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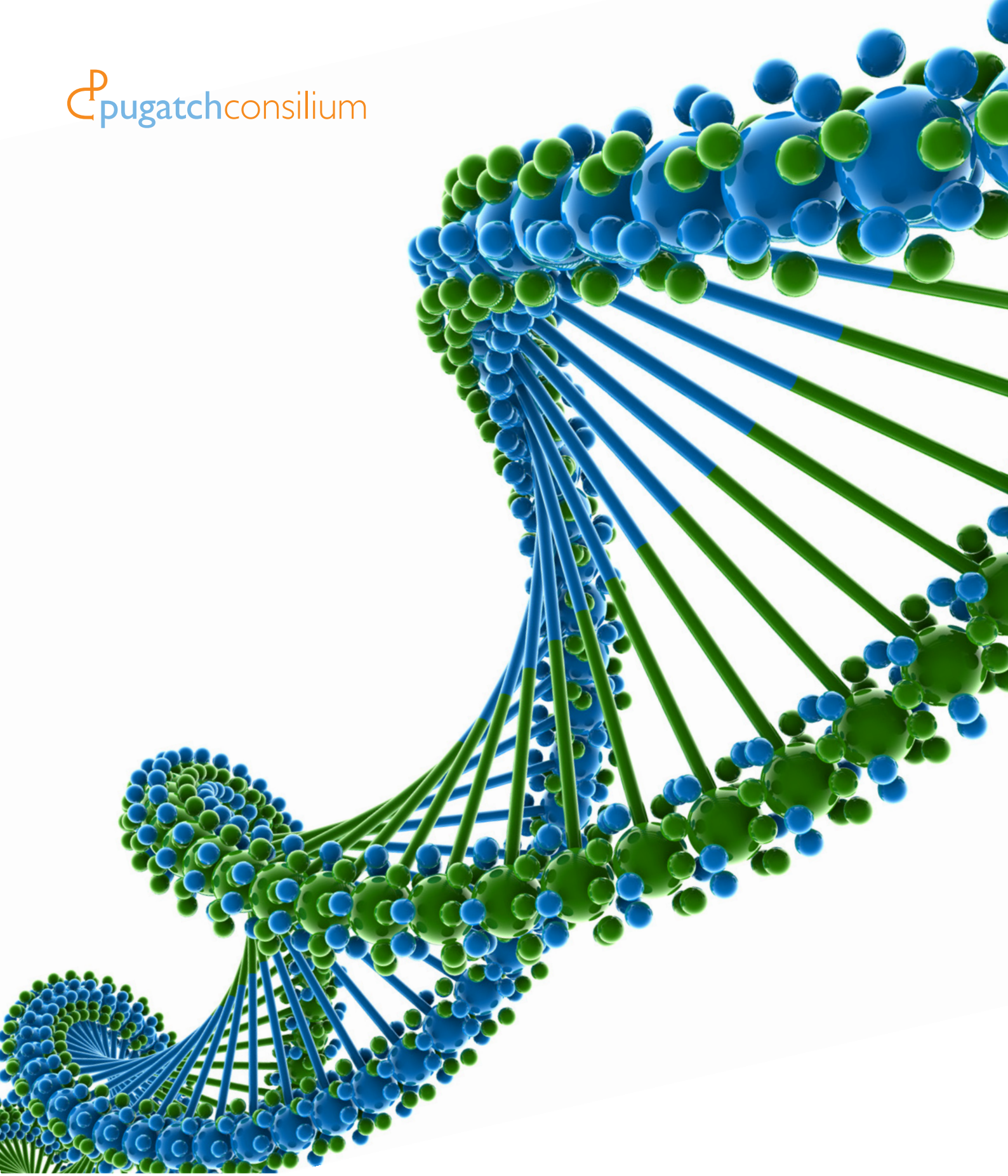

BUILDING THE BIOECONOMY 2015

Examining National Biotechnology Industry Development Strategies Globally

This report was commissioned by the Biotechnology Industry Organization. The views represented here are those of the authors only.

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EXECUTIVE SUMMARY

Building the Bioeconomy examines and identifies policies and best practices that pave the way for a creating an environment and ecosystem that enables biotech innovation. The 2015 edition focuses on 13 countries: Brazil, China, India, Korea, Malaysia, Mexico, Russia, Singapore, South Africa, Switzerland, Turkey, the UK and the United States. Using a comparative perspective and looking in detail at the country specific-level, the report identifies several important findings as well as lessons learned.

