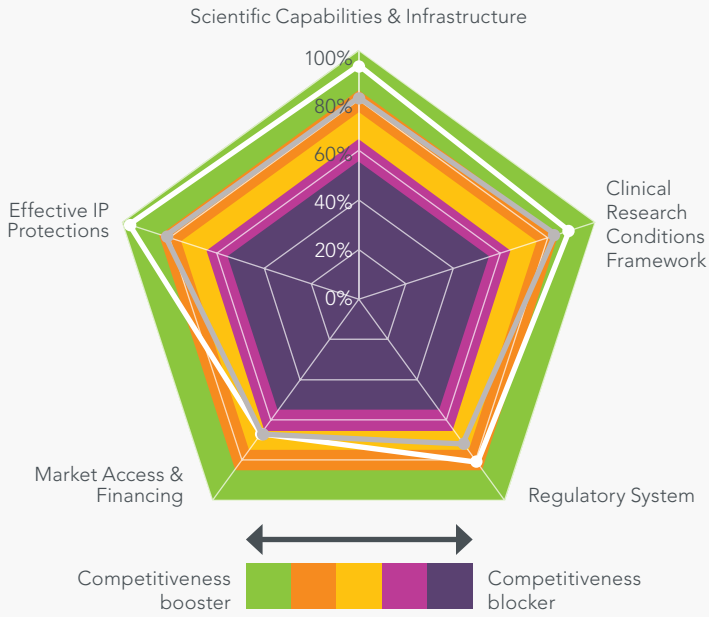
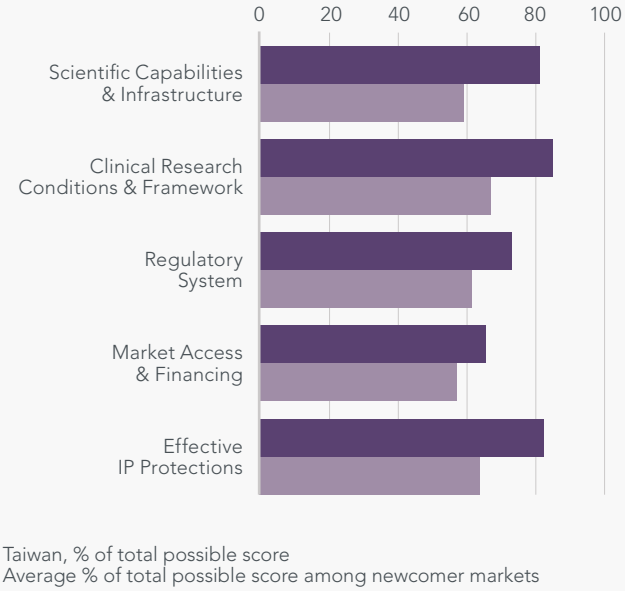


Comparison to Newcomer Markets



BCI Results In Depth: What helps and what hinders Taiwan's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Efforts to strengthen the science base/ private sector R&D into biopharmaceuticals within wider development plans are welcome, but require implementation under new administration.
- ✔ Academia-industry collaboration is seen as occurring frequently, with room for growth.

Clinical Research Conditions & Framework

- ✔ Executives cite broadly supportive clinical research conditions, with some limitations in the ability to recruit volunteers.
- ✔ Clinical research capacity among hospitals and CROs is considered to be high.

The Regulatory System

- ✔ The quality of drug review and approval is seen as generally good, though at times inconsistent.
- ✘ Long approval timelines (due to inadequate resources and a high rate of turnover at the drug regulator, CDE) act as a deterrent for innovators.

Market Access & Financing

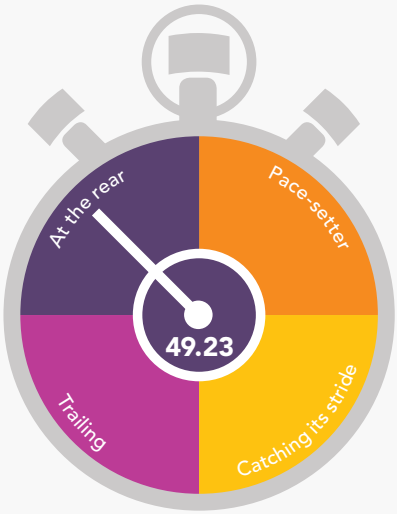
- ✘ Payers are seen as primarily focusing on cost, leading to delays and gaps in market access.
- ✔ Executives note that the public reimbursement framework is relatively comprehensive, with some gaps.

Effective Intellectual Property Protections

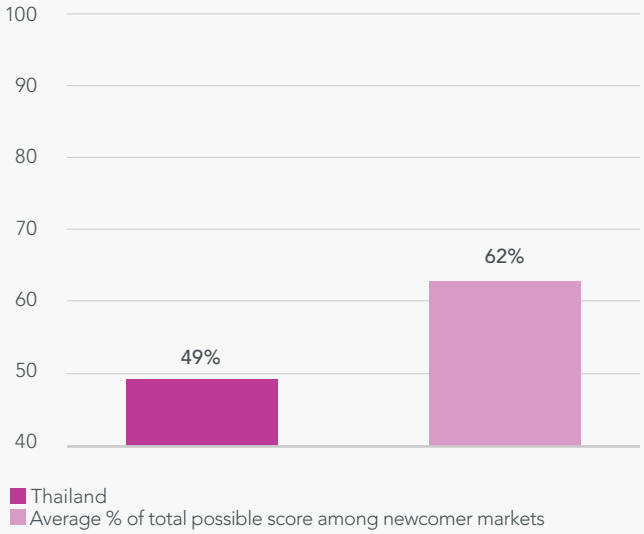
- ✔ The biopharmaceutical IP environment is generally viewed as relatively strong.
- ✘ Executives cite some gaps in biopharmaceutical patent enforcement (though efforts to improve it are ongoing).

THAILAND

BCI Survey 2016 – Overall Scores



Comparison to Newcomer Markets



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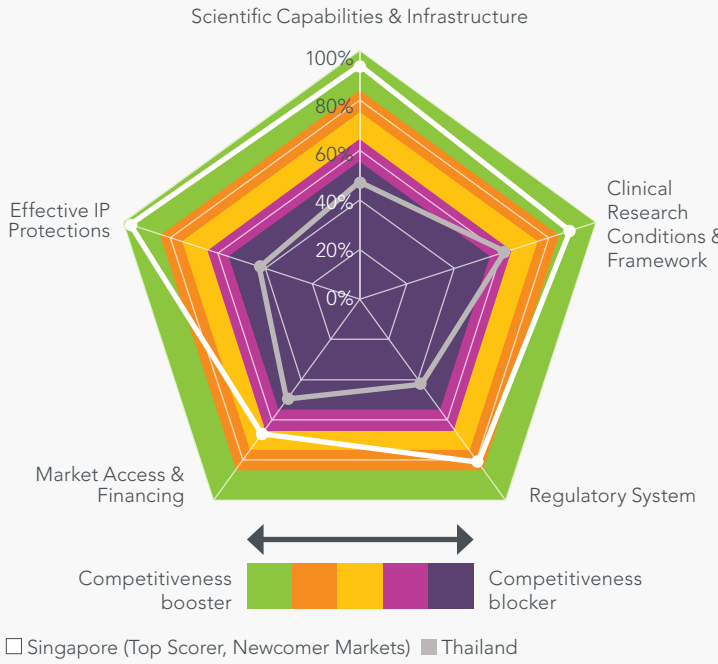
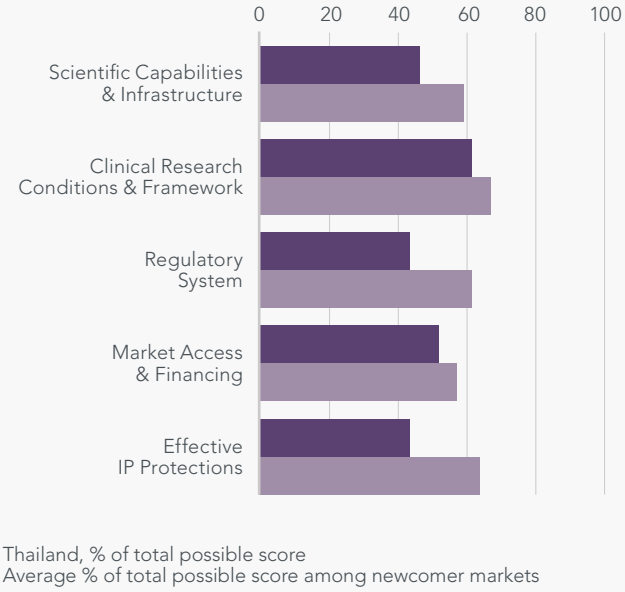


Comparison to Newcomer Markets



BCI Results In Depth: What helps and what hinders Thailand's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ The science base is viewed as small but present.
- ✘ Thailand is seen as lacking an adequate budget and incentives for scaling up and commercializing R&D.

Clinical Research Conditions & Framework

- ✔ Clinical trial conditions are considered to be relatively supportive (e.g. compared to rest of region).
- ✘ Significant delays exist around approval of clinical trials.

The Regulatory System

- ✘ Proposal to link registration with price and IP is viewed as discriminating against innovative firms.
- ✘ Regulatory delays are considered to be significant, undermining attractiveness.
- ✔ Pharmaceutical quality controls and pharmacovigilance are seen as improving.

Market Access & Financing

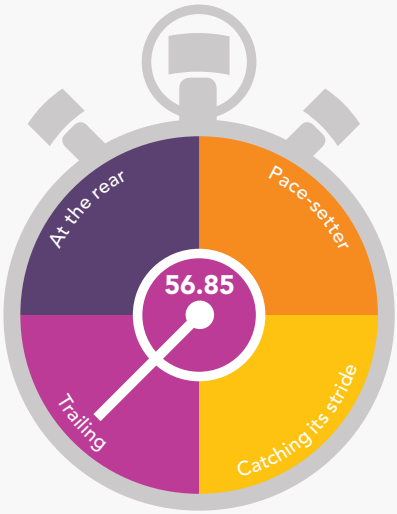
- ✘ Executives note that the manner in which the publicly-owned pharmaceutical company GPO acts as the main domestic supplier hinders market access.
- ✘ Pricing decisions are considered to be non-transparent and lead to highly restrictive price controls.

Effective Intellectual Property Protections

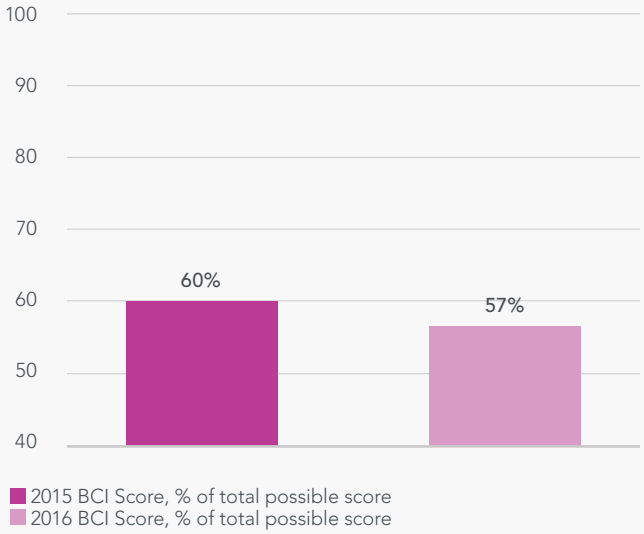
- ✘ Overall, IP protection and enforcement are viewed as being weak.
- ✘ A history of issuing compulsory licenses for medicines and ongoing discussion around their further use create substantial uncertainty for innovators.

TURKEY

BCI Survey 2016 – Overall Scores



2015 vs. 2016



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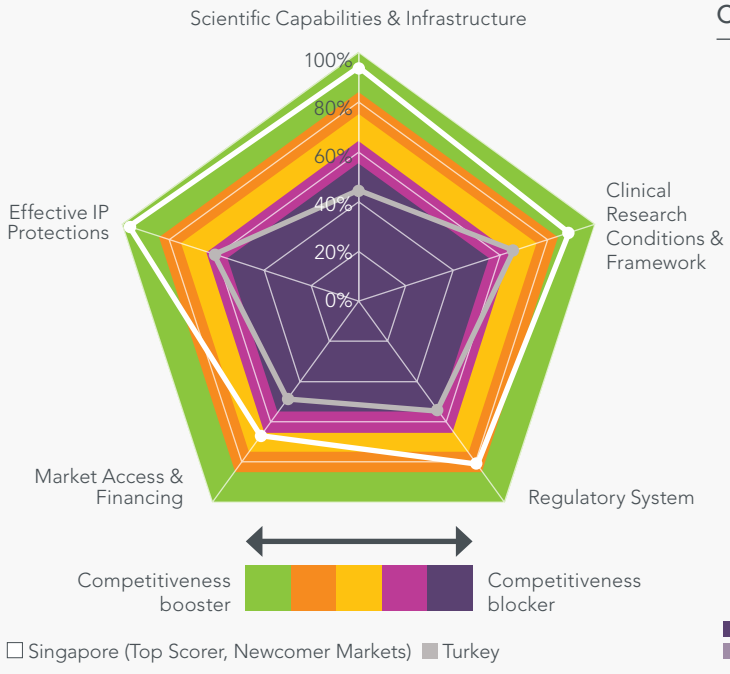
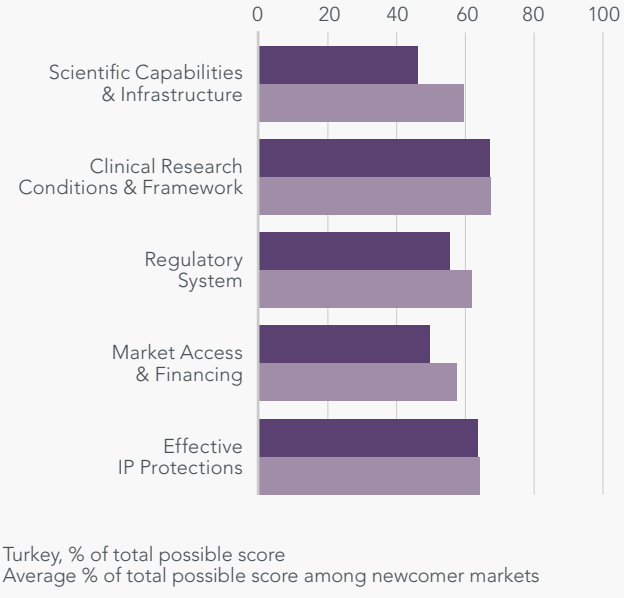


Comparison to Newcomer Markets



BCI Results In Depth: What helps and what hinders Turkey's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✘ R&D capabilities continue to be viewed as limited and collaborative R&D as remaining small in scale.
- ✔ New spending and incentives under the pharmaceutical strategy and recent bioclusters/ research centers are largely seen as positive developments.

Clinical Research Conditions & Framework

- ✘ Clinical trial approval delays hold back investment in R&D.
- ✔ Hospitals and local CROs are viewed as having adequate capacity for clinical research.

The Regulatory System

- ✘ Regulatory delays (including due to difficult GMP rules) are still viewed as a significant challenge, with knock-on effects in other areas (such as market access and IP).
- ✘ Executives report remaining gaps in regulators' capacity for drug review (though the quality control framework specifically is seen as satisfactory).

Market Access & Financing

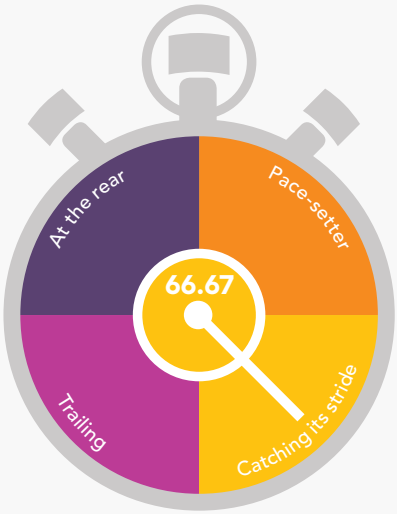
- ✘ Concerns over localization and potential de-listing of foreign products is present under a new government action plan.
- ✔ Special access programs are welcome but are currently very limited (and are seen as prioritizing local products).

Effective Intellectual Property Protections

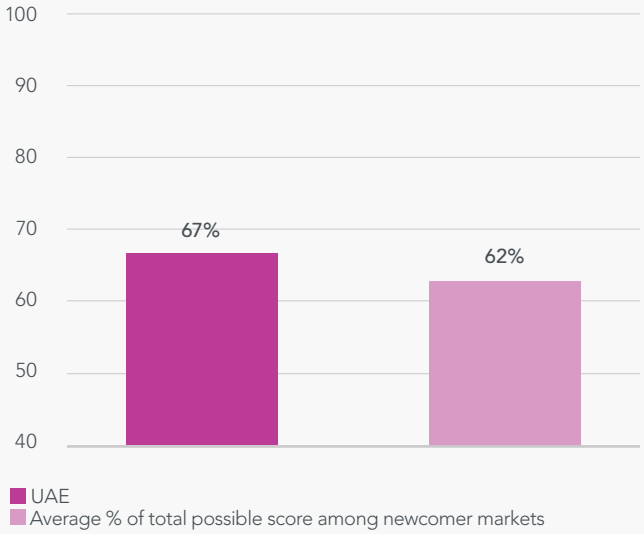
- ✘ Draft IP amendments are perceived as mixed, with potential for further deterioration.
- ✘ The RDP framework and erosion of that framework due to registration delays still represents a barrier.

UAE

BCI Survey 2016 – Overall Scores



Comparison to Newcomer Markets



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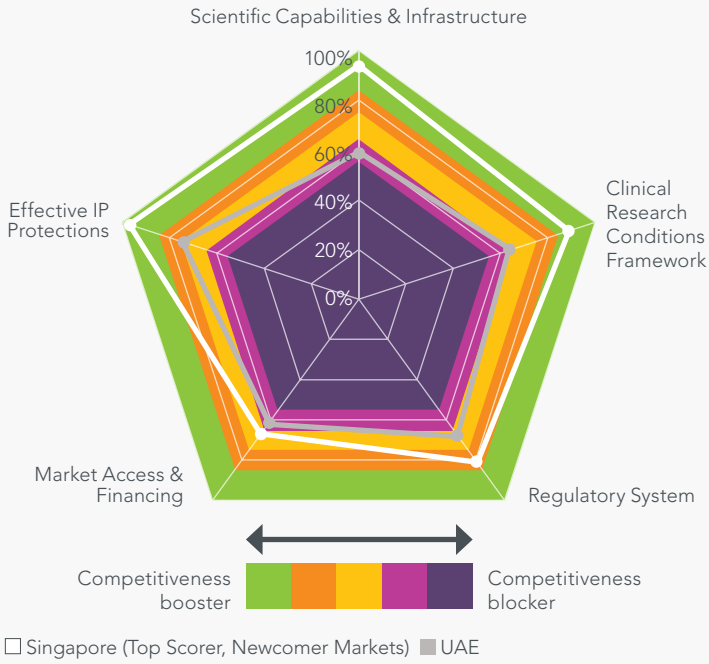
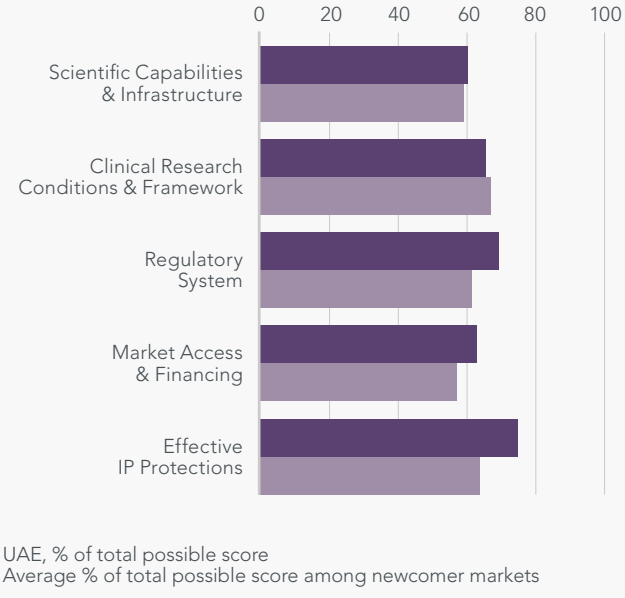


Comparison to Newcomer Markets



BCI Results In Depth: What helps and what hinders the UAE's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✘ Biopharmaceutical R&D capabilities are considered to be at a basic level.
- ✔ Efforts to strengthen the science base and resources available for R&D, including as part of the 2015 Science, Technology & Innovation Policy, are considered important steps forward.

Clinical Research Conditions & Framework

- ✔ Compliance with global clinical standards among clinical research organizations and hospitals is considered to be fairly high.
- ✘ Substantial delays in obtaining clinical trial approval are cited as a key barrier to clinical research.

The Regulatory System

- ✘ Capacity for regulatory approval is perceived to be reasonable, with some room for improvement.
- ✔ Quality control and pharmacovigilance frameworks are viewed as being relatively effective.