Enabling factors for growing a robust a national biotechnology echo system

Designing an environment that is conducive to the innovation, research, commercialization and marketing of biotechnological products and technologies is not an exact science. There are a myriad of factors that potentially can affect, encourage or discourage rates of biotech innovation. Relevant policies and factors range from those specific to the biotechnology sector and the life sciences to more general ones affecting broader levels of innovation and economic activity. Yet based on the existing empirical literature and the experience of economies that have been successful in building an advanced biotech capacity, it is possible to identify seven enabling factors that together create a national environment conducive to the biotech field.

1. Nurturing human capital
   A basic and fundamental building block for the biotech sector is the availability of high skilled and technically trained human capital.

2. Investing in physical and technological infrastructure for R&D
   R&D infrastructure and capacity is critical to fostering innovation and activity in high tech sectors including biotechnology.

3. Protection of intellectual property rights (IPRs)
   IPRs such as patents and regulatory data protection are historically of real importance to the biotech and biopharmaceutical innovation process as they incentivise the development of new technologies and products.

4. Maintaining a stable, efficient and predictable regulatory environment
   The regulatory and clinical environment in a given country or region plays a significant role in shaping incentives for innovation and establishing levels of quality and safety for biotech products.

5. Introducing technology transfer frameworks and enhancing public-private collaborations
   Technology transfer is an important mechanism for commercializing and transferring research from public and governmental bodies to private entities and private to private entities.

6. Providing for market and commercial incentives
   Market and commercial incentives can come through a number of different forms such as tax incentives and R&D credits for investments in plant, equipment and other R&D infrastructure. For the biopharmaceutical sector pricing and reimbursement systems for medicines and health technologies can have a profound impact on the incentives for biopharmaceutical innovation.

7. The existence of legal certainty and protecting the rule of law
   The general legal environment including as it relates to the rule of law and the rule of law within a business context is crucial to commercialization and business activities.

Together these factors create the policy infrastructure upon which different countries can develop and promote their biotech ecosystems. Still while these factors are fundamental at the systemic macro level, there is also a need to supplement them with policies and actions that are more nuanced and sector-specific.

One size does not fit all – Different biotech sectors have different policy needs

The individual significance of related policies for each biotechnology sector, such as in the fields of biopharmaceutical, ag-bio and industrial biotechnology, may vary, at times significantly, depending on the specific needs of that particular sector. A national strategy or set of policies that are aimed at growing the capacity and productivity of one biotech sector (for example in the field of ag-bio), may not necessarily be suitable for the ability to grow or develop products in other sectors, such as the development of new biopharmaceutical medicines.

Some interesting lessons can be found in the desire and ability of different countries to grow their own biotechnological base in the life sciences. For instance, while Brazil has through EMBRAPA and long-term support for the sugar-cane ethanol industry built a world-leading ag-bio and industrial biotech capacity, so far success has been more elusive in the innovative biopharmaceutical sector. South Africa and India also face a similar situation. A possible explanation for the relatively more limited success these countries have experienced is the fact that there are still a number of grey or incomplete policy areas that are pivotal to the ability to enhance the biopharmaceutical sector, and that are still absent in these countries. Such policy areas include: the need to introduce and protect different forms of IPRs specific to the biopharmaceutical sector; incomplete or ineffective technology transfer policies and frameworks; regulatory delays and inefficiencies in the review and approval of new products; and the absence of satisfactory market incentives.

In contrast other countries have developed and are developing more holistic sector-specific programs that help drive forward their biopharmaceutical sector. For example, Singapore, the US, the UK and Switzerland have built state-of-the-art biopharmaceutical R&D and manufacturing facilities through targeted policies on biopharmaceutical IPRs, high-standard regulations, and commercial and market incentives.

The table on the next page provides a summary overview of some of the major success stories and remaining stumbling blocks for each of the thirteen economies mapped.

The importance of tracking and measuring policy inputs and outputs –the Biotech Policy Performance Measure

Being able to track progress and identify areas of weakness is key to any national policy framework; including in the field of biotechnology. In this respect it is also important not only to focus on the policy inputs but also to try and understand how they may translate into national outputs.