Market Access & Financing

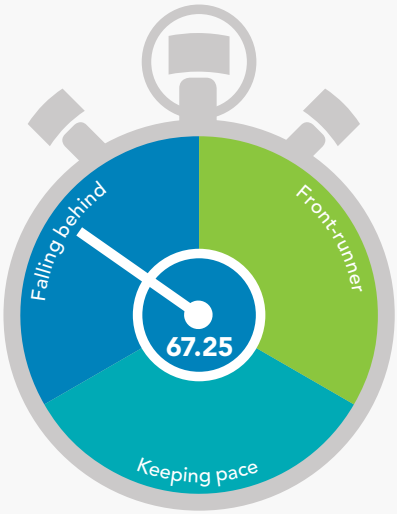
- ✔ Public reimbursement of medicines is seen as generally strong.
- ✘ Executives cite price controls on innovative biopharmaceuticals as a key challenge.
- ✔ Fairly supportive tax conditions, including through health-related "free zones", are seen as supporting investment.

Effective Intellectual Property Protections

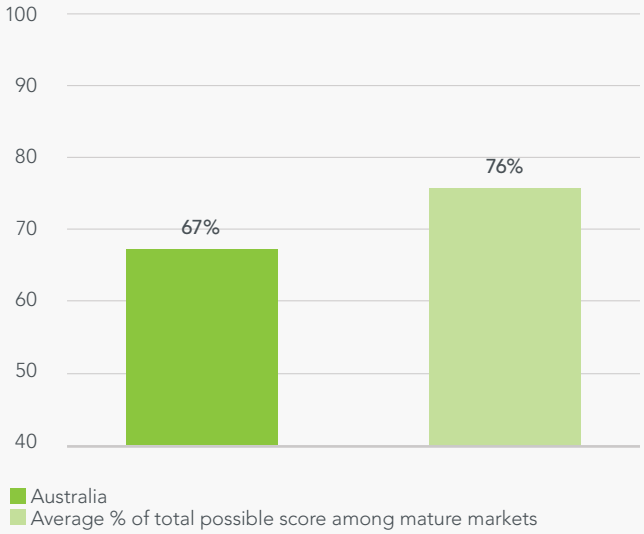
- ✔ Biopharmaceutical IP protection are viewed as relatively effective, with key exceptions.
- ✘ Executives cite some gaps in enforcement of IP rights through the court system as well as availability of RDP.

AUSTRALIA

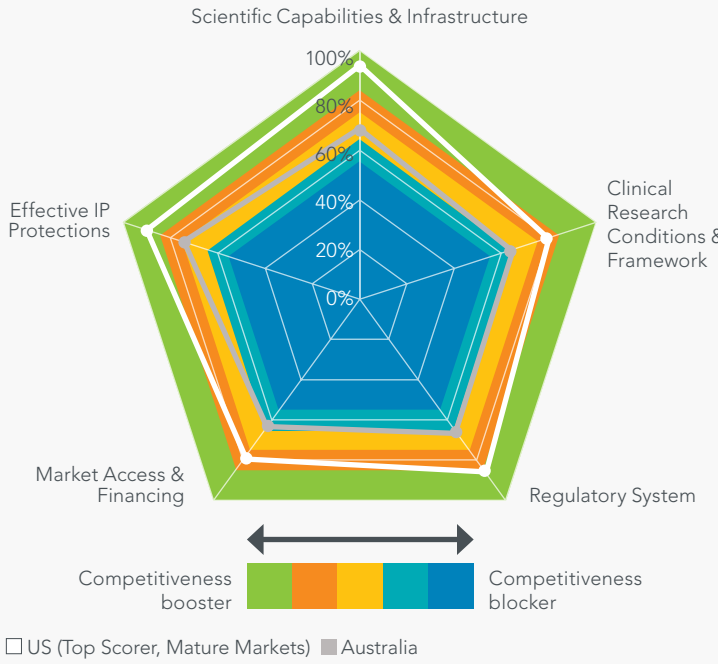
BCI Survey 2016 – Overall Scores



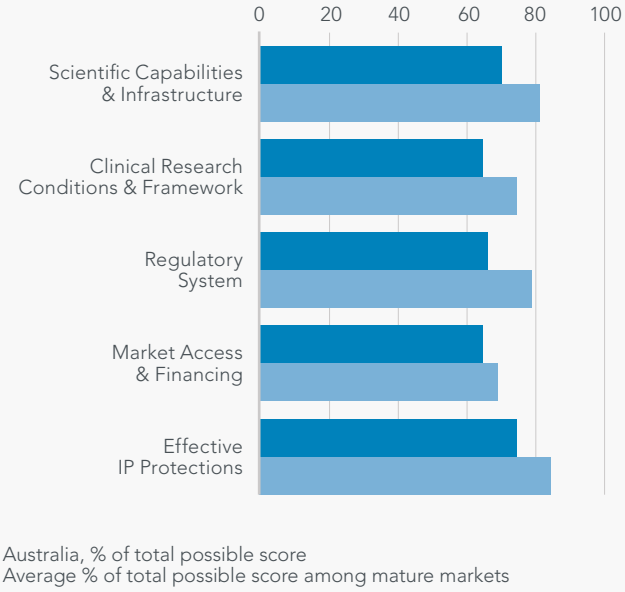
Comparison to Mature Markets



BCI Survey 2016 – Category Scores



Comparison to Mature Markets



BCI Results In Depth: What helps and what hinders Australia's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Executives find the level of scientific research to be satisfactory.
- ✘ They cite missed opportunities and lack of incentives for industry collaboration and translational R&D.

Clinical Research Conditions & Framework

- ✔ Clinical research capabilities are viewed as relatively strong.
- ✘ Costs and approval times for clinical trials are seen as impediments to investment, though a new initiative to streamline ethics committee approval is welcome.

The Regulatory System

- ✘ Ranked as one of the most challenging among mature markets in terms of regulatory delays.
- ✔ Recent government review of timelines and consideration of a fast-track pathway for approval of innovative drugs is seen as encouraging.

Market Access & Financing

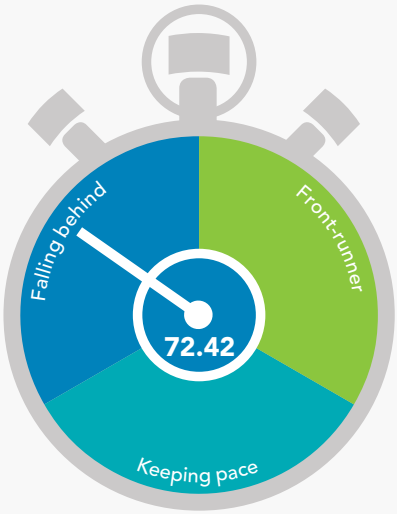
- ✘ Price controls are viewed as highly restrictive, with a heavy focus on price and cost (including recent price cuts) undermining competitiveness.
- ✔ Executives recognize the presence of R&D tax incentives, but say more are needed.

Effective Intellectual Property Protections

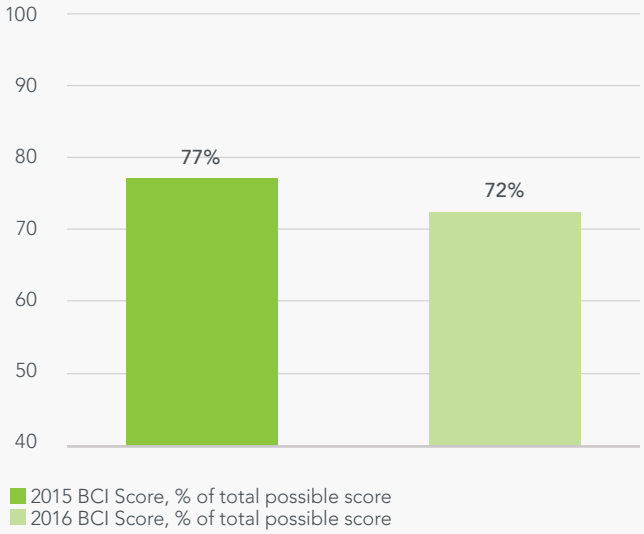
- ✘ RDP is considered to be out of sync with other developed countries, eroding market attractiveness.
- ✘ The practice of requiring damages from originator companies (and other methods sought to address "evergreening" reinforced by recent policy discussions on IP) introduces significant uncertainty and risks to R&D investment.

CANADA

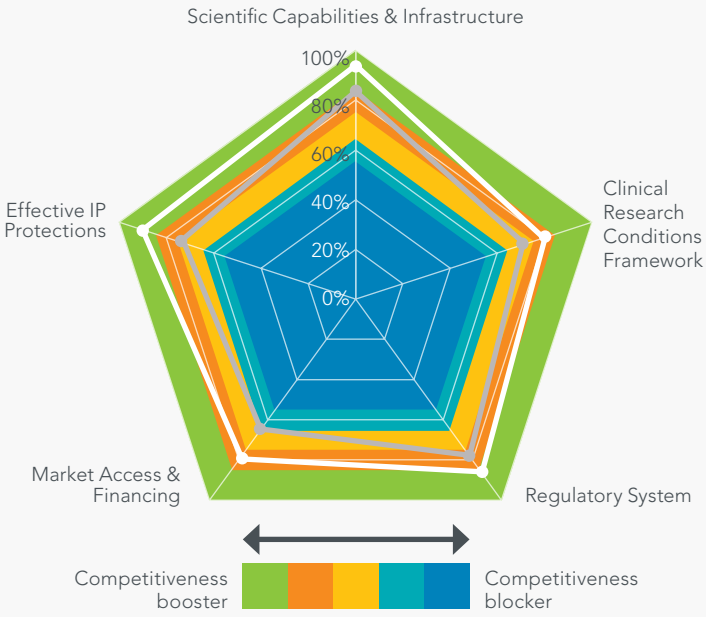
BCI Survey 2016 – Overall Scores



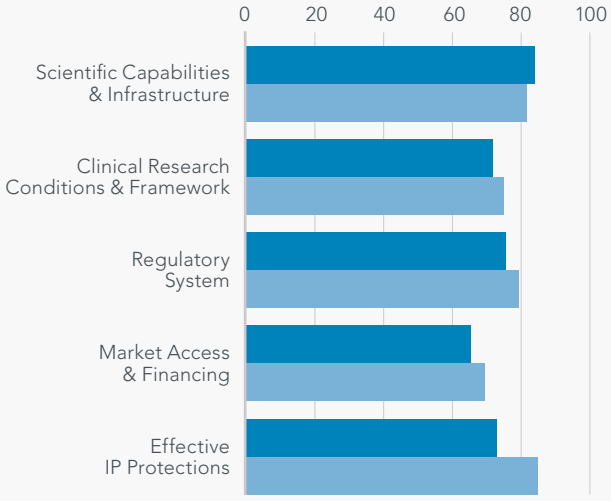
2015 vs. 2016



BCI Survey 2016 – Category Scores



Comparison to Mature Markets



BCI Results In Depth: What helps and what hinders Canada's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Government funding targeted toward enhancing scientific research (including the 2016 Budget and the Innovation Agenda) supports what is seen as a high quality science base.
- ✘ Executives indicate that some barriers exist between academia and the multinational biopharmaceutical industry, though the Trudeau Government's announced efforts to strengthen commercialization of research represents a potential step forward.

Clinical Research Conditions & Framework

- ✔ Efforts to streamline clinical trial regulations and processes on top of strong clinical research capacity and specific R&D tax benefits are cited as enabling factors.
- ✘ Nevertheless, at present some inconsistency and delays in trial approval as well as financial costs of clinical research overall are noted as setting Canada back in its attractiveness for investment.

The Regulatory System

- ✔ Drug review and approval capacity is cited as high overall, with the biosimilar pathway in particular recognized as being strong in global comparison.
- ✘ Executives raise concerns regarding regulatory delays and lack of fast-track pathways for priority drugs, although efforts to develop a special pathway for orphan drugs are welcome.

Market Access & Financing

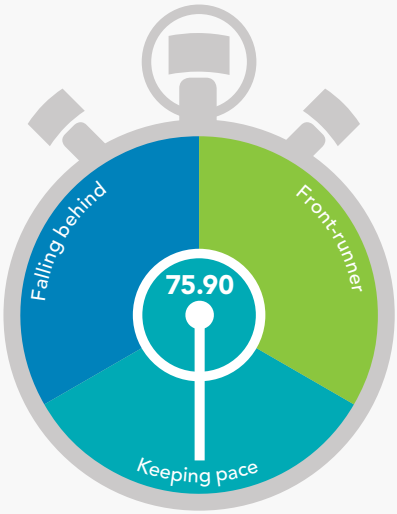
- ✘ What is perceived as restrictive pricing, as well as delays and limits to public reimbursement and procurement, of new medicines (particularly biologics) are seen as hindering the investment environment.
- ✔ Tax conditions are viewed as a positive incentive for investment.

Effective Intellectual Property Protections

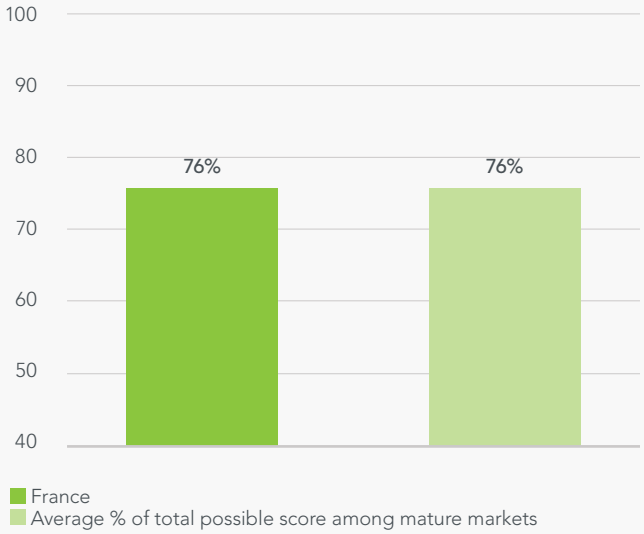
- ✘ Biopharmaceutical IP protection overall is cited as continuing to negatively affect Canada's attractiveness for R&D investment compared to other mature markets.
- ✘ Executives raise concerns over the heightened patent utility requirement and deviation from international standards, as well as legislation allowing for release of confidential business information.
- ✔ Potential introduction of patent term restoration under the CETA Agreement with the EU and the TPP Agreement is expected to help strengthen the IP regime in certain respects.

FRANCE

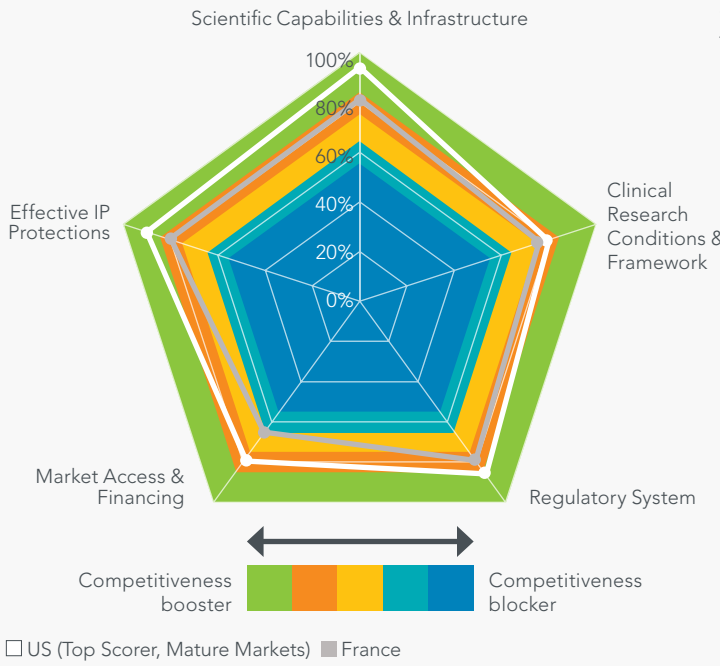
BCI Survey 2016 – Overall Scores



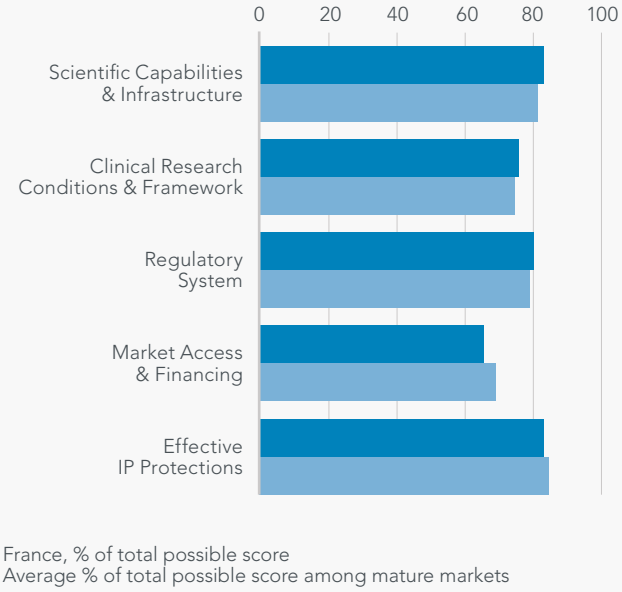
Comparison to Mature Markets



BCI Survey 2016 – Category Scores



Comparison to Mature Markets



BCI Results In Depth: What helps and what hinders France's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Executives view research capabilities as adequate by international comparison.
- ✔ A fairly strong level of cooperation between public life science research entities and the research-based industry is noted, with some exceptions.

Clinical Research Conditions & Framework

- ✔ Clinical research capacity among hospitals is considered to support France's competitiveness, but some limitations are identified in the ability to recruit participants.
- ✘ Clinical trial approval delays are seen as a roadblock, though recent measures to simplify procedures (such as standardization of contracts with public hospitals) are welcome.

The Regulatory System

- ✔ Drug approval capacity is considered to be satisfactory.
- ✘ Executives view long approval times and lack of effective fast-track pathways for innovative products as a significant barrier to investment.

Market Access & Financing

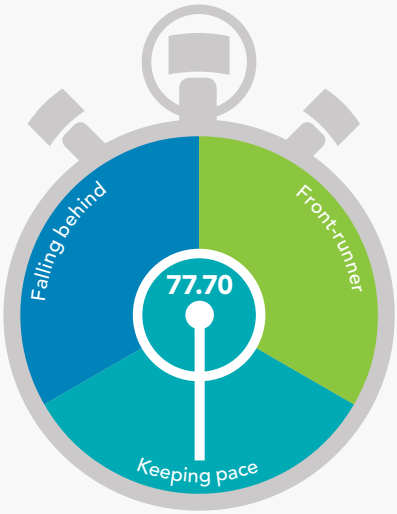
- ✘ Executives consider France's competitiveness for R&D investment to be held back considerably by challenging market access and tax conditions and substantial time lags.
- ✘ The pricing and reimbursement system is seen as increasingly shaped by cost-containment measures (with less recognition of value) and reduction of special funds for reimbursement of innovative drugs.

Effective Intellectual Property Protections

- ✔ The biopharmaceutical IP environment is viewed as quite strong.
- ✔ The patenting process is regarded as satisfactory, with efforts to further streamline examination seen as encouraging.

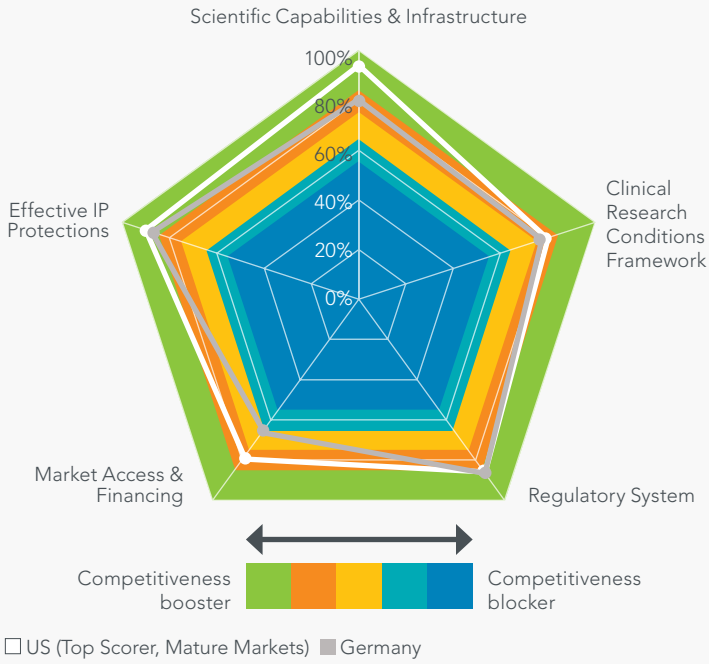
GERMANY

BCI Survey 2016 – Overall Scores

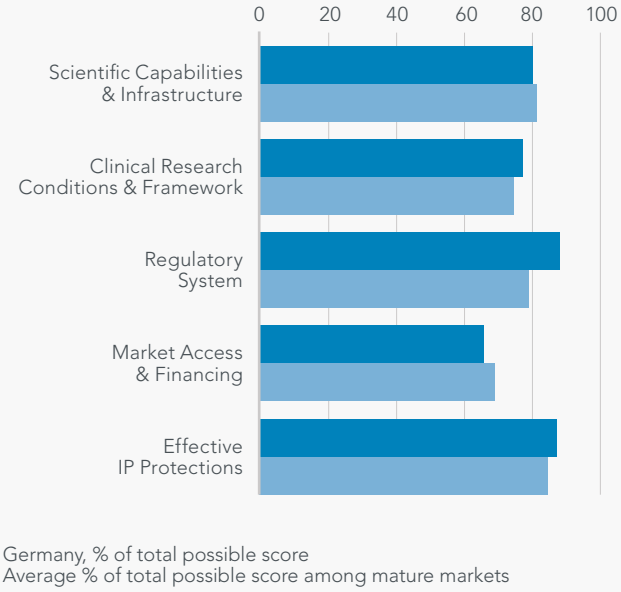


Comparison to Mature Markets

BCI Survey 2016 – Category Scores



Comparison to Mature Markets



BCI Results In Depth: What helps and what hinders Germany's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Scientific research capabilities, including in terms of cutting edge research fields, are perceived as a key strength.
- ✔ The level of collaborative R&D and commercialization is regarded as fairly strong, though some areas could be improved.