Building the Bioeconomy 2015 includes a new tool: the Biotech Policy Performance Measure. This tool (the "Measure") provides readers a quick overview of a given economy's policy framework and performance in relation to the other economies sampled. The Measure includes some of the most important elements for each of the seven enabling factors used to map a given economy's policy framework including relevant biotechnology policy inputs and outputs. It uses a simple three-tier classification system of policy performance: "Attractive", "Mixed", and "Challenging".

While the purpose of the Measure is not to 'score' or benchmark individual countries to a pre-determined set of criteria it does provide users an idea of how a sample of policies (including inputs and outputs) for each enabling factor compares with the same policy input or output for all economies included in the report. Overall the results show the great variety between economies as well as for each enabling factor for a given economy. For instance, economies can have quite attractive policies and frameworks in place for some enabling factors yet face more significant challenges in other areas. The full results of the Biotech Policy Performance Measure are included in the table on pages 12 and 13.

Country overview - Success stories and Stumbling blocks

	Success stories	Stumbling blocks
Brazil	• Government support for ag-bio and industrial biotechnology e.g. EMBRAPA and sugar-cane ethanol • Brasil Maior initiative - focus on life sciences and need for improving human capital	• Challenging IP environment • Biopharmaceutical P&R environment challenging - strict pricing policies and local preferencing • Cumbersome tech transfer framework
China	• Significant investor in human capital and R&D infrastructure • High levels of IP creation through patenting (general and biotech	• Challenging regulatory environment for clinical trials and seed registration and commercialization • Strict reimbursement policies have limited the number of biological drugs available • Challenging IP environment
India	• Tradition of strong Government focus on biotech • Potential policy change by Modi Government – focus on innovation, improving IP standards	• No comprehensive national tech transfer framework • Uncertainty over Government support for commercialization and registration of ag-bio products • IP environment: Section 3(d) and patentability requirements; no RDP; use of compulsory licenses and patent revocations for biopharmaceuticals
Korea	• High levels of R&D investment • Comprehensive tech transfer legal framework in place • Strong IP environment	• No commercialized ag-bio products • Data requirements for pharmaceutical patent applications exceed international best practices • Strict pricing policies and limited reimbursement
Malaysia	• Generous high tech and biotech specific credits e.g. BioNexus • Relatively high level of technology transfer and patenting by palm oil PRO (Malaysian Palm Oil Board)	• RDP legally in place but limited in practical availability • Delays in marketing approval of biopharmaceuticals • P&R environment challenging - long formulary delays
Mexico	• Growing biopharmaceutical FDI - circa USD1 billion in 2012 • Cut in market approval processing times by COFEPRIS	• Biopharmaceutical P&R environment challenging • Limited tech transfer framework in place • RDP available but unclear for large molecules
Russia	• High number of natural science PhDs • Generous R&D tax credits available	• Limited commercial use of ag-bio products – regulatory infrastructure not in place • Strict localization and P&R policies
Singapore	• World class biopharmaceutical R&D and manufacturing hub • High levels of clinical trials • Strong IP, regulatory and tech transfer environment • Generous R&D tax credits available	• No commercial cultivation of ag-bio products • Limited industrial biotech
South Africa	• Strong tradition of ag-bio use and production • Generous R&D tax super deduction available • Technology transfer framework in place	• Challenging life sciences IP environment • Limited biopharmaceutical R&D capacity • Long delays for pharmaceutical market authorization
Switzerland	• High levels of human capital • Leading global investor in biopharmaceutical R&D • Strong clinical trials environment	• No commercial production of ag-bio products • GM foods in effect banned
Turkey	• Generous general R&D tax credits available - 150% dedication • Growing number of life sciences graduates - 250% increase since 2000	• Challenging biopharmaceutical IP environment • Ag-bio R&D taking place but no commercialization • Strict P&R policies for biopharmaceuticals
UK	• Top life sciences universities in the world; Cambridge and Oxford ranked 3rd and 4th • High levels of clinical trials - per capita and total • Biopharmaceutical R&D almost 25% of total private sector R&D	• EU regulations on ag-bio not conducive to wide-spread commercialization and use of ag-bio products
US	• Top life sciences universities in the world • World's highest total of clinical trials • High total biopharmaceutical R&D • Biggest producer of ag-bio crops in the world • Leading producer of biofuels in the world	• Uncertainties over patentability of basic biotech inventions e.g. 2013 Molecular Pathology v Myriad Genetics and 2012 Prometheus Laboratories, Inc v Mayo Collaborative Services