Clinical Research Conditions & Framework

- ✔ Executives view clinical research capacity as being of fairly high quality, although conducting clinical trials is seen as being relatively costly.
- ✘ Some delays in approval of clinical trials are identified.

The Regulatory System

- ✔ Drug approval capacity is considered to be excellent.
- ✔ Executives view approval timelines as relatively satisfactory.

Market Access & Financing

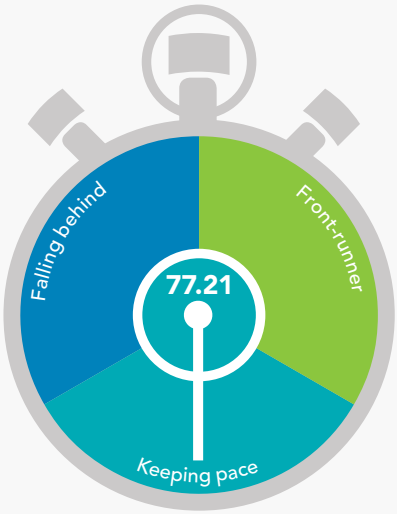
- ✘ Cost considerations are regarded as playing a significant role in pricing and reimbursement, with price discounts and reference pricing limiting market access.
- ✘ Tax conditions are also viewed as a barrier to investment in some respects.

Effective Intellectual Property Protections

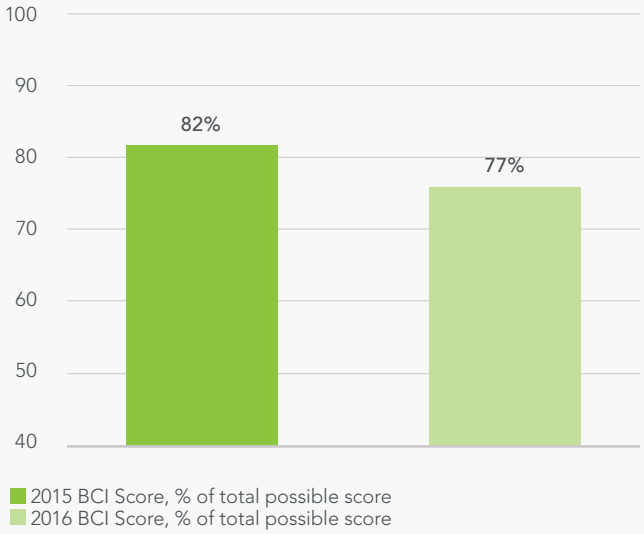
- ✔ The biopharmaceutical IP environment is viewed as strong.
- ✔ Availability of civil and criminal remedies for IP infringement is generally considered to be satisfactory.

IRELAND

BCI Survey 2016 – Overall Scores



2015 vs. 2016



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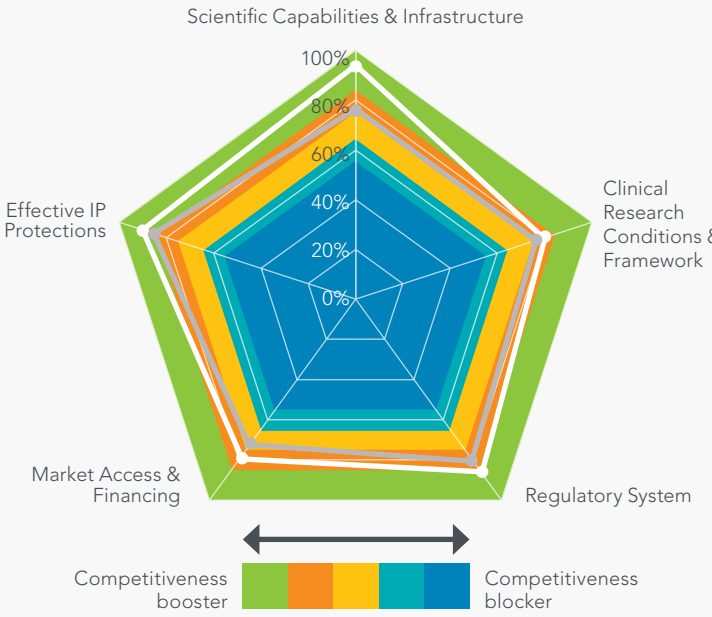
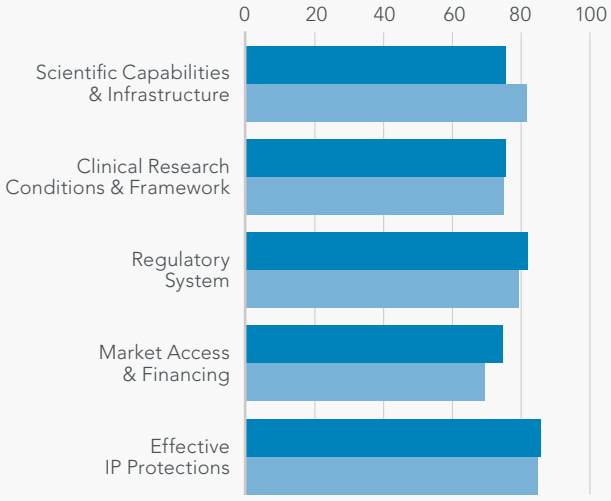


Comparison to Mature Markets



BCI Results In Depth: What helps and what hinders Ireland's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Biopharmaceutical R&D capabilities are viewed as being relatively strong, with some room for improvement in terms of rare diseases and personalized medicine.
- ✔ Executives cite a fairly high degree of academic-industry collaboration, which the government has pledged to develop even further.

Clinical Research Conditions & Framework

- ✔ Clinical research conditions are regarded as competitive, supported by research networks and a coordinating entity for multicenter trials.
- ✘ Executives consider that the environment could be enhanced through further streamlining approval procedures and reducing costs.

The Regulatory System

- ✔ The biopharmaceutical regulatory system is seen as satisfactory, with room for improvement in terms of approval delays and availability of fast-track pathways for innovative drugs.
- ✔ New biosimilar guidelines are viewed as balanced and ensuring a high degree of quality control.

Market Access & Financing

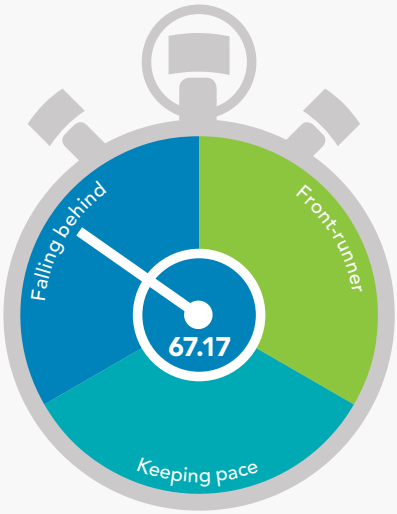
- ✘ Executives note an increasingly cost-driven approach to pricing and reimbursement that does not fully reflect the value of breakthrough treatments, though exceptions exist.
- ✔ Tax conditions are reported as supportive of biopharmaceutical investment.

Effective Intellectual Property Protections

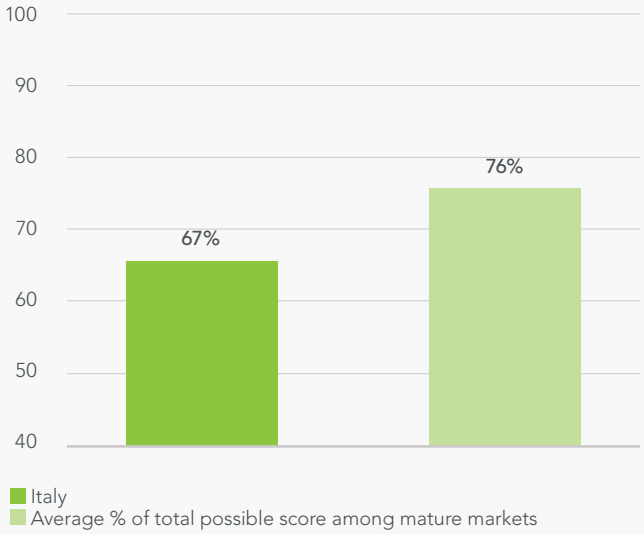
- ✔ Ireland's biopharmaceutical IP environment is generally regarded as effective and strong.
- ✔ IP enforcement is expected to be further enhanced once Ireland formally approves and begins participation in the European Unified Patent Court.

ITALY

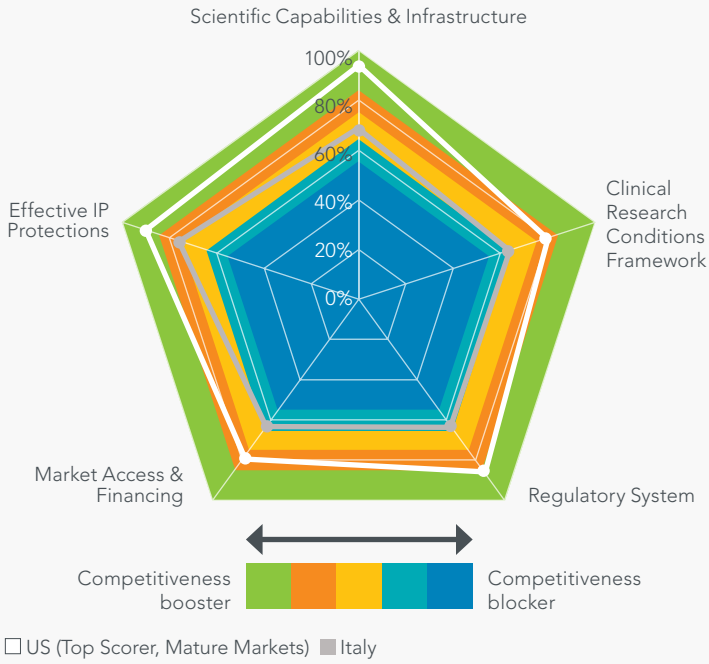
BCI Survey 2016 – Overall Scores



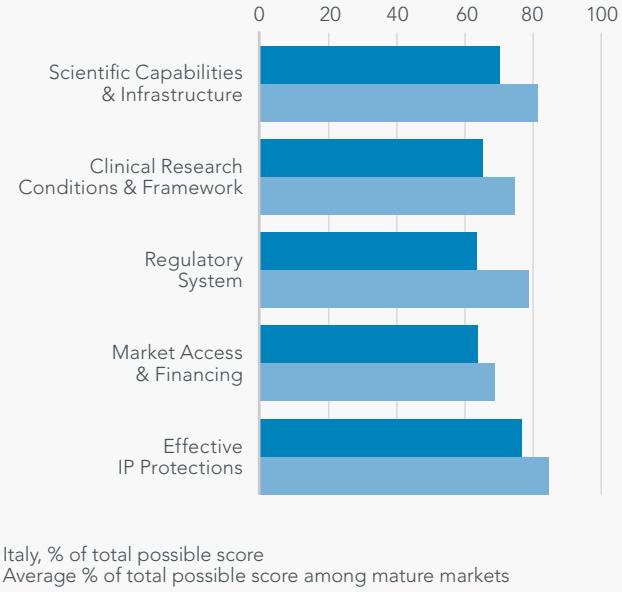
Comparison to Mature Markets



BCI Survey 2016 – Category Scores



Comparison to Mature Markets



BCI Results In Depth: What helps and what hinders Italy's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Executives cite an adequate science base and recent R&D tax incentives as some of the advantages of Italy's R&D environment, although important regional disparities in available infrastructure and incentives exist.
- ✘ Overall, however, the innovation system is seen as being hindered by bureaucratic hurdles and a weak connection between researchers and the biopharmaceutical industry.

Clinical Research Conditions & Framework

- ✔ Executives note a relatively good ability to recruit participants and growing capabilities in early phase trials as strengths of the clinical research environment.
- ✘ Long approval delays, mainly due to a complex ethics review system, as well as a heavy fiscal burden for clinical research are reported as key roadblocks.

The Regulatory System

- ✔ Drug review capacity, supported by EMA, is viewed as fairly strong.
- ✘ A major hurdle exists around approval delays and lack of fast-track pathways for priority treatments.

Market Access & Financing

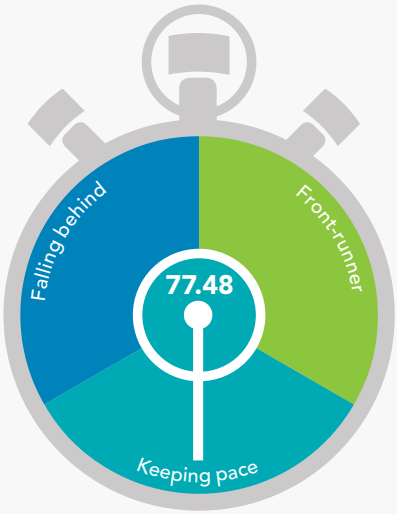
- ✘ The pricing and reimbursement environment is generally considered to be difficult vis-à-vis innovative treatments, with what are perceived as very stringent price controls and caps on hospital spending presenting particular challenges.
- ✘ Tax conditions are viewed as another barrier, involving uncertainty and lacking special incentives for R&D.

Effective Intellectual Property Protections

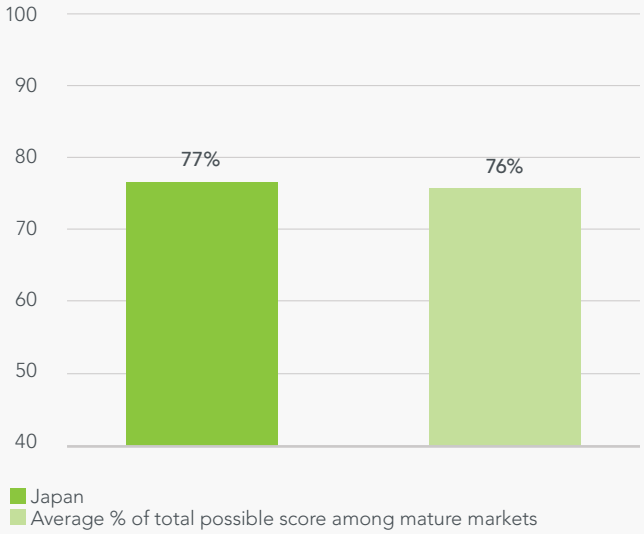
- ✔ Biopharmaceutical IP protection is viewed as increasingly favorable, partly as a result of ongoing compliance with EU standards.
- ✘ Enforcement of IP rights is regarded as improving, but with some remaining gaps and inconsistencies.

JAPAN

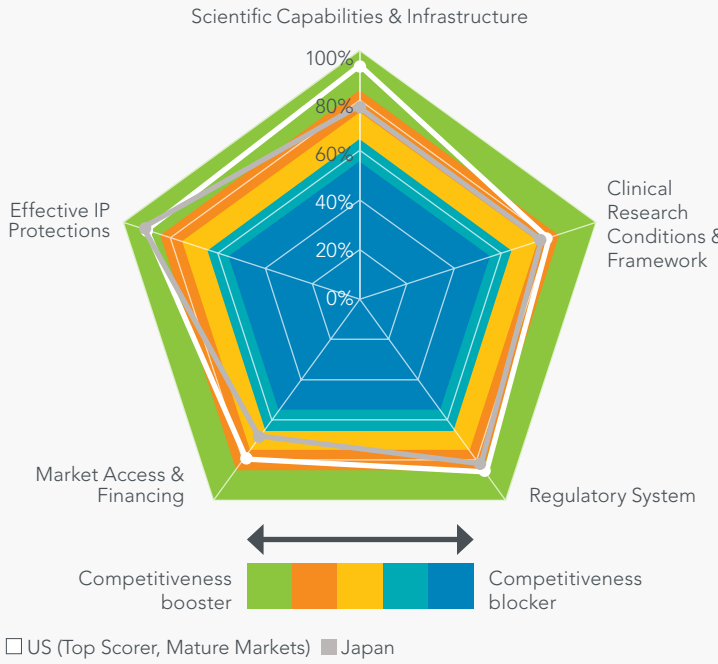
BCI Survey 2016 – Overall Scores



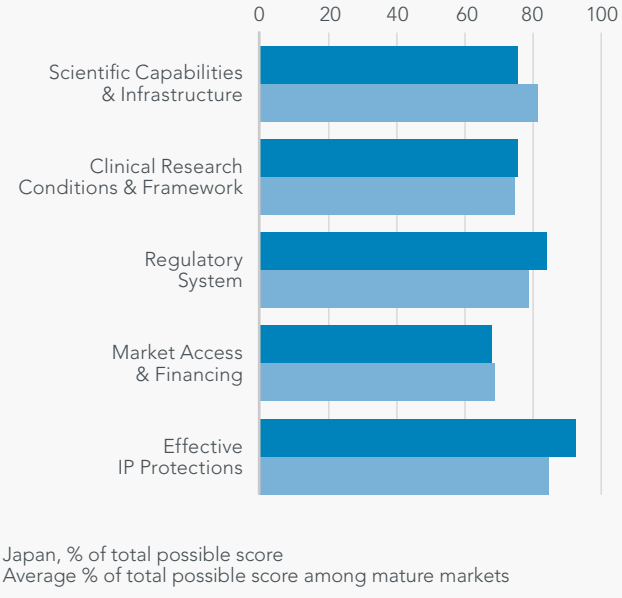
Comparison to Mature Markets



BCI Survey 2016 – Category Scores



Comparison to Mature Markets



BCI Results In Depth: What helps and what hinders Japan's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Biopharmaceutical R&D capabilities are viewed as adequate, with some gaps existing around new disease areas and personalized medicines.
- ✘ Executives note that room for improvement exists in industry-academic collaboration, but welcome efforts by the government to support greater collaboration (including under the recent Basic Plan and Comprehensive Strategy).

Clinical Research Conditions & Framework

- ✔ Clinical research capacity is viewed as satisfactory, with increased prioritization by the government through, for instance, the recent launch of a clinical research coordination agency and a clinical innovation network to improve data sharing.
- ✘ High costs and hurdles to recruiting participants are seen as key barriers to investment in clinical trials.

The Regulatory System

- ✔ The regulatory environment is seen as strong, with the drug regulator (PMDA) having strengthened its capacity and reduced approval delays.
- ✔ Efforts to streamline approval of new medicines in priority areas (for example, as part of the Sakigake Strategy) are welcome.

Market Access & Financing

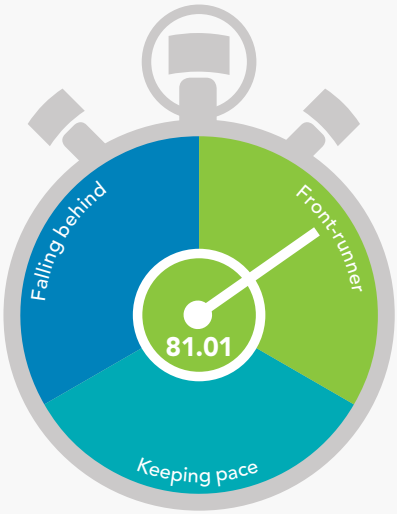
- ✘ The pricing and reimbursement environment is seen as mixed, with executives citing the possibility to secure adequate prices for innovative treatments in certain cases, but with general downward pressure on biopharmaceutical prices and some uncertainty around the pricing environment.
- ✘ Executives note that the tax framework displays gaps in terms of special incentives for biopharmaceutical R&D.

Effective Intellectual Property Protections

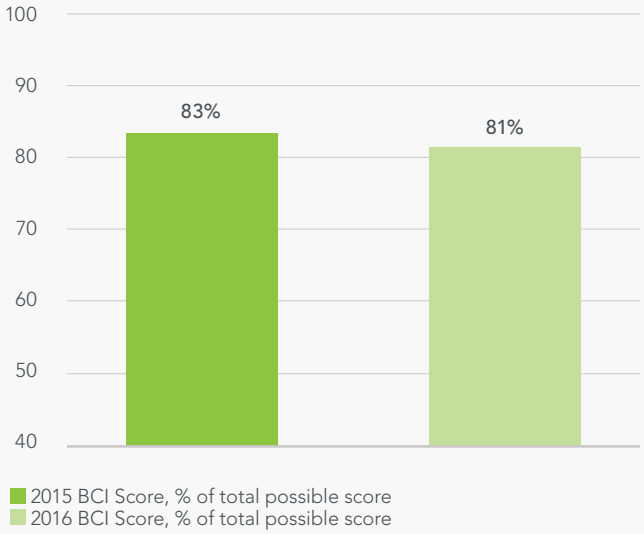
- ✔ Biopharmaceutical IP protection is considered to be very strong.
- ✔ Civil and criminal remedies for IP infringement are regarded as adequate.