The Biotech Policy Performance Measure: Overall results

	Brazil	China	India	Korea	Malaysia	Mexico	Russia
Factor 1: Human capital							
No of researchers per capita (million population)	710	1020	160	5928	1642	386	3096
% of population in tertiary education	0.13	0.04	N/A	0.4	0.05	0.18	0.53
Performance compared to Sample	**Challenging**	**Challenging**	**Challenging**	**Attractive**	**Mixed**	**Mixed**	**Attractive**
Factor 2: Infrastructure for R&D							
R&D spending % of GDP	1.21	1.98	0.76	4.36	1.07	0.43	1.12
Clinical trials per capita	20.08665605	3.9398228	2.009078952	112.4663863	14.27980132	18.21854186	19.21017825
Performance compared to Sample	**Mixed**	**Mixed**	**Challenging**	**Attractive**	**Challenging**	**Challenging**	**Mixed**
Factor 3: Intellectual property protection							
RDP	Challenging	Challenging	Challenging	Attractive	Challenging	Challenging	Challenging
PTE	Challenging	Challenging	Challenging	Attractive	Challenging	Challenging	Attractive
Performance compared to Sample	**Challenging**	**Challenging**	**Challenging**	**Attractive**	**Challenging**	**Challenging**	**Mixed**
Factor 4: The regulatory environment							
Existence of regulatory framework and efficiency	**Challenging**	**Challenging**	**Challenging**	**Attractive**	**Challenging**	**Mixed**	**Challenging**
Factor 5: Technology transfer frameworks							
Frameworks in place	**Mixed**	**Attractive**	**Challenging**	**Attractive**	**Challenging**	**Challenging**	**Challenging**
Factor 6: Market and commercial incentives							
P&R policies	**Challenging**	**Challenging**	**Challenging**	**Challenging**	**Challenging**	**Challenging**	**Challenging**
Factor 7: Legal certainty (including the rule of law)							
RoL index ranking	42	76	66	14	35	79	80
Performance compared to Sample	**Mixed**	**Challenging**	**Challenging**	**Attractive**	**Mixed**	**Challenging**	**Challenging**

The Biotech Policy Performance Measure: Overall results

	South Africa	Singapore	Switzerland	Turkey	UK	US
Factor 1: Human capital						
No of researchers per capita (million population)	363	6437	5500	987	4042	3978
% of population in tertiary education	0.06	N/A	0.35	0.15	0.41	0.42
Performance compared to Sample	**Challenging**	**Attractive**	**Attractive/ Mixed**	**Mixed**	**Attractive/ Mixed**	**Attractive/ Mixed**
Factor 2: Infrastructure for R&D						
R&D spending % of GDP	0.76	2.23	2.87	0.86	1.77	2.79
Clinical trials per capita	36.14435091	245.9623648	445.2940239	21.11706151	149.0663077	251.1714383
Performance compared to Sample	**Challenging**	**Attractive**	**Attractive**	**Mixed**	**Mixed**	**Attractive**
Factor 3: Intellectual property protection						
RDP	Challenging	Attractive	Attractive	Challenging	Attractive	Attractive
PTE	Challenging	Attractive	Attractive	Challenging	Attractive	Attractive
Performance compared to Sample	**Challenging**	**Attractive**	**Attractive**	**Challenging**	**Attractive**	**Attractive**
Factor 4: The regulatory environment						
Existence of regulatory framework and efficiency	**Challenging**	**Attractive**	**Mixed/ Attractive**	**Challenging**	**Attractive**	**Attractive**
Factor 5: Technology transfer frameworks						
Frameworks in place	**Mixed**	**Attractive**	**Attractive**	**Mixed**	**Attractive**	**Attractive**
Factor 6: Market and commercial incentives						
P&R policies	**Challenging**	**Mixed**	**Mixed**	**Challenging**	**Mixed**	**Attractive**
Factor 7: Legal certainty (including the rule of law)						
RoL index ranking	40	10	N/A	59	13	19
Performance compared to Sample	**Mixed**	**Attractive**	**N/A**	**Mixed**	**Attractive**	**Attractive**