SWITZERLAND

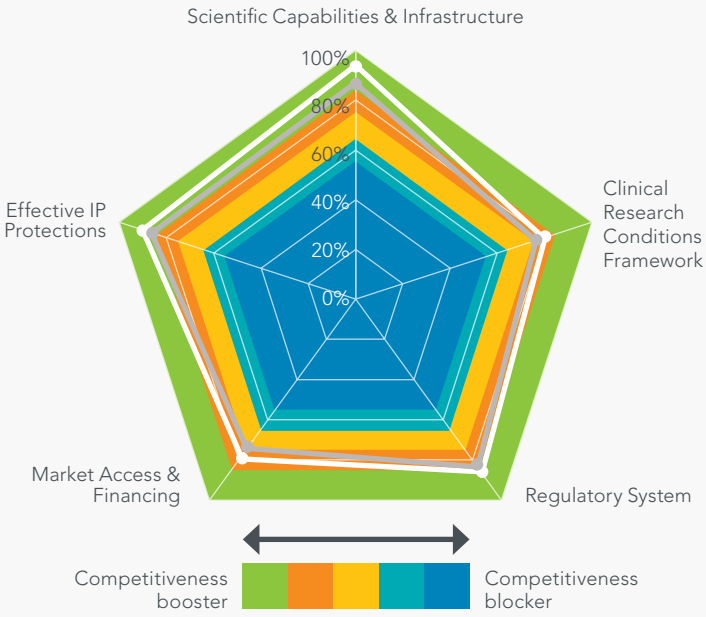
BCI Survey 2016 – Overall Scores



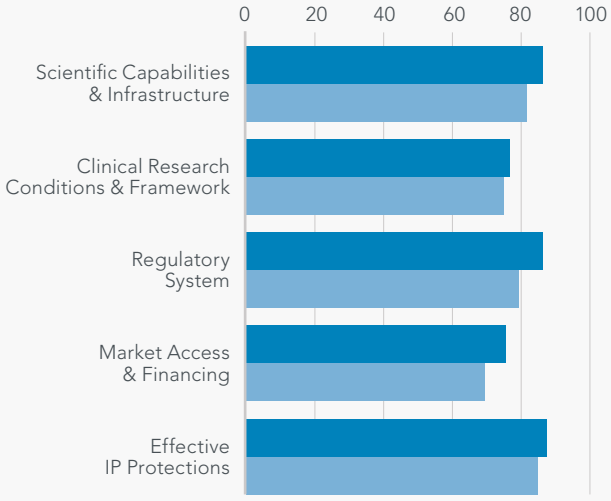
2015 vs. 2016



BCI Survey 2016 – Category Scores



Comparison to Mature Markets



BCI Results In Depth: What helps and what hinders Switzerland's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Executives regard biopharmaceutical R&D capabilities, including human capital and infrastructure, as top ranking.
- ✔ Collaboration between academic institutions and the private sector is viewed as robust, enhanced by the recent launch of several "innovation hubs" around local universities.

Clinical Research Conditions & Framework

- ✔ Executives cite a network of ready and capable hospitals as one key draw to investing in R&D in Switzerland.
- ✘ Though competitive, the clinical research environment is seen as losing some ground due to challenges around enrollment, costs and trial approval delays.

The Regulatory System

- ✔ The regulatory framework is viewed as strong, with a highly regarded drug regulatory agency.
- ✔ While executives note general delays in market authorization as a challenge, they cite the availability of fast-track pathways for certain drugs as supporting investment.

Market Access & Financing

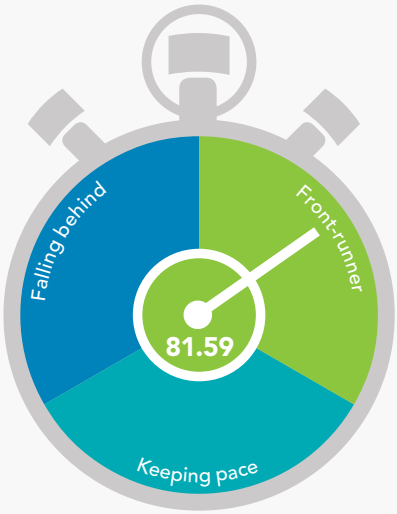
- ✘ Though executives indicate that adequate prices for innovative drugs are available in some instances, overall price controls are perceived as relatively stringent.
- ✔ Executives cite a supportive tax environment, and suggest it would be further strengthened through additional proposed R&D tax incentives.

Effective Intellectual Property Protections

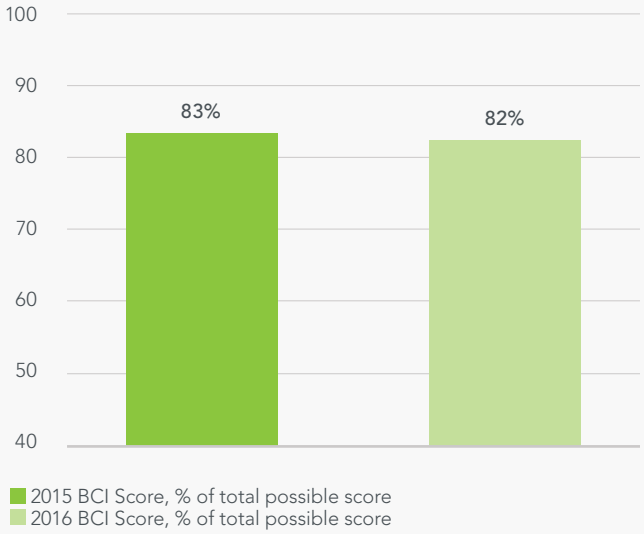
- ✔ Executive note that strong biopharmaceutical IP protection is in place.
- ✔ Civil remedies and criminal penalties are generally regarded as deterrent.

UNITED KINGDOM

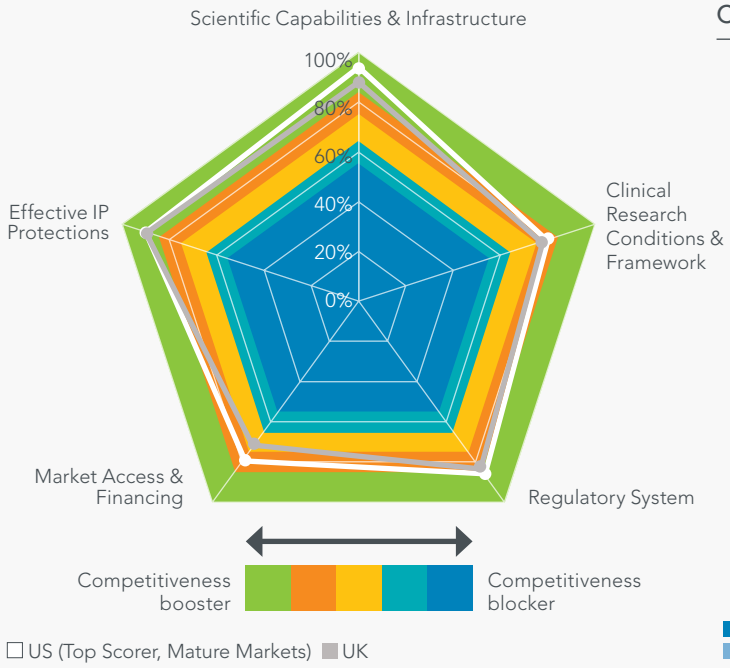
BCI Survey 2016 – Overall Scores*



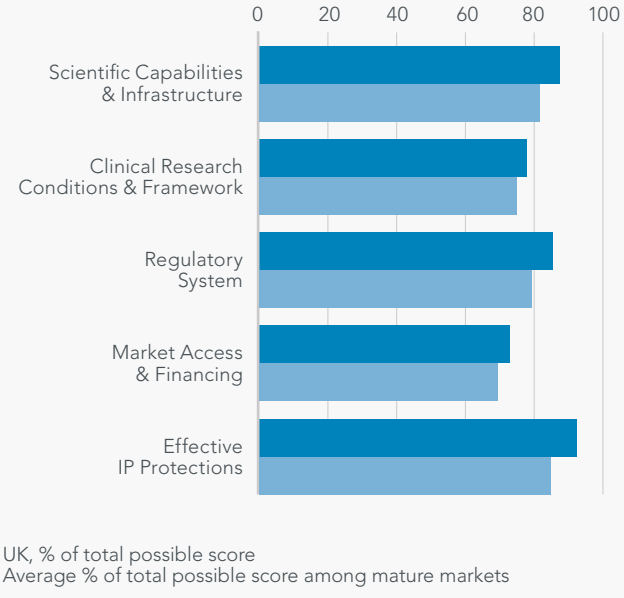
2015 vs. 2016



BCI Survey 2016 – Category Scores



Comparison to Mature Markets



* Responses and scoring reported here took place prior to the British vote to leave the European Union and do not necessarily reflect the biomedical investment environment in the UK following this vote.

BCI Results In Depth: What helps and what hinders the UK's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ The science base and research infrastructure are regarded as being of high quality.
- ✔ A long-term funding structure for R&D is cited as an incentive for investment, although planned funding cuts and the move from grants to loans for SMEs, among other developments, introduce some uncertainty for future funding.

Clinical Research Conditions & Framework

- ✔ Executives cite expertise across all phases of clinical research as a factor supporting investment.
- ✘ Conducting clinical trials is seen as being relatively costly and involving substantial delays in trial approval.

The Regulatory System

- ✔ Capacity for drug approval is seen as excellent.
- ✘ Executives note some delays in market authorization and launch of innovative drugs.

Market Access & Financing

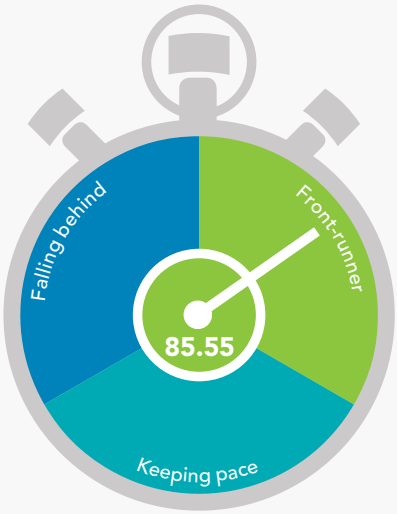
- ✘ Obtaining market access through pricing, reimbursement and HTA is seen as becoming increasingly challenging and costly, though opportunities for prioritizing cutting edge treatments exist.
- ✔ Executives note an attractive tax environment as being one important incentive supporting investment in the UK.

Effective Intellectual Property Protections

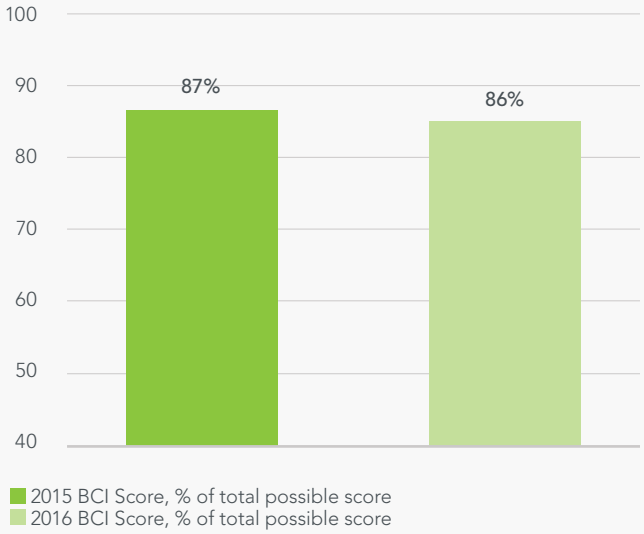
- ✔ Biopharmaceutical IP protection is viewed overall as being very strong.
- ✔ Civil remedies and criminal penalties are generally available and effective.

UNITED STATES

BCI Survey 2016 – Overall Scores



2015 vs. 2016



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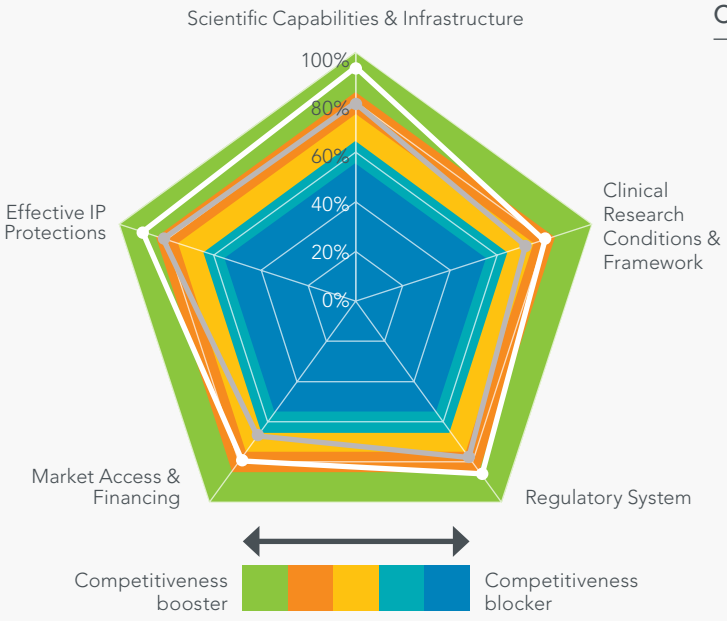
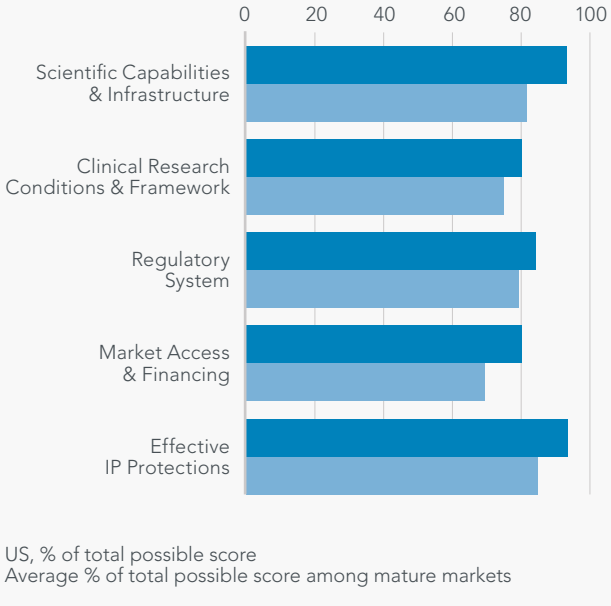


Comparison to Mature Markets



BCI Results In Depth: What helps and what hinders the US's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Biopharmaceutical R&D capabilities are regarded as world-class, building on the presence of top-ranking universities and sustained R&D investment (including funding targeted toward new areas and unmet needs).
- ✔ Executives view public and private R&D collaboration and commercialization activities as pillars of the country's strong innovation performance.

Clinical Research Conditions & Framework

- ✔ Adequate capabilities for clinical research are seen as existing, although conducting trials is viewed as relatively expensive.
- ✘ Executives raise another area for improvement around streamlining approval procedures, an issue partially tackled by the NIH mandating a single ethics review for NIH-funded multi-center trials.

The Regulatory System

- ✔ The regulatory framework and the drug regulator (FDA) are seen as enforcing rigorous standards.
- ✔ Executives cite well-established fast-track pathways as enhancing the US' attractiveness for investment (with the biosimilars pathway viewed as satisfactory and gaining clarity over time).

Market Access & Financing

- ✔ Access to innovative treatments through private reimbursement schemes is considered to be relatively high.
- ✘ Some concerns are expressed regarding cost containment measures, with drug prices in the public sector seen as increasingly coming under fire from federal and state-level initiatives.

Effective Intellectual Property Protections

- ✔ Biopharmaceutical IP protection is generally viewed as being of the highest standards globally, with some important exceptions.
- ✘ Executives note some uncertainty around patentability of biotech and biopharmaceutical inventions.

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APPENDIX: 2016 BCI SURVEY TEXT

NEWCOMER MARKETS BCI SURVEY

SCIENTIFIC CAPABILITIES & INFRASTRUCTURE

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
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) ☐

CLINICAL RESEARCH CONDITIONS AND FRAMEWORK

Question 4
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 5
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 6
Compared to newcomer markets, 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 (infrastructure and manpower of adequate quality are relatively inexpensive to secure) ☐

Question 7
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 8
How compliant are organizations participating in clinical trials in your country with global clinical standards (GCP) and procedures?

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

Question 9
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) ☐

THE REGULATORY SYSTEM – DRUG APPROVAL, QUALITY ASSURANCE AND PHARMACOVIGILANCE

Question 10
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 11
In your view, how long are delays in the registration of an innovative drug that has already been approved by a major drug agency in a mature market (such as the FDA or EMA)?

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 12
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 13
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 14
In your view, to what extent are locally manufactured products in your country compliant with GMP rules that conform to international standards?

Compliance is lacking and/ or GMP rules are below international standards ☐	Compliance varies ☐	Relatively compliant (with exceptions) vis-à-vis international GMP standards ☐	Very compliant (across the board) and GMP rules are in line with international standards ☐

Question 15
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, with some exceptions) ☐	High-level (effective reporting system; rapid and comprehensive response) ☐

MARKET ACCESS AND FINANCING

Question 16
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 17
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 18
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 19
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 20
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) ☐

EFFECTIVE IP PROTECTIONS

Question 21
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 22
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 23
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 and does not cover biologic products) ☐	Very effective (the framework generally applies to all types of innovative medicines, including biologics and new indications) ☐

Question 24
In your view, how effective are civil and criminal remedies for infringement of intellectual property rights and battling counterfeit medicines 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, seizures and penalties; ability to challenge validity of a patent) ☐

Question 25
To what extent does your country have in place a regulatory patent enforcement mechanism for biopharmaceuticals that allows for patent dispute resolution prior to the marketing of a potentially infringing product?

Non-existent (no patent linkage framework exists and judicial remedies are ineffective) ☐	On a limited basis (a partial mechanism is in place but is applied inconsistently or is restricted to certain types of patents ☐	To a reasonable extent (a formal mechanism is in place that effectively enables timely dispute resolution, with some exceptions) ☐	To a great extent (a strong mechanism is in place and allows for timely and effective biopharmaceutical patent enforcement across the board ☐

MATURE MARKETS BCI SURVEY

SCIENTIFIC CAPABILITIES & INFRASTRUCTURE

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

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 4

How would you rank the R&D capacity in your country in terms of exploring treatments for new areas and unmet needs, including localized needs, rare diseases and personalized medicine?

Low (R&D capabilities for new areas are lacking) ☐	Basic (despite certain areas of strength, capabilities have yet to be translated into concrete platforms) ☐	Significant (notable initiatives for R&D into new diseases areas and personalized treatments exist) ☐	Excellent (the capacity and application of R&D into new areas and tailored needs is at the top globally) ☐

CLINICAL RESEARCH CONDITIONS AND FRAMEWORK

Question 5
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 6
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 7
Compared to other mature markets, 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 inexpensive ☐	Financially attractive (high quality infrastructure and manpower are relatively inexpensive to secure) ☐

Question 8
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 ☐

THE REGULATORY SYSTEM

Question 9
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 10
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, even where data from prior approval in other countries is available) ☐	Relatively long (takes 12 months or more) ☐	Fairy short (takes 6-12 months) ☐	Very short (takes no more than 6 months) ☐

Question 11
To what extent do designated fast-track pathways for priority innovative biopharmaceutical products exist in your country?

None (such pathways do not exist at the moment) ☐	Basic (framework for a fast-track pathway(s) exist but are not actually operational or effective) ☐	Satisfactory (designated fast-track pathways are in place and are being used) ☐	Excellent (fast-track pathways are fully operational and produce concrete results in terms of the ability to introduce priority products to the market) ☐

Question 12
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) ☐

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Question 15
How stringent are price controls on publicly reimbursed products in your country?

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 16
To what extent are innovators in your country able to secure an adequate price for breakthrough treatments that provide significant therapeutic value compared to existing treatments?

Rarely (payers are mostly focused on the price and cost of these medicines and not on their value) ☐	Partially (while acknowledging the therapeutic value of these products, the reimbursement framework does not fully reflect this value) ☐	Reasonably (most breakthrough treatments are reimbursed or financially supported in a manner that also takes into account their high value to the patient ☐	Fully (a real understanding of the need for reimbursing breakthrough products in a manner consistent with their long term contribution to patients and society, and is applied on the ground ☐

Question 17
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 18
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) ☐

Question 19
To what extent do alternative market entry agreements exist in your country for biopharmaceutical products that are not (fully) reimbursed through the relevant/dominant national, regional or private payer?

Non-existent (such agreements are not utilized) ☐	On a limited basis (such agreements are piloted or used for a small number of products) ☐	Partially (such agreements are being applied to and enabling market access for a growing number of strategic products) ☐	Regularly (such agreements are used frequently for strategic products and allow for effective market access) ☐

Question 20
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) ☐

EFFECTIVE IP PROTECTIONS

Question 21
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 22
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 23
How effective are mechanisms in your country aimed at safeguarding clinical trial data (i.e. regulatory data protection)?

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Question 24
In your view, how effective are administrative, civil and criminal remedies for infringement of intellectual property rights?

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 the process allows for delays and additional costs in some cases) ☐	Very effective (including compensation, injunctions and penalties, without involving delays and additional costs to innovators) ☐

Question 25
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 of medical conditions, but industry is 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.) ☐

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